The Effects of Flotation REST on the Symptoms of Fibromyalgia

Roderick Borrie, Ph.D., Tamara Russell, Ph.D. and Stefan Schneider, Ph.D.

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Abstract

Flotation centers in five countries recruited 81 people diagnosed with fibromyalgia and donated three float sessions to each of them. In return, the participants were asked to complete uniform questionnaires regarding their illness and their floatation experience. The data were collected and analyzed to produce compelling evidence that flotation REST can have a beneficial impact on fibromyalgia. Results demonstrated that flotation REST provided significant temporary reductions in pain, muscle tension, stress, anxiety and sadness, as well as significant increases in relaxation, feelings of well being, energy and ease of movement. There was also significant improvement in the quality of sleep.

Introduction

Flotation REST (Restricted Environmental Stimulation Therapy) utilizes a pool of heavy water in a light and sound attenuated environment to produce a maximum reduction of external stimulation. This has been shown to produce a variety of therapeutic and health benefits (see Suedfeld and Borrie, 1999). One significant application of this therapy has been to reduce physical pain (Fine and Borrie,). Treatment with flotation REST has been shown to provide temporary reduction of pain from rheumatoid arthritis (Meriday et al, 1990), muscle tension (Kjellgren et al, 2001, Bood et al, 2007), headaches (Walbaum et at. 1992), back injury (Borrie, 1993), and fibromyalgia (Bood, 2007).

Fibromyalgia was suggested as a target population for this study because the characteristics and symptoms of this disorder correspond closely with the demonstrated benefits reported from prior Floatation REST studies. Fibromyalgia is a disorder characterized by widespread musculoskeletal pain, described as a constant dull ache, typically arising from muscles. It effects 2% of general population and women are much more likely to develop it than are men by a ratio of 9:1.

The characteristics and symptoms of fibromyalgia are:

- Linked to Stress both as a trigger and as a causal factor
- Muscle pain
- Muscle tightness
  (pattern of muscle knots called tender or trigger points, sometimes tension headaches, TMJ, and IBS)
- Mood disturbances (depression and anxiety)

- Inability to achieve restful sleep
  (People with fibromyalgia often awaken tired, even though they report sleeping for long periods of time. Sleep is frequently disrupted by pain, and many patients with fibromyalgia have other sleep disorders, such as restless legs syndrome and sleep apnea, that further worsen symptoms.)
- Magnesium deficiency (London, 2007)

Floatation REST has been shown to have a significant beneficial effect on each of the factors.

- Stress reduction
- Decreased pain in general
- Decreased muscle tension
- Decreased pain caused by muscle tension
- Lessening of anxiety
- Mood elevation
- Improved sleep
- Magnesium absorption
  A study by Waring (U of Birmingham, UK, 2004) found significant rises in plasma magnesium after subjects floated in a 12-minute Epsom salt bath of 1% solution (600g Epsom salt/60 liters water).

Method

Historically research on floatation REST has been underfunded. The majority of studies have been pilot studies, case studies, and clinical studies with no control groups. While there are an abundance of controlled studies utilizing Chamber REST, controlled studies of floatation REST are few and rarely have large numbers of subjects. The enthusiasm of participants of the Float Summit in 2010 was the stimulus for the present study. Floatation centers were asked to donate three floats to each volunteer subject diagnosed with fibromyalgia. Individual float centers issued press releases seeking people with fibromyalgia interested in trying floatation REST as part of an international study. Volunteers were asked to complete a questionnaire with personal information regarding their diagnosis of fibromyalgia and other illnesses, the amount of pain they experience and how that pain restricted their activities and their normal sleep patterns. To ascertain the diagnosis, volunteers were asked to take a form to their personal physician. This form explained the study to the subjects' physicians and asked the physician to sign off on the subjects' participation as a person with fibromyalgia.

Floatation centers in 5 countries participated in the study, one each in Britain, the United States, Belgium and Germany, and several in Sweden. There were 81 volunteer subjects in all with the breakdown as follows:

Country	No. of Participants	Percent
GER	8	9.88
NL	11	13.58
SWE	47	58.02
UK	5	6.17
US	10	12.35

Each subject was told they were to have three one-hour floatation REST sessions within a three-week period. They were told they would need to complete a form immediately prior to each session and immediately afterwards. The pre and post float questionnaires had 10 questions using 11-point Likert Scales (0 to 10) for the following variables: Pain, Bothered by Pain, Muscle Tension, Freedom of Movement, Stressed, Energy, Sadness, Well-Being, Relaxation and Anxious. At the time of the pre-float questionnaire for the second and third session subjects were given additional question about effects following their last session, such as, how long their relief lasted, how well they slept and how much stress they had been feeling. They were also given an opportunity to make open-ended comments regarding how they were affected by the experience.

Each floatation center used its own standard orientation to the floatation experience and address subjects' concerns about what to expect. The uniform questionnaires for the study were translated into German, Dutch and Swedish for the respective countries. UK and US subjects used the original English versions. The original plan was to include an audio program that made therapeutic suggestions for relaxation and pain relief. An English version was provided however no translation was made of this, so it was used only with UK and US subjects. No analysis was done on this aspect of the study except examining differences between countries.

Results

Missing Data

As a first step it is useful to examine the amount of missing data participants were offered a total of 3 sessions, but some dropped out after the first or second session. Of the 81 participants, 9 (11%) dropped out after session #1, 7 (9%) dropped out after session #2, and 65 (80%) completed the 3rd session. Thus the amount of attrition is moderate but not a major concern as later analysis will show.

Analysis of intervention effects

Participants received the treatment up to 3 times, which generates several interesting questions regarding the effects of the intervention:

(1) immediate intervention effects: Are there significant Pre-post effects in a given session?
(2) "longer-term" change in pre- or post-intervention symptoms:
    a. Are there significant changes across session in pre-intervention ratings?
    b. Are there significant changes across session in post-intervention ratings?
(3) Do the immediate intervention effects change (become more or less pronounced) across sessions?

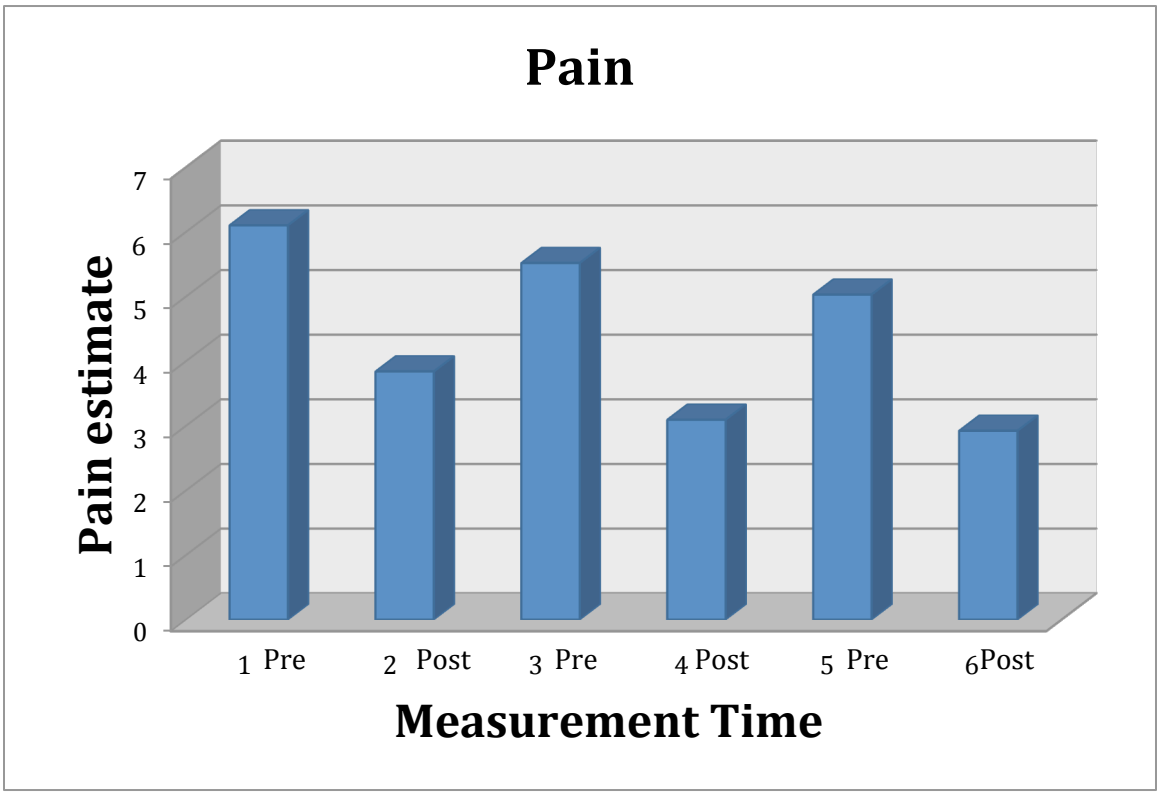
To address each of these question we conducted repeated measures analyses of variance with pre-post scores and session as two repeated (within-person) factors. The full factorial is a 2 (pre-post) by 3 (session) within-person design.

[Technical details: Traditional RMAOV would require list-wise deletion of participants with missing values, which would bias the results. For this reason, the analyses were conducted using multilevel-modeling (PROC MIXED in SAS) to generate full information maximum likelihood (FIML) estimates of the RMAOV. Under the assumption that the missing data are either Missing Completely at Random (MCAR) or Missing at Random (MAR), this method yields intent-to-treat parameter estimates that are consistent with what would be expected if there were no missing data. An unstructured covariance model of the residual variances was used. Degrees of freedom were determined using the Kenward-Rogers procedure, which corrects for downward bias in the standard errors and is recommended for repeated measures designs with missing data.]

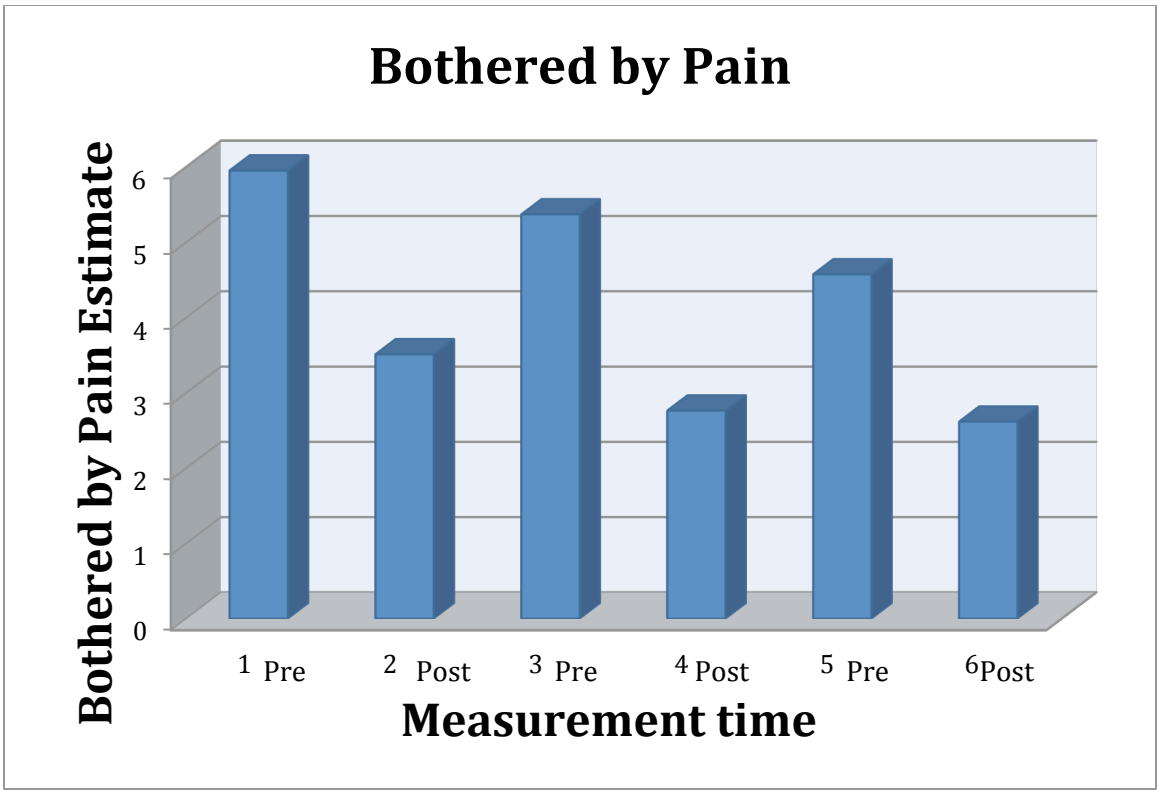
The results are largely consistent across outcome variables:

(1) Without exception, the immediate intervention effects (average pre-post change) are highly significant for all variables in the expected direction (e.g., pain ratings decrease on average by 2.3 points on an 11 point scale from pre- to post-intervention).
(2) With few exceptions (exceptions are energy, well-being and relaxation), linear changes in session-to-session ratings over time are significant for both pre- and post- intervention ratings. One possibility is that the intervention created significant longer-term improvement for most outcome variables
(3) In addition, the magnitude of immediate intervention effects (Change in pre-post difference across session) did not significantly change over time for most outcomes. Exceptions are muscle tension, stress, and relaxation, for which the immediate effect became less pronounced over time.

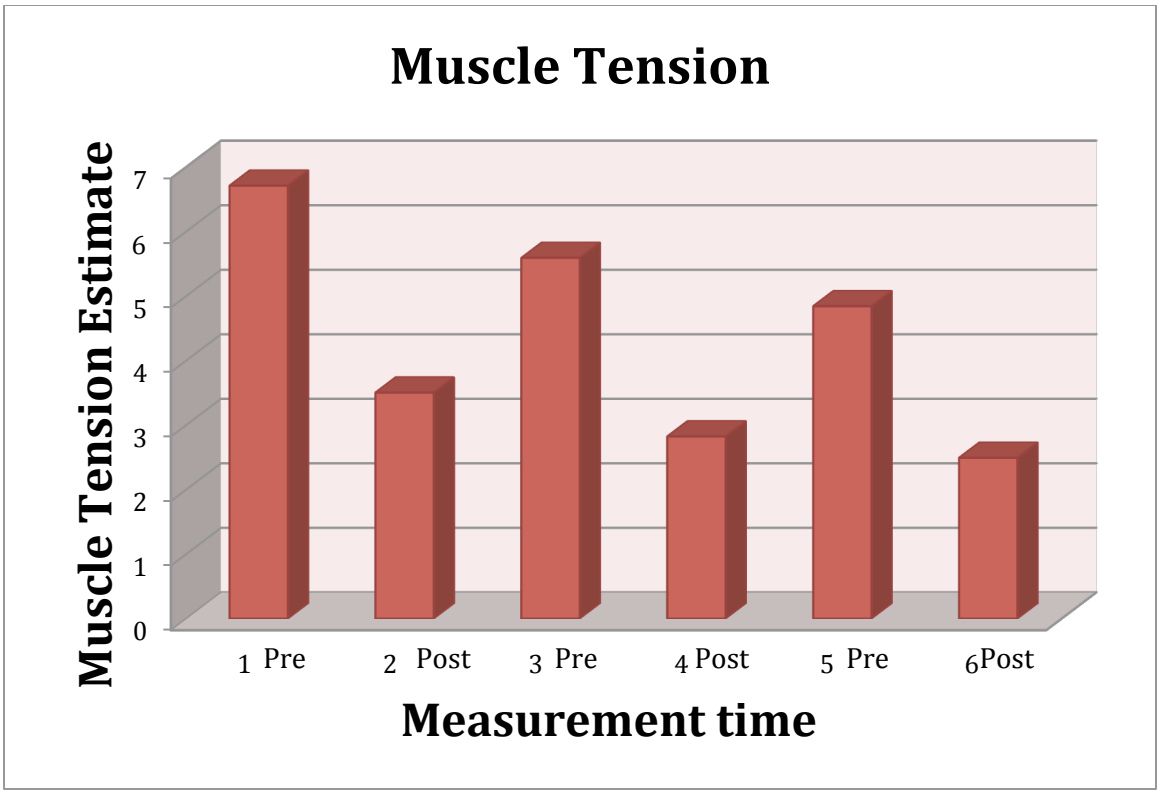
The individual outcome variable graphs demonstrate these effects nicely. The results of these initial RMAOV analyses are summarized in the accompanying tables.



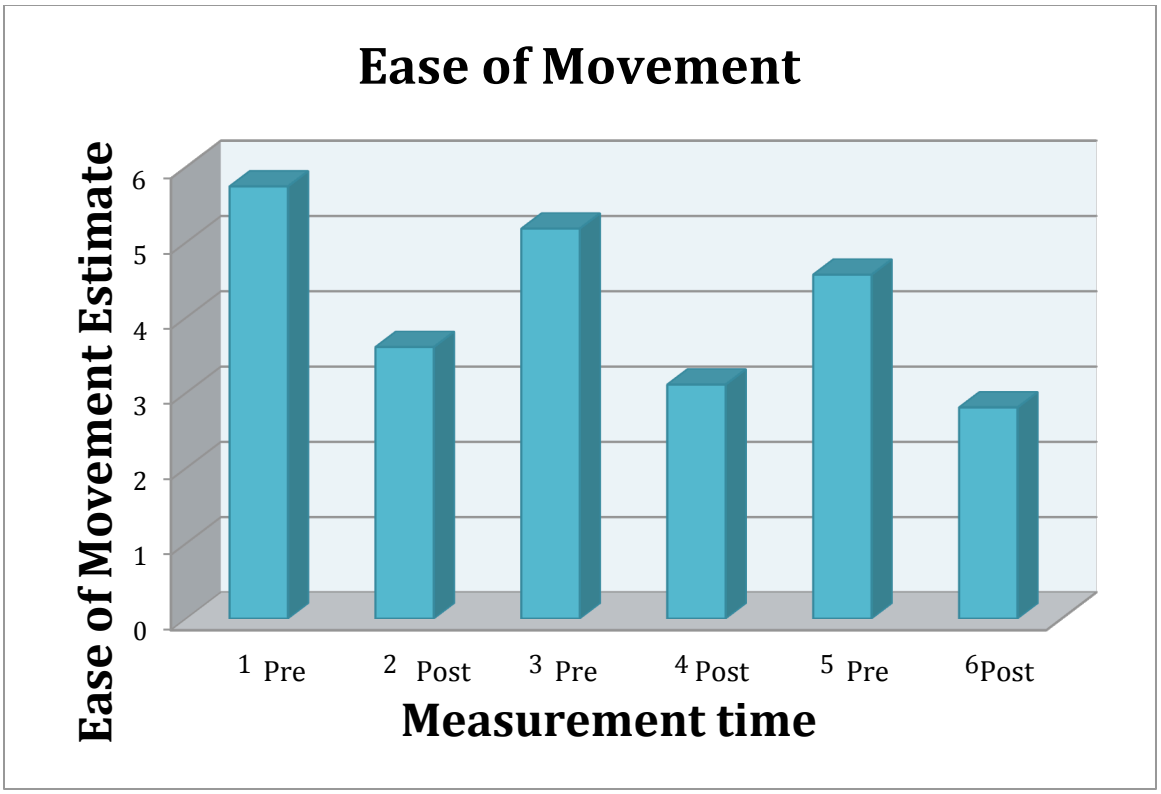
	M (est)	t-value	p-value
Average pre-post chg	-2.2644	-12.32	<.0001
Pre- Chg across sessions	-.5359	-3.58	0.0006
Post- Chg across sessions	-.4586	-3.07	0.003
Pre-post diff across sns	.0773	0.45	.6522



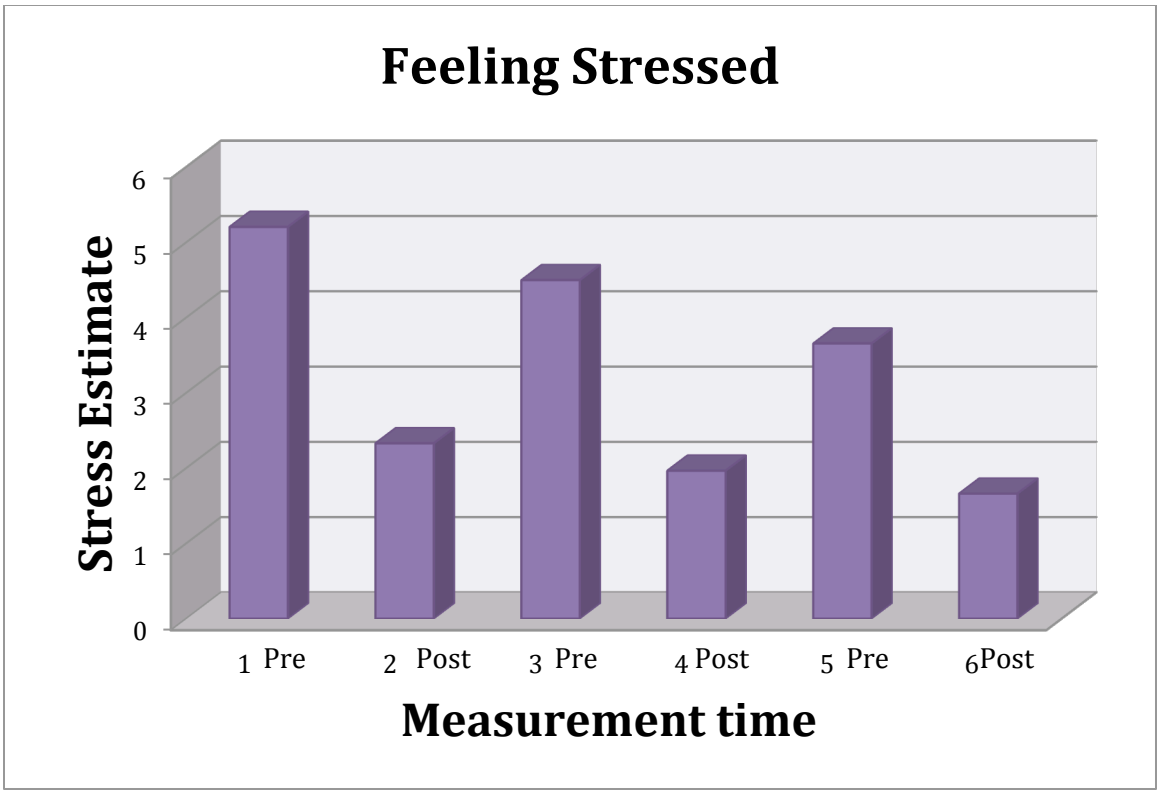
	M (est)	t-value	p-value
Average pre-post chg	-2.3352	-12.39	<.0001
Pre- Chg across sessions	-.6893	-4.24	<.0001
Post- Chg across sessions	-.4475	-3.10	0.0029
Pre-post diff across sns	.2418	1.32	.1928



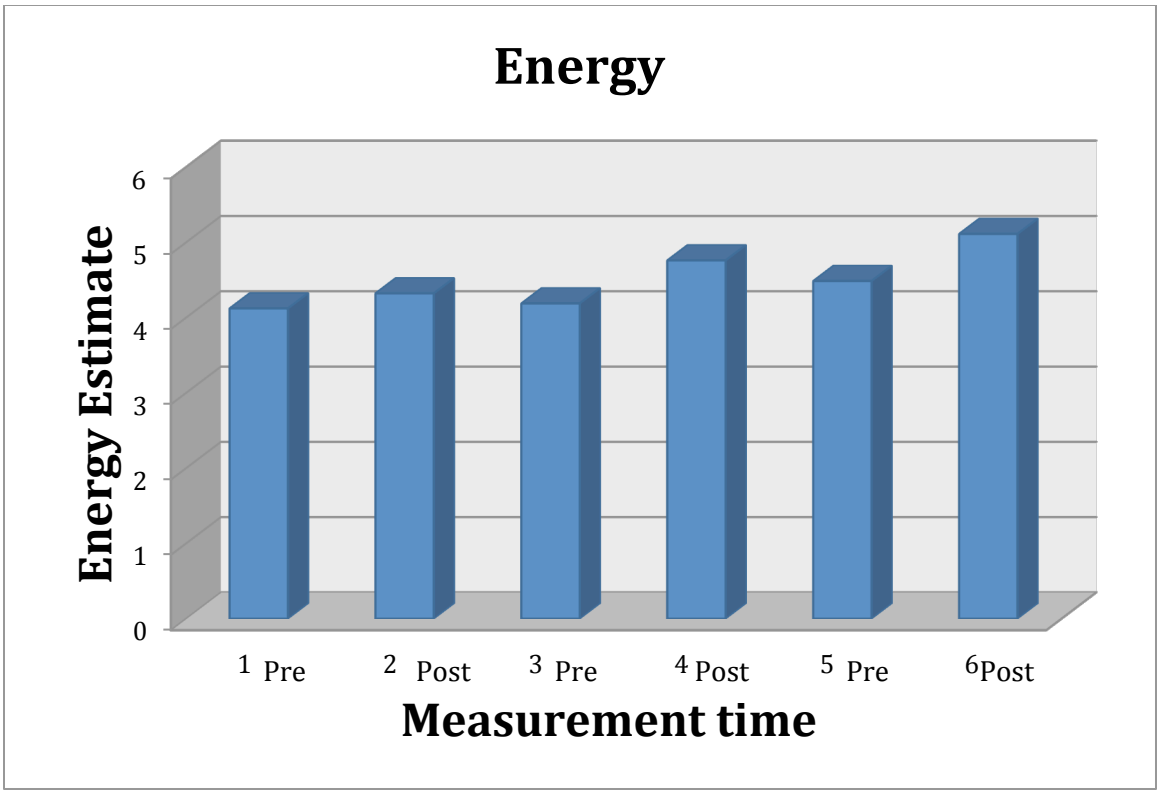
	M (est)	t-value	p-value
Average pre-post chg	-2.7748	- 14.32	<.0001
Pre- Chg across sessions	-.9341	- 5.58	<.0001
Post- Chg across sessions	-.5055	- 4.13	0.0001
Pre-post diff across sns	.4286	2.50	0.0152



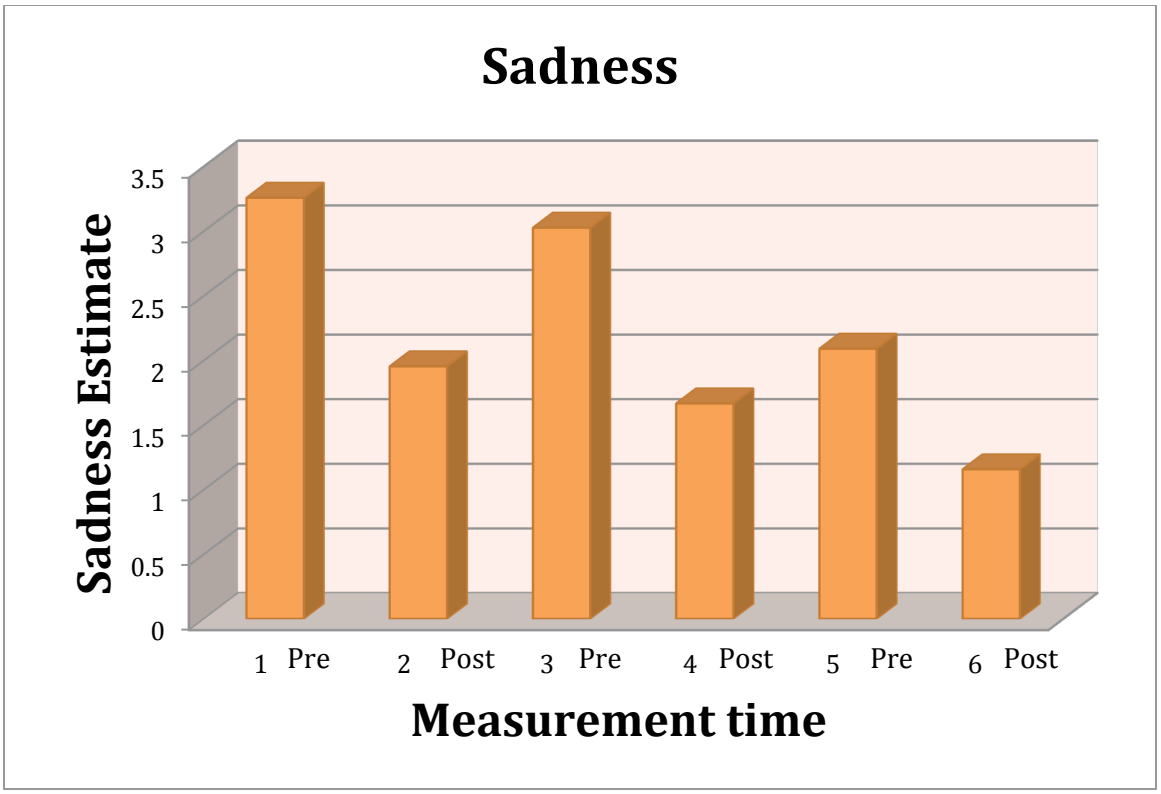
	M (est)	t-value	p-value
Average pre-post chg	-1.9902	-11.9	<.0001
Pre- Chg across sessions	-.5863	-3.95	0.0002
Post- Chg across sessions	-.4013	-2.98	0.0039
Pre-post diff across sns	.1849	1.34	0.1855



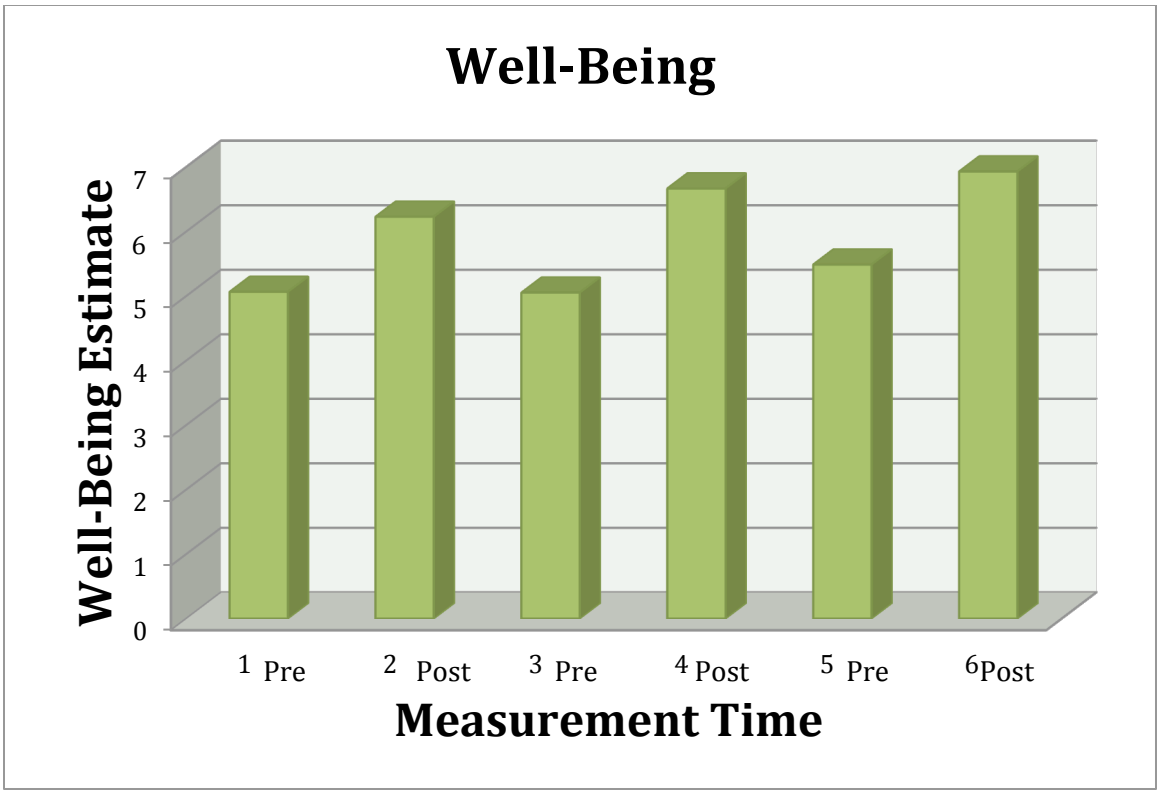
	M (est)	t-value	p-value
Average pre-post chg	-2.4669	-12.13	<.0001
Pre- Chg across sessions	-.7750	-4.96	<.0001
Post- Chg across sessions	-.3342	-2.98	0.0076
Pre-post diff across sns	.4408	2.65	0.01



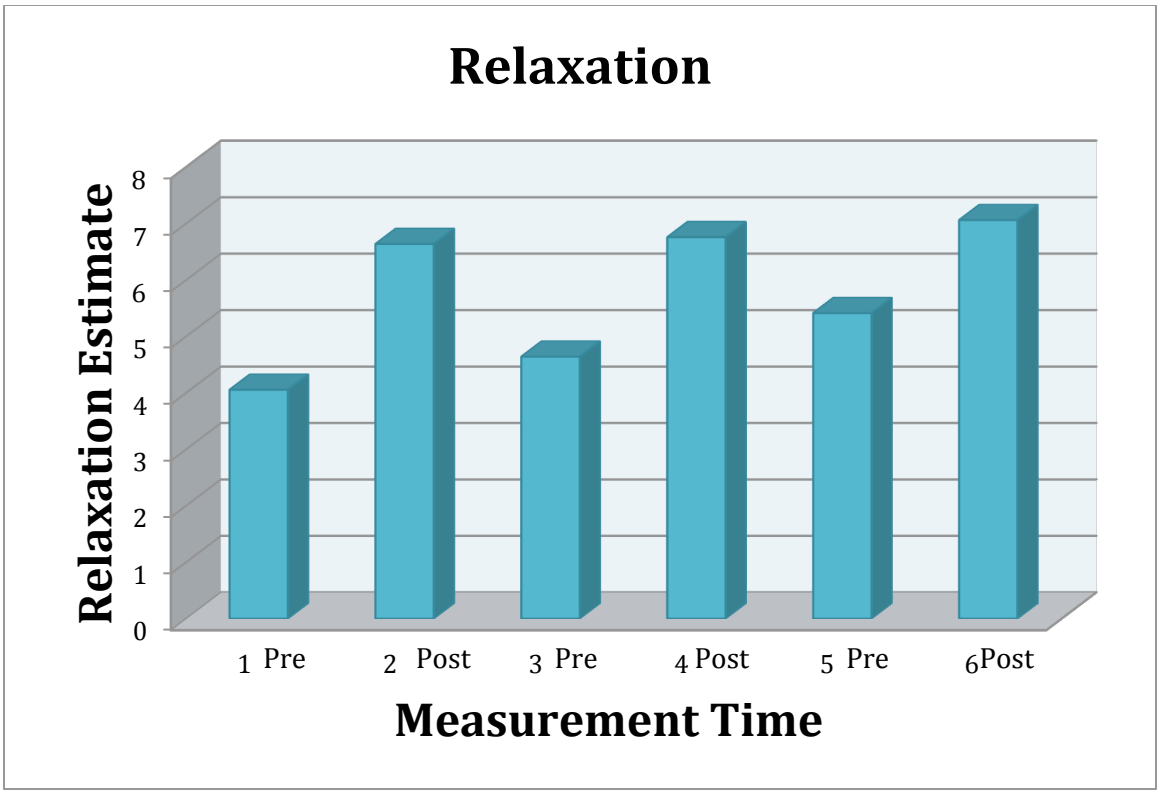
	M (est)	t-value	p-value
Average pre-post chg	.4658	2.94	0.0043
Pre- Chg across sessions	0.1821	1.25	0.2168
Post- Chg across sessions	.3949	2.64	0.0102
Pre-post diff across sns	0.2128	1.35	0.1807



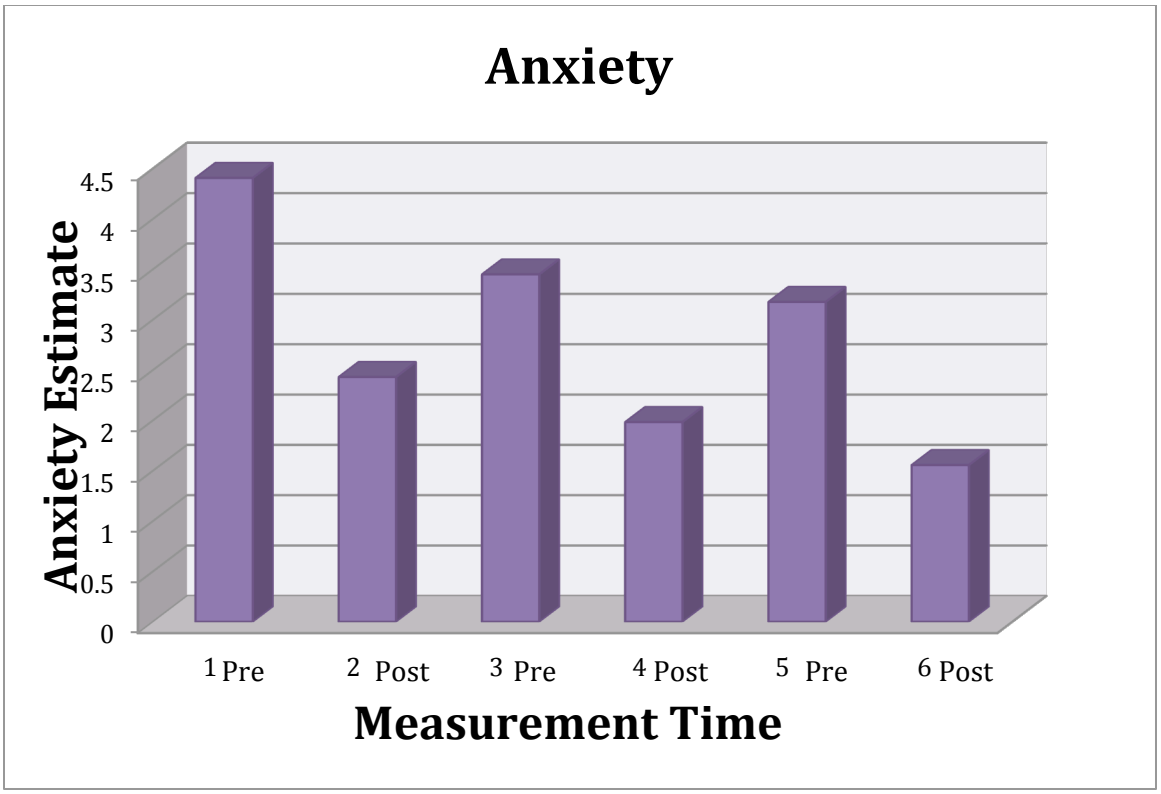
	M (est)	t-value	p-value
Average pre-post chg	-1.1997	-7.81	<.0001
Pre- Chg across sessions	-.5339	-3.73	0.0004
Post- Chg across sessions	-.3986	-3.54	0.0008
Pre-post diff across sns	0.1853	1.41	0.1646



	M (est)	t-value	p-value
Average pre-post chg	1.4071	7.52	<.0001
Pre- Chg across sessions	0.2117	1.42	0.1610
Post- Chg across sessions	0.3509	2.05	0.0445
Pre-post diff across sns	0.1392	0.81	0.4189



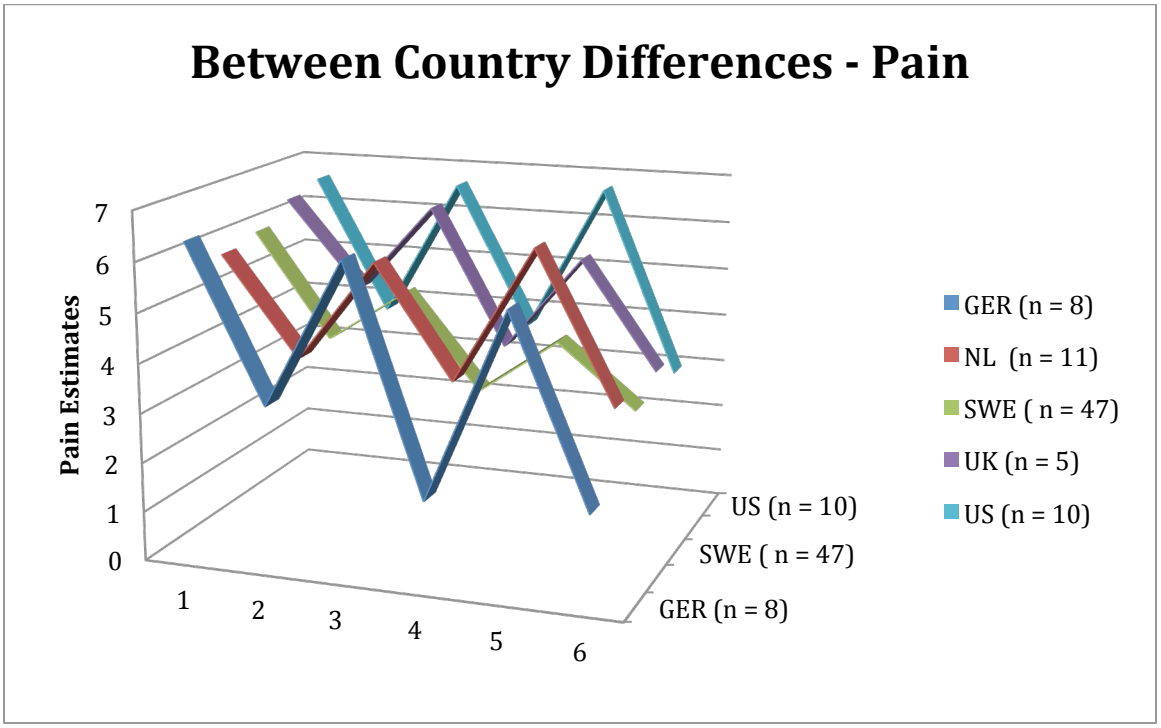
	M (est)	t-value	p-value
Average pre-post chg	2.1155	8.92	<.0001
Pre- Chg across sessions	0.6793	3.93	0.0002
Post- Chg across sessions	0.2114	2.05	0.2696
Pre-post diff across sns	-0.4680	-2.03	0.0465



	M (est)	t-value	p-value
Average pre-post chg	-1.6877	-9.57	<.0001
Pre- Chg across sessions	-.6157	-4.31	<.0001
Post- Chg across sessions	-.4373	-3.56	0.0007
Pre-post diff across sns	.1784	1.28	0.2048

Between Country differences

The same comparisons were examined using Country as an independent variable. For most outcomes – pain, bothered by pain, muscle tension, ease of movement, stress, sadness, well-being, relaxation and anxiety – the Country by immediate pre-post change interaction is significant. This indicates that the immediate pre-post effect was significantly more pronounced in some countries than in others. The effect was generally more pronounced in Germany than in the other countries. However, the intervention effect was observed in all countries. The effect was not absent or reversed in any country. Only the data for Pain is presented here to illustrate.



	F Value	p-value
Country difs in symptom levels	**1.23**	**0.307**
Country X pre-post change	**4.53**	**0.0025**
Country X chg across sessions	**0.93**	**0.4949**
Country X pre-post dif across sns	**1.37**	**0.223**

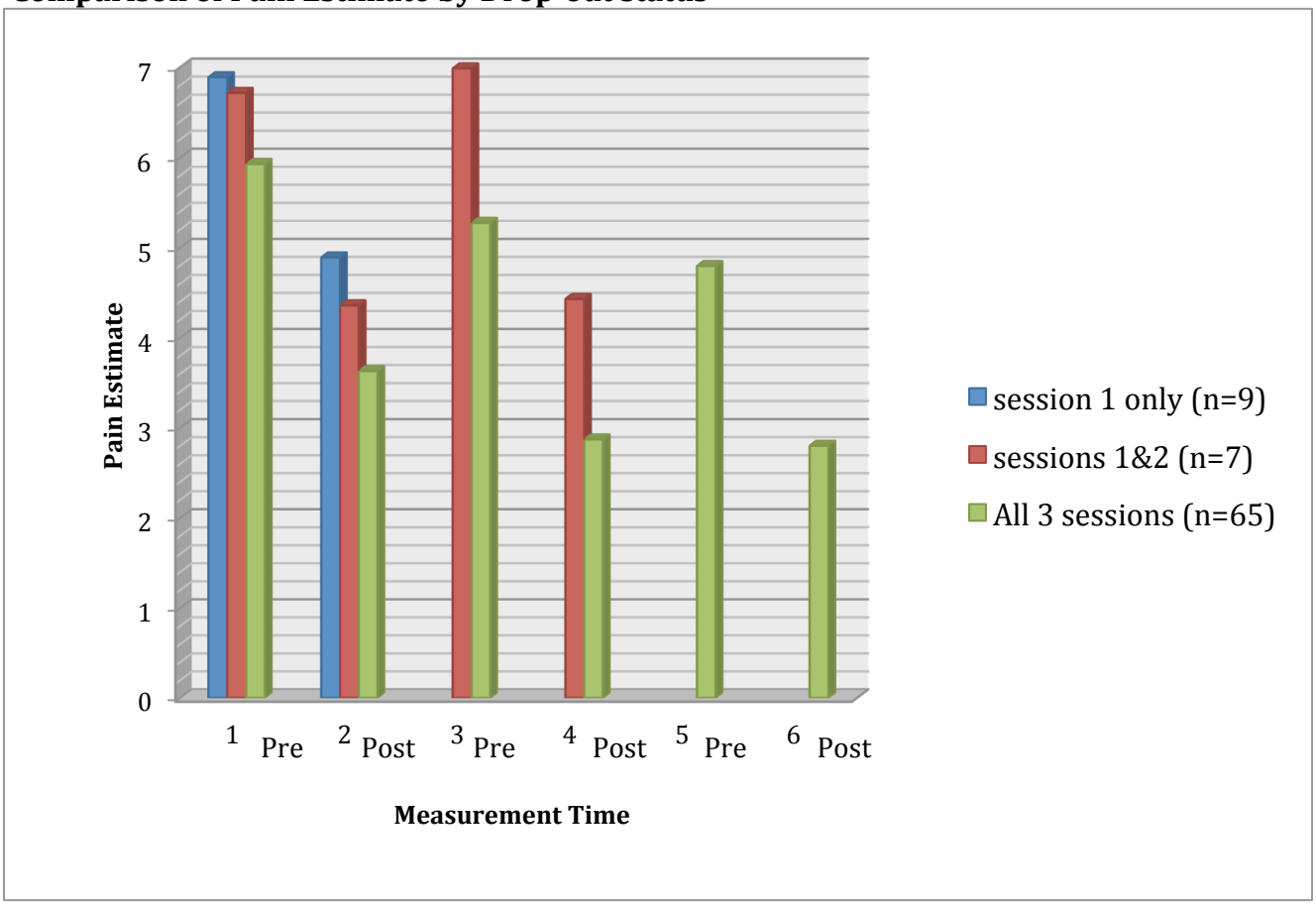
The influence of drop-out on estimated intervention effects

Systematic drop-outs from the intervention could undermine the Missing At Random assumption, which forms the basis of the previous results. To further examine the influence of missing data on the estimated intervention effects, a "pattern-mixture" modeling approach was used. For this approach, participants are first divided into groups depending on their missing data pattern and then variables based on these groups are used as model covariates. In this way we are able to directly examine the effect of drop-out patterns on intervention effects.

The groups used in the "pattern-mixture" model were created in accordance with the maximum number of sessions completed by the participants: one session (n=9), two sessions (n=7), three sessions (n=65).

The Table shows that drop-out status did not significantly interact with any change parameter for any outcome, suggesting that drop-out status did not influence the estimated intervention effects. Interestingly, patients who dropped out after the first or second session generally had higher symptom levels but showed the same amount of symptom relief.

Comparison of Pain Estimate by Drop-out status



	F Value	p-value
Dropout status difs in symptom levels	4.66	0.0120
Dropout X pre-post change	0.10	0.9092
Dropout X change across sessions	2.59	0.1133
Dropout X pre-post dif across sessions	0.01	0.9057

Participant Comments

Here is a sampling of comments made by participants about their floatation experience. These comments were made a few days after their float. Not all participants made comments. The comments give more of the subjective experience participants had in reaction to the effects of floatation. It is possible to see the heightened somatic sensitivity from the detailing of pain in some of these comments.

German #1

- "better sleep, better ability to relax, better memory, much better concentration"
- "well-balanced because of better ability to relax; more attentive; much better concentration; it´s harder now if pain is coming back"
- "good sleep, more balanced; not bothered by stress anymore, because the reminder of floating relaxes me; better concentration because I´m not distracted by pain anymore"
-

German #2

- "I´m suffering very hard under my disease because I´m a burden for my family, especially for my kids. After the float it was so wonderful. The floating feeling last very long, It has been years since could care for my kids and our whole family was so happy."
- "In the first forty minutes of the float session the pain became so hard, like an explosion, but only in my arms and legs. However, after the session I felt so free, like never before - free in the mind, my body so light, now all is going peacefully and I´m humbled. It´s unbelievable."
- "Floatation was for me the best experience, thank you so much!"

German #6

- "at first very tired, but then day by day better, lighter, more relaxed"
- "a little less pain, again very tired the day after floating, but next day okay"
- "after the float very tired again, next day very fit, the night after float I had deep sleep and nice dreams"

Netherlands #2

- "For four days my muscles were more relaxed. I'm feeling less tense in general, but pain more intense. More energy, more active. After four days, same pain as usual."
- "Totally different then after first floating session. Pain was more intense. I'm feeling lazy and tired. After three days, I'm feeling more relaxed."
- "I have more energy. If I am floating to cure long term pain, I will have to float more than 3 times."

Netherlands #6

- "I sleep deeper than before. I notice changes in my body, difficult to define what really improved. My body has also responded very violently in terms of tiredness and severe pain in my weakest spot - my neck. Three days after floating, I feel fewer painful reactions."
- "Although I had again a painful response after floating, it lasted shorter than after the the first time floating. And I felt - and still feel - more relaxation in my body. I felt tired the first two days after floating, but that was a reaction and also lasted a lot shorter."
- "Before I floated I was having a lot of pain in my neck. After floating the pain was less - until just starting again recently."

UK #1

- "If anything I have felt a little worse than usual."
- "I was amazed how good I felt after the float. I felt a lot brighter and had more energy. I was twitching a lot on the night I had the float and I was twitching in the tank. Sometimes my whole body, but the twitching's pretty much gone."
- "I didn't feel as good after this float as the second one, but I had had a very busy weekend. Usually I would have been flat on my back, but I wasn't. I had more energy generally and I actually felt like doing things. Felt like I had my life back. Come Friday I was starting to feel worse and I think my depression level is increasing again."

UK

- Patient 2 "My mood has lifted. I am able to stay out of bed longer and my pain level has been much lower. Today is very cold and that always makes my pain worse – which then aggravates the fatigue."
- Patient 3 "Slightly more relaxed and less muscle pain" "More energy and slightly less muscular pain. Sleep appears to be a bit more refreshing."

- Patient 4 "Trigger Points better for the 2 days after float; marginally better now. Hands have been more painful."

US

- Patient 2 "More relaxed, able to lift left arm, noticeable decrease in pain"
- Patient 3 "Soreness in neck and shoulders two days after float" "Not sure if float related, but had more stiffness this week"
- Patient 4 "Great float, more stress due to family problems though" "Can relax quicker, calm while at rest, can somewhat recall floatation feeling"
- Patient 5 "Some dizziness day after, but much more relaxed."

Sleep duration and Quality

One comment that appears repeatedly concerns sleep. Many participants volunteered that their sleep was considerably improved following their floats. It was our intention to measure the effect of floatation REST on sleep duration and quality of these participants. Dr. Schneider brought to our attention that there were some problems in our collection of this data that make the results on sleep less reliable.

The first problem was that the wording of the questions from baseline to follow-up were not identical and could bias the results as recall questions are typically underestimated.

Self-report questions are:

Sleep duration:
Baseline question: How many hours of sleep do you get on an average night?
Follow-up floatation question: (On the night after you last Floatation experience) -- How many hours did you sleep?

Sleep quality (response scale: 0 to 10, not at all – best ever):
Baseline question: How well do you normally sleep?
Follow-up floatation questions:

A) On the night after you last Floatation experience how well did you sleep? (0 to 10, not at all – best ever)
B) How well have you been sleeping since then? (0 to 10, not at all – best ever)

The second problem was that here are a fair amount of missing values in the sleep questions (see table below). Moreover, the missing value patterns are not "monotone"; that is, some patients have only responses for visit 2, or only for visit 3 (but missing for baseline and visits 1 and 2), for example. If we were to use list wise deletion (i.e., excluding every patient that has a missing value at any given assessment time-point), the sample size would be reduced to n = 33, and the estimates would be biased if the missingness is not "missing completely at random" (MCAR). We will generate full-information maximum likelihood parameter

estimates, which uses all the information available. The estimates are unbiased as long as the missing values are "strongly ignorable", a much more lenient (and often accurate) assumption than assuming MCAR. However, the results have to be interpreted cautiously, given the large amount of missings.

Missing values:

	Observed	Missing
Sleep duration		
Baseline	77	4
Float follow-up 1	63	18
Float follow-up 2	61	20
Float follow-up 3	50	31
Sleep quality		
Baseline	79	2
"night after question" Float follow-up 1	71	10
"since then question" Float follow-up 1	71	10
"night after question" Float follow-up 2	64	17
"since then question" Float follow-up 2	63	18
"night after question" Float follow-up 3	53	28
"since then question" Float follow-up 3	51	30

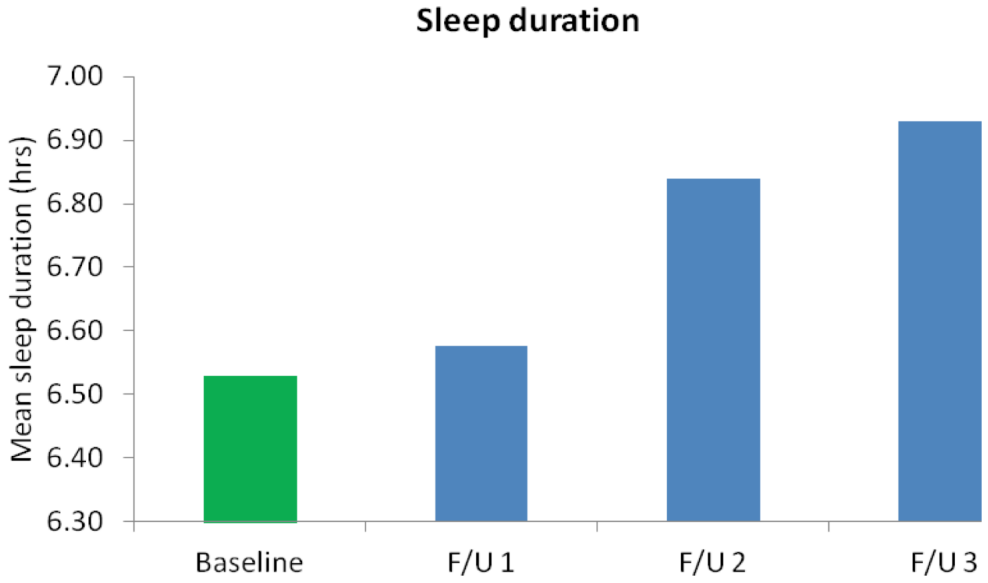
Estimated means (SDs) at each time-point:

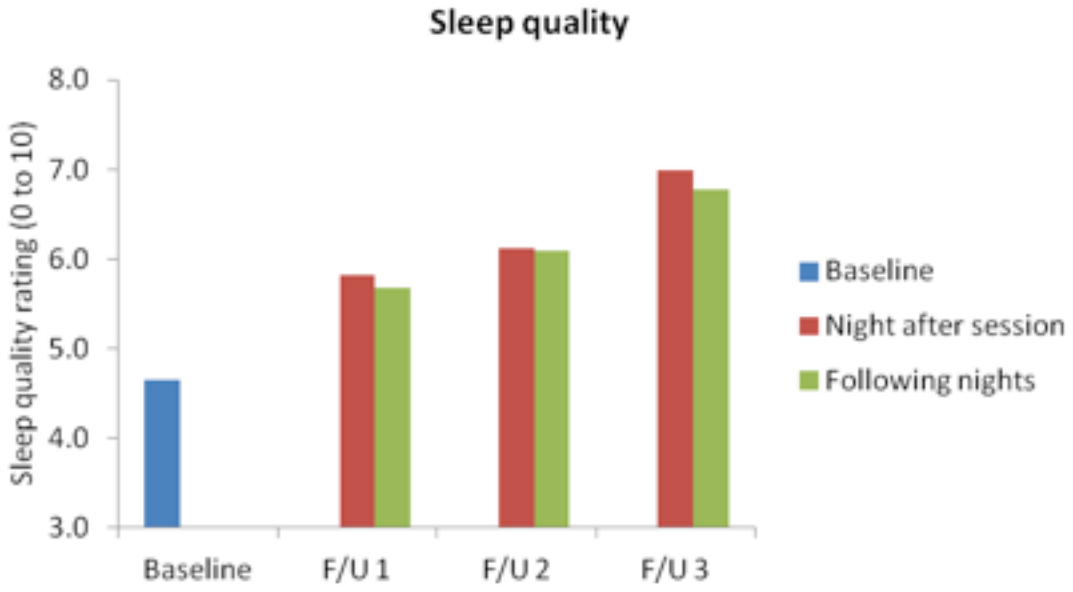
	Mean	SD
Sleep duration		
Baseline	6.53	1.74
Float follow-up 1	6.58	1.93
Float follow-up 2	6.84	1.53
Float follow-up 3	6.93	1.81
Sleep quality		
Baseline	4.64	1.82
"night after question" Float follow-up 1	5.82	2.43
"since then question" Float follow-up 1	5.68	1.71
"night after question" Float follow-up 2	6.12	2.36
"since then question" Float follow-up 2	6.10	1.87
"night after question" Float follow-up 3	7.00	2.06
"since then question" Float follow-up 3	6.78	1.87

Given that the wording of the baseline questions differs from the wording at follow-up, we will use the baseline means descriptively. However, we can test changes across follow-up sessions: The increase in sleep duration from follow-up 1 to follow-up 3 is not significant ($p = .18$). On the other hand, sleep quality ratings significantly

increase from follow-up 1 to follow-up 3, both for the "night after" question ($p < .001$) and for the "since then" question ($p < .001$).

The figures below illustrate the means at each time point.





Conclusion and Discussion

This study provides compelling evidence that Floatation REST can produce significant temporary relief to the symptoms of fibromyalgia. This finding was consistent and robust across all ten measured variables. Participants experienced reduced pain, how much they were bothered by pain, muscle tension, stress sadness and anxiety after each floatation experience. In addition, they experienced increased ease of movement, energy, feeling of well-being and relaxation form the intervention. Increase in energy from a one-hour float was the smallest increase but remained statistically significant. This may have been a lesser effect because relaxation can produce fatigue in those who are under much stress. The main effects of Floatation REST on the symptoms of fibromyalgia were not affected by the country or by whether the participant completed all three session.

Furthermore, there was a carry over effect for many of the variables in that the pre scores moved progressively in the direction of improvement even while the amount of improvement remained the same for each float. This was so for pain, bothered by pain, muscle tension, ease of movement, stress, sadness, relaxation and anxiety. This means that floatation REST may be producing longer term or cumulative relief for these symptoms. Naturally this raises the question of what would happen with continued repeated exposure to Floatation REST? Would the relief continue to improve or would it eventually plateau?

Fibromyalgia revisited

Symptoms of fibromyalgia sometimes begin after a physical trauma, surgery, infection or significant psychological stress. In other cases, symptoms gradually accumulate over time with no single triggering event. Current thinking around the mechanisms involved centers around a theory called central sensitization. This theory states that people with fibromyalgia have a lower threshold for pain because of increased sensitivity in the brain to pain signals.

Researchers believe repeated nerve stimulation causes the brains of people with fibromyalgia to change. This change involves an abnormal increase in levels of certain chemicals in the brain that signal pain (neurotransmitters). In addition, the brain's pain receptors seem to develop a sort of memory of the pain and become more sensitive, meaning they can overreact to pain signals.

"Re-setting" of the central pain sensitivity

Continued improvement and even remission from symptoms of fibromyalgia could be possible if Floatation REST can produce a "re-setting" of the central pain sensitivity. REST refocuses attention onto internal events, both physical and mental, in a manner that leads to self-regulation. Repeated exposure to physical symptoms in a deeply relaxed and calm physical and mental state can have profound effects. Regular exposure to this combination of pain sensations and low arousal levels may

help to re-set the sensitivity to pain in the same way that bringing up a traumatic memory during a deeply relaxed state helps to recondition the emotional context of that memory.

Normally when one experiences pain there is an increase in arousal. People with fibromyalgia are believed to have developed an increased sensitivity to pain, which means the pain/arousal connection would be amplified. An increased sensitivity to pain sensations may produce a heightened arousal response and consequent exaggerated perception of pain. If one can experience pain sensations with a decrease in arousal (which is what happens in Floatation REST) there would be a lessened perception of pain and, perhaps, a decrease in sensitivity to pain could develop. Theoretically if the person was repeatedly exposed to pain sensations in a reduced arousal state the pain sensitivity might "re-set" to normal.

What is next?

I want to thank all of those who gave of their time and efforts to make this study happen. We can congratulate ourselves for what we accomplished. Given the difficulty of securing funding for research on Floatation REST I believe we should continue to pursue this process of collaborative research. It takes a mountain of data to attract scientific attention and even more for the attention of the medical community. This promising beginning with fibromyalgia is a good step that needs follow-up to accumulate larger numbers of subjects and over longer periods to explore how far the benefits will go. There is always the temptation to move on to exploring the benefits of floatation on other specific pain syndromes. This would undoubtedly be fruitful but there has always been a shotgun approach to Floatation REST research because the technique appears to benefit so many problems. Unfortunately our resources are limited and even volunteer research has its limits. People can only give away so much. In addition, the medical community is looking for an effective treatment for fibromyalgia.

I propose that we continue to build a significant body of data supporting the use of Floatation REST for fibromyalgia. Enough to get scientific, medical and public attention so that we can move on to the next stage of seeking funding to conduct controlled studies on this and other populations.

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