
Locally Produced Cloth Face Mask and COVID-19 Like Illness Prevention

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT04471766

Recruitment Status: Enrolling by invitation
First Posted: July 15, 2020
Last Update Posted: November 24, 2020

Sponsor:
Bandim Health Project

Collaborators:
University of Southern Denmark
Engineers without Borders, Denmark (https://iug.dk/en)

Information provided by (Responsible Party):
Bandim Health Project

Study Description

Brief Summary:
The number of cases of COVID-19 is still increasing and transmission of SARS-CoV-2 seems to occur mainly through person-to-person transmission through respiratory droplets, indirect contact with infected people and...
The use of face masks is recommended as a public health measure, but in many settings only domestic cloth made masks are available to the majority of the people. However, masks can be of different quality and very little is known about the utility of cloth face masks at the community level.

In Bandim Health Project's Health and Demographic Surveillance System we will evaluate the effect of providing locally produced cloth face masks on severity of COVID-19 like illness and mortality in an urban population. The locally produced cloth mask is made according to a laboratory certified model and will be provided to the intervention group alongside information of how the risk of transmission can be reduced. The control group will receive information alone.

Follow-up will be implemented through telephone calls and post-epidemic home visits.

<table>
<thead>
<tr>
<th>Condition or disease</th>
<th>Intervention/treatment</th>
<th>Phase</th>
</tr>
</thead>
</table>
| COVID-19 Respiratory Illness | Other: Certified cloth face mask plus preventive information  
Behavioral: Preventive information | Not Applicable |

Study Design

**Study Type**: Interventional (Clinical Trial)

**Estimated Enrollment**: 66000 participants

**Allocation**: Randomized

**Intervention Model**: Parallel Assignment

**Masking**: Single (Outcomes Assessor)

**Primary Purpose**: Prevention

**Official Title**: Evaluation of Locally Produced Cloth Face Mask on COVID-19 and Respiratory Illnesses Prevention at the Community Level - a Cluster-randomized Trial

**Actual Study Start Date**: July 20, 2020
Estimated **Primary Completion Date**: June 2021

Estimated **Study Completion Date**: August 2021

### Arms and Interventions

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental: Certified cloth face mask plus preventive information</td>
<td>Other: Certified cloth face mask plus preventive information Provision of two face masks sewed locally following a certified model tested for FORCE in the laboratory per residents &gt; 10 years old Behavioral: Preventive information Advice on how to prevent COVID-19 according to the government’s policy</td>
</tr>
<tr>
<td>Certified cloth face mask</td>
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</tbody>
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### Outcome Measures

**Primary Outcome Measures**:

1. Reported COVID-like illness [Time Frame: Four months follow-up]
   - Self-reported main symptoms of COVID-19 (three or more - fever, cough, fatigue, shortness of breath, loss of smell / taste)

2. Consultation [Time Frame: Four months follow-up]
   - Consultation for COVID-19 like illness or/and reported positive test

3. Severe illness [Time Frame: Four months follow-up]
   - Self reported COVID-19 like illness plus hospitalization or death
4. Mortality [ Time Frame: Four months follow-up ]

   Any death during the follow-up period

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**Eligibility Criteria**

**Information from the National Library of Medicine**

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, [Learn About Clinical Studies](https://clinicaltrials.gov/ct2/show/NCT04471766?term=Bandim&cond=Covid&cntry=GW&draw=2).

**Ages Eligible for Study:**

10 Years and older (Child, Adult, Older Adult)

**Sexes Eligible for Study:**

All

**Accepts Healthy Volunteers:**

No

**Criteria**

Inclusion Criteria:

- Household resident
- Age: 10 years and older

Exclusion Criteria:

- Refusal to participate

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**Contacts and Locations**

**Information from the National Library of Medicine**

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.
Please refer to this study by its ClinicalTrials.gov identifier (NCT number): NCT04471766

Locations

Guinea-Bissau

**Bandim** Health Project
Bissau, Bissau Codex, Guinea-Bissau

Sponsors and Collaborators

**Bandim** Health Project
University of Southern Denmark
Engineers without Borders, Denmark (https://iug.dk/en)

More Information

**Responsible Party:**
Bandim Health Project

**ClinicalTrials.gov Identifier:**
NCT04471766  History of Changes

**Other Study ID Numbers:**
BHP MASK01

**First Posted:**
July 15, 2020  Key Record Dates

**Last Update Posted:**
November 24, 2020

**Last Verified:**
November 2020

**Individual Participant Data (IPD) Sharing Statement:**

**Plan to Share IPD:**
No

**Studies a U.S. FDA-regulated Drug Product:**
No
Studies a U.S. FDA-regulated Device Product:
No

Keywords provided by Bandim Health Project:
Face mask
COVID-19
Respiratory illness
Mortality