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MIXED MUSIC THERAPY INTERVENTION FOR YOUNG ASTHMATICS IN INHALATION THERAPY DURING A CLIMATIC VACATION – A PILOT RCT STUDY

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Place and date of study: Fusine(Tarvisio), 19 – 26 August 2018

Introduction: Asthma, one of the most common chronic, non-communicable diseases in children and adults, is characterised by variable respiratory symptoms and variable airflow limitation. Asthma is a consequence of complex gene–environment interactions, with heterogeneity in clinical presentation and the type and intensity of airway inflammation and remodelling. Clinical manifestations in young people can considerably disturb their daily activities. This RCT aims to determine the effectiveness in asthma of mixed interventions of music therapy in a short term study.

Keywords: Asthmatic young people, music therapy, physiological and psychological response.

Objective: to investigate the physiological and psychological effects of an high dose of music therapy treatments on the experimental group compared with a control group in the short term.

Methods: An open RCT, single centre, with a pre-test/post-test design. 37 young asthmatics of both sexes from the urban area of Udine aged between 8 and 18 were assigned according to a randomization obtained through a remotely administered computer. The epidemiologist had no contact with the involved clinicians and participants during the study and provided individual concealment of the allocation sequence in the two comparable groups (18+19) by e-mail.Eligible participants were selected based on average age, history of illness and severity of symptoms. Standard care available to all participants included medication(inhalation therapy), sports and other social activities, like hiking and other outings in the natural surroundings of the mountains around the house used for the climatic vacation. Participants of the experimental group were aware that the aim of the study had to do with music therapy.

Procedure: Active and receptive methods, were chosen and applied to the experimental group, by a qualified music therapist and a psychologist in training, twice a day for 6 consecutive days. A total of 12 sessions. Each sitting was about 90 minutes long and took place in an airy room of the holiday home. The 2 colleagues of the clinical music therapy setting shared their previous experience of working with young adolescents. The morning session involved improvisational free vocal technique and listening to personal and meaningful music. Each moment of the music therapy session was followed by a verbalization of the experience. The afternoon session involved singing of pre-composed music (canons and songs) added to the same formula of listening to music. After each moment of this second daily session there was a verbal discussion/reflection about the therapy process.

Assessment instruments: Everyday: A.Individual analysis of daily improvised videotaped sessions, through the MT SAS for every participant. Pre-test/Post-test ('weekly'), B. Clinical evaluations: incentive spirometry, nitric oxide dosage, salivary cortisol test. C. Psychological evaluations: STAI-S and STAI-T ; POMS 2; KINDL for quality of life.

Results: Medical: At the beginning, there were no significant differences in the clinical status of the patients assigned to the 2 groups: music therapy (experimental) and control. Even at the final control no significant differences were found. Spirometry, the dose of exhaled nitric oxide and that of salivary cortisol showed no statistically significant differences between the 2 groups, between the beginning and the end of the stay, even if the group that performed the music therapy had lower single values of salivary cortisol, but not enough to improve the statistical result. It is possible that, with a longer stay of at least two weeks, the results reach a statistically significant value.

Psychological: Also in the psychological assessment section, although there was no significant short-term effect, we observed a tendency towards a *reduction in state and trait anxiety (STAI);a little* improvement in perception of confusion, unchanged perception of depression, a little increase of tiredness and anger, a little decrease in vigour (**POMS2**); a little improvement in perception of relationship with friends and family, a very short *decrease in*physical well-being, *emotional well-being and self-esteem (KINDL).*

Music Therapy: Mixed MT interventions was well accepted by a large part of young asthmatics.

Conclusion: Overall, it appears plausible that music therapy can affect social functioning. Mixed music therapy approaches demonstrated adequate for this kind of population because a large amount of participants can be involved. For those who had a major reluctance to feel free in singing, the second part of the session in which participants focus on listening to "their personal favourite music" contributed to maintaining participants engaged in the path of the process. Probably we will obtain statistical significance increasing sample's numerousness, extending the duration of the clinical study and improving the data collection methodology, in this aspect we encountered a lot of missed adhesion to answer to the psychological tests from children and some adolescents. Starting from this RCT, it could be advantageous build a prospective longitudinal study to observe clinical effect of mixed music therapy interventions in the long term.

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cortisol salivary measurement

Experimental group pre post

	1st	2nd		1st	2nd		1st	2nd		1st	2nd
1	0,54	0,98	**6**	0,71	1,78	**11**	0,75	1,00	**16**	0,54	0,72
2	0,54	0,54	**7**	0,54	0,54	**12**	0,54	0,54	**17**	1,04	2,70
3	1,24	0,57	**8**	0,70	0,54	**13**	0,54	0,62	**18**	0,54	0,54
4	1,22	1,63	**9**	0,76	0,54	**14**	0,60	0,54			
5	1,09	3,34	**10**	0,54	0,54	**15**	0,54	1,16			

In yellow the values ≤ 0,54 ng/mL

reference interval for nocturnal salivary cortisol (ng/mL) 0,5 - 2,5

Control group pre post

	1st	2nd		1st	2nd		1st	2nd		1st	2nd
1	0,84	0,65	**6**	2,03	2,41	**11**	1,10	4,08	**16**	1,24	2,88
2	0,54	0,60	**7**	0,54	0,54	**12**	1,80		**17**	0,55	1,35
3	1,18	1,33	**8**	1,00	0,54	**13**	2,79	1,69	**18**	0,54	0,54
4	0,54	0,54	**9**	0,54	0,67	**14**	0,54	0,72	**19**	1,66	5,64
5	0,54	0,54	**10**	0,54	0,54	**15**	0,54	0,60			

Psychological Test: POMS 2, KINDL, STAI-S, STAI-T

Experimental Group-POMS 2 Summary Table-Profile of Mood States - 1 drop out

18 Subj.	Anxiety		Depression		Anger		Vigour		Tiredness		Confusion	
Average	2,11	1,78	0.78	0,78	1,67	1,89	11,33	10,34	2,11	2,44	2,55	2,22
Stand.Dev.	2,76	4,06	2,47	1,64	1,87	4,28	3,80	3,32	1,76	2,07	2,35	3,70
P signif.	>0,2		>0,2		>0,2		>0,2		>0,2		>0,2	

Control Group - POMS 2Summary Table –Profile of Mood States - 1 drop out

19 Subj	Anxiety		Depression		Anger		Vigour		Tiredness		Confusion	
Average	2,5	3,5	0,6	2,5	0,25	1,62	10,88	13,88	2,5	4,75	2,5	2,38
Stand.Dev.	2,07	4,58	1,86	4,41	0,76	2,60	2,20	5,33	3,12	5,36	2,33	4,10
P signif.	>0,2		>0,2		>0,2		>0,2		>0,2		>0,2	

Experimental Group-KINDL Summary Table-Health-Related Quality of Life 1 drop out

18 Subj.	Physicalwell-being		Emotional well-being		Self-esteem		Family		Friends		School	
Average	9,53	9,4	9,4	8,73	14,2	12,87	12,07	12,86	13,58	14,5	12,07	11
Stand.Dev.	2,73	1,83	2,10	1,37	3,89	3,62	2,13	1,10	3,30	2,56	4,14	3,11
p Signif.	> 0.2		> 0.2		> 0.2		> 0.2		> 0.2		> 0.2	

Control Group - KINDL Summary Table - Health-Related Quality of Life administered

19 subj.	Physicalwell-being		Emotional well-being		Self-esteem		Family		Friends		School	
Average	8,84	9,68	9,37	9,58	13,42	13,84	13	11,89	13,78	14,83	12,05	10,94
Stand.Dev	1,85	1,69	2,14	2,01	3,96	3,92	1,24	3,63	3,61	2,81	4,12	4,72
p Signif.	> 0.2		> 0.2		> 0.2		> 0.2		> 0.2		> 0.2	

Experimental Group – State Anxiety: STAI-S and Trait Anxiety: STAI-T Summary Table - 1 drop out

18 subjects	PRE STAI-S	POST STAI-S	PRE STAI-T	POST STAI-T
Average	34,86	33,14	38,29	35
Stand.Dev.	6,50	5,13	6,16	5,42
p Signif.	> 0.2		> 0.2	

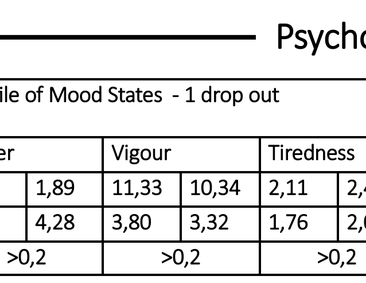
Control Group - State Anxiety: STAI-S and Trait Anxiety: STAI-T Summary Table

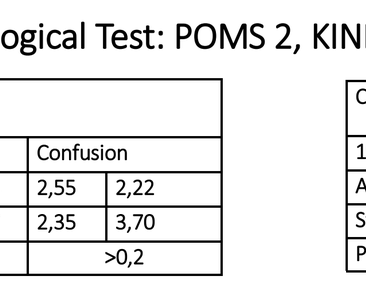
19 Subjects	PRE STAI-S	POST STAI-S	PRE STAI-T	POST STAI-T
Average	32,45	30,27	33,36	34,82
Stand.Dev.	11,55	6,29	8,22	9,95
p Signif.	> 0.2		> 0.2	

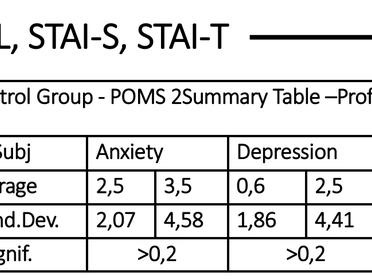
STAI-S is the State Anxiety (Now) ; STAI-T is the Trait Anxiety (in this period of life)

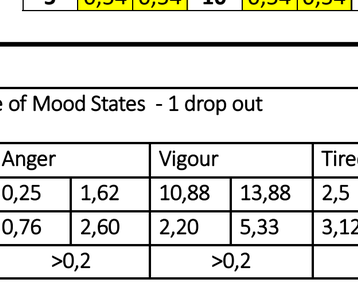
Non-parametric tests were used to characterise significance, since there was no "normal" pattern in any group. Specifically, the significance shown in the tables was evaluated for safety with two tests: the Wilcoxon Test and the Mann-Whitney Test. According to both results are not statistically significant ($p > 0.2$). However, the number of observations is very low and could influence the outcome

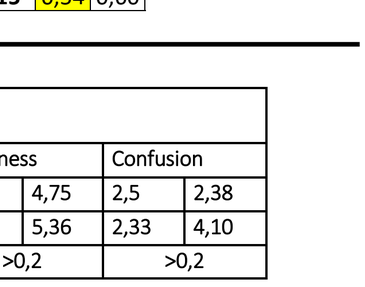
Assessment MT SAS











	day1	day 2	day 3	day 4	day 5	day 6	Average	Day 1 %	Day 2 %	Day 3 %	Day 4 %	Day 5 %	Day 6 %
Eye contact	18	15	13	16	11	12	14,17	100,00	88,24	81,25	94,12	68,75	70,59
Body reciprocity	10	13	10	14	11	11	11,50	55,56	76,47	62,5	82,35	68,75	64,71
Countenance and body signals	12	14	10	13	12	11	12,00	66,67	82,35	62,5	76,47	75,00	64,71
Refusal or disturbed behaviours	14	13	12	13	11	12	12,50	77,78	76,47	75	76,47	68,75	70,59
Sonorous musical production	13	13	10	13	11	11	11,83	72,22	76,47	62,5	76,47	68,75	64,71
Attuned son. mus.production	15	13	8	13	11	10	11,67	83,33	76,47	50	76,47	68,75	58,82
Dynamism or variations	16	13	10	7	10	9	10,83	88,89	76,47	62,5	41,18	62,50	52,94
Number of participants	18	17	16	17	16	17