FULL TITLE OF THE STUDY

Preoxygenation with high-flow nasal oxygen using Optiflow™ - does speech have an effect on end-tidal oxygen achieved when compared to closed-mouth nasal breathing?

SHORT STUDY TITLE

Preoxygenation with Optiflow™ – the effect of speech on oxygenation.

Statistical Analysis Plan

Methods of randomisation

Participants were randomly allocated to the either the speech or non-speech arm of the study according to a random number generator and a key drawn up prior to randomisation. This was done following the consent and recruitment process to maintain allocation concealment. Figure 3. demonstrates the randomisation of participants.

Number Generated	Assigned Group
Odd	Speech
Even	Non-speech

Figure 3: A reference table to randomly allocate participants to both arms of the study.

Power calculations

The primary outcome measure was ETO_2 after 3 minutes of oxygen via the Optiflow^{TM} device. In order to ascertain a sample size, data was taken from a previous study by J. Powell and P. Butler[47] showing that an ETO_2 of 0.85 could be achieved using the Optiflow device without speech. An estimate for the speech group was then decided (rendering an ETO_2 of 0.75, SD= 0.1) based off detecting a minimally significant difference. The sample size was generated by `G*Power` software. This yielded a sample size of 28 whereby $\alpha=0.05$ and $1-\beta=0.8$. An unpaired t-test was performed, and all statistical analysis was carried out using GraphPad Prism 8.

Statistical Analysis

The data was imported from an excel spreadsheet into GraphPad Prism 8. Prior to analysis, some normality tests were run to determine whether the data was parametric or non-parametric. 18 participants in the `Speech` group and 12 participants in the `Non-Speech` group were included in the analysis using parametric statistics for normally distributed data. The confidence intervals were set at 95% and a P value of <0.05 was used to confirm any statistical significance.

An unpaired t-test was then conducted to investigate the likelihood that the difference between the means had been caused by chance. This would help establish a relationship between ETO_2 achieved at the end of three minutes between those in the speech arm compared against those in the non-speech arm.

To determine demographics, the mean (standard deviation) was used to calculate average age, whilst median and Interquartile range were used as a measure of distribution for BMI and height.