

Comparison of the effect of two types of acupuncture on quality of life in secondary progressive multiple sclerosis: a preliminary single-blind randomized controlled trial

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Objective: To compare the effect of two types of acupuncture on the quality of life of individuals with secondary progressive multiple sclerosis and provide preliminary evidence regarding the safety of this intervention for this population.

Design: Preliminary single-blind randomized controlled trial.

Setting: Outpatient attendance at rehabilitation unit.

Participants: Fourteen participants with secondary progressive multiple sclerosis.

Interventions: Chinese medical acupuncture or minimal acupuncture. Participants received 10 treatments over five weeks.

Measures: Multiple Sclerosis Impact Scale 29, Fatigue Severity Scale and General Health Questionnaire 12 were measured pre and post intervention. Adverse events and other responses during treatment were recorded prospectively.

Results: Participants receiving minimal acupuncture demonstrated statistically significant greater improvement in the Multiple Sclerosis Impact Scale 29 psychological subscale compared with those receiving Chinese medical acupuncture in an intention-to-treat analysis ($P=0.04$), with mean change in Chinese acupuncture group of 6.0 (SD 13.9) and in minimal acupuncture group of 23.0 (SD 21.0). No other statistically significant difference between the groups was found. No major adverse events were noted. Minor adverse events such as lower limb muscle spasms or pain were noted in some participants in both intervention groups.

Conclusion: Minimal acupuncture resulted in greater improvement of Multiple Sclerosis Impact Scale 29 psychological subscale compared with Chinese medical acupuncture. No other differences between the groups were found. In view of the small sample these results are not conclusive. This study provides preliminary evidence to suggest that acupuncture is safe for people with secondary progressive multiple sclerosis. A large-scale trial is required to provide more definitive evidence.

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Introduction

Multiple sclerosis is the most common neurological disorder affecting young adults.¹ People with multiple sclerosis commonly use complementary and alternative medicine including acupuncture, despite a limited evidence base.²⁻⁵ Acupuncture research in non-multiple sclerosis populations has demonstrated a variety of benefits such as reduced pain, improved mood, improved sleep quality, reduced fatigue, improved bladder function, enhanced energy levels and improved quality of life.⁶⁻¹⁰ People with multiple sclerosis are reported to have a poorer quality of life compared to the general population, and to people with other chronic diseases.¹¹ Depression and fatigue are common in multiple sclerosis and both factors are linked to poorer self-rated quality of life.¹² Possible benefits from acupuncture such as improved mood, sleep and energy levels may be valuable to individuals with multiple sclerosis and may contribute to an overall enhancement in perceived quality of life.

This preliminary study was designed to compare the effect of different types of acupuncture in multiple sclerosis. Acupuncture currently provided for people with multiple sclerosis is based on Chinese medicine principles.^{4,13-14} Therefore this study compared Chinese medical acupuncture with a superficial form of acupuncture designed to be less effective called 'minimal acupuncture'.⁷ Individuals with the secondary progressive form of multiple sclerosis (SPMS) were selected, since the course of this type is usually one of gradual deterioration rather than episodic relapses and remissions.¹⁵ Therefore any improvements noted would be less easily attributed to spontaneous remission. The study had two main aims: (1) to compare the effect of Chinese medical acupuncture and minimal acupuncture on the perceived quality of life of individuals with SPMS; (2) to provide preliminary information regarding the safety of acupuncture for this population including the occurrence of adverse events.

Methods

Participants

Participants were recruited by convenience sampling at a multiple sclerosis clinic of a large

teaching hospital and through the local multiple sclerosis society. Participants aged 18 years and above were included in the study if they had a confirmed diagnosis of SPMS, were able to walk 5m or more with or without aids, and were prepared to attend for treatment twice a week for five consecutive weeks. Participants were excluded if they were medically unstable, had started new medication or therapy or experienced a relapse within the last three months, or if they had conditions that were contraindicated for acupuncture.

Interventions

Participants received 10 acupuncture treatments, of 25 minutes duration, over five consecutive weeks. The researcher developed a manualized treatment protocol, following examination of the Chinese medical acupuncture literature, based on the work of Schnyer and Allen¹⁶ (with their permission). The protocol included a general health questionnaire with questions relating to all Chinese medical patterns commonly seen in multiple sclerosis. The researcher examined the completed questionnaires, and generated individualized Chinese medical acupuncture treatment plans for all participants, based on predetermined, documented guidelines (see Appendix 1; more details available from researcher). One group received Chinese medical acupuncture according to the individualized plan. The other group received minimal acupuncture, involving the insertion of acupuncture needles just through the skin and away from true acupuncture sites (see Appendix 1).¹⁷ All participants received an initial assessment before their first treatment. This included screening for any precautions or contraindications to acupuncture, as well as a brief neurological assessment to determine the Expanded Disability Status Scale score (EDSS).²³ All acupuncture interventions were provided by the researcher.

Outcome measures

Self-rated questionnaires were used to assess the impact of acupuncture on different aspects of the

participant's quality of life. These were completed within 10 days before the first treatment and within 10 days after the last treatment. This provided sufficient time for the postal questionnaires to be received by participants, completed and returned. The Multiple Sclerosis Impact Scale 29²⁴ was the primary endpoint. It has physical and psychological subscales, which yield individual scores between 0 and 100. Studies show that fatigue and psychological status also influence quality of life in multiple sclerosis.¹² Therefore the Fatigue Severity Scale²⁵ and the General Health Questionnaire 12²⁶ were also used. Fatigue Severity Scale has a scale range of 1–7. The General Health Questionnaire 12 has a scale range from 0 to 36. Higher scores on each of these questionnaires indicate poorer functioning in the assessed domain. The outcome questionnaires and Chinese medical screening questionnaire were posted to each participant. A return envelope was included and addressed to the independent assessor.

Adverse events and other responses to treatment

Studies have examined the safety of acupuncture including the incidence of adverse events.^{27,28} However, no studies have systematically recorded the occurrence of adverse events during acupuncture treatments for individuals with multiple sclerosis. Therefore this study recorded adverse events prospectively. The classification of adverse events described by White *et al.*²⁷ was used with an adverse event being 'any ill-effect, no matter how small, that is unintended and non-therapeutic'. White *et al.*²⁷ also provided examples of major adverse events such as broken needles, faint or convulsion, and minor events such as pain, feeling faint and sweating. Frequency of such events was recorded prospectively in this study. In addition, any other responses reported by the participant or noted by the researcher were recorded.

Sample size

This study was designed to be a small-scale exploratory study with a view to informing a large-scale study at a later date. The study aimed to recruit 20 participants.

Randomization and allocation concealment

Completed questionnaires were returned directly to the independent assessor (JN) who then rang a local randomization centre to obtain treatment allocation for participants. A randomization schedule had been prepared by a statistician using random number tables. This was stratified for gender, since this is known to influence the perceived quality of life of individuals with chronic diseases.²⁹ The two interventions were described as treatment A and treatment B. Neither the statistician nor the independent assessor had any knowledge of the types of treatments being offered or any details of the study. The independent assessor placed a preprinted letter A or B in an opaque sealed envelope and filed this with the participant's Chinese medical screening questionnaires. Individualized Chinese acupuncture treatment schedules had been generated for all participants by the researcher, prior to breaking of allocation concealment. Therefore an equivalent level of clinical reasoning had been completed for all participants. The researcher opened the treatment allocation envelope after all initial assessment procedures were completed, and immediately before the insertion of needles.

Blinding

The researcher remained blind to treatment allocation until all assessment processes had been completed. After this point blinding of the researcher was not feasible. Therefore a reference question and answer sheet was developed to ensure communication with participants was standardized, and options for discussion of treatments minimized.⁶ In addition, outcome questionnaires were not available to the researcher at any time during the intervention phase. Participants returned their completed questionnaires directly to the independent assessor. He coded each questionnaire with a new unique number and stored them securely. Codes for these questionnaires were only broken after data analysis.

Participants were blind to treatment allocation. Success of blinding was evaluated by the use of a credibility questionnaire used

in previous acupuncture studies.³⁰ This was adapted to make the questions relevant to participants with multiple sclerosis. The questionnaire required participants to rate the credibility of the intervention by answering four questions on a scale from 1 to 6, with 1 meaning not credible and 6 meaning very credible. This questionnaire was administered after the second treatment to explore early impressions of the intervention, and after the ninth treatment to identify whether blinding had been maintained throughout the intervention phase in both groups. Scores for each participant were summed and divided by the number of questions, to gain a credibility score ranging from 1 to 6.

Ethics

The study was carried out in accordance with the protocol approved by the relevant research ethics committees. Since individuals with multiple sclerosis may be vulnerable to overestimating the value of new treatments, the study explicitly attempted to avoid raising participant's hope inappropriately by giving accurate information at each stage of the research process. Information sheets were posted out to participants on recruitment to the study. Written consent forms were completed at each participant's first attendance after they had been given the opportunity to discuss any questions or concerns about the study. All participants were informed that they could withdraw from the study at any time, and without giving any reason.

Statistical analysis

Data were analysed using the Statistical Package for Social Sciences 11.5 (SPSS Inc., Illinois, USA). Mann-Whitney *U*-tests were used on the outcome change data, credibility questionnaires and adverse events between the two groups. Significance level of 0.05 was used for all tests. Intention-to-treat and per-protocol analyses were completed.

Results

Twenty participants were assessed for eligibility for entry to the study. Fourteen participants were included and randomized to receive treatment. See Figure 1 for details.

Seven participants were randomized into each treatment group (Table 1). Outcome data are presented in Table 2.

In the per-protocol analysis there were no statistically significant differences between the two treatment groups. On intention-to-treat analysis participants in the minimal acupuncture group demonstrated statistically significantly greater improvement in Multiple Sclerosis Impact Scale 29 psychological score compared with the true acupuncture group. No other statistically significant differences were found between the two treatment groups on intention-to-treat analysis (Table 3).

Mean credibility scores were similar in both treatment groups with values of 4.18 and 4.89 in the Chinese and minimal acupuncture group respectively after treatment 2, and 4.29 and 4.79 respectively after treatment 9. These scores fall within the higher range of possible scores. Analysis revealed no statistically significant differences in credibility change scores between the two treatment groups in per-protocol or intention-to-treat analysis, highlighting that neither treatment was perceived as more credible than the other towards the beginning or the end of the intervention phase.

No major adverse responses were noted during or immediately after any treatment in either group. A number of minor adverse events were noted in both groups, but there was no statistically significant difference in occurrence between the groups. Muscle twitching or muscle spasm causing leg movement was noted most frequently, with 5 participants in the Chinese acupuncture group and 4 participants in the minimal acupuncture group experiencing this event (Table 4).

No participants reported nausea, excessive drowsiness, heavy sweating, feeling faint or aggravation of symptoms during treatment. Bleeding of more than 10 seconds was not observed in any participant. A wide range of

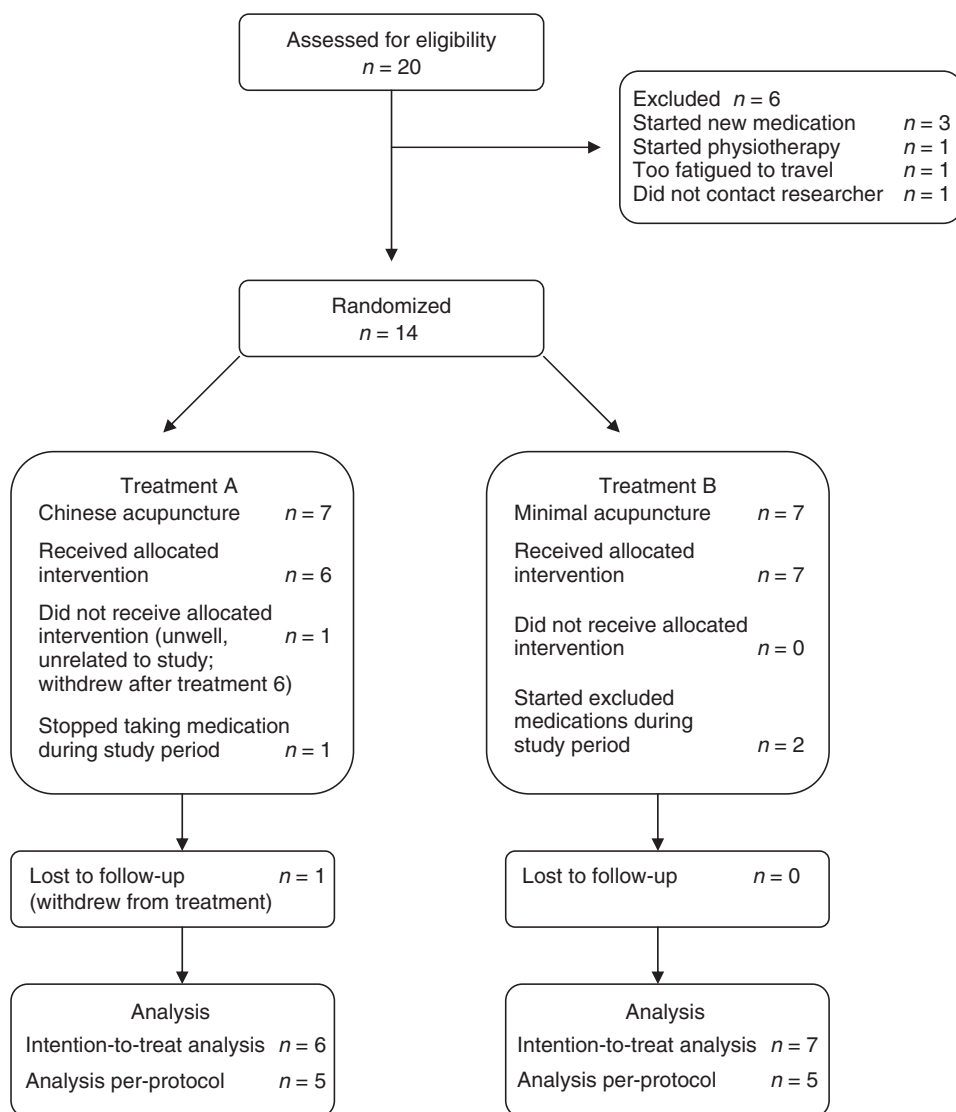


Figure 1 Flow of participants through the study.

other responses were reported by the participants such as sensations of aching, tingling, warmth, cold, numbness and heaviness as well as general sleepiness. Responses of participants observed by the researcher included audible stomach rumbles, sighing, yawning, deep breathing, snoring and sleeping as well as visible needle tremors. In general, more responses

were noted in the Chinese acupuncture treatment group. Two individuals reported a temporary worsening of fatigue and muscle power between some treatments. Both participants were receiving Chinese medical acupuncture. It was unclear whether these changes were due to the acupuncture or a reflection of the variability of these individual's multiple sclerosis.

Table 1 Participant characteristics

Characteristics	Chinese acupuncture (n = 7)	Minimal acupuncture (n = 7)	Total (n = 14)
Gender – M/F	2/5	2/5	4/10
Received acupuncture before Y/N	2/5	2/5	4/10
Age in years			
Mean (SD)	53 (9)	50 (8)	52 (8)
Range	39–70	38–62	38–70
Sensory function, n (%)			
Normal	1 (7)	2 (14)	3 (21)
Mild–moderate impairment	5 (36)	5 (36)	10 (72)
Severe impairment	1 (7)	0 (0)	1 (7)
Co-existing pathology, n (%)			
Epilepsy	1 (7)	1 (7)	2 (14)
Past history of carcinoma	1 (7)	0 (0)	1 (7)
Nil	5 (36)	6 (43)	11 (79)
Current medications, n (%)			
Spasticity	1 (7)	4 (29)	5 (36)
Pain	2 (14)	1 (7)	3 (21)
Depression	1 (7)	4 (29)	5 (36)
Sleep	0 (0)	1 (7)	1 (7)
Fatigue	1 (7)	0 (0)	1 (7)
Bladder	0 (0)	2 (14)	2 (14)
Bowel	1 (7)	1 (7)	2 (14)
Living circumstances, n (%)			
With spouse	6 (43)	5 (36)	11 (79)
Alone	0 (0)	1 (7)	1 (7)
Alone with input from carers	1 (7)	1 (7)	2 (14)
Employment status, n (%)			
Employed	1 (7)	1 (7)	2 (14)
Retired due to MS	5 (36)	6 (43)	11 (79)
Retired	1 (7)	0 (0)	1 (7)
Commonest TCM patterns, n (%)			
Spleen-Qi Deficiency and Damp	6 (43)	7 (50)	13 (93)
Painful Bi-Syndrome	5 (36)	6 (43)	11 (79)
Liver-Blood Deficiency and Wind	6 (43)	2 (14)	8 (57)
Kidney-Yang Deficiency	3 (21)	3 (21)	6 (42)
Heart-Blood Deficiency	0 (0)	2 (14)	2 (14)

TCM, Traditional Chinese Medicine.

Discussion

Research into the effect of acupuncture in multiple sclerosis is very limited. Current knowledge is based on anecdotal case reports,^{13,18–19,21} one single case study,⁴ one matched-pairs study³ and one randomized controlled trial.⁵ This study aimed to explore this subject further, and showed that in individuals with SPMS, minimal acupuncture caused a greater improvement in Multiple Sclerosis Impact Scale 29 psychological subscale on intention-to-treat analysis. No other differences between the

groups were found. No significant adverse events were noted at any time during the study. A number of minor adverse events were noted in both groups.

Minimal acupuncture is an invasive technique and will cause physiological effects. Some authors⁴ suggest the need for gentler acupuncture treatments for people with multiple sclerosis, and minimal acupuncture may represent a gentler and more effective therapeutic stimulus. However with such a small sample size firm conclusions cannot be drawn.

Table 2 Outcome data (n= 14)

Participant	Acup group	Years with MS	EDSS Score (0.0–10.0)	MSIS-29 Phys Before (0–100)	MSIS-29 Phys After (0–100)	MSIS-29 Psysc Before (0–100)	MSIS-29 Psysc After (0–100)	FSS Before (1–7)	FSS After (1–7)	GHQ-12 Before (0–36)	GHQ-12 After (0–36)
1	CM	28	7.0	78.75	75.00	38.89	38.89	4.78	4.89	22	23
2	CM	10	5.5	72.50	43.75	38.89	36.11	6.67	6.78	12	13
3	CM	8	6.5	87.50	–	80.56	–	5.67	–	31	–
4	CM	17	3.5	47.50	16.25	33.33	00.00	6.44	5.00	9	3
5	CM	10	7.0	71.25	73.75	72.22	66.67	6.22	4.00	33	23
6	CM	24	4.5	45.00	21.25	22.22	22.22	2.11	2.67	12	8
7	CM	26	6.5	16.25	15.00	0.00	5.55	1.22	1.00	7	5
8	MA	17	6.0	22.50	21.25	38.89	30.55	5.22	4.67	18	10
9	MA	31	6.5	58.75	53.75	33.33	16.67	3.00	4.22	7	9
10	MA	1	1.5	52.50	36.25	88.89	52.78	5.00	4.22	27	11
11	MA	7	6.0	91.25	66.25	91.67	30.56	6.89	6.89	34	5
12	MA	6	3.0	33.75	30.00	16.67	13.89	6.33	6.56	12	11
13	MA	30	6.5	72.50	36.25	44.44	13.89	3.89	2.11	14	1
14	MA	1	6.5	72.50	63.75	25.00	19.44	4.44	3.33	12	9

CM, Chinese medical acupuncture; MA, minimal acupuncture; MSIS-29, Multiple Sclerosis Impact Scale 29; Phys, physical subscale; Psysc, psychological subscale; FSS, Fatigue Severity Scale; GHQ-12, General Health Questionnaire 12.

Table 3 Primary and secondary endpoint analysis (intention-to-treat analysis, $n = 13$)

	Chinese acupuncture ($n = 6$)				Minimal acupuncture ($n = 7$)				Mann-Whitney U -test	
	Before Mean (SD)	After Mean (SD)	Change Mean (SD)	Range of change (IQR)	Before Mean (SD)	After Mean (SD)	Change Mean (SD)	Range of change (IQR)	Z statistic	P-value (2-tailed)
MSIS-29 Physical	55.2 (23.6)	40.8 (28.0)	14.4 (15.2)	33.8 (29.0)	57.7 (23.8)	43.9 (17.4)	13.8 (12.9)	35.0 (21.3)	-0.29	0.77
MSIS-29 Psychol	34.3 (23.7)	28.2 (24.5)	6.0 (13.9)	38.9 (13.9)	48.4 (30.0)	25.4 (14.0)	23.0 (21.0)	58.3 (30.6)	-2.08	0.04*
FSS	4.6 (2.4)	4.1 (2.0)	0.5 (1.1)	2.8 (1.9)	5.0 (1.3)	4.6 (1.7)	0.4 (1.0)	3.0 (1.3)	0.00	1.00
GHO-12	15.8 (9.9)	12.5 (8.8)	3.3 (4.3)	11.0 (8.0)	17.7 (9.5)	8.0 (3.7)	9.7 (10.7)	31.0 (15.0)	-1.00	0.32

* $P < 0.05$.

SD, standard deviation; IQR, interquartile range; MSIS-29, Multiple Sclerosis Impact Scale 29; FSS, Fatigue Severity Scale; GHQ-12, General Health Questionnaire 12.

No major adverse responses were noted during the study. Minor adverse responses of muscle twitches or flexor muscle spasms in the lower limbs were noted in 64% of all participants in this study. Participants were not unduly concerned by these responses since they experienced similar spasms at other times. Muscle spasms, clonus and tonic-clonic contractions in people with multiple sclerosis during acupuncture, were noted by Steinberger in 1986,³¹ but we are unaware of any other similar reports in the literature since this time. The possibility of provoking lower limb muscle spasms in those individuals with multiple sclerosis with spasticity needs to be discussed as part of the consent process. In addition, the practitioner needs to consider carefully whether to use acupuncture points such as Stomach 34 or Spleen 10, which lie within the quadriceps muscle. Flexor spasms are likely to cause needles at these points to bend and may cause the recipient discomfort.

There are a number of limitations to this study. As the sample size was small any observations noted may be due to chance. The sample varied widely in many characteristics such as age, EDSS score and years since diagnosis. These factors may influence the response of participants to acupuncture. The researcher also provided the acupuncture interventions introducing the possibility of bias. Manualized approaches to researching acupuncture interventions in complex conditions can add rigour to a study.¹⁶ However, the Chinese medical screening questionnaire was not validated and the administration of a postal questionnaire is not the usual method of arriving at a traditional Chinese medical diagnosis. This, combined with the lack of interaction between researcher and participant may have led to an underestimation of the effects of Chinese medical acupuncture as usually practised. Most participants reported no change or improvement following treatment. Improvements seen may have been due to non-specific effects of needling or placebo effect.

Despite these limitations, we think that this study represents one of the first attempts to rigorously evaluate the application of Chinese medical pattern-based acupuncture to individuals with SPMS and to report adverse events prospectively. Treatment options in SPMS are

Table 4 Adverse events during Chinese or minimal acupuncture treatment

Adverse events All adverse events are listed	Chinese acupuncture (n = 66 treatments)	Minimal acupuncture (n = 70 treatments)	Total (n = 136 treatments)
Major adverse events	0 (0)	0 (0)	0 (0)
Minor adverse events ²⁷			
Muscle twitching or muscle spasm causing leg movement	20 (5)	4 (4)	24 (9)
Bleeding less than 5 seconds	12 (7)	4 (2)	16 (9)
Pain on needle insertion	5 (2)	2 (1)	7 (3)

Figures indicate number of adverse events; figures in brackets indicate number of participants who experienced the event.

limited, and interventions that reduce symptoms and improve quality of life are needed.¹⁵ We therefore suggest that the positive changes in some participants following acupuncture reported in this study may be clinically important and warrant further investigation. This study provides useful information to inform a larger scale study in the future.

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Clinical messages

- Different types of acupuncture had similar effects on quality of life in secondary progressive form of multiple sclerosis.
- Lower limb muscle spasms may be provoked when needling points on the legs in people with multiple sclerosis and spasticity; practitioners need to consider carefully which acupuncture points to needle in this situation.

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Appendix 1 – Details of acupuncture intervention (according to STRICTA guidelines¹⁷)

Acupuncture rationale

Chinese medical acupuncture based on identification of traditional Chinese medical patterns. Before receiving treatment, participants completed a questionnaire designed to screen for Chinese medical patterns commonly found in multiple sclerosis. Questionnaire developed by the researcher following examination of the literature^{4,13–14,16,18–22} and piloted on one patient prior to the study. Style of questionnaire based on the work of Schnyer and Allen¹⁶ (with their permission). Standard lists of acupuncture points to treat each of these patterns were identified from the Chinese medical literature.^{4,13–14,16,18–22} Points from these lists were selected to treat the three most important patterns for each participant as

highlighted by review of their completed questionnaire. (*Details available from researcher on request*)

Control intervention

Minimal acupuncture – a standardized treatment schedule of minimal acupuncture points was developed by the researcher according to principles reported in previous studies⁷ (i.e. points located away from real acupuncture points and away from points important in the treatment of multiple sclerosis). ‘Minimal points’ on arms, legs and trunk were identified to help maintain credibility of the intervention over 10 treatments. (*Details available from researcher on request*)

Needling details

Chinese medical acupuncture – points were commonly although not exclusively needled bilaterally; needles inserted to recommended depths ranging from 0.5 to 1.5 cun. (Note: cun = Chinese proportional unit – standard unit of measurement in acupuncture.) Mean number of points needled was 5. ‘De Qi’ elicited at all points. (Note: De Qi = sensation of heaviness, aching and fullness reported by recipient of acupuncture.) Manual stimulation of needles at 5-minute intervals; needles remained in situ for 25 minutes. Chinese Kangnian and Japanese Seirin needles were used with length ranging from 25 to 40 mm and gauge ranging from 0.20 to 0.25.

Minimal acupuncture – bilateral needling; insertion just through skin. Mean number of points needled was 4. No ‘De Qi’ elicited or stimulation of needles. Needles inspected visually at 5-minute intervals – no stimulation. Needles remained in

situ for 25 minutes. Chinese Kangnian needles 13 mm length, gauge 0.20.

Blackwell⁴ suggests gentler treatments may be needed for people with multiple sclerosis, hence smaller number of needles used in this study, compared to many musculoskeletal acupuncture studies.

Treatment regimen

Total of 10 Chinese medical or minimal acupuncture treatments, lasting 25 minutes each; two treatments each week for five consecutive weeks.

Information provided

Information leaflet provided following inclusion into the study stated: ‘Participants in each group will receive a different type of acupuncture, of which neither may work.’

Co-intervention

No co-interventions

Practitioner background

Researcher had spent over 10 years studying and applying Chinese medical principles to clinical practice; worked as a physiotherapist for 18 years, with 14 years working exclusively in neurorehabilitation; used acupuncture to treat people with multiple sclerosis and other neurological conditions for over five years.