Clinical validation
of Unani pharmacopoeial formulation

Jawārish Bisbāsa

in cases of Siman Mufriṭ
Central obesity (NUMC: M-37)

Central Council for Research in Unani Medicine

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A Technical Report

CENTRAL COUNCIL FOR RESEARCH IN UNANI MEDICINE

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PREFACE

Obesity has emerged as a potential global public health threat, with its prevalence steadily increasing since the beginning of the 21st century. Among its various forms, *Siman Mufriṭ* (Central obesity) characterized by excessive fat accumulation around the abdomen, has gained particular attention due to its strong association with metabolic disorders such as type 2 diabetes, cardiovascular diseases, and non-alcoholic fatty liver disease. Despite the availability of modern pharmacological interventions and lifestyle modification programs, the burden of central obesity continues to rise, especially in low-resource and culturally diverse settings.

In India, central obesity has become an increasingly significant public health concern. Data from the National Family Health Survey (NFHS-5) reveal that 40% of women and 12% of men exhibit central obesity. These figures underscore the urgent need for effective, affordable, and culturally acceptable treatment strategies.

In the Unani system of medicine, *Siman Mufriṭ* (Central obesity) is classified as a *Balghamī* (phlegmatic) disorder, attributed to the predominance of *Khilṭ-i-Balgham* (phlegmatic humour). Drawing upon centuries of empirical wisdom, Unani scholars have developed a comprehensive line of treatment that includes both single and compound drugs. Unlike synthetic anti-obesity medications, which are often costly, associated with adverse effects, and may lead to rebound weight gain upon cessation, Unani formulations offer a holistic, natural, and potentially safer alternative.

In this context, the Central Council for Research in Unani Medicine (CCRUM) initiated a clinical study to evaluate the efficacy of *Jawārish Bisbāsa*, a semi-solid Unani formulation known for its digestive, carminative, and metabolism-enhancing properties, in the management of central obesity. The formulation was selected based on classical Unani literature and the recommendations of

Unani physicians serving on the Council's Scientific Advisory Committee (SAC).

The present compilation, entitled "Clinical validation of Unani pharmacopoeial formulation *Jawārish Bisbāsa* in cases of *Siman Mufriṭ (NUMC: M-37)* (Central obesity)", is based on the results of a multicentric clinical study conducted at various CCRUM Institutes involving 220 confirmed cases of *Siman Mufriṭ*. The study outcomes suggest promising potential of Unani medicinal system in the development of effective management strategies for central obesity. Moreover, the safety evaluations demonstrated an absence of any adverse effects throughout the study period, thereby indicating that the test drug was well-tolerated and exhibited a favorable safety profile among the participants.

This monograph advocates for the integration of *Jawārish Bisbāsa* into central obesity management, drawing upon classical Unani texts, contemporary research, and experiential evidence. It aims to bridge traditional wisdom with modern scientific inquiry, highlighting the formulation's potential to regulate appetite, improve gastrointestinal function, and modulate fat metabolism. Special attention is given to its role in enhancing *Ḥarārat-i-Gharīziyya* (innate heat), balancing *Mizāj* (temperament), and promoting *Istifrāgh* (elimination of morbid matter), the core principles in Unani pathology that align with current understandings of metabolic health.

By foregrounding *Jawārish Bisbāsa* within a framework of integrative medicine, this work seeks to empower clinicians and researchers to consider culturally embedded, accessible, and inclusive strategies for obesity care.

I am grateful to all the scientists who have contributed to this study at various levels, and to the members of the Council's Scientific Advisory Committee for their guidance and encouragement.

Dr. N. Zaheer Ahmad
Director General, CCRUM New Delhi

Contents

INTRODUCTION

Obesity has emerged as a pressing global public health issue, with estimates indicating that nearly one-third of the world's population is either overweight or obese (Molla,2020). Alarmingly, the global prevalence of obesity has nearly tripled between 1975 and 2016 (Apovian,2016). According to the World Health Organization (WHO), as of 2022, one in eight individuals worldwide was living with obesity. Approximately 2.5 billion adults were overweight, of whom 890 million were living with obesity (WHO,2025). Although obesity prevalence varies globally, its impact on life expectancy is profound. The Framingham Cohort Study has shown a direct relationship between the duration of being overweight or obese and an increased risk of premature mortality (Golzar, 2023). In India, central obesity has become an increasingly significant public health concern. Data from the National Family Health Survey (NFHS-5) reveal that 40% of women and 12% of men exhibit central obesity. Among women aged 30–49 years, 5 to 6 out of every 10 were found to be abdominally obese. Asian Indians are particularly predisposed to visceral fat accumulation, heightening their vulnerability to associated metabolic and cardiovascular complications (Chaudhary & Sharma, 2023).

WHO distinguishes between overweight and obesity by defining overweight as the presence of excessive fat deposits, while obesity is a chronic complex disease defined by excessive or abnormal fat accumulation that may impair health (Bosomworth, 2019). Although WHO's definition may appear simplistic, obesity is a complex condition driven by a sustained positive energy balance where caloric intake consistently exceeds energy expenditure. The surplus energy is converted into triglycerides and stored in adipose tissue, leading to its expansion and subsequent weight gain (WHO, 2025).

Obesity is broadly categorized into general and central (abdominal) obesity, based on the distribution of adipose tissue. Central obesity refers to excessive fat accumulation in the abdominal region and is defined by a waist circumference exceeding 80 cm in women and 94 cm in men (Chaudhary & Sharma, 2023).

The Body Mass Index (BMI), which adjusts weight for height, remains the most commonly used metric for assessing overweight and obesity. However, emerging evidence suggests that indicators of abdominal adiposity, such as waist

circumference, waist-to-hip ratio, and waist-to-height ratio, may be more accurate predictors of cardiovascular disease (CVD) risk than BMI alone. This is largely due to the strong association between visceral fat and metabolic disturbances, including insulin resistance, impaired glucose tolerance, and dyslipidaemia, all of which are key risk factors for type 2 diabetes and CVD. While elevated BMI provides a general measure of body fat, it does not reliably predict cardiovascular or metabolic risk. In contrast, central obesity metrics, particularly waist circumference, offer more precise insights into these health risks (Apovian,2016; WHO,2011).

Obesity is a significant risk factor contributing to the development of various health conditions, including hypertension, coronary artery disease, type 2 diabetes, gallbladder disorders, and certain cancers—particularly colorectal cancer. Globally, obesity is responsible for approximately 2.8 million adult deaths each year. It accounts for 44% of diabetes cases, 23% of ischemic heart disease, and between 7% to 41% of the burden from specific types of cancer. Beyond life-threatening illnesses, obesity is linked to numerous non-fatal but debilitating conditions that impact quality of life. These include varicose veins, abdominal hernias, osteoarthritis affecting the knees, hips, and lower spine, as well as psychological distress, especially during adolescence. In addition to reducing life expectancy, obesity may also impair fertility (Wani, 2024).

Diagnosis

The diagnosis of overweight and obesity is made by measuring weight and height and then calculating the body mass index (BMI) using the formula weight (kg)/height² (m²). The body mass index is a surrogate marker of fatness and additional measurements, such as the waist circumference, can help the diagnosis of obesity. The BMI categories for defining obesity vary by age and gender in infants, children and adolescents. For adults, WHO defines overweight and obesity as follows:

Overweight is a BMI greater than or equal to 25; and Obesity is a BMI greater than or equal to 30. (WHO,2025).

Table 1: WHO classification of Obesity based on BMI (WHO,2025)

Classification	BMI (Kg/m^2)	Risk of Co-morbidities
Underweight	<18.50	Low
Normal	18.50-24.99	Average
Overweight	≥25.00	
Pre-obese	25.00-29.99	Increased
Class 1 obesity	30.00-34.99	Moderate
Class 2 obesity	35.00-39.99	Severe
Class 3 morbid obesity	≥40.00	Very severe

Concept of *Siman Mufriṭ* (Obesity) in Unani Medicine

In classical Unani literature, Obesity (including general and central types) is referred to as *Siman Mufriṭ* (NUMC: M-37) in Arabic, meaning "excessive fat," and its Persian counterpart is *Farbahī*, denoting a state of being obese. Within the Unani system of medicine, obesity is classified as a *Balghamī* (phlegmatic) disorder, attributed to the predominance of *Khilṭ-i-Balgham* (phlegmatic humour) in the body, which plays a central role in its pathogenesis. The earliest comprehensive account of *Siman Mufriṭ* (Obesity) is attributed to *Buqrāṭ* (Hippocrates, 460 BC), who not only described its complications but also proposed preventive strategies. He warned of its potential to cause infertility and even sudden death. (Mand, 2015; Khan, 2020; Wani, 2024)

Rufās (98–117 AD) expanded on this by highlighting the increased vulnerability of obese individuals to various diseases. He linked advanced obesity to serious complications such as *Ṣar'* (epilepsy), breathlessness, *Fālij* (hemiplegia), and *Ghashī* (syncope). *Jālīnūs* (Galen, 119–200 AD) contributed a conceptual framework for understanding the pathogenesis of *Siman Mufriṭ*, laying the groundwork for later physiological interpretations.

Abū al-Ḥasan Raban Ṭabarī (780–850 AD) identified excessive food intake and physical inactivity as primary etiological factors. He offered general guidance on weight-reducing diets and regimens. (Mand, 2015; Khan, 2020; Wani, 2024)

A significant contribution in the management of *Siman Mufriṭ* (obesity) was introduced by *Zakariyyā Rāzī* (865–925 AD), who developed the first systematic approach to its treatment. He categorized obesity into two distinct types: *Maqāmī* (local) and *'Umūmī* (general), prescribing tailored therapies for each. *Rāzī* identified *Tar Ghidhā'* (oily and

rich foods) as a key contributor to fat accumulation. He explained that when *Shaḥm* (fat) collects in a specific organ, such as the abdomen, it leads to local or central obesity, whereas widespread fat deposition throughout the body results in general obesity. His comprehensive treatment plan included a combination of pharmacological remedies, dietary regulation, physical exercise, massage, hydrotherapy, and lifestyle modifications, reflecting a holistic approach rooted in Unani principles. Subsequent Unani scholars such as *'Alī ibn 'Abbās Majūsī, Ibn Sīnā* (980–1037 AD), and *Ismā'īl Jurjānī* (12th century AD) echoed these therapeutic strategies. However, they placed particular emphasis on *Ḥarārat- Gharīziyya* (innate heat), noting its decline in obese individuals, which facilitates abnormal fat accumulation. (Mand, 2015; Khan, 2020; Wani, 2024)

Ibn Sīnā focuses on the *Taqlīl-i-Ghidhā'* (gradual reduction in food intake) as the important tool for obesity treatment. He has prescribed the *Adwiya Mulaṭṭifa* (attenuant drugs) and described detailed pharmacological action of these drugs. He also described the mechanism of non-absorption of food from intestine which is the same as the modern drugs, used in the treatment of obesity. *Ibn Hubal Baghdādī* (1121–1213 AD) suggested that obese persons should avoid fatty diets and suggested gradual decrease in diet. *Ibn al-Bayṭār* (1197-1248 AD) in his book *Kitāb al-Jāmi' al Mufradāt al-Adwiya wa'l Aghdhiya* enlisted some *Muhāzzil* (anti-obesity) drugs and recommended their use in the treatment of Obesity. *Dā'ūd Anṭākī* (1541-1599AD) mentioned complication and treatment of obesity in his book *Tadhkira 'Ūlī al-Albāb* .A significant shift in understanding came with *Ibn Nafīs* (1207–1288 AD), who was the first to explicitly associate *Siman Mufriṭ* with cardiovascular and cerebrovascular conditions, as well as respiratory and reproductive disorders. While earlier physicians had briefly mentioned such symptoms, *Ibn Nafīs* provided a detailed and systematic exposition of these links. (Mand, 201 5; Khan, 2020; Wani, 2024)

Pathophysiology

According to the humoral theory in Unani medicine, *Balgham* (phlegm) is characterized by a *Bārid Raṭb* (cold and moist) temperament. This quality extends to all bodily matters (*Mādda*) that share a similar temperament or perform functions similar to phlegm. Consequently, fats are considered phlegmatic in nature and are further classified into two distinct types: *Shaḥm* and *Samīn* (Urooj, 2021).

Samīn refers to a lighter, softer, and semi-solid form of fat. It typically adheres to muscles, blood vessels, and nerves, playing a role in blood formation and serving as a source of metabolic energy. *Shaḥm*, on the other hand, is denser and more solid—comparable to adipose tissue. It tends to accumulate in various body tissues and organs, especially those with a naturally cold temperament (Urooj, 2021).

During the metabolic process, *Shaḥm* is formed as a refined end-product (*Nuzj Fazila*) of food digestion and is distributed to different organs to provide nourishment. However, under pathological conditions, *Shaḥm* has a tendency to deposit in colder regions of the body, where it may solidify. The primary site of fat accumulation is the *Al-Tharb* i.e. Omentum (Mand, 2015).Excessive accumulation of free fat in these areas can lead to *Siman Mufriṭ* (obesity), which in turn contributes to the narrowing of blood vessels. Due to overlapping causes, symptoms, and complications, Unani scholars have often grouped obesity and hyperlipidemia under the broader diagnostic category of *Siman Mufriṭ* (Urooj, 2021).

Etiopathogenesis

Siman Mufriṭ (Obesity), according to Unani scholars, is deeply rooted in the imbalance of temperament and humoral pathology. The accumulation of fat (*Shaḥm*), particularly under the influence of a dominant cold temperament (*Burūdat -i-Mizāj*), leads to a reduction in innate heat (*Ḥarārat Gharīziyya*) and constriction of blood vessels. This impairs the flow of pneuma (*Rūḥ*) to vital organs (*A'ḍā'*), further diminishing physiological heat and triggering systemic dysfunctions that may culminate in premature death (Urooj, 2021).Additionally, the viscosity (*Ghilẓat*) and stickiness (*Lazoojat*) of humors obstruct the smooth passage of pneuma through vessels. Coldness contributes to *Taṣallub al-Sharāyīn* i.e. arteriosclerosis —the hardening and fat deposition in arteries leading to atherosclerosis (*Tasaddud Shaḥmī Kilsī*). Fat accumulation in tissues predisposes individuals to obesity and its associated disorders (Urooj, 2021).

Causative Factors

Unani scholars attribute obesity to a range of lifestyle and constitutional factors viz. Dietary habits including *Sū' al-Haḍm* i.e. indigestion; Excessive intake of *Martoob Ghidhā'* i.e. fatty diet, meat and sweets; *Kathra al Ghidhā'* i.e. over-eating; frequent use of oils and fats (*Martoob Roghaniyat*). Lifestyle patterns includes excessive sleep

(*Ifrāṭ - al-Nawm*), Prolonged rest (*Ifrāṭ - al- Sukūn*), lack of physical activity (*Qillat-i--Harkat-i-Badanī*), over-indulgence in joy (Farḥat), use of soft bedding and luxurious clothing, alcohol consumption, especially post-meal, frequent sauna use after meals (*Ḥammām*). However, constitutional factors include Hereditary (*Warāthī*) and congenital (Khilqī) predispositions, and Cold temperament (*Burūdat-i-Mizāj*). These factors collectively lead to an overproduction of *Balgham* (phlegm), disrupting metabolic balance and contributing to dyslipidemia and obesity (Mand,2015; Urooj, 2021).

Signs and Symptoms

The usual signs and symptoms of *Siman Mufrit* are *Kas'l* (lethargy), *Sū' al-Tanaffus* (dyspnoea), *Is'haal* (diarrhoea), *Khafaqān* (Palpitation), *Ḍīq al-Nafas* (asthma), *'Usr al-Tanaffus* (breathlessness), *Ḍu'f al-Bāh* (loss of libido) and *Tahabbuj* (Puffiness of face) (Mand,2015).

Complications

Patient may have complications of concealed hemorrhage, *Taḍayyuq-i-'Urūq* (narrowing of vessels), *Ghashī* (syncope), *Fālij* (hemiplegia), *Sakta* (Apoplexy), *'Iẓam al-Kabid* (hepatomegaly), *Ḍu'f al-Bāh* (loss of libido), '*Uqr* (infertility) and even sudden death (Mand,2015).

Uṣūl-i- 'Ilāj (Principles of treatment)

Unani principles have systematic approaches to reducing risk and associated chronic diseases. They begin by defining visceral obesity and its major outcomes and also discuss the importance and challenges of holistic approaches to reduce abdominal obesity, as compared to clinical approaches, with major costs and risks. The basic principles of treatment of obesity are as follows: (Anonymous, 2016; Mand,2015).

- *'Tadil-i- Mizāj* (Moderation of temperament)
- *Tajfīf-i Badan* (Desiccation)
- *Tahzīl* (To induce weight loss)
- *Taqlīl- Ghidhā'* (To reduce the quantity of food)
- *Tadabīr* (Regimens) producing *Ḥarārat* and *Yubūsat* in the body

- Removal of causative factors is the key to the management.

- Drugs having the temperament opposite to that of the disease i.e. hot and dry temperament should be employed for correction of *Sū'-i-Mizāj Bārid Raṭb* (cold & wet) according to *'Ilāj bi'l Ḍidd (heterotherapy)* principle of Unani medicine.
- Single and compound Unani drugs having properties like *Muhazzil* (anti-obesity/ slimming) *Mujaffif* (desiccant), *Mushil-i-Balgham* (purgatives), *Muḍirr* (diuretics), *Mulattif* (Demulscent), *Munaffith-i-Balgham* (expectorant) and *Mu'arriq* (diaphoretics) should be administered.
- Adoption of *Tadabīr* (Regimens) which produce *Ḥarārat* and *Yubūsat* in the body like *Riyāḍat, Ḥammām* etc.

Management in Unani medicine

The management of *Siman Mufriṭ* or Central obesity (Anonymous, 2016; Mand, 2015; Khan, 2020) can be categorized into three parts:

'Ilāj-bi'l-Tadbīr (Regimenal therapy)

Ḥammām Yābis (dry bath) on empty stomach, *Ta'rīq* (Diaphoresis), frequent *Ishāl* (Purgation) and *Idrār* (Diuresis) by use of *Mus'hilāt* (purgatives) wa *Mudirrāt* (diuretics) for inducing *Yubūsat* (dryness), *Ḥammām Muḥallil* (Bath causing resolution of fluids) to increase *Taḥlīl* (dissolution) of accumulated fat. *Taqlīl-i-Nawm* (reduce sleep hours), encouraging sleeping on hard-bed, *Riyāḍat Shāqqa* (vigorous exercise) e.g. fast running, vigorous body massage with *Ḥārr* and *Muḥallil Roghaniyāt* viz. *Roghan Shibbat*, *Roghan-i-Qusṭ*, *Raghan Yasmin* and *Roghan Nardin*, and *Ḥijāma* (cupping) are equally useful in management of *Siman Mufriṭ*.

Ilāj-bi'l-Ghidhā' (Dieto therapy)

Dietary recommendations: Diets less in nutrition but more in quantity (*Qalīl al-Ghidhā'* but *Kathīr al-Kaymūs* diets) should be advised, as decreased consumption casts less burden on *Quwwat* (power) of digestion; judicious use of vinegar and hot water must be recommended, fasting should be advised.

Ḥārr Yābis Mizāj' (hot and dry temperament) diet i.e. *Aghdhiya Ḥirrīfa* (pungent taste), *Aghdhiya Māliḥ* (salty diet), lemon, piper, garlic, cumin, mint, piper longum should be added in food as their *Mulaṭṭif* property help to metabolize the accumulated body fat. Beside these measures, small quantity of meal should be taken at one point of time in a day.

Dietary restrictions include Meat, Milk, Sweet dishes, and rigid avoidance of fatty, roasted and fried edibles.

Taḥaffuẓ (Prevention/Precaution): Avoidance of luxurious and sedentary lifestyle.

'Ilāj-bi'l-Dawā' (Pharmacotherapy)

Ibn Sīnā proposed that drugs and regimens used for obesity manifest their actions on body fat via three possible ways:

1) Anti-obesity drug act by *Tarqīq-i-Khilṭ* (liquefaction of thick humors) and thus decrease the *In'eqaad- i-Khilṭ* (consistency of humors).

2) By inducing *Idrār* (diuresis), excessive *Akhlāṭ* are removed from the vessels.

3) These drugs increase *Hiddat* in blood, and *Ṭabīʿat* dislike these *Akhlāṭ*, hence not absorbed properly by *Quwwat Jādhiba* (Khan,2020).

According to the *Unani* principles of treatment of disease, the drugs used to treat the obesity should have *Ḥārr Yābis* temperament as the obese person generally have *Bārid Ratb* temperament, and exert *Musakhin*, and *Mulaṭṭif*actions on fat which result in increased *Ḥarārat* and *Yubūsat* in the body. These drugs play a key role in metabolism of *Shaḥm*, resulting in weight reduction (Khan,2020).

Adwiya Mufrida (Single Unani Drugs)

Commonly used drugs are *Sīr* (*Allium sativum* L.*), Luk Maghsūl* (Coccus lacca), *Ajwā'in* (*Trachyspermum ammi* (Linn.) Sprague.), *Soya* (*Anethum sowa* R.), *Kamūn* (*Carum carvi* L.), *Anīsūn* (*Pimpinella anisum* L.), *Fitrāsālīyūn* (*Petroselinum crispum* (Mill.) Fuss, *Bādiyān* (*Foeniculum vulgare* M.), *Tukhm-i-Karafs* (*Apium graveolens* L.), *Marzanjosh* (*Origanum majorana* L.), *Tukhm-i Sudāb* (*Ruta graveolens* L.), *Kaloṉjī* (*Nigella sativa* L.), *Khardal* (*Brassica nigra* (Linn.) Koch.), *Filfil Siyāh* (*Piper nigrum* L.), *Halīla Siyāh* (*Terminalia chebula* R.), *Halūn* (*Lepidium sativum* L.), *Jawakhar* (Pottasium carbonate), *Juntiyānā (Gentiana lutea* L.*),Unsul* (*Allium cepa* L.), *Nana* (*Mentha arvensis* L.), *Shīṭraj Hindī* (*Plumbago zeylanica* L..), *Zarāwand Ṭawīl* (*Aristolochia longa* L.), *Sandrus* (*Hymenaea verrucosa* G.), Sirka (Vinegar) are useful in the management of obesity (Khan,2020).

Adwiya Murakkaba (Compound Formulations)

Compound Unani formulations include-*'Araq-i Zīra, 'Araq-i -Bādiyān, Ayārij Fayqrā, Jawārish Kamūnī, Jawārish Falafili, Ma'jūn-i-Balādur, Majoon Kamūnī, Anqarūyā, Dawā'-al-Luk, Iṭrīfal Saghīr, Dawā'-al-Kurkum, Safūf Muhazzil, Amroosiya, Asnasiya, Ḥabb-i-Sandarus* and other drugs are useful in the treatment of obesity. Besides these measures, *Mulattif, Mudirr-i-Bawl* and *Ḥārr Yābis* drugs are also useful in its management (Khan,2020).

STUDY RATIONALE

Globally, *Siman Mufriṭ* (Obesity) is responsible for the deaths of approximately 2.8 million adults each year. It accounts for 44% of diabetes cases, 23% of ischemic heart disease, and 7% to 41% of the burden from specific types of cancers. Data from the National Family Health Survey (NFHS-5) reveal that 40% of women and 12% of men exhibit central obesity in India. *Siman Mufriṭ* or central obesity is considered a *Balghamī* (phlegmatic) disorder, driven by the predominance of *Khilṭ-i-Balgham* (phlegmatic humour) in Unani medicine. Based on ancient wisdom Unani scholars devised a complete line of treatment which includes the use of single and compound drugs having *Muhazzil* (anti-obesity), *Mujaffif* (desiccant), *Mushil* (purgative), *Muḍirr* (diuretics) and *Mulaṭṭif* (Demulscent) properties; adoption of diet and regimens, to induce weight loss (*Tahzil*), through reduction in quantity of food (*Taqlīl-i-Ghidhā'*). Modern treatment typically involves synthetic anti-obesity drugs alongside lifestyle changes, but these medications are costly and often associated with adverse effects. Moreover, there could be rebound weight gain after cessation of these drugs. Currently approved drugs such as Orlistat, Liraglutide and Phentermine/Topiramate have limitations, including side effects,high treatment cost and restricted accessibility.

Given these challenges, there is a growing global interest in safer, natural alternatives. The Unani system offers a rich repository of single and compound formulations for managing central obesity. *Jawārish Bisbāsa*, a polyherbal Unani pharmacopoeial formulation, is traditionally used for obesity and is known for *Mufattiḥ* (deobstruent), *Mujaffif* (desiccant) , and *Mufattiḥ-i-'Urūq* (vessel-relaxing) properties. Several of its ingredients also exhibit anti-hyperlipidemic and antidiabetic effects e.g. *Heel Kalan* (*Amomum subulatum* Roxb.); *Bisbāsa* (*Myristica fragrans* Houtt.); *Hīl Khurd* (*Elettaria*

cardamomum (Linn.) Maton); *Zanjābīl* (*Zingiber officinale* Roscoe); *Dārchīnī* (*Cinnamomum zeylanicum* Blume); *Filfil Siyāh* (*Piper nigrum* Linn.) & *Qaranful* (*Syzygium aromaticum* Merr. & L.M. Perry). The present study is therefore designed to re-evaluate the efficacy and safety of *Jawārish Bisbāsa* in treating *Siman Mufriṭ* (central obesity) through an open-label clinical trial.

STUDY OBJECTIVES

- To evaluate the safety of Unani pharmacopoeial formulation *Jawārish Bisbāsa* in *Siman Mufriṭ* [NUMC: M-37] (Central Obesity)
- To evaluate the efficacy of Unani pharmacopoeial formulation *Jawārish Bisbāsa* in *Siman Mufriṭ* [NUMC: M-37] (Central Obesity)

STUDY DESIGN

The study was designed as an open-label, single arm, multi-centric clinical trial carried out at two distinct institutes of CCRUM.

Study Sites

The clinical study was conducted at the following centres:

- Regional Research Institute of Unani Medicine (RRIUM), Mumbai
- Regional Research Institute of Unani Medicine (RRIUM), Aligarh

Ethical Approval & CTRI registration

The study was approved by the Institutional Ethics Committee (IEC) of each of the participating Institute viz. RRIUM Mumbai & RRIUM Aligarh. The trial got registered prospectively under CTRI on 23.08.2018 at Headquarters with the reference number CTRI/2018/08/015446. Before enrolment of participants into the trial, a signed Informed consent was obtained from eligible participants.

STUDY DURATION

The duration of study was two years to achieve the allotted sample size. The sample size was achieved well in time by the respective Principal Investigators at both the centres.

DURATION OF PROTOCOL THERAPY

The total duration of treatment of each patient was 8 weeks with fortnightly follow up.

Follow-Up Evaluation

The participants were assessed clinically at every 2 weeks interval for 8 weeks. The subjective and objective clinical observations were recorded in the follow up sheet. Any missed follow up visit was rescheduled within an interval of +/ – 3 days.

ASSESSMENT OF *MIZĀJ* (TEMPERAMENT)

Mizāj of every patient of *Siman Mufriṭ* (Central Obesity) [NUMC: M-37] was assessed at baseline as per Unani classical parameters (*Annexure III*).

SUBJECT SELECTION

Patients of *Siman Mufriṭ* (Central Obesity) attending the OPD of respective centres were selected for the study. The chief complaints included heaviness in chest, budging of abdomen, breathlessness, heartburn or burning sensation in chest full time or after taking food or in case of over eating. The cases were selected on the basis of history taking, physical examination and anthropometric parameters including-ICO (Index of Central Obesity), BMI (Body Mass Index), WHR (Waist-to-Hip Ratio), WHtR (Waist-to-Height Ratio) and SAD (Sagittal Abdominal Diameter) in the given specific range followed by baseline investigations as per the protocol. A detailed clinical history was taken and complete physical examination was carried out along with laboratory investigations to meet inclusion and exclusion criteria.

Inclusion Criteria (All of the following)

The participants with following conditions were included in the study:

1. Participants of either Gender in the age group 18-65 years.
2. Participants of *Siman Mufriṭ* (Central Obesity) presenting with either of the following:
    - BMI (Male = ≤ 34.99 kg/m2 and Female = ≤ 32.49 kg/m2)
    - Waist Circumference (>94cms in Males and > 80cms in Females)
    - Waist -to-hip ratio between (Female 80 to 85cm and male >90cm to <1m)
    - Sagittal Abdominal Diameter (SAD) > 25cms

3. Participants presenting with central obesity with or without following complaints:
    - Heart burn
    - Fullness of stomach
    - Breathing difficulties
    - Sleep apnea

Exclusion Criteria (Any of the following)

The participants with following conditions were excluded from the study:

1. Medications causing secondary weight gain e.g. Phenothiazines, sodium valproate, carbamazepine, lithium, glucocorticoids, thiazolidinediones, sulphonylureas, adrenergic, antagonists, etc
2. Participants on Oral contraceptive pills or Hormone Replacement therapy
3. Participants having systemic illness requiring long term treatment
4. Participants unable to exercise
5. Pregnant and lactating females

MATERIAL AND METHODS

After initial screening, patients diagnosed with *Siman Mufriṭ* [NUMC: M-37] were enrolled based on protocol-defined eligibility criteria and administered the trial drug *Jawārish Bisbāsa* for eight weeks in prescribed doses i.e.7gms BD. All participants were provided with bilingual Patient Information Sheet and a written Informed-Consent was obtained prior to any study-related procedures. Demographic details, current disease status, co-morbidities, and concurrent therapies were documented, followed by comprehensive physical and systemic examinations. Obesity-related signs and symptoms were recorded in the Case Report Form (CRF), and vital signs, including blood pressure, heart rate, temperature, and respiratory rate, were also recorded. Laboratory investigations were conducted at baseline, first follow up and after the treatment, covering haematological profile (Hb%, TLC, DLC, RBCs, PCV, ESR), lipid profile (Total Cholesterol, LDL, VLDL, HDL, Triglycerides), liver function tests (S. Bilirubin, SGOT, SGPT, S. Alkaline Phosphatase), kidney function tests (S. Urea, S. Creatinine, S. Uric Acid), fasting blood sugar (baseline only to exclude diabetics), insulin levels baseline only, thyroid profile (T3, T4, TSH at baseline), and

routine/microscopic urine analysis. Clinical assessments were conducted fortnightly, and the efficacy of *Jawārish Bisbāsa* was evaluated based on changes in anthropometric indices *viz.*ICO (Index of Central Obesity), BMI (Body Mass Index), WHR (Waist-to-Hip Ratio), WHtR (Waist-to-Height Ratio), SAD (Sagittal Abdominal Diameter) and relevant clinical parameters.

Anthropometric parameters

Waist Circumference (WC):

Waist circumference was measured at the level of the belly button using a flexible tape around the widest part of the abdomen. The measurement was taken 2–3 times, and the average was recorded (Fig. 1).

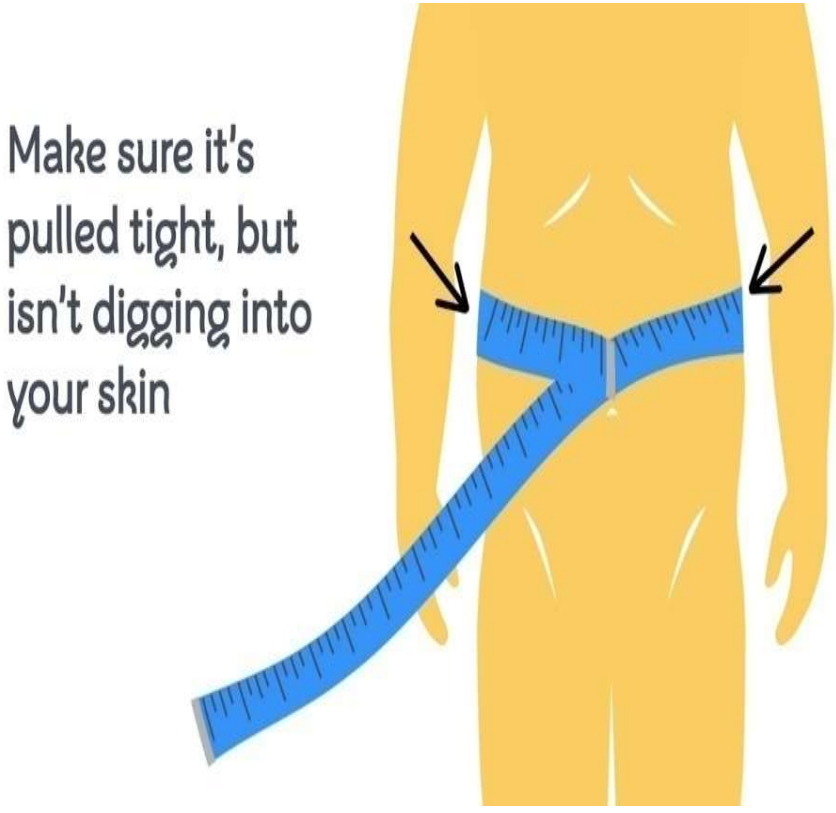

Fig.1

Body Mass Index (BMI):

The weight and height were measured by a manual weighing machine and a stadiometer respectively to calculate BMI according to WHO criteria (Table:2 Fig. 2)

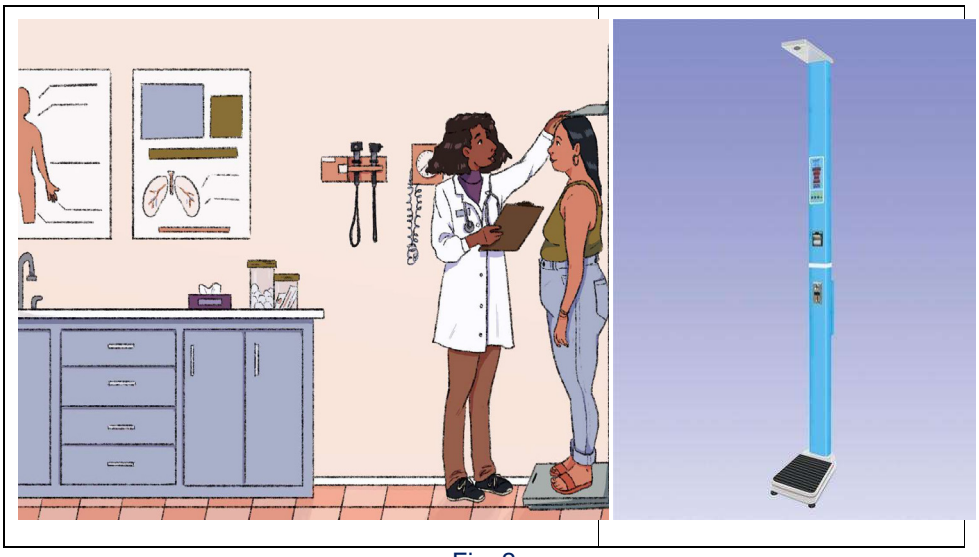

Fig. 2

Table 2: Body Mass Index (BMI)

Classification	BMI(kg/m^2)	
	Principal cut-off points	**Additional cut-off points**
Obese	**≥30.00**	**≥30.00**
Obese class I	30.00 - 34.99	30.00 - 32.49
		32.50 - 34.99
Obese class II	35.00 - 39.99	35.00 - 37.49
		37.50 - 39.99
Obese class III	≥40.00	≥40.00

Source: Adapted from WHO, 1995, WHO, 2000 and WHO 2004.

Waist to Hip Ratio (WHR):

Waist to Hip Ratio was measured with the help of a measuring tape:

Table3: Waist to Hip Ratio (WHR)

Male	Female	Health Risk
0.95 or below	0.80 or below	Low Risk
0.96 to 1.0	0.81 to 0.85	Moderate Risk
1.0+	0.85+	High Risk

Waist-to-Height ratio (WHtR):

This is also called as waist-to-stature ratio (WSR); in this ratio, waist circumference of individuals is divided by their height (Fig.3). The WHtR is a measure of the distribution of body fat. Higher values of WHtR i.e. WHtR greater than 0.5 indicate higher risk of obesity-related cardiovascular diseases (Hu, 2008).

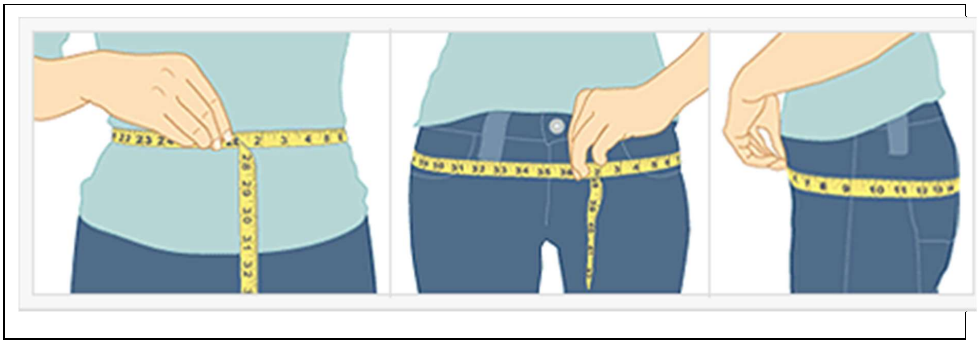

Fig. 3

Sagittal Abdominal Diameter (SAD):

SAD, or abdominal height, was measured using a sagittometer to assess visceral fat (Fig. 4). It's a strong indicator of coronary risk, independent of BMI. A normal SAD is under 25 cm; values above 30 cm are linked to higher cardiovascular risk and insulin resistance.

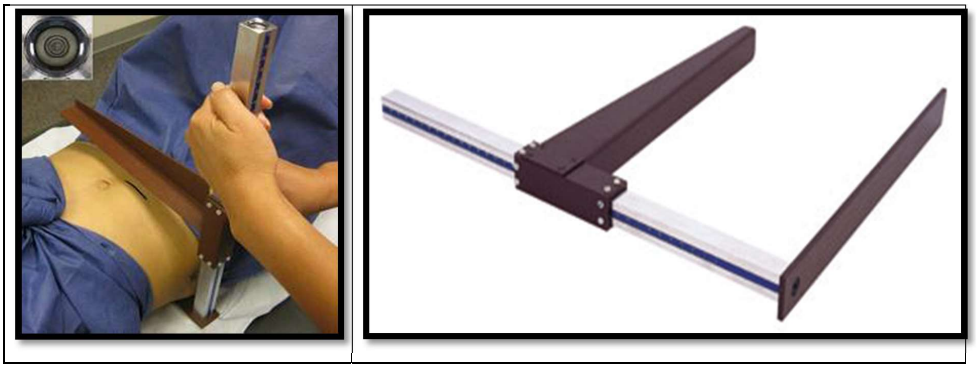

Fig. 4

SIGNS AND SYMPTOMS

Scoring of the clinical signs & symptoms was done as follows:

Table 4:

Sign & symptoms	Details Sign & symptoms		Score
Heart burn	1	No heart burn	0
	2	Mild: awareness of heart burn but easily tolerated	1
	3	Moderate: discomforting heartburn sufficient to cause interference with normal activity, including sleep	2
	4	Severe: incapacitating heartburn, with inability to perform normal activities	3
Fullness of stomach	1	No Fullness of stomach	0
	2	Mild: Feeling fullness of abdomen uncomfortable but tolerated	1
	3	Moderate: discomforting fullness sufficient to cause interference with normal activity, including sitting and sleeping	2
	4	Severe: incapacitating fullness, with inability to perform normal activities	3
Breathing difficulties	1	No Breathing difficulties	0
	2	Breathing difficulties after heavy work, relieved soon, tolerable	1
	3	Breathing difficulties after moderate work, relieved soon, tolerable	2
	4	Breathing difficulties after light work, relieved later, tolerable	3
	5	Breathing difficulties after light work, relieved later, intolerable	4
Sleep apnea	1	AHI = 0–5 Normal range	0
	2	AHI = 5–15 Mild sleep apnea	1
	3	AHI = 15–30 Moderate sleep apnea	2

	4	AHI > 30 Severe sleep apnea	3

Note: Apnea–hypopnea index (AHI): Number of apneas and/or hypopneas per hour of sleeps (or study time)

All the patients were examined by the physician PI / Co-PI. Laboratory investigations were done at baseline, at first follow up and at the end of the study. After obtaining the screening and baseline reports, each patient was instructed to take the study drug *Jawārish Bisbāsa*-7gm twice daily after meals with luke-warm water. The investigation reports of each of the patients were attached with the CRF and the figure/ values were also noted down in their respective CRF form. A diet chart according to the gender and the physical activity was also provided to each patient.

Dietary Instructions for Enrolled Patients

Patients were categorized into **Active** and **Sedentary** groups based on their physical activity levels:

- **Sedentary**: Minimal physical activity limited to daily routines, no structured exercise.
- **Active**: Includes daily walking (≥3 miles at 3–4 mph) or regular sports activity.

Caloric intake was tailored according to gender and activity level to support weight maintenance or loss:

Table 5:

Gender	Sedentary Lifestyle	Active Lifestyle
Adult Women	1800 calories/day	2200 calories/day
Adult Men	2200 calories/day	2800 calories/day

All participants were instructed to follow a personalized diet chart alongside the prescribed research medication throughout the study.

STUDY DRUG MANAGEMENT

Description of study drug and dosage regimen(s)

The following Unani pharmacopoeial formulation was used in this study: (Anonymous, 2006, Anonymous, 2019)

Study drug	Form	Route	Dose &Frequency	Instructions
Jawārish Bisbāsa	Semi solid	Oral	7gm Twice Daily	Take after meals with lukewarm water

The study drug was prepared at GMP Certified Pharmacy, National Research Institute of Unani Medicine for Skin Disorders (NRIUMSD), Hyderabad as per National Formulary of Unani Medicine, Part I. The drug was packed in 100gm containers and supplied to respective Institutes according to sample size with 20% dropout.

STUDY DRUG COMPOSITION

The composition of study drug *Jawārish Bisbāsa* is as follows: (Anonymous, 2006, Anonymous, 2019)

Table 6:

S.No.	Unani name	Botanical name	Part used	Form	Quantity
1.	*Hīl kalān*	*Amomum subulatum* Roxb.	Fruit	Powder	17.5 g
2.	*Bisbāsa*	*Myristica fragrans* Houtt.	Aril	Powder	3.5 g
3.	*Salīkha*	*Cinnamomum cassia* (L.)J.Presl.	Bark	Powder	3.5 g
4.	*Hīl Khurd*	*Elettaria cardamomum* Maton.	Fruit	Powder	3.5 g
5.	*Zanjabīl*	*Zingiber officinale* Roscoe.	Rhizome	Powder	3.5 g
6.	*Dārchīnī*	*Cinnamomum zeylanicum* Blume.	Bark	Powder	3.5 g

7.	*Asārūn*	*Asarum europaeum* L.	Root	Powder	3.5 g
8.	*Filfil Siyāh*	*Piper nigrum* L.	Fruit	Powder	7 g
9.	*Qaranfal*	*Syzygium aromaticum* Mer. & L.M.Perry.	Bud	Powder	5.25 g
10.	*Nabāt Safayd*	Crystallised Sugar	As such	Solid	70 g
11.	*'Asal*	*Apis mellifera* L.	Honey	Viscous liquid	Q.S.

CONCOMITANT/ADJUVANT THERAPY

No concomitant medication was allowed during the protocol therapy.

LABORATORY INVESTIGATIONS

Each case of *Siman Mufriṭ* (Central Obesity) selected for the study was subjected to the following pathological and biochemical investigations at baseline, 1st follow-up and at the end of treatment and the reports received from the laboratory were attached to the CRF.

Pathological Investigations

- Hematology profile (CBC): Hb, TLC, DLC, RBCs, PCV, and ESR
- Lipid profile: Total Cholesterol, LDL, VLDL, HDL, Triglycerides
- LFTs: S. Bilirubin, SGOT, SGPT, S. Alkaline Phosphatase
- KFTs: S. Urea, S. Creatinine, S. Uric Acid
- Blood sugar Fasting (only at baseline)
- T3,T4 &TSH (only at baseline)
- Urine Examination: Routine & Microscopic

ASSESSMENT OF SAFETY

Safety and tolerability of the trial drug were assessed by the reported adverse events (AEs) during the course of study and any deviation from standard laboratory values at the end of the treatment.

ASSESSMENT OF EFFICACY

The efficacy of the study drug in the treatment of *Siman Mufriṭ* (Central Obesity) (NUMC: M-37) was assessed on the basis of anthropometric parameters including sign and symptoms scoring as per the protocol. All the complaints were scaled on numeric basis.

OBSERVATION AND DISCUSSION

Total 554 subjects were screened for the disease *Siman Mufriṭ* (Central Obesity) (NUMC: M-37) at both the participating centers viz. RRIUM Mumbai and RRIUM Aligarh. Out of them 189 were excluded as they failed to fulfill the criteria of selection. Amongst 189 participants 28.57% (n=54) were excluded because of high blood sugar and interestingly among them 65.21% of individuals were not aware that they were having hyperglycemia; 24.34% (n=46) were hypertensive, out of these 38.70% hypertensive subjects were aware about their hypertensive status; 7.94% (n=15) were found to have insulin level > 15 µU/mL; 21.69% (n=41) participants were found in the screening with deranged thyroid profile; 8.99% (n=17) participants were found with hyperlipidemia; and 8.47% (n=16) participants did not agree to sign the informed consent form after knowing the study details. In this manner, a total of 365 subjects were enrolled in the study, out of them 220 participants completed the trial and 145 participants were dropped out.

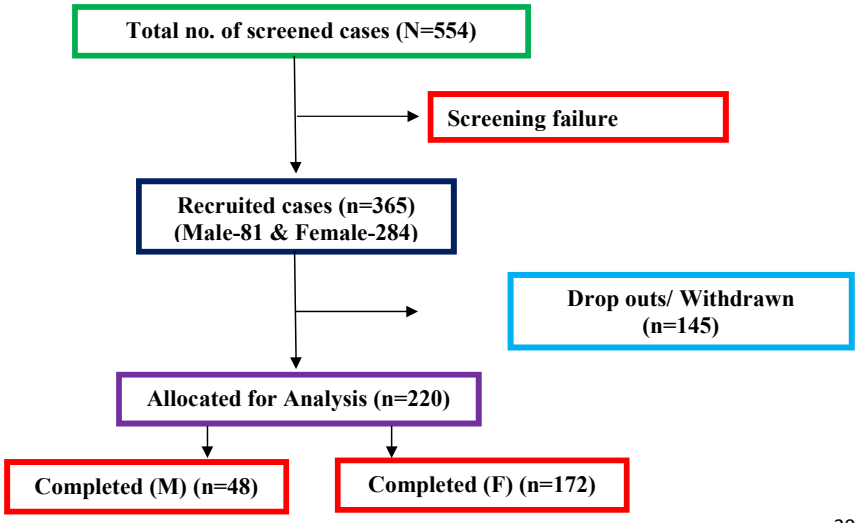

Table 7 Distribution of Excluded participants

Total no. of Exclusion	High Blood Sugar	High Blood Pressure	High Insulin Level	Deranged Thyroid Profile	Deranged Lipid profile	Refused to sign Consent
189	54	46	15	41	17	16

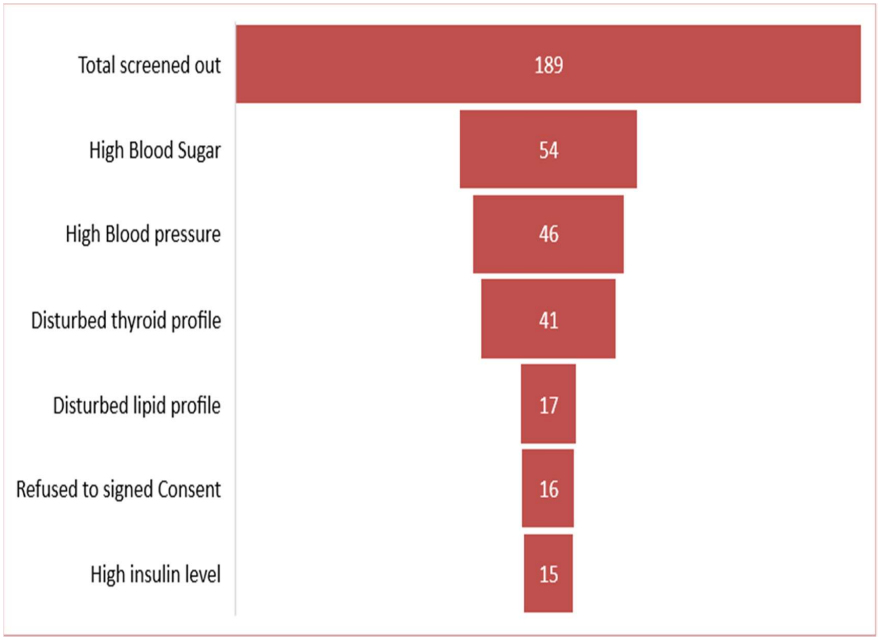

Fig. 5

In present study involving 220 participants, 48 (21.81%) were male and 172 (78.19%) were female, indicating a higher prevalence of central obesity among women. These findings align with data from the National Family Health Survey-5 (2019–2021), which reported abdominal obesity rates of 40% in women and 12% in men (Chaudhary & Sharma, 2023). National data suggest that 5 to 6 out of every 10 women aged 30–49 are abdominally obese. Several Indian studies also highlight that pregnancy contributes significantly to long-term abdominal obesity, with gestational fat often

persisting post-delivery in most cases. (Jain, 2012; Dasgupta, 2014; Quiner, 2017;Kutchi, 2020). The disproportionate representation of females in our sample further supports this trend (Table 8; Fig.6)

Table 8- Distribution of participants according to the Gender

Characteristics	Number of Cases
Male (n%)	48 (21.81%)
Female (n%)	172 (78.19%)

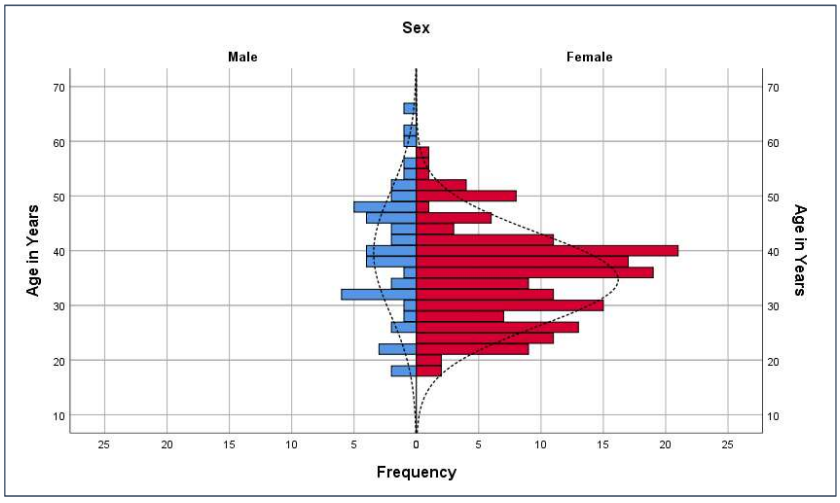

Fig. 6

In this study, out of the total participants, 32 (14.55%) identified as Hindu and 188 (85.45%) as Muslim. This distribution may be attributed to the geographic locations of the study centers which are situated in areas with predominantly Muslim populations.

While analyzing the data by gender and religion, it was found that among Muslim participants, 156 were female and 32 were male. In contrast, the non-Muslim group comprised 16 females and 16 males, indicating a balanced gender representation among Hindus. Among the Muslim subgroup, 17.02% (32) were male and 82.97%(172) were female. This suggests a significantly higher enrollment of Muslim females in the study.

Table 9- Cross-tab distribution of participants according to Marital status, Religion & Gender:

Gender		Religion	Marital Status		Total
			Married	Unmarried	
Male	Religion	Hindu	14	2	16
		Muslim	30	2	32
	Total		44	4	48
Female	Religion	Hindu	15	1	16
		Muslim	124	32	156
	Total		139	33	172
Total	Religion	Hindu	29	3	32
		Muslim	154	34	188
	Total		183	37	220

The study also revealed that a majority of participants i.e. 83.19%were married, while only 16.81% were unmarried. The prevalence of central obesity among pregnant women appeared consistent across both religious communities. Among the 37 unmarried participants, 34 were Muslim and 3 were Hindu, indicating a higher proportion of unmarried individuals within the Muslim subgroup.

Table10- Distribution of participants according to Addiction

Addiction		Number of Cases	Percentage (%)
Smoking	No	211	95.90%
	Yes	09	4.10%
Tobacco chewing	No	210	95.45%
	Yes	10	4.54%

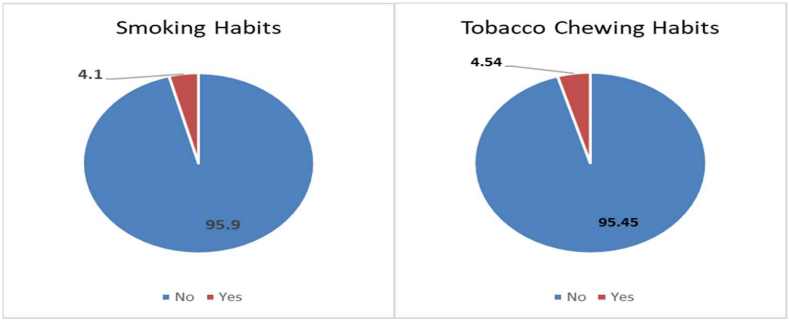

Fig. 7

Table 11- Distribution of participants according to Dietary Habits:

Characteristics	Number of Cases
Vegetarian	17(7.73%)
Non - Vegetarian	203 (92.27%)

Fig. 8

Table 12-Cross-tab distribution of participants according to Gender, Dietary Pattern &Religion:

Religion	Gender		Dietary Pattern		Total
			Non-Vegetarian	Vegetarian	
Hindu	Sex	Male	10	6	16
		Female	10	6	16
	Total		**20**	**12**	**32**
Muslim	Sex	Male	32	0	32
		Female	151	5	156
	Total		**183**	**5**	**188**
Total	Sex	Male	42	6	48
		Female	161	11	172
	Total		**203**	**17**	**220**

In this study, dietary preferences showed that 17 participants were vegetarian, while the majority—203 participants—consumed a non-vegetarian diet. Among the vegetarians, 12 were non-Muslim and 5 were Muslim. Gender-wise, 11 of the vegetarian participants were female and 6 were male.

Table13- Distribution of participants according to Duration of disease

Duration of diseases	Male	Female	Total	Percentage
≤1 yr.	9	28	37	16.81%
>1 - ≤2 yrs.	9	38	47	21.36%
>2 - ≤3 yrs.	15	50	65	29.54%
>3 yrs.	15	56	71	32.29%
Total	**48**	**172**	**220**	

Graph: Distribution of participants according to duration of disease condition

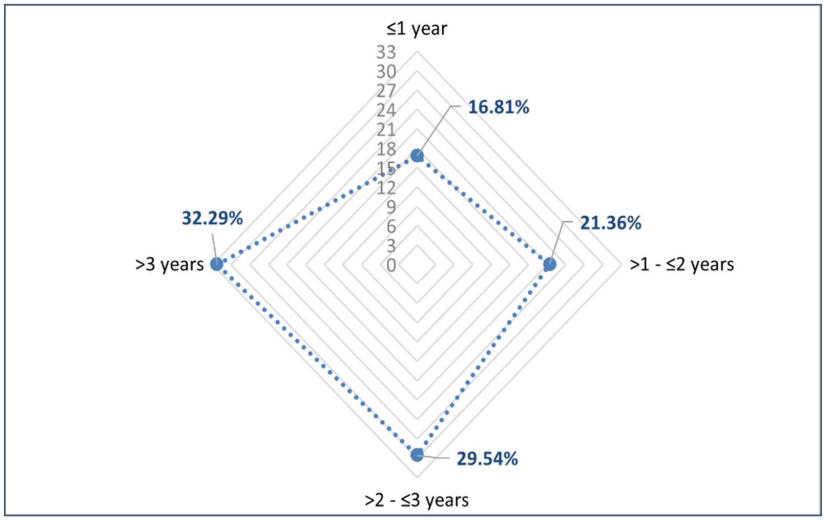

Fig. 9

The prevalence of obesity in India stands at 40.3%, with notable regional variations i.e.southern India reports the highest rate at 46.51%, while the eastern region has the lowest at 32.96(Subramanyam,2010).

In the present study, the largest proportion of participants, 71 individuals (32.29%), had been living with central obesity for three years or longer, reflecting a tendency toward delayed intervention within the study population. This was followed by 65 participants (29.54%) who reported a duration of 2–3 years. A comparatively smaller group of 37 participants (16.18%) had experienced central obesity for less than one year, while 47 participants (21.36%) indicated a duration of 1–2 years.

Table14- Distribution of participants according to *Mizāj* (Temperament)

***Mizāj* (Temperament)**	**Male**	**Female**	**Total**	**Percentage**
***Damawī* (Sanguine)**	13	59	72	32.73%
***Balghamī* (Phlegmatic)**	22	98	120	54.55%
***Ṣafrāwī* (Bilious)**	10	11	21	9.54%
***Sawdāwī* (Melancholic)**	3	4	7	3.18%
Total	**48**	**172**	**220**	

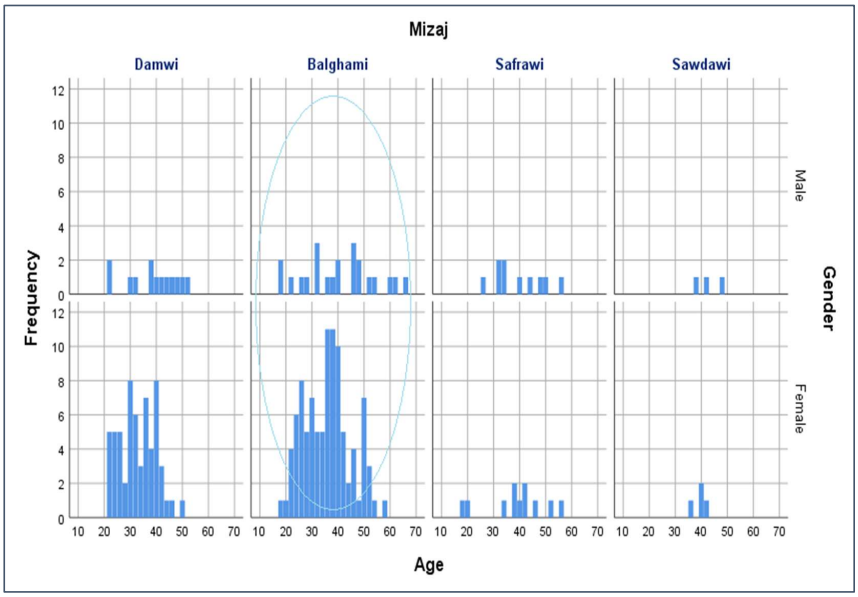

Fig. 10

In this study, the majority of participants (120 out of 220 i.e. 54.55%) exhibited a phlegmatic or *Balghamī* temperament. The second most common *Mizāj* was sanguine or *Damawī*, observed in 72 individuals (32.73%), followed by bilious i.e. *Ṣafrāwī* temperament in 21 participants (9.54%), and *Sawdāwī* (melancholic) in only 7 participants (3.18%).

Among those with a phlegmatic temperament, 81.66% were female and 18.44% were male. A similar gender distribution was noted in the sanguine group, with 81.94% female and 18.05% male. Although the bilious and melancholic groups were much smaller in number, their gender ratios were nearly balanced. Specifically, among bilious participants, 10 were male and 11 were female; among melancholic participants, 4 were female and 3 were male.

These findings suggest that while phlegmatic and sanguine temperaments are more prevalent among females, there is no significant gender-based variation in the distribution of bilious and melancholic temperaments in relation to central obesity.

Table 15- Distribution of Participants according to Socio-economic Status

Income Group	Total	Percentage
Low	63	28.64%
Middle	100	45.45%
High	57	25.91%
Total	**220**	

An analysis of central obesity in relation to socio-economic status revealed that the largest proportion of participants belonged to the middle-income group (100 individuals; 45.45%), followed by those from low-income backgrounds (63 individuals; 28.64%), and finally the high-income group (57 individuals; 25.91%). These findings challenge the prevailing societal perception that central obesity is primarily associated with higher socio-economic status. Instead, they underscore the importance of considering additional contributing factors such as physical inactivity, frequent consumption of street and junk foods, and lifestyle-related behaviors that may exert a stronger influence on the development of central obesity across all economic strata. Furthermore, the predominance of middle and lower-income populations seeking care in government health facilities may partly explain the observed distribution in this study.

Table 16 Effect of *Jawārish Bisbāsa* on Body weight

Baseline	After treatment	Mean difference	Statics (Paired t test)	'p' value
76.41±10.67	73.74±10.68	2.67	(1.965-3.375)	<0.001*

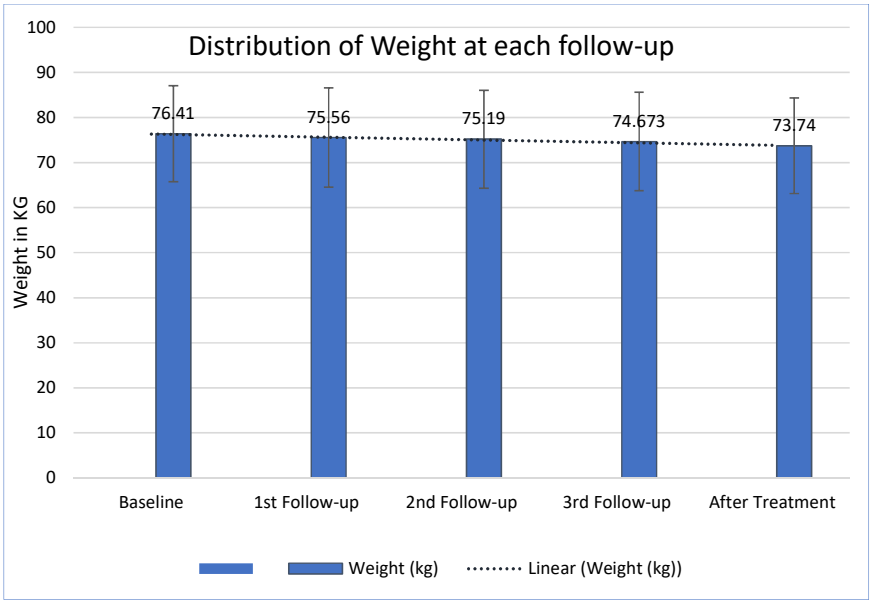

Fig. 11

The obesity epidemic in India is impacting individuals across all age groups and poses a serious threat to active life expectancy. Notably, the prevalence of overweight and obesity among children and adolescents has shown a sharp rise from 11.7% in 2006 to 22.1% in 2011 (Venkatrao2020).

Although Body Mass Index (BMI) is commonly used as a proxy for adiposity, it primarily reflects excess weight relative to height rather than actual body fat. Its interpretation in children and adolescents is further complicated by dynamic changes in growth, including fluctuations in weight, height, and body composition (Gupta 2012; Franklin 1999).

In the present study, participants had an average body weight of 76.41 kg prior to treatment. Following an eight-week treatment of *Jawārish Bisbāsa*, the average weight reduced to 73.74 kg. This reduction was found to be statistically significant, indicating that *Jawārish Bisbāsa* may be effective in managing body weight among individuals with central obesity.

Table 17: Effect of *Jawārish Bisbāsa* on BMI

Baseline	After treatment	Mean difference	Statics (Paired t test)	'p' value
31.038±3.71	30.14±3.80	1.07	10.521	<0.001*

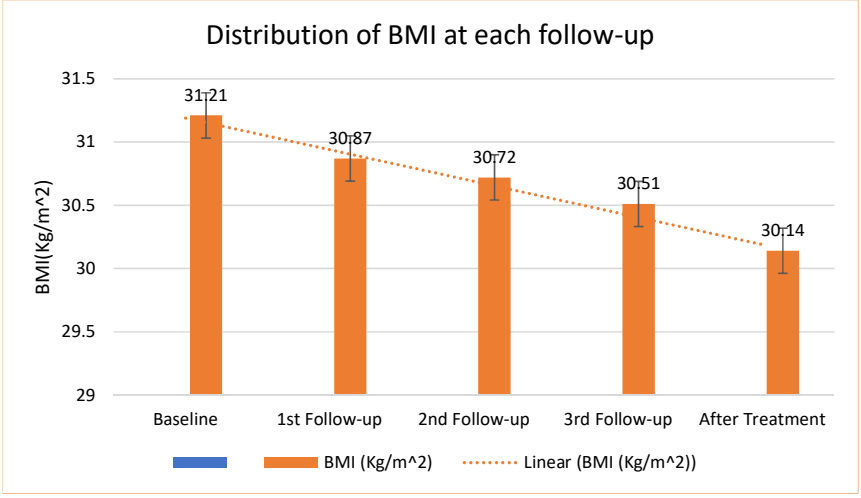

Fig.12

Body Mass Index (BMI) is a widely accepted screening tool for identifying overweight and obesity, calculated as weight in kilograms divided by height in meters squared (kg/m²). Though commonly used, BMI reflects excess weight relative to height rather than direct body fat. In this study, the mean baseline BMI was 31.038 ± 3.71, which significantly decreased to 30.14 ± 3.80 after eight weeks of treatment with the Unani pharmacopoeial formulation *Jawārish Bisbāsa*. The mean reduction of 1.07 was statistically significant ($P < 0.001$), indicating the formulation's potential efficacy in managing obesity.

This outcome aligns with findings from other traditional and herbal interventions, such as the Korean formulation LI85008F (a blend of Moringa oleifera, Murrayakoenigii, and Curcuma longa), as well as *Itrifal Sagheer*, 18KHT01, *Carum carvi* L., *Nigella sativa* L., *Trigonella foenum-graecum* L., and *Ziziphus jujube* Mill (Li 2023;Choi 2021;Kamali

2012; Pandeya 2021; Kazemipoor 2013; Najmi 2008; Razavi 2014; Chevassus2010; Gao 2013; Mostafa 2013; Kubota 2009).

Table 18: Effect of *Jawārish Bisbāsa* on Waist Circumference

Mean+SD		Mean difference	Statics (Paired t test)	'p' value
Baseline	**After treatment**			
100.33±10.247	96.93±10.49	3.39	16.951	<0.001*

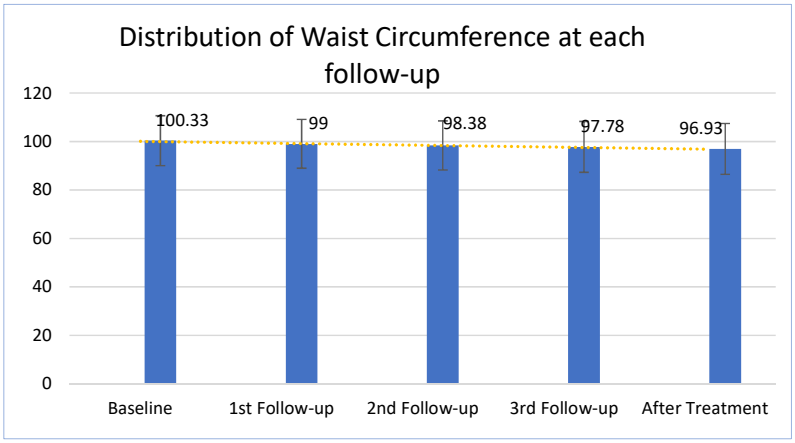

Fig.13

Body fat distribution has long been recognized as a critical risk factor for diseases such as cardiovascular disease (CVD), hypertension, stroke, and type 2 diabetes mellitus (T2DM). Jean Vague first highlighted this in 1956 by classifying obesity into 'android' and 'gynoid' types (Vague 1956), later interpreted by Kissebah *et al.* as upper versus lower body fat accumulation, and measured via waist–hip ratio (WHR) (Kissebah1982). WHR gained prominence when studies in the USA and Sweden linked it to increased mortality and disease risk (Krotkiewski 1983; Hartz 1983; Larsson 1984). However, subsequent research showed that waist circumference (WC) alone is a stronger indicator of visceral fat and associated health risks (Ohlson 1985; Snijder 2006).

In this study, the mean WC decreased from 100.33 ± 10.25 cm to 96.93 ± 10.49 cm after 8 weeks of treatment with *Jawārish Bisbāsa,* showing a statistically significant reduction of 3.39 cm ($p < 0.001$). This supports the efficacy of the Unani formulation in managing central obesity, consistent with findings from other herbal interventions such as turmeric with black seed (Neeland 2019) and cardamom supplementation (Amin 2015).

Table 19: Effect of *Jawārish Bisbāsa* on Waist Hip Ratio (WHR)

Baseline	After treatment	Mean difference	Statics (Paired t test)	'p' value
0.92±0.06	0.89±0.07	0.03	7.817	<0.001*

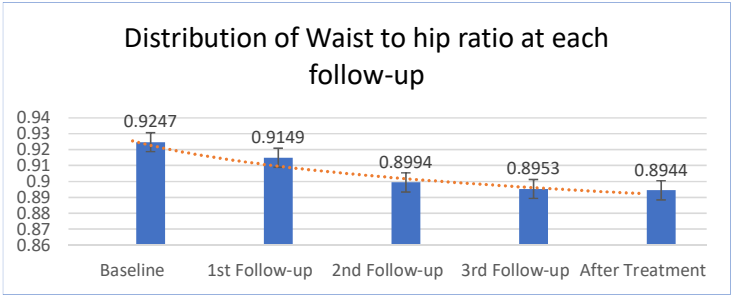

Fig. 14

Waist circumference (WC) is a key indicator of central obesity and a diagnostic tool for metabolic risk. According to WHO, WC > 94 cm in men and > 80 cm in women signals increased risk, with higher thresholds (> 102 cm in men and > 88 cm in women) indicating significantly elevated risk. For Asian populations, the cut-offs are lower: > 90 cm for men and > 80 cm for women. WC is simple to measure and avoids confounding factors like skeletal muscle mass (Fatemeh, 2017; Han, 2006; Baioumi, 2019).

In this study, the mean waist–hip ratio (WHR) decreased from 0.92 ± 0.06 to 0.89 ± 0.07 after eight weeks of treatment with *Jawārish Bisbāsa.*The mean reduction of 0.03 was statistically significant ($p < 0.001$), indicating the formulation's efficacy in reducing WHR among individuals with central obesity. Similar reductions in WHR have been reported with other Unani and herbal interventions, including *Nigella*

sativa(Datau, 2010), catechin-rich green tea(Wang, 2009), whole grains(Venn, 2010), and *Lycium barbarum* (Amagase, 2011; Chu, 2011).

Table20- Effect of *Jawārish Bisbāsa* on Sagittal Abdominal Diameter (SAD)

Baseline	After treatment	Mean difference	Statics (Paired t test)	'p' value
29.29±2.28	27.06±2.22	2.23	1.89-2.56	<0.001*

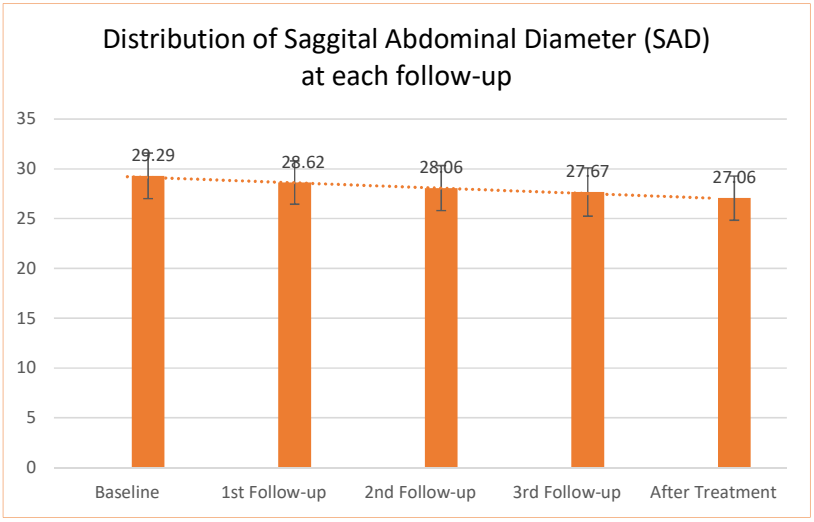

Fig.15

Sagittal abdominal diameter (SAD), which measures the anteroposterior dimension of the abdomen, is a reliable anthropometric indicator of visceral adipose tissue (VAT), particularly in Asian populations. SAD reflects VAT by accounting for the gravitational displacement of subcutaneous fat. Although SAD has been explored for its association with visceral obesity and related cardiovascular and metabolic risks (Kvist, 1988; K van, 1993; Zamboni, 1998; Kullberg, 2007; Empana, 2004; Risérus, 2004), existing studies are limited by small sample sizes and selection bias and are mostly from Western populations. More large-scale, population-based research is needed in Asian contexts.

In this study, the mean SAD decreased from 29.29 ± 2.28 cm at baseline to 27.06 ± 2.22 cm after 56 days of treatment with *Jawārish Bisbāsa*, showing a statistically significant reduction of 2.23 cm ($p < 0.001$). This suggests the test formulation may effectively reduce visceral obesity.

Table 21: Distribution of Participants based on Heart Burn and effect of *Jawārish Bisbāsa*

Heart Burn (n%)	Follow-ups				
	BL	1st	2nd	3rd	AT
No heart burn	0 (0.0%)	10 (4.55%)	14 (6.36%)	37 (16.82%)	108 (49.09%)
Awareness of heart burn but easily tolerated	50 (22.73%)	98 (44.55%)	134 (60.91%)	163 (74.09%)	104 (47.27%)
Discomforting heartburn sufficient to cause interference with normal activity, including sleep	102 (46.36%)	92 (41.82%)	69 (31.36%)	17 (7.73%)	8 (3.64%)
Incapacitating heartburn, with inability to perform normal activities	68 (30.91%)	20 (9.09%)	3 (1.36%)	3 (1.36%)	0 (0.0%)

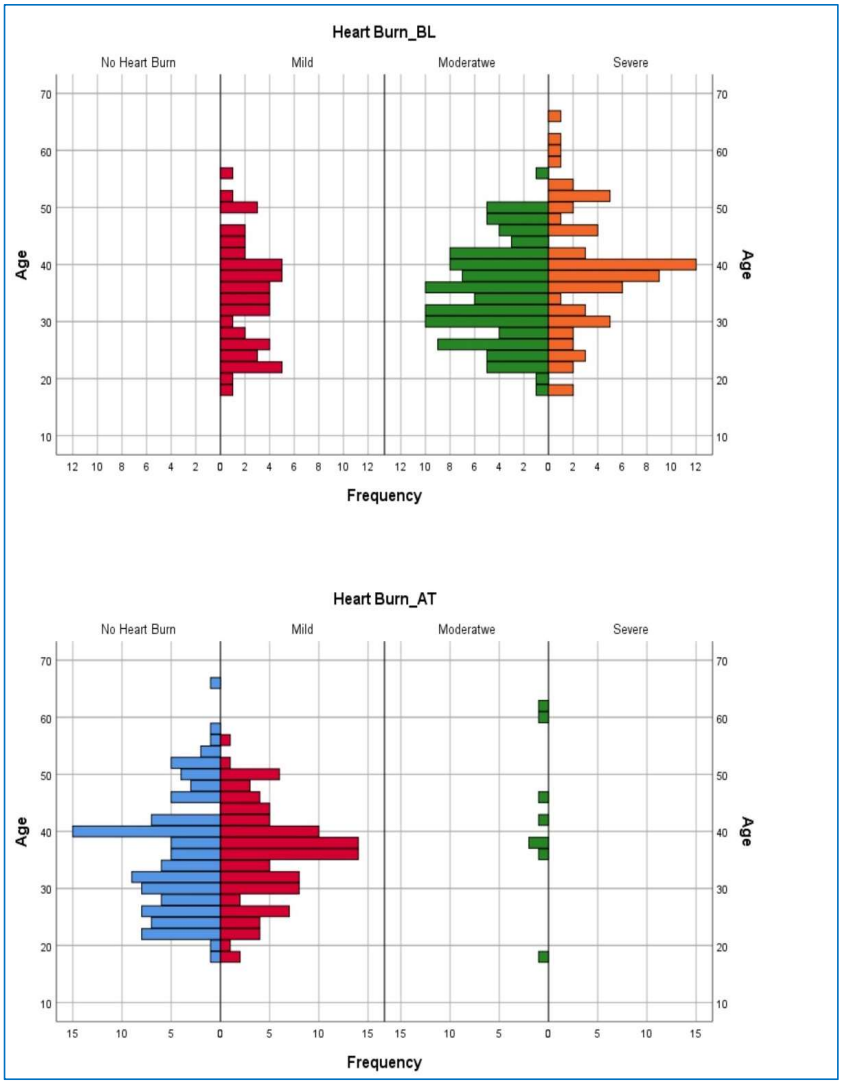

Fig.16

In this study, heartburn severity was categorized as none, mild, moderate, or severe. At baseline, 22.73% of participants reported mild symptoms, 46.36% moderate, and 30.91% severe. After eight weeks of treatment with *Jawārish Bisbāsa*, 108 participants (49.09%) reported no symptoms, 104 (47.27%) had mild symptoms, and only 8 (3.64%) experienced moderate discomfort. Notably, no participants reported severe heartburn post-treatment, indicating a significant therapeutic effect. These findings align with previous studies on herbal remedies for heart burn, including Chinese

formulations and a combination of *Pistacia lentiscus* and *Coriander,Triphala,- Terminalia chebula R., Terminalia bellirica R., Emblica officinalis G.,* which have shown similar improvements in reflux -related symptoms (Dai, 2020; Sadeghi, 2020).

Table 22 Distribution of Participants based on Fullness of Stomach and effect of *Jawārish Bisbāsa*

Fullness of Stomach (n%)					
No Fullness of stomach	1 (0.45%)	9 (4.09%)	23 (10.45%)	44 (20.0%)	129 (58.64%)
Mild: Feeling fullness of abdomen uncomfortable but tolerated	22 (10.0%)	66 (30.0%)	106 (48.18%)	146 (66.36%)	80 (36.36%)
Moderate: discomforting fullness sufficient to cause interference with normal activity, including sitting and sleeping	94 (42.73%)	128 (58.18%)	88 (40.0%)	29 (13.18%)	11 (5%)
Severe: incapacitating fullness, with inability to perform normal activities	103 (46.82%)	17 (7.73%)	3 (1.36%)	1 (0.45%)	0 (0.0%)

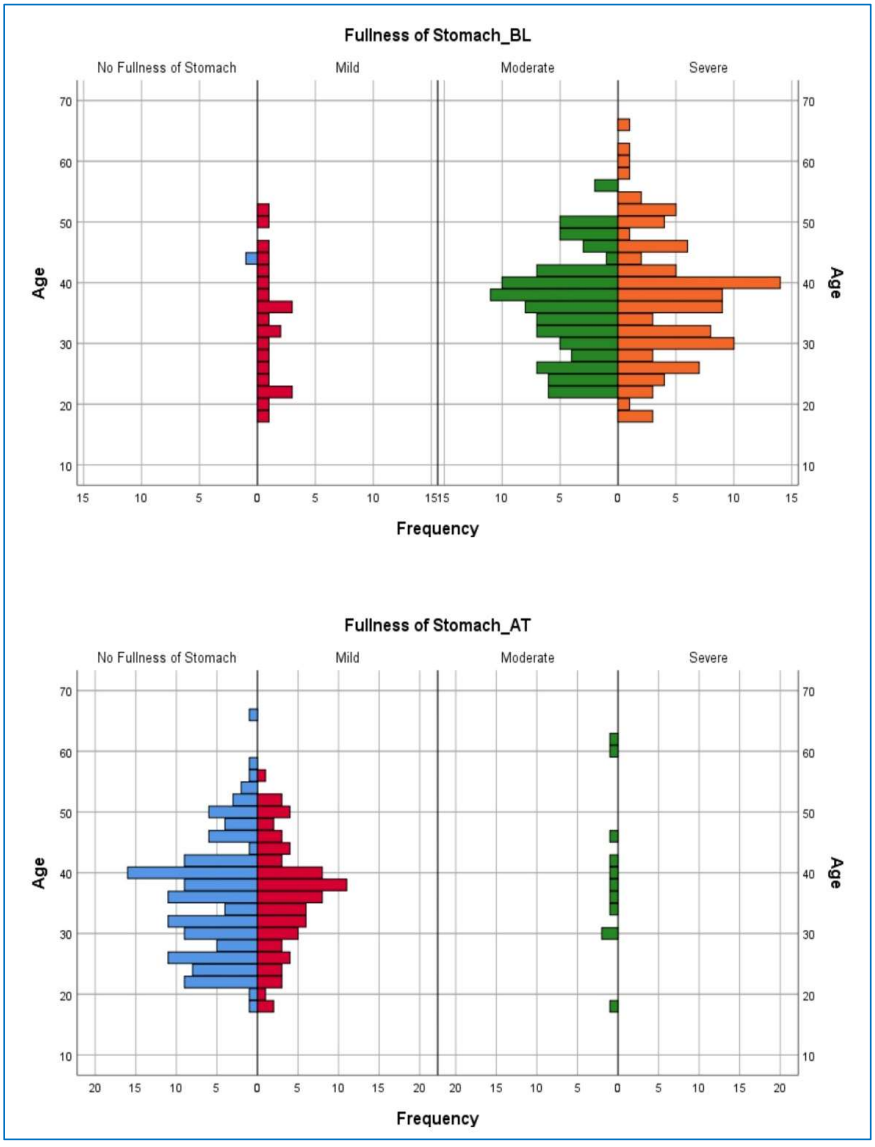

Fig.17

In this study, at baseline, 103 participants (46.82%) reported severe abdominal fullness, 94 (42.73%) moderate, 22 (10%) mild, and only 1 (0.45%) reported no fullness. After eight weeks of treatment with *Jawārish Bisbāsa*, no participants reported severe fullness. Instead, 129 (58.46%) experienced no symptoms, 80 (36.36%) had mild fullness, and only 11 (5%) reported moderate discomfort. This improvement suggests that *Jawārish Bisbāsa* may alleviate abdominal fullness,

possibly due to its carminative, digestive, and anti-adipose properties (Trayhurn, 2013; Wang, 2013).

Table 23: Distribution of Participants based on Breathing difficulties and effect of *Jawārish Bisbāsa*

Breathing difficulties (n%)					
No Breathing difficulties	1 (0.45%)	10 (4.55%)	16 (7.27%)	56 (25.45%)	107 (48.64%)
Breathing difficulties after heavy work, relieved soon,tolerable	17 (7.73%)	49 (22.27%)	108 (49.09%)	120 (54.55%)	94 (42.73%)
Breathing difficulties after moderate work, relieved soon, tolerable	79 (35.91%)	127 (57.73%)	82 (37.27%)	37 (16.82%)	18 (8.18%)
Breathing difficulties after light work, relieved later, tolerable	123 (55.91%)	34 (15.45%)	14 (6.36%)	7 (3.18%)	1 (0.45%)
Breathing difficulties after light work, relieved later, intolerable	0	0	0	0	0

Obesity Hypoventilation Syndrome (OHS), also known as Pickwickian Syndrome, is a respiratory condition seen in individuals with obesity. It shares many clinical features with Obstructive Sleep Apnea (OSA), and while the two often coexist, they can occur independently. A prior diagnosis of OSA significantly increases the risk of developing OHS. The syndrome is characterized by inadequate ventilation, resulting in elevated carbon dioxide and reduced oxygen levels in the blood. Although the exact cause remains unclear, it is believed to involve impaired respiratory control in the brain, compounded by excess body weight restricting chest wall movement. This mechanical and neurological interplay disrupts normal breathing patterns. (Malhotra, 2024; Mokhlesi, 2019 & 2022).

Present study demonstrates that only 01(0.45%) patient reported no breathing difficulty at baseline, while the majority 123(55.91%) experienced mild breathlessness after light activity, which was tolerable and resolved later. Another 79(35.91%) reported moderate breathlessness after exertion, and 17(7.73%) had general breathlessness even at rest. After eight weeks of treatment with *Jawārish Bisbāsa*, significant improvement was observed, i.e. 94% of participants reported no breathing difficulty, with only 01participantcontinuing to experience mild symptoms after light work. Additionally, 18 participants reported moderate breathlessness after heavy exertion, which was tolerable and resolved quickly. These findings suggest that *Jawārish Bisbāsa* may effectively alleviate breathing difficulties associated with OHS.

Table 24: Distribution of Participants based on Sleep Apnea and effect of *Jawārish Bisbāsa*

Sleep Apnea (n%)					
AHI = 0–5 Normal range	48 (21.82%)	82 (37.27%)	130 (59.09%)	167 (75.91%)	197 (89.55%)
AHI = 5–15 Mild sleep apnea	90 (40.91%	91 (41.46%)	74 (33.64%)	43 (19.55%)	19 (8.64%)
AHI = 15–30 Moderate sleep apnea	53 (24.09%)	41 (18.64%)	14 (6.36%)	10 (4.55%)	4 (1.82%)
AHI > 30 Severe sleep apnea	29 (13.18%)	6 (2.73%)	2 (0.91%)	0	0

Obstructive Sleep Apnea (OSA) is a clinical disorder characterized by repeated episodes of upper airway (UA) collapse during sleep, resulting in reduced (hypopnea) or absent (apnea) airflow. These events often lead to oxygen desaturation and are typically interrupted by brief arousals, causing sleep fragmentation and excessive daytime sleepiness. This sleepiness significantly impairs quality of life, cognitive

function, and social performance, and is associated with increased risk of road traffic and occupational accidents (McNicholas, 2006). The major health burden of OSA, however, lies in its strong association with cardiovascular diseases such as hypertension, coronary artery disease, heart failure, and stroke (McNicholas, 2007). Obesity is strongly linked with OSA. Its prevalence in obese subjects exceeds 30%, and approximately 60–90% of OSA subjects are obese (Peppard,2000). In obese individuals, fat deposition around the pharyngeal walls and external compression narrows the airway and increases tissue pressure, promoting UA collapsibility. (Shelton, 1993; Schwartz, 2010).

In this study, 90(40.91%) of obese participants had mild sleep apnea (AHI 5–15), 53(24.09%) had moderate (AHI 15–30), and 29(13.18%) had severe apnea (AHI >30), while 48(21.82%) had normal AHI scores (0–5). Following 8 weeks of treatment with JB, no participants remained in the severe category; 197(89.55%) had normal AHI scores, 19(8.64%) had mild apnea, and only 4(1.82%) had moderate apnea. These findings suggest that *Jawārish Bisbāsa* improved sleep quality and reduced the severity of OSA in this population.

Table 25: Distribution of Male participants based on Waist to Hip Ratio

Health Risk	Male (n=48)	At Baseline	After Treatment
Low Risk	≤0.95	13	30
Moderate Risk	0.96 to 1.0	23	10
High Risk	>1.0	12	8

In this study, obesity risk among male patients was assessed before and after eight weeks of treatment with JB. At baseline, 13 participants were classified as low risk, 23 as moderate risk, and 12 as high risk. Following treatment, the number of low-risk participants increased to 30. Among the moderate-risk group, 10 remained in that category, while in the high-risk group, only 8 participants continued to be classified as high risk. The most notable improvement was observed in participants initially at

moderate and high risk, indicating that JB treatment had an impact in reducing obesity-related risk levels in these groups.

Table 26: Distribution of Female participants based on Waist to Hip Ratio

Health Risk	Female (n=172)	At Baseline	After Treatment
Low Risk	≤0.80	0	13
Moderate Risk	0.81 to 0.85	31	45
High Risk	>0.85	141	114

In this study, female participants were assessed for cardiovascular risk based on waist-to-hip ratio. At baseline, 31 participants were classified as moderate risk and 141 as high risk, while only a small number were at low risk. After eight weeks of treatment with JB, the distribution shifted notably: 13 participants were now at low risk, 45 at moderate risk, and 114 remained at high risk. This reduction in the number of high-risk individuals and increase in those at lower risk suggests that JB may contribute to lowering cardiovascular risk among female patients. The findings indicate a positive therapeutic effect in mitigating obesity-related risk factors and potentially reducing the likelihood of developing cardiovascular diseases.

SAFETY EVALUATION

Table 27: Effect of *Jawārish Bisbāsa* on Haematological profile

Name of Parameter	Mean ± SD		Paired 't' test	
	Before Treatment	After Treatment	Statistic value	p-value
Hb (gm/dL)	12.39±1.50	12.16 ± 1.88	1.786	0.078
TLC	7907.73 ± 1732.75	7876.67 ± 2391.19	0.172	0.864

DLC	N (%)	60.20 ± 9.72	59.76 ± 10.06	0.482	0.631
	L (%)	30.68 ± 7.45	33.57 ± 20.79	-1.176	0.243
	E (%)	7.54 ± 3.60	6.88 ± 4.05	1.461	0.148
	M (%)	1.37 ± .78	1.45 ± .99	-0.604	0.548
	B (%)	0.09 ± 0.80	0.01 ± 0.115	0.847	0.400
ESR 1st Hr.		33.14 ± 11.83	32.55 ± 12.04	0.623	0.535
ESR 2nd Hr.		43.58 ± 10.59	40.81 ± 15.22	1.760	0.083

In this study, the test drug *Jawārish Bisbāsa* showed no significant impact on participants' hemogram profiles, indicating its safety in cases of central obesity. Hemoglobin levels showed a minimal decrease from 12.39 g/dL at baseline to 12.16 g/dL post-treatment, which was statistically insignificant. Similarly, total leukocyte count (TLC) changed slightly from 7900 to 7876, with no meaningful clinical significance. Neutrophil levels decreased marginally from 60.20% to 59.76%, while lymphocyte counts rose from 30.68% to 33.57%; both changes were statistically non-significant. Eosinophil levels dropped from 7.54% to 6.88%, and monocytes increased from 1.37% to 1.45%. Basophils showed a decrease from 0.09% to 0.01%, but given their limited clinical relevance in this context, the change was not considered impactful. Erythrocyte Sedimentation Rate (ESR) also remained stable, with first-hour values shifting from 33.14 mm/hr to 32.55 mm/hr, and second-hour values from 43.58 mm/hr to 40.81 mm/hr—none of which were statistically significant. Overall, these findings confirm that *Jawārish Bisbāsa* does not adversely affect hematological parameters and can be considered safe for long-term use in patients with central obesity.

Table 28: Effect of *Jawārish Bisbāsa* on Liver profile

S. Bilirubin	0.65±0.25	0.64±0.25	0.177	0.860
SGOT (IU/L)	27.12±15.06	24.55±14.45	3.318	0.001
SGPT (IU/L)	31.73±25.67	27.80±21.49	3.837	0.000

S. Alkaline Phosphates	81.53±25.67	79.56±24.93	1.241	0.216

Table 28 highlights the effect of *Jawārish Bisbāsa* on liver functions in participants having central obesity. Total serum bilirubin showed a minimal decrease from 0.65 mg/dL at baseline to 0.64 mg/dL post-treatment, which was not statistically significant. SGOT levels dropped from 27.12 U/L to 24.55 U/L, and SGPT levels from 31.73 U/L to 27.80 U/L—both reductions remained within normal limits and did not indicate any hepatic toxicity. Serum alkaline phosphatase also decreased slightly from 81.53 U/L to 79.56 U/L, with no significant change observed. These findings suggest that *Jawārish Bisbāsa* does not adversely affect liver function and can be considered safe for use over an eight-week period in participants with central obesity.

Table 29: Effect of *Jawārish Bisbāsa* on Kidney profile

S. Creatinine (mg/100 ml)	0.86 ± 0.13	0.79 ± 0.19	3.170	0.002
BUN (mg/dL)	10.48 ± 4.47	10.25 ± 3.97	0.500	0.618

It is well established that most drugs are metabolized in the liver and excreted through the kidneys, raising the potential for renal side effects. However, in this study, *Jawārish Bisbāsa* showed no significant impact on kidney function. Table 29 showed, Serum creatinine levels decreased slightly from 0.86 mg/dL at baseline to 0.79 mg/dL post-treatment, and blood urea nitrogen (BUN) levels dropped from 10.48 mg/dL at baseline to 10.25 mg/dL after treatment. These changes were not statistically significant, indicating that the drug does not adversely affect renal function and can be considered safe for use in participants with central obesity.

Table 30: Effect *of Jawārish Bisbāsa* on Lipid profile

Total Cholesterol	171.85 ± 44.33	177.30 ± 33.09	-0.998	0.322
HDL	50.08 ± 8.51	51.67 ± 22.46	0.634	0.528
LDL	107.61 ± 31.01	111.58 ± 31.93	-0.996	0.322
VLDL	28.00 ± 25.06	25.65 ± 11.37	0.879	0.382

Triglycerides	117.63 ± 62.56	122.80 ± 56.03	-0.711	0.479

The effect of *Jawārish Bisbāsa* on lipid profile was evaluated in this study. In table 30 Total cholesterol levels showed a slight increase from 171.85 mg/dL at baseline to 177.30 mg/dL after treatment. Among other parameters HDL showed minor increase from 50.08 at baseline to 51.67 after treatment. LDL also got increased from 107.61 at baseline to 111.58 after treatment. Similarly Triglycerides also showed a slight increment from baseline value 117.63 to 122.80 after treatment. VLDL on the other hand showed slight decrease from baseline 28.0 to 25.65 after treatment. However, all these changes were not statistically significant and remained within the normal range suggesting that the test drug does not have any adverse effects on lipid profile.

.SUMMARY AND CONCLUSION

Globally, obesity is responsible for approximately 2.8 million adult deaths each year. It accounts for 44% of diabetes cases, 23% of ischemic heart disease, and between 7% to 41% of the burden from specific types of cancer. Obesity is broadly categorized into general and central (abdominal) obesity, based on the distribution of adipose tissue. Central obesity refers to excessive fat accumulation in the abdominal region and is defined by a waist circumference exceeding 80 cm in women and 94 cm in men. The Body Mass Index (BMI), which adjusts weight for height, remains the most commonly used metric for assessing overweight and obesity. However, emerging evidence suggests that indicators of abdominal adiposity, such as waist circumference, waist-to-hip ratio, and waist-to-height ratio, may be more accurate predictors of cardiovascular disease (CVD) risk than BMI alone.

Siman Mufriṭ or central obesity is considered a *Balghamī* (phlegmatic) disorder, driven by the predominance of *Khilṭ-i-Balgham* (phlegmatic humour) in Unani medicine. Based on ancient wisdom Unani scholars devised a complete line of treatment which includes the use of single and compound formulations.

This clinical study aimed to evaluate the safety and efficacy of one such formulation i.e.*Jawārish Bisbāsa* in treating central obesity. *Jawārish Bisbāsa* demonstrated a beneficial effect in alleviating signs and symptoms associated with central obesity. Across the clinical study parameters *viz.* anthropometric indices, clinical &respiratory

symptoms, sleep quality, and other cardiovascular risk factors, showed measurable improvement. Importantly, the drug did not produce any statistically significant changes in hematological profiles, liver profile, renal function, or inflammatory markers such as ESR. These findings affirm the safety profile of *Jawārish Bisbāsa* over the eight-week treatment period.

One notable observation was the higher-than-anticipated dropout rate. While an attrition rate of 20% was initially projected, the actual dropout reached approximately 40%. This discrepancy highlights the need for future herbal clinical trials to account for higher participant attrition, possibly due to the longer duration, lifestyle demands, or expectations associated with traditional formulations. Despite the dropout, the study yielded promising results.

In conclusion, *Jawārish Bisbāsa* appears to be a safe and potentially effective herbal formulation for treating central obesity. Its use did not compromise key organ functions and showed encouraging results in symptom control. Future studies with larger sample sizes and strategies to minimize dropout will be essential to further validate these outcomes and support its integration into obesity management protocols.

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Annexure-I

SCREENING FORM

Clinical Validation of a Unani Pharmocopoeial Formulation *Jawārish Bisbāsa* in *Siman Mufriṭ* (Central Obesity) (NUMC: M-37)

Protocol No: SM/CO/JB/CLNVAL/CCRUM/16-17 Version No: 01

1. Centre Code: _____ Code No. _____
2. Trial code: _____
3. Screening No.: _____
4. Date of Birth: _____
5. Age (in years): _____
6. Gender: Male/ Female
7. Caste: SC/ ST/ BC/ OC
8. Address:

   _____

   _____

   _____
9. Phone: _____
10. Marital Status Married/ Unmarried
11. Social Status Poor/ Average/ Good
12. Occupation: _____
13. Dietary Pattern Veg/ Non-Veg
14. Smoking: Yes/ No
15. Tobacco chewing: Yes/ No
16. History of addiction (drugs/Alcohol Consumption): Yes/ No
17. Height (cm.):
18. Weight (kg.):
19. B.P.: _____ Pulse: _____
20. Is the patient on any other treatment including use of alternative medicine
    Yes/ No
21. Previous treatment taken for ***Siman Mufriṭ*** (Central Obesity)

Treatment	Duration	Response
Allopathy		
Ayurvedic		
Unani		
Homeopathy		

21. Is the patient having ***Siman Mufriṭ*** (central obesity) as indicated by the following parameters:

- BMI (Male = ≤ 34.99 kg/m2 and Female = ≤ 32.49 kg/m2) Yes/ No
- Waist Circumference (>94cms in Males and > 80 cms in Females) Yes/ No
- Waist –to- hip ratio between (≥80cm to ≤ 1m), (Female 80 to 85 and male >90cm to <1m) Yes/ No
- Saggital Abdominal Diameter (SAD) > 25 cms Yes/ No

22. Presence of any of the following Symptoms and signs:

- Heart burn Yes/ No
- Fullness of stomach Yes/ No
- Breathing difficulties Yes/ No
- Sleep apnea Yes/ No

23. Is pt is taking, OCPs or HRT (hormone replacement therapy) Yes/ No

24. Is patient is known case of allergy and immunology disease Yes/ No

25. Is patient have H/O systemic illness requiring long term T/t e.g. (CVS, GIT, CNS, Asthma, COPD) Yes/ No

26. Is patient having otherendocrinal disorders like such as , thyroid disorder, pituitary disorder, and gonadal disorder Is patient having otherendocrinal disorders like such as , thyroid disorder, pituitary disorder, and gonadal disorder Yes/ No

27. Is patient having H/o Stroke, Alzheimer or otherwise unable to exercise Yes/ No

28. Is patient having H/o any medication for weight control within 3 months Yes/ No

29.	Is the patient pregnant or lactating	Yes/ No
30.	Eligible for inclusion:	Yes/ No
31.	Written Informed Consent obtained	Yes/ No

Name & Signature of the Investigator	**Counter Signature of the Incharge**

* If the Answer to Q No 21&22, is YES and Answer to Q. No 23-29 is NO then include the patient.

Annexure-II

CASE RECORD FORM (CRF)

Clinical Validation of a Unani Pharmacopoeial Formulation *Jawārish Bisbāsa* in *Siman Mufriṭ* (Central Obesity) (NUMC: M-37)

Protocol No: SM/CO/JB/CLNVAL/CCRUM/16-17 Version No: 01

Centre Name: …….. S. No.: ……

Reg. No.: …….. Date of Registration: ……..

Date of Starting Treatment: …….. Date of Stopping Treatment: ……..…

Date of Completion: ……

DEMOGRAPHIC DATA

Patient's Name: ……..……

Father's/ Guardian's/ Husband's Name: ……..

Age: ……. Years Sex: Male/Female Address: ……..

……

Contact No.: …….. Religion: ……..…

Nationality: …….. Marital Status: Married/Unmarried

Patient's Status: New/ Known Case Duration of Disease: ……..……

CLINICAL OBSERVATIONS

Mawjūda Shikāyāt (Present complaints with duration):

_____

_____

_____

_____

Rūdād Marz Mawjūda (History of Present Illness):

_____

_____

_____

Rūdād Marz Sābiqa (History of Past Illness):

_____

_____

_____

_____

Rūdād Shakhsī (Personal History):

_____

_____

_____

Rūdād Khāndānī (Family History):

_____

_____

_____

Rūdād al-'Ilāj (Treatment History):

_____

_____

_____

GENERAL PHYSICAL EXAMINATION

Look of the patient: well/ ill Physique: Obese/ Lean/ Broad Muscular/ Thin Muscular

Nutritional Status: Good/ Average/ Poor Gait: Normal/ Abnormal

Vital Signs:

Blood Pressure: ..... mmHg Pulse Rate: ..... BPM

Respiratory Rate: ..... /m Temperature: ..... °F

Jugular Venous Pressure (JVP): ……..…….. Pedal Oedema:.....

Pallor / Cyanosis / Icterus/ Pigmentation/ Purpura/ Rashes/ Nodules

Buccal Mucosa: ……..…….. Tongue: ……..…….. Nail/ Nail Beds: ……..……..

Lymph Nodes: ……..…...…..

Any other specific finding……..

ASSESSMENT OF *Mizāj* (TEMPERAMENT)

***Mizāj* (Temperament)**	**At Baseline**	**At End of Treatment**
***Damwī* (Sanguine)**		
***Balghamī* (Phlegmatic)**		
***Safrāwī* (Bilious)**		
***Sawdāwī* (Melancholic)**		

(The chart for assessment of Mizāj (Temperament) is attached as Annexure-III)

EXAMINATION OF *NABZ* (PULSE)

(Please record the characteristics present)

S. No.	***Adilla al-Nabz***	**Characters**			**At Baseline**
		A	**B**	**C**	
1.	Miqdār al-Inbisāt	‘Azīm	Saghīr	Mu‘tadil	
		Ghalīz	Raqīq	Mu‘tadil	
2.	Kayfiya al-Qar‘	Qawī	Za‘īf	Mu‘tadil	
3.	Zamāna-i-Harakat	Sarī	Batī	Mu‘tadil	
4.	Zamāna-i-Sukūn	Mutawātir	Mutafāwit	Mu‘tadil	
5.	Qiwām-i-Āla	Sulb	Layyin	Mu‘tadil	
6.	Khalā-o-Imtilā’	Mumtalī	Khālī	Mu‘tadil	
7.	Malmas	Hārr	Bārid	Mu‘tadil	
8.	Istiwā’-o-Ikhtilāf	Mustawī	Mukhtalif	Mu‘tadil	
9.	Nizām-o-‘Adm-i-Nizām	A Muntazim		B Ghayr Muntazim	
10.	Wazn	A Jayyid-al-Wazn		B Radī-al-Wazn	

SYSTEMIC EXAMINATION

Body System	Finding		Comments (if abnormal, give brief description)
	Normal	Abnormal	
Cardiovascular			
Respiratory			
Urogenital			
Nervous			
Endocrine			
Haemolymphatic			
Musculoskeletal			

CLINICAL ASSESSMENT

S. No	Anthropometric Parameters	Grading at Baseline
1.	BMI (Male = ≤ 34.99 kg/m2 and Female = ≤ 32.49 kg/m2)	
2.	Waist Circumference (>94cms in Males and > 80 cms in Females)	
3.	Waist –to- hip ratio between (≥80cm to ≤ 1m), (Female 80 to 85 and male >90cm to <1m)	
4.	Saggital Abdominal Diameter (SAD) > 25 cms	

S.No.	Symptoms/Signs	Grading at Baseline
1.	Heart burn	Yes/ No
2.	Fullness of stomach	Yes/ No
3.	Breathing difficulties	Yes/ No
4.	Sleep apnea	Yes/ No

LABORATORY INVESTIGATIONS

(Please record the findings of the investigations in concerned column)

S. No.	Laboratory Investigations			At Baseline
1.	**Haemogram**	Hb (g/dL)		
		TLC/mm^3		
		DLC	N (%)	
			L (%)	
			E (%)	
			M (%)	
			B (%)	
		ESR (mm)	1st hr.	
			2nd hr.	
2.	**LFTs**	S. Bilirubin (mg/dL)		
		SGOT (U/L)		
		SGPT (U/L)		
		S. ALP (U/L)		
3.	**KFTs**	S. Creatinine (mg/dL)		
		BUN (mg/dL)		
4.	**Lipid Profile**	Serum Cholesterol		
		HDL		
		LDL		
		VLDL		
		Triglycerides		
5.	**Fasting Blood Glucose (mg/dL)**			
6.	**Insulin Level**			
7.	**TSH**			
8.	**Urine Examination**	**Routine**		
		Colour		
		Transparency		
		Deposit		
		Specific gravity		
		Chemical		
		Reaction		

		Albumin	
		Phosphate	
		Sugar	
		Microscopic	
		RBC	
		Pus cell	
		Epithelial Cell	
		Crystala	
		Cast	
		Other	
9.	**Stool Examination**	**Routine**	
		Colour	
		Consistency	
		Mucous	
		Blood	
		Chemical	
		Reaction	
		Occult Blood	
		Microscopic	
		Ova	
		Cyst	
		RBC	
		Pus Cell	
		Vegetable cell	
		Ova of Helminthiasis	
		Others	

Drug	Dosage	Route	Duration	Quantity of medicine given
Jawārish Bisbāsa	7 g Twice Daily	Oral	15 days	

Date of Next follow up: _____

Name & Signature of the Lab Incharge	**Name & Signature of the Investigator**
Counter Signature of the Institute Incharge	

Annexure

1st FOLLOW-UP SHEET

Clinical Validation of a Unani Pharmocopoeial Formulation *Jawārish Bisbāsa* in *Siman Mufriṭ* (Central Obesity) (NUMC:M-37)

Protocol No.: SM/CO/JB/CLNVAL/CCRUM/16-17 Version No :01

Centre Name: …….. S. No.: ……

Reg. No.: …….. Date of Follow Up: ……..……...

Date of Last Visit: ……

Compliance

Quantity of medicine returned_____

Were any doses missed? Yes ☐ No ☐

If yes, how many ☐

Reasons for missed doses: _____

Over all compliance: 1. Excellent ☐ 2. Good ☐ 3. Poor ☐

Adverse events

Whether the patient experienced any of the following:

	Yes	No
Nausea	☐	☐
Vomiting	☐	☐
Abdominal Discomfort/ Pain	☐	☐
Anorexia	☐	☐
Heartburn	☐	☐
Skin Rash/ Pruritus	☐	☐
Malaise	☐	☐
Headache	☐	☐
Dizziness	☐	☐
Any other adverse effect		

GENERAL PHYSICAL EXAMINATION

Look of the patient: well/ ill Physique: Obese/ Lean/ Broad Muscular/ Thin Muscular

Nutritional Status: Good/ Average/ Poor Gait: Normal/ Abnormal

Vital Signs:

Blood Pressure: ..... mmHg Pulse Rate: ..... BPM

Respiratory Rate: ..... /m Temperature: ..... °F

Jugular Venous Pressure (JVP): ……..…….. Pedal Oedema:

……..……..

Pallor / Cyanosis / Icterus/ Pigmentation/ Purpura/ Rashes/ Nodules

Buccal Mucosa: ……..……..….. Tongue: ……..……..….. Nail/ Nail Beds:

……..……..…..

Lymph Nodes: ……..…..…..…....

.Any other specific finding……..

EXAMINATION OF *NABZ* (PULSE)

(Please record the characteristics present)

S. No.	*Adilla al-Nabz*	Characters			At 1st FU
		A	**B**	**C**	
1.	Miqdār al-Inbisāt	‘Azīm	Saghīr	Mu‘tadil	
		Ghalīz	Raqīq	Mu‘tadil	
2.	Kayfiya al-Qar‘	Qawī	Za‘īf	Mu‘tadil	
3.	Zamāna-i-Harakat	Sarī	Batī	Mu‘tadil	
4.	Zamāna-i-Sukūn	Mutawātir	Mutafāwit	Mu‘tadil	
5.	Qiwām-i-Āla	Sulb	Layyin	Mu‘tadil	
6.	Khalā-o-Imtilā’	Mumtalī	Khālī	Mu‘tadil	
7.	Malmas	Hārr	Bārid	Mu‘tadil	
8.	Istiwā’-o-Ikhtilāf	Mustawī	Mukhtalif	Mu‘tadil	
9.	Nizām-o-‘Adm-i-Nizām	AMuntazim		BGhayr Muntazim	
10.	Wazn	AJayyid-al-Wazn		BRadī-al-Wazn	

CLINICAL ASSESSMENT

S. No.	Anthropometric Parameters	1st Follow up
1.	BMI (Male = ≤ 34.99 kg/m2 and Female = ≤ 32.49 kg/m2)	
2.	Waist Circumference (>94cms in Males and > 80 cms in Females)	
3.	Waist –to- hip ratio between (≥80cm to ≤ 1m), (Female 80 to 85 and male >90cm to <1m)	
4.	Sagital Abdominal Diameter (SAD) > 25 cms	

S. No.	Symptoms/Signs	1st Follow up
1.	Heart burn	
2.	Fullness of stomach	
3.	Breathing difficulties	
4.	Sleep apnea	

LABORATORY INVESTIGATIONS

S. No.	Laboratory Investigations			At Baseline
1.	**Haemogram**	Hb (g/dL)		
		TLC/mm^3		
		DLC	N (%)	
			L (%)	
			E (%)	
			M (%)	
			B (%)	
		ESR (mm)	1st hr.	
			2nd hr.	

2.	**LFTs**	S. Bilirubin (mg/dL)	
		SGOT (U/L)	
		SGPT (U/L)	
		S. ALP (U/L)	
3.	**KFTs**	S. Creatinine (mg/dL)	
		BUN (mg/dL)	
4.	**Lipid Profile**	Serum Cholesterol	
		HDL	
		LDL	
		VLDL	
		Triglycerides	
5.	**Fasting Blood Glucose (mg/dL)**		
6.	**Insulin Level**		
7.	**TSH**		
8.	**Urine Examination**	**Routine**	
		Colour	
		Transparency	
		Deposit	
		Specific gravity	
		Chemical	
		Reaction	
		Albumin	
		Phosphate	
		Sugar	
		Microscopic	
		RBC	
		Pus cell	
		Epithelial Cell	
		Crystala	
		Cast	

		Other	
9.	**Stool Examination**	**Routine**	
		Colour	
		Consistency	
		Mucous	
		Blood	
		Chemical	
		Reaction	
		Occult Blood	
		Microscopic	
		Ova	
		Cyst	
		RBC	
		Pus Cell	
		Vegetable cell	
		Ova of Helminthiasis	
		Others	

Drug	Dosage	Route	Duration	Quantity of medicine given
Jawārish Bisbāsa	7 g Twice Daily	Oral	15 days	

Date of Next follow up_____

Name & Signature of the Lab Incharge	Name & Signature of the Investigator

Annexure

2nd FOLLOW-UP SHEET

Clinical Validation of a Unani Pharmacopoeial Formulation *Jawārish Bisbāsa*

in *Siman Mufriṭ* (Central Obesity) (NUMC:M-37)

Protocol No.: SM/CO/JB/ CLNVAL/CCRUM 16 Version No :01

Centre Name: …….. S. No.: ……

Reg. No.: …….. Date of Follow-Up: ……..……..

Date of Last Visit

Compliance

Quantity of medicine returned_____

Were any doses missed? Yes ☐ No ☐

If yes, how many ☐

Reasons for missed doses: _____

Over all compliance: 1. Excellent ☐ 2. Good ☐ 3. Poor ☐

Adverse events

Whether the patient experienced any of the following:

	Yes	No
Nausea	☐	☐
Vomiting	☐	☐
Abdominal Discomfort/ Pain	☐	☐
Anorexia	☐	☐
Heartburn	☐	☐
Skin Rash/ Pruritus	☐	☐
Malaise	☐	☐
Headache	☐	☐

Dizziness		
Any other adverse effect		

GENERAL PHYSICAL EXAMINATION

Look of the patient: well/ ill Physique: Obese/ Lean/ Broad Muscular/ Thin Muscular

Nutritional Status: Good/ Average/ Poor Gait: Normal/ Abnormal

Vital Signs:

Blood Pressure: ..... mmHg Pulse Rate: ..... BPM

Respiratory Rate: ..... /m Temperature: ..... °F

Jugular Venous Pressure (JVP): ……..…….. Pedal Oedema: ……..

Pallor / Cyanosis / Icterus/ Pigmentation/ Purpura/ Rashes/ Nodules

Buccal Mucosa: ……..…….. Tongue: ……..……..Nail/ Nail Beds: ……...…..

Lymph Nodes: ……..…...…..

.Any other specific finding……..

EXAMINATION OF *NABZ* (PULSE)

(Please record the characteristics present)

S. No.	*Adilla al-Nabz*	Characters			At 2nd FU
		A	B	C	
1.	Miqdār al-Inbisāt	‘Azīm	Saghīr	Mu‘tadil	
		Ghalīz	Raqīq	Mu‘tadil	
2.	Kayfiya al-Qar‘	Qawī	Za‘īf	Mu‘tadil	
3.	Zamāna-i-Harakat	Sarī	Batī	Mu‘tadil	
4.	Zamāna-i-Sukūn	Mutawātir	Mutafāwit	Mu‘tadil	
5.	Qiwām-i-Āla	Sulb	Layyin	Mu‘tadil	
6.	Khalā-o-Imtilā’	Mumtalī	Khālī	Mu‘tadil	

7.	Malmas	Hārr	Bārid	Mu'tadil	
8.	Istiwā'-o-Ikhtilāf	Mustawī	Mukhtalif	Mu'tadil	
9.	Nizām-o-'Adm-i-Nizām	AMuntazim		BGhayr Muntazim	
10.	Wazn	AJayyid-al-Wazn		BRadī-al-Wazn	

CLINICAL ASSESSMENT

S. No.	Anthropometic Parameters	2nd Follow up
1.	BMI (Male = ≤ 34.99 kg/m2 and Female = ≤ 32.49 kg/m2)	
2.	Waist Circumference (>94cms in Males and > 80 cms in Females)	
3.	Waist –to- hip ratio between (≥80cm to ≤ 1m), (Female 80 to 85 and male >90cm to <1m)	
4.	Saggital Abdominal Diameter (SAD) > 25 cms	

S. No.	Symptoms/ Signs	2nd Follow up
1.	Heart burn	
2.	Fullness of stomach	
3.	Breathing difficulties	
4.	Sleep apnea	

Drug	Dosage	Route	Duration	Quantity of medicine given
Jawārish Bisbāsa	7 g Twice Daily	Oral	15 days	

Date of Next follow up_____

Name & Signature of the Lab Incharge	**Name & Signature of the Investigator**
Counter Signature of the Institute Incharge	

3rd FOLLOW-UP SHEET

Clinical Validation of a Unani Pharmocopoeial Formulation *Jawārish Bisbāsa* in *Siman Mufriṭ* (Central Obesity) (NUMC: M-37)

Protocol No.: SM/CO/JB/ CLNVAL/CCRUM 16 Version No :01

Centre Name: …….. S. No.: ……

Reg. No.: …….. Date of Follow-Up: ……..……..……...

Date of Last Visit

Compliance

Quantity of medicine returned_____

Were any doses missed? Yes ☐ No ☐

If yes, how many ☐

Reasons for missed doses:

_____

Over all compliance: 1. Excellent ☐ 2. Good ☐ 3. Poor ☐

Adverse events

Whether the patient experienced any of the following:

	Yes	No
Nausea	☐	☐
Vomiting	☐	☐
Abdominal Discomfort/ Pain	☐	☐
Anorexia	☐	☐
Heartburn	☐	☐
Skin Rash/ Pruritus	☐	☐
Malaise	☐	☐
Headache	☐	☐
Dizziness	☐	☐
Any other adverse effect	☐	

GENERAL PHYSICAL EXAMINATION

Look of the patient: well/ ill Physique: Obese/ Lean/ Broad Muscular/ Thin Muscular

Nutritional Status: Good/ Average/ Poor Gait: Normal/ Abnormal

Vital Signs:

Blood Pressure: ..... mmHg Pulse Rate: ..... BPM

Respiratory Rate: ..... /m Temperature: ..... °F

Jugular Venous Pressure (JVP): ……..…….. Pedal Oedema: ……..…..

Pallor / Cyanosis / Icterus/ Pigmentation/ Purpura/ Rashes/ Nodules

Buccal Mucosa: ……..…….. Tongue: ……..……..Nail/ Nail Beds: ……..……..…..

Lymph Nodes: ……..…...….....

Any other specific finding…….

EXAMINATION OF *NABZ* (PULSE)

(Please record the characteristics present)

S. No.	*Adilla al-Nabz*	Characters			At 3rd FU
		A	**B**	**C**	
1.	Miqdār al-Inbisāt	‘Azīm	Saghīr	Mu‘tadil	
		Ghalīz	Raqīq	Mu‘tadil	
2.	Kayfiya al-Qar‘	Qawī	Za‘īf	Mu‘tadil	
3.	Zamāna-i-Harakat	Sarī	Batī	Mu‘tadil	
4.	Zamāna-i-Sukūn	Mutawātir	Mutafāwit	Mu‘tadil	
5.	Qiwām-i-Āla	Sulb	Layyin	Mu‘tadil	
6.	Khalā-o-Imtilā’	Mumtalī	Khālī	Mu‘tadil	
7.	Malmas	Hārr	Bārid	Mu‘tadil	
8.	Istiwā’-o-Ikhtilāf	Mustawī	Mukhtalif	Mu‘tadil	
9.	Nizām-o-‘Adm-i-Nizām	AMuntazim		BGhayr Muntazim	
10.	Wazn	AJayyid-al-Wazn		BRadī-al-Wazn	

CLINICAL ASSESSMENT

S. No.	Authropometic Parameters	3rd Follow up
1.	BMI (Male = ≤ 34.99 kg/m2 and Female = ≤ 32.49 kg/m2)	
2.	Waist Circumference (>94cms in Males and > 80 cms in Females)	
3.	Waist –to- hip ratio between (≥80cm to ≤ 1m), (Female 80 to 85 and male >90cm to <1m)	
4.	Sagittal Abdominal Diameter (SAD) > 25 cms	

S. No.	Symptoms/Signs Authropometic Parameters	3rd Follow up
1.	Heart burn	
2.	Fullness of stomach	
3.	Breathing difficulties	
4.	Sleep apnea	

Drug	Dosage	Route	Duration	Quantity of medicine given
Jawārish Bisbāsa	7 g Twice Daily	Oral	15 days	

Date of Next follow up_____

Name & Signature of the Investigator	Counter Signature of the Incharge

4TH FOLLOW-UP SHEET

Clinical Validation of a Unani Pharmocopoeial Formulation *Jawārish Bisbāsa* in *Siman Mufriṭ* (Central Obesity) (NUMC:M-37)

Protocol No.: SM/CO/JB/ CLNVAL/CCRUM 16 Version No :01

Centre Name: …….... S. No.: ……

Reg. No.: …….... Date of Follow-Up: ……..……...

Date of Last Visit

Compliance

Quantity of medicine returned_____

Were any doses missed? Yes ☐ No ☐

If yes, how many ☐

Reasons for missed doses: _____

Over all compliance: 1. Excellent ☐ 2. Good ☐ 3. Poor ☐

Adverse events

Whether the patient experienced any of the following:

	Yes	No
Nausea	☐	☐
Vomiting	☐	☐
Abdominal Discomfort/ Pain	☐	☐
Anorexia	☐	☐
Heartburn	☐	☐
Skin Rash/ Pruritus	☐	☐
Malaise	☐	☐
Headache	☐	☐
Dizziness	☐	☐
Any other adverse effect	☐	

GENERAL PHYSICAL EXAMINATION

Look of the patient: well/ ill Physique: Obese/ Lean/ Broad Muscular/ Thin Muscular

Nutritional Status: Good/ Average/ Poor Gait: Normal/ Abnormal

Vital Signs:

Blood Pressure: ..... mmHg Pulse Rate: ..... BPM

Respiratory Rate: ..... /m Temperature: ..... °F

Jugular Venous Pressure (JVP): ……..…….. Pedal Oedema: ……..……

Pallor / Cyanosis / Icterus/ Pigmentation/ Purpura/ Rashes/ Nodules

Buccal Mucosa: ……..…….. Tongue: ……..……..Nail/ Nail Beds: ……..…..

Lymph Nodes: ……..…...…..…....

.Any other specific finding……..

EXAMINATION OF *NABZ* (PULSE)

(Please record the characteristics present)

S. No.	*Adilla al-Nabz*	Characters			At 4th FU
		A	**B**	**C**	
1.	Miqdār al-Inbisāt	‘Azīm	Saghīr	Mu‘tadil	
		Ghalīz	Raqīq	Mu‘tadil	
2.	Kayfiya al-Qar‘	Qawī	Za‘īf	Mu‘tadil	
3.	Zamāna-i-Harakat	Sarī	Batī	Mu‘tadil	
4.	Zamāna-i-Sukūn	Mutawātir	Mutafāwit	Mu‘tadil	
5.	Qiwām-i-Āla	Sulb	Layyin	Mu‘tadil	
6.	Khalā-o-Imtilā’	Mumtalī	Khālī	Mu‘tadil	
7.	Malmas	Hārr	Bārid	Mu‘tadil	
8.	Istiwā’-o-Ikhtilāf	Mustawī	Mukhtalif	Mu‘tadil	

9.	Nizām-o-'Adm-i-Nizām	AMuntazim	BGhayr Muntazim	
10.	Wazn	AJayyid-al-Wazn	BRadī-al-Wazn	

CLINICAL ASSESSMENT

S. No.	Authropometic Parameters	4th Follow up
1.	BMI (Male = ≤ 34.99 kg/m2 and Female = ≤ 32.49 kg/m2)	
2.	Waist Circumference (>94cms in Males and > 80 cms in Females)	
3.	Waist –to- hip ratio between (≥80cm to ≤ 1m), (Female 80 to 85 and male >90cm to <1m)	
4.	Saggital Abdominal Diameter (SAD) > 25 cms	

S. No.	Symptoms/Sign	4th Follow up
1.	Heart burn	
2.	Fullness of stomach	
3.	Breathing difficulties	
4.	Sleep apnea	

LABORATORY INVESTIGATIONS

S. No.	Laboratory Investigations			At Baseline
1.	**Haemogram**	Hb (g/dL)		
		TLC/mm^3		
		DLC	N (%)	
			L (%)	
			E (%)	
			M (%)	
			B (%)	
		ESR (mm)	1st hr.	

		2nd hr.	
2.	**LFTs**	S. Bilirubin (mg/dL)	
		SGOT (U/L)	
		SGPT (U/L)	
		S. ALP (U/L)	
3.	**KFTs**	S. Creatinine (mg/dL)	
		BUN (mg/dL)	
4.	**Lipid Profile**	Serum Cholesterol	
		HDL	
		LDL	
		VLDL	
		Triglycerides	
5.	**Fasting Blood Glucose (mg/dL)**		
6.	**Insulin Level**		
7.	**TSH**		
8.	**Urine Examination**	**Routine**	
		Colour	
		Transparency	
		Deposit	
		Specific gravity	
		Chemical	
		Reaction	
		Albumin	
		Phosphate	
		Sugar	
		Microscopic	
		RBC	
		Pus cell	
		Epithelial Cell	
		Crystal	
		Cast	

		Other	
9.	**Stool Examination**	**Routine**	
		Colour	
		Consistency	
		Mucous	
		Blood	
		Chemical	
		Reaction	
		Occult Blood	
		Microscopic	
		Ova	
		Cyst	
		RBC	
		Pus Cell	
		Vegetable cell	
		Ova of Helminthiasis	
		Others	

Drug	Dosage	Route	Duration	Quantity of medicine given
Jawārish Bisbāsa	7 g Twice Daily	Oral	15 days	

Date of Next follow up_____

Name & Signature of the Lab Incharge	Signature of Principal Investigator

GLOBAL EVALUATION

Patient Global Assessment of Response to Therapy (PGART):

Poor ☐ Satisfactory ☐ Good ☐ Excellent ☐

Investigator Global Assessment of Response to Therapy (IGART):

Not Effective ☐ Effective ☐ Very Effective ☐

Patient completed study: Yes ☐ No ☐

If No: Reason for drop out / Discontinuation

1. Poor Compliance
2. Lost to follow up
3. Adverse event
4. Abnormal Lab parameter
5. Poor efficacy
6. Concurrent illness
7. Any other reason: Give details:

Name & Signature of the Investigator	Counter Signature of the Incharge

SUMMARY DATA SHEET

Centre: _____

S. No.: _____

Subject ID: _____ Age: _____ Years

Gender: M / F

Date of start of Treatment: _____

Date of completion of treatment: _____

Quantity of Study Drug consumed: _____

Side-effects observed: No Yes

If yes, details:

_____

Abnormalities detected on Clinical Examination: No Yes

If yes, details:

_____

Abnormalities detected on Lab. Investigations: No Yes

If yes, details:

_____

Other medication given: No Yes

If yes, details:

_____

Overall impression of the Investigator about the drug:

1 = Safe

2 = Doubtful

3 = Unsafe

Name & Signature of the Investigator	**Counter Signature of the Incharge**

Annexure

ASSESSMENT OF RESULTS
Clinical Validation of a Unani Pharmacopoeial formulation *Jawārish Bisbāsa* in *Siman Mufriṭ* (Central Obesity) (NUMC:M-37)

S. No.: _____ Reg. No.: _____

Date of Registration: _____

Name: _____ Age: _____ Years

Sex: M / F _____

S. No.	Authropometic Parameters	Grading at Baseline	1st FU	2nd FU	3rd FU	4th FU
1.	BMI (Male = ≤ 34.99 kg/m2 and Female = ≤ 32.49 kg/m2)					
2.	Waist Circumference (>94cms in Males and > 80 cms in Females)					
3.	Waist –to- hip ratio between (≥80cm to ≤ 1m), (Female 80 to 85 and male >90cm to <1m)					
4.	Sagittal Abdominal Diameter (SAD) > 25 cms					

S. No.	Symptoms/Sign	Grading at Baseline	1st FU	2nd FU	3rd FU	4th FU
1.	Heart burn					
2.	Fullness of stomach					
3.	Breathing difficulties					
4.	Sleep apnea					

Reduction in Score: ----------
Percentage Efficacy: ---------- **%**

Name & Signature of the Investigator	Counter Signature of the Incharge

Annexure-II

PARTICIPANT INFORMATION SHEET (PIS)

Clinical Validation of a Unani Pharmacopoeial formulation *Jawārish Bisbāsa* in *Siman Mufriṭ* (Central Obesity) (NUMC:M-37)

Protocol No.: SM/CO/JB/CLNVAL/CCRUM 16-17 Version No :01

Name of the Investigator: ……..……...……

Phone/ Mobile No.: ……...……..……..……...

Invitation to Participate

You are invited to participate in a research study on *Siman Mufriṭ* (Central Obesity). The study is part of a multi-centric study sponsored by Director General, CCRUM, Ministry of AYUSH, Government of India. The study doctor or study staff will provide answers to any queries you may have regarding this form or the study. This form may contain words or information that you may not understand; in which case you could seek clarification from the study doctor or designated study staff. After going through the content you will be asked to sign the form or give your thumb impression. You will be provided with a copy of the signed consent form to take home and keep for your records.

Before you decide whether or not to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. **What is the purpose of this study?**
   The purpose is to investigate whether the Unani Pharmacopoeial formulation *Jawārish Bisbāsa* used in the management of *Siman Mufriṭ* (Central Obesity) is useful and to study the safety profile of the same formulation in human subjects.
2. **Why have I been invited to participate in this study?**
   You are eligible to participate in this study because you are suffering from *Siman Mufriṭ* (Central Obesity)
3. **What if I don't want to take part in this study, or if I want to withdraw later?**
   Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your

relationship with the staff caring for you. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

4. **What does this study involve?**

   If you agree to participate in this study, you will be asked to sign the informed consent form (ICF). This study will be conducted for 8 weeks. There will be tests to be done during this period.

5. **How is this study being funded by?**

   The study is being sponsored and funded by CCRUM.

6. **Are there risks to me in taking part in this study?**

   All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. In spite of all reasonable precautions, you might develop medical complications from participating in this study.

7. **What happens if I suffer injury or complications as a result of the study?**

   If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible, who will assist you in arranging appropriate medical treatment.

8. **Will I benefit from the study?**

   This study aims to further medical knowledge and may improve future treatment of *Siman Mufriṭ* (Central Obesity) and as a personal gain you may not go into chronic state and result in complications.

9. **Will taking part in this study cost me anything, and will I be paid?**

   You will be provided free medicines and the laboratory tests will be conducted free of cost.

10. **What will happen to my blood sample after it has been used?**

    The blood sample you provide during the study will be destroyed after use.

11. **How will my confidentiality be protected?**

    Of the people treating you only will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission or except as required by law. Only the researchers named above will have access to your details and results that will be held secretly at institution.

12. **What will happen with the results?**

If you give us your permission by signing the consent document, we plan to discuss/publish the results (State the possible persons to whom the information will be disclosed, the nature of the information disclosed and the purpose of the disclosure e.g. the sponsor (DG, CCRUM) and the IEC for monitoring purposes, publication of the data in peer-reviewed journals and presentations at various conferences or other processional forums). In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish.

13. What will happen if new information becomes available?

New information about the treatment being studied may become available during the course of the study. You will be kept informed of any significant new finding that may affect your willingness to continue in the study.

14. What happens to my treatment when the study is finished?

The treatment will be available after the study finishes. You may be able to continue treatment following completion of this study if found to be of benefit to you. This decision will be made in consultation between you and your treating doctor about the most appropriate treatment for you at that time.

15. What should I do if I want to discuss this study further before I decide?

When you have read this information, the researcher will discuss it with you and any queries which you may have will be answered. If you would like to know more at any stage, please do not hesitate to contact him/her.

16. Who should I contact if I have concerns about the conduct of this study?

For further information/ questions, you can contact one of our following researchers:

Principal Investigator

Name : _____

Institute :

_____

Address: _____

Telephone:_____

Fax/E-mail:_____

Co-Investigator

Name: _____

Institute: _____

Address: _____

Telephone: _____

Fax/E-Mail:_____

Thank you for taking the time to consider this study. If you wish to take part in it, please sign the attached consent form. This information sheet is for you to keep.

Annexure

INFORMED CONSENT FORM (ICF)

Clinical Validation of a Unani Pharmacopoeial formulation *Jawārish Bisbāsa* in *Siman Mufriṭ* (Central Obesity)

Protocol No. SM/CO/JB/CLNVAL/CCRUM 16-17

Patient Identification Number for this Study:

I_____ son/daughter/wife of _____ agree to participate as a participant in the study described in the participant information sheet set out above (or attached to the form)

1. I acknowledge that I have read the participant information sheet, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation and the information sheet has been explained to me to my satisfaction.
2. Before signing this consent form, I have been given the opportunity of asking any question relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers. I understand that I can withdraw from the study at any time without prejudice to my relationship to the (insert if applicable) University (name) and the Hospital, Research Institute)
4. Confidentiality: I understand that my information can be accessed by the Ethics committee members and institutional/regulatory authorities, if required
5. I agree that research data gathered from the result of the study may be published, provided that I cannot be identified.
6. I understand that if I have any question relating to my participation in this research, I may contact _____on telephone.
7. I acknowledge receipt of a copy of this consent form and the participant information sheet.

Complaints may be directed to the research office, (Details of office).

میں ..... ولد/دختر / زوجہ/..... شرکا معلومات شیٹ میں موجود معلومات مجھے بتا دی ہیں گیئں ہیں اور میں اس بات اس اتفاق کرتے ہوے اس میں حصہ لینےکو تیار ہوں

میں یو بات بھلی بھٹی جانتی ہوں اور میں نے معلوماتی شیٹ اچّھی طرح پردہ اور سمجھ لی ہے جو یو جانکاری دیتی ہے ک مجھے اس میں کیوں منتخب کیا گیا ہے مطالعہ کا مقصد اور فطرت اور تحقیقات اور معلومات کے شیٹ کے ممکنہ خطرات کو میری اطمینان سے بیان کیا گیا ہے.

اس رضامند فارم پر دستخط کرنے سے پہلے، مجھے کسی ممکنہ جسمانی اور ذہنی نقصان سے متعلق کسی بھی سوال سے متعلق سوال کا موقع دیا گیاہے. میری شراکت کے نتیجے میں میں نے شاید تکلیف دہ ہوسکتے ہیں اور مجھے تسلی بخش جواب مل چکا ہے میں سمجھتا ہوں کہ میں کسی بھی وقت تعصب کے بغیر اپنے تعلقات سے (اگر قابل اطلاق ہوتا ہے) یونیورسٹی (نام) اور ہسپتال، ریسرچ انسٹی ٹیوٹ) کے بغیر مطالعہ سے نکال سکتا ہوں.

رازداری: میں سمجھتا ہوں، اگر ضرورت ہو تو میری معلومات اخلاقی کمیٹی کے اراکین اور ادارہ / ریگولیٹری حکام کی طرف سے حاصل کی جاسکتی ہے.

میں اس بات سے اتفاق کرتا ہوں کہ تحقیق کے نتائج سے جمع ہونے والی تحقیق کے اعداد و شمار شائع کئے جا سکتے ہیں، اس کے مطابق میں اس کی شناخت نہیں کی جا سکتی.

میں سمجھتا ہوں کہ اگر میرے پاس اس تحقیق میں میری شرکت سے متعلق کوئی سوال ہے،

میں..... ٹیلی فون سے رابطہ کر سکتا ہوں .

میں اس رضاکارانہ فارم اور شراکت دار کی معلومات کی شناخت کی نقل کی تصدیق کرتا ہوں.

شکایات تحقیقاتی دفتر کو ہدایت کی جا سکتی ہیں، (دفتر کی تفصیلات).

Signature of Participant	**Name**	_____	**Date**	_____
Signature of Witness	**Name**	_____	**Date**	_____
Signature of Investigator	**Name**	_____	**Date**	_____

Annexure-III

ASSESSMENT OF *MIZĀJ* (TEMPERAMENT)

PARAMETER	SANGUINE	PHLEGMATIC	BILIOUS	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 & Lustry 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 hours)	In excess	Inadequate	Insomnia
PULSE	Normal in Rate (70-80/min) Large in Volume	Slow in Rate (60-70min) 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

(Maximum number of ticks in a particular column denotes the dominant temperament.)

Central Council for Research in Unani Medicine

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