MS Proof of Concept Study – Interim Update

Abstract
This Proof of Concept (POC) study was designed to consider the validity of the Lightning Process as an approach to provide benefit, or not, to those with MS. A POC is a Phase 1b, or Phase 2 trial, regardless of sponsorship, that could generate, confirm, provide an adequate benefit-risk, or establish a response relationship that could be used as the basis for a decision to move forward with an approach. The outcome measures from the POC can also be used to add weight to future grant and funding applications for larger-scale Randomised Controlled Trials. Participants for this study were recruited through the MSRC. The interim data shows that the LP provided benefit to all participants and there have been no incidents of negative effects. The data suggests that it would be worth pursuing a full Randomised Controlled Trial.

Participants
49 people responded to the original request. All 49 were sent the 'Introduction to the Lightning Process' book and asked to complete a form outlining more details about themselves. 33 returned this form. The volunteers were asked about their ability to travel and the distance that they could manage to travel to attend a Lighting Process course. They were then grouped into regions. 12 Lightning Process practitioners and 12 volunteers with MS were then randomly selected. The randomly selected group was made up of 8 women and 4 men, all had a diagnosis of MS with varying symptoms. The age range of the participants was 40 years to 79 years. The date of onset of symptoms ranged from 1970 to 2008.

After randomisation 1 person identified that they are already involved in a drug trial so they were excluded from this study, an alternative volunteer was selected. Another volunteer decided not to start the course just prior to the seminars so an alternative volunteer could not be recruited at this stage. This person also decided not to complete any data. The final number of volunteers on the Proof of Concept Study is therefore 11.

Outcome Measures
All volunteers were asked to complete 3 questionnaires: Rand SF36 (36-Item Short Form Health Survey), Functional Assessment of MS scale (FAMS) and FSS Fatigue Severity Scale (FSS). These questionnaires are completed at time intervals of: before attending the LP seminars; 6 weeks after attending the LP seminar; 3 months after attending the LP seminar; 6 months after attending the LP seminar and 12 months after attending the seminar.

Missing data was excluded from the analysis.

Interim Results
Functional Assessment of Multiple Sclerosis (FAMS)

	Pre LP (n=11)	6 weeks (n=9)	3 months (n=10)	6 months (n=7)
Score	91.88	122.78	118.25	117.6

Table 1: mean FAMS scores – increase in number means increase in functional abilities

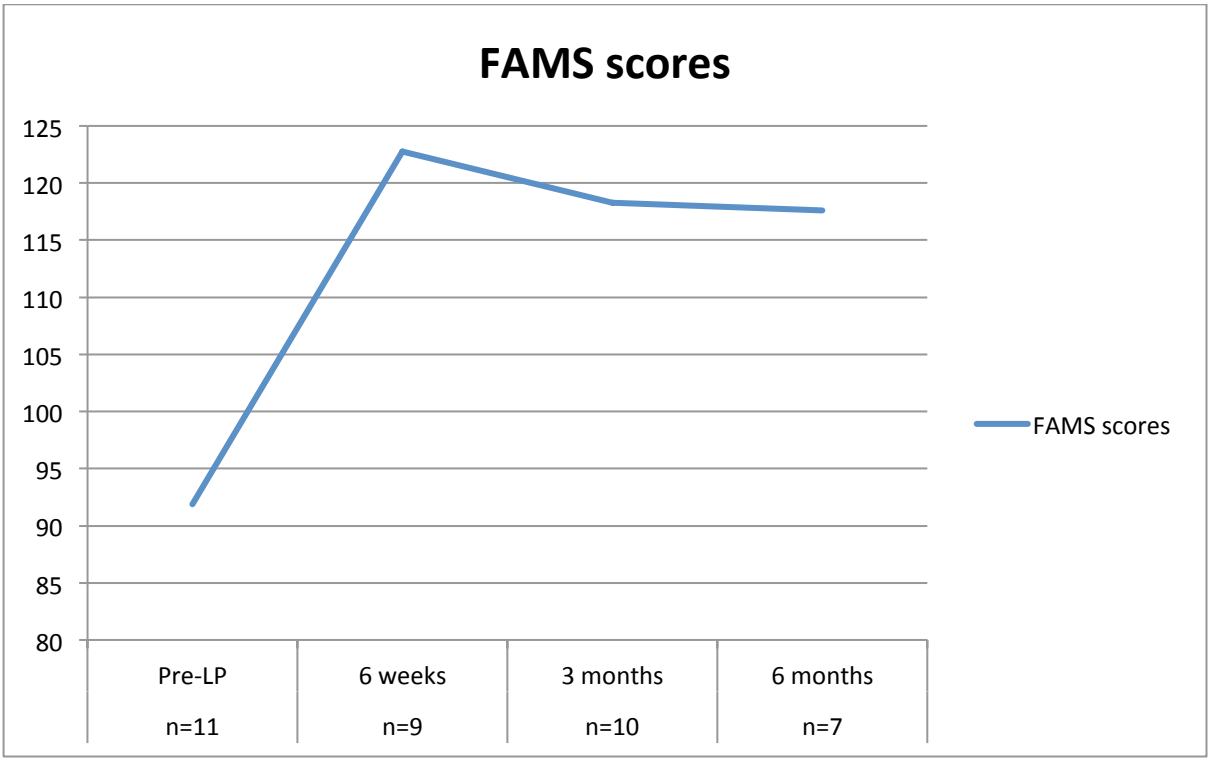

Figure 1: mean FAMS score

Fatigue Severity Scale (FSS)

	Pre LP (n=11)	6 weeks (n=8)	3 months (n=10)	6 months (n=7)
Score	5.56	4.14	4.44	4.23

Table 2: mean FSS scores – decrease in number means decrease in fatigue

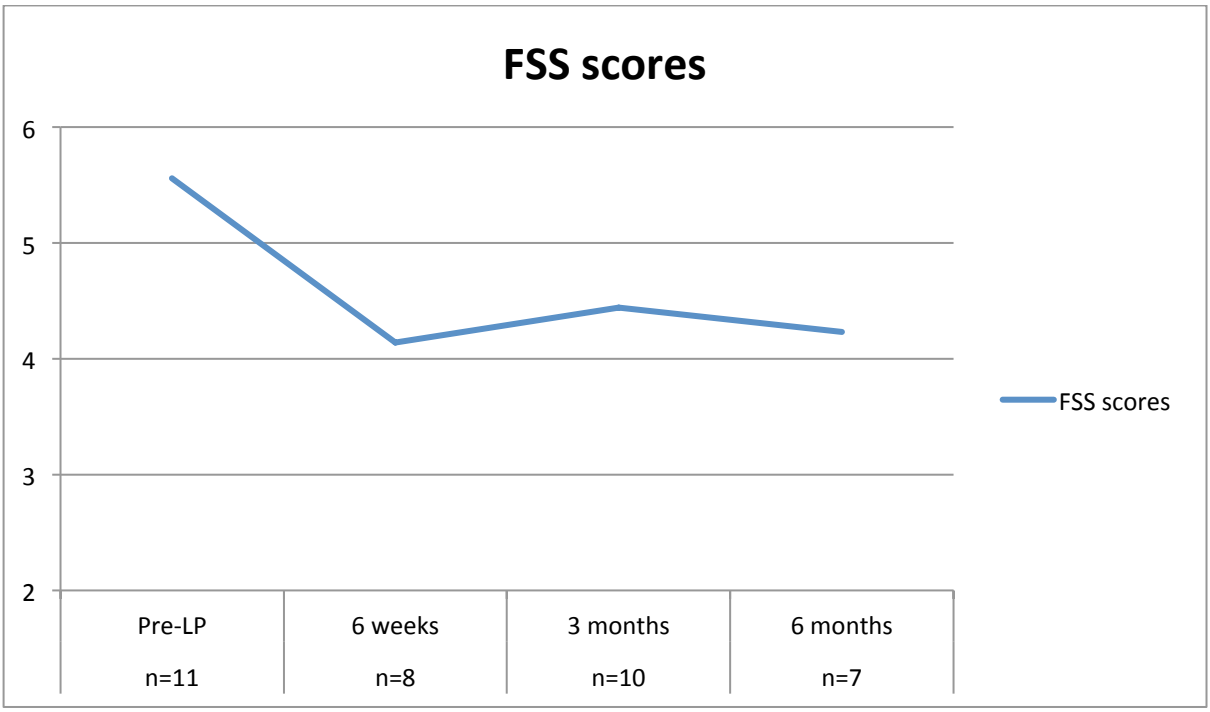

Figure 2: mean FSS score

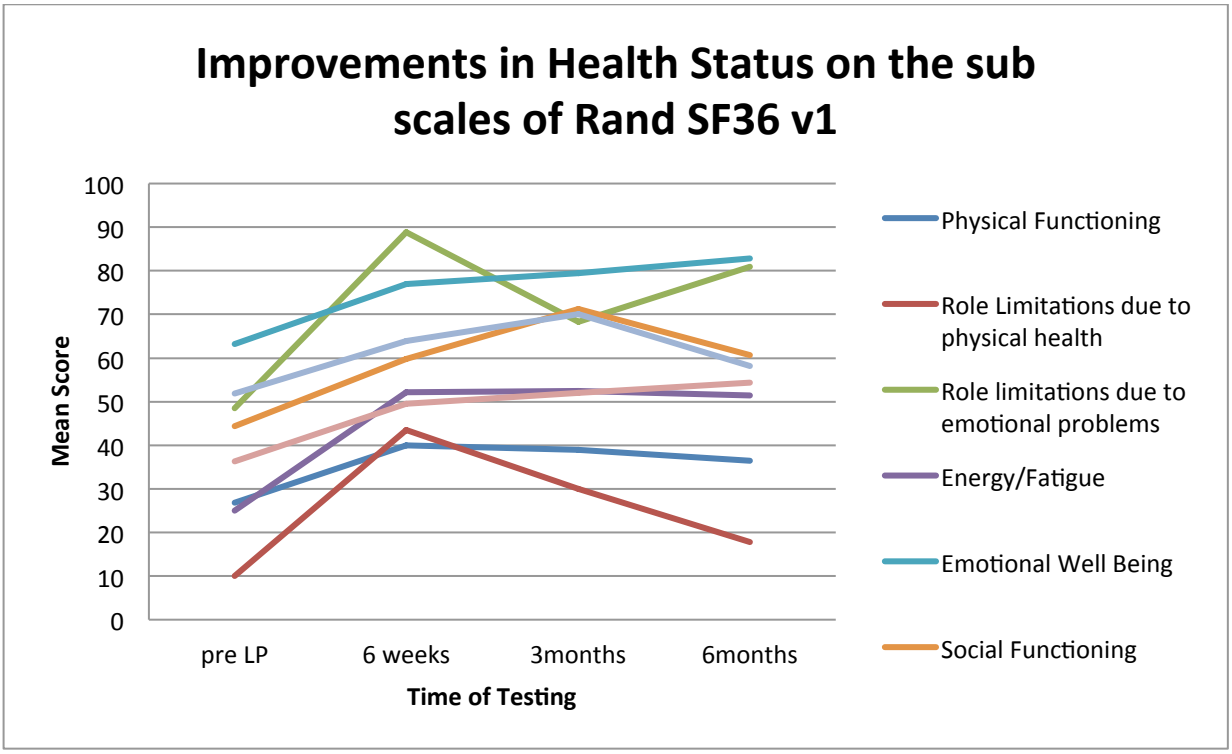

Figure 3: mean improvements in health status on the sub scales of Rand SF36 v1

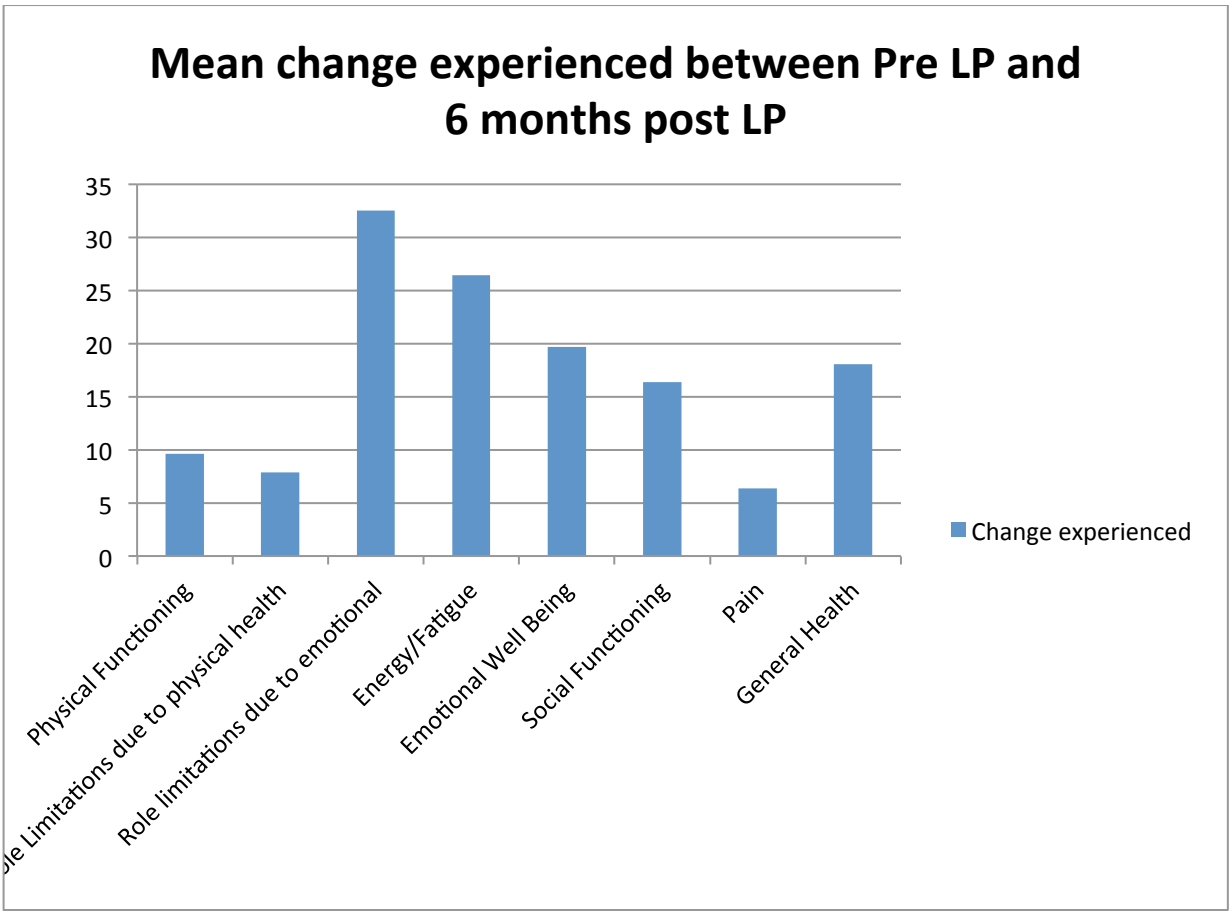

Figure 4: mean change experienced between Pre LP and 6 months Post LP

All sub-scales of the Rand SF-36 showed improvements across Time of Testing. The largest mean ranges of change were in role limitations due to emotional problems, energy/fatigue levels, emotional well-being and general health. The volunteers will continue to complete questionnaires in order to provide further data in order to further demonstrate the effect of LP on people with MS. The sample size is small and the study limited but the interim data suggests that the concept is demonstrated and therefore a full randomised controlled trial would be advised.

The Proof of Concept steering group decided to collect some additional subjective data to highlight factors that volunteers reported, yet were not being captured effectively by the data collection tools. These additional questionnaires picked up qualitative comments such as “a calmer approach to life, no longer getting worked up about situations I cannot influence”. They also highlighted that some volunteers felt they could have got better results by applying the tools more consistently in the long term but had, for various reasons, not felt they had put the time and effort in that they needed to. All the subjective questionnaires returned demonstrated that volunteers had benefitted from attending the Lightning Process course. Some requested additional support from their practitioner. This data has been very useful and will inform future developments and delivery of the Lightning Process.

Comment from MSRC

This Proof of Concept study, although being in a small number of subjects, produced some very encouraging and worthwhile results over a 6 month period following participation in the Lightning Process. They indicate that the Lightning Process provides measurable benefits to those with MS and suggest that a further larger randomised study would be beneficial to investigate the role the Lightning Process plays in the well-being and quality of life of MS patients. *(MSRC September 2011)*