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Original Article

A Study on Patients Drop-Out in Unani Pharmacopeial Validation of An Anti-obesity Drug

Misbahuddin Azhar^{1*}, Rashidul Islam Ansari², Sadia Ayub³, Nighat Anjum⁴, Anirban Rej⁵

¹Research Officer Scientist-III (U), Regional Research Institute of Unani Medicine (RRIUM), Aligarh
²Research Officer Scientist-I (U), RRIUM, Aligarh
³Research Officer Scientist-III (Biochem), RRIUM, Aligarh
⁴Research Officer Scientist-III (U), Central Council for Research in Unani Medicine (CCRUM), Headquarters, New Delhi
⁵Investigator (Statistics), CCRUM, Headquarters, New Delhi

ABSTRACT

Background: In clinical research, the researcher always has control over the human subject, which makes the dropout rate in clinical studies a significant problem. The high rate of dropout in herbal clinical research is a significant concern for researchers, as it extends the period of the study and imposes additional financial strain on the project.

Objective of the study: This study aims to identify the potential factors contributing to dropout rates in a validation programme.

Materials and methods: Prior to the study, all participants were provided with detailed information regarding the experimental medication, its dosage, timing of administration, frequency of follow-up visits, and laboratory tests. The rationales for discontinuing recruited patients in the validation research on the anti-obesity medicine Jawarish Bisbasa were documented in the case record form. Upon the conclusion of the study, all assertions were subjected to analysis.

Results: A total of 49 patients discontinued their participation in the trial for various reasons such as lack of discipline, social unfairness, ineffectiveness and unpleasant taste of the medicine, pregnancy, and domestic responsibilities.

Conclusion: Dropout rates are more prevalent among the middle-income group, followed by the lower middle-income group. The lowest dropout rate was reported among individuals from socio-economically disadvantaged backgrounds. House makers have a higher dropout rate compared to other groups in terms of vocation. Additionally, their preferences for flavour, palatability, and slow action of formulation are also notable. This is an endeavour to comprehend and elucidate the course for designing future trials.

Keywords: Dropout, Unani medical system, clinical pharmacopeial validation, Jawarish Bisbasa

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Corresponding Author

Dr. Misbahuddin Azhar
Research Officer (Unani) Scientist-III
Regional Research Institute of Unani
Medicine, Shahjahan Manzil, Near
AMU Riding Club Qila Road, Aligarh-
202002 (Uttar Pradesh-INDIA)
Email: ccrum619@gmail.com

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INTRODUCTION

The subject is taught and investigated in various nations such as

India, Bangladesh, Pakistan, Sri Lanka, Nepal, China, Iran, Iraq, Malaysia, Indonesia, as well as countries in Central Asia, the Middle East, Africa, and Europe. USM, also known as Yunani Nizam-e-Tib or Tibb, has its roots in ancient Greece (Yunan) and was influenced by Egypt and Mesopotamia. The Arabs greatly enhanced, refined, and advanced the USM to a significant extent.

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Unani Medicine is commonly referred to as Greco-Arab Medicine. During the 18th century, scientific development in India gradually took place and became an integral part of the healthcare delivery system, being cultivated and incorporated systematically over time. The Central Council for Research in Unani Medicine (CCRUM) is a top-level independent research institution operating under the Ministry of AYUSH, which is part of the Government of India. The research agenda of the CCRUM primarily focuses on conducting clinical research, particularly randomised controlled trials (RCTs), to validate the therapeutic effectiveness of Unani formulations and therapies that have been utilised for centuries. The Regional Research centre of Unani Medicine (RRIUM) in Aligarh is a significant clinical research centre. The institute is now conducting over fifteen validation programmes for pharmacopoeial medicines.² Researchers are greatly concerned about the dropout rates of human subjects in clinical studies, as the participants have little influence over the situation, leading to increasing rates of dropout. The researchers are greatly concerned about the significant dropout rate in clinical research, since it often leads to longer study durations and imposes additional financial strain on the project or the sponsoring agency.³ Despite the fact that Unani therapy methods have demonstrated positive therapeutic outcomes in certain medical states, while allopathic treatments have limited therapeutic effects or may generate unpleasant reactions alongside therapeutic actions.⁴⁻¹⁰

The investigation aimed to evaluate the safety and effectiveness of the Unani Pharmacopoeial formulation Jawarish Bisbasa in patients with Saman-e-Mufrat (Central Obesity). The components of the Jawarish Bisbasa are displayed in Table-1.¹¹

Even though herbal medicine e.g. Unani, Ayurvedic medicines are efficacious and safe, but it takes time to resolves the health issues. Central obesity is an important issue of health nowadays for urban areas due to a sedentary lifestyle. The aforesaid project was designed to validate a pharmacopoeial formulation in central obesity. It was an open-label multi-centric clinical study, and 20% dropouts were considered at the time of designing the protocol on the bases of earlier results of different studies (RCT & Validation) conducted in the council.

Table-1. Ingredients of Jawarish Bisbasa (NFUM-1-1)¹¹

S.No.	Unani name	Botanical name	Part used	Quantity
1	Heel kalan	<i>Amomum subulatum</i>	fruit	50gm
2	Bisbasa	<i>Myristica fragrans</i> Houtt.	Arillus	30gm
3	Saleekha	<i>Cinnamomum cassia</i> Blume.	Stem bark	30gm
4	Heel Khurd	<i>Elettaria cardamomum</i> (L) Maton	Fruit	30gm
5	Zanjabeel	<i>Zingiber officinale</i> Rosc.	Rhizome	30gm
6	Daarchini	<i>Cinnamomum zeylanicum</i> Blume.	Stem bark	30gm
7	Asaaron	<i>Asarum europaeum</i> Linn.	Rhizome	30gm
8	Filfilisyah	<i>Piper nigrum</i> Linn.	Fruit	20gm
9	Qaranfal	<i>Syzygium aromaticum</i> (L.) Merr.	Flower bud	15gm
10	NabatSafaid	Sugar crystal		200gm
11	Qandsafaid	Sugar		800gm

1.1 Aims and Objective

The objective of this presentation is to find out the possible reasons for dropout in the validation programme Unani

Pharmacopoeial formulation *Jawarish Bisbasa* in cases of *Saman-e-Mufrat*.

MATERIAL & METHODS

The study was cleared by Institutional Ethics committee F. No. 5-11/2011-12/RRI/ALG/Tech/150 and registered under CTRI with REF/2018/08/021125AU at RRIUM, Aligarh. During the registration process, human subjects were provided with explicit information regarding the test medicine (*Jawarish Bisbasa*), including its dosage form, timing of administration, number of follow-ups, laboratory investigations, and diet chart. The explanations provided by human participants who were unable to attend the follow-up session within the specified ± 3 day window, as outlined in the protocol, and who told us either by phone or in person at the institution, and subsequently submitted their withdrawal statement, were all documented in the case record form. Upon completion of the study, an analysis was conducted on all the dropout case record forms to determine the reasons for participants dropping out of the trial.

2.1 Statistical analysis

The data was analysed using Statistical Analysis System (SAS) version 9.4 and Statistical Package for the Social Sciences (SPSS) version 25.0.

RESULT & DISCUSSION

The reasons for dropouts were recorded as informed by the subjects on the telephone or when visited institute and submitted their statement for withdrawal from the study. The findings of demographic and subjective parameters were as follows:

During the course of study trial total of 49 patients out of 131 cases registered of different sex, age, height, weight, etc. were dropouts from the clinical validation on obesity at Regional Research Institute of Unani Medicine, Aligarh. Out of the total dropouts of human subjects in the said trial, 41% were male and 59% were females¹². Their range of age was between 19-62 years, height between 141-179 cm and the weight ranged between 54-100 kg. The systolic blood pressure ranges between 107-155 mmHg and diastolic range between 65-100 mm Hg, pulse rate ranges between 68-114/min as shown in Table-2.

Table:2. Basic Statistics of different variables (Mean \pm SEM)

S. No.	Characteristics	Number of Cases
1.	Male	20 (41%)
	Female	29 (59%)
	Total cases	49
2.	Age (Mean \pm SEM)	33.73 \pm 1.33
	Age (Range)	19 – 62
3.	Height (Mean \pm SEM)	158.63 \pm 1.37
	Height (Range)	141 – 179
4.	Weight (Mean \pm SEM)	77.90 \pm 1.46
	Weight (Range)	54 – 100
5.	Systolic (Mean \pm SEM)	126.69 \pm 1.61
	Systolic (Range)	107 – 155
6.	Diastolic (Mean \pm SEM)	85.61 \pm 1.20
	Diastolic (Range)	65 – 100
7.	Pulse Rate (Mean \pm SEM)	89.59 \pm 1.46
	Pulse Rate (Range)	68 – 114

In this clinical trial, the duration of treatment was 8 weeks with fortnightly follow-up. The enrolled patients in the study were dropouts at different follow-ups. Maximum 40.8% were dropout at first follow-up, then on third follow-up 28.6%, and then on second follow-up 20.4% and least were on 4th follow-up 10.2% as shown in Table-3.

Table-3. Drop-out classification over different follow-ups

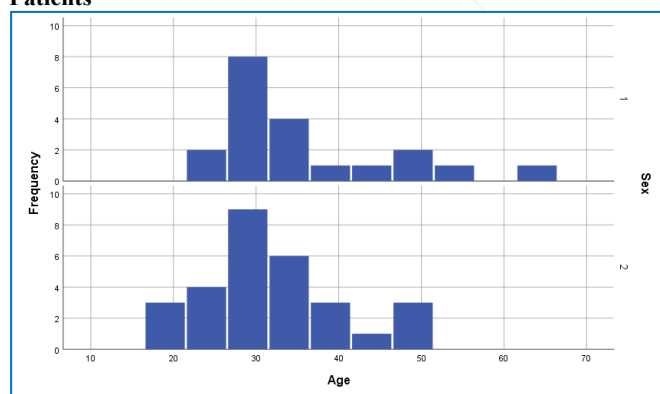
Dropout	Frequency	Percentage	Cumulative Percent
1st Follow-up	20	40.8	40.8
2nd Follow-up	10	20.4	61.2
3rd Follow-up	14	28.6	89.8
4th Follow-up	5	10.2	100.0
Total	49	100.0	

The dropout according to age group ranges between 29-39 years were highest 49% of patients, thereafter 29% between 18-28 years of age, 18% were aged between range of 40-50 years only 2% from 51-60 and more than 61 years age respectively were dropout as shown in Table-4 and Fig-1. It showed that mature people are more serious about their health issues in comparison to younger ones.¹³

Table-4: Age and Sex-wise Distribution of Patients

Age (inyrs)	Gender		Total	Percentage (%)
	Male	Female		
18-28	4	10	14	29%
29-39	10	14	24	49%
40-50	4	5	9	18%
51-60	1	0	1	2%
>61	1	0	1	2%
Total	20	29	49	100%

Fig-1: Age and Sex-wise (Male-1, Female-2) Distribution of Patients



Health consciousness in married and unmarried are common but it is identified that unmarried individuals generally report poorer health and have a higher risk of mortality than their married counterparts. In this trial married and unmarried of both sexes subjects were enrolled.¹⁴ Among all the dropouts from the study, 74% were married and 26% were unmarried. It shows those unmarried are more conscious of their health in comparison to married showed in Table-5.

The socio-economic condition of subjects also plays an important role in compliance with the instructions of a physician with respect to medication and investigations.¹⁵ The maximum

dropouts of 44.9% were among the higher income group followed by middle income 42.9% group then lower income group 12.2% as shown in Table-5. It indicates that lower-income group needs health care benefit from government schemes.

In clinical trials multiple measures of abstinence are reported, quitting smoking may be a cause. In this trial among the total dropouts, 73.5% were non-smoker and 26.5% were smokers. Likewise, non-tobacco chewers (including pan and pan masala) were 65% and 35% were tobacco chewers as shown in table 5. It was reviewed by Society for Research on Nicotine and Tobacco and suggested cessation of smoking is one of the measures for dropout in clinical trials.¹⁶

Dietary pattern of the subject also plays an important role; dropout among non-vegetarians is very high in comparison to vegetarian, i.e. 88% and 12% respectively as shown in Table-5. It may be due to non-vegetarians taking the animal fat feels drug is not affecting them quite the trial.

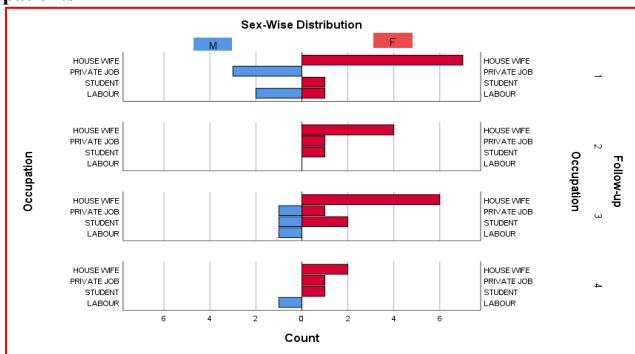
Table: 5 Distribution of patients according to marital status, socio-economic status, addiction and dietary habits

Characteristics	Number of Cases (n=49)	Percentage (%)
Marital status		
Married	36	74%
Unmarried	13	26%
Socio-eco Status		
Lower	6	12.2
Lower Middle	21	42.9
Middle	22	44.9
Addiction		
Smoker	13	26.5
Non-smoker	36	73.5
Tobacco chewer	17	35%
Tobacco non chewer	32	65%
Dietary habit		
Vegetarian	6	12%
Non-Vegetarian	43	88%

Adherence to protocol is a major challenge to clinical researchers. Human subjects that were dropout/withdrawn from the trial at different stages explained various reasons. It is very difficult to judge the reasons behind the high rate of dropout. Sometime patients left the trial due to official engagement and some social liabilities.¹⁷ In this presentation, we observed that the occupations of subjects play an important role in not attending the follow-up. The government servant 4% were the least among the dropout and the housewives are the highest 39% of total dropouts. Followed by private jobs, 14%, students 12%, business and labour 10% each as showed in Table-6 and Fig-2. Further this dropout more among females in comparison of male subject 59.18% and 40.81 % respectively Table-4 and Fig-2.

Table-6. Occupation status-wise distribution of the patients

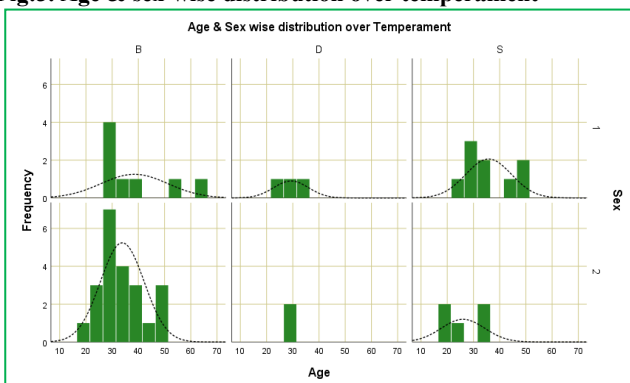
Occupation Status	Number of Cases	Percentage (%)
House wife	19	39
Business	5	10
Business small	3	6
Private job	7	14
Student	6	12
Labour	5	10
Contractual job	2	4
Government job	2	4
Total	49	100%

Fig.2. Occupation, sex and follow-up wise distribution of dropout patients

The Unani system of medicine is based on the Hippocratic theory of temperament. Each living and non-living material in this universe has a unique temperament that showed its quality. In multi-organ living organisms, every organ has its own temperament and showed work. Derangement in temperament due to any cause resulted in malfunctioning. This disturbed the normalcy in the body and developed the disease. Observation shows that women are colder than men because they have a smaller build. They are also moist because their greater cold leads to the excessive formation of excrements, they do not indulge in much activity and their tissues are loose and lax. The temperament of every individual shows its personality as well as the food they like and the disease condition they may be prone. According to USM philosophy, there are four types of temperament e.g. *Balghami* (phlegmatic), *Safravi* (bilious), *Damvi* (sanguine) and *Saudavi* (melancholic).¹⁸ In this observation, only three types of temperamental human subjects were dropout from the study. 61% of *Balghami* (phlegmatic) temperamental patients were dropout followed by *Safravi* and *Balghami* 29% and 10% respectively as shown in Table-7. According to USM philosophy, the person of *Balghami* temperament is weak in taking the decision and lazy in his day-to-day life. They are less active in comparison to *Safravi* and *Damvi* temperamental groups. That's why maximum dropout was observed in this temperamental group.¹⁸ Patients were divided according to their age, sex-wise over temperament in Fig-3.

Table: 7. Distribution of patients according to Temperament

Temperament	Number of Cases	Percentage (%)
<i>Balghami</i> (Phlegmatic)	30	61%
<i>Safravi</i> (Bilious)	14	29%
<i>Damvi</i> (Sanguine)	5	10%
Total	49	100%

Fig.3. Age & sex-wise distribution over temperament

In this study patients of both sexes were dropout due to various reasons e.g. in-discipline, social injustice, non-effectiveness or bad taste of the drug, education, conception, domestic work, referred for the higher centre and seeking jobs.¹⁹ It is also observed that some factors are common in both sexes and some are observed in females and some in males. The common factors in both the sexes are social injustice, not the effectiveness or bad taste of the drug. The female patient did not continue their treatment due to education, conception, and domestic-related works while males are not present on the day of their respective visit due to seeking a job and referred to a higher centre for their complication as shown in Table-8.

It may also be observed that the dropout has happened at different follow-up and showed that patients tolerated the bad taste of the medicine up to second follow-up and did not continue their treatment due to this. The study suggests that the shape and taste of Unani medicine may be a cause for concern in terms of patient acceptance. Therefore, it is necessary to make modifications in the near future in order to increase its popularity among the general population.²⁰

Furthermore, it is noteworthy that females discontinued their participation in the study as a result of becoming pregnant after a six-week period of taking the medication, as depicted in Figures 4 and 5.²¹⁻²³ The possible cause could be the constituents of Jawarish Bisbasa.

Several components have been identified as beneficial for promoting conception in cases of female sterility. For example, Cinnamon (*Cinnamomum zeylanicum* Blume) aids in maintaining optimal ovarian function and may therefore be successful in addressing infertility.²⁴⁻²⁷

Table:8. Probable Reason for Dropout

Variables	Number of Cases	Percentage (%)
In-disciplined	12	25
Social Injustice	11	22
Not effective	8	16
Bad taste	6	13
Study	5	10
Conception	3	6
Domestic Work	2	4
Referred	1	2
Seeking the jobs	1	2
Total	49	100%

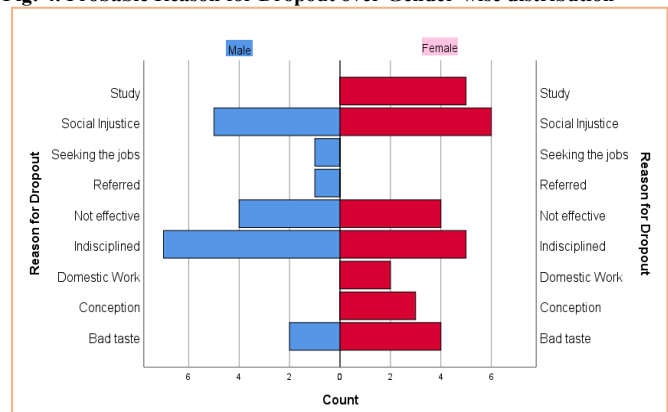
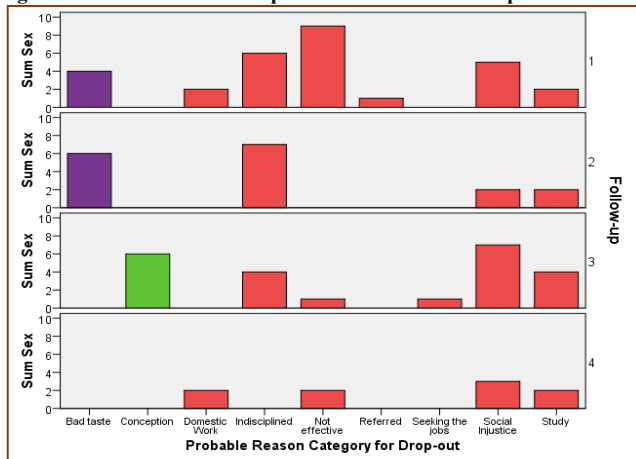
Fig: 4. Probable Reason for Dropout over Gender-wise distribution

Fig. 5. Probable reason of drop-out at different follow-up



Patients who dropped from the study due to indiscipline at first three follow-ups, the ratio is almost the same there is not remarkable difference in their number. The patient dropout at first follow-up due to not effectiveness of drug indicated the slow action of the Unani drug. Most of the patient believes that they could get cure immediately, so they did not continue the treatment for long-duration even they were informed in advance, the duration of treatment would be eight weeks as shown in Fig-5.

Patients who developed complications like raised blood pressure were referred to a higher centre for consultation after 2 weeks of treatment, at first follow-up. Most of the ingredients of *Jawarish Bisbasa* are Hot and dry in the temperament of grade two and three. It may be possible that they cause some dryness and hotness in the body that leads to high blood pressure.

Only male patients who were drop-out from the trial because of going for an interview and other related to the job. It is an indication that the male is more concerned for the job in comparison to female.

We are living in a society in which social injustice is very common and for this, both males and females are affected. In this trial, patients are dropout at every follow-up due to this reason. It showed that social injustice in society is quite relevant.¹⁹

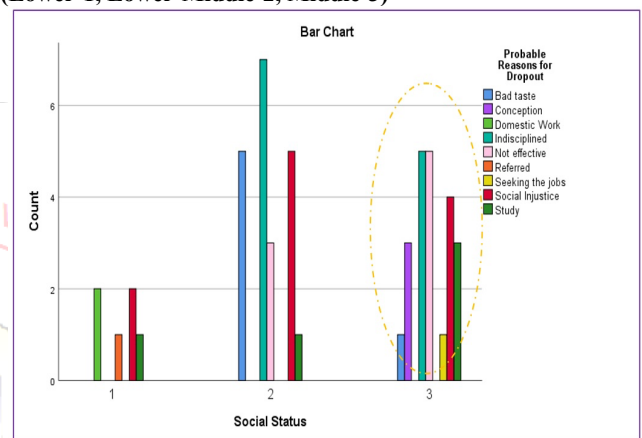
It is also observed that only female subjects are drop-out due to education, it showed that females are more concerned about their studies in comparison to the males.¹⁹

In a cross tab between probable reason for dropout and income of patient, it showed that patients from lower-middle and middle class of income are more dropouts in comparison to the lower-income group. It showed that the lower-income group people are more dependent on government scheme for their health-related issues in comparison to the lower middle and middle-income group society as shown in Table-9 and Fig-6. Out of total dropout, only 12.24 % were from the lower-income group while remaining are from lower-middle to middle-income group. It is also observed that lower-income group people did not complaint about the bad taste of the medicine, and they are not undisciplined and completed the trial on time. It showed that lower-income people totally depend on government scheme for their health problems, and they obediently follow the instruction of a physician Table-9 and Fig-6.²⁸⁻²⁹

Table: 9. Social Status vs probable reason of dropout (Crosstab)

Soci al statu s	Bad taste	conception	Domestic work	In-disciplined	Not effective	Referred	Seeking the job	Social injustice	Study	total
Lower (1)	0	0	2 33.30 %	0	0	1 16.70 %	0	2 33.30 %	1 16.70 %	6 100.00 %
Lower Middle (2)	5 23.80 %	0	0	7 33.30 %	3 14.30 %	0	0	5 23.80 %	1 4.80 %	21 100.00 %
Middle (3)	1 4.55 %	3 13.60 %	0	5 22.70 %	5 22.75 %	1 4.50 %	1 4.50 %	4 18.20 %	3 13.60 %	22 100.00 %
	6 12.20 %	3 6.10 %	2 4.10 %	12 24.50 %	8 16.35 %	1 2.00 %	1 2.00 %	11 22.40 %	5 10.20 %	49 100.00 %

Fig-6. Probable reasons of dropout according to social status (Lower-1, Lower-Middle-2, Middle-3)

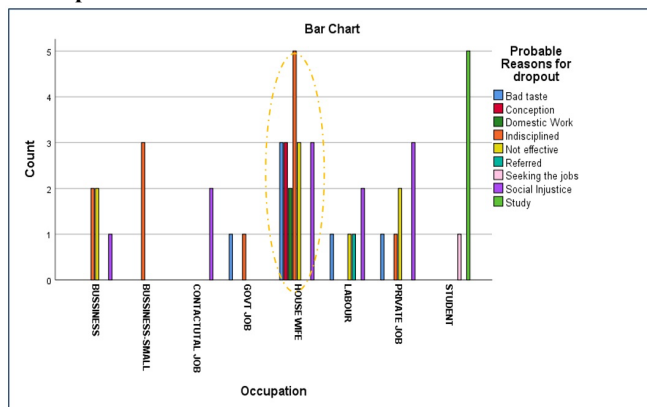


It is observed that the probable reasons of dropout e.g. bad taste of drug, conception, undisciplined and not effectiveness of drug were complained mainly by the house maker section of society which is 38.77% among the dropout as shown in Table 10 and Fig-7.

Table 10: Occupation *Probable Reason for dropout (Crosstab)

Soci al statu s	Bad taste	conception	Domestic work	In-disciplined	Not effective	Referred	Seeking the job	Social injustice	Study	total
Business	0	0	0	2 (40.0 %)	2 (40.0 %)	0	0	1 (20.0 %)	0	5 (100.00 %)
Business-Small	0	0	0	3 (100.0 %)	0	0	0	0	0	3 (100.00 %)
Contractual Job	0	0	0	0	0	0	0	2 (100.00 %)	0	2 (100.00 %)
Govt Job	1 (50.00 %)	0	0	1 (50.00 %)	0	0	0	0	0	2 (100.00 %)
House Wife	3 (15.8 %)	3 (15.8 %)	2 (10.5 %)	5 (26.3 %)	3 (15.8 %)	0	0	3 (15.8 %)	0	19 (100.00 %)
Labour	1 (20.00 %)	0	0	0	1 (20.00 %)	1 (20.00 %)	0	2 (40.00 %)	0	5 (100.00 %)
Private Job	1 (14.3 %)	0	0	1 (14.3 %)	2 (28.6 %)	0	0	3 (42.8 %)	0	7 (100.00 %)
Student	0	0	0	0	0	0	1 (16.7 %)	0	5 (83.3 %)	6 (100.00 %)
Total	6 (12.2 %)	3 (6.1 %)	2 (4.1 %)	12 (24.5 %)	8 (16.3 %)	1 (2.0 %)	1 (2.0 %)	11 (22.4 %)	5 (10.2 %)	49 (100.00 %)

Fig: 7. Probable reason of dropout among a group of house makers patients



CONCLUSION

Clinical trials in herbal drugs are very critical to at the time of designing. At the time designing of this study protocol 20% dropout were calculated. After execution of this study it is observed that for completion of a sample size of 80 cases, the dropout rate was 37.12%. This dropout is reflecting the tolerability, status of society, palatability of the drug, need of the society and concept of Government health scheme. The study discontinuation of various reasons was a primary outcome measure for this analysis. Total 49 cases were discontinuing their treatment protocol of eight weeks of treatment with fortnightly follow-up. The high rate of dropout in clinical studies on AYUSH medicine is not new. Many of them are dropout only due to the long term of their treatment and slow reactivity of the medicine. The current results demonstrate that the major role of dropout due to some social factors and on other hand, taste, palatability and slow action of Unani formulation are also among them. Human subjects are not in our control but the modification in Unani formulation is the need of the time. This should be modified and make the dosage for palatable and fast-acting so that to attract the people towards Unani medical system. The current presentation is an attempt to showcase the possible reason for dropout in the validation programme of the council. The results indicate that dropout rates are significantly influenced by the trial duration, slow reactivity of drug and long term of protocol therapy. These findings may provide a significant increase in our knowledge to take care of dropout data for designing future clinical trials in AYUSH sector.

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