ANALYSIS AND REPORTING

In this study we will have two categorical predictor variables. The first is experimental condition, which is a between-groups factor with two levels, probiotic and placebo. The second predictor variable will be time, which is a within-groups factor with two levels, baseline (T_1) and post-treatment (T_2). There will be one within-groups continuous outcome variable, apathy score, which is measured at T_1 and T_2. IBM ® SPSS ® Statistics Version 29.0.1.0 will be used to conduct statistical analysis.

Factorial Mixed Analysis of Variance

This study hypothesises that participants in the probiotic condition will have a greater mean improvement in apathy scores from T_1 to T_2 compared to those in the placebo condition. Additionally, we will hypothesise that there will be no change in apathy score from T_1 to T_2 in the placebo condition to show that any change in apathy scores in the probiotic condition were not due to chance.

Since we have both within- and between-groups predictor variables, a factorial mixed analysis of variance (ANOVA) will be used to detect a potential interaction between experimental condition and time. This analysis will tell us if the condition, time, or the interaction of the two has a significant effect on apathy score.

Post hoc testing

If the ANOVA test finds significant main effects, we will conduct post hoc testing. Paired samples t-tests will allow us to compare T_1 and T_2 based on experimental condition.

This analysis will clarify whether there is a significant change in apathy scores from T_1 to T_2 in the probiotic or placebo conditions.

Assumptions

First, we will ensure that our data meets the assumptions required of an ANOVA analysis. First, we will determine whether our data follows a normal distribution using the Kolmogorov-Smirnov test due to our large sample size, which should be $p > .05$ for each experimental condition. Then, we will check the within-groups assumptions. First, we will verify the assumption of the equality of covariance matrices with Box's test, which should be $p > .001$. Second, we can assume that the data meets the assumption of sphericity because there are only two levels of the within-groups variable. Finally, we will check that the data has met the assumption of homogeneity of variances using Levene's test, which should be $p > .05$ for both experimental conditions. If any of these assumptions are violated, we will run a robust mixed ANOVA instead.

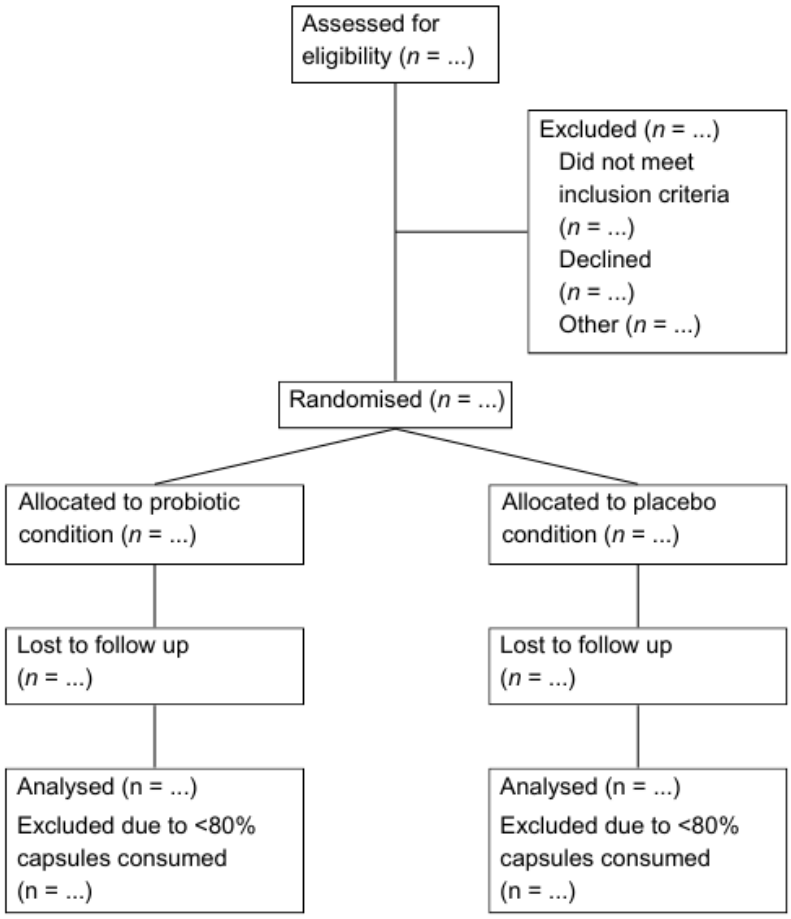
Reporting Results

Participant Progression

First, we will report the progression of participants through each stage of the trial from recruitment, randomisation to experimental condition, follow-up at T_2, and analysis (Schulz et al., 2010). Figure 3 shows an example flow diagram for this trial.

Figure 3

Flow Diagram of Participant Progression



Note. Adapted from "CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials," by K. F. Schulz, 2010, *The BMJ, 340* (c332), 10.1136/bmj.c332. CC BY-NC 2.0.

Descriptive Statistics

We will report descriptive statistics for participant characteristics as shown in Table 2. This is example data only (see Appendix D) and will be used throughout this section to demonstrate reporting.

Table 2

Participant Characteristics

Characteristic	Probiotic (*n* = 160)	Placebo (*n* = 160)	Total (*N* = 320)
Age, mean (*SD*)	83.09 (10.54)	82.00 (10.03)	82.55 (10.29)
Female *n* (%)	85.00 (53.13)	86.00 (53.75)	171 (53.44)
BMI, mean (*SD*)	26.70 (5.02)	26.13 (5.45)	26.42 (5.24)

The mean apathy scores will be presented as shown in Table 3 as well as in a column chart (see Figure 4) grouped by experimental condition. The white columns represent T_1 scores while the shaded columns represent T_2 scores.

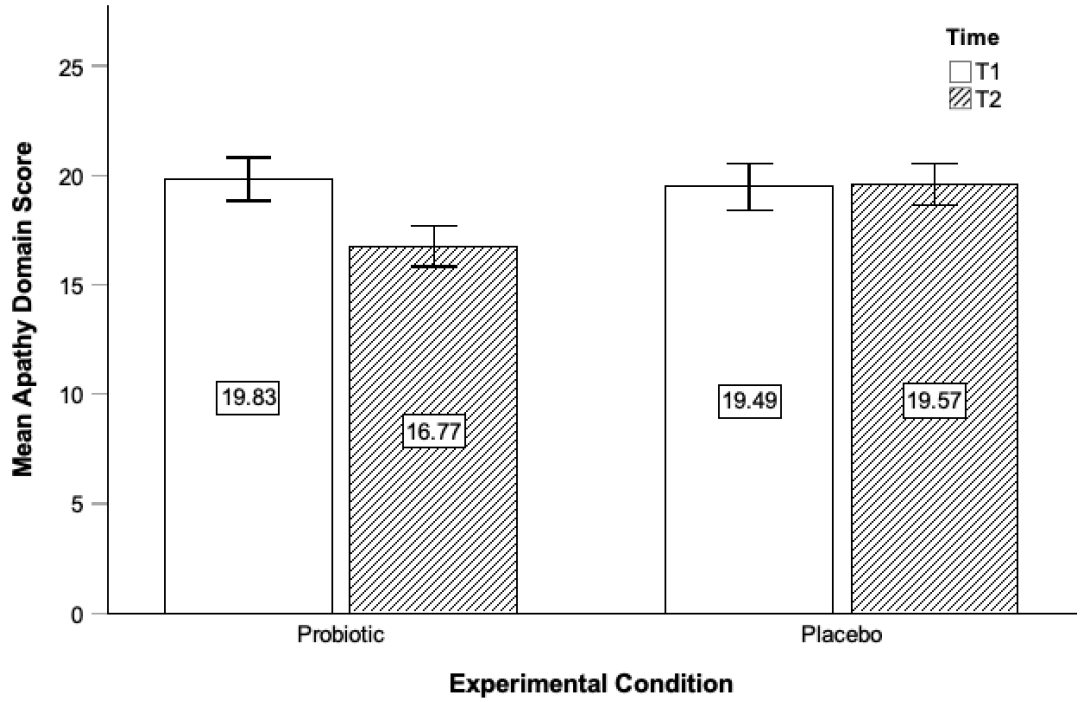
Table 3

Mean Apathy Scores

Apathy Score	Probiotic (*n* = 160)	Placebo (*n* = 160)	Total (*N* = 320)
T1, mean (*SD*)	19.83 (6.37)	19.49 (6.86)	19.66 (6.61)
T2, mean (*SD*)	16.77 (6.05)	19.57 (6.07)	18.17 (6.21)

Figure 4

Mean Apathy Scores



Note. Error bars represent 95% CI.

ANOVA Results

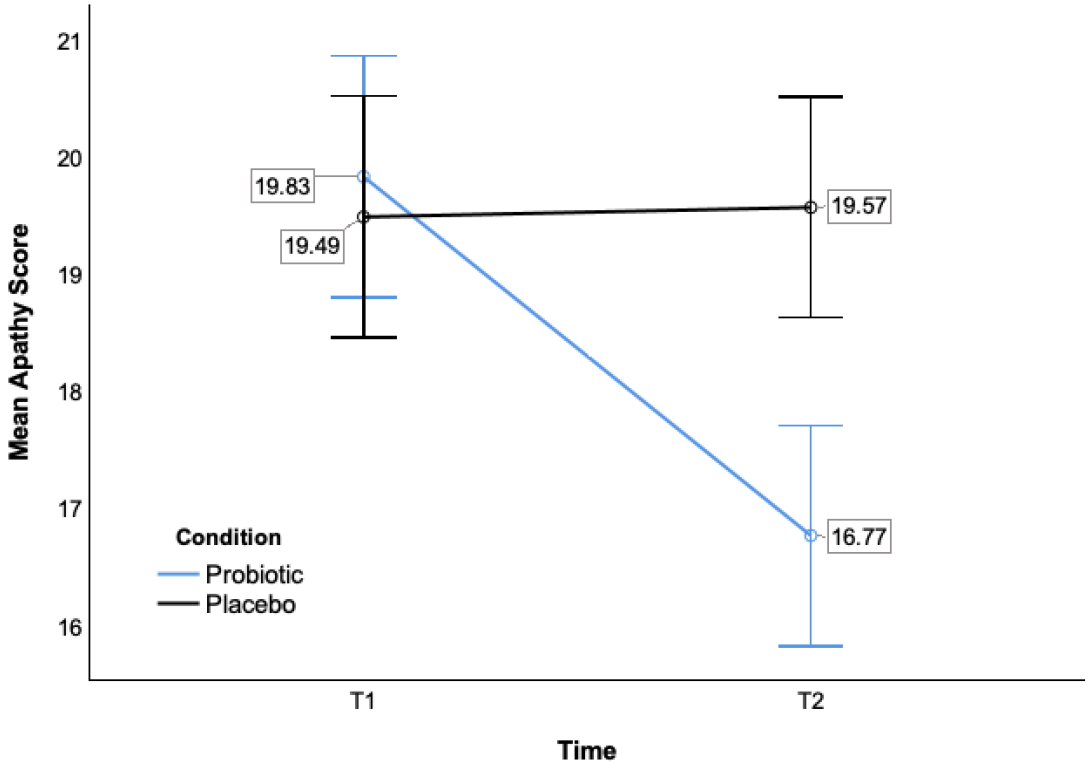
We will report the main effects of each predictor variable as well as the interaction between the two with the within- and between-groups degrees of freedom, the *F*-statistic, and the *p*-value.

In this example, there was a significant effect for both time ($F(1, 318) = 9.52$, $p = .002$) and experimental condition ($F(1, 318) = 5.59$, $p = .019$) on apathy scores. There was also a significant interaction effect of time and experimental condition on apathy scores, $F(1, 318) = 10.59$, $p = .001$. Figure 5 depicts this interaction. The blue line represents

the change in mean apathy scores from T_1 to T_2 in the probiotic condition and the black line represents the same change in the placebo condition.

Figure 5

Interaction Plot



Note. Error bars represent 95% CI.

Paired samples t-tests

If the result of the mixed factorial ANOVA is significant, we will conduct and report paired samples t-tests with the *t*-value, two-tailed *p*-values, and Cohen's *d*, comparing apathy scores from T_1 to T_2 based on experimental condition.

In our example, post hoc analyses using paired samples t-tests revealed that participants in the probiotic condition had significantly lower apathy scores post-treatment (M = 16.77, SD = 6.05) than at baseline (M = 19.83, SD = 6.37), $t(159) = 4.69$, $p < .001$, $d = 0.37$. In the placebo condition, post-treatment apathy scores (M = 19.57, SD = 6.07) were not significantly different than baseline apathy scores (M = 19.49, SD = 6.86), $t(159) = -0.11$, $p = .909$, $d = -0.01$.