Cover Page

Title: Adhesive Tape Placement on Patients' Masks in the ED Increases Compliance of Proper Face Mask Use

Nicholas Pettit

11/9/2021

NCT04812184

Protocol ID IUMASKstudy

Study Design and Setting:

This study was an open-label randomized control trial at Eskenazi Hospital ED from April 2020 to October 2020. Eskenazi Hospital is a busy, urban, academic, level 1 trauma center in downtown Indianapolis serving a racially diverse, underserved population with over 100,000 annual ED visits. This study was approved by the Indiana University Institutional Review Board (protocol #2004425945) and registered on ClinicalTrials.gov (NCT04812184).

Selection of Participants:

Patients presenting to the ED were screened for enrollment by trained research personnel when one of the study authors was working. All patients in the ED were required to wear facial coverings by institutional policy, and patient-provided personal masks were acceptable. Patients were excluded if they were: (1) pregnant; (2) prisoners; (3) not English- or Spanish-speaking; (4) intoxicated or with decompensated psychiatric illness; (5) presenting to the ED with a life-threatening condition; (6) allergic to standard tape and/or tegaderm. Patients were approached and verbal consent was obtained in their private ED room, then participants were randomized to either the control or intervention arms by simple randomization.

Randomization:

The randomization sequence was generated by a computerized random number generator (simple randomization). The randomization assignment was concealed from the study team and was provided within our REDCap database only after participants had been enrolled and provided informed consent.

Interventions:

Participants in the intervention arm had standard surgical tape placed over the bridge of the nose to adhere to the top of the mask (Supplemental Figure 1). Control participants had no intervention. Participants were told the study was about PPE use, but no additional instruction was given to participants regarding proper mask use, nor were reminders made by the research staff on proper mask use. No blinding was used in this study.

Sample Size:

Assuming 50% baseline proper mask use, 58 participants per arm were needed to have 80% power to detect a 25% relative difference in proper mask adherence assuming a two-sided chi-square test and alpha = 0.05.

Measurements:

At time of consent, a researcher assessed participants for their mask type, age, gender, race, ethnicity, Charlson Comorbidity Index (CCI)[8], and chief complaint, which were then entered into a REDCap database. After randomization, the participants were reevaluated at 60 minutes by the same researcher, and the mask location (correct placement, on chin, nose exposed, mask removed, nose/mouth exposed) and patient disposition (admission/discharge) were recorded (Supplemental Figure 1). Participants were reevaluated without notice and were blinded as to why the investigator was entering the room.

Outcomes:

The primary outcome of this trial was proper mask utilization at 60 minutes assessed by a researcher. A subgroup analysis was performed comparing the frequency of correct mask wearing by mask type (hospital-provided versus patient-supplied masks).

Analysis:

Patient demographics and characteristics were compared between the control and treatment groups (self-reported) to ensure balance after randomization. To test for differences between groups on outcomes, Microsoft Excel (Microsoft Corporation, Redmond, WA) was used, and the Chi-square test (or Fisher's exact test for <5 counts) was used for categorical variables and the Wilcoxon test for continuous variables. All analyses were conducted by intention-to-treat.