

Principles and Practice of Clinical Research

A Global Journal in Clinical Research



PPCR

ISSN: 2378-1890

COVID-19 – The efficacy of the LEAF-mask measured by assessing the viral load of the mask's inner and outer surface used by nurses in ICUs compared to the N95: a phase II, multicenter, randomized, controlled, open-label, clinical trial protocol

HU. Richarz^{1*}, AJ. Mendes², SM. Hincapie Arias³, AM. Santos Cury Marduy³, SA. Chottera⁵, OF. Yanque Robles⁶, A. de Moura Brasil Matos⁷, ACM. Gomes⁸, V. Henriques Carvalho⁹, P. Bottamedi Ratto Guimaraes¹⁰, MS. Grigorescu Vlass¹¹, AH. Motoyama Caiado¹², AA. Boto¹³, ER. Diaz¹⁴, J. Colleti Junior¹⁵, N. Chaves¹⁶

#All authors have contributed equally to this work.

**Corresponding author: Hans-Udo Richarz, Fascia Research Group, Department of Experimental Anesthesia, Ulm University, Germany, richarz@gmx.at.*

Rest of the author's affiliation at the end of the manuscript.

Received December 13, 2020; accepted March 8, 2021; published March 30, 2021.

APPENDICES

Appendix 1

Participant Code: _____

Site Center: _____

Date: __/__/__

Self-Report Questionnaire

This questionnaire is to be filled out at the end of each shift. The document is separated into two main sections: the first one is related to general information about number and length of time of the donning and doffing of your mask during your shift and the second one is related to potential adverse effects of the mask used by you. In case of any doubt, please ask the researcher.

1. Information about the shift

- Number of hours of work: _____

Appendix 2

Participant Code: _____

Site Center: _____

Date: __/__/__

Comfort Rating Scale (CRS)

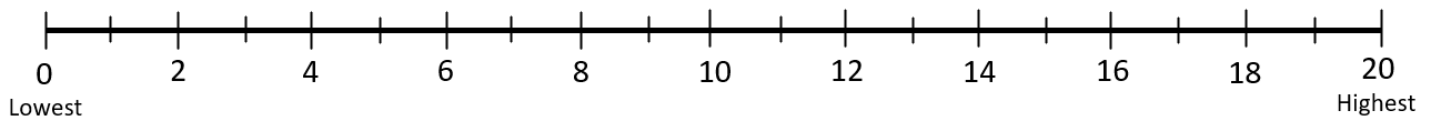
(Adapted from Malik et al. 2006)

For each question, please indicate from 0 (“Lowest”) to 20 (“Highest”) the most adequate response. Each question evaluates the comfortability in several domains, namely, emotion, attachment, physical effect, perceived change, movement, and anxiety.

There is a total of 11 questions. Please clearly circle the most adequate number.

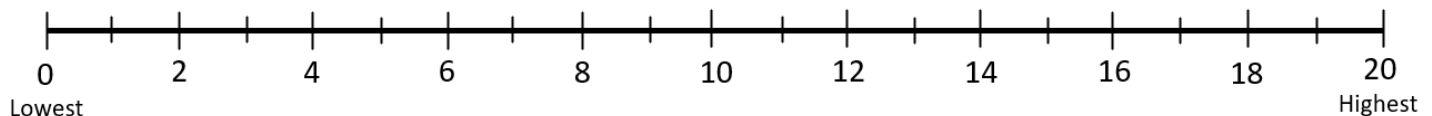
1. Emotion

Did you feel uncomfortable with the temperature during the duration of your shift?



2. Attachment

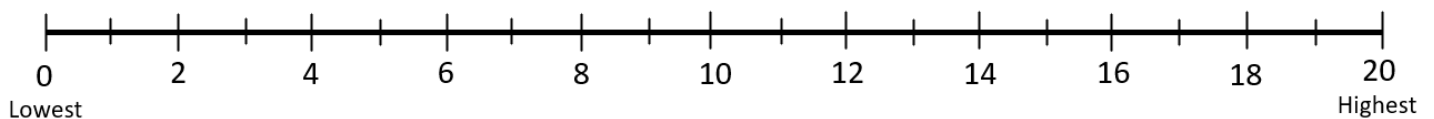
How difficult was the mask to don?



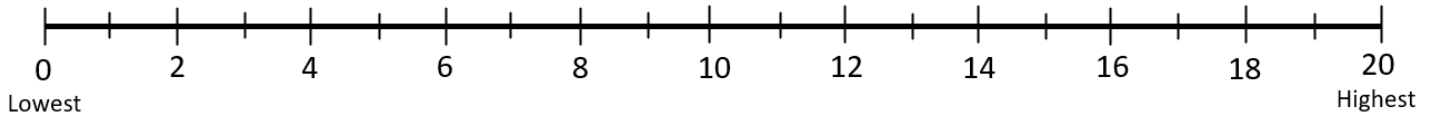
3. Physical Effect

Did you encounter any:

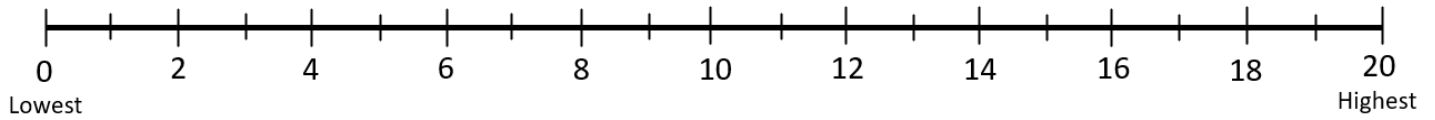
i. Auricular discomfort?



ii. *Tightness around the ears?*



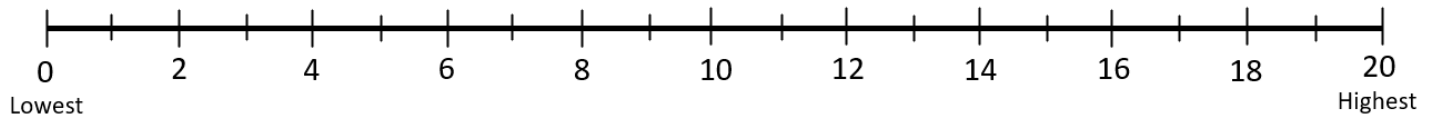
iii. *Headache?*



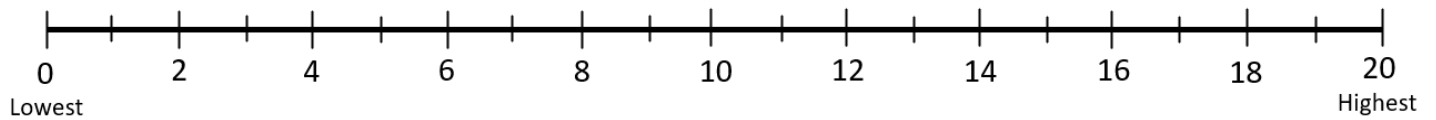
4. Perceived Change

Could you not:

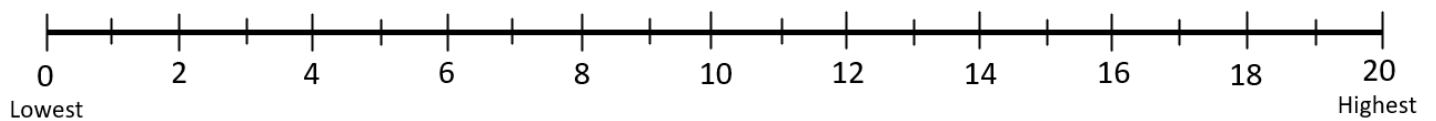
i. *Be heard by your colleagues?*



ii. *Hear your colleagues?*

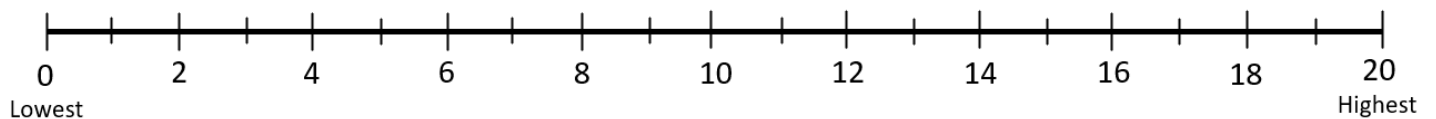


Was your field of vision restricted in any way?



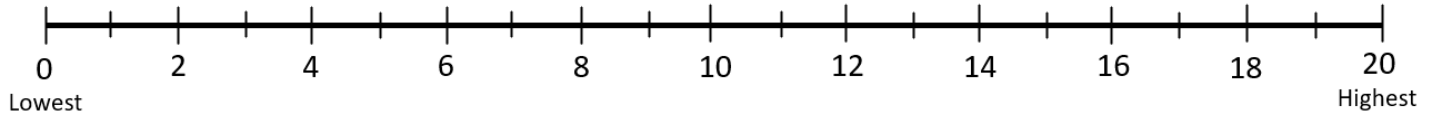
5. Movement

Did the mask restrict your movement?



6. Anxiety

i. *Did you feel that your mask compromised sterility?*



ii. *Did you feel that the mask failed to protect you from strike-through or splashes?*

