# Analysis Plan

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**Introduction**

While there is some literature regarding correlations between back pain and backpack load, fitting, etc. in military personnel and school children, the same research is lacking in recreational hikers and backpackers. The aim of this research is to examine back pain in recreational day hikers and back packers, and to explore correlations between hiking/backpacking experience, backpack load, backpack fit, and activity level in the two groups. The goal is to provide some baseline research for future development of safety guidelines to minimize back pain in recreational hikers and backpackers.

**Hypotheses and/or research questions and/or specific aims**

**Hypothesis:** The prevalence of back pain in recreational backpackers will be comparable to the prevalence found in other populations.

**Secondary Hypothesis:** The lumbar spine with have the highest prevalence compared to thoracic and cervical spine.

**Hypothesis:** Individuals that have been properly fit for their backpack will have less back pain.

**Data description**

**Back pain:** “Over the last 3 years have you experienced back pain?”

**Back pain location:** “If you experience back pain, choose the area from the picture below where you have the most pain (choose one).”

**Exposure:** “Have you ever had someone professionally fit your backpack?”

**Other:** Descriptive variables including (but not limited to) age, gender, height, weight, and activity level will be included in a table 1 for both the full cohort and for day hikers and backpackers separately.

**Analysis Methods**

Descriptive statistics (mean and SD for normally distributed, median and IQR for non-normal, and percentages for categorical variables) for anthropometric and demographic variables will be calculated and presented in two tables. The first will be for the full cohort and the other one by group (day hikers and backpackers).

Prevalence of general back pain and back pain location will be reported as percentages, also for the full cohort and by group. For now, pain prevalence will not require any hypothesis testing although this is subject to change after initial analysis.

The effect of professional backpack fitting on back pain will be assessed using a chi-squared test. If investigators decide to adjust for other covariates (perhaps age), logistic regression will be used instead. Covariates to include in the model will be determined based on clinical relevance as determined by the investigators, and the results of univariate analyses.

For the project as a whole, and for each research question, aim, or hypothesis, describe the proposed analytic method and any necessary details for its implementation. At a minimum, this should address the hypotheses mentioned above. For further detail, describe any followup or secondary analyses, any assessments of assumptions, and sensitivity or subgroup analyses.

Example:

*A univariable analysis between outcomes and exposure will be performed using general linear regression. Assumptions of linearity, homoscedasticity, and normality will be confirmed using diagnostic plots. Relationship between possible covariates and outcomes will be analyzed. Covariates with a significant association with the outcome will be considered for a multivariable model. P values <0.05 will be considered significant. Baseline FEV, gender, and age will be included in the adjusted model based on their biological associations with the outcome. Since participants were randomly assigned, there should be no relationship between possible covariates and exposure, this will be confirmed using χ2/fisher’s exact for categorical covariates and ANOVA for continuous covariates. The secondary hypothesis will be evaluated with a partial F- test. The full model will include treatment group, whether the parent ever reported smoking and the interaction of the two, the reduced model will be the full minus the interaction term.*

**Proposed tables/figures**

To supplement the analysis methods, describe the potential statistical outputs to be delivered to the investigator. These should include some form of “Table 1” describing the data itself as well as all intermediate or final tables addressing the research goals. While table shells are entirely appropriate, it is sufficient to just describe the proposed tables or graphs.

Example:

*Analyses that have significant overall F statistics will be considered for inclusion in tables.*

*Table 1. Characteristics of Study Participants by Treatment Group*

**Other info**:

As an optional useful supplement, include timelines, project contacts, and the intended final products (article, abstract, etc.). The included information should help focus how the results above will be described, to whom they are targeted, and how quickly they need to be produced.