

Effect of Six Months of Naturopathy Practice on Psychological Parameters in Hypothyroid Patients

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Abstract: In Hypothyroid patients effect of Naturopathy modalities i.e. massage, steam bath, neck and abdomen packs, was seen on quality of life [WHO-QOL-BREF (WHO quality of life Brief version)], depression [BDI-II (Beck Depression Inventory) and sleep quality [PSQI (Pittsburgh sleep quality index)] at baseline, three and six months. Quality of life for physical and psychological domain was statistically significant in Naturopathy group ($p \leq 0.001$) after 3 and 6 months. Depression score in both groups demonstrated significant, within group improvement ($p=0.003$ for group I and $p=0.000$ for group II at 6 months) and between group improvement in Naturopathy group as compared to control group after 6 months ($p=0.000$). At baseline, quality of sleep in control group was better as compared to naturopathy group ($p=0.000$) but after 6 months it improved significantly in Naturopathy group as compared to control group ($p=0.000$). In both groups $fT4$ increased ($p=0.001$ for control and $p=0.003$ for Naturopathy group) and TSH decreased ($p=0.000$). TSH levels in Naturopathy group were found to be within Physiological range. Naturopathy helps to manage sleep, depression and quality of life in a better way.

Keywords: Hypothyroidism, Naturopathy, WHO quality of life (WHO-QOL), Beck Depression Inventory (BDI-II), Pittsburgh sleep quality index (PSQI)

1. Introduction

Thyroid hormones play an important role in regulating the mood, cognitive functions. They are important for neurogenesis, myelination, dendrite proliferation and formation of synapses [1]. Despite appropriate standard T4 therapy, hypothyroid patients experience significant psychological morbidity. So there is a great need for additional activities which patients can carry out so as to manage the overall impact of hypothyroidism. In recent times Complementary and Alternative Medicine therapies as adjuncts to modern medicine have been increasingly used. A natural regime integrating Naturopathy with conventional treatment may present the best hope for preventing hypothyroid conditions and reversing normal health of patients.

Our approach was focussed on improving the quality of life, sleep and depression in hypothyroid patients by Naturopathy treatment. Till date such effects of Naturopathy in psychological symptoms of hypothyroid patients have not been studied

2. Material and Methods

The study was a randomized controlled trial carried out at the Babu Nature Cure Hospital and Yogashram, Delhi. Duration of the study was two years (March 2017-March 2019) and the study was conducted after due approval from the Ethical Committee of Babu Nature Cure Hospital and Yogashram. Biochemical investigations were carried out at GIPMER, Delhi.

Subjects and Study design: 100 hypothyroidism patients in the age group 21-65 years with TSH level >10 mIU/L and

satisfying the American Association of Clinical Endocrinologist (AACE) eligibility criteria were recruited. The patients were divided randomly into Groups of 50 each i.e. Group I (the control group) and Group II (Naturopathy group). Out of the 100 patients, 81 participants successfully completed the trial [41 in control (6 Male and 35 Female) and 40 in naturopathy group (4 Male and 36 Female)]. Patients were educated about the disease, associated risk factors and about the benefits of Naturopathy. Written consent was obtained from patients and they were provided a daily diary to record the compliance to the trial protocol and medicines. Complete clinical history, present and past medications were recorded for each patient at baseline.

Naturopathy interventions: Participants received 60 minutes sessions of Naturopathy treatment, thrice a week for first 2 months and twice in a week for next 4 months. The frequency of sessions was based on the earlier studies conducted at the Babu Nature Cure Hospital and Yogashram. Naturopathy sessions were scheduled between 6 AM to 5 PM and at least three hour gap was maintained between meal and treatment session. Massage was done with non aromatic sesame oil having anti inflammatory properties. Details of Naturopathy treatment are mentioned in Table 1.

Table 1: Naturopathy schedule for Group II hypothyroid patients

S.No.	Modality	Duration
1	Massage Legs - 8 min Hip -5 min Abdomen -7 min Neck -5 min	25 minutes
2	Steam Bath	10 minutes
3	Neck and Abdomen Pack	25 minutes
4	Total duration	60 minutes

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Doses of Thyroxine were modified as per patient requirement. Thyroid profile and psychological parameters were studied at baseline and after 3rd and 6th month.

Estimations

Thyroid profile: Thyroid function tests were performed using Roche CLIA-e411 analyzer.

Psychological Assessments: Pittsburgh Sleep Quality Index (PSQI) – A self report questionnaire was used to measure the quality and patterns of sleep. It differentiates sleep quality by measuring the seven areas (Table 2) over the last month [2]. The 7 components produce one Global Pittsburgh Sleep (GPS) quality score. Improvement in QOS was observed through reduction in PSQI score.

Table 2: Components for PSQI

Components for PSQI	Nomenclature (measured on 0-3 interval scale)
Com_1	Subjective sleep quality
Com_2	Sleep latency
Com_3	Sleep duration
Com_4	Habitual sleep efficiency
Com_5	Sleep disturbances
Com_6	Use of sleeping medication
Com_7	Daytime dysfunction
GPS score	Totalling the score of seven components i.e.0-21 (higher scores denote less sleep)

Beck Depression Inventory (BDI-II) - A 21 items self-report questionnaire was used to assesses depressive symptoms

Table 5: Effect of intervention therapy on BDI-II within control group (Group I) and Naturopathy group (Group II) group

	Group	Baseline	3rd Month	6th month	RM ANOVA	
		Mean±SD	Mean±SD	Mean±SD	F-stat	P-Value
BDI – II (No severity to 63 point severity)	I	12.93±7.85	10.07±9.52	8.70±7.53	7.60	0.001***
	II	15.27±7.19	6.87±6.89	3.55±5.51	83.03	0.000***

* p<0.05, ** p<0.01, *** p<0.001

So between group comparison of control and Naturopathy group was also done (Table 6) and it was observed that at baseline and at 3rd month there was no significant change in depression between control and Naturopathy group but after 6 months, group undergoing Naturopathy showed significant improvement (Lower scores denote less depression) as compared to control group(p=0.000)

Table 6: Effect of intervention therapy on BDI-II between control group (Group I) and Naturopathy group (Group II) group

	Group I	Group II	P value
(Baseline)	12.93 ± 7.85	15.27±7.19	0.166
BDI (3month)	10.07±9.52	6.87±6.89	0.087
BDI-II (6 month)	8.70±7.53	3.55±5.51	0.000***

* p<0.05, ** p<0.01, *** p<0.001

Table 7: Effect of intervention therapy on component wise sleep quality and Global PSQI score in control group (Group I) and Naturopathy group (Group II) group

	Baseline	3 rd Month	6 th Month	Baseline vs. 3 rd month		Baseline vs. 6 th month	
				Z-Stat	P-Value	Z-Stat	P-Value
Group I							
Com_1 Subjective sleep quality	1.39	1.10	0.98	1.75	0.080	2.23	0.026*
Com_2	1.54	1.39	1.32	0.66	0.504	0.88	0.382

experienced during the past two weeks [3]. BDI-II items were measured on scale 0 to 3 (higher scores denote more depression). The maximum score was 63.

WHO- Quality of Life-in brief (WHO-QOL-BREF) - was used for assessment of an individual's perception of QOL. It comprises of 26 items which are measured in the four broad domains (Table 3). The range of score is 4–20 for each domain [4]. Improvement in QOL was observed through improvement in the score.

Table 3: WHO-QOL-BREF Domains

WHO-QOL-BREF DOMAINS	Area for perception of QOL
DOMAIN-I	Physical health
DOMAIN-II	Psychological health
DOMAIN-III	Social relationships
DOMAIN-IV	Environment

Data processing and analysis: Data was expressed as mean ± standard deviation and analyzed by paired t-test (Student's t-test). P ≤ 0.05 was considered statistically significant. Data was analyzed using SPSS 16.0 software.

3. Results

Table 4 shows that at baseline there was no significant difference in depression (BDI-II) and quality of life (WHO-BREF) between two groups. But sleep quality (Global PSQI) score in Naturopathy group at baseline was significantly less as compared to control group (p=0.000).

Table 7 shows component wise Pittsburgh Sleep Quality Index for control and Naturopathy groups. Both groups demonstrated significant improvement in global PSQI (GPS) (p<0.001). Analysis of individual components showed significant improvement of component 1, 5 and 7 in both groups. Component 6 showed significant improvement only in Control group (p=0.014) and components 2, 3 and 4 showed improvement (P= 0.005, p= 0.013 and p= 0.002 for component 2, 3 and 4 respectively), only in Naturopathy group after 6 months

Sleep latency							
Com_3 Sleep duration	1.37	1.32	1.05	-0.05	0.964	1.68	0.093
Com_4 sleep efficiency	0.51	0.51	0.29	-0.48	0.633	1.02	0.306
Com_5 Sleep disturbances	1.32	1.10	0.90	0.98	0.326	2.05	0.041*
Com_6 Use of sleeping medication	0.61	0.27	0.20	1.46	0.145	2.45	0.014*
Com_7 Daytime dysfunction	0.80	0.24	0.29	3.68	0.001**	3.25	0.001***
GPS	7.54±0.58	5.93±0.57	5.02±0.53	2.07	0.039*	3.34	0.001***
Group II							
Com_1 Subjective sleep quality	1.28	0.90	0.88	2.44	0.015*	2.50	0.012**
Com_2 Sleep latency	1.53	1.03	0.90	2.40	0.016**	2.82	0.005**
Com_3 Sleep duration	1.28	0.98	0.78	1.59	0.111	2.48	0.013**
Com_4 sleep efficiency	0.88	0.28	0.25	2.96	0.003**	3.16	0.002**
Com_5 Sleep disturbances	1.43	0.95	0.95	3.09	0.002**	2.89	0.004**
Com_6 Use of sleeping medication	0.73	0.35	0.33	0.71	0.477	0.75	0.452
Com_7 Daytime dysfunction	0.98	0.40	0.43	3.30	0.001**	3.35	0.001**
GPS	8.08±0.66	4.88±0.48	4.50±0.50	3.78	0.001**	3.99	0.001**

* p<0.05, ** p<0.01, *** p<0.001

Table 8 shows that at baseline sleep was significantly less (p=0.000) in Naturopathy group as compared to control group but after 6 months it improved significantly (p=0.000) in Naturopathy group as compared to control group.

Table 9 shows that Social and environment behaviour significantly improved in both groups (p= 0.028 for control and p=0.000 for Naturopathy group) but physical and psychological parameters significantly improved (p=0.000) only in Naturopathy group.

Table 8: Effect of intervention therapy on PSQI between control group (Group I) and Naturopathy group (Group II) group

	Group I	Group II	P value
Baseline	7.54±0.58	8.08±0.66	0.000***
PSQI (3month)	5.93±0.57	4.88±0.48	0.27
PSQI (6 month)	5.02±0.53	4.50±0.50	0.000***

* p<0.05, ** p<0.01, *** p<0.001

Table 9: Effect of intervention therapy on quality of life (WHO-QOL-BREF) in control group (Group I) and Naturopathy group (Group II) group

Domain (4-20 score) higher scores denote higher QOL)	Group	Baseline	3 month	6 month	F- value	p- Value
DOMAIN-I (Physical health)	I	12.10±1.77	12.24±1.71	12.46±1.73	0.742	0.450
	II	12±2.08	13.33±2.26	13.58±1.52	9.52	0.000***
DOMAIN-II (Psychological health)	I	12.80±2.48	12.63±2.53	13.32±1.96	1.60	0.210
	II	12.65±2.35	14.55±2.15	15.53±2.10	28.30	0.000***
DOMAIN-III (Social relationships)	I	13.10±3.75	14.49±2.94	14.39±3.20	3.99	0.028*
	II	13.18±3.34	15.13±2.02	15.53±2.79	12.79	0.000***
DOMAIN-IV (Environment)	I	12.44±2.47	12.95±2.38	13.39±2.06	3.75	0.028*
	II	12.35±2.49	14.58±2.07	15.43±2.23	29.84	0.000***

* p<0.05, ** p<0.01, *** p<0.001

Tables 10 shows Pair wise mean effect between the test intervals using Bonferroni comparison for BDI-II and WHO-BREF in control (group I). Depression (BDI-II) improved significantly from baseline to 3rd month (p=0.029) and baseline to 6th months (p=0.003). Quality of life for

Domain III showed significant improvement between baseline and 3rd months only (p=0.025) and for domain IV significant improvement was observed between baseline and 6th months (p=0.035).

Table 10: Pair wise mean effect between the test interval using Bonferroni comparison in control group (Group I) for depression (BDI-II) and quality of life (WHO-BREF)

	Time Interval		Mean Difference	SE	P-Value	95% Confidence Interval for Difference	
						Lower Bound	Upper Bound
BDI-II	Baseline	3rd Month	2.85	1.050	0.029*	0.231	5.477
		6th Month	4.22	1.186	0.003**	1.257	7.182
	3rd Month		1.366	1.07	0.632	-1.316	4.048
WHO-BREF (Domain III)	Baseline	3rd Month	-1.390	0.496	0.025*	-2.63	-0.150
		6th Month	-1.293	0.649	0.160	-2.91	0.329
	3rd Month	6th Month	0.098	0.489	1.0	-1.120	1.316
WHO-BREF (Domain IV)	Baseline	3rd Month	-0.512	0.355	0.469	-1.398	0.347
		6th Month	-0.951	0.359	0.035 *	-1.849	-0.053
	3rd Month	6th Month	-0.439	0.328	0.564	-1.258	0.380

* p<0.05, ** p<0.01, *** p<0.001

For Naturopathy group, Pair wise mean effect between the test intervals using Bonferroni comparison for BDI-II and WHO-BREF showed that domain I to IV showed significant

increase after 6 months but domain II and IV showed increase from 0 to 3rd and 3rd to 6th month and domain III showed increase from 0 to 3rd month (Tables 11)

Table 11: Pair wise mean effect between the test interval using Bonferroni comparison in Naturopathy group (Group II) for BDI-II and WHO-BREF

	Time Interval		Mean Diff	SE	P-Value	95% Confidence Interval for Difference	
						Lower Bound	Upper Bound
BDI-II	Baseline	3rd Month	3.310	1.366	0.060	-1.0	6.71
		6th Month	8.405	1.310	0.000***	5.13	11.67
	3rd Month	6th Month	5.095	1.358	0.002**	1.70	8.48
WHO-BREF (Domain- I)	Baseline	3rd Month	-1.32	0.43	1.00	-2.405	-0.245
		6th Month	-1.57	0.36	0.000***	-2.497	-0.653
	3rd Month	6th Month	-0.25	0.35	1.00	-1.149	-0.649
WHO-BREF (Domain-II)	Baseline	3rd Month	-1.90	0.37	0.000***	-2.834	-0.966
		6th Month	-2.87	0.42	0.00**	-3.932	-0.818
	3rd Month	6th Month	-0.97	0.36	0.035*	-1.895	-0.55
WHO-BREF (Domain- III)	Baseline	3rd Month	-1.95	0.50	0.001***	-3.213	-0.687
		6th Month	-2.35	0.58	0.001***	-3.810	-0.890
	3rd Month	6th Month	-0.40	0.38	0.904	-1.356	0.556
WHO-BREF (Domain- IV)	Baseline	3rd Month	-2.22	0.41	0.000***	-3.268	-1.182
		6th Month	-3.07	0.48	0.000***	-4.275	-1.875
	3rd Month	6th Month	-0.85	0.32	0.035*	-1.654	-0.046

* p<0.05, ** p<0.01, *** p<0.001

Table 12 shows that both groups were matched for Thyroid function tests and there was no statistical significant difference at the beginning of the study.

Table 12: Baseline Thyroid Function Test of control group (Group I) and Naturopathy group (group II)

Parameters	Group I (Mean±SD)	Group II (Mean±SD)	P-Value
fT3 (pg/ml)	2.9±0.44	2.68±0.58	0.07
fT4 (ng/dl)	1.04±0.23	1.06±0.24	0.70
Serum TSH (uIU/ml)	14.53±9.58	17.16±9.28	0.21

* p<0.05, ** p<0.01, *** p<0.001

Table 13 shows that there was significant improvement in fT4 levels in both groups (P=0.001, P=0.003 in control and Naturopathy groups respectively). After intervention TSH concentration showed a significant reduction (p= 0.000) in both the groups. However only in the group given Naturopathy treatment, levels of TSH were found to be in normal physiological range.

Table 13: Comparison of changes in Thyroid function test in the control group (Group I) and Naturopathy group (Group II)

Parameters	Groups	Baseline	3 rd Month	6 th Month	RM ANOVA	
		Mean ± SD	Mean ±SD	Mean±SD	F-stat	P-Value
fT3 (pg/ml)	I	2.90±0.44	3.01±0.79	2.97±0.42	0.42	0.61
	II	2.68±0.58	2.82±0.50	2.84±0.42	1.81	1.72
fT4 (ng/dl)	I	1.04±0.23	1.18±0.24	1.19±0.25	7.48	0.001**
	II	1.06±0.24	1.16±0.22	1.24±0.24	7.40	0.003**
TSH (uIU/ml)	I	14.53±9.58	7.33±8.35	7.74±8.08	26.38	0.000***
	II	17.16±9.28	4.98±2.97	3.93±2.75	62.29	0.000***

*p<0.05, ** p<0.01, *** p<0.001

4. Discussion

In hypothyroid patients, in spite of replacement therapy, persistent complaints such as reduced health-related quality of life, reduced daily functioning are common [5]. Lifestyle measures can reduce stress and improve the way immune system functions and thus may help in easing the symptoms of hypothyroidism [6]. In this study we used Naturopathy for treating hypothyroidism and various psychological symptoms associated with the disease.

After intervention therapy, it was observed that in both groups levels of fT4 increased and TSH decreased. The decrease observed in TSH values in Naturopathy group was found to be within normal physiological range. As per the AACE recommendations, the effective treatment of Hypothyroidism is restoring the elevated serum TSH levels to the normal physiological range [7]. This shows that Naturopathy intervention, which included massage, steam bath, neck and abdomen packs along with Thyroxine replacement, was more effective in controlling hypothyroidism when compared to the control group patients having only Thyroxine replacement therapy. Different studies have shown that Naturopathy has effect on body metabolism. Naturopathy treatment Protocol has been found to have impact on central obesity [8]. Cold application capable of inducing shivering has shown to encourage production of adipokine Irisin which facilitates white adipose tissue to mimic functions similar to brown adipose tissue and enhance metabolism [9]. Though the exact effect of cold abdominal pack on adiposities is not so evident, it had marked effects on skin microcirculation, with a very large blood flow increase and vasomotor stimulation [10]. Steam bath induces perspiration in a natural way and significantly reduces the total body weight in high muscle mass male athletes [11]. Increased secretion of hormones like Noradrenaline, growth hormone and prolactin by the sauna bath has also been reported [12]. However Literature reports of Naturopathy on Hypothyroid patients is lacking.

Sleep disorders like sleep apnoea is a common symptom of hypothyroidism caused by poor cortisol balance [13]. Hypothyroid patients, at the time of enrolment in our study, were also found to have poor sleep quality. In patients with hypothyroidism, apnoea index does not decrease significantly even when euthyroidism is achieved by thyroxine [13]. In our study baseline mean global PSQI values in both Control and Naturopathy group were above the score of 5 which indicate poor sleep quality [14]. After intervention therapy participants demonstrated significant improvement in sleep quality (PSQI) in both the groups as compared to their own baseline values. Between group comparisons of control and Naturopathy group at baseline, showed that sleep was significantly less in Naturopathy group as compared to control group but after 6 months it improved significantly.

In both the groups, individual components of PSQI showed significant improvement in subjective sleep quality, sleep disturbances and daytime dysfunction. In Naturopathy group, improvement was observed in sleep latency, sleep duration and sleep efficiency. In control group, usage of sleeping medication was found to decrease significantly. The

reason for this may be that Global Pittsburgh Sleep quality index in Naturopathy group at baseline was significantly less as compared to control group ($p=0.000$). So Naturopathy group was more dependent on the sleep medication having value of 8.08 ± 0.66 vs 7.54 ± 0.58 value in control group ($p=0.000$). Steam bath was given for a period of 10 minutes. Heat of steam can make the body release endorphins, which are known as feel good hormones as it helps in reducing stress in the body. Massage has a normalizing effect on the sympathetic and the parasympathetic automatic nervous system (ANS), thereby reducing the false stress reflex. Breast cancer patients showed improvement in sleep quality among women after 4 weeks of massage therapy [15]. Accumulation of Lactic acid can result in muscular fatigue and/or cramps and people with hypothyroidism are more likely to produce lactic acid [16]. Massage and steam bath reduce fatigue by improving circulation thus decreasing lactic acid and causing muscles relaxation and improving sleep.

Disturbances in thyroid function frequently result in depression and cognitive dysfunction. Meta-analysis of seven studies showed TSH to be negatively correlated and total T4 to be positively related to a depressed mood [17]. Results of our study show that mean BDI-II scores in both groups at baseline were within the range of 11 – 16 score which according to the BDI-II interpretation is a mild mood disturbance [18]. In case of hypothyroidism there is decreased serotonin synthesis, which increases after T3 administration [19]. Results of our study show that BDI-II showed significant improvement from baseline levels in both the groups. After six months of Naturopathy, significant decrease was observed as compared to control group also. In Naturopathy group besides Thyroxine, the integrated approach of Naturopathy help in better control of function of Thyroid and Adrenal gland and in overall metabolism. With massage therapy reduction in the levels of anxiety and depression were earlier reported in older patients having acute coronary syndrome [20]. Significant improvement in depression and anxiety after massage therapy was reported in patients suffering from conditions of back, neck, shoulders, head and limbs [21].

Patients with untreated hypothyroidism have diminished quality of life [22]. In our study it was observed that Domain III and VI i.e. Social and environment behaviour significantly improved in control as well as Naturopathy group But Domain 1 and II i.e. Physical and psychological parameters significantly improved after 6 months and 3 months in group receiving Naturopathy and not in control group. Massage, an aid for well-being, is considered to be among the oldest of all treatments and has become an accepted part for many physical rehabilitation programs. It relieves muscular pain, relieves mental stress and tension, facilitates healing and relaxation and is also beneficial in many chronic conditions. It increases general circulation in the endocrine system and thus helps with the transport of hormones. Steam bath treatment has also been found to reduce pain and preserve muscle strength. The heat soothes nerve endings and relaxes muscles [23]. Proper massages and acupressure are used to rejuvenate the sluggish thyroid and adrenal glands. Bullen et al studied the effect of massage on Health-Related Quality of Life of haemodialysis

patients. Twenty minutes of massage session, once a weeks for eight weeks, improved overall quality of life [24].

Unlike Allopathy that solves just the symptoms of hypothyroidism by prescribing artificial hormones, naturopathy tries to address the root cause of the problem. Massage accelerates the passage into the gut and also accelerates the rate of absorption [25]. It is also possible that massage may improve the tone of large and small intestines and has a stimulating effect on the digestive organs, which helps improving digestion. Better absorption of ingested Thyroxine in the intestine after Naturopathy could have resulted in enhanced control of serum TSH levels in the Naturopathy group.

Our study is the only study of its kind where effects of naturopathy on psychological parameters have been studied on patients suffering from hypothyroidism. The study has reported therapeutic benefits of Naturopathy in Hypothyroid patients by way of improving sleep, quality of life and in reducing depression, not reported in any of the earlier studies.

5. Short Comings of the Study

To validate the effectiveness of Naturopathy, large scale RCT would be of enormous relevance to public health. Besides, it would also be relevant to study the effectiveness of individual Naturopathy modalities in controlling hypothyroidism.

6. Conclusion

Naturopathy as adjunct therapy was more effective in controlling quality of life, quality of sleep and depression score. So use of Naturopathy in daily life can help in preventing and treating thyroid gland dysfunction and in attaining better psychological health.

Declaration of interests: None.

Ethical approval -Ethical approval obtained from institutional ethics committee of BNCHY.

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Access to data by all the authors –Yes

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