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Acceptance and Commitment Therapy for enclosed spaces phobia: A randomized clinical trial

Terapia de Aceitação e Compromisso para fobia de espaços fechados: Um estudo clínico randomizado

Terapia de Aceptación y compromiso para fobia a espacios cerrados: Un ensayo clínico aleatorizado

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ABSTRACT

Several medical procedures, especially magnetic resonance imaging (MRI), can be severely distressing for individuals who suffer from enclosed space phobia. The psychotherapeutic approach to minimize the discomfort for these patients can be a safe and effective alternative to increase these patients' acceptance of the exam. A cohort of 30 subjects with MRI aversion was randomly divided into 2 intervention groups: 15 subjects received 1 session of Acceptance and Commitment Therapy (ACT) based psychotherapy, and 15 subjects received 7 sessions ACT based psychotherapy. The primary outcome was considered being able to undergo an MRI simulation after therapy completion. Subjects also filled a set of questionnaires at baseline and after 1 month and 3 months of treatment completion. The self-assessment questionnaires were performed before and after the treatment: Rachmann and Taylor Claustrophobia Inventory (1993), Beck Depression Inventory (1961) and the State-Trait Anxiety Inventory (STAI) (1970). Subjects who received the seven-session therapy were more likely to complete the simulation. Subjects from the seven-session therapy also showed improvement in the claustrophobia scale, which lasted for at least three months after treatment completion. The study showed that a one-session therapy was of inferior efficacy compared to the seven-session therapy. The seven-session therapy group showed a high success rate with lasting benefits. A brief psychotherapy course may be a safe and effective alternative for individuals with MRI avoidance.

Keywords: claustrophobia; fear; enclosed spaces; anxiety; acceptance and commitment therapy.

RESUMO

O objetivo deste estudo foi avaliar se uma abordagem psicoterapêutica breve poderia ajudar a minimizar o desconforto dos pacientes que sofrem para realizar procedimentos médicos, como é o caso da ressonância magnética (MRI), principalmente naqueles indivíduos com fobia de espaços fechados. Participaram do estudo sujeitos que apresentam esquiva ou recusa de realizar exames de ressonância magnética e que foram divididos em dois grupos com as seguintes intervenções: um grupo recebeu uma sessão de Terapia de Aceitação e Compromisso, e outro grupo recebeu sete sessões do mesmo modelo. Os dois grupos foram avaliados antes e depois do tratamento em escalas de claustrofobia, ansiedade (Idate) e depressão (BDI). O estudo mostrou que o grupo de uma sessão obteve eficácia inferior se comparado com o grupo de sete sessões. Os resultados mostram que o protocolo de psicoterapia breve de sete sessões se mostrou uma alternativa segura e eficaz para os indivíduos com dificuldade de realizar exames de ressonância magnética.

Palavras-chave: claustrofobia; fobia; espaços fechados; ansiedade; terapia de aceitação e compromisso.

RESUMEN

El objetivo de este estudio fue evaluar el efecto de un enfoque psicoterapéutico breve para ayudar a minimizar el sufrimiento de pacientes que presentan altos niveles de malestar al someterse a procedimientos médicos como la resonancia magnética nuclear (RMN), especialmente las personas que padecen de fobia a espacios cerrados. Una cohorte de 30 participantes con aversión al RMN se dividieron en dos grupos de intervención, 15 participantes recibieron 1 sesión de Terapia de Aceptación y Compromiso (ACT) y en el segundo grupo 15 participantes recibieron 7 sesiones de ACT. Los dos grupos fueron evaluados antes y después del tratamiento con el Inventario de Claustrofobia y Ansiedad (IDATE) y el Inventario de Depresión de Beck (BDI). Los resultados muestran que la intervención con psicoterapia breve de 7 sesiones puede ser una alternativa efectiva y segura para las personas con miedo de realizar RMN.

Palabras clave: claustrofobia; fobia; espacios cerrados; ansiedad; terapia de aceptación y compromiso.

Magnetic resonance imaging (MRI) is a valuable diagnostic tool for numerous medical conditions (Medelez & Crank, 1993). It is estimated that near 80 million MRIs are performed every year around the world. (Enders et al., 2011).

For a significant proportion of individuals, medical procedures including diagnostic, dental, or surgical procedures can be experienced with severe anxiety. Many patients respond to such conditions with aversive behavior (Choy, Stein, & Hermann, 2013), which makes difficult the completion of some procedures. For individuals who suffer from enclosed spaces specific phobia (or claustrophobia), having an MRI is experienced with extreme anxiety and discomfort. Among the patients frequently referred fears of undergoing MRIs are: fear of being stuck, fear of being immobilized, fear of being hurt, fear of losing of control, fear of the exam's result, and fear of the contrast (Katz, Wilson, & Frazer, 1994). Individuals under these circumstances can present several symptoms during the exam, including severe mental distress, muscular jitters, and restlessness, which may interfere with the procedure (Margis, Picon, Cosner, & Silveira, 2003).

Enclosed spaces phobia and other specific phobias are a group of disorders classified as anxiety disorders according to the *Diagnostic and Statistical Manual of Mental Disorders – V* (APA, 2013). Specific phobias are among the anxiety disorders with better response to treatment (Barlow, 2002). In some cases of specific phobia, up to 90% of patients present a significant and lasting improvement of the disorder after a few psychotherapy appointments, which is considered standard treatment (Ost, Setrner, & Fellenius, 1989). Hence, the development of a psychotherapy based strategy to minimize patients' distress and increase acceptance and access to MRI is encouraging.

The present study aims to test an alternative approach to sedation because of its contraindications, possible side effects, and the risks inherent to the procedure (Marshall, Martin, Downie, & Malisza, 2007). A psychotherapeutic intervention for individuals with aversion to MRI may be suggested as a low risk alternative treatment. The main objective is to verify the differential effects of one and of seven sessions of an Acceptance and Commitment approach for patients with enclosed spaces phobia. Both

psychotherapy protocols were based on Páez-Blarrina, Luciano, Gutiérrez-Martinez, Valdivia, Ortega, Rodríguez-Valverde (2008) and the principles of Acceptance and Commitment Therapy (ACT). We hypothesize that a one-session therapy is as effective as a seven-session therapy for MRI avoidance due to one-session evidence outcome in literature.

METHOD

For the present study, 30 subjects were recruited to participate in a psychotherapy treatment for MRI avoidance, advertised through various internet sites. The study was conducted in the Institute of Psychiatry of the University of São Paulo from February 2012 to September 2013 and approved by the institution's research ethics committee. Individuals were willing to enroll in a formal assessment at the institute. The calculation of the sample size was based on literature – about 2% of patients need anesthesia for the exam – and made by using a logistic regression simulation that suggested the number of 30 patients.

The assessment conducted by the team of psychiatrists was aimed to ensure that participants met inclusion criteria, which were: 1) age 18-60; 2) history of MRI avoidance, defined and having been prescribed a MRI and failing to attend due to fear; 3) adequate level of literacy and understanding to respond to self-assessment questionnaires and sign the informed consent form. MRI avoidance was defined as having been prescribed an MRI and failing to attend due to fear of the procedure, or having failed to complete an MRI due to fear. Exclusion criteria were: 1) suicide risk or self-injurious behavior; 2) diagnosis of a psychotic disorder; 3) acute medical condition or urgent indication of an MRI. Also, the assessment involved a semi-structured interview aimed to diagnose specific phobia, according to DSM-IV-TR criteria, focusing on the presence of situational phobia/enclosed spaces phobia. Information regarding age, marital status, education level, and use of psychotropic medication was also collected. Finally, subjects were asked to respond to self-assessment questionnaires before and after treatment: Rachmann and Taylor Claustrophobia Inventory (1993), Beck Depression Inventory (1961), and the State-Trait Anxiety Inventory (STAI) (1970).

Subjects who agreed to participate in the study and met inclusion criteria were randomized into two intervention groups. The interventions consisted of a psychotherapy protocol based on Acceptance and Commitment Therapy principles, following the protocol by Páez-Blarrina et al. (2008). The group of 15 subjects underwent a 2-hour session, and the other group underwent seven 50-minute sessions. All sessions were performed by the principal investigator.

Upon treatment completion, subjects were invited to undergo a 30-minute MRI simulation. The primary outcome of the study was considered the ability of the subject to remain in the simulation during the entire period. Treatment success was considered if the subject could complete the simulation, whereas subjects who left the simulation before the stipulated time, or who failed to attend the simulation appointment, were considered as failure. As secondary outcome, patients were invited to fill in self-assessment questionnaires at one month and three months after treatment completion. The consort flow diagram is described in Figure 1.

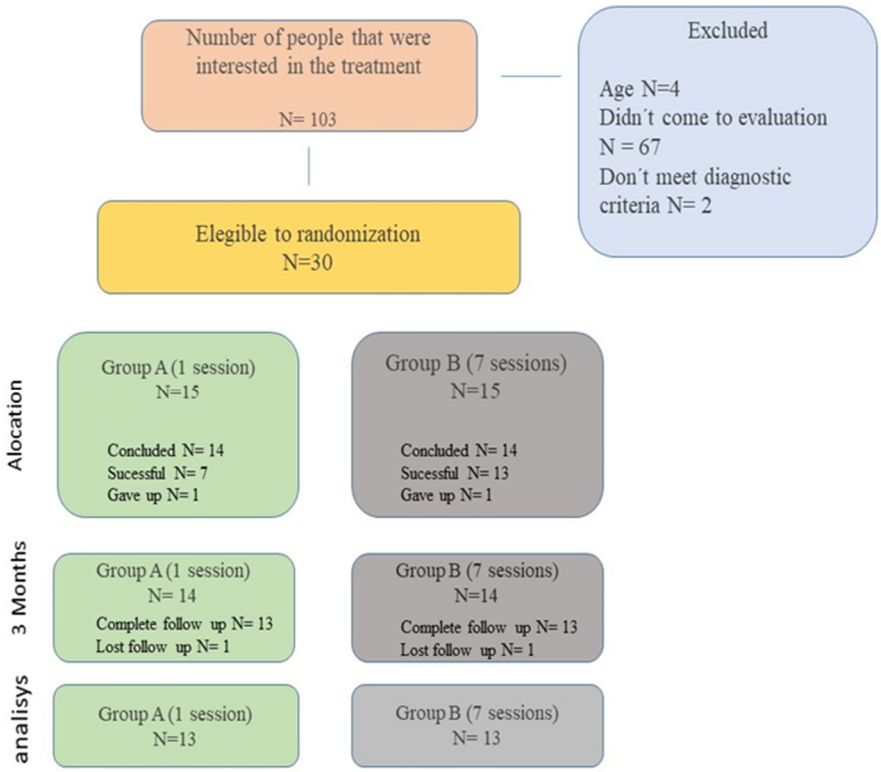

Figure 1. Consort flow diagram

STATISTICAL ANALYSIS

The data was first inserted into an Excel spreadsheet and processed by the SPSS program (Statistical Package for the Social Sciences). The significance level adopted for the tests was 5%. Data concerning demographical and clinical variables were compared between the two intervention groups using Fisher's exact test and chi-square for discrete variables, and independent samples t-test for continuous variables. Also, frequencies of primary outcome between groups were analyzed with Fisher's exact test. For secondary outcome analysis, baseline scores for self-assessment questionnaires were compared with those of one month and three months after treatment completion using paired samples t-test.

As a supplementary analysis, the whole sample was divided into subjects who had treatment success and those who had treatment failure. A series of univariate analysis were performed to identify variables associated with success, using Fisher's exact test and chi-square for discrete variables, and independent samples t-test for continuous variables. Finally, a stepwise forward logistic regression was performed, having the primary outcome as dependent variable, and baseline demographical and clinical variables as independent.

RESULTS

Initial analysis revealed that there are no significant differences regarding demographical or clinical variables between subjects randomized to the one-session treatment and to the seven-session treatment, as shown in Table 1. Concerning the primary outcome, it was found a significantly higher proportion of individuals that underwent the seven-session treatment and achieved treatment success.

Considering secondary outcome, 2 subjects from each group did not attend the reevaluation, and the

analyses were performed for the remaining 13 subjects in each group. Subjects from the seven-session treatment showed a significant improvement on the claustrophobia scale after one month, which remained at the three-month evaluation. This group also had an improvement of the BDI after one month, but this effect was not seen at three months. There was no significant change in any psychopathology scale in the one-session treatment group's follow-up. Details on this analysis are shown on Table 2.

The univariate analysis for possible baseline predictors of treatment success revealed that younger age, lower scores of depression and having undergone seven therapy sessions were positively associated with treatment success, as seen on Table 3. In the multivariate analysis with logistic regression the only remaining variable associated with treatment success was having received the seven-session treatment, as seen on Table 4. The estimated odds ratio of treatment success for subjects who underwent seven sessions was 7.4.

Table 1

Demographic and clinical characteristics of the clinical trial sample divided into intervention groups, and primary outcome

	1 session (n=15)	**7 sessions (n=15)**	**p-value**
Gender[1]			0.700
Man	6 (40%)	4 (26.7%)	
Woman	9 (60%)	11 (73.3%)	
Education [2]			0.223
Elementary	2 (13.6%)	0 (0%)	
High	1 (6.7%)	3 (20%)	
College	12 (80%)	12 (80%)	
Marital Status [2]			0.632
Single	4 (26.7%)	4 (26.7%)	
Married	7 (46.7%)	9 (60%)	
Divorced	4 (26.7%)	2 (13.3%)	
Claustrophobia [1]			1.0
No	3 (20%)	3 (20%)	
Yes	12 (80%)	12 (80%)	
Psychotropic Med. [1]			0.700
No	9 (60%)	11 (73.3%)	
Yes	6 (40%)	4 (26.7%)	
Claustrophobia Questionnaire (mean- SD) [3]	63.7 (15.5)	60.8 (26.2)	0.719
Beck Depression Inventory (mean- SD) [3]	13.9 (9.7)	11.7 (6.1)	0.464
STAI state (mean- SD) [3]	43.4 (5.3)	42.9 (4.2)	0.763
STAI trace (mean- SD) [3]	44.0 (4.2)	44.2 (5.4)	0.911
PRIMARY OUTCOME			
Completed the Simulation [1]			
Failure	8 (53.3%)	2 (13.3%)	**0.025**
Success	7 (46.7%)	13 (86.7%)	

[1] Fisher's Exact Test
[2] Chi-Square
[3] Independent Sample t-test

Table 2

Psychopathological scores differences between baseline and one and three months after intervention, divided into intervention groups

	1 session (n=13)	p-value	7 sessions (n=13)	p-value
Claustrophobia Questionnaire - 1 Month [1]	7.2 (15.0)	0.096	28.7 (27.6)	**0.002**
Claustrophobia Questionnaire - 3 Months [1]	3.6 (16.9)	0.458	20.1 (26.5)	**0.018**
Beck Depression Inventory -1 month [1]	1.7 (5.6)	0.280	4.0 (5.3)	**0.015**
Beck Depression Inventory -3 months [1]	0.3 (6.8)	0.844	2.0 (7.2)	0.341
STAI state -1 month [1]	0.1 (3.7)	0.945	-1.5 (5.0)	0.287
STAI state -3 months [1]	-0.3 (3.5)	0.758	-0.2 (4.5)	0.857
STAI trace -1 month [1]	-0.7 (6.2)	0.674	0.1 (8.4)	0.957
STAI trace -3 months [1]	-0.6 (5.2)	0.679	2.6 (5.8)	0.123

[1] Paired Sample t-test

To summarize, the seven-session group had better results (p = 0.033) with 92.9% of the participants with a favorable outcome, that is, they could undergo a magnetic resonance imaging (MRI) in the simulator, whereas only 50% of patients in the one-session group performed in the simulator. After treatment, a significant difference was observed between the means of the groups in the inventory of claustrophobia (p = 0.014). The results of the claustrophobia inventory were lower for the group that had seven sessions of psychotherapy, indicating that these patients improved more.

DISCUSSION

Contrary to our main hypothesis, results show that there is a significant difference between the one-session and the seven-session treatment for MRI avoidance, with superior results being obtained from the latter. A positive response to treatment in the seven-session treatment could also be observed in the follow-up evaluation, as they presented a lasting improvement in the claustrophobia scale. The one-session treatment group had a significant higher failure frequency in the primary outcome, and failed to show any improvement in psychopathology scales, which supports the superiority of the seven-session treatment. The high frequency of individuals with specific phobia – claustrophobia – (80%) probably increased the severity of the MRI avoidance, which might explain why most individuals responded mainly to a lengthier treatment. Still, considering the high prevalence of the condition among individuals who refuse MRI or require sedation for the procedure, it may be expected that those patients benefit from a more intensive treatment.

Nevertheless, the present study shows encouraging results from the seven-session treatment. Out of 15 subjects, 13 (86.6%) successfully completed the MRI simulation, and the improvements on the claustrophobia questionnaire were maintained to up to 3 months after treatment. This suggests that, although more prolonged, that treatment option may be highly satisfactory for approaching MRI avoidance, and may represent a safe and effective alternative for these individuals.

Table 3

Univariate analysis of baseline variables associated with treatment success

	Failure (n=10)	Success (n=20)	p-value
Gender[1]			
Man	3 (30%)	7 (35%)	0.560
Woman	7 (70%)	13 (65%)	
Education [2]			
Elementary	2 (20%)	0 (0%)	0.116
High	1 (10%)	3 (15%)	
College	7 (70%)	17 (85%)	
Age (mean- SD) [3]	50.2 (5.9)	43.8 (11.0)	**0.048**
Marital Status [2]			
Single	3 (30%)	5 (25%)	0.519
Married	4 (40%)	12 (60%)	
Divorced	3 (3%)	3 (15%)	
Claustrophobia [1]			
No	1 (10%)	5 (25%)	0.326
Yes	9 (90%)	15 (75%)	
Psychotropic Med. [1]			
No	6 (60%)	14 (70%)	0.440
Yes	4 (40%)	6 (30%)	
Claustrophobia Questionnaire (mean- SD) [3]	69.1 (20.5)	58.9 (21.2)	0.221
Beck Depression Inventory (mean- SD) [3]	16.9 (9.7)	10.1 (5.1)	**0.048**
STAI state (mean- SD) [3]	43.2 (4.0)	43.2 (5.1)	1.0
STAI trace (mean- SD) [3]	44.7 (4.7)	43.9 (4.8)	0.672
Intervention [1]			
1 session	8 (80%)	7 (35%)	**0.025**
7 session	2 (20%)	13 (65%)	

[1] Fisher's Exact Test
[2] Chi-Square
[3] Independent Sample t-test

Table 4

Logistic regression analysis of baseline variables associated with treatment success

							95% C.I.for EXP(B)	
	B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
7 sessions	2.00	0.91	4.76	1	0.02	7.42	1.22	45.00
-Constant	-0.13	0.51	0.06	1	0.79	0.87		

Accuracy for identification: 70%

Ost, Sterner and Fellenius (1989) pointed out that 90% of claustrophobic patients can achieve a significant improvement with a reduced number of psychotherapeutic treatment (up to 10 sessions). It corresponds to the present study, which presented improvement rates in 92% for the participants in the seven-session group.

Concerning the strengths of the present study, proper randomization with comparable groups regarding demographical and clinical variables, and short time lapse between treatment and outcome suggest that the results obtained can be due to the intervention. However, a control group would be necessary to better evaluate if positive outcomes were truly yielded by the ACT protocol.

The short time lapse in which the results were observed after psychotherapy increases the reliability of causation effects (Starling, 2010). Also, broad inclusion criteria allowed the selection of a sample with more similarity with the clinical practice, and thus yielding results with higher external validity.

The study has several limitations that should be addressed. The study was not blinded, and the same therapist performed the treatment for both groups. Though it is likely that these flaws significantly biased the study, the result was still in contradiction with the main hypothesis. Concerning predictors of MRI simulation completion, other unknown variables may have influenced the result, such as the presence of a non-anxiety mental disorder. This may have shed light in our finding of a trend towards better results in younger individuals and those with lower depression scores. Medical indication for an MRI may have also influenced the result. Although acute and/or life-threatening disease was an exclusion criteria, individuals' perception of one's medical condition may have encouraged or discouraged them to undergo MRI simulation. It must also be considered that, besides therapy effects, the fact of having successfully completed the MRI simulation may be implicated in the maintenance of positive results as individuals who successfully face their phobic stimuli are more prone to do so in future occasions and thus presenting a better prognosis.

Future studies should focus on the optimal number of sessions. The understanding of further predictors of success or failure may also improve clinical decision and therapeutic approach for the patient. Risk and cost-effectiveness studies should be considered to compare the psychotherapy approach for MRI aversion with sedation and other strategies.

CONCLUSION

The present study showed that an ACT based brief psychotherapy protocol might be effective for the treatment of MRI avoidance with potential benefits for individuals suffering from enclosed space phobia. That approach can be offered in MRI clinics as an alternative to sedation for individuals with MRI avoidance and/or enclosed space phobia.

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