Project 4

Read and present the clinical trial of Fluge et al (2019). Describe and re-analyze the data focusing on the primary outcome (response) and using the intention-to-treat principle. Construct an appropriate statistical model where you can determine which the factors (age; gender; infection – whether disease symptoms started with an infection; SykVarig - disease duration in years with the following categories: 1 – 2-<5, 2 – 5-<10, 3 – 10-15; weight – in centimeters; height – in kilograms; body mass index; FSmean_0 - Fatigue score at baseline; Stepsmean_0m – step count at baseline; FSS_m0; and treatment center) are significantly affecting the primary outcome. Quantify the proportion of individuals who complied with the treatment protocol exactly in each treatment group (see the corresponding data on Figure 1). Quantify the statistical uncertainty associated with this proportion in each treatment group. Compare that proportion between the two treatment groups using a statistical test. Finally, compare the frequency of each adverse effect outcome between the two treatment arms (see the corresponding data in Table 3) using appropriate statistical tests. Draw your conclusions.

Reference:

Fluge Ø, Rekeland IG, Lien K, et al. B-Lymphocyte Depletion in Patients With Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: A Randomized, Double-Blind, Placebo-Controlled Trial. Ann Intern Med. 2019;170(9):585-593. doi:10.7326/M18-1451