


LETTER

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# Homeopathy for Covid-19 in Primary Care: A structured summary of a study protocol for a randomized controlled trial

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## Abstract

**Objectives:** To investigate the effectiveness and safety of homeopathic medicine *Natrum muriaticum* (LM2) for mild cases of COVID-19 in Primary Health Care.

**Trial design:** A randomized, two-armed (1:1), parallel, placebo-controlled, double-blind, clinical trial is being performed to test the following hypotheses:

- H0: homeopathic medicines = placebo (null hypothesis) vs.
- H1: homeopathic medicines  $\neq$  placebo (alternative hypothesis) for mild cases of COVID-19 in Primary Care.

**Participants:** Setting: Primary Care of São Carlos – São Paulo – Brazil.

One hundred participants aged 18 years or older, with Influenza-like symptoms and a positive RT-PCR for SARS-CoV-2. Willingness to give informed consent and to comply with the study procedures is also required. Exclusion criterium: severe acute respiratory syndrome.

### Intervention and comparator:

- Homeopathy: 1 globule of *Natrum muriaticum* LM2 diluted in 20 mL of alcohol 30% and dispensed in a 30 ml bottle.
- Placebo: 20 mL of alcohol 30% dispensed in a 30 ml bottle.

Posology: one drop taken orally every 4 hours (6 doses/day) while there is fever, cough, tiredness, or pain (headache, sore throat, muscle aches, chest pain, etc.) followed by one drop every 6 hours (4 doses/day) until the fourteenth day of use. The bottle of study medication should be submitted to 10 vigorous shakes (succussions) before each dose. Posology may be changed by telemedicine, with no break in blinding.

Study medication should be maintained during home isolation. According to the Primary Care protocol, the home  
(Continued on next page)

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(Continued from previous page)

isolation period lasts until the 10<sup>th</sup> day after the appearance of the first symptom, or up to 72 hours without symptoms.

**Main outcomes:** The primary endpoint will be time to recovery, defined as the number of days elapsed before all COVID-19 Influenza-like symptoms are recorded as mild or absent during home isolation period. Secondary measures are recovery time for each COVID-19 symptom; score of the scale created for the study (COVID-Simile Scale); medicines used during follow-up; number of days of follow-up; number of visits to emergency services; number of hospitalizations; other symptoms and Adverse Events during home isolation period.

**Randomisation:** The study Statistician generated a block randomization list, using a 1:1 ratio of the two groups (denoted as A and B) and a web-based tool (<http://www.random.org/lists>).

**Blinding (masking):** The clinical investigators, the statistician, the Primary Care teams, the study collaborators, and the participants will remain blinded from the identity of the two treatment groups until the end of the study.

**Numbers to be randomised (sample size):** One hundred participants are planned to be randomized (1:1) to placebo (50) or homeopathy (50).

**Trial Status:** Protocol version/date May 21, 2020. Recruitment is ongoing. First participant was recruited/included on June 29, 2020. Due to recruitment adaptations to Primary Care changes, the authors anticipate the trial will finish recruiting on April 10, 2021.

**Trial registration:** COVID-Simile Study was registered at the University Hospital Medical Information Network (UMIN - <https://www.umin.ac.jp/ctr/index.htm>) on June 1<sup>st</sup>, 2020, and the trial start date was June 15, 2020. Unique ID: UMIN000040602.

**Full protocol:** The full protocol is attached as an additional file, accessible from the Trials website (Additional file 1). In the interest in expediting dissemination of this material, the familiar formatting has been eliminated; this Letter serves as a summary of the key elements of the full protocol.

**Keywords:** COVID-19, Homeopathy, Unified Health System, Primary Care, Telemedicine, Randomized Controlled Trial protocol

## Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s13063-021-05071-5>.

### Additional file 1.

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## Authors' contributions

All authors certify that they have participated sufficiently in the work to take public responsibility for the content, including participation in the concept (UCA), design (UCA, MSA, LMH, AEP, ATC, JNMD, CAAM, KRS, LS, HFS, EZM), analysis (EMZ), writing (UCA), or revision of the manuscript (UCA, MSA). The author(s) read and approved the final manuscript.

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## Availability of data and materials

The data will be available from the author on reasonable request.

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## Ethics approval and consent to participate

COVID-Simile study Presentation Certificate for Ethical Appreciation (CAAE) number is 30638220.0.0000.0008, which was approved by the Brazilian National Research Ethics Commission (CONEP) on May 31<sup>st</sup>, 2020 (report # 4.059.759).

Ethical approval is available at:

<https://plataformabrasil.saude.gov.br/login.jsf?jsessionid=1D49B939CC1FB7279B4E8A7117C2C664.server-plataformabrasil-srvjpdf130> [Portuguese]. Please click on "Confirmar Aprovação pelo CAAE ou Parecer" (Confirm Approval by CAAE or report #. The system only shows approved protocols.

Informed Consent (IC) is presented and explained during recruitment by telemedicine. Two counterparts of the IC (pre-signed by the principal investigator) are sent to the participant's home address, through a delivery company, which returns the signed IC to the study centre, completing the Inclusion process.

## Consent for publication

Not applicable.

## Competing interests

The authors declare that they have no competing interests.

Cesar AT is co-owner of HN-Cristiano Homeopatia, the pharmacy that has donated the study medication, however, *Natrum muriaticum* has been in use for over 150 years and is not patentable.

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