

Evaluating N95 Respirator Designs: A Mixed-Methods Pilot and Feasibility Study

Fatima Sheikh, MS.c¹, Myrna Dolovich, P.Eng^{2,3}, Lisa Schwartz, Ph.D¹, Sarah Khan, M.D^{4,5}, Zeinab Hosseinidoust, Ph.D⁶, and Alison E. Fox-Robichaud, M.D ^{1,2,5}

1. Department of Health Research Methods, Evidence and Impact, McMaster University, Hamilton, ON, Canada.

2. Department of Medicine, McMaster University, Hamilton, ON, Canada.

3. St. Joseph's Hospital, Firestone Institute for Respiratory Health, McMaster University, Hamilton, ON, Canada.

4. Department of Pediatrics, McMaster University, Hamilton, ON, Canada.

5. Hamilton Health Sciences, Hamilton, ON, Canada.

6. Department of Chemical Engineering, McMaster University, Hamilton, ON, Canada.

Corresponding Author: Dr. Alison-Fox Robichaud

David Braley Research Institute C5-106

237 Barton St E Hamilton, ON L8L 2X2

Telephone: (905)-521-2100 ext. 40742

Email: afoxrob@mcmaster.ca

Short Title: Gender, Ethnicity and N95 Respirator Designs

Keywords: COVID-19, Personal Protective Equipment, Infection Prevention, Health Equity, Health Policy.

Word count: 3445 words (excluding the abstract)

ABSTRACT (300/300 words)

Background. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has had a global impact, underscoring the importance of personal protective equipment (PPE). The use of N95s reduces the risk of airborne infection; however, in the absence of equitable designs, health care workers (HCWs) who do not fit the average White male head and face are at an increased risk of airborne infectious diseases.

Objectives. Primary: Feasibility of a mixed-method study, with a sample size of 100, 50% of participants self-identifying as non-White and having at least one characteristic of interest.

Secondary: (1) Generate quantitative evidence on N95 fit using a PortaCount fit test, (2) describe participant-reported feelings on fit and breathability, and (3) evaluate the impacts of the pandemic on a HCW's overall physical and mental well-being.

Methods. This was a mixed-method prospective pilot and feasibility study. Quantitative fit was assessed using a TSI PortaCount test and measurements of bizygomatic breadth and Menton-Sellion length. A survey was administered to collect sociodemographic information, HCWs' assessment of N95 fit, comfort, and the impact of PPE-related challenges on well-being.

Results. This study did not meet feasibility criteria due to the COVID-19 pandemic restrictions; however, we describe key findings that should inform ongoing analyses of the impact of gender and ethnicity on N95 respirator fit. Following a study amendment to increase eligible sites, 37 of the 41 (90.2%) approached HCWs consented to participate. Compared to other HCWs, non-White females had the lowest mean fit factor. Differences in Menton-Sellion length and bizygomatic breadth were observed between males, females, and White and non-White HCWs.

Most HCWs reported physical discomfort and/or negative impacts on their psychological well-being due to fit.

Conclusions. We identified gender and ethnicity as key factors in the fit of N95s. Differences in gender, ethnicity, and anthropometric measures must be considered in future respirator designs.

BACKGROUND

Coronavirus disease (COVID-19) has had a global impact, with more than 770 million confirmed cases and 6.9 million deaths reported worldwide (1). Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, can be transmitted by respiratory droplets and aerosols (2,3). In healthcare settings, SARS-CoV-2 can be aerosolized during aerosol-generating procedures (AGP); aerosolized viral particles less than 5µm in size can pass through the pores of surgical masks. N95 respirators have been the recommended PPE for HCWs involved in caring for patients requiring AGPs throughout the pandemic (4,5). SARS-CoV-2 and other airborne pathogens are an ongoing concern in healthcare settings.

N95 respirators offer the greatest protection and are essential for protection against airborne infectious agents (6–8). According to the National Institute for Occupational Safety and Health (NIOSH), the national body that regulates N95 standards in the United States (US) and Canada, N95s must have at least 95% filtration efficiency to prevent inhalation of airborne particles less than 0.3µm in size and be closely fitted to the face (9). The majority of current PPE, including masks and respirators, have been designed based on the anthropometric facial measurements of average men in the US and Europe (10,11). The reliance on historical anthropometric data poses challenges for those who do not fit these criteria, including women (12–15). In Canada, women represent 82% of HCWs (16). With the vast majority of PPE designed for the average male head and face, a sizeable portion of the workforce may be wearing poorly fitting PPE for long periods. The inability to access appropriately fitting protection not only increases the risk of COVID-19, but can lead to physical and psychological discomfort (17).

This bias in design affects more than women. An international study of facial morphology found significant differences in nose height and width between Caucasian North Americans compared to Asian and Black ethnic groups, and significantly greater bizygomatic width in Caucasian men and Asians, among other differences (18). Women and ethnic men who do not meet these standards are challenged to find well-fitted and comfortable N95s. In the absence of a tight fit or an appropriate seal, N95s may not provide the required protection, putting HCWs at risk of contracting airborne pathogens (11).

The purpose of this mixed-methods study was to (1) assess the feasibility of examining the fit of N95s in a diverse population of Canadian HCWs; (2) examine the outcomes of quantitative fit testing; and (3) describe qualitative measures of HCW-reported perceptions of N95 fit, breathability and comfort, and the impacts of PPE-related challenges on the physical and mental well-being of HCWs.

METHODS

Study Design

We conducted a mixed-method prospective pilot feasibility study designed to assess the qualitative and quantitative fit, comfort, and breathability of N95s in a diverse population of HCWs. A convergent parallel design was used in which qualitative and quantitative data were collected in parallel, analyzed separately, and then merged for interpretation (19,20). Incorporation of the results of the quantitative fit test with the qualitative data of the survey occurred in the interpretation phase. The objectives and outcome measures of this study are shown in **Appendix 1**.

Quantitative Study Methods

To assess the fit of an N95, a trained professional performed a quantitative fit test, using the TSI 8030 PortaCount Respirator Fit Tester, according to the NIOSH standard testing procedures (21). The quantitative fit test consisted of seven exercises designed to assess the amount of leakage around the face seal. The results of the quantitative test were recorded for each of the following exercises: normal breathing (performed at the start and end), deep breathing, turning the head side-to-side, nodding the head up and down, speaking out loud, and bending over. The overall fit factor, a ratio of aerosol concentration outside and inside the respirator, was also recorded (22,23). A minimum overall fit factor of 100 was necessary to pass. If the individual failed the test with the first respirator, the fit test was stopped, reported as an unsuccessful fit, and repeated at least once more prior to testing with a different N95 respirator. The following

respirators were available: 3M 1870+, 1860, 1860S, 1804S, and the Honeywell DC 365. Healthcare workers previously fitted to an N95 were offered the same respirator to start. The bizygomatic breadth, defined as the maximum horizontal breadth of the face, and the Menton-Sellion length, defined as the distance between the Menton and Sellion landmarks, were measured using sliding calipers (VWR Model: 12777-830). Both measures were recorded in millimeters for each participant, according to NIOSH testing procedures (24). These facial measurements were mapped to the NIOSH bivariate panel (24) corresponding to a range of face widths and lengths.

Qualitative Study Methods

To determine the diversity of experiences with wearing N95s, we conducted a qualitative description study to explore the perspective of healthcare workers (25,26). We designed a paper-based survey which was administered to frontline HCWs who underwent the quantitative fit test (**Appendix 2**). Prior to administering the survey, we assessed the suitability of the questions, readability, and overall clarity with a sample of critical care HCWs (n = 3). Minor changes were made to improve the clarity of questions. No questions were added or removed, and no other significant changes were made.

Recruitment and Participants

Potential participants included HCWs, defined as a healthcare provider (e.g., physician, nurse, respiratory therapist, etc.) or any patient-facing staff, at one of the three Hamilton Health Sciences (HHS) hospitals in Hamilton, Ontario, Canada.

149
150 Convenience and purposive sampling strategies were used to recruit participants who were
151 readily accessible, willing to participate, and would facilitate an analysis of the effects of gender
152 and ethnicity on the fit of N95s (27). Participants were restricted to HCWs who worked on-site
153 during the study period due to pandemic-related restrictions.

154 *Inclusion Criteria*

- 155 • 18 years of age or older
- 156 • Healthcare worker or patient-facing staff at HHS
- 157 • Informed consent to participate in the fit test and complete the survey.

158 And 50% of the sample must also meet at least one of the following conditions:

- 159 • Self-identity as being non-White
- 160 • Have at least one of the following characteristics: religious head covering (e.g., Hijab,
161 Turban), glasses, and/or facial hair (e.g., beard and/or mustache)
- 162 • Identify as female

163

164 *Exclusion Criteria*

- 165 • Unable to safely complete a PortaCount fit test

166

167 **Analysis**

168 *Co-primary Feasibility Outcomes*

169 The co-primary outcomes are described in detail in **Appendix 1**.

170

Secondary Outcomes

(1) Quantitative Fit Test Results. The results of the quantitative fit test are described with descriptive statistics. Specifically, the results for each of the seven exercises and the overall fit factor are reported as mean $\pm$ standard deviation (SD). These results are presented in aggregate, by gender, and by ethnicity. Data were reported by male and female, as no other genders were reported, and as White and Non-White due to limited sample size across each individual ethnicity. All data analysis was performed using *SPSS Statistics Version 27* (IBM, Chicago, IL). Due to the small sample size and risk of detecting a significant difference between males and females or the various ethnic groups, when, in fact, there was no difference (i.e., Type II error), no inferential statistics were run (28).

(2) Measure of N95 Fit; and (3) Impacts related to PPE on physical and mental health. Domains evaluated in the survey using Likert scales, are summarized using medians and frequencies, where applicable (29). Qualitative description was used to guide the reporting and analysis of the open-ended survey results, to ensure that the reported data directly reflect what the HCWs said, and how it was said (25). HCW-reported data on N95s were narratively summarized, and reported in tables, organized by N95 fit, comfort, and breathability and their impacts on the physical and mental health of the HCWs.

To represent the convergent integration of both datasets, these data were summarized in the form of a “statistics-by-theme joint display”(30), where de-identified quotes are reported along

with relevant numeric results and sociodemographic information collected in the two phases of the study.

Ethics

Ethics approval was obtained from the Hamilton Integrated Research Ethics Board (project # 12776). Recruitment began on January 4th, 2022 and ended on May 6th, 2022. Participants provided written informed consent.

RESULTS

Feasibility Results

Feasibility results were collected up to May 6th, 2022. The flow of potentially eligible participants, beginning with the total number of fit tests conducted between January 4th and May 6th at Hamilton General Hospital (HGH), and between March 14th and May 6th, at Juravinski Hospital (JH) and McMaster Children's Hospital (MCH), are shown in **Figure 1**.

The results of the primary objectives, designed to assess the feasibility of conducting this study, are summarized in **Table 1**. Overall, study recruitment was well below the target (100 HCWs), with only 36 of the target 100 (36%) HCWs enrolled in the study. The primary reasons for low enrollment were the increased need for fit tests, the limited amount of time HCWs had, and for the first two months of the study, the limited number of days the fit test clinic was run. There were some additional challenges with equipment failure and the time required to have it repaired. Study recruitment increased slightly following the addition of two study sites

(Appendix 3); however, challenges persisted, and the recruitment rate was low with only 36 of the 653 (5.5%) potentially eligible HCWs recruited. No other reasons, beyond time, were reported by HCWs or observed by the study team.

In the sample of HCWs approached for inclusion in the study, 37 of the 41 (90.2%) HCWs consented to participate in the study and 36 of the 41 (97.3%) were successfully fitted via the quantitative method. Additionally, 23 of the 36 (63.9%) included HCWs were fitted on the first try, while the remaining 13 required more than one fit test. One HCW was could not be fitted using the quantitative method due to equipment failure.

Among the 654 fit tests completed between January 4th and May 2nd, we were still unable to approach 612 potentially eligible HCWs due to time constraints or, on occasion, due to equipment failure. The research team felt it was important to ensure that the research did not “compromise the public health response to [the] outbreak or the provision of clinical care.”(31) As a result, HCWs were approached for study participation if (1) there was no line-up at the fit test clinic, (2) the HCW did not express time constraints or the need to return to clinical duty, and (3) the addition of one more person to the room, while other fit tests were ongoing, did not exceed the capacity limit. A summary of the feasibility results are displayed in **Table 1**.

Quantitative Fit Test Results

Thirty-six HCWs were recruited and completed the quantitative fit test and survey (**Figure 1**). The characteristics of the included participants are reported in **Table 2**.

The overall mean fit factor for all HCWs was 173 (SD = 29.96), while male HCWs had a mean fit factor of 184 (SD = 28.0) compared to female HCWs, who on average had a fit factor of 170 (SD = 30.0). White HCWs had a fit factor of 178 (SD = 30.0), approximately 11 points higher than their non-White counterparts. Both the mean Menton-Sellion length, 122.87mm (SD = 8.56) vs. 111.4mm (SD = 9.37), and the mean bizygomatic breadth, 121.93mm (SD = 8.4) vs. 109.26mm (SD = 10.17), were longer in males compared to females. White HCWs had a slightly longer Menton-Sellion length, and non-White HCWs had a higher bizygomatic breadth value, compared to non-White and White HCWs, respectively.

To assess the combined effects of gender and ethnicity, the results of the quantitative fit test from 35 HCWs are summarized by gender and ethnicity in **Table 3**. One HCW was excluded from this analysis as they were fitted to a P100, the results of which were out of range. White males had a mean fit factor of 200 (SD = 0), the maximum score attainable, and non-White males had a mean fit factor of 175 (SD = 31.0), compared to White and non-White females who had mean fit factors of 175 (SD = 32.0) and 165 (SD = 30.0), respectively.

The Menton-Sellion length was longer in White males compared to non-White males, and the bizygomatic breadth showed the opposite trend. Non-White female HCWs had the shortest Menton-Sellion length and bizygomatic breadth, with mean values of 108.99mm (11.31) and 107.82mm (9.12), compared to White female and male HCWs. When these values were assigned to the NIOSH bivariate panel, 27 of the 36 (75%) HCWs were out of range, 4 of the 36

(11.1%) were assigned to panel 6, 3 (8.3%) were assigned to panel 3, 1 (2.8%) was assigned to panel 4, and 1 (2.8%) was assigned to panel 1 (**Figure 2**).

Qualitative Survey Results

Thirty-six (100%) HCWs completed the survey and responded to at least 80% of the questions. On a scale of one to ten, where one is poor and ten is excellent, HCWs, on average, reported their experiences with N95s as a 6. There were no differences in reported experiences between White and non-White HCWs; however, male HCWs had a higher average score of 6.5, compared to female HCWs. Twenty-eight (77.8%) HCWs reported experiencing physical discomfort, 23 (63.9%) experienced pressure/pain, 14 (38.9%) experienced headaches, and 12 (33.3%) reported experiencing itching wearing an N95 respirator. Less frequent concerns included dizziness, reported by 8 (22.2%) HCWs, and nausea, reported by 2 (5.6%) HCWs.

A summary of quantitative and qualitative measures of N95 fit, comfort, and breathability, grouped by gender and ethnicity, are reported in **Tables 4a** and **4b**, respectively. On a five-point Likert scale, where 0 is poor and 4 is excellent or very good, both male and female HCWs had a median value of 3, corresponding to an agreement with the statement “N95 respirators fit me well”. While male HCWs reported the comfort of N95 respirators as a 2, female HCWs reported the comfort of N95 respirators as a 1 out of 5. This was reflected in the open responses, with one female HCW stating that “With the 1860s mask, it was extremely uncomfortable, difficult to breathe in. I would say it fit fine, but everything else was not great.” In terms of breathability, male HCWs reported an average score of 3, compared to females who reported

an average score of 2. In addition to the perceived fit of N95s, females reported lower measures of N95 comfort and breathability.

When comparing the experiences of wearing N95s between White and non-White HCWs, the median scores for fit and breathability were the same. HCWs in each of these groups reported similar concerns, including respirators being too tight and causing red marks on their face when worn for prolonged periods of time. In terms of comfort, the median score in White HCWs was 1 compared to a median score of 2 in non-White HCWs. However, both groups reported feelings of tightness and negative experiences exacerbated by wearing glasses or unique facial characteristics. For example, a HCW who self-identified as White stated “Find it challenging to wear with my glasses. Find my mask a bit awkward on my face. Breathable but give me headaches when I wear all day.” Similarly, a HCW who self-identified as Vietnamese reported that it was “difficult finding appropriately sized masks due to small nasal bridge.”

Additional qualitative results, including the impact of N95s on the mental health of HCWs, are summarized in **Appendix 4**. These direct excerpts illustrate the negative impacts of existing N95s on the mental health of healthcare workers, and, more importantly, the breadth of these impacts, including their ability to communicate with patients, feel safe while at work, and their overall comfort.

DISCUSSION

This study aimed to explore the fit, comfort, and breathability of N95 respirators in a diverse population of HCWs, and the first, to our knowledge, to compare fit testing outcomes with

qualitative descriptions from the perspective of front-line HCWs during the peak of the COVID-19 pandemic. Although we were unable to approach the majority of potentially eligible HCWs who came to the fit test clinic, due to the increased need for fit tests and limited time, all HCWs with whom the project was discussed were eager to participate, highlighting the importance of this study and reflected in the high consent rate.

In addition to the primary feasibility outcomes, we evaluated the results of the quantitative N95 fit test and the survey data of the 36 included HCWs. When comparing the results between male and female HCWs, we found that, on average, male HCWs had a higher fit factor compared to female HCWs. In a study that examined the fit factor in a group of HCWs, Wardhan et al. found that women had higher fit failure rates, defined as a fit factor less than 100, compared to men (32). These findings are consistent with studies by McMahon et al. (15) and Lee et al. (33), which demonstrated a 10% difference in fit failure rate between males and females, with females having a higher fit failure rate. Consistent with previous studies comparing anthropometric measures between males and females, we also identified differences in the key measures used to inform the design of N95s, between males and females. Although differences in N95 fit between men and women have been widely reported (15,33,34), few studies have explored the effects of ethnicity (35).

When stratified by ethnicity, White HCWs had a higher fit factor compared to non-White HCWs, and both White and non-White males had higher fit factors, compared to their female counterparts. During the first wave of the COVID-19 pandemic, Green et al. analyzed the

outcomes of fit tests across National Health Service hospitals in the United Kingdom. In addition to demonstrating differences in fit failure rates between men and women, they found that Black, Asian, and Minority Ethnic (BAME) HCWs had significantly higher fit failure rates compared to non-BAME HCWs (34). Similarly, Chopra et al. found that females and BAME participants had lower fit factor scores and fit test pass rates, which was attributed to differences in facial features. Specifically, they identified 14 standardized anthropometric measures that were significantly smaller for females. Despite limited disaggregated data on facial measurements of BAME individuals, they also reported differences in facial geometry, face size and nose measurements between Asian, Black, and Caucasian individuals (35). These differences in fit failure rates between men, women, and various ethnic groups can be explained by differences in head and face anthropometrics, as these studies have demonstrated significant differences between genders (12,13) and ethnicities (18,35,36).

This study was limited by the number of HCWs we were able to recruit and the shortened study period. The small sample size, specifically in the quantitative arm of our study, limited our analyses and our ability to run inferential statistics and report statistical differences. There may also have been differences in HCW characteristics and N95 fit testing outcomes between HCWs we were able to approach and HCWs we were unable to approach, which may limit the generalizability of the study results. Recruitment challenges were the result of the COVID-19 pandemic and persisted even after the study amendment was submitted. Despite these limitations, our study has several strengths: (1) this study of N95s in a diverse sample of HCWs, particularly in the absence of recognized Canadian standards by hospitals and limited Canadian

respirator designs, is timely (2) used rigorous and objective methodology for conducting fit tests, and (3) included the collection of quantitative and qualitative data on N95 fit, comfort, and breathability.

In summary, we identified differences in the outcomes of the quantitative fit test and perceived measure of N95 and surgical mask fit between males, females, and various ethnic groups. Women make up approximately 82% of the current healthcare workforce, many of whom identify as a visible minority. The challenges around N95s and other PPE, including the negative impacts to physical and psychological well-being, will persist in the absence of equitable designs. Future studies, to assess the fit and comfort of current respirators, are necessary to inform evidence-based testing and new national standards for N95s used in healthcare settings. Specifically, future studies should (1) employ strategies for recruiting a truly diverse sample of HCWs, (2) include additional anthropometric measures that better account for face and head shape, and (3) explore factors such as occupation and duration of wear that may contribute to the fit and comfort of N95 respirators worn over the HCW working shift of 10-12 hours.

CONCLUSION

The COVID-19 pandemic has highlighted and exacerbated concerns around the fit, comfort, and breathability of PPE, and specifically N95 respirators. The results of this pilot study highlight the differences in fit between males and females and HCWs of different ethnic groups, as well as the disproportionate impacts on the physical and mental well-being of female and non-White HCWs. Importantly, this pilot study provides the scientific rationale for conducting the main

study, particularly in the absence of pandemic restrictions, to answer this equity-focused and policy-relevant research question.

DECLERATIONS

Ethics Approval: Ethics approval was obtained from the Hamilton Integrated Research Ethics Board (project # 12776).

Consent for Publication: All authors have agreed to the publication of this manuscript.

Competing Interests: Not applicable.

Acknowledgments: We would like to thank Jeff Mallany, Senior Safety Specialist (Hamilton Health Sciences), and Bonnie Peacock, Safety Fit Tester (Hamilton Health Sciences), for their expertise and willingness to support this research project.

Author Contributions: FS and AFR conceived and designed the study with input from LS, MD, and ZH. Data acquisition, analysis, and interpretation of the data were led by FS and informed by content experts, AFR, LS, MD, ZH and SK. FS drafted the manuscript. All authors provided feedback throughout and reviewed the final draft of the manuscript. FS and AFR have full access to the data in the study.

Data Sharing Agreement: Additional data not reported in the manuscript will be made available upon a reasonable request to the corresponding author.

Funding: This study was funded by the Canadian Institute for Health Research (CIHR) (202005VR4-447804-CCF) for one year beginning June 1st, 2020. FS was also supported by an Ontario Graduate Fellowship Award during the conduct of this study.

Role of the Funder: The funders (CIHR) had no role in the design, conduct or reporting of this study.

REFERENCES

1. Weekly epidemiological update on COVID-19 - 1 September 2023 [Internet]. [cited 2023 Oct 12]. Available from: <https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---1-september-2023>
2. Jarvis MC. Aerosol Transmission of SARS-CoV-2: Physical Principles and Implications. Front Public Health [Internet]. 2020 [cited 2023 Oct 12];8. Available from: <https://www.frontiersin.org/articles/10.3389/fpubh.2020.590041>
3. Morawska L, Cao J. Airborne transmission of SARS-CoV-2: The world should face the reality. Environ Int. 2020 Jun;139:105730.
4. Howard BE. High-Risk Aerosol-Generating Procedures in COVID-19: Respiratory Protective Equipment Considerations. Otolaryngol Neck Surg. 2020 Jul 1;163(1):98–103.
5. D'Silva DF, McCulloch TJ, Lim JS, Smith SS, Carayannis D. Extubation of patients with COVID-19. Br J Anaesth. 2020;125(1):e192–5.
6. Chu DK, Akl EA, Duda S, Solo K, Yaacoub S, Schünemann HJ, et al. Physical distancing, face masks, and eye protection to prevent person-to-person transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis. The lancet. 2020;395(10242):1973–87.
7. Plana D, Tian E, Cramer AK, Yang H, Carmack MM, Sinha MS, et al. Assessing the filtration efficiency and regulatory status of N95s and nontraditional filtering face-piece respirators available during the COVID-19 pandemic. BMC Infect Dis. 2021 Jul 29;21(1):712.
8. Greenhalgh T, MacIntyre CR, Baker MG, Bhattacharjee S, Chughtai AA, Fisman D, et al. Masks and respirators for prevention of respiratory infections: a state of the science review. Clin Microbiol Rev. 2024 May 22;0(0):e00124-23.
9. NIOSH guide to the selection and use of particulate respirators certified under 42 CFR 84. 2020 Oct 6 [cited 2022 Jun 26]; Available from: <http://www.cdc.gov/niosh/docs/96-101/default.html>
10. PPEandwomenguidance.pdf [Internet]. [cited 2022 Jun 22]. Available from: <https://www.tuc.org.uk/sites/default/files/PPEandwomenguidance.pdf>
11. Janson DJ, Clift BC, Dhokia V. PPE fit of healthcare workers during the COVID-19 pandemic. Appl Ergon. 2022 Feb 1;99:103610.
12. Zhuang Z, Bradtmiller B. Head-and-face anthropometric survey of US respirator users. J Occup Environ Hyg. 2005;2(11):567–76.
13. Hsiao H, Whitestone J, Kau TY, Whisler R, Routley JG, Wilbur M. Sizing Firefighters: Method and Implications. Hum Factors. 2014 Aug 1;56(5):873–910.

- 450 14. Christopher L, Rohr-Kirchgraber T, Mark S. The PPE Pandemic: Sex-Related Discrepancies of
451 N95 Mask Fit. *EMJ Microbiol Infect Microbiol Infect Dis* 21 2021. 2021 Aug 19;2(1):57–63.
- 452 15. McMahon E, Wada K, Dufresne A. Implementing fit testing for N95 filtering facepiece
453 respirators: Practical information from a large cohort of hospital workers. *Am J Infect*
454 *Control*. 2008 May;36(4):298–300.
- 455 16. Bourgeault IL, James Y, Lawford K, Lundine J. Empowering women leaders in health: a gap
456 analysis of the state of knowledge. *Can J Physician Leadersh*. 2018;5(2):1.
- 457 17. Çiriş Yildiz C, Ulaşlı Kaban H, Tanriverdi FŞ. COVID-19 pandemic and personal protective
458 equipment: Evaluation of equipment comfort and user attitude. *Arch Environ Occup Health*.
459 2022 Jan 2;77(1):1–8.
- 460 18. Farkas LG, Katic MJ, Forrest CR. International anthropometric study of facial morphology in
461 various ethnic groups/races. *J Craniofac Surg*. 2005;16(4):615–46.
- 462 19. Creswell JW, Clark VLP. Designing and conducting mixed methods research. Sage
463 publications; 2017.
- 464 20. Tariq S, Woodman J. Using mixed methods in health research. *JRSM Short Rep*.
465 2013;4(6):2042533313479197.
- 466 21. Healthcare Respiratory Protection Resources, Fit Testing | NPPTL | NIOSH | CDC [Internet].
467 2021 [cited 2022 Jul 6]. Available from:
468 <http://www.cdc.gov/niosh/npptl/hospresptoolkit/fittesting.html>
- 469 22. Fit Test FAQs | NPPTL | NIOSH | CDC [Internet]. 2021 [cited 2022 Jun 27]. Available from:
470 http://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource3fittest.html
- 471 23. Hospital respiratory protection program toolkit: resources for respirator program
472 administrators. 2022 Apr 6 [cited 2022 Jun 27]; Available from:
473 <http://www.cdc.gov/niosh/docs/2015-117/default.html>
- 474 24. NIOSH Conformity Assessment Interpretation Notice (CA 2019-1011) | NPPTL | NIOSH |
475 CDC [Internet]. 2022 [cited 2022 Jul 6]. Available from:
476 [http://www.cdc.gov/niosh/npptl/resources/pressrel/letters/conformityinterp/CA-2019-](http://www.cdc.gov/niosh/npptl/resources/pressrel/letters/conformityinterp/CA-2019-1011.html)
477 [1011.html](http://www.cdc.gov/niosh/npptl/resources/pressrel/letters/conformityinterp/CA-2019-1011.html)
- 478 25. Bradshaw C, Atkinson S, Doody O. Employing a Qualitative Description Approach in Health
479 Care Research. *Glob Qual Nurs Res*. 2017 Jan 1;4:2333393617742282.
- 480 26. Sandelowski M. Whatever happened to qualitative description? *Res Nurs Health*.
481 2000;23(4):334–40.

27. Etikan I, Musa SA, Alkassim RS. Comparison of convenience sampling and purposive sampling. *Am J Theor Appl Stat.* 2016;5(1):1–4.
28. Allua S, Thompson CB. Inferential statistics. *Air Med J.* 2009;28(4):168–71.
29. Slattey EL, Voelker CC, Nussenbaum B, Rich JT, Paniello RC, Neely JG. A practical guide to surveys and questionnaires. *Otolaryngol--Head Neck Surg.* 2011;144(6):831–7.
30. Guetterman TC, Fettes MD, Creswell JW. Integrating quantitative and qualitative results in health science mixed methods research through joint displays. *Ann Fam Med.* 2015;13(6):554–61.
31. Organization WH. Guidance for managing ethical issues in infectious disease outbreaks. World Health Organization; 2016.
32. Wardhan R, Brennan MM, Brown HL, Creech TB. Does a Modified Adhesive Respirator Improve the Face Seal for Health Care Workers Who Previously Failed a Fit Test?: A Pilot Study During the Coronavirus Disease 2019 Pandemic. *Aa Pract.* 2020 Jun 15;14(8):e01264.
33. Lee K, Slavcev A, Nicas M. Respiratory Protection Against Mycobacterium tuberculosis: Quantitative Fit Test Outcomes for Five Type N95 Filtering-Facepiece Respirators. *J Occup Environ Hyg.* 2004 Jan 1;1(1):22–8.
34. Green S, Gani A, Bailey M, Brown O, Hing CB. Fit-testing of respiratory protective equipment in the UK during the initial response to the COVID-19 pandemic. *J Hosp Infect.* 2021 Jul;113:180–6.
35. Chopra J, Abiakam N, Kim H, Metcalf C, Worsley P, Cheong Y. The influence of gender and ethnicity on facemasks and respiratory protective equipment fit: a systematic review and meta-analysis. *BMJ Glob Health.* 2021 Nov 1;6(11):e005537.
36. Low CS, Ngui SZ, Casey MJ, Vuong C, Afroz A, Sengupta S, et al. Pass rates of four P2/N95 respirators or filtering facepiece respirators in Australian healthcare providers: A prospective observational study. *Anaesth Intensive Care.* 2023 Jun 20;0310057X231154017.

Figure 1. Study Flow Diagram

^aRecruitment began at Juravinski and McMaster Children's Hospital on March 10th. The total number of fit tests completed at each of these sites prior to March 10th is not reported.

Figure 2. Facial Anthropometric Measurements. The facial measurements of the 36 included HCWs are displayed alongside the NIOSH bivariate panel. These panels correspond to a range of face widths (120.5 – 158.5 mm) and lengths (98.5 – 138.5mm) and recommend number of participants to include from each panel when testing new respirators. Twenty-seven of the

thirty-six (75%) included HCWs in this study were out of range, demonstrating differences in this sample and the testing standards.

Table 1. Summary of the Study Feasibility Outcomes

Outcome	Outcome Description	Proportion (%)
Recruitment	A sample size of 100 HCWs recruited within 4 months and 50% meet one of the following criteria: Self-identify as non-white	36/100 (36%) Proportion of eligible HCWs: 36/653 (5.5%)

	• Have one or more of the following characteristics: religious head covering, glasses, and/or facial hair • Identify as female	Characteristics of included participants are reported in Table 3 .
Consent	Consent rate of $\geq 80\%$ in approached HCWs.	37/41 (90.2%)
Fit Test	Successful completion of a PortaCount fit test or partial completion with a reason for why the test was ended.	36/37 (97.3%) Proportion of successful fit tests on the first attempt: 23/37 (62.2%)
Survey	Completion of the survey, defined as at least 80% of the questions have been fully responded to.	36/36 (100%)

HCW Healthcare workers.

Table 2. Characteristics of Included Participants (n = 36)

Variable	N (%)
Age, (SD)	31.97 (10.8)
Gender	
Male	6/36 (16.7)
Female	30/36 (83.3)
Ethnicity	
White (Caucasian)	19 (52.8)
Black	2 (5.6)
Chinese	3 (8.3)
Filipino	4 (11.1)
Latin American	1 (2.8)
Polish*	1 (2.8)
South Asian	1 (2.8)
Southeast Asian	1 (2.8)
Vietnamese*	1 (2.8)
Mixed ethnicity	2 (5.6)
Physical Characteristics[†]	
Glasses	16 (44.4)

SD Standard deviation.

*These ethnic categories were not included in the survey. The participants selected “prefer to self-identify”. Responses are displayed as listed by participants.

[†]The fit test protocol requires individuals to be clean-shaven. For safety reasons, and in the context of COVID-19, we were unable to include HCWs with facial hair (even for research purposes). No individuals with a head covering were recruited.

Table 3. Summary of Quantitative Fit Test Results (n = 35)

Variable	Male (n = 6)		Female (n = 29)*	
	Non-White	White	Non-White	White
Number of fit tests, Mean (SD)	2.25 (1.5)	1 (0)	1.62 (0.9)	1.65 (1.1)
Fit Factor, Mean (SD)	175 (31)	200 (0)	165 (30)	175 (32)
Normal breathing	200 (0)	200 (0)	185 (29)	199 (5)
Deep breathing	200 (0)	200 (0)	189 (26)	189 (33)
Head side to side	200 (0)	200 (0)	174 (49)	180 (42)
Head up and down	199 (1.5)	200 (0)	167 (55)	161 (60)
Talking out loud	168 (52)	200 (0)	196 (16)	187 (30)
Bending over	157 (66)	200 (0)	174 (52)	180 (36)
Normal breathing	173 (53)	200 (0)	168 (51)	188 (23)
Anthropometric Measures, Mean (SD)				
Menton-Sellion length	122.07 (9.6)	124.46 (9.0)	108.88 (11.3)	113.32 (7.3)
Bizygomatic breadth	126.46 (4.7)	112.87 (6.4)	107.82 (9.1)	110.36 (11.0)

SD Standard deviation. mm Millimeters.

*All 36 included HCWs were fit tested; however, one female participant was excluded from the quantitative analysis because they were fitted to a P100, the results of which are out of range, relative to the N95 respirator fit test. Among the 35 HCWs included, 27 (75%) were fitted to a 3M 1870+, 4 (11.2%) were fitted to a Honeywell DC 365, 3 (8.3%) were fitted to a 3M 1804s, and 1 (2.8%) was fitted to the 3M 1860s.

Table 4a. Summary of Survey Results, Reported by Gender

Domain	Median (IQR)		Domain descriptions & illustrative examples	
	Male	Female	Male (n = 6)	Female (n = 29)
Fit	3 (1)	3 (1)	“I use the 1860 N95 and have issues with the nose clamp.” “Nose pain – bridge of nose” “Prolonged use was uncomfortable”	“Hard to get proper fit, some slide & move on face. Drawing blood – required to bend head to chest à lots of movement.”
Comfort	2 (1)	1 (1)		“Uncomfortable after long periods of time. Difficult to get a comfortable seal across the nose.”
Breathability	3 (1)	2 (2)		“With the 1860s mask it was extremely uncomfortable, difficult to breath in. I would say it fit fine, but everything else was not great.”

Table 4b. Summary of Survey Results, Reported by Ethnicity

Domain	Median (IQR)		Domain descriptions & illustrative examples	
	White	Non-White	White (n = 19)	Non-White (n = 17)
Fit	3 (1)	3 (1)	"Fit tightly to point where causes facial markings, redness + bruising. Especially at bridge of nose."	"They feel tight but move around, not well formed to nose and chin."
Comfort	1 (1)	2 (1)	"Find it challenging to wear with my glasses. Find my mask a bit awkward on my face."	"Difficult finding appropriately sized masks due to small nasal bridge."
Breathability	2 (2)	2 (2)	Breathable but gives me headaches when I wear all day (but I am generally prone to headaches)."	"Tight and quite uncomfortable."

IQR Interquartile range

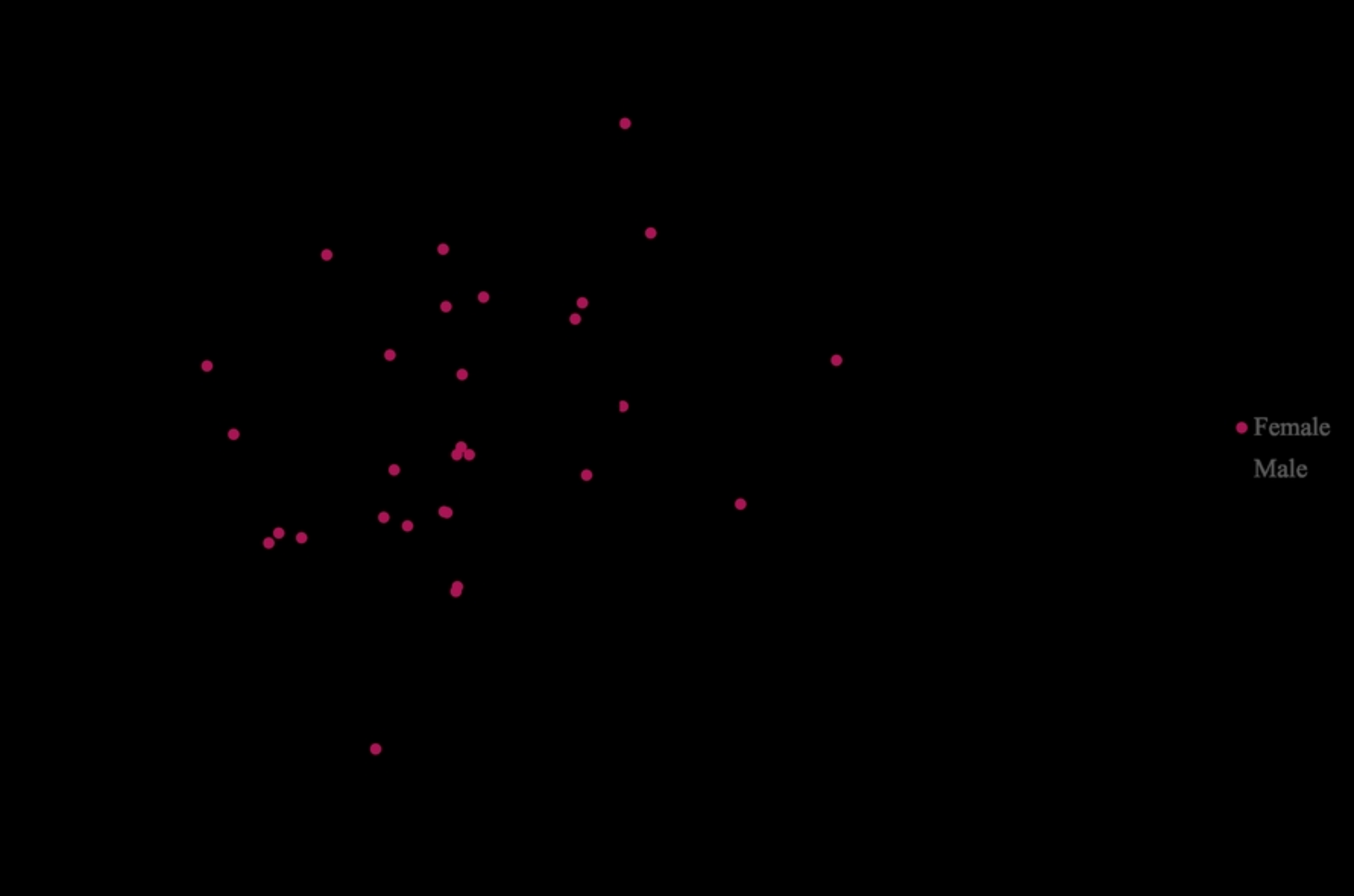


Figure 2

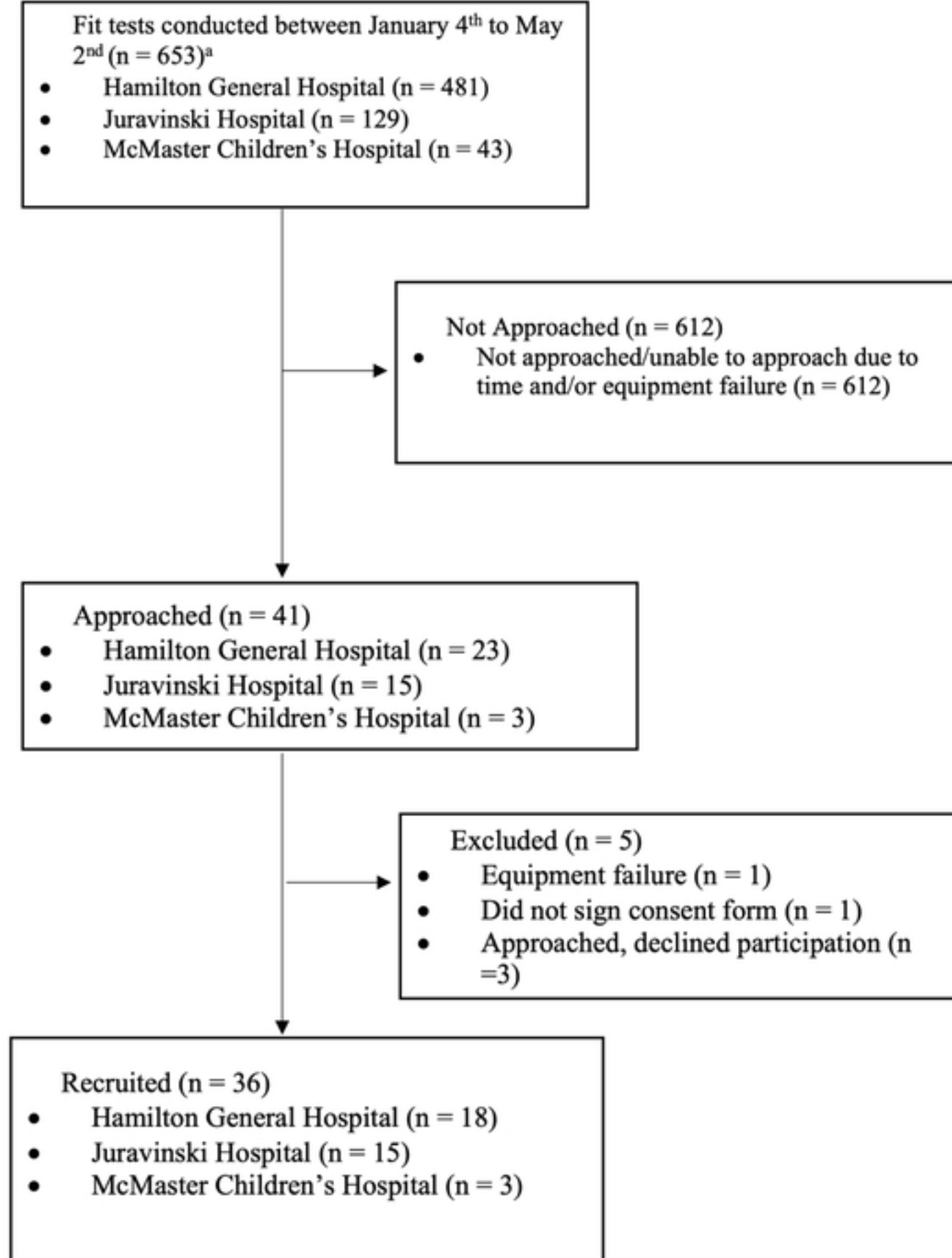


Figure 1