Impact of Ayurvedic Interventions in prevention of COVID-19 infection in containment areas of Delhi- A community based study

Introduction: Amid all the gloom spread across the world due to the outbreak of novel coronavirus (COVID-19), which has now infected more than a million people around the world, everyone is focusing on preventive measures. Ayurveda has been an intrinsic part of Indian culture be it kitchen species or usual daily regimen. Further to address the pandemic, Ministry of AYUSH has released certain guidelines for prevention of COVID through certain common kitchen species, herbs and practices.

In order to capture the effectiveness of such preventive measures, guidelines and Ayurveda advocacies, a community study is planned to capture the relative risk and incidence of COVID 19 among Ayurveda users..

Objective(s):

Primary objectives:

1) To know the efficacy of Ayurveda interventions in the community of containment area

Secondary objectives:

1) To investigate the risk of COVID 19 among community of containment zone
2) To investigate improvement in general well-being of people living in containment area
3) To observe and study health seeking trends of general public of the area under study
4) To observe and study acceptance of Ayurvedic advocacies among public

Inclusion Criteria

- Aged ≥18 -70 years male or female
- Residents of the identified containment zones, marked by Govt. of NCT Delhi for high risk of COVID 19
- Willing to take study medication;
- Provides written informed consent prior to initiation of studyProcedures (or legally authorized representative).

Only the copy ofPhotography of informed consent would be kept for records.

Exclusion Criteria

- Persons already treated with any of the study drugs during thelast 30 days;
- Pregnant and lactating females and those who have a pregnancy plan
- Participants with any immunosuppressive medication or in an immuneCompromised state or haematological disease.

- Laboratory confirmed COVID-19 with or without symptoms.

- Known allergy to any of the medications used in this trial.

- Not willing to participate in the study.

- Any other criteria, as per the investigator would jeopardize the study.

Outcome measures

Primary Outcome measures

1) Incidence of COVID 19 positive cases (as confirmed by hospital by standard investigation (real-time polymerase chain reaction test) among Ayurveda users

Secondary Outcome Measure

1) Incidence of severe COVID 19 positive cases (admitted in hospital and requiring ventilation and/or multi-organ failure as reported by hospital) among Ayurveda users
2) Incidence of mortality due to COVID 19 among Ayurveda users as compared to non users
3) Incidence of any other ailment like cough, fever, sore throat etc (as per questionnaire annexed) during this study
4) Change in appetite, bowel habit, sleep among the users (assessed on VAS scale and status of the same among routine Ayurveda advocacies users).
5) ADR/AE due to use of any particular Ayurveda advocacies

Methodology:

Study Design: The study will be conducted as aopen label prospectivecommunity based study is designed to capture the desired objectives of the study, based on pre-defined close ended and certain open ended questions to collect the data.

Study Population: The study population consists of all the residents of the identified containment zones, marked by Govt. of NCT Delhi for high risk of COVID 19.

Sample Size: 1500

Study period: 3 months

Data Collection Methods:In the form of Questionnaire (google forms)

1) This is an open label questionnaire based study, the participants after informed consent will be directly interviewed by visiting to the identified containment zones and thereafter further follow up will be done as per the convenience of the participant either through telephonic interview/whatsapp/email etc. (particular preferences will be documented at the time of first visit)

2) All participant data will be made anonymous which ensures full data protection of the participants.
3) After enrolment on day one, assessment will be done on day 7, 14 and 22 by telephonic communication or as convenient to the participant.

Data Analyses: Stratified incidence rates with 95% CIs will be estimated for each endpoint within the strata each Ayurveda users practicing advocacies regularly, sometimes and rarely and type of advocacies and other Ayurveda practices being used.

Ayurveda users are categorised as elaborated in the annexed questionnaire as

1) Yogasana/Pranayama/Meditation
2) Chyavanprasha
3) Herbal tea with Tulsi, Dalchini, kalimirch/Sunti/Munakka
4) Haldi-milk
5) Nasal application of sesame oil/coconut oil/ ghee
6) Gargling/oil pulling in mouth with sesame oil or coconut oil
7) Drinking warm water
8) Fumigation
9) Others (Specified) will be taken in single category unless any particular practices is being noticed in more than 30% users

Further, these categories are sub grouped into:

1) Frequent users: Using for more than 5 days a week for 30 days (more than 20 days in 30 days)
2) Less Frequent: Using for 10 to 20 days in past 30 days
3) Occasional: Using for less than 10 days in a week

Milestone

1. Identification of study areas
2. Ethical approval and necessary regulatory approvals
3. preparation of google forms/Printing of questionnaires
4. Survey
5. Online/Telephonic follow up
6. Collation of data and interpretation