Self-Efficacy Improvement in Multiple Sclerosis (SIMS): A Pilot Study

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OBJECTIVE
This pilot study aimed to determine whether an outreach program consisting of industry-based nursing outreach augmented with recorded MS-specific guided imagery stress reduction training results in superior self-efficacy and adherence compared to outreach alone.

BACKGROUND & SIGNIFICANCE
- Immunotherapy treatment effectiveness is highly dependent upon treatment adherence.
- Self-Efficacy has been shown to be a strong predictor of adherence. 1
- Nursing outreach programs have been very effective at improving self-efficacy and treatment adherence but have not been very effective in improving self-efficacy or treatment adherence in patients with depression, anxiety, or chronic stress. 2,3
- Depression is highly prevalent in multiple sclerosis, and reduction of depression is associated with improved treatment adherence. 3
- Relaxation training is a behavioral medicine modality that is often effective in reducing symptoms of depression, anxiety, and chronic stress.
- Guided imagery is a form of relaxation training that utilizes auditory stimuli to generate relaxation responses via induced perceived sensory effects.
- A guided imagery program specific to MS has been developed for persons who are starting subcutaneous or intramuscular immunotherapy. 3 This program is available via audio recording and can be delivered in a standardized, dose-dependent fashion using MP-3 or iPod devices.

METHODS
Design: Pilot study, prospective, convenience sampling, randomized, 12 months duration, no placebo.

Randomization: 1. Nursing outreach + guided imagery relaxation training (intervention) 2. Nursing outreach alone (control)

Inclusion Criteria: 1. CIS or RRMS 2. Starting interferon beta-1b treatment

Exclusion Criteria: 1. Antipsychotic medication use 2. Bipolar affective disorder or psychotic disorders 3. History of suicidal ideation

Current Status: Full enrollment (N=23) completed. The study was completed in April 2012.

PRIMARY HYPOTHESES
The intervention group will demonstrate superior self-efficacy and treatment adherence compared to control.

RESULTS

Table 1: Characteristics of Participants (n=23)

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<thead>
<tr>
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<th>Intervention (n=14)</th>
<th>Control (n=9)</th>
<th>p</th>
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</thead>
<tbody>
<tr>
<td>Age at Enrollment</td>
<td>44.3 (n=14)</td>
<td>42.6 (n=9)</td>
<td>0.66</td>
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<td>Gender (% Male)</td>
<td>35.7% (n=5)</td>
<td>0</td>
<td>0.04</td>
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<td>CIS (%)</td>
<td>7.1% (n=1)</td>
<td>0</td>
<td>0.41</td>
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<tr>
<td>EDSS at Enrollment</td>
<td>2.3 (n=14)</td>
<td>2.1 (n=9)</td>
<td>0.82</td>
</tr>
<tr>
<td>2 Yr. Annualized Relapse Rate at Enrollment</td>
<td>0.57</td>
<td>0.55</td>
<td>0.95</td>
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1) Working memory processing speed (age and education adjusted Z scores) differed significantly at baseline and month 12 (p<0.05).

2) No other significant differences between groups were observed for any measure (self-efficacy, depression, cognition, or anxiety) at any time point.

QUALITATIVE RESULTS
Qualitative results suggested an overall benefit to the intervention. Examples of common themes elicited are given below:

Ease of Use
"It was super easy... the iPod was convenient... I listened to the recordings during breaks at work or to relax before going to bed."

Effectiveness
"I was surprised by how well it worked... after a few weeks I was doing much better with my [DMT] injection anxiety... over time I was using less [PRN] medications for anxiety... I was impressed."

DMT Adherence/Tolerability
"I didn't really think that this [relaxation] program would help me to get over my [DMT] injection anxiety, but it actually helped... it took a few weeks, but over time I became less anxious about the shots... I don't miss many now."

Recommend to Others
"This is easy and has no side effects. Made a difference for me... I would recommend it... definitely worth a try."

REFERENCES

This study was supported by a research grant from Bayer Healthcare.