Analysis of a Spinal Mobilisation Intervention in People with Multiple Sclerosis.

NCT number: 05090709

Study Protocol Ethics Approval by Edinburgh Napier University Research & Integrity Ethics Committee in October 2018.

Study Protocol

Participants

20 participants were recruited for this study in a mixed factor study design. The recommended number of participants for repeated measures, between factors ANOVA is 36 (18 participants in each group). This was shown from a G-power calculation with a large effect size (0.4), a power of 0.8 and a significance level of 0.05. Due to time constraints, participant availability and feasibility, recruitment and data collection was completed after 20 participants. Participants were recruited via posters, social media, word of mouth and contacts made with multiple sclerosis (MS) therapy centres.

Procedure

If interest was shown, an information sheet with inclusion and exclusion criteria was given to the participant and a link to a Novi Survey to gather information about their MS and health condition. Only the main researcher had access to this information on the Novi Survey. All participant information was pseudonymised according to their participant number. If the participant was eligible, they were randomly allocated to group A or group B by a random group generator on Microsoft Excel™, to organise suitable times for their sessions. Group A received a general massage for four sessions and group B received the mobilisation intervention for four sessions.

Participants were required to attend on four separate occasions, receiving the same treatment for each session. Though previous studies have recommended more sessions from their results, the time constraints on this project did not allow for more than four sessions per participant. Four sessions would still allow analysis for a cumulative effect, however previous research would indicate that eight - twelve sessions is more likely to show benefit from a manual therapeutic intervention. This was a single-blind trial, so participants were blind as to which treatment they were receiving. All testing took place at the Edinburgh Napier University Sighthill campus Engage building in a physiotherapy room which was maintained at standard room temperature (20-25°). The participants were asked to attend sessions at the same time on four consecutive weeks, to have a consistent gap between sessions.

Upon arrival, participants had the opportunity to read through the information sheet again and the researcher ran through the protocol with each participant. Participants were invited to ask any questions about the study before consent forms were given and encouraged to ask throughout the sessions if they wanted. They were informed they could withdraw from the study at any point and it would not affect their treatment. Their data could be removed up until the point of dissemination of summarised results. Once written consent was given, anthropometric measures were taken for age, weight, and height. Information was also taken regarding their most prominent symptoms and location of symptoms. Results from their Novi Survey were reviewed to go through their MS condition and Expanded Disability Status score.

The licensed massage therapist worked under their own liability and performed both treatments on all participants for this study. The therapist received training to perform the spinal mobilisation intervention. This training was monitored with force plate measurements (Kistler Instruments Ltd., Force Plate Type 2875A, Hampshire, UK) until the desired force was repeatedly applied. These forces were monitored during the intervention treatment sessions to retain the same treatment as much as possible.

For the spinal mobilisation intervention, the therapist performed a 30-minute spinal mobilisation intervention (rate = 0.37Hz, 22 beats per minute, force = less than grade 1, threshold of 80N, location = L1-L5). The force for both the intervention and the massage treatment were controlled using real-time force plate data collection. The massage therapy involved a 30-minute general massage, with no specificities or consistencies. Manual contact was applied on mid-lower back; rate and force magnitude of touch was not constant. This treatment acted as an alternative therapy, allowing comparison of the specificities of the intervention, and blinding of treatment.

During the first session, the participant carried out baseline tests for myometry, balance, pain, and fatigue pre their first session for both massage and intervention sessions. The myometer, balance and pain tests were then tested post the first session. During the subsequent three sessions, the participants completed the myometer, balance and pain tests post treatment and the final fatigue test following their last session. Participants therefore completed five sets of tests for the myometer, balance and pain, to test the cumulative effect. The fatigue test was only completed pre and post all treatment sessions due to the set-up of the questionnaire. Once all testing sessions were complete, participants were thanked for their

contribution and given a debrief sheet with further information and contact details to give to their GP or carer as appropriate.

Outcome Measures

Participants self-reported pain using a visual analogue scale (VAS). The VAS uses a pain rating scale from 0-10, 0 represented no pain and 10 represented worst pain felt. Participants were given a visual scale to rate their resting lower back pain in each of the testing sessions.

Participants completed a shortened version of the Modified Fatigue Impact Scale consisting of five questions on the impact of fatigue in their lives over the past 4 weeks. There was a total possible score of 20. This was completed at the start of the first session and at the end of the fourth session.

Myometer tests were completed using a myometer palpation device (MyotonPRO, Myoton Ltd., London UK). This previously validated handheld device has been documented to give reliable results for muscle stiffness, tone and elasticity. The myometer is a form of indenter and the main form of measuring viscoelastic properties of tissue. The indenter is placed above the desired tissue and produces a series of short force impulses from the electromagnetically activated device. This causes small deformations in the tissue for a predetermined period, to which the tissue responds with damped oscillations determined by its viscoelastic properties. These oscillations are recorded by an accelerometer on the testing end of the indenter, recording the muscle deformation characteristics via an acceleration signal. Stiffness is calculated as the ratio of resisting force response and the change in length of the tissue, tone is calculated as responding tissue acceleration signal frequency and elasticity is calculated as the logarithm decrement of the acceleration signal dampening frequency (the natural log of the ratio of two successive the acceleration signal peaks). The stiffness, tone and elasticity parameters are reported as a mean of these impulses along with a coefficient of variation (CV). Values were only accepted if the CV was less than 3%, complying with the manufacturer recommendations.

Measurements were collected on both sides of erector spinae muscle and using the higher mean value to determine the stiffer side of the spine for treatment. Measurements were taken from the central belly of this muscle by asking the participant to lift their head and feet

at the same time, contracting their back muscles to allow for muscle belly palpation. This spot was then marked and measured.

The participants then performed two balance tests positioned on the force plates. Test one involved a single leg stance test, collecting measurements for body sway total path length, anterior-posterior path length, medial-lateral path length and velocity using the tracked centre of pressure recording. The second test used was a sit-to-stand test. This required a calibration of force plates to the participant's body weight. Participants were seated on a chair directly in front of the force plate, with their feet resting on the force plate. They were asked to move from a sit to stand position, using only their leg strength. This was repeated five times. The researcher was available to help at any time if participants felt uncomfortable or unstable during the tests or therapy session. Participants were encouraged to rest between the balance tests or at any time they felt tired.

The software used to collect the force data (Kistler, MARS) gave an automatic output for the variables used in analysis. These were centre of pressure body sway velocity, rising index (the percentage of body weight applied to the force plates during the standing movement) and weight transfer (the time taken to stand). A total of five testing sessions were completed for each participant, pre and post session one, and post sessions two, three and four.

Statistical Analysis Plan

Participant data were extracted and stored on password protected Microsoft Excel spreadsheets on university computers. Data was reduced using the mean value of the 5 trials for each variable in each testing session was calculated, resulting in 5 values for each variable (except fatigue) and each participant used for statistical analysis. The fatigue scores were a numerical value between 0-20 and only collected twice, pre and post all sessions, resulting in 2 values for each participant. Data collected from their Novi Survey and in their first session were collated and summarised into mean, range and dispersion values for their anthropometric and MS data. Analysis was carried out on SPSS (version 23) using mean values with standard error dispersion values. All dependent variables for muscle response, single stance balance, sit-to-stand stability, pain, and fatigue scores were analysed each in a between-subjects repeated measures ANOVA. This was to determine differences between the two treatment groups and between the different time points.