

Name *	Summer Anderson
Email *	summer-r-anderson@uiowa.edu
Educational Level *	Undergraduate
If Selected Other	
College *	College of Liberal Arts and Sciences
Department *	Health Psychology
Title of Research *	Multimodal Intervention and QOL in Secondary Progressive Multiple Sclerosis
Other Authors *	Susan Lutgendorf, Andrew Schrepf, Warren Darling, E. Torage Shivapour, Linda Snetselaar, Michael Hall, Terry Wahls
Introduction & Purpose *	<p>Secondary Progressive Multiple Sclerosis (SPMS) is an autoimmune disorder characterized by cognitive and physical impairment, along with pain and fatigue. Depression and decreased quality of life (QOL) are often associated with SPMS, which at this time has no cure. The current study investigates subjects' willingness and ability to follow a complex multimodal intervention and effect sizes for QOL and affective measures that would be needed to adequately power a larger randomized trial. Preliminary data from this innovative intervention is presented here.</p>
Experimental Design *	<p>This is an open label, non-randomized, feasibility study of a multimodal lifestyle intervention for SPMS. The intervention utilizes a stretching and exercise program, a modified Paleolithic diet, nutritional supplements, neuromuscular electrical stimulation (NMES), stress management, and massage. Compliance is monitored through self-reported daily logs. Adverse events are monitored through monthly logs. Subjects received instructions for the intervention and subsequently completed a one-month pre-trial "run-in" period to determine ability to adhere to the intervention. Subjects successfully completing the "run-in" were consented for the Main Study, and continued the intervention for 6 months with data collection at 0, 3, and 6 months. The sample includes 8 female subjects with SPMS (mean age: 53.5, range: 46-58, mean years with SPMS: 16.38, range 3-37). Outcome data includes Beck Depression Inventory-II (BDI-II), Beck Anxiety Inventory (BAI), and Medical Outcomes Study Short Form-36 (SF-36).</p>
Results *	<p>Twelve subjects consented to the "run-in" and nine were consented for the Main Study. One subject withdrew from the Main Study for unknown reasons. Even with this small sample, repeated measures ANOVA tests showed significant increases in general health ($F_{2,14}=6.98$, $p=0.008$, $d=.80$) and physical role functioning ($F_{2,14}=6.19$, $p=0.012$, $d=1.08$), significant decreases in pain over time ($F_{2,14}=5.87$, $p=0.014$, $d=1.06$), and a trend towards increasing energy ($F_{2,14}=2.57$, $p=0.112$, $d=.73$) on the SF-36. Meaningful trends were not observed for other SF-36 subscales, depression, or anxiety (all p-values > 0.27), although moderate effect sizes were observed for depression ($d=.31$).</p>
Conclusions *	<p>Two-thirds of the subjects enrolled in the "run-in" phase maintained the study intervention. Of the subjects entering the Main Study, 8/9 were able to maintain the complex multimodal lifestyle intervention. Moderate to large effect sizes in QOL suggest this intervention holds promise. Findings will be used to support a larger randomized</p>

controlled trial testing the efficacy of this multimodal intervention in an SPMS population.

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