

Title: Reducing Spread of COVID-19 in a University Community Setting: Role of a Low-Cost Reusable Form-Fitting Fabric Mask for Community Use

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Key Information for Reducing Spread of SARS-CoV-2 in a University Community Setting: Role of a Low-Cost Reusable Form-Fitting Fabric Mask for Community Use

What Am I Being Asked To Do?

You are being asked to be a volunteer in a research study. This page will give you key information to help you decide if you would like to participate. Your participation is voluntary. As you read, please feel free to ask any questions you may have about the research.

What Is This Study About and What Procedures Will You be Asked to Follow?

The purpose of the study is to test the role of the newly developed reusable form-fitting fabric mask – named the “focal” mask – in reducing the spread of SARS-CoV-2 in a community setting comprising undergraduate students living in dormitories at Georgia Tech. Out of 200 students in the six-week study, 100 will be given the new mask and asked to use it during a two-week period of the study. The other 100 will continue to follow their regular practice regarding the use of face coverings. Each subject will fill out a profile form at the beginning of the study. At the end of each day of the study, you will fill out a brief survey, which should take you about five minutes. At the end of the study, you will fill out another survey about your experience with masks. At the end of the study, you can keep the focal masks given to you.

Are There Any Risks or Discomforts you Might Experience by Being in this Study?

The materials used in the focal mask that 100 of the 200 participants will be testing are present in everyday clothing including fabric masks. Therefore, the risks or discomforts involved are no greater than those involved in daily activities when wearing/using clothes, including masks. There is a risk that the device may not be effective for its intended use and may not protect you from contracting SARS-CoV-2 and/or other diseases.

What Are the Reasons You Might Want to Volunteer For This Study?

You are not likely to benefit in any way from joining this study. We hope that what we learn will inform the public about the benefits of using the focal mask to prevent the spread of SARS-CoV-2 in a community setting. The study will also contribute to understanding better the role of any type of face covering and thereby inform public policy. You will be given a compensation of \$150 at the end of the study. If you are required to withdraw during the study because you no longer meet the study’s guidelines (e.g., you fall sick with COVID-19), you will still be compensated at the end of the study. If you voluntarily decide to withdraw from the study, you will not be compensated.

Do You Have to Take Part in This Study?

It is fully your decision if you wish to be in this study or not. If you choose not to participate, or choose to participate and later determine you no longer wish to, you will not lose any rights or services as a result of your withdrawal. The study is completely voluntary.

CONSENT DOCUMENT FOR ENROLLING ADULT PARTICIPANTS IN A RESEARCH STUDY

Georgia Institute of Technology

Project Title: Reducing Spread of SARS-CoV-2 in a University Community Setting: Role of a Low-Cost Reusable Form-Fitting Fabric Mask for Community Use

Investigators: *Sundaresan Jayaraman, PhD; Sungmee Park, PhD*

Protocol and Consent Title: Reusable Fabric Mask Study V1, 08/03/2021

You are being asked to be a volunteer in a research study. The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might. If you agree to be in the study, you will be one of 200 students participating at Georgia Tech. This form will give you key information to help you decide if you would like to participate. Your participation is voluntary. As you read, please feel free to ask any questions you may have about the research.

Purpose:

The purpose of the study is to test the role of the newly developed reusable form-fitting fabric mask – named the “focal” mask – in reducing the spread of SARS-CoV-2 in a community setting comprising undergraduate students living in dormitories at Georgia Tech. A corollary aim is to assess the role of wearing any type of face covering in reducing spread in the same community setting. A final aim is to assess the social, aesthetic, and usability aspects of wearing face coverings in public settings. We expect to enroll 200 students in this study. One hundred of these students will be testing the focal mask while the other hundred will continue to follow their own practice regarding the use of facial coverings. Please note that the facemask being tested in this study has not been approved or cleared by the FDA for this intended purpose.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Exclusion/Inclusion Criteria:

The subject population will comprise 200 undergraduate students staying in the dormitories at Georgia Tech, preferably freshmen and sophomores with meal plans. There will be no restriction of race, gender, or sexual orientation for this study. The study population will be restricted to students who are eighteen years or older.

Procedures:

The total duration of the study is six weeks. At the beginning of the study, you will complete a profile form in which you will provide information about your dormitory living arrangement,

among others. During the first two weeks, you will receive an e-mail each evening with a Form to be completed about that day's activities. After two weeks, 100 of you will receive the new focal mask, which you will use during the next two weeks; the other 100 will continue their practice of using facial coverings. Both groups of participants will continue to respond to the email each evening with the Form to record that day's activities for the two weeks. Following that period, you will receive an e-mail each evening with a Form to document that day's activities. During this period, you can choose to use whichever mask you want to wear. At the end of the final two-week period, all of you will complete a survey on your experience focusing on social and usability facets of the mask. You can keep the focal mask after the study has concluded.

Completing and submitting the Form at the end of each day of the Study will require a maximum of five minutes per day. At the end of the study, you will fill out another survey about your experience with masks, which should take you from five to ten minutes.

During the six-week study, you will be asked to respond to an e-mail during the day asking you to send a picture of yourself within a short time window; this will be done randomly three to five times during the entire six-week study and it should take you five minutes each time to respond.

If you contract COVID-19 during the course of the study, you will be asked to withdraw from the study so that you can take care of your health.

Risks or Discomforts:

The materials used in the focal mask that 100 of the 200 students will be using are present in everyday clothing, including fabric masks. Therefore, the risks or discomforts involved are no greater than those involved in daily activities when wearing/using clothes, including masks. There is a risk that the device may not be effective for its intended use and may not protect you from contracting SARS-CoV-2 and/or other diseases. During the recruitment phase, you will also be shown how to put on and take off the focal mask, which should be similar to the processes you follow with your use of masks. If you have not used masks or are not familiar with them, you will be fully informed about its use.

Benefits:

You are not likely to benefit in any way from joining this study. We hope that what we learn will inform the public about the benefits of using the focal mask to prevent the spread of SARS-CoV-2 in a community setting. The study will also contribute to understanding better the role of any type of face covering and thereby inform public policy.

Compensation to You:

You will be given a compensation of \$150 at the end of the study. If you are required to withdraw during the study because you no longer meet the study's guidelines (e.g., you fall sick

with COVID-19), you will still be compensated at the end of the study. If you voluntarily decide to withdraw from the study, you will not be compensated.

U.S. Tax Law requires that a 1099-misc be issued if U.S. tax residents receive \$600 or more per calendar year. If non-U.S. tax residents receive more than \$75, mandatory 30% withholding is required. Your address and Tax I.D. may be collected for compensation purposes only. This information will be shared only with the Georgia Tech department that issues compensation, if any, for your participation.

Storing and Sharing your Information:

Your data will not be used for any future research. After the minimum period of three years from the conclusion of the study, the period for which study data must be stored, the data will be deleted from Georgia Tech systems.

Information gathered during the study about vaccination will not be used by the Institute in any way. This information will not affect class enrollment and will not affect housing decisions. This information is only being used for research purposes and will not be shared with Georgia Tech.

Use of Photographs, Audio, or Video Recordings:

Any photographs you submit as part of the study will be stored electronically on Georgia Tech information storage systems; the photographs will be cropped to deidentify and ensure that the retained part of the photograph cannot be traced back to you; the deidentified pictures will be used for data analysis. Access will be restricted to the research team, which will abide by Georgia Tech's requirements of protecting such information. After the minimum period of three years from the conclusion of the study, the period for which study data must be stored, the data will be deleted from Georgia Tech systems.

We may want to use some of the de-identified photographs of you in public presentations related to the research. We will not use any identifiable photographs or other identifiable information about you in any future presentation or publication.

Confidentiality:

The following procedures will be followed to keep your personal information confidential in this study: We will comply with any applicable laws and regulations regarding confidentiality. To protect your privacy, your records will be kept under a code number rather than by name. Your records will be kept securely (password-protected) on Georgia Tech's information storage system. Only the research study team will be allowed to access the records. Physical records, if any, will be stored in locked rooms with access restricted only to the research study team. Your name and any other fact that might point to you will not appear when results of this study are presented or published.

You should be aware that the experiment is not being run from a 'secure' https server of the kind typically used to handle credit card transactions, so there is a small possibility that

responses could be viewed by unauthorized third parties such as computer hackers. In general, the web page software will log as header lines the IP address of the machine you use to access this page, e.g.,102.403.506.807, but otherwise no other information will be stored unless you explicitly enter it.

The Georgia Institute of Technology IRB, the Office of Human Research Protections, the Food and Drug Administration, and/or the Centers for Disease Control and Prevention may look over study records during required reviews.

Costs to You:

There are no costs to you, other than your time, for being in this study.

Alternative Treatments:

Not applicable since the study does not involve clinical or medical treatment.

Conflict of Interest:

The research team members have no conflicts of interest with the study.

Questions about the Study:

If you have any questions about the study, you may contact Professor Sundaresan Jayaraman, Principal Investigator, at telephone 404.894.2461 or via e-mail at Sundaresan.Jayaraman@gatech.edu.

In Case of Injury/Harm:

This study does not pose greater than minimal risk.

Questions about Your Rights as a Research Participant:

- Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
- You have the right to change your mind and leave the study at any time without giving any reason and without penalty.
- Any new information that may make you change your mind about being in this study will be given to you.
- You will be given a copy of this consent form to keep.
- You do not waive any of your legal rights by signing this consent form.

If you have any questions about your rights as a research participant, you may contact

Ms. Melanie Clark, Georgia Institute of Technology
Office of Research Integrity Assurance, at (404) 894-6942

or

Ms. Kelly Winn, Georgia Institute of Technology
Office of Research Integrity Assurance, at (404) 385- 2175

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.

Participant Name (printed)

Participant Signature

Date Time

Signature of Person Obtaining Consent

Date