

The relaxation response resiliency program (3RP) in patients with neurofibromatosis 1, neurofibromatosis 2, and schwannomatosis: results from a pilot study

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Abstract NF1, NF2, and Schwannomatosis are incurable tumor suppressor syndromes associated with poor quality of life. The aim of this study was to determine the feasibility, acceptability, and preliminary efficacy of an NF adapted, 8-week group mind body skills based intervention, the relaxation response resiliency program (3RP) aimed at improving resiliency and increasing satisfaction with life. Patients seen at MGH's Neurofibromatosis Clinic were offered participation if they described difficulties coping to a treating physician. Participants completed measures of life satisfaction, resiliency, stress, mood, lifestyle, pain, post-traumatic growth and mindfulness at baseline and after completing the 3RP program. The intervention had relative feasible enrollment rate (48 % rate, 32 out of 67 of patients signing the informed consent form). However, out of the 32 patients who signed the informed consent, only 20 started the study (62.5 %) and only 16 completed it (50 %), suggesting problems with feasibility. The main reason cited for non-participation was burden of travel to the clinic. The intervention was highly acceptable, as

evidenced by an 80 % completion rate (16/20). Paired *t* tests showed significant improvement in resiliency, satisfaction with life, depression, stress, anxiety, mindfulness and post traumatic growth, with effect sizes ranging from 0.73–1.33. There was a trend for significance for improvement in somatization and sleepiness ($p = 0.06$), with effect sizes of 0.54–0.92 respectively. Statistically nonsignificant improvement was observed in all other measures, with effect sizes small to medium. In sum, the 3RP was found to be relatively feasible, highly acceptable and preliminary efficacious in decreasing symptom burden in this population, supporting the need of a randomized controlled trial.

Keywords Relaxation response · Mind–body therapies · Neurofibromatoses · Psychological resilience

Introduction

The neurofibromatoses, including neurofibromatosis 1 (NF1), neurofibromatosis 2 (NF2), and schwannomatosis, comprise a group of genetically distinct disorders of the nervous system unified by the predisposition to nerve sheath tumors. These histologically benign tumors can occur anywhere in the body and often cause significant morbidity including disfiguring cutaneous tumors (NF1); complete hearing loss, facial weakness, and poor gait (NF2); and chronic disabling pain (schwannomatosis). In addition to the increased risk of benign tumors, patients with these genetic syndromes are at higher risk for malignant tumors and can develop non-tumor manifestations that affect the nervous system, eyes, and skin. Currently there is no cure for NF, with symptom management provided by surgery and palliative measures as the primary means of treatment.

The current health care model for neurofibromatosis (NF) is almost entirely biomedical. In this model, health

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care providers have focused on identifying various manifestations of NFs (e.g., nerve sheath tumors, learning disability, pseudoarthrosis) and providing medical treatments. This model of care is incomplete, as it does not address the consistent research findings showing that patients with NFs have lower quality of life compared to general population [1]. Patients with NFs also have significantly more symptoms of depression and anxiety, higher levels of perceived stress, lower levels of self-esteem and more pain as compared with general population norms [2]. Furthermore, research has shown that there is no association between severity of NF and emotional functioning [2], suggesting that psychosocial factors are more important than, or as important as, severity of disease.

Within the past decade, the care of patients with medical illnesses (e.g., diabetes, chronic pain, cancer) has transitioned from biomedical to biopsychosocial, where mind–body treatments are integrated within medical care [3]. Research on such biopsychosocial models has shown that they not only improve quality of life and enhance outcomes of medical treatments including surgeries, but also reduce medical care utilization and cost [4]. In spite of all the aforementioned factors, such biopsychosocial models of care have not yet been studied in patients with NFs. This represents an unexplored opportunity to improve quality of life and to decrease cost of care for patients with NFs.

For this reason the main purpose of this study was to assess the feasibility and acceptability of an adapted version of the relaxation response resiliency program (3RP) for patients with NFs. We followed guidelines established by Rounsaville [5] for psychosocial clinical trials, and conducted an open pilot study prior to investing in a large randomized controlled trial. The 3RP [6] is a group-format mind–body treatment that has been found efficacious in improving quality of life, emotional functioning and decreasing pain and stress in a group of patients with a variety of chronic illnesses including chronic pain, diabetes, cardiovascular problems, IBS, headaches [7, 9] and in a group of patients with chronic temporomandibular joint disease [8]. Within this treatment, patients learn methods to elicit the relaxation response to decrease the physiological effects of stress, stress awareness strategies, and positive psychology coping skills. The main goals of the program are improving satisfaction with life and increasing resiliency (the ability to cope with stress and disease symptoms). Secondarily we wanted to test the preliminary efficacy of the adapted 3RP for patients with NF in improving satisfaction with life and resiliency (primary study variables) as well as improving depression, anxiety, somatization, mindfulness, posttraumatic growth, healthy eating, social support, optimism, and reducing pain catastrophizing (negative thoughts about pain), perceived stress and daytime sleepiness.

Materials and methods

Patients were recruited from a Neurofibromatosis Clinic from an academic medical center. Recruitment occurred between November 2012 and October 2013, with breaks for major holidays and during the summer. Only 1 group was conducted at the time, and recruitment stopped during the duration of the group. During this period approximately 330 patients presented to the clinic, but not all were offered participation. The neurologist routinely asks patients about their stress level, and those endorsing stress during the recruitment periods were asked if they were interested in hearing about the current study. We chose this method of screening as it can be easily incorporated in clinics, does not require training, and allows patients to self select for participation. Sixty-seven patients were then approached by a study member to discuss details of the study and see if they meet inclusionary and exclusionary criteria. Of these 32 signed the informed consent form and agreed to participate. Inclusion criteria for the current study were: (1) age 18 or older; (2) can read and speak English; and (3) diagnosis of neurofibromatosis type 1, neurofibromatosis type 2, or schwannomatosis. Exclusion criteria included the following: (1) severe active or untreated major mental illness that would interfere with study participation (e.g. untreated psychosis or active suicidality); (2) recent (within the past 3 months) change in antidepressant medication; (3) history or current use of formal relaxation training (including past participation in a mind–body program); and (4) inability or unwillingness to complete psychological assessments online via the RedCap (Research Electronic Data Capture) system [10].

The study was approved by our institution's Review Board and all study subjects provided written consent. The 3RP mind body program included 8 weekly sessions, each 90 min long, delivered in a face-to-face group setting by a clinical psychologist. Pre- and post-intervention assessments were completed online from the patients' home via the secure, web-based RedCap [10]. Participants completed a total of 15 instruments that were mapped onto the 3RP and measure concerns that are typical to patients with chronic illnesses. Some of these questionnaires assessed constructs such as sleep, healthy eating and mindfulness that have not been assessed before in patients with NF, but have been found to be important markers of quality of life in patients with chronic illness [11]. Because we grouped patients across the 3 diagnoses, we chose instruments that can be applied for all patients, rather than diseases specific measures. Further, we chose measures with good psychometric properties. The surveys were tested prior to study commencement and found to take 10–20 min to complete. To guard against patient fatigue, patients were told to take breaks during questionnaire completion, save the data, and

then simply return and finish the questionnaire at a future timepoint. Exit interviews conducted by the second author with a subsample of patients did not show difficulties or patient burden due to completion of questionnaires.

The relaxation response resiliency enhancement program (3RP)

The 3RP mind–body program is a comprehensive outpatient program based on the principles and practice of mind–body medicine. It is designed to improve quality of life and increase resiliency (coping with stress) through the teaching of self-care strategies. The crux of the clinical program is the elicitation of the relaxation response in each session, using a variety of methods, including single pointed meditation, imagery, mindful awareness, contemplation and yoga. The program incorporates educational information about the mind–body connection, training to develop mind–body awareness, cognitive and behavioral skills such as cognitive restructuring and promotion of healthy lifestyle behaviors (e.g., sleep and mindful eating), as well as skills incorporated from positive psychology (e.g., cultivation of positive emotions and thoughts (e.g., appreciation, optimism), use of humor, empathy, and support).

The original program manual was modified in our study to address specific needs of patients with NF, which were identified previously during 2 focus groups (N = 15 participants) and literature search. During this focused groups patients were asked open ended questions about the need for a mind body group, interest in potential participation, difficulties managing the NF, and about specific stressors associated with NF1, NF2 and Schwannomatosis. Specific modifications included: (1) learning to manage NF specific stressors such as burden of medical appointments, dating and difficulties hearing; (2) restructuring NF specific thoughts such as those associated with self image, career, etc.; (3) learning acceptance techniques to address issues associated with making sense of having NF and dealing with the uncertainty of having this condition. The original 3RP manual was modified to address these changes and was used uniformly with each group. Each of the 8 sessions involved a review of previously learned skills, introducing and practicing a new relaxation response technique, and learning a specific cognitive behavioral or positive psychology based skills and applying it to specific patient specific issues. Groups were small (3–6 participants/group) which allowed the facilitator to ensure that patients understood and practiced the skills taught. The 3 diagnostic categories were grouped together for the purpose of this study for several reasons. First, there are many similarities among patients with NF1, NF2 and Schwannomatosis such as common stressors associated with symptoms (e.g., appearance concerns, pain, uncertainty about progression/

growth of tumors, social isolations, concerns about transmission through pregnancy). In fact, it can be argued that there is more heterogeneity of symptoms within each diagnoses category than between the 3 diagnoses. Second, patients within the 3 categories, as a group, share similar psychosocial difficulties and decreased quality of life. Third, the 3RP is not aimed to target underlying diseases processes, as would a drug; rather, it is aimed at improving coping with stress and symptoms (e.g., increase resiliency) and satisfaction with life. We dealt with the heterogeneity of NF by asking patients to set general and weekly practice goals that are specific to them, and teaching them to apply them to their individual goals and concerns. For example, a patient with NF1 who has facial tumors might set a goal of decreasing self consciousness while a patient with schwannomatosis might set a goal of improving coping with pain. Both patients can benefit from relaxation response strategies as well as from cognitive behavioral and positive psychology skills to help them develop acceptance and an adaptive response to a chronic incurable situation.

Survey measures

The satisfaction with life scale is a 5-item reliable and valid self-report measure of global life satisfaction. Responses are made on a 7-point scale with higher scores reflecting higher life satisfaction [12].

The Resiliency Scale [13] is a 14 item self report measure assessing resiliency—that is, the ability to successfully deal with adversity of life. This is a psychometrically sound measure with high scores showing higher resiliency.

The Perceived Stress Scale (PSS; Cohen [14]) is a 10-item scale designed to measure the degree to which situations in one's life are appraised, or considered as stressful. Items were designed to detect how unpredictable, uncontrollable and overloaded respondents find their lives. The measure is reliable and valid with higher scores representing higher stress [15].

The Cognitive and Affective Mindfulness Scale-Revised (CAMS-R) is a 12-item scale that measures everyday mindfulness, and focuses on the degree to which patients experience their thoughts and feelings. This is a reliable and valid scale with higher scores representing higher mindfulness [16].

The Life Orientation Test Revised (LOT-R) is a 10 item self-report measure developed to assess individual differences in generalized optimism versus pessimism. The measure is reliable and valid with higher scores representing optimism and lower pessimism [17].

The Post Traumatic Growth Inventory (PTGI; [18] is a 21 item reliable and valid scale assessing how successful people are in coping with challenging life events, in

reconstructing or strengthening their perceptions of self, others and meaning of events. Higher scores depict higher posttraumatic growth.

The Pain Catastrophizing Scale (PCS) is a 13-item scale that measures negative pain related cognitions and catastrophic thinking (thinking of the worst) [19]. The measure is reliable and valid [20], with higher scores depicting higher catastrophizing.

The Numerical Rating Scale is an 11-point rating scale that measures pain intensity. The measure is reliable and valid [21].

The Epworth Sleepiness Scale (ESS) is an 8-item scale that measures daytime sleepiness [22] with good psychometric properties [23]. The scale measures an individual's likelihood of falling asleep in routine situations. Higher scores depict higher sleepiness.

The CIGNA Healthy Eating Survey–Section H is a 7 item self report instrument that measures behavioral eating—that is, patterns of eating in response to an emotional need rather than hunger cues [24].

The Medical Outcomes Study social support, the emotional support subscale is an 8-item subscale that measures perceptions of emotional support in medical population [24]. It has good reliability and validity [25].

Patient-Health Questionnaire Depression (PHQ-9) is a 9 item reliable and valid scale that measures presence and severity of symptoms of depression consistent with the DSM-V [26]. Higher scores depict more severe depression.

Patient Health Questionnaire Somatic Symptoms Severity (PHQ-15) is a 15 item reliable and valid scale that assesses the impact of various bodily symptoms on ones life [26].

Patient-Health Questionnaire Anxiety is an 11 item reliable and valid scale that measures severity of anxiety symptoms [26]. Higher scores depict more severe anxiety.

Statistics

Descriptive statistics were used to summarize data. Chi square and *t* tests were used to test for differences between program completers (*N* = 16) and non-completers (*N* = 4). ANOVAs and *t* tests were used to assess for the effect of demographics on main study variables. Main analyses were conducted with paired samples *t* tests.

Results

Demographics

At enrollment, there were no differences between completers and noncompleters in demographic variables or survey measures (*p* > 0.1). There were also no significant

Table 1 Demographics for program completers (*N* = 16)

Variable	N	%
NF type		
NF1	9	56.25
NF2	6	37.5
Schwannomatosis	1	6.25
Gender		
Men	7	43.75
Women	9	56.25
Race		
White	14	75
Asian	2	25
Marital status		
Never married/single	6	37.5
Married	9	56.25
Divorced	1	6.25
Work status		
Employed for wages	11	68.75
Out of work for more than 1 year	1	6.25
Out of work for less than 1 year	2	12.5
Unable to work	1	6.25
Student	1	6.25
Income		
10,000–20,000	2	12.5
20,001–40,000	1	6.25
40,0001–80,000	6	37.5
80,001–100,000	2	12.5
100,001–150,000	2	12.5
>150,001	2	12.5
Missing	1	6.25

differences between the 3 diagnostic groups. Results are thus reported for completers only. The completer cohort (*N* = 16) included 9 patients with NF1, 1 with Schwannomatosis and 6 with NF2. Participants had a mean age of 57 and were 9 (56.2 %) women and 7 (43.8 %) men. Table 1 details all demographics. Out of the entire sample, 3 patients underwent outpatient surgery during the 8 weeks groups, but surgery did not prevent them from attending the subsequent group sessions.

Feasibility and acceptability

Feasibility of enrollment was moderate with 32 out of the 67 participants approached signing the informed consent form (48 % rate). Feasibility of study completion was low; out of the 32 participants who signed the consent form, only 20 started the intervention (62.5 %) due to inability to attend the group at the specific date/time, and only 16 of these 32 (50 %) completed the intervention. The burden of

traveling to the clinic for face-to-face groups was the reason for declining participation in the majority of patients. Other reasons included: difficulties with the group setting due to shyness [1], not free at the assigned time [9] and not feeling the program is a good fit (1 participant).

Acceptability was determined by percent patients who completed the intervention. Of the 20 participants who completed pre-program measure 16 (80 %) completed post-program measures. Two of the patients were wheelchair bound and dropped out after the first session due to difficulties with transportation. One participant attended 6 out of the 8 sessions but refused to complete the posttest. One participant completed the pretest questionnaire but then stated she would like to participate in an NF2 specific group. Due to an administrative oversight the questionnaires assessing depression, somatization and anxiety were completed only by 10 participants.

Preliminary efficacy

There were no significant differences in pre- or post-intervention outcome measures by any of the demographic variables ($p > 0.1$). Paired t tests showed significant improvement in resiliency, satisfaction with life, stress, depression, anxiety, somatization, sleepiness, mindfulness and post traumatic growth, with effect sizes ranging from 0.73–1.33. There was a trend for significance for improvement in somatization and sleepiness ($p = 0.06$), with effect sizes of 0.54–0.92 respectively. Of note, the ES for somatization is high, yet is not significant, likely due to the fact that due to an oversight only 10 participants completed this measure. No significance differences were observed in optimism, social support and eating behaviors. With regard to pain catastrophizing, scores decreased in 9

patients, stayed the same in 3 and worsened in 4. Of the 4 patients whose coping with pain worsened, 3 had surgeries during the course of the intervention. Analyses with the 3 participants excluded showed an overall improvement in the sample of 13 participants, but it remained not significant with this small sample ($E.S. = 0.399$) (Table 2).

Discussion

The aim of the study was to examine the acceptability, feasibility and preliminary efficacy of the comprehensive NF-adapted mind body intervention, the 3RP. We found the intervention to have relatively low general feasibility but high acceptability in this population. We found the intervention to be efficacious as evidenced by improvement in resiliency, satisfaction with life, stress, depression, worry, mindfulness and posttraumatic growth. There were trends for improvements in sleepiness and somatization. Improvement in pain coping was also significant for a subsample of patients who did not have any medical procedures during the course of the intervention. Results of this study provide support for a future randomized controlled trial to test the efficacy of the intervention when compared to a control group.

Results of this study should be viewed in light of several limitations. First, this is an open pilot with no control group. Because of the absence of random assignment to a control group, it does not allow us to draw robust conclusions about the efficacy of the 3RP. Second, we do not know percent of patients who endorsed stress out of the entire pool of patients presenting to the clinic, which may impact feasibility. Third, several participants underwent medical procedures during the course of the study, which impacted results, particularly their reports of pain, and may

Table 2 Paired sample t tests for main study variables (N = 16)

Variable	Pre		Post		t	p	Cohen's d
	Mean	SD	Mean	SD			
Satisfaction with life	17.86	7.20	21.33	6.38	−2.77	0.015	−0.72
Resiliency	68.85	11.73	75.92	15.04	−3.02	0.01	−0.86
Stress	19.00	3.46	15.57	5.84	2.86	0.01	0.82
Mindfulness	28.80	4.93	30.93	3.57	−2.56	0.02	−0.71
Sleepiness	6.86	4.35	5.26	3.30	1.99	0.06	0.54
Depression ^a	15.20	3.70	13.70	3.49	2.29	0.04	0.73
Anxiety ^a	20.50	4.03	16.20	3.45	4.16	0.00	1.33
Somatization ^a	17.62	3.70	16.50	2.87	2.18	0.06	0.92
Social support	27.40	2.81	27.00	2.20	0.21	0.83	0.22
Optimism	11.53	4.38	11.46	2.41	0.04	0.96	0.00
Pain catastrophizing	14.53	11.01	15.86	15.01	−0.57	0.57	−0.16
Pain catastrophizing ^b	15.00	8.1	12.91	9.30	1.27	0.23	0.39
Posttraumatic growth	77.53	21.02	84.06	21.03	−2.24	0.04	−0.56
Emotional eating	16.68	2.62	15.62	4.12	1.34	0.19	0.37

^a N = 10 for depression, somatization and anxiety

^b Score reported after eliminating data from 3 participants who underwent surgery before completion of time 2 questionnaire. N = 13

have underestimated improvement for all patients. Further, although the participants represented clinic attendees, this was a fairly homogenous group of participants. Further studies are needed to examine whether the 3RP is effective for racial/ethnic minorities as well as for people with lower education levels who have NF. Although we did not find differences in psychosocial functioning among patients with NF1, NF2 and Schwannomatosis, future studies should assess for these differences in improvement with a larger sample, and if such are found, to subsequently modify the intervention to address these potential differences. Further, the 3RP may have differential results in patients with NF who have a cognitive component to their disease. We have taken this into account by ensuring that the intervention is appropriate for a 7th grade reading level, but this issue should further be explored in future studies. Additionally, the efficacy of the 3RP may be different for patients who have a biological (e.g., brain) component to their mood symptoms, as opposed to those whose mood is negatively impacted purely by coping with symptoms. Future studies should explore these concerns. Lastly, because of the small sample size, we did not correct for multiple comparisons and type 2 error.

Although acceptability was high, general feasibility was low in this open trial. The majority of the patients who refused to participate or did not finish participation did so due to the burden of traveling to the clinic. NF is a rare condition and to our knowledge this is the first mind body intervention developed for patients with NF; future studies should test the efficacy of the 3RP when delivered via video conferencing with flexibility in the timing of the groups, to improve feasibility. Although we allowed hearing impaired patients in the study, we excluded patients who were deafened. Future studies should adapt and test the intervention on a format that would be accessible to deafened participants. Lastly, the lack of long-term follow-up data does not allow for conclusions about the maintenance of symptom improvements. Patients who show improvement immediately post-treatment may not sustain these gains over time. Thus, further research is needed to evaluate the long-term effects of the 3RP.

Conflict of interest The authors declare that they have no conflict of interest.

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