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## Six versus Twelve Weeks of Swedish Massage Therapy for Generalized Anxiety Disorder: Preliminary Findings

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### Abstract

Acute treatment of Generalized Anxiety Disorder often requires 3 months or more of care in order to optimize response. As part of an exploratory grant we have previously demonstrated that six weeks of twice-weekly Swedish Massage Therapy (SMT) was more effective than an active control in decreasing Hamilton Anxiety Rating Scale Scores (HAM-A). An additional goal of this project was to determine if an additional six weeks of twice-weekly SMT led to greater clinical and statistical benefit. We found that HAM-A scores did continue to decrease with an additional six weeks of therapy but that the greatest benefit occurred during the first versus the second 12 sessions ( $-9.91$  vs.  $-3.09$ ,  $t=2.21$ ;  $df=10$ ;  $p=0.052$ ). These preliminary findings suggest that the

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**PREVIOUS PRESENTATION:** The material is original research, has not been previously published, and is not currently submitted for publication elsewhere. The primary outcomes of the study (6-week data) have been published in the *Journal of Clinical Psychiatry* (2016). Some of the preliminary analyses of these data were presented at the 2014 ACNP meeting, Phoenix, Arizona, USA.

#### Conflict of Interest

**Dr. Rapaport** has provided consulting services to PAX, Inc (unpaid) and has been funded by the NIH.

**Dr. Schettler** works part-time both as Senior Research Associate in the Department of Psychiatry and Behavioral Sciences at the Emory University School of Medicine, Atlanta, Georgia; as well as Principal Statistician in the Department of Psychiatry of the School of Medicine at the University of California, San Diego. Dr. Schettler has been funded by the NIH. She has no other direct or indirect affiliations or financial interests in connection with the contents of this paper.

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majority of benefit in symptom reduction occurs in the first six weeks and that six weeks of twice-weekly SMT may be sufficient for the majority of patients.

## Keywords

Swedish Massage; Generalized Anxiety Disorder; Dose; Anxiety; Treatment

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## 1. Introduction

Generalized Anxiety Disorder (GAD) has a prevalence rate of 5.8% and is characterized by a constellation of both physical and psychological symptoms.<sup>1-3</sup> Relief from anxiety and stress are two of the most common reasons people seek out complementary and alternative medicine (CAM) treatments<sup>4-6</sup>, with massage as one of the most frequently employed therapies for anxiety.<sup>1,7</sup> In fact, 43% of participants in the Coordinated Anxiety Learning and Management study endorsed using some form of CAM.<sup>8</sup> As a secondary outcome, anxiety symptoms decreased in multiple studies on the efficacy of massage for medical disorders (see<sup>9</sup> for review) including therapeutic effects in infants who were pre-term, cocaine-exposed, HIV-exposed and full-term<sup>10-12</sup>; decreased pain and *anxiety* associated with childbirth, labor, severe burns, the post-operative period, juvenile rheumatoid arthritis, fibromyalgia, lower back pain, and migraine headaches<sup>13-20</sup>; and decreased *anxiety* and depression associated with multiple sclerosis<sup>21</sup> and spinal cord injuries<sup>22, 23</sup>. Previous meta-analyses suggest that massage is a useful intervention for people with problems with anxiety, fatigue, muscle tension, muscle soreness, and headaches.<sup>9</sup> To date there has been one case series and two randomized controlled trials of massage for GAD.<sup>24, 25</sup> The case series reported that patients with GAD benefited from Swedish Massage therapy (SMT).<sup>24</sup> However, the trial by Sherman and colleagues<sup>25</sup> in a mixed population of medicated and unmedicated participants employing approximately weekly sessions versus a non-intervention control condition, did not demonstrate any benefit for massage therapy. More recently, we performed a randomized, singly masked, six-week monotherapy trial of twice-weekly SMT versus a light touch control (LT) condition for participants with GAD, with outcomes evaluated by masked raters.<sup>26</sup> This trial demonstrated significant improvements in ratings of anxiety and depression for the group receiving SMT. The exploratory goal of this study was to gather preliminary data employing the Hamilton Rating Scale for Anxiety (HAM-A) comparing the first six weeks of twice-weekly SMT from the clinical trial (12 sessions) with a second six weeks of twice-weekly SMT (for a total of 24 sessions). The aim was to determine if there was a significant added value to continuing therapy for the 24 total sessions delivered over three months.

## 2. Methods

### 2.1. Trial Design and Participants

The trial design and participants for the initial 6 weeks of the study are fully described in Rapaport et al., 2016 and briefly below.<sup>26</sup> The study was a randomized, single-masked, two-arm clinical trial comparing six weeks of twice-weekly SMT vs. LT as monotherapy for GAD. It was conducted at the Mood and Anxiety Disorders Program of Emory University in

Atlanta, Georgia, between March of 2012 and May of 2013. Forty-seven participants with GAD were recruited from the surrounding community by means of flyers, referrals, and word of mouth and signed written informed consent. The Emory Institutional Review Board approved the study protocol.

Participants had to be medically healthy as demonstrated by a normal medical history and physical exam, meet criteria for a primary diagnosis of current GAD as determined by a structured clinical interview for DSM-IV (SCID),<sup>27</sup> and have a HAM-A<sup>28</sup> total score >14 in order to enter the acute randomized trial. The HAM-A was chosen as the only assessment of anxiety because 1) it has validated subscales for both psychic anxiety and somatic anxiety, and 2) we wanted to minimize the assessment burden on participants. Participants were permitted to have comorbid but secondary major depressive disorder, dysthymic disorder, or another anxiety disorder except obsessive compulsive disorder. Exclusion criteria included current suicidal ideation, schizophrenia, bipolar disorder, borderline personality disorder, illicit drug use, current psychotropic medication use, current participation in psychotherapy, pregnancy, shift work, current dieting, active medical problems, excessive regular use of alcohol (more than two 5 -oz glasses of wine or equivalents/day), or a history of binge drinking (more than seven drinks/24 hour period) within the last six months.

For inclusion in this analysis, the participants had to complete the twelve SMT sessions in the randomized clinical trial and agree to participate for an additional six weeks of twice-weekly SMT. Three of the 14 eligible participants declined to participate in this open extension phase, two because of conflicts with their job and one because of complications after a car accident. The three participants who discontinued after six weeks of SMT were similar to the 11 who continued SMT in terms of mean age and baseline HAM-A, and they had an identical mean score (10.0) at the six-week point. All 11 participants who began the second period of SMT completed the full six weeks.

## 2.2. Interventions

SMT treatment occurred between 12:00 PM – 6:00 PM. Prior to the start of each visit participants were asked about changes in health or pregnancy status, use of prescription or over-the-counter medication, illicit substance use, and any new life events

The 45 minute SMT sessions were performed by licensed massage therapists from the Atlanta School of Massage, who adhered to a script that standardized their interactions with participants and followed a manualized treatment protocol<sup>29</sup> performed at pressure level 1 on the Massage Therapy Pressure Scale.<sup>30</sup> The room was dimly lit and a sound machine was used to mask ambient noise. The participant was draped with a sheet and in a prone position on a massage table, the therapist worked slowly down the body from the shoulders to the feet. The participant then turned over to the supine position and the therapist continued the protocol from the feet back up to the shoulders. SMT techniques included effleurage (slow, rhythmic, continuous stroking), petrissage (slow, rhythmic kneading of underlying muscles), and tapotement (various forms of percussive touching/tapping). Quality control was maintained by review of audio taped sessions, quarterly reliability sessions, weekly discussion of issues arising during intervention sessions, periodic spot checks of SMT

protocol adherence, as well as feedback from participants about consistency across therapists.<sup>29, 31</sup>

### 2.3. Outcome Assessment

At baseline prior to the initiation of the randomized masked trial, the HAM-A was performed and this rating serves as the pre-treatment measure of anxiety. The HAM-A performed at the end of visit 12 serves as both the end-point for assessment of change during the first 12-session period and the baseline value for comparison of change during the additional 12 sessions of SMT. After all visits, the study psychiatrist conducted a HAM-A interview and assessed the participant for suicidality. The HAM-A consists of 14 items scored 0–4 (range 0–56).

### 2.4. Statistical Approach

A repeated measures t-test was employed to evaluate within-participant change in HAM-A during six and twelve weeks of SMT, as well as to compare change in HAM-A scores during the first vs. second six-week period.

## 3. Results

All eleven participants who started the second six weeks of SMT completed the entire 24 sessions. Mean HAM-A scores dropped from 19.91 (2.17 SD) at baseline, to 10.00 (5.80 SD) at week 6 ( $t=6.31$ , DF 10,  $p<0.0001$ ), to 6.91 (3.11 SD) by week 12 ( $t=6.13$ , DF 10,  $p<0.0001$ ) (Figure 2A). The majority of improvement on HAM-A scores occurred in the first six weeks during the single masked trial: mean change of  $-9.91$  (5.20 SD) compared to  $-3.09$  (5.61 SD) in the second six weeks, a difference that approached the level of statistical significance ( $t=2.21$ , DF 10,  $p=0.052$ ) (Figure 2B). This small reduction in the HAM-A does not meet the criteria for a clinically meaningful change based on our group and others definition of a clinically meaningful change.

## 4. Discussion

GAD is a common, chronic and debilitating condition.<sup>32</sup> People with GAD have increased sympathetic nervous system (SNS) activity (as evidenced by heightened heart rate and skin conductance) as well as decreased parasympathetic nervous system (PNS) activity (as evidenced by lower heart rate variability).<sup>33, 34</sup> Further, basal activity of the amygdala, an integral part of the neural circuit that controls peripheral targets of stress response (*i.e.*, SNS and PNS) through the hypothalamus<sup>35</sup> is elevated in those with GAD. Worry and GAD are also associated with altered reactivity to stressors. In particular, greater levels of SNS arousal immediately pre-stressor predicts a lesser increase in sympathetic adrenergic activity in response to a stressor<sup>36, 37</sup>. Thus, increased basal physiological arousal (reflecting a state of pre-stressor worry) may explain dampened physiological reactivity to the stressor in GAD. Although both pharmacological and psychotherapeutic approaches are available, the response and remission rates are inadequate and leave many individuals with ongoing symptoms and impairment.<sup>38–42</sup> Other challenges include societal and individual feelings of stigma, which frequently lead patients suffering from GAD to suffer without seeking help. In

addition, many individuals prefer a somatic treatment like massage over either medication or psychotherapy.

Our previous work with patients suffering from GAD demonstrates that carefully manualized SMT produces a clinically and statistically significant reduction in measures of anxiety, general distress and depression, superior to an active control condition, LT.<sup>26</sup> The current study assessed the impact of twelve additional sessions of SMT on the overall change in anxiety. These data need to be viewed as preliminary and require replication in a larger study because our sample is small and only includes those participants from the acute treatment trial who elected to continue for an additional six weeks of twice-weekly massage. In addition, the lack of a comparison group is a weakness of the study. Although continued improvement occurred over the additional twelve sessions of SMT, 71% of the total improvement occurred during the first twelve sessions. This suggests that a time limited intervention with twice-weekly SMT for six weeks may be sufficient acute treatment for many individuals with GAD. At a time when massage therapy is frequently a non-reimbursed expense, it is important to ascertain the quantity of care that provides sufficient treatment for most patients. Such information will empower patients to make a more informed decision about employing this treatment approach

## 5. Conclusions

In conclusion, this preliminary analysis suggests that participants who continued with SMT for a second twelve sessions did continue to experience less anxiety as measured by the HAM-A. Yet the amount of improvement was clinically and statistically greater during the first twelve sessions. Thus, six weeks of twice-weekly SMT may be sufficient for most individuals with GAD.

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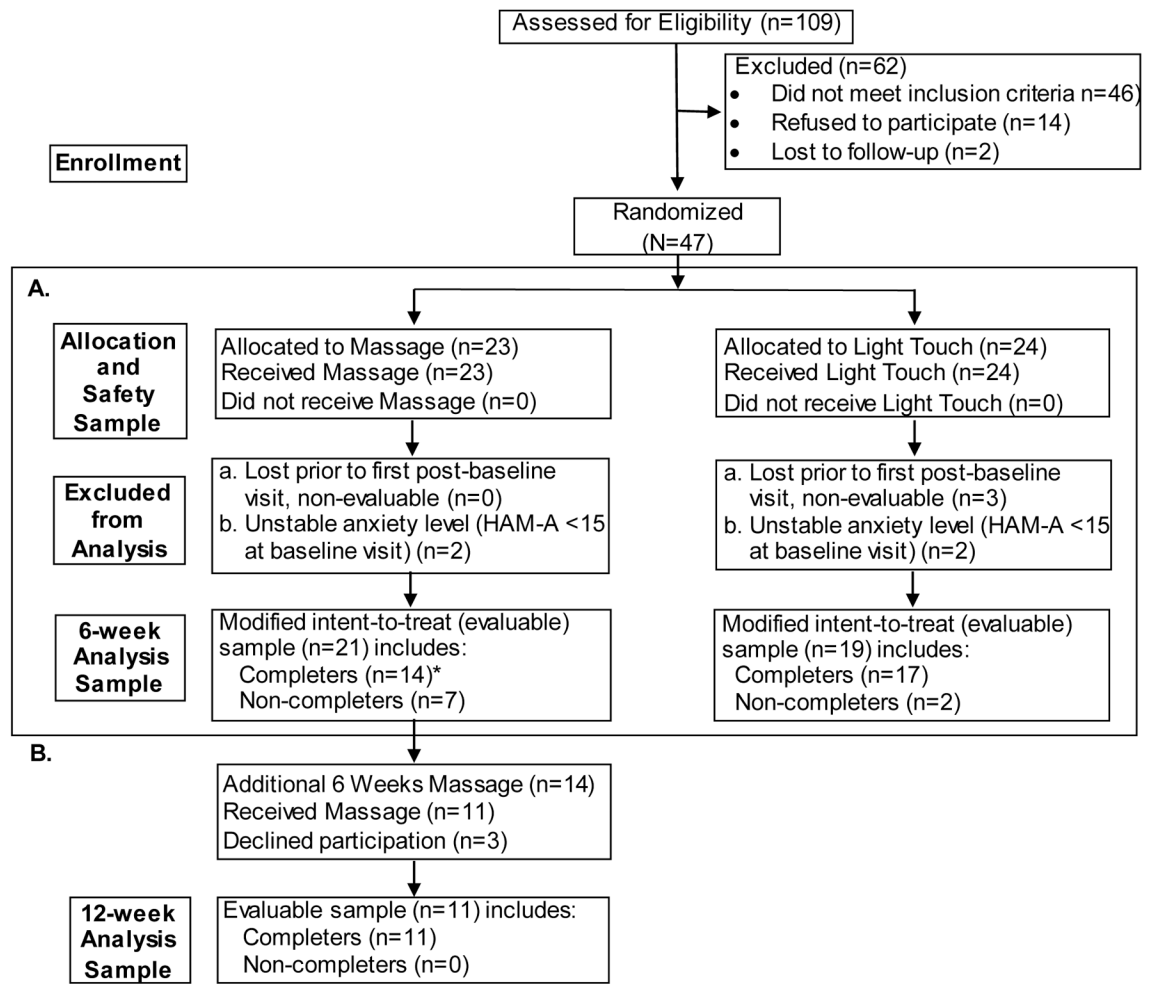
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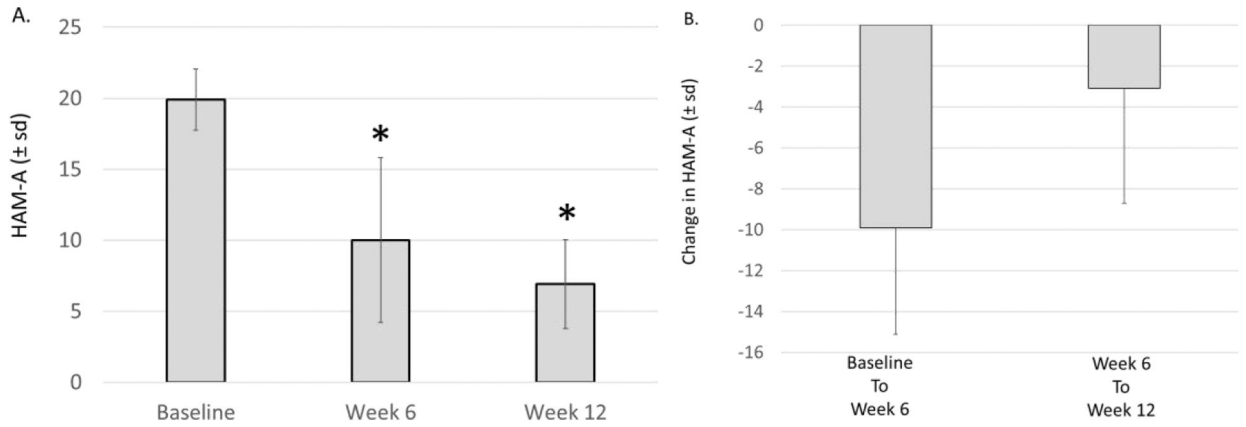
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A. Participant flow and analysis sample for the 6-week randomized trial of Swedish Massage Therapy (SMT) vs Light touch (LT) for generalized anxiety disorder (GAD) (Rapaport et al., 2016).  
 B. Participant flow and analysis sample for the additional 6-week of Swedish Massage Therapy (SMT) for evaluation of 6-week vs 12-week SMT for generalized anxiety disorder (GAD).

**Figure 1.**  
 CONSORT Statement Diagram of Participant Flow: 6- vs 12-weeks of Swedish Massage for Generalized Anxiety Disorder.





**Figure 2.** HAM-A ratings in participants undergoing Swedish massage therapy as monotherapy treatment of generalized anxiety disorder (GAD). A) HAM-A at baseline, week 6 (after 12 sessions of SMT), and week 12 (after 24 sessions of SMT). Data are mean  $\pm$  standard deviation (SD). \*  $p < 0.0001$ . B) Change in HAM-A from baseline to week 6, and from week 6 to week 12. Data are mean  $\pm$  standard deviation (SD).