

NATIONAL INSTITUTE OF UNANI MEDICINE, BANGALORE

Ministry of AYUSH, Govt of India



Case Record Form

for

**A Prospective Cohort Interventional Study Assessing the Safety and Outcome of Unani
Medicine as a Prophylaxis in Population at risk of COVID-19**

NATIONAL INSTITUTE OF UNANI MEDICINE, BANGALORE

**A Prospective Cohort Interventional Study Assessing the Safety and Outcome of Unani
Medicine as a Prophylaxis in Population at risk of COVID-19**

Name of Investigator: _____

Participants Name: _____

Age: _____ **Sex:** _____ **S/D/W/o:** _____

Address: _____

Telephone/Mobile No: _____

Name of the Participating Centre: _____

Date of induction into the clinical trial (Baseline visit-day1): _____

Dates of Subsequent visits:

Day1 **Day 10** **Day 20** **Day 35**

Status:

The participant completed / was withdrawn / Dropped out from the trial

Signature of Investigator

Signature of In-charge

NATIONAL INSTITUTE OF UNANI MEDICINE, BANGALORE
**A Prospective Cohort Interventional Study Assessing the Safety and Outcome of Unani
 Medicine as a Prophylaxis in Population at risk of COVID-19**

CASE RECORD FORM – SCREENING

BEFORE TREATMENT

Reg No (Screening No.):_____ Name of the Participant:_____

Age:_____ Sex:_____ S/D/W/o_____

Address: _____

Telephone/Mobile No: _____

Criteria for Inclusion

S.No	Parameter	Yes	No
1	Individuals of either sex above 18 and below 68 years		
2	Population as described in Low Risk zone		
3.	Individuals who are from the identified containment zone with at least 1 confirmed COVID-19 positive case.		
4.	Subjects who are ready to provide written informed consent and who are willing to participate and follow the protocol requirements of the clinical study		

(For the inclusion ‘YES to 1, 2, 3, 4 are compulsory)

Exclusion Criteria

S.No	Parameter	Yes	No
1.	Persons with severe primary respiratory disease or related complications that may be identified with COVID-19		
2.	Laboratory confirmed COVID-19 with or without symptoms		
3.	Pregnant and lactating mothers and those who have a pregnancy plan.		
4.	Persons with serious critical illness, or severe mental illnesses		
5.	Individuals with uncontrolled, unstable co morbidities		
6.	individuals on immune-suppressants and steroids		
7.	Subjects having a past history of allergy to any medicine that is part of the Unani intervention		

(For the Exclusion ‘YES’ to any one of the above)

Whether the participant is suitable for enrollment in the study? Yes No

If enrolled: - Participant Enrollment No.:

Name of the Investigator

Signature

NATIONAL INSTITUTE OF UNANI MEDICINE, BANGALORE
**A Prospective Cohort Interventional Study Assessing the Safety and Outcome of Unani
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CASE REPORT FORM – BASELINE

Participant Enrollment Number: _____ Date of enrollment: _____

DEMOGRAPHIC PROFILE

1. Marital status: Married (1) Unmarried (2) Widow(er) (3) Divorcee (4)
 Any other (5)
2. Educational status: Illiterate (1) Read & Write (2)
3. Past occupation: Desk Work (1) Field work with physical labour (2)
 Field work (3)
 If (2) or (3), specify _____
4. Present Occupation: Desk Work (1) Field work with physical labour (2)
 Field work (3) House Wife (4)
 If (2) or (3), specify _____
5. Socio-economic status: Above Poverty line (1) Below Poverty Line (2)
6. Habitat: Urban (1) Semi-Urban (2) Rural (3)
7. Religion: Hindu (1) Muslim (2) Sikh (3)
 Christian (4) Others (5)

8. Clinical Assessment

Immune Status Questionnaire (ISQ)

Please indicate how often you have had the following complaints in the **past 12 months**

S. No	Symptoms	Never	Sometimes	Regularly	Often	(Almost) Always
1.	Sudden high fever					
2.	Diarrhea					
3.	Headache					
4.	Skin problems (e. g. acne & eczema)					
5.	Muscle and joint pain					
6.	Common Cold					
7.	Coughing					

How you feel **at this moment?**

A	I score my general health the following grade (0=very bad; 10=very good)	
B	I score my immune functioning the following grade (0=very bad; 10=very good)	
C	Do you have reduced immune functioning at this moment?	Yes No
D	Do you have a chronic disease? If yes, please specify í í í í í í í í í í	Yes No

WHOQOL-BREF

Do you get the kind of support from others that you need?	Not at all	Not much	Moderately	A great deal	Completely
	1	2	3	4	5

You should circle the number that best fits how much support you got from others over the last two weeks. So you would circle the number 4 if you got a great deal of support from others as follows.

Do you get the kind of support from others that you need?	Not at all	Not much	Moderately	A great deal	Completely
	1	2	3	4	5

You would circle number 1 if you did not get any of the support that you needed from others in the last two weeks.

Please read each question, assess your feelings, and circle the number on the scale for each question that gives the best answer for you.

1 (G1)- How would you rate your quality of life?	Very Poor	Poor	Neither poor no good	Good	Very good
	1	2	3	4	5

2 (G4) - How satisfied are you with your health	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
	1	2	3	4	5

The following questions ask about how much you have experienced certain things in the last two weeks.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3 (F1.4)	To what extent do you feel that physical pain prevents you from doing what you need to do?	1	2	3	4	5
4(F11.3)	How much do you need any medical treatment to function in your daily life?	1	2	3	4	5
5(F4.1)	How much do you enjoy life?	1	2	3	4	5
6(F24.2)	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremely
7(F5.3)	How well are you able to concentrate?	1	2	3	4	5
8 (F16.1)	How safe do you feel in your daily life	1	2	3	4	5
9 (F22.1)	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about how completely you experience or were able to do certain things in the last two weeks.

		Not at all	A little	Moderately	Mostly	Completely
10 (F2.1)	Do you have enough energy for everyday life?	1	2	3	4	5
11 (F7.1)	Are you able to accept your bodily appearance?	1	2	3	4	5
12	Have you enough money to meet your	1	2	3	4	5

(F18.1)	needs?					
13 (F20.1)	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14 (F21.1)	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Very Poor	Poor	Neither poor no good	Good	Very good
15 (F9.1)	How well are you able to get around?	1	2	3	4	5

The following questions ask you to say how **good or satisfied** you have felt about various aspects of your life over the last two weeks.

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
16 (F3.3)	How satisfied are you with your sleep?	1	2	3	4	5
17 (F10.3)	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18(F12.4)	How satisfied are you with your capacity for work?	1	2	3	4	5
19 (F6.3)	How satisfied are you with yourself?	1	2	3	4	5
20(F13.3)	How satisfied are you with your personal relationships?	1	2	3	4	5
21(F15.3)	How satisfied are you with your sex life?	1	2	3	4	5
22(F14.4)	How satisfied are you with the support you get from your friends	1	2	3	4	5
23(F17.3)	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24(F19.3)	How satisfied are you with your access to health services?	1	2	3	4	5
25(F23.3)	How satisfied are you with your transport?	1	2	3	4	5

26 (F8.1) - How often do you have negative feelings such as blue mood, despair, anxiety, depression?	Never	Seldom	Quite often	Very often	Always
	1	2	3	4	5

Did someone help you to fill out this form?.....

How long did it take to fill this form out?.....

Do you have any comments about the assessment?

Assessment of Mizaj (Temperament) _____

Note the Concomitant Medications already being taken by the subject

S. No.	Concomitant Medicine	Disease condition	Quantity
1.			
2.			
3.			

Date for Next Assessment _____

Name of the Investigator _____ **Signature** _____ **Date** _____

NATIONAL INSTITUTE OF UNANI MEDICINE, BANGALORE

**A Prospective Cohort Interventional Study Assessing the Safety and Outcome of Unani
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Drug Compliance Form (Unani Regimen)

S. No.	Date	Khamira Marwareed	Unani Joshanda (Decoction)	Remarks
		Morning	Morning	
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				
11.				
12.				
13.				
14.				
15.				
16.				
17.				
18.				
19.				
20.				

NATIONAL INSTITUTE OF UNANI MEDICINE, BANGALORE

**A Prospective Cohort Interventional Study Assessing the Safety and Outcome of Unani
Medicine as a Prophylaxis in Population at risk of COVID-19**

CASE RECORD FORM

Assessment on 10th day of intervention

Participant Enrollment Number: _____ Date of enrollment: _____

Date of Assessment : _____

Clinical Assessment - Immune Status Questionnaire (ISQ)

Please indicate how often you have had the following complaints in the **past 12 months**

	Never	Sometimes	Regularly	Often	(Almost) Always
Sudden high fever					
Diarrhea					
Headache					
Skin problems (e. g. acne& eczema)					
Muscle and joint pain					
Common Cold					
Coughing					

How you feel **at this moment?**

A	I score my general health the following grade (0=very bad; 10=very good)	í	í
B	I score my immune functioning the following grade (0=very bad; 10=very good)	í	í
C	Do you have reduced immune functioning at this moment?	Yes	No
D	Do you have a chronic disease? If yes, please specify í í í í í í í í í í	Yes	No

WHOQOL-BREF

Do you get the kind of support from others that you need?	Not at all	Not much	Moderately	A great deal	Completely
	1	2	3	4	5

You should circle the number that best fits how much support you got from others over the last two weeks. So you would circle the number 4 if you got a great deal of support from others as follows.

Do you get the kind of support from others that you need?	Not at all	Not much	Moderately	A great deal	Completely
	1	2	3	4	5

You would circle number 1 if you did not get any of the support that you needed from others in the last two weeks.

Please read each question, assess your feelings, and circle the number on the scale for each question that gives the best answer for you.

1 (G1)- How would you rate your quality of life?	Very Poor	Poor	Neither poor no good	Good	Very good
	1	2	3	4	5

2 (G4) - How satisfied are you with your health	Very	Dissatisfi	Neither	Satisfied	Very
---	------	------------	---------	-----------	------

	dissatisfied	ed	satisfied nor dissatisfied		satisfied
	1	2	3	4	5

The following questions ask about how much you have experienced certain things in the last two weeks.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3 (F1.4)	To what extent do you feel that physical pain prevents you from doing what you need to do?	1	2	3	4	5
4(F11.3)	How much do you need any medical treatment to function in your daily life?	1	2	3	4	5
5(F4.1)	How much do you enjoy life?	1	2	3	4	5
6(F24.2)	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremely
7(F5.3)	How well are you able to concentrate?	1	2	3	4	5
8 (F16.1)	How safe do you feel in your daily life	1	2	3	4	5
9 (F22.1)	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about how completely you experience or were able to do certain things in the last two weeks.

		Not at all	A little	Moderately	Mostly	Completely
10 (F2.1)	Do you have enough energy for everyday life?	1	2	3	4	5
11 (F7.1)	Are you able to accept your bodily appearance?	1	2	3	4	5
12 (F18.1)	Have you enough money to meet your needs?	1	2	3	4	5
13 (F20.1)	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14 (F21.1)	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Very Poor	Poor	Neither poor no good	Good	Very good
15 (F9.1)	How well are you able to get around?	1	2	3	4	5

The following questions ask you to say how **good or satisfied** you have felt about various aspects of your life over the last two weeks.

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
16 (F3.3)	How satisfied are you with your sleep?	1	2	3	4	5
17 (F10.3)	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18(F12.4)	How satisfied are you with your capacity for work?	1	2	3	4	5

19 (F6.3)	How satisfied are you with yourself?	1	2	3	4	5
20(F13.3)	How satisfied are you with your personal relationships?	1	2	3	4	5
21(F15.3)	How satisfied are you with your sex life?	1	2	3	4	5
22(F14.4)	How satisfied are you with the support you get from your friends	1	2	3	4	5
23(F17.3)	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24(F19.3)	How satisfied are you with your access to health services?	1	2	3	4	5
25(F23.3)	How satisfied are you with your transport?	1	2	3	4	5

26 (F8.1) - How often do you have negative feelings such as blue mood, despair, anxiety, depression?	Never	Seldom	Quite often	Very often	Always
	1	2	3	4	5

Did someone help you to fill out this form?.....

How long did it take to fill this form out?.....

Do you have any comments about the assessment?

THANK YOU FOR YOUR HELP

Date to come on for next assessment _____

Name of the Investigator _____ Signature _____ Date _____

Concomitant Medication: Need for any concomitant medication: Yes No

If yes, then

Sr. No.	Medicine	Dose	Duration	Reason for taking

Rescue Medication: Need for any rescue medication: Yes No

If yes, then

Sr. No.	Medicine	Dose	Duration	Reason for taking

Adverse Drug Reactions/ Adverse Events: Any Adverse effects/ other complains: Yes No

Date	Complaint	Treatment given	Remarks

Did the patient drop out on his / her own? Yes (1) No (0)

If yes, date & reasons (in detail): _____

Was the patient withdrawn from the trial? Yes (1) No (0)

If yes, date & reasons (in detail): _____

Drug Compliance:

Approximate Quantity of Unani regimen consumed:

Percentage of Drug Compliance:

Sr. No.	Medicine	Batch No.	Quantity

Drug Compliance Report – compliance/noncompliance

Next visit due on: _____

Name of the Investigator _____ Signature _____ Date _____

NATIONAL INSTITUTE OF UNANI MEDICINE, BANGALORE

**A Prospective Cohort Interventional Study Assessing the Safety and Outcome of Unani
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CASE REPORT FORM

Assessment on 20th day of Intervention

Participant Enrollment Number: _____ Date of enrollment: _____

Name of the Participant: _____

Date of this assessment: _____

Assessment Parameters: Clinical Assessment

Immune Status Questionnaire (ISQ)

Please indicate how often you have had the following complaints in the **past 12 months**

	Never	Sometimes	Regularly	Often	(Almost) Always
Sudden high fever					
Diarrhea					
Headache					
Skin problems (e. g. acne& eczema)					
Muscle and joint pain					
Common Cold					
Coughing					

How you feel at this moment?

A	I score my general health the following grade (0=very bad; 10=very good)	í	í
B	I score my immune functioning the following grade (0=very bad; 10=very good)	í	í
C	Do you have reduced immune functioning at this moment?	Yes	No
D	Do you have a chronic disease? If yes, please specify í í í í í í í í í í	Yes	No

WHOQOL-BREF

Do you get the kind of support from others that you need?	Not at all	Not much	Moderately	A great deal	Completely
	1	2	3	4	5

You should circle the number that best fits how much support you got from others over the last two weeks. So you would circle the number 4 if you got a great deal of support from others as follows.

Do you get the kind of support from others that you need?	Not at all	Not much	Moderately	A great deal	Completely
	1	2	3	4	5

You would circle number 1 if you did not get any of the support that you needed from others in the last two weeks.

Please read each question, assess your feelings, and circle the number on the scale for each question that gives the best answer for you.

1 (G1)- How would you rate your quality of life?	Very Poor	Poor	Neither poor no good	Good	Very good
	1	2	3	4	5

2 (G4) - How satisfied are you with your health	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
	1	2	3	4	5

The following questions ask about how much you have experienced certain things in the last two weeks.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3 (F1.4)	To what extent do you feel that physical pain prevents you from doing what you need to do?	1	2	3	4	5
4(F11.3)	How much do you need any medical treatment to function in your daily life?	1	2	3	4	5
5(F4.1)	How much do you enjoy life?	1	2	3	4	5
6(F24.2)	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremely
7(F5.3)	How well are you able to concentrate?	1	2	3	4	5
8 (F16.1)	How safe do you feel in your daily life	1	2	3	4	5
9 (F22.1)	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about how completely you experience or were able to do certain things in the last two weeks.

		Not at all	A little	Moderately	Mostly	Completely
10 (F2.1)	Do you have enough energy for everyday life?	1	2	3	4	5
11 (F7.1)	Are you able to accept your bodily appearance?	1	2	3	4	5
12 (F18.1)	Have you enough money to meet your needs?	1	2	3	4	5
13 (F20.1)	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14 (F21.1)	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Very Poor	Poor	Neither poor no good	Good	Very good
15 (F9.1)	How well are you able to get around?	1	2	3	4	5

The following questions ask you to say how **good or satisfied** you have felt about various aspects of your life over the last two weeks.

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
16 (F3.3)	How satisfied are you with your sleep?	1	2	3	4	5
17 (F10.3)	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18(F12.4)	How satisfied are you with your	1	2	3	4	5

	capacity for work?					
19 (F6.3)	How satisfied are you with yourself?	1	2	3	4	5
20(F13.3)	How satisfied are you with your personal relationships?	1	2	3	4	5
21(F15.3)	How satisfied are you with your sex life?	1	2	3	4	5
22(F14.4)	How satisfied are you with the support you get from your friends	1	2	3	4	5
23(F17.3)	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24(F19.3)	How satisfied are you with your access to health services?	1	2	3	4	5
25(F23.3)	How satisfied are you with your transport?	1	2	3	4	5

26 (F8.1) - How often do you have negative feelings such as blue mood, despair, anxiety, depression?	Never	Seldom	Quite often	Very often	Always
	1	2	3	4	5

Did someone help you to fill out this form?.....

How long did it take to fill this form out?.....

Do you have any comments about the assessment?

Date to come on for next assessment _____

Name of the Investigator _____ **Signature** _____ **Date** _____

Concomitant Medication:

Need for any concomitant medication: Yes No

If yes, then

Sr. No.	Medicine	Dose	Duration	Reason for taking

Rescue Medication:

Need for any rescue medication: Yes No

If yes, then

Sr. No.	Medicine	Dose	Duration	Reason for taking

Adverse Drug Reactions/ Adverse Events:

Any Adverse effects/ other complains: Yes No

Date	Complaint	Treatment given	Remarks

Did the patient drop out on his / her own? Yes (1) No (0)

If yes, date & reasons (in detail): _____

Was the patient withdrawn from the trial? Yes (1) No (0)

If yes, date & reasons (in detail): _____

Drug Compliance:

Approximate Quantity of Unani Regimen consumed:

Percentage of Drug Compliance:

Collection of the Drug Compliance Report:

Next visit due on: _____

Name of the Investigator _____ **Signature** _____ **Date** _____

NATIONAL INSTITUTE OF UNANI MEDICINE, BANGALORE

**A Prospective Cohort Interventional Study Assessing the Safety and Outcome of Unani
Medicine as a Prophylaxis in Population at risk of COVID-19**

CASE RECORD FORM

Assessment on 35th day

Participant Enrollment Number: _____ Date of enrollment: _____

Name of the Participant: _____

Date of this assessment: _____

Assessment Parameters: Clinical Assessment

Immune Status Questionnaire (ISQ)

Please indicate how often you have had the following complaints in the **past 12 months**

	Never	Sometimes	Regularly	Often	(Almost) Always
Sudden high fever					
Diarrhea					
Headache					
Skin problems (e. g. acne & eczema)					
Muscle and joint pain					
Common Cold					
Coughing					

How you feel at this moment?

A	I score my general health the following grade (0=very bad; 10=very good)		
B	I score my immune functioning the following grade (0=very bad; 10=very good)		
C	Do you have reduced immune functioning at this moment?	Yes	No
D	Do you have a chronic disease? If yes, please specify í í í í í í í í í í	Yes	No

WHOQOL-BREF

Do you get the kind of support from others that you need?	Not at all	Not much	Moderately	A great deal	Completely
	1	2	3	4	5

You should circle the number that best fits how much support you got from others over the last two weeks. So you would circle the number 4 if you got a great deal of support from others as follows.

Do you get the kind of support from others that you need?	Not at all	Not much	Moderately	A great deal	Completely
	1	2	3	4	5

You would circle number 1 if you did not get any of the support that you needed from others in the last two weeks.

Please read each question, assess your feelings, and circle the number on the scale for each question that gives the best answer for you.

1 (G1)- How would you rate your quality of life?	Very Poor	Poor	Neither poor no good	Good	Very good
--	-----------	------	----------------------	------	-----------

	1	2	3	4	5
--	---	---	---	---	---

2 (G4) - How satisfied are you with your health	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
	1	2	3	4	5

The following questions ask about how much you have experienced certain things in the last two weeks.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3 (F1.4)	To what extent do you feel that physical pain prevents you from doing what you need to do?	1	2	3	4	5
4(F11.3)	How much do you need any medical treatment to function in your daily life?	1	2	3	4	5
5(F4.1)	How much do you enjoy life?	1	2	3	4	5
6(F24.2)	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremely
7(F5.3)	How well are you able to concentrate?	1	2	3	4	5
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The following questions ask about how completely you experience or were able to do certain things in the last two weeks.

		Not at all	A little	Moderately	Mostly	Completely
10 (F2.1)	Do you have enough energy for everyday life?	1	2	3	4	5
11 (F7.1)	Are you able to accept your bodily appearance?	1	2	3	4	5
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13 (F20.1)	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14 (F21.1)	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Very Poor	Poor	Neither poor no good	Good	Very good
15 (F9.1)	How well are you able to get around?	1	2	3	4	5

The following questions ask you to say how **good or satisfied** you have felt about various aspects of your life over the last two weeks.

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16 (F3.3)	How satisfied are you with your sleep?	1	2	3	4	5
17 (F10.3)	How satisfied are you with your ability to perform your daily	1	2	3	4	5

	living activities?					
18(F12.4)	How satisfied are you with your capacity for work?	1	2	3	4	5
19 (F6.3)	How satisfied are you with yourself?	1	2	3	4	5
20(F13.3)	How satisfied are you with your personal relationships?	1	2	3	4	5
21(F15.3)	How satisfied are you with your sex life?	1	2	3	4	5
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24(F19.3)	How satisfied are you with your access to health services?	1	2	3	4	5
25(F23.3)	How satisfied are you with your transport?	1	2	3	4	5

26 (F8.1) - How often do you have negative feelings such as blue mood, despair, anxiety, depression?	Never	Seldom	Quite often	Very often	Always
	1	2	3	4	5

Did someone help you to fill out this form?.....

How long did it take to fill this form out?.....

Do you have any comments about the assessment?

THANK YOU FOR YOUR HELP

Status of the study participant:

Completed the study (1) Drop out (2) Died (3)

Reason, if dropped out or died: _____

Name of the Investigator: _____ **Signature:** _____ **Date** _____

NATIONAL INSTITUTE OF UNANI MEDICINE, BANGALORE

A Prospective Cohort Interventional Study Assessing the Safety and Outcome of Unani Medicine as a Prophylaxis in Population at risk of COVID-19

PATIENT INFORMATION SHEET (PIS)

Introduction:-

The current pandemic of COVID-19 requires strict measures of isolation and quarantine for preventing its spread in community. Governments across the globe have taken several measures to avoid social contacting and therefore social-physical distancing has become the norm of the day. Along with this personal hygiene measures like hand washing and sanitizing have been in focus to avoid community spread. However, COVID-19 being a viral infection it becomes imperative to boost our immunity and strengthen the body's defence mechanism to not only prevent but also reduce the severity of the disease it occurs.

Aim of the Study:

The aim of this clinical study is to evaluate whether consumption of Unani Regimen for 20 days by healthy individuals can act as a preventive remedy for COVID-19.

Subject Eligibility for participation in the Study:

Before recruiting you in the study you will be screened on certain eligibility criteria. Healthy male and female participants between the age of 18 years to 68 years will be eligible to participate if they are not having any acute or chronic medical condition that requires regular medical monitoring and care. The study investigator (study doctor) will decide on your eligibility to participate based on his/her clinical assessment of your health.

Study Procedure:

The study will be carried out at hospitals and at community level in Bangalore, India. Like you there will be a total of about 4000 subjects who will be recruited in the study out of 2000 subjects will receive Unani Regimen and rest of the subjects will be used as control. Before recruiting you in the study a written informed consent will be taken from you. The investigator (study doctor) will do a detailed clinical assessment of your health. If there are laboratory tests, the PI will inform and plan for the same. However, you may be undergoing laboratory testing including COVID-19 tests as and when required and advised by National /State Government Health authorities. If you meet all the eligibility criteria for participation in the study you will be allocated into one of the two study groups i.e. Test Group and Control Group.

The total duration for which you will be asked to take *Unani Regimen* in test group will be **20 days**. During this period, the study team will enquire about your health-related problems on a regular basis. If you are not able to understand anything on the same you will be free to ask the study team anytime during the study.

You will be asked to follow COVID-19 related guidelines (prevention and containment of infection) provided by the local health authorities and other government agencies from time to time. You will be asked to take any mass mandatory remedy recommended by the Government of India/State or Local Health Authorities irrespective of your allotted group.

Subject Responsibilities:

You are required to co-operate with the study investigator/ study team for all the study related procedures. Kindly inform the study investigator/study team details of your past medical problems and other conditions along with the medication you are taking for any other condition as these may affect how you respond/react to the use of study product. You are required to report any kind of health-related issue, which may or may not be related to consuming the study product. The used/unused packet of *Unani Regimen* should be returned at end of the study. You are also required to provide accurate and timely data of your health as well as when the study team contacts you for assessing the same. You will be following all preventive measures like hand hygiene; wearing mask, social distancing etc. issued by the Govt. and health authorities during the entire study period.

During the study period if you experience any of the COVID related symptoms (like fever, cough, sore throat, weakness, difficulty in breathing etc) subject will be advised to follow guidelines issued by Government of India/State health authorities/Local Health Authority for COVID-19 as and when available from time to time. The following will be followed as per the current guidelines:

- Visit nearest health care center/government hospital or clinic and follow advice given by the same.
- If you are not asked for any COVID-19 test you may be advised to follow instructions and take treatment of the same from local physician/site investigator.
- ☐ If you are asked to undergo test for COVID-19 and your test is tests negative, you will be advised to follow the guidelines issued by local health authorities/Physician/Study doctor. If you test positive for COVID-19, you will be asked to follow instructions for admission/isolation and further treatment as recommended by the local health authority/Hospital.

All government (central and state) and local authority guidelines will be strictly followed during the entire duration of the study. All study related staff including the investigators (study doctor) will be trained on the study protocol as well as COVID-19 guidelines from time to time.

Foreseeable Risks: There is no expected risk except, the intervention is a time-tested remedy which is already in the public health guidelines issued by AYUSH. The formulation included in the Unani Regimen is not reported with any side effects so far

Expected Benefits: If the product works in accordance with the proposed hypothesis on immune-modulation, the NK Cell activity and MHC-1 mast cells would help in prevention of illness and would boost your general health.

Confidentiality:

Your medical records will be treated with confidentiality and will be revealed only to doctors/scientists/ auditors of this study and if required to the drug regulatory authority. The results of this study may be published in a scientific journal, but your identity will not be disclosed.

Your participation in the study and your rights:

Before agreeing to participate in the present study, it is important that you read and understand the information given in Informed Consent Form. Take all the time you need to do so. Your participation in this study is voluntary and you may withdraw from the study any time without having to give reasons for the same. Your refusal to participate will not involve any penalty in terms of subsequent participation in research studies. If your participation in this study appears to be unsuitable for you & your child, the study doctor will stop it. It is possible that the study could be stopped without your consent. The study doctor and study team will tell you if any information becomes known during the study, which may affect your willingness to continue in the study.

Compensation for study related Injury:

~~If all the instructions for the study are followed and you /your child encounters study related injury or death, you have right to claim complete medical care as well as compensation for the injury or death.~~ Compensation could be in the form of payment for immediate medical or surgical management of research related injuries or for research related injuries leading to temporary or permanent disabilities. In case of death, compensation will be paid to the legal heir/lawful guardian. Compensation will be available for injury or death due to adverse effects due to study drug, deviation from protocol and negligence on part of investigator or sponsor and for adverse effects due to concomitant medications allowed as per protocol. You/Your child are covered under clinical study liability insurance policy. In case of study related injury or death, the sponsor or its representative will provide complete medical care as well as compensation for the injury or death.

For further questions / problems you may have, you should contact the following person:

(Investigators Name (Study doctor), address & telephone)

For any ethical issues you may have, you should contact the following person:

(Ethics Committee Chairperson Name, address & telephone)

NATIONAL INSTITUTE OF UNANI MEDICINE, BANGALORE

**A Prospective Cohort Interventional Study Assessing the Safety and Outcome of Unani
Medicine as a Prophylaxis in Population at risk of COVID-19**

Informed Consent Form (ICF)

Participant enrollment Number: -----

Name of the Investigator -----

- I confirm that I have read / the study has been explained to me adequately and I have understood the information sheet for the above study and had the opportunity to ask questions.
- I hope to complete the study, but I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason, and without my medical care or legal rights being affected.
- I understand that my doctor will provide information about my progress, in confidence, to the related officers of _____. I understand that the information held by the Investigators and researchers and records maintained by the Central Monitoring Unit, _____ might be used to follow up my health status.
- I understand that the information will be used for medical research only and that I will not be identified in any way in the analysis and reporting of the results. I understand that sections of any of my medical notes may be looked at by the Sponsors or responsible individuals from the members of the IEC, Regulatory authorities or Court, if necessary. I give permission for these individuals to have access to my records.
- I understand what is involved in this trial and agree to take part in the clinical study.

Name of the Patient _____ Signature _____ Date _____

Name of the Investigator _____ Signature _____ Date _____

Translation of Consent form into regional languages to be done by Investigator

ASSESSMENT OF 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 & Lustrous Thick, Rapid Growth	Black & Thin Slow Growth	Brown & Thin Rapid Growth	Brown & Thin Slow Growth
MOVEMENT	Active	Dull	Hyperactive	Less Active
DIET (MOST LIKED)	Cold & Dry	Hot & Dry	Cold & Moist	Hot & Moist
WEATHER (MOST SUITABLE)	Spring	Summer	Winter	Autumn
SLEEP	Normal (6-8 hours)	In excess	Inadequate	Insomnia
PULSE	Normal in Rate (70-80/min) Large in Volume	Slow in Rate (60-70/min) Normal in Volume	Rapid in Rate (80-100/min) Normal in Volume	Slow in Rate (60-70/min) Less in Volume
EMOTIONS	Normal	Calm & Quiet	Angry	Nervous

(Maximum no. of ticks in a particular column denote the dominant temperament)