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Using a novel exercise programme for patients with muscular dystrophy. Part II: a quantitative study

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Abstract

Purpose: To quantitatively evaluate the effects of qigong in patients with muscular dystrophy.
Methods: Thirty-six patients with muscular dystrophy were assigned to either a treatment or comparison group, by means of a stratified randomization procedure. The intervention period lasted for 3 months. Balance and respiratory function were assessed by means of Berg's Balance Scale and an electronic spirometer, respectively. Health-related quality of life was tested by means of a Swedish version of the Medical Outcome Study Short Form Health Survey (SF-36), coping levels by means of a Swedish version of the Ways of Coping Questionnaire and depression levels by means of a modified version of the Montgomery Åsberg Depression Rating Scale.
Results: Perceived general health was maintained in the treatment group whereas this was not the case in the comparison group ($p = 0.05$). Positive reappraisal coping decreased in the treatment group but not in the comparison group ($p = 0.05$). There was a tendency to maintain balance function during training and performance of qigong whilst there was a decline when not training.
Conclusion: Qigong may be useful as an adjunct therapy regimen in patients with muscular dystrophy in that it can bring about a decreased rate of decline in general health. The change in coping pattern in this study needs more investigation. More research is also needed in order to more fully investigate the effects of qigong on such physical variables as balance function.

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Introduction

Training and exercise is important in order for patients with muscular dystrophy (MD) to maintain posture and mobility, even though more research is needed to develop optimal exercise guidelines.[1] Since these patients have a diminished capacity for exercise, a submaximal strengthening programme is recommended.[2] In addition, the development and testing of novel approaches to enhance physical activity in patients with neuromuscular diseases has been recommended in a recent literature review.[3]

The different exercises contained in such activities as qigong[4] and tai chi are performed at submaximal level and may therefore serve as an alternative exercise regimen for patients with chronic neuromuscular disease. For example, a pilot study of the effects of qigong and tai chi has shown improved balance and symptom management in patients with multiple sclerosis.[5] There are also studies performed on the effects of tai chi on elderly people, showing both maintenance and improvement of cardiorespiratory[6, 7] and balance function.[8]

Thus the aim of part II of the present pilot study was to quantitatively evaluate the effects of qigong on balance and respiratory functions in persons with muscular dystrophy. Through questionnaires, the effects of qigong training on quality of life, levels of depression and coping styles were also to be examined. Additionally, in order to enhance the understanding of how the effects of qigong may be mediated, the qualitative results of part I of the study[4] will to some extent be compared with the results of this quantitative part.

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Methods

SAMPLE

Eligible for inclusion were adult patients with muscular dystrophy in the county of Örebro, registered at the Department of Neurology and Neurophysiology at Örebro University Hospital. The catchment area of the hospital had a population of 273 000.

Seventy-five patients with muscular dystrophy were first invited by mail to participate in the study, then contacted and informed about the study by telephone. Thirty-six of them accepted this invitation to participate, covering the following diagnoses: myotonic dystrophy, proximal MD, and distal MD. Demographic characteristics are shown in table 1. The study was approved by the Ethical Research Committee at Örebro University Hospital. Informed consent was received.

DESIGN OF PILOT STUDY

Patients agreeing to take part in this study were randomized, either to study group A (received qigong training during the first study period) or to study group B (received qigong training during the second study period (see figure 1)). The randomization procedure used stratified selection in order to achieve comparable groups with regard to the three diagnostic groups and level of impairment (ability to rise from the floor unaided or not). The first study period was an *intervention period* where group A was the treatment group and group B the comparison group (did not receive any qigong training). However, the second study period was only a *follow-up period* where group B received training in qigong while patients in group A either continued on their own or stopped doing qigong altogether. Both study periods lasted for 3 months.

During the intervention period, group A and group B consisted of 16 and 15 patients, respectively. During the follow-up period, group A was split up into two subgroups: one subgroup of 9 patients continued qigong on their own while the other subgroup consisting of 7 patients gave it up. Twelve patients in group B learned and performed qigong during the follow-up period (see figure 1).

Table 1 The study groups by number, gender and age

	n	*Male/female*	*Age (range)*
Myotonic dystrophy	19	10/9	48 (33–60)
Proximal MD	12	7/5	50 (29–75)
Distal MD	5	2/3	68 (60–80)

ATTRITION

Five out of 36 patients dropped out before the end of the intervention period and consequently did not participate in the second testing session (test 2), which represents a 14% attrition rate. One person suffered a heart attack and another suffered a stroke, 2 patients did not feel they would be able to perform the qigong exercises because of their limited physical ability, and one person was not contactable by mail or telephone. In addition, 3 patients dropped out before the end of the follow-up period and did not participate in the third and last testing session (test 3), 1 person had a severe pain in the foot, the other 2 patients were in a general state of ill health (see figure 1).

The remaining 28 patients participated in the 3 testing sessions. However, 3 of these patients did not complete the physical testing (balance and/or respiratory function measurement) at the third testing session. Similarly, 3 patients did not complete the coping questionnaire at the third testing session (1 of whom did not answer the coping questionnaire at testing sessions 1 and 2 either).

INSTRUMENTS

Balance function was assessed by means of the Balance Scale developed by Berg,[9] which covers 14 movements common in everyday life. A physiotherapist, blinded to the outcome of the randomization procedure, evaluated patients' performance on a scale from 0 to 4 with a maximum possible total score of 56 (higher scores indicate greater ability to balance).[9] The reliability and validity of this scale has been shown to be satisfactory in the case of elderly people and of patients who have suffered an acute stroke.[9]

Health-related quality of life was measured by means of a Swedish version of the 36-item Short Form Health Survey (SF-36).[10] The SF-36 is a self-assessment instrument organized into 8 scales or health dimensions, namely physical functioning (10 items), role limitation due to physical problems (4 items), bodily pain (2 items), general health perceptions (5 items), vitality (4 items), social functioning (2 items), role limitation due to emotional problems (3 items), and mental health (5 items). Items were re-coded and recalibrated, summated into a raw scale score that were transformed into a scale from 0–100 according to the standard SF-36 scoring algorithms (higher scores indicate higher health-related quality of life).[11] Missing data on single items of a scale

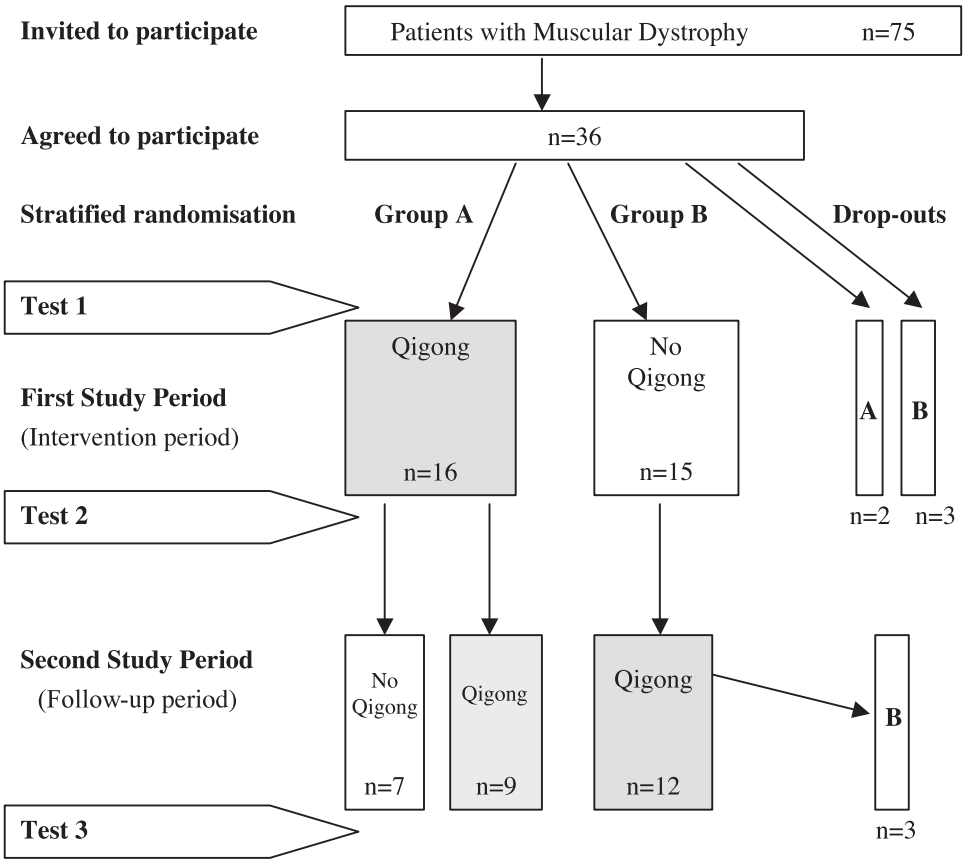

Figure 1. Description of design and attrition of the study groups.

were replaced by mean substitution (i.e. the respondent's average score was substituted in each case) before the scoring algorithm was used. The Swedish translation of SF-36 by the International Quality of Life Assessment Project has shown satisfactory results with regard to psychometric properties.[12]

A Swedish version of the Ways of Coping Questionnaire (WCQ) was used to estimate mode and frequency of coping with stressful situations.[13] The WCQ is one of the most widely used measures of basic coping responses.[14] The psychometric properties of the Swedish version of the WCQ have been evaluated[15] and further testing is in progress. The WCQ consists of 8 scales or coping strategies: confrontive coping (6 items), distancing (6 items), self-controlling (7 items), seeking social support (6 items), accepting responsibility (4 items), escape-avoidance (8 items), planful problem solving (6 items), and positive reappraisal (7 items). The respondents in this study were asked to recall a recent stressful situation that was difficult or troubling and in some way related to their chronic disease. They rated how they coped with this situation on a 4-point Likert scale (0–3), indicating the frequency with which each strategy is used. The raw scores were calculated according to the WCQ manual.[13]

Originating from the Montgomery Åsberg Depression Rating Scale (MADRS), which measures depressive symptoms and has been shown to have high reliability and validity,[16] a self-assessment scale called MADRS-S has been developed.[17] This self-rating scale consists of 9 items and has been validated.[17, 18] Respondents were asked to assess their state of mind for the past 3 days, using 4 scale steps (1–4). Higher values indicate a more depressed state. The last item of MADRS-S concerning zest for life was slightly reworded in order to better adapt the instrument to the present patient population. Mean substitution was used for any missing value.

Compliance was measured by means of a weekly compliance instrument. The subjects were asked to indi-

cate how often they had done qigong during the past week. The alternatives were as follows: 0 times, 1–2 times, 3–4 times, 5–7 times, more than 7 times. Full compliance (100% compliance) would mean that all subjects in the treatment group did qigong daily during the intervention period.

PROCEDURE

When first arriving at a testing session at the rehabilitation unit at Örebro University Hospital, people were greeted by a physiotherapist (EE) who was to perform the physical testing. This physical therapist was blind to the outcome of the randomisation procedure. Respiratory function was investigated by means of an electronic spirometer (Vitalograph Alpha). Forced vital capacity (FVC) and the forced expiratory volume in 1 (FEV_1) were measured in the sitting position. The balance function was then evaluated by the physiotherapist, using Berg's Balance Scale. Finally, the 3 instruments regarding health-related quality of life, coping and depression were completed. This testing procedure was repeated in all sessions (tests 1–3).

INTERVENTION

Each study period (figure 1) started with a brief weekend course in qigong. Group A learned qigong during the first period and group B learned it during the second period. The China-trained qigong instructor (AÖ) instructed participants, in groups of 6–10, how to correctly do qigong. At the end of this introductory weekend, the participants received instructions both on audiotape and in writing about how to perform the different qigong exercises at home. Besides this exercise at home, the qigong groups met once a week with the instructor during the first month in order to do qigong together. During the last 2 months of the study periods, the groups met with the instructor every other week. There were a total of nine meetings. For a description of the qigong exercises used in this study, see part I.[4]

STATISTICAL ANALYSES

Apart from the use of descriptive statistics, *t*-tests for related samples were used to test for within-group differences in respiratory variables during the intervention period. In addition, *t*-tests for independent samples were used to test for between-group differences in respiratory variables, using change scores (test 2 minus test 1) as the dependent variable. The nonparametric Wilcoxon matched-pair signed-ranks test was used to test for within-group differences on Berg's Balance Scale, the SF-36 Health Survey, the WCQ and the MADRS-S during the intervention period. The nonparametric Mann–Whitney test was used to test for between-group differences on these instruments, using change scores (test 2 minus test 1) as the dependent variable.

In addition, sample size calculation based on the outcome of the treatment effect on the Balance Scale was performed using a two-group *t*-test with a 0.05 two-sided significance level.[19] The common standard deviation used in this calculation was estimated by pooling the estimates derived from sample data in this study[20] (see table 2).

ANALYSIS OF ATTRITION

Analysis of attrition was performed on the group of 36 patients that underwent the first testing session. Five patients who dropped out after this session (test 1) were compared with the 31 patients that completed the second testing session (test 2). The drop-outs had significantly lower scores at test 1 (i.e. pretest values) on the Balance Scale ($p = 0.024$). However, when excluding the two drop-outs who were bound to wheel-chairs and had very low balance scores, there was no longer any significant difference between the two groups. The scores of these 2 patients were very low because of their physical handicap (4 out of a maximum 56, while the average score, including all 36 patients at test 1, was 44.7, SD 13.1). There were also differences on two of the SF-36 scales at pretest, the drop-out group having higher scores on pain ($p = 0.038$) and social functioning ($p = 0.020$).

Results

The treatment (A, $n = 16$) and comparison (B, $n = 15$) groups that underwent the intervention period were comparable at the first testing session, with no statistically significant pretest differences on any of the

Table 2 Balance function in qigong intervention study

	Berg's balance scale		
	Test 1 *Mean* (SD)	*Test 2* *Mean* (SD)	*Change score* *Mean* (SD)
Treatment, group A ($n = 16$)	50.0 (7.3)	50.2 (5.8)	+ 0.2 (3.4)
Comparison, group B ($n = 15$)	45.0 (9.6)	43.7 (9.4)	− 1.3 (1.9)

Note: Higher scores indicate better balance function.

Table 3 Health-related quality of life in qigong intervention study

	Group A (treatment group)		*Group B (comparison group)*	
	n = 16		n = 15	
SF-36 Scales	*Test 1* *Mean* (SD)	*Test 2* *Mean* (SD)	*Test 1* *Mean* (SD)	*Test 2* *Mean* (SD)
Physical functioning	49.1 (27.7)	44.4 (26.8)	40.3 (21.3)	35.3 (16.7)
Role physical	62.5 (36.5)	51.6 (37.0)	66.7 (37.4)	58.3 (46.9)
Bodily pain	69.7 (26.3)	75.5 (23.7)	74.7 (26.0)	71.7 (26.5)
General health	44.6 (28.1)	46.5 (26.1)	48.8 (28.1)	42.2 (28.3)
Vitality	39.4 (26.2)	43.8 (18.1)	56.7 (20.5)	52.7 (18.7)
Social functioning	85.9 (17.0)	87.5 (15.1)	83.3 (18.1)	85.8 (16.3)
Role emotional	77.1 (35.9)	70.8 (40.1)	75.6 (36.7)	75.6 (38.8)
Mental health	78.0 (18.4)	78.0 (16.3)	75.2 (20.9)	79.2 (13.8)

Note: Higher scores indicate higher health-related quality of life.

Table 4 Ways of coping in qigong intervention study

	Group A (treatment group)		*Group B (comparison group)*	
	n = 16		n = 14	
Coping scale	*Test 1* *Mean* (SD)	*Test 2* *Mean* (SD)	*Test 1* *Mean* (SD)	*Test 2* *Mean* (SD)
Confrontive coping	4.3 (3.1)	2.9 (2.3)	3.3 (1.9)	3.6 (2.3)
Distancing	7.1 (3.9)	6.8 (5.0)	6.6 (3.8)	6.1 (4.1)
Self-controlling	7.1 (3.3)	6.6 (3.3)	7.5 (3.3)	7.4 (3.3)
Seeking social support	7.3 (4.4)	5.7 (3.5)	4.6 (3.5)	4.0 (3.5)
Accepting responsibility	1.7 (1.9)	2.4 (2.6)	2.9 (2.6)	2.3 (2.8)
Escape-avoidance	4.9 (3.7)	4.6 (3.9)	6.1 (4.0)	5.4 (3.6)
Planful problem solving	6.9 (4.8)	5.8 (3.4)	6.9 (3.4)	5.4 (3.7)
Positive reappraisal	6.8 (4.7)	4.8 (4.2)	4.6 (2.6)	4.6 (3.2)

Note: Higher scores indicate greater use of specific coping strategies.

outcome variables. With regard to respiratory parameters, there were no within-group or between-group differences after the intervention period. The average value of FVC for all participants at the initial testing session was 2.9 L, and FEV_1 was reduced to 2.3 L. This is a significant decrease in vital capacity as compared to a healthy population.

The other physical parameter measured in this study was balance. Table 2 shows scores for the Balance Scale in the treatment and comparison groups measured before (test 1) and after (test 2) the intervention period. The mean balance score of group A (treatment group) was virtually unchanged while the mean score of group B (comparison group) decreased ($p = 0.025$, within-group difference). There was no between-group difference in balance between group A and group B during the intervention period ($p = 0.128$). Sample size calculations indicated that a sample size of 54 in each group would have had 80% power to detect a mean difference of 1.5, the between-group treatment difference in the Balance Scale found in this study.

In addition, *post hoc* analysis of descriptive data collected for balance function before and after the follow-up period (tests 2 and 3) was performed. Group B, which received qigong-training during this period ($n = 11$), had a mean change score (test 3 minus test 2) of + 0.2 (SD 3.6). The subgroup of A that continued with qigong during the follow-up period ($n = 8$) had a change score of + 1.6 (SD 1.8), while the subgroup of A that discontinued their qigong training ($n = 6$) had a change score of − 1.5 (SD 2.4).

Table 3 shows the scores of the eight scales of the SF-36 Health Survey in groups A and B before and after the intervention period. There was one within-group difference found, on the scale that measures general health perceptions. Group B significantly decreased in reported health ($p = 0.009$), while the scores of group A did not significantly change. In addition, there was a significant

between-group difference in general health perceptions ($p = 0.051$) after the intervention period.

Table 4 shows the scores of the 8 scales of the WCQ in groups A and B during the intervention period. There were within-group differences on 2 scales, confrontive coping ($p = 0.027$) and positive reappraisal ($p = 0.013$). The scores on these 2 scales decreased significantly in group A, while there were no within-group differences in group B. In addition, there was a significant between-group difference in positive reappraisal after the intervention period ($p = 0.052$), but not in confrontive coping ($p = 0.131$)

The final instrument employed in this study, the MADRS-S, did not detect any within- or between-group differences at all during the intervention period. Only 8 out of 36 patients scored 3 or higher (on a scale from 1 to 4) on any of the 9 items comprising the MADRS-S scale.

There was 87% compliance when it came to attendance at the group meetings led by the qigong instructor. With regard to self-reported compliance: during the intervention period, 4 patients (25%) did qigong five times or more per week, 6 patients (38%) did it three or four times per week, while 6 patients (38%) did it two times or less per week. The total self-reported compliance was 45%.

Discussion

Since a large proportion of patients with chronic disease use different complementary treatments, it is important to scientifically evaluate such treatments. With respect to the effects of qigong on mental health, coping patterns as measured by the WCQ were unchanged between groups in this pilot study except for positive reappraisal, which was lower in the treatment group. No other mental effects were seen, i.e. no difference in levels of depression as measured by MADRS-S. Since the qigong exercises used in this study mainly are physical in nature,[4] it is not surprising that qigong did not elicit any substantial mental effects. In the qualitative part of the study, less than half of the patients doing qigong during the intervention or follow-up periods felt some form of tangible psychological or mental effect that they could attribute to the qigong.[4]

The significance of a diminished coping response in patients with chronic disease, in the form of decreased positive reappraisal when doing qigong, is not clear. Positive reappraisal may be classified as an emotion-focused coping strategy in that it helps the individual control the meaning of a stressor.[21] In one study, patients with chronic obstructive pulmonary disease who regularly participated in submaximal exercise programmes used fewer emotion-focused coping strategies than did non-exercisers.[22] In addition, positive reappraisal coping was less common in chronic disease groups then among students.[15] More research is needed on the influence of qigong on the coping patterns of chronic patients in order to supplement this preliminary finding with further empirical data.

With regard to health-related quality of life, there was a treatment difference on one of the subscales of SF-36. Participants' perceptions of their general health were more constant or stable as a result of qigong. Previous research shows no or only modest beneficial effects of tai chi on general health in healthy older people as assessed by SF-36.[8] However, this may be an effect of the relatively high SF-36 scores in healthy populations,[8] as compared with patients with chronic conditions.[23] Therefore the perception of general health, which has been shown to be associated more with physical than with mental health,[24, 25] appear to be influenced by the physical nature of the qigong exercises used in this study. Furthermore, in a retrospective survey in Korea, 67% of long-term practitioners of qigong reported improvements in their perceived physical health.[26]

With regard to physical variables, no between-group difference in balance function was found. However, there was a significant within-group difference in that the comparison group decreased their mean score on the Balance Scale during the intervention period from 45.0 to 43.7. Since 'a score of 45 seems to be a cut-off point between those individuals who are safe in independent ambulation and those requiring investigation concerning their need for assistive devices or supervision' (p. S8),[27] the observed effect in this study may still be clinically meaningful. *Post hoc* analysis of descriptive data regarding the follow-up period also showed a decline in balance function when participants stopped practising qigong. Furthermore, in the qualitative part of the study over half of the participants reported that they gained increased mobility through the qigong.[4]

These preliminary findings are similar to the results of a meta-analysis performed on the effects of tai chi on balance. There was moderate evidence in support of the use of tai chi to improve balance and postural control in the elderly.[28] These novel exercise programmes may therefore have a potential role as an adjunct to physiotherapy, for the elderly as well as for chronic populations, but further investigation is necessary. Regarding respiratory function, no treatment effects were observed. This is not surprising since the

qigong regimen used in this intervention study did not specifically focus on breathing exercises.[4]

The limitations of this study are several. First of all, there was a drop-out rate of 14%. However, taking into account the frailty of the patients, this attrition may be considered acceptable. Similar attrition rates have been noted in a regular exercise trial for elderly women,[29] and in tai chi intervention trials.[6, 7] Another concern with respect to attrition is the pretest equivalence of groups. However, there were no initial pretest differences between the participants of the treatment and comparison groups that completed the intervention period. In addition, this study was initially designed as a cross-over study, which is especially vulnerable to drop-outs.[30] Since some patients in group A decided to continue with qigong at the end of the first study period and could therefore not be included in the cross-over study, the planned cross-over design had to be abandoned. Between-group comparisons were thus performed only on data collected during the intervention period and not on data collected during the follow-up period.

Besides attrition, the level of compliance or adherence to treatment can influence both the validity and the outcome of a study. For instance, home exercise programmes are marred by low compliance, and the importance of supervising the compliance levels is stressed.[31] In the present study, the self-reported compliance with the prescribed treatment regimen at home (45% compliance level) was comparable to that of other exercise regimens in chronic populations (40–55%)[32] and to pharmacological interventions in the case of elderly outpatients (40–75%).[33] For a better understanding of the complex issues of compliance, ancillary qualitative research is recommended.[33] The qualitative part of this study did also provide an insight into why participants did not adhere to the treatment intervention.[4]

The effects of alternative or complementary treatments often consist of the combined effects of two or more treatment modalities, like the physical and mental aspects of the qigong training. The focus of this study was on the overall effects of an untested and novel exercise programme, not on the specific effects of the different treatment components or the mechanisms of action. In this research approach, the details of treatment are handled like a 'black box'. General knowledge and information about possible beneficial or negative effects of the whole treatment package are favoured over the detailed study of the determinants of specific effects.[34]

Regarding questions about more non-specific (placebo) effects, one inherent weakness of the present study was the lack of a comparison group controlling for the psychosocial effects of group training. Owing to the limited number of patients in the original study population, a third study group was not attainable. Sample size calculations also revealed that this study was underpowered. MD is a rare disease with a prevalence of 39 per 100 000 population, which gives an estimation of 3200 in Sweden with MD.[35] Therefore a future intervention study concerning this patient population needs to be performed as a multi-centre study.

To conclude, a significantly larger study is needed to further investigate the influence of complementary treatments on patients with muscular dystrophy in order to be able to detect statistically significant treatment effects. Furthermore, long-term treatment studies with recurrent training periods are needed to examine the sustained effects of qigong. This is crucial in patients with progressive deterioration of muscle function where the rehabilitation process must continually be re-evaluated and adapted to the changing needs of the patient. In addition, this study shows that the combination of quantitative and qualitative methods is valuable when evaluating novel exercise regimens in patient groups with neuromuscular diseases.

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