

COVID-19 is an emerging, rapidly evolving situation.

Get the latest public health information from CDC: <https://www.coronavirus.gov>.

Get the latest research information from NIH: <https://www.nih.gov/coronavirus>.

 U.S. National Library of Medicine

**ClinicalTrials.gov**



## 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 Details](#)

[Tabular View](#)

[No Results Posted](#)

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[How to Read a Study Record](#)

## Study Description

Go to

### 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

surfaces. 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.

<u>Condition or disease</u> ⓘ	<u>Intervention/treatment</u> ⓘ	<u>Phase</u> ⓘ
COVID-19 Respiratory Illness	Other: Certified cloth face mask plus preventive information Behavioral: Preventive information	Not Applicable

## Study Design

Go to

### 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**Go to 

<b>Arm</b> ⓘ	<b>Intervention/treatment</b> ⓘ
<p>Experimental: Certified cloth face mask plus preventive information</p> <p>Certified cloth face mask</p>	<p>Other: Certified cloth face mask plus preventive information</p> <p>Provision of two face masks sewed locally following a certified model tested for FORCE in the laboratory per residents &gt; 10 years old</p> <p>Behavioral: Preventive information</p> <p>Advice on how to prevent COVID-19 according to the government' policy</p>
<p>Active Comparator: Information on COVID-19 prevention</p> <p>Advice on how to prevent COVID-19 according to the government' policy.</p>	<p>Behavioral: Preventive information</p> <p>Advice on how to prevent COVID-19 according to the government' policy</p>

**Outcome Measures**Go to **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

## Eligibility Criteria

Go to

### 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](#).*

### 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

## Contacts and Locations

Go to

### 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

Go to

### 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