

Evaluation of blood parameters concerning *mizaj* of dry cough patients before and after administration of *Sharbat-e-ejaz*, a polyherbal Unani formulation

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Sharbat-e-ejaz, a polyherbal Unani formulation, has been used to treat dry cough for a long time. According to the Unani system of medicine, various factors, including derangement of *mizaj* (temperament), can predispose individuals to disease. In this open-label clinical study, we evaluated, for the first time, blood parameters related to *mizaj* in dry cough patients before and after 2 weeks of administering *Sharbat-e-ejaz*. A total of 75 patients completed the study and were screened for *mizaj* (temperament) using the *Ajnas-e-ashariya* criteria. The majority of patients (n=27) had *Saudvi mizaj*, followed by *Safrawi mizaj* (n=26), *Bhulgami mizaj* (n=17), and the fewest (n=5) had *Damvi mizaj*. Blood parameter values remained within normal ranges before and after treatment in all patients, with no significant difference ($p>0.001$). When analyzing patients across different *mizaj* groups, no significant difference ($p>0.001$) in these parameters was observed before and after treatment. Blood parameters do not change with *mizaj* in patients with dry cough.

Keywords: Blood biochemistry, Dry cough, *Mizaj*, Unani medicine

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Cough is one of the important defense mechanisms of the human body which helps in clearing excessive secretions, foreign materials and infectious organisms from the airway¹. Cough can be broadly categorised into productive (wet) cough and non-productive (dry) cough, wherein dry cough is a common symptom in patients of upper respiratory tract infections. Distinguishing wet and dry cough types is important for evaluating respiratory health as well as monitoring disease progression². Dry cough is typically caused by irritation, airborne irritants, or due to oedema and mild post-illness secretion during the recovery phase of some diseases³. It may be benign and self-limiting, but sometimes it can be a warning sign of serious disease and may profoundly affect the patient's quality of life¹. Various pathologies can cause a dry cough, and appropriate treatment depends on identifying the specific cause and diagnosis. An enhanced cough reflex sensitivity can be observed in patients with a dry cough; thus, the measures to alleviate the cough symptoms are essential when it disrupt the patient's daily activities. The currently available treatment is anti-tussive preparations which are available as a combination of antihistamines, decongestants, and

expectorants. The cough suppressants may produce nausea, vomiting, constipation, decreased effectiveness (tolerance), pain relief, and the risk of physical dependence⁴. Moreover, the treatment offered by conventional medicine is efficacious yet often fall short of expectations and comes with excessive cost.

Consequently, an integrative approach across various forms of medicine, specifically the Unani system of medicine, a type of traditional medicine, could be highly beneficial. This system of medicine has a rich treasure of therapeutically active products and extensive patient-beneficial clinical experience on many diseases, including dry cough. Various physicians of Unani medicine have described the dry cough as *Surfa Yaabis* which is mentioned in the Unani classical literature. In Unani medicine, both *Surfa* and *Suāl*, are Arabic terms used to refer to cough, and in Hindi, the word for cough is *Khansi*⁵. *Majūsī*, in his book *Kāmil al-Sanā'a*, has described the *Surfa Yābis* as a type of cough wherein phlegm is not coughed up. *Surfa Yābis* or dry cough is arbitrarily defined as a non-productive cough with no expectoration. Its risk factors can be external, like dust, smoke, fumes, and cold air, and internal, such as imbalance/derangement of temperament⁵⁻⁷. The temperament or *mizaj* is regarded as one of the most important principles in the

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Unani system of medicine. Temperament describes an individual's unique constitutional makeup, encompassing physical aspects and disease susceptibility. The temperament of the human body is determined by the humors or a bodily fluid which consists of a combination of elements⁸. Human beings have been categorized into four qualitative types based on *Mizaj* as *Damwi* (Sanguineous), *Safravi* (bilious), *Balghami* (phlegmatic), and *Saudawi* (melancholic).

The present open-label clinical study was conducted primarily to assess the safety and efficacy of a Unani formulation, *Sharbat-e-ejaz*, in patients with dry cough, and part of it was published recently⁹. However, in the present paper, kidney and liver functions and hematological parameters were assessed and evaluated concerning the *mizaj* of dry cough patients. To our best knowledge, this is the first study wherein the evaluation of given blood parameters concerning the *mizaj* of dry cough patients was done before and after administration of *Sharbat-e-ejaz*.

Methodology

Study design, inclusion, and exclusion criteria

This was an open-label quasi-controlled clinical trial with a 2-week treatment. The study was approved by the institutional ethical committee (IEC) of the Regional Research Institute of Unani Medicine Srinagar vide no. RRIUM/KU/2013-14/Tech/IEC dated 17.3.2014.120. Patients with dry cough attending the OPD of RRIUM, Srinagar from July 2014 to July 2015 were screened and only 93 patients were found eligible and enrolled in the study. Patients were enrolled only after obtaining their written informed consent. Patients of both genders with a history of dry cough of less than 3 weeks duration in

the age group of 18 years to 60 years were included in the study. Patients suffering from Lower Respiratory Tract Infections including pneumonia, lung abscess, and acute bronchitis were excluded so were chronic obstructive airway diseases (COAD) like bronchiectasis, pulmonary tuberculosis, pulmonary oedema, interstitial pulmonary fibrosis, tumors of larynx, bronchi, and lungs. Smokers and patients with Drug-induced Cough (e.g., ACE Inhibitors) were also excluded.

Mizaj assessment

The patients with dry cough enrolled in the study had their *mizaj* (temperament) determined using a standard proforma, which was based on the *Alamat Ajnase Ashra* (10 determinants) as given in (Table 1)¹⁰. Subsequently, based on this proforma, a particular *Mizaj* as *Damvi* (Sanguine temperament), *Balghami* (Phlegmatic temperament), *Safravi* (Choleratic temperament) and *Saudavi* (Melancholic temperament) was assigned to the patient.

Intervention

A trial drug *viz.*, Unani pharmacopoeial formulation *Sharbat-e-jaz* was given to the patient orally at 20 mL diluted in 40 mL of lukewarm water twice a day for 2 weeks. The constituents of the *Sharbat-e-ejaz* are given in (Table 2)¹¹. The patients were assessed every week clinically and the collection of blood samples for laboratory investigations was obtained twice *i.e.*, before (at the baseline) and after the end of the trial (after 2 weeks). The observations were recorded in a separate follow-up sheet.

Outcome measurement

The primary outcome measure for this study was the assessment of hematological profile, and liver and

Table 1 — Proforma for the assessment of *Mizaj* (Temperament) according to *Ajnas-e-ashra*

Parameter	<i>DAMWĪ</i> (Sanguine)	<i>BALGHAMĪ</i> (Phlegmatic)	<i>SAFRĀWĪ</i> (Bilious)	<i>SAWDĀWĪ</i> (Melancholic)
Complexion	Ruddy (Reddish/ Wheatish brown)	Chalky (Whitish)	Pale (Yellowish)	Purple (Blackish)
Built	Muscular & Broad	Fatty & Broad	Muscular & Thin	Skeleton
Touch	Hot & Soft	Cold & Soft	Hot & Dry	Cold & Dry
Hair	Black & Lustrous Thick, Rapid Growth	Black & Thin Slow Growth	Brown & Thin Rapid Growth	Brown & Thin Slow Growth
Movement	Active	Dull	Hyperactive	Less Active
Diet (Most liked)	Cold & Dry	Hot & Dry	Cold & Moist	Hot & Moist
Weather (Most suitable)	Spring	Summer	Winter	Autumn
Sleep	Normal (6-8 h)	In excess	Inadequate	Insomnia
Pulse	Normal in rate (70-80/min) large in volume	Slow in rate (60-70 min) normal in volume	Rapid in rate (80-100/min) normal in volume	Slow in rate (60-70/min) less in volume
Emotions	Normal	Calm & Quiet	Angry	Nervous

Note: The maximum number of ticks in a particular column denotes the dominant temperament

kidney functions concerning the *mizaj* of patients. For hematological and biochemical assessment, a fasting blood sample (8.0 mL) was taken from each participant twice, at baseline and the end of the treatment. Whole blood was used for the determination of hemoglobin (Hb), total leucocyte count (TLC), and absolute eosinophil count (AEC) on a Hematology analyzer (Sinduri make, India); erythro sedimentation rate (ESR) was done by standard Westergren method; whereas, isolated serum was utilized for the assessment of the markers of liver function (serum glutamate pyruvate transaminase [GPT], glutamate oxaloacetate transaminase [GOT], and alkaline phosphatase [ALP] activities, Bilirubin), renal function (urea and creatinine and uric acid), at

baseline and the end of the treatment using readymade kits of ERBA make on clinical chemistry analyzer (EM200, ERBA Germany) according to the manufacturer's specifications. The cough severity was assessed and recorded using a cough visual analog scale (VAS). The cough VAS is a vertically marked 10-point (0-9) linear scale that is responsive to changes in cough severity¹². Any adverse event in clinical parameters during treatment was documented.

Statistical analyses

The data was analyzed by using the software SPSS Statistics 17.0. Values were presented as mean \pm SD and results were analyzed by students paired t-test.

Results

A total of 120 patients were screened for dry cough, only 93 were registered in the study and 27 patients were excluded for not fulfilling the inclusion criteria. The qualified participants started the trial whereas only 75 completed the 2-weeks intervention and follow-up investigations. Patients were also screened for the *mizaj* (temperament) as per the *Ajnas-e-ashariya* criteria of the Unani system of medicine (Given in Methodology) and patients were subsequently placed under the given group concerning their temperament of *Damvi*, *Bhulgami*, *Safrawi*, and *Saudavi*, respectively. The 75 completed patients were of different *mizaj* (Fig. 1). The maximum number of patients (n=27) were of *Saudvi*

Table 2 — Constituents of the *Sharbat-e-ejaz*, a polyherbal Unani formulation

S. No.	Ingredients	Botanical/ Chemical Name	Quantity
1.	Barg-e-Arusa	<i>Adhatoda vasica</i>	500 g
2.	Unnab	<i>Zyzifus sativa</i>	50 g
3.	Sapistan	<i>Cordia latifolia</i>	50 g
4.	Asl-us-Soos	<i>Glycyrrhiza glabra</i>	25 g
5.	Tukhm-e-Khatmi	<i>Althaea officinalis</i>	25 g
6.	Tukhm-e-Khubazi	<i>Malva sylvestris</i>	25 g
7.	Gul-e-Neelofar	<i>Nymphaea alba</i>	25 g
8.	Gul-e-Banafsha	<i>Viola odorata</i>	25 g
9.	Behidana	<i>Cydonia oblonga</i>	20 g
10.	Kateera	<i>Astragalus gummifer</i>	10 g
11.	Samag-e-Arabi	<i>Acacia arabica</i>	10 g
12.	Qand Safaid	<i>Saccharaum officinale</i>	1 kg
13.	Aab	<i>Oxidane (Water)</i>	Q.S.

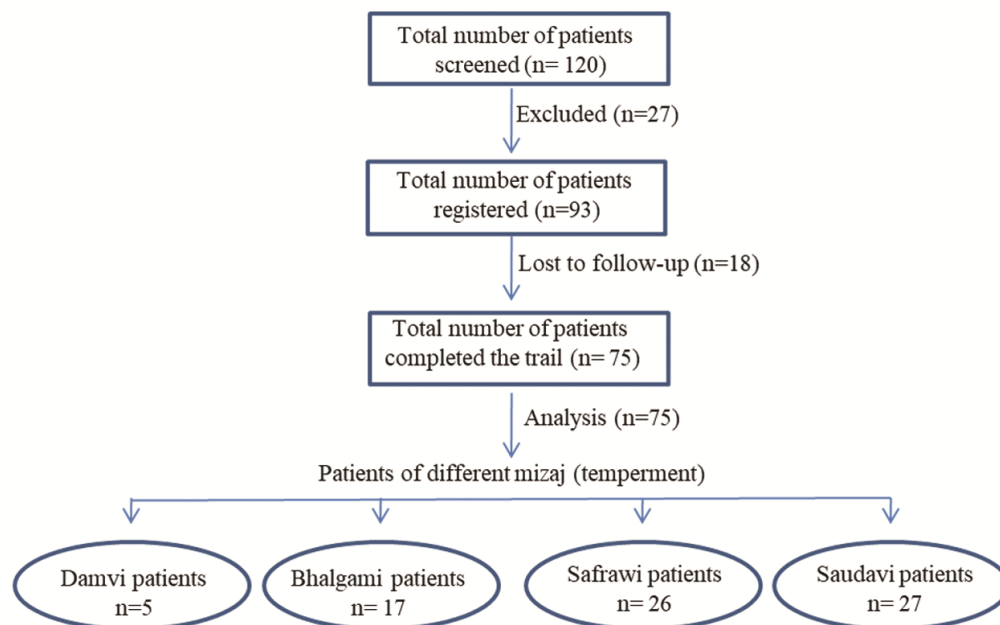


Fig. 1 — The flowchart of participants through the trial

mizaj followed by *Safrawi mizaj* (n=26) and *Bhalmami mizaj* (n=17) with the least of *Damvi mizaj* (n=5).

The characteristics *i.e.*, age and gender of all patients as well as of different *mizaj* (temperament) at the start of the trial baseline given in Table 3.

As a part of safety evaluation, the serum levels of GOT, GPT, ALP, and Bilirubin representing liver function were evaluated before and after 2 weeks of PHUF treatment. Further, urea, creatinine, and uric acid representing kidney function were evaluated before and after 2 weeks of PHUF treatment. The values of liver and kidney function markers remained well within the normal range before and after 2 weeks of treatment in all patients with no statistically

significant difference (p<0.001). While analyzing the patients under different *mizaj* groups, no statistically significant difference (p<0.001) was observed in LFT and KFT before and after treatment concerning *mizaj* (Table 4).

The hematological profile of patients as analyzed by evaluating hemoglobin, leucocyte count, eosinophyl sedimentation rate, and absolute eosinophyl count is given in Table 5. The values of the hematological markers remained well within the normal range before and after 2 weeks of treatment in all patients with no statistically significant difference (p<0.001). While analyzing the patients under different *mizaj* groups, no statistically significant difference (p<0.001) in

Table 3 — Characteristics of dry cough patients of different *mizaj* (Temperament)

Characteristic	Patients of all Mizaj (n=75)	Damvi patients (n = 5)	Bhalmami patients (n = 17)	Safrawi patients (n = 26)	Saudavi patients (n = 27)
Age (Years)	39.92±12.32 (19 to 62)	46.60±12.36 (35 to 60)	44.47±11.08 (24 to 62)	44.47±11.08 (24 to 62)	36.81±12.47 (21 to 60)
Gender	43 Female 32 Male	3 Female 2 Male	6 Female 11 Male	14 Female 12 Male	20 Female 7 Male

Values are means ± SD (range).

Table 4 — Liver and Renal function parameters before and after treatment of dry cough patients of different *mizaj* (temperament)

Parameters	Treatment	All Mizaj patients (n=75)	Damvi patients (n = 5)	Bhalmami patients (n = 17)	Safrawi patients (n = 26)	Saudavi patients (n = 27)
AST (SGOT)	Before	24.95±6.68	22.4±2.36	25.99±6.88	26.50±6.55	23.27±6.96
	After	24.29±6.11	21.26±4.44	27.04±6.37	23.65±7.05	23.74± 4.79
ALT (SGPT)	Before	27.15±10.31	24.34±3.80	29.18±11.81	27.53±10.74	26.03±9.89
	After	24.45±9.38	19.64±4.77	28.88±11.57	24.80±10.18	22.23±6.50
ALP	Before	71.12±19.17	78.28±30.19	70.27±14.30	71.44±15.27	69.98±23.19
	After	72.69±19.52	71.74±22.63	72.34±11.26	71.08±19.59	74.63±23.50
Bilirubin	Before	0.80±0.66	0.66±0.19	0.68±0.20	0.76±0.23	0.74±0.31
	After	0.68±0.18	0.68±0.13	0.66±0.15	0.66±0.13	0.72±0.25
Urea	Before	28.04±6.37	30.18±2.69	27.66±6.52	27.85±6.03	28.08±7.23
	After	29.10±9.74	29.22±3.55	32.72±11.16	29.67±12.01	26.25±5.95
Creatinine	Before	0.80±0.12	0.80±0.07	0.79±0.13	0.80±0.08	0.81±0.15
	After	0.84±0.17	0.84±0.17	0.86±0.22	0.85±0.17	0.80±0.12
Uric acid	Before	4.70±1.09	5.34±1.32	4.79±1.01	4.56±1.01	4.66±1.18
	After	4.87±1.38	6.34±1.52	5.01±0.98	4.82±1.41	4.57±1.43

Values are means ± SD; PHUF: poly herbal Unani formulation, AST: Aspartate aminotransferase, ALT: Alanine aminotransferase ALP: Alkaline Phosphatase. No statistically significant difference (p>0.001) was analyzed before and after treatment in all groups

Table 5 — Hematological parameters before and after treatment of dry cough patients of different *mizaj* (temperament)

Parameters	Treatment	All Mizaj patients (n=75)	Damvi patients (n = 5)	Bhalmami patients (n = 17)	Safrawi patients (n = 26)	Saudavi patients (n = 27)
Haemoglobin (g %)	Before	11.11±1.16	11.1±1.08	9.12±0.99	11.01±1.45	10.90±0.97
	After	11.05±1.20	10.5±1.90	11.65±0.88	10.85±1.41	10.97±0.90
T.L.C. (10 ³ /mm ³)	Before	7707±1328	7500±790	7911±1494	7951±1352	7418±1275
	After	7657±1360	7800±1151	7247±1223	7907±1524	7648±1316
ESR (1 st h)	Before	15.61±14.90	13.8±15.32	14.12±14.03	13.27±11.49	19.15±18.09
	After	12.40±10.74	12.8±15.25	10.76±9.66	13.04±12.60	12.74±8.95
AEC	Before	173.76±58.09	180.00±44.72	183.12±62.11	168.24±54.86	171.81±62.59
	After	168.87±56.66	204.00±59.10	157.24±53.44	162.88±62.70	175.44±51.52

Values are means ± SD; PHUF: poly herbal Unani formulation, TLC: Total Leucocyte count, ESR: Eosinophyll sedimentation rate, AEC: Absolute eosinophyll count. No statistically significant difference (p>0.001) was analyzed before and after treatment in all groups

hematological profile was noted before and after treatment concerning *mizaj* as given in Table 5.

Further, the patients showed a significant decrease ($p < 0.05$) in the frequency and severity of cough on VAS after 2 weeks of treatment in all *mizaj* groups as given in Table 6.

Discussion

Chronic cough is a common problem that directly impacts the quality of life and decreases productivity globally Kubo *et al.*¹³. The traditional medicine has been used to treat chronic cough since thousands of years Lee *et al.*¹⁴. The increasing demand for safe and effective alternative drugs for the treatment of dry cough can be addressed by identifying promising formulations from alternative and complementary forms of medicine including the Unani system of medicine. One of the potent Unani pharmacopeial poly herbal formulations, *Sharbat ejaz* has been prescribed for a long time by Unani physicians for *Surfa Yabis i.e.*, dry cough¹¹. We have recently published the part of the present study wherein, *Sharbat ejaz* was found effective in the management of dry cough with no side effects⁹. Clinically the patients show a decrease in the frequency and severity of cough after 2 weeks of treatment. These actions could be due to the diverse pharmacological action of the ingredients of the test drug. One of the main ingredients of *Sharbat ejaz* is *Barg-e-Arusa (Adhatoda vasica L.)*, which has been traditionally used to treat respiratory disorders. Further, the primary alkaloid of *Adhatoda i.e.*, vasicine and vasicone are well established as therapeutically respiratory agents with anti-allergic activity^{15,16}. Further the other constituents of the *Sharbat ejaz* have proved to be very effective in cough management by reducing allergic reactions, reducing inflammation of the respiratory tract, etc. and the same has been discussed earlier⁹.

This study is the first of its kind wherein, the given blood parameters were evaluated in dry cough patients concerning their *mizaj*. Out of 75 dry cough patients, we found a maximum number of patients

with *Saudavi* and *Safrawi mizaj* comprising 70% of patients and the least with *Balghami* and *Damvi mizaj* comprising 30% patients. A good concordance was found between the *mizaj* of patients and the disease. The dry cough being dry and as per the Unani principles occurs mostly in persons with dry temperament *i.e.*, *saudavi* and *safrawi*, and is caused by derangement of temperament (*Sui mizaj*) either *sui mizaj harsada* (hot & dry) or *sui mizaj baridsada* (cold & dry). Further, our results have resemblance with the description of the eminent Unani physicians as they have mentioned in the classical literature that an individual is more prone to develop such diseases having the same temperament as that of self¹⁷⁻²⁰, whereas, the patients who don't show concordance with the *mizaj*, may be due to various factors like age, weather, and regimens habitat^{17,18}. One of the important factors that may affect the correct evaluation of *mizaj* may be the patient as well as the observer; the same has also been felt essential by others¹⁰. Moreover, in the Unani system of medicine, the determination of *mizaj* depends on whether the trait is innate (*jibli/congenital*) or acquired (*iktisabi* or disease-related). Dry cough is generally linked with *yabusat* (dryness) which points towards a hot dry (*Harr yabis*) or cold dry (*Barid yabis*). The participants of the present study have no previous history of dryness, and it appeared that the same is due to their illness and the *mizaj* can most likely be regarded as *iktisabi* (acquired). The Unani physicians have also explained that the dry cough indicates a dry *mizaj* of lungs, which may be *iktisabi* due to disease²⁰.

We evaluated the liver and renal function and other blood parameters of all dry cough patients and compared these parameters with *mizaj*. There was no significant difference in these parameters in all *mizaj* groups of dry cough patients and the values were well within the normal reference range. Further to monitor the safety in terms of liver function, renal function, and other hematological parameters of the *sharbat ejaz*, there were not any significant differences in given parameters after administration of the drug in all *mizaj* groups. The present study revealed that

Table 6 — Visual analog scale values before and after treatment of dry cough patients of different *mizaj* (temperament)

Parameters	Treatment	All Mizaj patients (n=75)	Damvi patients (n = 5)	Bhalgami patients (n = 17)	Safrawi patients (n = 26)	Saudavi patients (n = 27)
Visual analog scale (VAS) values	Before	8.66±1.24	7.60±0.89	9.12±0.99	8.73±1.34	8.52±1.25
	After	1.96±1.78	3.00±2.74	2.25±1.98	2.00±1.57	1.56±1.67

Values are means ± SD; PHUF: poly herbal Unani formulation. No statistically significant difference ($p > 0.05$) was analyzed before and after treatment in all groups

sharbat ejaz did not negatively impact the liver function or renal function and there was not any impact on other haematological parameters of the dry cough patients.

The most important finding in the present study is that there is no significant change in the blood parameters in patients with dry cough concerning their *mizaj*. Although no specific reason can be put forward as the study being preliminary in nature, however, it may be discussed that the *mizaj* is primarily based on qualitative attributes which manifests in physical, psychological and behavioural traits of a person, whereas, laboratory parameters are reductionist and numeric, focusing on measurable entities. Moreover, *mizaj* represents a holistic, constitutional and qualitative state while blood parameters capture quantitative biochemical change and due to different diagnostic paradigms, correlation is not always one-to-one. Subsequently, there was no significant difference in these parameters even after the administration of Unani formulation, *Sharbat-e-ejaz*. This is the first study to our knowledge and its outcome will also help to determine the safety and tolerability of *Sharbat ejaz* at a given dose. Further, *mizaj* does not affect given hematological parameters of dry cough patients. The study encountered limitations related to the small sample size, especially the number of patients in the *Damvi Mizaj* group, as we could not find patients with dry cough in this *mizaj* group, which is in tune with the concept of *mizaj* in the Unani system of medicine²¹.

Conclusion

It can be concluded that the parameters representing liver function, renal function, and other hematological parameters do not change with *mizaj* in patients with dry cough, possibly because a person's holistic nature is captured by *mizaj*, whereas blood parameters capture reductionistic, measurable entities. Moreover, the administration of Unani formulation *Sharbat-e-ejaz*, does not have any effect on the given blood parameters in all *mizaj* groups of dry cough patients, and the values are well within the normal biological reference range. The study with a large sample size and on different groups of populations is warranted for better conclusive results.

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Conflict of Interest

Authors declare that there is no conflict of interest.

Author Contributions

TAR: Conceptualize and lab investigations; Huma; Clinical investigation; SR: Clinical data collection; SA: Supervision, & IA: Supervision.

Ethics Statement

The study was approved by the Institutional Ethics Committee (IEC) of the Regional Research Institute of Unani Medicine, Srinagar, vide no. RRIUM/KU/2013-14/Tech/IEC dated 17.3.2014.

Informed Consent

Informed consent was taken from all the participants. The authors certify that they have obtained all appropriate patient consent forms and that due efforts have been made to conceal their identity for publication of results.

Data Availability

As per the policy of the journal.

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