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EFFICACY OF SARASWATA CHOORNA ON QUALITY OF LIFE AND MANASIKA PARIKSHA BHAVA'S IN GENERALIZED ANXIETY DISORDER: ANCILLARY FINDINGS

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ABSTRACT

Generalized anxiety disorder (GAD) is characterized by a pattern of frequent, persistent worry and anxiety that is out of proportion to the impact of the event or circumstance that is the focus of the worry. The present study was based on the ancillary findings of the main study (which was based on scoring of Hamilton Anxiety Rating scale- HAM-A) in GAD. The main study findings based on HAM-A scoring reported, 51.1 % improvement in trial group (Saraswata choorna) and 47.7 % improvement in control group (Placebo) ($P < 0.001$). Saraswata choorna didn't provide relief in GAD on HAM-A scoring. The present ancillary findings are based on the measurement tools like, Internet Mental Health Quality of Life scale (IMHQOL) and Manasika Pariksha Bhava's (MPB) on same sample, with same materials and methods and intervention as of the main study. The objective of this study was to evaluate the efficacy of Saraswata choorna on IMHQOL and MPB. Two assessments were done before and after treatment, based on the scorings of IMHQOL and MPB. Paired and unpaired 't' test were used for statistical analysis. In trial group ($n = 51$), 35.17 % on IMHQOL, 21.19 % on MPB-PE (Positive emotions) and 36.10 % on MPB-NE (Negative emotions) whereas in control group ($n = 51$), 32.55 % on IMHQOL and 18.49 % on MPB-PE and 37.94 % on MPB-NE was observed ($P < 0.001$). No statistically significant difference ($P > 0.05$) found in between the two groups on both scales. Saraswata choorna did not prove better than placebo on IMHQOL and MPB scales in GAD.

Keywords: Generalized Anxiety Disorder, Saraswata choorna, Placebo, IMHQOL, Manasika Pariksha Bhava's

INTRODUCTION

Generalized anxiety disorder (GAD) is characterized by a pattern of frequent, persistent worry and anxiety that is out of proportion to the impact of the event or circumstance that is the focus of the worry.¹ Adults with GAD often worry about routine life circumstances such as job responsibilities, finances, health of family members, misfortune to their children and other minor matters.² GAD is associated with substantial reductions in quality of life and impairment in role functioning, significant impairment in social and occupational functioning.³ GAD is similar to the condition of "Chittodvega" in Ayurveda according to previous works⁴. The present work consist the ancillary findings of the main study, which was conducted on Saraswata choorna by using the assessment tool, Hamilton Anxiety Rating Scale – HAM-A; this trial reported 51.1 % improvement in trial group and 47.7 % in control group (placebo). Saraswata choorna was not proved better than placebo on HAM-A in this main study.⁵ The present article deals with the findings on the measurement tools like, Internet Mental Health Quality of Life – IMHQOL⁶ and Manasika Pariksha Bhava's – MPB⁷ scales on the same sample with same materials and methods and intervention as that of main study.

Aim and Objective

To evaluate the efficacy of Saraswata choorna on IMHQOL and MPB scales in GAD patients

MATERIALS AND METHODS

Study design, subjects of the study, inclusion and exclusion criteria, randomization and intervention were same as that of the main study⁵ which was conducted as per the ethical guidelines and cleared through the ethical committee of the institute (on 14.12.2009 at Institute of Post Graduate Teaching and Research in Ayurveda, Gujarat Ayurved University, Jamanagar, India). Written consent was taken from each patient willing to participate before the start of the study.

Intervention

In trial group, Saraswata choorna with the dose of one gram thrice a day along with honey and cow's ghee was given for the period of sixty days. In control group, placebo (roasted wheat powder) was given with similar dose as trial drug. Fifteen days follow up period was kept after the treatment period in both groups.

Assessment

Before and after treatment total two assessments were carried out. Criteria of assessment were based on the scoring of Internet Mental Health Quality of Life scale (IMHQOL) and Manasika Pariksha Bhava's - MPB scales. The IMHQOL is composed of seventy eight items (questions) which are divided in to fifteen categories. This scale measures the quality of life of the patient in various domains especially focused on mental health. In Charaka

Samhita, twenty two manasika bhava's (emotions) and their method of examination is mentioned. Based on this, questionnaire was prepared with twenty two items divided in to two groups, positive emotions (PE) which contains fifteen items and negative emotions (NE) which consist seven items.

Statistical Analysis

The information gathered on the basis of observations was subjected to statistical analysis in terms of Mean difference, Standard deviation (S.D), Standard error (S.E), Paired and unpaired 't' test. Statistical analysis was done by using 'Sigma stat' software version 3.5. Statistical significance level was kept at $P < 0.05$.

Table 1: Effect of Therapy on Internet Mental Health Quality of Life (IMHQOL) scale in both groups (n = 51)

S. No	IMHQOL	Group	Mean BT	Mean AT	M. D*	% of Relief	SD** ±	t value	P value
1	Physical Functioning (1-9)	Trial	8.96	5.41	3.55	39.60	2.11	12	< 0.001
		Control	9.13	5.62	3.51	38.41	2.14	11.71	< 0.001
2	Social Functioning (10-13)	Trial	1.19	0.96	0.23	19.67	0.52	3.25	< 0.01
		Control	1.19	0.84	0.35	29.50	0.69	3.63	< 0.001
3	Employment / Economic Functioning (14-18)	Trial	1.56	1.25	0.31	20	0.91	2.45	< 0.05
		Control	1.68	1.50	0.17	10.46	0.71	1.75	> 0.05
4	Impulsive / Anti Social Behavior (19-21)	Trial	0	0	0	0	0	0	> 0.05
		Control	0.01	0	0.01	100	0.14	0.99	> 0.05
5	Substance Abuse (22-24)	Trial	0.35	0.29	0.05	16.66	0.23	1.75	> 0.05
		Control	0.33	0.23	0.09	29.41	0.36	1.92	> 0.05
6	Anxiety (25-28)	Trial	1.49	0.62	0.86	57.89	1.15	5.33	< 0.001
		Control	1.82	0.86	0.96	52.68	1.51	4.51	< 0.001
7	Dysphoric Mood (29-33)	Trial	6.11	2.66	3.45	56.41	1.70	14.46	< 0.001
		Control	5.54	2.56	2.98	53.71	1.44	14.75	< 0.001
8	Hyperactivity / Excitement (34-36)	Trial	0.03	0.02	0.01	50	0.14	0.99	> 0.05
		Control	0.01	0.01	0	0	0	0	> 0.05
9	Reality Testing (37-39)	Trial	0	0	0	0	0	0	> 0.05
		Control	0	0	0	0	0	0	> 0.05
10	Intellectual Functioning (40-48)	Trial	2.56	1.15	1.41	54.96	1.69	5.96	< 0.001
		Control	2.37	0.80	1.56	66.11	1.70	6.58	< 0.001
11	Need for Institutional Care (49)	Trial	0.05	0	0.05	100	0.42	0.99	> 0.05
		Control	0.01	0	0.01	100	0.14	0.99	> 0.05
12	Lack of Insight (50)	Trial	0	0	0	0	0	0	> 0.05
		Control	0	0	0	0	0	0	> 0.05
13	Overall Psychosocial Functioning (51)	Trial	5.05	4.35	0.70	13.95	1.25	4.01	< 0.001
		Control	5.11	4.58	0.52	10.34	1.16	3.24	< 0.01
14	Cluster A + C Personality Traits (52-66)	Trial	6.15	4.51	1.64	26.75	2.49	5.22	< 0.001
		Control	6.54	5.09	1.45	22.15	2.25	4.60	< 0.001
15	Cluster B Personality Traits (67-78)	Trial	2.94	2.39	0.54	18.66	1.05	3.71	< 0.001
		Control	3.52	3.01	0.50	14.44	1.19	3.03	< 0.01

*Mean difference, **Standard Deviation

Table 2: Comparison of Effect of Therapy on IMHQOL scale

S. No	IMHQOL	Trial Group		Control Group		t value	P value
		M. Diff*	SD**	M. Diff	SD		
1	Physical Functioning (1-9)	3.55	2.11	3.51	2.14	0.09	> 0.05
2	Social Functioning (10-13)	0.23	0.52	0.35	0.69	0.1	> 0.05
3	Employment / Economic Functioning (14-18)	0.31	0.91	0.17	0.71	0.86	> 0.05
4	Impulsive / Anti Social Behavior (19-21)	0	0	0.01	0.14	0.51	> 0.05
5	Substance Abuse (22-24)	0.05	0.23	0.09	0.36	0.66	> 0.05
6	Anxiety (25-28)	0.86	1.15	0.96	1.51	0.37	> 0.05
7	Dysphoric Mood (29-33)	3.45	1.70	2.98	1.44	1.50	> 0.05
8	Hyperactivity / Excitement (34-36)	0.01	0.14	0	0	0.51	> 0.05
9	Reality Testing (37-39)	0	0	0	0	0	> 0.05
10	Intellectual Functioning (40-48)	1.41	1.69	1.56	1.70	0.44	> 0.05
11	Need for Institutional Care (49)	0.05	0.42	0.01	0.14	0.64	> 0.05
12	Lack of Insight (50)	0	0	0	0	0	> 0.05
13	Overall Psychosocial Functioning (51)	0.70	1.25	0.52	1.16	0.75	> 0.05
14	Cluster A + C Personality Traits (52-66)	1.64	2.49	1.45	2.25	0.40	> 0.05
15	Cluster B Personality Traits (67-78)	0.54	1.05	0.50	1.19	0.18	> 0.05

*Mean difference, **Standard Deviation

Table 3: Effect of Therapy on Manasika Pariksha Bhava – Positive Emotions (MPB-PE) in both Groups (n = 51)

S. No	Positive Emotions	Group	Mean BT	Mean AT	M. D*	% of Relief	SD** ±	t value	P value
1	Vigyanam	Trial	1.80	2.21	0.41	22.82	0.49	5.49	< 0.001
		Control	1.78	2.17	0.39	21.97	0.53	5.23	< 0.001
2	Harsha	Trial	1.21	1.74	0.52	43.54	0.67	5.58	< 0.001
		Control	1.21	1.70	0.49	40.32	0.61	5.69	< 0.001
3	Preeti	Trial	1.19	1.76	0.56	47.54	0.64	6.30	< 0.001
		Control	1.19	1.78	0.58	49.18	0.60	6.93	< 0.001
4	Dhairyam	Trial	1.29	1.80	0.50	39.39	0.57	6.27	< 0.001
		Control	1.25	1.80	0.54	43.75	0.57	6.79	< 0.001
5	Veeryam	Trial	1.35	2.17	0.82	60.86	0.62	9.35	< 0.001
		Control	1.56	2.21	0.64	41.25	0.71	6.44	< 0.001
6	Avastha	Trial	1.90	2.32	0.37	19.58	0.60	4.41	< 0.001
		Control	2.07	2.45	0.37	17.92	0.60	4.41	< 0.001
7	Shraddha	Trial	1.52	2.50	0.98	64.10	2.94	2.37	< 0.05
		Control	1.60	2.15	0.54	34.14	0.64	6.08	< 0.001
8	Medha	Trial	2.29	2.70	0.41	17.94	0.53	5.46	< 0.001
		Control	2.33	2.74	0.41	17.64	0.53	5.46	< 0.001
9	Sangya	Trial	2.45	2.76	0.31	12.8	0.51	4.36	< 0.001
		Control	2.43	2.72	0.29	12.09	0.50	4.15	< 0.001
10	Smriti	Trial	2.50	2.90	0.40	15.62	0.63	4.38	< 0.001
		Control	2.50	2.72	0.21	8.59	0.41	3.68	< 0.001
11	Hree	Trial	2.86	2.90	0.03	1.36	0.19	1.41	> 0.05
		Control	2.80	2.90	0.10	3.49	0.36	1.92	> 0.05
12	Sheela	Trial	2.58	2.80	0.21	8.33	0.46	3.31	< 0.01
		Control	2.47	2.68	0.21	8.73	0.46	3.31	< 0.01
13	Dhriti	Trial	1.96	2.05	0.09	5	0.30	2.31	< 0.05
		Control	2.03	2.09	0.05	2.88	0.37	1.12	> 0.05
14	Vasyata	Trial	2.33	2.39	0.05	2.52	0.37	1.12	> 0.05
		Control	2.21	2.33	0.11	5.30	0.52	1.61	> 0.05
15	Manasa	Trial	1.72	2.15	0.43	25	0.54	5.69	< 0.001
		Control	1.74	2.15	0.41	23.59	0.49	5.89	< 0.001

*Mean difference, **Standard Deviation

Table 4: Comparison of Effect of Therapy on MPB – PE

S. No	Positive Emotions	Trial Group		Control Group		t value	P value
		M. Diff*	SD**	M. Diff	SD		
1	Vigyanam	0.41	0.49	0.39	0.53	0.2	> 0.05
2	Harsha	0.52	0.67	0.49	0.61	0.23	> 0.05
3	Preeti	0.56	0.64	0.58	0.60	0.16	> 0.05
4	Dhairyam	0.50	0.57	0.54	0.57	0.35	> 0.05
5	Viryam	0.82	0.62	0.64	0.71	1.36	> 0.05
6	Avastha	0.37	0.60	0.37	0.60	0	> 0.05
7	Shraddha	0.98	2.94	0.54	0.64	1.04	> 0.05
8	Medha	0.41	0.53	0.41	0.53	0	> 0.05
9	Sangya	0.31	0.51	0.29	0.50	0.2	> 0.05
10	Smriti	0.39	0.63	0.21	0.41	1.71	> 0.05
11	Hree	0.03	0.19	0.10	0.36	1.22	> 0.05
12	Sheela	0.21	0.46	0.21	0.46	0	> 0.05
13	Dhriti	0.09	0.30	0.05	0.37	0.60	> 0.05
14	Vasyata	0.05	0.37	0.11	0.52	0.67	> 0.05
15	Manasa	0.43	0.54	0.41	0.49	0.2	> 0.05

*Mean difference, **Standard Deviation

Table 5: Effect of Therapy on Manasika Pariksha Bhava – Negative Emotions (MPB - NE) in both Groups (n = 51)

S. No	Negative Emotions	Group	Mean BT	Mean AT	M. D*	% of Relief	SD** ±	t value	P value
1	Rajah	Trial	1.33	0.70	0.62	47.05	0.80	5.56	< 0.001
		Control	1.60	1	0.60	37.80	0.72	5.95	< 0.001
2	Moha	Trial	1.19	0.72	0.47	39.34	0.70	4.75	< 0.001
		Control	1.58	0.88	0.70	44.44	0.67	7.43	< 0.001
3	Krodha	Trial	0.49	0.25	0.23	48	0.41	4.01	< 0.001
		Control	0.54	0.29	0.25	46.42	0.44	4.10	< 0.001
4	Shoka	Trial	1.88	1.09	0.78	41.66	0.78	7.09	< 0.001
		Control	1.82	0.96	0.86	47.31	0.62	9.82	< 0.001
5	Bhaya	Trial	2.03	1.27	0.76	37.5	0.67	8.04	< 0.001
		Control	2.03	1.29	0.74	36.53	0.56	9.42	< 0.001
6	Dvesha	Trial	0.39	0.19	0.19	50	0.40	3.46	< 0.001
		Control	0.45	0.25	0.19	43.47	0.40	3.46	< 0.001
7	Upadhi	Trial	2.05	1.74	0.31	15.23	0.51	4.36	< 0.001
		Control	2.05	1.58	0.47	22.85	0.64	5.19	< 0.001

*Mean difference, **Standard Deviation

Table 6: Comparison of Effect of Therapy on MPB –NE

S. No	Negative Emotions	Trial Group		Control Group		t value	P value
		M. Diff*	SD**	M. Diff	SD		
1	Rajah	0.62	0.80	0.60	0.72	0.13	> 0.05
2	Moha	0.47	0.70	0.70	0.67	1.69	> 0.05
3	Krodha	0.23	0.41	0.25	0.44	0.24	> 0.05
4	Shoka	0.78	0.78	0.86	0.62	0.57	> 0.05
5	Bhaya	0.76	0.67	0.74	0.56	0.16	> 0.05
6	Dvesha	0.19	0.40	0.19	0.40	0	> 0.05
7	Upadhi	0.31	0.51	0.47	0.64	1.39	> 0.05

*Mean difference, **Standard Deviation

Table 7: Effect of Therapy on Total Scores of IMHQOL and MPB

S. No	Scale	Group	Mean BT	Mean AT	M. D*	% of Relief	SD** ±	t value	P value
1	IMHQOL	Trial	36.50	23.66	12.84	35.17	6.02	15.12	< 0.001
		Control	37.35	25.17	12.17	32.59	6.92	12.55	< 0.001
2	MPB - PE	Trial	29.02	35.17	6.15	21.19	5.29	8.31	< 0.001
		Control	29.26	34.67	5.41	18.49	3.98	9.70	< 0.001
3	MPB -NE	Trial	9.39	6.0	3.39	36.10	2.68	9.03	< 0.001
		Control	10.12	6.28	3.84	37.94	2.26	12.16	< 0.001

*Mean difference, **Standard Deviation

RESULTS AND DISCUSSION

Effect of therapy on IMHQOL

In trial group, improvement was observed in physical functioning, anxiety, dysphoric mood and intellectual functioning with the percentage of relief 39.60, 57.89, 56.41 and 54.96 ($P < 0.001$) respectively. In control group, improvement was observed in physical functioning, social functioning, anxiety, dysphoric mood and intellectual functioning with the percentage of relief 38.41, 29.50, 52.68, 53.71 and 66.11 respectively ($P < 0.001$) (Table 1). On total score of IMHQOL, 35.17 % and 32.59 % improvement was observed in trial and control groups respectively ($P < 0.001$) (Table 7). There was no statistically significant difference found in between the two groups ($P > 0.05$) (Table 2). Sarasvata choorna is a medhya (nootropic) compound formulation which is indicated in durmedhas (dull witted), vichetas (stupidity) like conditions and for improving the cognitive functions like buddhi (intellect), smriti (memory) etc; Sarasvata Choorna contains medhya drugs like Brahmi (*Bacopa monniera*), Shankhapushpi (*Convolvulus pluricaulis* Choisy), Vacha (*Acorus calamus*) and Kushta (*Saussurea lappa* C. B. Clarke).⁸ All medhya and medhya rasayana drugs are claimed to be nutraceutical agents. They are called medhya because they are beneficial for medha (i.e., intellect). All such herbs have been found to possess nootropic effect besides varying degrees of anxiolytic activity. In addition to other aspects of the rasayana (nutraceutical) effect, they possess anti stress effect and improve the memory and cognitive functions.⁹ Due to these properties sarasvata choorna was able to provide relief in the items like physical functioning, anxiety, dysphoric mood and intellectual functioning items of IMHQOL scale. Sarasvata choorna able to provide more relief on cluster A + C personality traits (paranoid, schizoid, schizotypal, avoidant, dependant and obsessive compulsive) compared to cluster B personality traits (anti social, borderline, histrionic and narcissistic) (Table 1). Due to the presence of ingredients which possess anxiolytic effect in Sarasvata choorna, it showed more relief on cluster A + C personality traits item of

IMHQOL scale. Placebo also provided good relief on items like physical functioning, social functioning, anxiety, dysphoric mood and intellectual functioning etc; this relief was obtained due to placebo effects. Sarasvata choorna was not proved better than placebo on IMHQOL scale.

Effect of therapy on MPB (PE and NE)

In trial group, statistically significant improvement was observed in MPB (PE) like Harsha (cheerfulness), Preeti (grace), Dhairyam (firmness) and Viryam (energy) with the percentage of relief 43.54, 47.54, 39.39 and 60.86 ($P < 0.001$) respectively. In control group, improvement was observed in domains like Harsha, Preeti, Dhairyam, Viryam and Shraddha (trust) with the percentage of relief 40.32, 49.18, 43.75, 41.25 and 34.14 ($P < 0.001$) (Table 3) respectively. On comparing the effect of therapy on MPB (PE) between the two groups, no difference was found in any of the bhava ($P > 0.05$) (Table 4). On total score of MPB (PE), there was 21.19 % improvement observed in trial group whereas in control group 18.49 % improvement was observed ($P < 0.001$) (Table 7). In trial group, improvement was observed on MPB (NE) in factors like, Rajah (passion), Moha (confusion), Krodha (anger), Shoka (grief), Bhaya (fear) and Dvesha (hatred) with the percentage of relief 47.05, 39.34, 48, 41.66, 37.5 and 50 respectively ($P < 0.001$). In control group also similar results were observed (Table 5). On comparing the effect of therapy on MPB (NE) between the two groups, no statistically significant difference was found in any of the bhava ($P > 0.05$) (Table 6). On total score of MPB (NE), there was 36.10 % improvement observed in trial group whereas in control group 37.94 % improvement was observed ($P < 0.001$) (Table 7). There was no significant difference found in between the two groups on MPB (PE and NE) ($P > 0.05$) (Table 4 and 6). Sarasvata Choorna may be acting on various neurotransmitters like GABA (Gamma Amino Butyric Acid) and 5-HT (5 – Hydroxy Tryptamine) transmission due to the presence of anxiolytic drugs like, Brahmi, Shankhapushpi, Vacha and Kushta in it. Based on these features it exhibits action on

negative emotions like krodha, bhaya, dvesha, rajah and moha by altering the mood as well as cognitive functions. Relief on negative emotions automatically leads to increase or improvement in positive emotions like harsha, preeti, dhairya, veerya and shraddha etc; based on these it can be concluded that, sarasvata choorna may be showing its effects by altering the various neurotransmitter pathways or acting on hypothalamo pituitary adrenal axis or may be due to its medhya rasayana properties. Placebo response may be due to some complex physiological process including change in mood, change in motivation / effort or cognitive set shifting. Reduction in negative emotions may be a critical component of placebo effect and perceived stress may impact placebo responsiveness to cognitive enhancement. Placebo is known to act on various neurotransmitter systems like opioid, serotonin and dopamine¹⁰; This may be the reason for improvement in negative emotions like krodha, shoka, bhaya, dvesha and moha etc; this improvement in negative emotions along with anticipation or expectancy effect of placebo¹⁰ might have caused improvement in positive emotions like harsha, preeti, dhairya, virya and shraddha. Sarasvata choorna was not proved better than placebo on both scales (IMHQOL and MPB) in GAD patients. These present ancillary findings are consistent with the results of the main study (trial drug ineffective).⁵

CONCLUSION

Sarasvata choorna was not better than placebo on IMHQOL and MPB (PE and NE) in GAD. The results were consistent with that of the main study.

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