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Statistical Plan

Official Title: The Role of Endogenous Opioidergic Systems in Breathing Based Analgesia

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The Role of Endogenous Opioidergic Systems in Breathing Based Analgesia

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Sample size determination: We will recruit up to 60 subjects to participate in this study. All subjects (age: 18-55 years) will be pain free, healthy, with no prior meditation experience, and will be recruited from the local community through multiple means. Based on our recent study (Zeidan et al., 2016), a sample size of 18 participants per group will provide 85% power with an alpha level set at 0.05 to detect a partial reversal of pain relief corresponding to a large effect size of $\eta_p^2 = .18$ (g power software 3.0.1). However, to better control for variability in naloxone effectiveness, we will recruit a total of 60 participants (20/group). This sample size was calculated to provide > 90% power to detect a significant difference between groups on VAS pain ratings.

Analyses: In order to test our study hypotheses, we will employ a 3 (group) X 2 (rest vs. manipulation) X 2 (naloxone vs. saline) repeated measures (RM) ANOVA followed by post-hoc paired samples t-tests (in each group) to test the hypotheses that sham-mindfulness meditation and slow-breathing induced analgesia will be reversed by administration of naloxone but not saline. Secondary exploratory analyses will be conducted using the percent change in pain ratings between rest (pre) and manipulation (post) in the presence of naloxone and saline to determine the efficacy of mindfulness meditation-based analgesia as compared to the other two groups. We will also conduct exploratory regression analyses to determine if sham-mindfulness meditation and slow breathing based analgesia are significantly associated with reductions in respiration rate.

References

Zeidan F, Adler-Neal AL, Wells RE, Stagnaro E, May LM, Eisenach JC, McHaffie JG, Coghill RC (2016) Mindfulness-Meditation-Based Pain Relief Is Not Mediated by Endogenous Opioids. *The Journal of neuroscience : the official journal of the Society for Neuroscience* 36:3391-3397.