

## Original Research Article

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# A study of clinical validation of Unani Pharmacopoeial formulation Habb-e-Hilteet in Zu‘f al-Ishtihā’ (anorexia)"at RRIUM, New Delhi: an open prospective clinical trial

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## ABSTRACT

**Background:** Anorexia is a serious condition, especially in older adults, often leading to malnutrition, weight loss, and other severe health problems. *Habb-e-Hilteet* is a commonly prescribed Unani pharmacopoeial formulation for anorexia. However, no scientific data are available regarding its safety and efficacy. This study assessed the appetite-inducing effect and safety of *Habb-e-Hilteet* in *Zu‘f al-Ishtihā’* (anorexia) patients.

**Methods:** An open prospective clinical trial was conducted in 82 clinically diagnosed anorexia patients of either gender (19-65 yrs old). The study was approved by the institutional ethics committee. *Habb-e-Hilteet*, one pill (500 mg), was administered orally to patients twice daily for 14 days. The safety of the formulation was assessed using important pathological and biochemical indices and by monitoring adverse events. Efficacy was assessed based on improvement in the Simplified Nutritional Appetite Questionnaire (SNAQ) score.

**Results:** There were 82 participants enrolled in this study. The mean age of the study population was found to be  $31.96 \pm 11.66$  years of male, and  $31.67 \pm 10.81$  years of female with a higher rate (69.5%) of occurrence in women. In relation to the Temperament of the Patients, our study found the most effective results in the categories of *Damvi* (SANGUINE) in 56% of the patients. Our study found a significant correlation ( $P < 0.000$ ) between the effects of drugs on clinical parameters.

**Conclusions:** The findings of the study suggest that *Habb-e-Hilteet* may be a safe and effective treatment for anorexia.

**Keywords:** Anorexia, CCRUM, *Habb-e-Hilteet*; Unani pharmacopoeal formulation

## INTRODUCTION

Anorexia nervosa is an eating disorder characterized by immoderate food restriction and irrational fear of gaining weight, as well as a distorted body self-perception. It typically involves excessive weight loss and usually occurs more in females than in males. Because of the fear of gaining weight, people with this disorder restrict the amount of food they consume. This restriction of food intake causes metabolic and hormonal disorders. Outside

of medical literature, the terms anorexia nervosa and anorexia are often used interchangeably; however, anorexia is simply a medical term for lack of appetite, and people with anorexia nervosa do not, in fact, lose their appetites. A BMI less than  $17.5 \text{ kg/m}^2$  in adults is one of the common physical features in diagnosing anorexia. Low BMI or body weight is just one physical feature for anorexia. Not all low BMI or body weight is related to anorexia.<sup>1,2</sup>

*Zu'f al-Ishtihā'* (anorexia) is a condition described in Unani Classical literature as *Nuqsān al-ShahwatwaButlān al-Shahwat*. *Shahwat* is an Arabic word meaning appetite. *Nuqsān* means decrease whereas *Butlān* means complete loss. It is a condition where the appetite of the person is decreased or lost. *Zu'f al-Ishtihā'* is another word for this condition where *Zu'f* means weakness and *Ishtihā'* means appetite.<sup>3,4</sup> According to the Unani literature the different causes of *Zu'f al-Ishtihā'* e.g., *Su'-i-Mizāj Hārr* (Impaired Hot Temperament): In this condition cardiac end of the stomach (*Fam-i-Mi'da*) becomes week (Loss of contractile power). *Su'-i-Mizāj Bārid* (Impaired Cold Temperament): causes the *Jū'al-Kalb* (Canine Appetite). Accumulation of *Safrā* and *BalghamMālih* (Saline Phlegm). Accumulation of *BalghamLazij* (Viscid Phlegm). Accumulation of *BalghamMuntin* (Mephitic Phlegm). Accumulation of *BalghamKhām* (Raw Phlegm) and *KhāmAkhlāt* (Raw Humours). *Zu'f al-Mi'da* (Weakness of stomach): In this condition the patient feels restless after having meals leading to Anorexia along with belching and nausea. *Zu'f al-Kabid* (Hepatic Insufficiency): In this condition all the four faculties of liver, i.e., *QuwwatHāzima* (Digestive power), *QuwwatMāsika* (Assimilative power), *QuwwatJāziba* (Absorptive power) and *QuwwatDāfi'a* (Expulsive power) or some of these faculties become weak leading to Anorexia. *Sudad al-Kabid* (Obstruction of Liver). These factors lead to the accumulation of viscous humours in the liver which in turn causes the inflammation of liver henceforth the obstruction of liver. As a result of this, patient feels heaviness at the site of liver and anorexia. Loss of sensory response of pylorus: Sensory nerve of pyloric end of the stomach becomes non-responsive resulting in Anorexia.<sup>3,5,6</sup> *Habb-e-Hilteet* are well known spices and food additives which are highly acclaimed in Unani medicine for their medicinal values including digestive and appetizing properties we used this drug with the aims and objectives to evaluate the safety and efficacy of a Unani Pharmacopoeial formulation-*Habb-e-Hilteet* in patients of *Zu'f al-Ishtihā'* (anorexia).

## METHODS

An open prospective clinical trial was carried out to assess the safety and efficacy of the Unani Pharmacopoeial formulation '*Habb-e-Hilteet*' in patients with anorexia at the Regional Research Institute of Unani Medicine (RRIUM), New Delhi, in the OPD setting. Ethical approval was obtained from the Institutional Ethics Committee, RRIUM, New Delhi. Each participant will be well informed about the study and provided a participant information sheet (PIS), and written informed consent will be obtained before the initiation of any study-related procedure. Demographic data and information regarding the present disease condition, concomitant disease, and therapy were recorded. Thorough general physical and systemic clinical examinations were performed. Signs and symptoms pertaining to *Zu'f al-Ishtihā'* (anorexia) will be recorded in CRF. Vital signs, including blood pressure, heart rate,

temperature, and respiratory rate, were noted. Blood samples will be collected for the evaluation of laboratory parameters, including hemogram, LFTs, KFTs, and fasting blood glucose, to establish and confirm the Inclusion and Exclusion criteria. Follow-up of clinical parameters will be performed once a week during treatment. Post-treatment follow-up will be conducted monthly for two months.

### Study design

An open-label, multi-centric clinical study will be conducted.

### Overview of the study design

This study is designed as an open-label, multi-centric clinical trial in patients with *Zu'f al-Ishtihā'* (Anorexia). The patients will be subjected to screening. After screening, patients suitable for participation in the study will receive Unani pharmacopoeial formulation *Habb-e-Hilteet* pill twice daily with water one hour after meals. The total duration of treatment will be 2 weeks. Clinical follow-up will be done once in a week. The laboratory investigations will be conducted at baseline and end of treatment (2 weeks) as per the CRF.

### Duration of study

The required number of study subjects will be attainable in the institute's OPD in two years between 01 January 2016 to 01 January 2018.

### Study site(s)

This clinical research will be conducted at the following Centers: Regional Research Institute of Unani Medicine (RRIUM), New Delhi, Regional Research Institute of Unani Medicine (RRIUM), Patna, Regional Research Institute of Unani Medicine (RRIUM), Chennai, and Clinical Research Unit (CRU), Bengaluru.

### Selection criteria

The patients of *Zu'f al-Ishtihā'* (Anorexia) attending the OPD of respective centres will be selected for the study. A detailed clinical history will be taken and complete physical examination will be carried out to make the clinical diagnosis of *Zu'f al-Ishtihā'* (Anorexia). Patients will be considered eligible for enrolment into this study if they fulfill all of the inclusion criteria and none of the exclusion criteria, as defined below:

### Inclusion criteria

Patients of any sex in the age group 19-65 years and patients having *Zu'f al-Ishtihā'* (anorexia) were included.

### Exclusion criteria

Patients having anorexia nervosa, patients having any systemic disease, chronic debilitating disease, T.B., diabetes mellitus etc., known cases of hepatic, renal or cardiac ailments, history of hypersensitivity to study drug or any of its ingredients, history of addiction (alcohol, drugs), pregnant and lactating women were excluded.

### Sample size

82 completed cases with *Zu'f al-Ishtihā'* (Anorexia). This sample size will be distributed equally among the participating centers. However, there is no restriction on the maximum number of participants to be recruited by each centre. A centre can recruit more than its expected share; the study will be terminated once the target is achieved.

### Duration of protocol therapy

The total duration of treatment will be 2 weeks.

### Study drug details and mode of intervention

The study drug, *Habb-e-Hilteet*, which contains four ingredients-Zanzabeel (Zingiber officianale Roscoe), *Hilteet* (Ferula foetida Regel), *Tankar* (borax), and *Namak-e-Sang* (rock salt) 15-was made available to the study site in a single batch at the Council's GMP-certified drug manufacturing unit at the National Research Institute of Unani Medicine for Skin Disorders (NRIUMSD), Hyderabad. All research medicines were maintained at room temperature and in a safe location with suitable storage conditions, including protection from moisture. One week at a time, the study participants received medication prescriptions with instructions to return any unused medication at the following appointment. This process was repeated throughout the study. One pack of *Habb-e-Hilteet* (14 pills of 500 mg each) was distributed in sealed plastic containers as part of each week's medication supply. As the trial lasted 14 days, each patient received a total of 28 tablets. Patients were instructed to take one tablet of water twice an hour after eating. Committed during this trial. Following seven and 14 days of treatment, patients underwent clinical evaluation. A Case Record Form was used to document objective and subjective clinical observations.

### Assessment of efficacy and safety

The Simplified Nutritional Appetite Questionnaire (SNAQ) was used to measure the improvement in appetite, which was used to determine the drug's efficacy. The SNAQ, a four-item single-domain questionnaire, was administered to each patient. A 5-point Likert-type scale with verbal labeling (A to E) was used to score the responses. The sum of the item scores determines the overall SNAQ score, with lower scores signifying a decline in appetite. The worst possible SNAQ score was 4 and the best possible score was 20. People with anorexia who have an SNAQ score of less than 14 may be at a considerable risk of losing at least 5% of their body weight within six months. Based on the increase in the SNAQ score, the study results were expressed as percentage efficacy. Drug safety was evaluated by documenting adverse events and pertinent pathological and biochemical indicators, including blood urea nitrogen (BUN), serum bilirubin, serum glutamic-oxaloacetic transaminase (SGOT/AST), serum glutamic-pyruvic transaminase (SGPT/ALT), alkaline phosphatase (ALP), serum creatinine, and hemoglobin. After 14 days of treatment, the results of these laboratory tests were compared to those obtained at baseline.

### Statistical analysis

After completion of the study, data obtained will be analyzed statistically to evaluate the significance of results. The discrete variables were expressed as frequency (percentage) and continuous variables were expressed as mean with standard deviation (Mean SD). To assess the mean SNAQ score changes and the mean difference in pathological and biochemical indices between the baselines and last follow up of treatment, paired t-test was used. All tests are two tailed and the P-value  $\leq 0.05$  and  $> 0.05$  between baseline and last follow-up.

## RESULTS

In the current study, a total number of 82 participants were enrolled, of which 25 participants were male and 57 participants were female completed the trial. Table 1 illustrates the demographic profile of participants with anorexia in the present study. The mean age of the study population was found to be  $31.96 \pm 11.66$  years of male, and  $31.67 \pm 10.81$  years of female with a higher rate (69.5%) of occurrence in women.

**Table 1: Age-wise distribution of the patients.**

Age group (years)	Sex		Total	Percentage (%)
	Male	Female		
<b>19-29</b>	13	25	38	46.3
<b>30-39</b>	5	13	18	22.0
<b>40-49</b>	4	17	21	25.6
<b>50-59</b>	2	2	4	4.9
<b>60 and above</b>	1	0	1	1.2
<b>Total</b>	25	57	82	100

Continued.

Age group (years)	Sex		Total	Percentage (%)
	Male	Female		
(%)	(30.50)	(69.5)	(100)	
<b>Mean±SD</b>	31.96±11.66	31.67±10.81	31.72±11.08	
<b>Mean±SEM</b>	31.96±2.33	31.67±1.43	31.72±1.22	

**Table 2: Response in relation to the age of the patients.**

Variables	Number of cases (n)	Complete relieved (90-100 %)	Relieved (60-89 %)	Partially relieved (30-59 %)	Not relieved (< 30 %)
<b>Age group (years)</b>					
19-29	38	23	7	7	1
30-39	18	12	3	2	1
40-49	21	15	2	0	4
50-59	4	2	1	1	0
60 and above	1	0	1	0	0
<b>Total</b>	<b>82</b>	<b>53</b>	<b>13</b>	<b>10</b>	<b>6</b>
<b>Gender (sex)</b>					
Male	25	15	6	2	2
Female	57	38	7	8	4
<b>Total</b>	<b>82</b>	<b>53</b>	<b>13</b>	<b>10</b>	<b>6</b>
<b>Chronicity of disease (days)</b>					
1-6	51	35	10	3	3
7-12	21	12	2	5	2
13-18	3	1	1	0	1
19-24	3	2	0	1	0
Above 24	4	3	0	1	0
<b>Total</b>	<b>82</b>	<b>53</b>	<b>13</b>	<b>10</b>	<b>6</b>
<b>Dietary habits status</b>					
Vegetarian	5	2	----	----	3
Non-vegetarian	13	6	1	3	3
Mixed	64	45	9	3	7
<b>Total</b>	<b>82</b>	<b>53</b>	<b>10</b>	<b>6</b>	<b>13</b>
<b>Response in relation to the new/known status</b>					
New Status	71	47	11	8	5
Known Status	11	6	2	2	1
<b>Total</b>	<b>82</b>	<b>53</b>	<b>13</b>	<b>10</b>	<b>6</b>
<b>Response in relation to the temperament of the patients</b>					
Damvi (SANGUINE)	46	32	9	4	1
Balghami (PHLEGMATIC)	24	13	3	3	5
Safravi (BILIOUS)	10	8	0	2	0
Saudavi (MELANCHOLIC)	2	0	1	1	0
<b>Total</b>	<b>82</b>	<b>53</b>	<b>13</b>	<b>10</b>	<b>6</b>
<b>General therapeutic response</b>					
No. of patients	82	53	13	10	6
Percentage (%)	100	64.60	15.90	12.20	7.30

**Table 3: Effect of drugs on clinical parameters.**

Clinical symptoms	Comparison	No. of observation (n)	Mean		SD		SEM		Efficacy (%) $\frac{(m(B.L)-m(A.L))}{m(B.L)}$ * 100 (m=mean)	Efficacy (score) Mean (B.L.A.L)	Paired 't' test Statistics value	P value
			B. T	A. T	B. T	A. T	B. T	A. T				
My	B.T vs A.T	82	1.94	4.34	0.67	0.77	0.07	0.08		-2.40	22.50	0.000

Continued.

Clinical symptoms	Comparison	No. of observation (n)	Mean		SD		SEM		Efficacy (%) $\frac{(m(B.L)-m(A.L))}{m(B.L)}$ * 100 (m=mean)	Efficacy (score)	Paired 't' test		
			B. T	A. T	B. T	A. T	B. T	A. T			Mean (B.L.A. L)	Statistics value	P value
<b>appetite is</b>													
When I eat	B.T vs A.T	82	2.07	4.06	0.64	0.67	0.07	0.07		-1.99	18.70	0.000	
Food tastes	B.T vs A.T	82	2.23	4.53	0.77	0.72	0.08	0.07		-2.30	17.96	0.000	
Normally I eat	B.T vs A.T	82	2.24	4.19	0.71	0.58	0.08	0.06		-1.95	18.77	0.000	

Table 4: Effect of drug on laboratory investigations.

Name of parameter	No. of observation (n)	Mean		SD		SEM		Efficacy (%) $\frac{(m(B.L)-m(A.L))}{m(B.L)}$ * 100	Efficacy (units)	Paired 't' test		
		B. T	A. T	B. T	A. T	B. T	A. T			Mean (B.L.A. L)	Statistic value	P-value
Hb (gm/dL)	82	12.64	12.81	1.71	3.26	0.19	0.36	2.14	↑	-0.16	↑	-0.53
TLC (/mm <sup>3</sup> )	82	6671.95	6550.00	1475.17	1363.21	162.90	150.54	2.31	↓	121.95	↓	0.91
RBC	82	4.50	4.56	0.92	1.20	0.10	0.13	1.31	↑	0.64	↑	-0.71
DLC	N (%)	82	56.71	56.69	9.70	10.01	1.07	1.10	1.2	↓	0.01	↓
	L (%)	82	37.30	36.88	9.24	9.92	1.02	1.09	1.13	↓	0.43	↓
	E (%)	82	2.55	2.91	1.26	1.26	4.53	0.14	1.24	↑	-0.36	↑
	M (%)	82	3.47	3.51	1.08	1.03	0.12	0.11	1.23	↑	-0.03	↑
	B (%)	82	0	0	0	0	0	2.41	-	0	-	-
ESR 1 <sup>st</sup> hr (mm)	82	25.88	23.41	19.39	15.93	2.14	1.76	1.32	↓	2.46	↓	1.75
ESR 2 <sup>nd</sup> hr (mm)	82	48.81	46.63	29.37	29.93	3.26	3.32	1.22	↓	2.18	↓	0.90
LFT	S. bilirubin (mg/100 ml)	82	0.67	0.60	0.36	0.37	0.04	0.04	2.5	↓	0.07	↓
	SGOT (IU/L)	82	23.24	23.18	8.30	7.99	0.92	0.88	2.4	↓	0.06	↓
	SGPT (IU/L)	82	21.70	20.75	12.29	11.30	1.36	1.25	4.38	↓	0.94	↓
	S. alkaline phosphatase	82	91.66	85.05	39.70	29.97	4.38	3.31	7.21	↓	6.60	↓
KFT	S. creatinine (mg/100 ml)	82	0.97	0.72	1.93	0.22	0.21	0.02	25.77	↓	0.25	↓
	Blood urea (20-40 mg/dL)	82	23.05	22.05	10.38	7.78	1.14	0.86	4.34	↓	1.01	↓
	Serum uric acid (2.6-7.2 mg/dL)	82	2.77	2.01	2.62	2.51	0.29	0.28	27.44	↓	0.76	↓

## DISCUSSION

Anorexia, often known as reduced appetite, is a prevalent condition that affects people of all ages, and is more common in the elderly. This can lead to malnutrition, weight loss, and other health problems. Elderly weight loss associated with anorexia has been identified as a separate predictor of morbidity and death.<sup>7</sup> Anorexia nervosa, bulimia nervosa, binge eating, and other eating disorders are distinct from appetite loss or weak appetite. These are illnesses that seriously impair a person's bodily

and mental well-being. While loss of appetite or low appetite typically does not require significant medical intervention, eating disorders require greater attention in terms of diagnosis and comprehensive treatment.<sup>8</sup> The present study investigated the safety and efficacy profiles of *Habb-e-Hilteet* in patients with *Zu'f al-Ishtihā'* (anorexia). The demographic profile of patients enrolled in the study showed a significant result of *Habb-e-Hilteet* in the age groups 19-29 found the most effective results in 46.3% (38 out of 82) of patients. In the gender categories, 57 female patients had more effective results

than male patients. We observed that the chronicity of disease in 1-6 days old chronic patients effectively resulted in 62.2% (51 of 82) patients. Our study found the most effective results in the categories of dietary habits in 81.7% (67 of 82) of non-vegetarian patients. In the categories of response in relation to new/known status, 86.6% (71 out of 82) of new patients found the most effective results. In relation to the temperament of the patients, our study found the most effective results in the categories of *Damvi* (SANGUINE) in 56% (46 of 82) of patients. Affirming the phenomenon that Excessive *harārats* or *burūdat*, alone or along with morbid matter, is the leading cause of anorexia or poor appetite.<sup>4,9,6</sup> Our study found a significant correlation ( $p<0.000$ ) between the effect of drugs on clinical parameters. The ingredients of the formulation viz *Zanjabeel* (Zingiber officianale), *Hilteet* (Ferula foetida), *Tankar* (borax) and *Namak-e-Sang* (rock salt) are well known spices and food additives which are highly acclaimed in Unani medicine for their medicinal values including digestive and appetizing properties. These drugs act by virtue of their temperament being hot and their inherent capability to cope with the underlying causes of anorexia or poor appetite.<sup>10-13</sup> *Hilteet* (asafoetida) and *Zanjabeel* (ginger) alone or in combination with other drugs are highly recommended by *Ibn Sīnā* for anorexia.<sup>9</sup> Spices are known not only for enhancing the sensory quality of food but also for exhibiting a wide range of medicinal properties.<sup>14</sup> Beside numerous pharmacological activities such as asafoetida and ginger have been reported to exert positive influence on digestive enzyme activity. Asafoetida and ginger have been shown to enhance pancreatic lipase activity and stimulate pancreatic amylase activity in vitro and in vivo. This positive influence could contribute to the established digestive stimulant action of spices.<sup>15,16</sup> It could be inferred from the observation that the combination of these species may have yielded a synergistic effect in the formulation, leading to early digestion and decreased feelings of fullness, thus improving appetite. In the present study, the safety profile of *Habb-e-Hilteet* was assessed using relevant pathological and biochemical indices, such as hemoglobin, ESR, serum bilirubin, SGOT, SGPT, ALP, serum creatinine, blood urea, and serum uric acid. All pathological and biochemical indices were within the normal range, and no significant difference was observed in the mean value between the baseline and after 14 days of treatment. The activity of serum uric acid after 14 days of treatment showed significant ( $p<0.000$  %) and S. bilirubin ( $P= 0.02$  %.) The decrease when compared to baseline, which was clinically in the normal range, was considered to be the beneficial effect of the treatment. No adverse events (AEs), serious adverse events (SAEs), or drug intolerance were reported during the study period. These results indicate that the drug '*Habb-e-Hilteet*' is safe and may be effectively used for the treatment of anorexia.

There were no limitations of the study. The authors covers all parameters which may be helpful for the clinical trial.

## CONCLUSION

The present study offers valuable insights into the appetite-stimulating effects of the Unani pharmacopoeal formulation *Habb-e-Hilteet* in patients suffering from *Zu'f al-Ishtihā* (anorexia). The findings suggest a statistically significant improvement in the mean SNAQ (Simplified Nutritional Appetite Questionnaire) score after 7 and 14 days of treatment, indicating a positive impact on appetite in these patients. The formulation was well-tolerated, with no reports of undesirable side effects during the course of the study, which suggests that it is a safe option for managing anorexia in the short term. However, the authors recommend further investigation with larger sample sizes and longer follow-up periods to confirm these findings. Such studies would also help evaluate whether the short-term improvements observed in appetite and associated weight gain can be sustained over time. In summary, *Habb-e-Hilteet* shows promise as a therapeutic intervention for anorexia, but more extensive research is needed to fully establish its efficacy and long-term safety.

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**Conflict of interest:** None declared

**Ethical approval:** The study was approved by the Institutional Ethics Committee

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