Subjective dyspnoea in mask wearing hospital personnel does not correlate to hypoxia

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20269

Source
Nationaal Trial Register

Brief title
SDS vs hypoxia in mask wearers RCT

Health condition

Anxiety, depression, hypoxia, dyspnoea

Sponsors and support

Primary sponsor: NONE
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Subjective dyspnoea, as assessed by a composite of the Borg scale and MRC dyspnoea scale and its correlation to hypoxia in mask wearers. Time point is 30 minutely oxygen saturation measurements and subjective dyspnoea scales as assessed during a 4 hour period of mask

wearing.

Secondary outcome

Subjective dyspnoea scale correlation to baseline PROMIS anxiety and depression, BMI, measured heart rate, past medical history including COPD, BMI and psychological diagnoses, activity.

Study description

Background summary

Hospital personnel were recruited to wear two masks for 4 hours each, a standard 3 layer surgical mask, fit tested N95 mask, and also a control arm of no facial covering (control arm). The order in which they wore the masks/control was randomised. Baseline demographics were collected, including psychometric testing (PROMIS anxiety and depression PROMs).

Study objective

Use of any mask (surgical or N95) in a standard day of work for hospital staff, may result in subjective feelings of dyspnoea. These symptoms of dyspnoea do not correlate to a decreased oxygen saturation, but do correlate to baseline participant anxiety or depression.

Study design

Baseline and 30 minutely measurements while wearing masks or control.

Intervention

Wearing of masks (surgical and N95) for 4 hours each. Crossover design, with each participant wearing both masks in a randomised order. Also included in randomisation is a control arm (no mask wearing).

Contacts

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Scientific

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Eligibility criteria

Inclusion criteria

Volunteer hospital personnel at Flinders Medical Centre and Noarlunga Health Services who are fit tested for N95 masks and shall work 3 days in a row.

Exclusion criteria

Allergy to masks, not fit tested, no fit tested N95 available, participant refusal, not working 3 consecutive days

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2021
Enrollment:	25
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N/A

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9143
Other	METC FMC : NONE yet

Study results