TITLE: Use of Fitbits During Breathing Meditation
NCT#: NCT5101343
DATE: 2/15/2021
Study Protocol with SAP and/or ICF

Study Protocol
Description
College students are currently experiencing unprecedented stress during the COVID-19 pandemic and a unique learning environment with many courses being taught online. Mindfulness practices and physical activity have previously been demonstrated to help reduce stress and anxiety among college students. This study will examine short breathing meditations paired with Fitbit technology in order to help students practice mindfulness and track physical activity. Measures including heart rate, physical activity, sleep patterns, as well as assessments of well-being and anxiety levels will be examined. Participants will be current undergraduate and graduate students at Winthrop University. The anticipated sample size is 20 subjects (10 in the experimental group and 10 in the control group). The anticipated sample size for interviews is 5 subjects.

Design and Methods
Participants will be divided into two groups – experimental and control group.
The experimental group will spend two weeks wearing the Fitbit for as close to 24 hours each day (including during sleep), except when showering or charging the device. For the second week, participants will also use the Fitbit meditation app, Relax, to complete a 5-minute breathing meditation once a day, every day for one week. The Fitbit will measure physical activity and record physiological data. Following the two weeks, a subset of the experimental group will participate in semi-structured interviews to discuss their experience.

The control group will wear the Fitbit for 2 weeks, but will not complete any meditation. They will be offered the opportunity to participate in the meditation activities after the study is complete.

Participants will complete the HADS survey, MHC-SF survey, UMC Penn State Worry Questionnaire, and MAAS survey, at baseline and at the end of the second week of the program (please see attached for all surveys). They will also complete a pre-program survey at baseline and a post-program survey (including demographic information and experience with COVID-19) after the 2-week program (please see attached surveys). All surveys will be administered via email and completed via Qualtrics.

Additionally, a subset of participants will be invited to complete semi-structured interviews with the research team about their experience (please see attached for interview questions). Each interview will have 6 questions, but the total number of questions may vary depending on the follow-up questions prompted by the subjects' responses. The estimated time to complete the interview is 30 minutes.

Statistical Analysis Plan (SAP)

Survey data collected via Qualtrics (Provo, UT). Fitbit data downloaded from participants' Fitbit accounts into Microsoft Excel for analysis. Statistical analysis using R (R Core Team, 2021, R Version 4.1.0, Vienna, Austria). Data combined across all three cohorts for all analysis. All data assessed for normality using the Shapiro-Wilk test, and $p > 0.05$ for all samples. Fisher's exact test used to analyze categorical variables (race, class, sex), and t-tests used to analyze continuous variables (age, BMI) between control and treatment groups in demographic data. Paired t-tests used to compare baseline/post-study survey data and week 2/week 1 Fitbit data, and t-tests used to compare control and treatment groups at each time point. All values are reported as mean ± standard deviation (SD). To examine the mean differences between groups, 95% confidence intervals (CI) were used (Cumming, 2014).