RESEARCH ANALYSIS DOCUMENTATION

Healthy Lifestyle Trial: Statistical Analysis Plan and Method

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Statistical analysis · t-tests · Chi-square · One-way ANOVA · Multiple regression

12	81	2	6
weeks of intervention	university students	campuses	questions, each with its own test

> Method and design only. The findings belong to the study's author and are not reproduced here.

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01 THE STORY BEHIND THE TRIAL

> *Imagine a university running a twelve-week programme to teach students how to eat, move and look after themselves. Half the students take part and half do not.*
>
> *At the end, did the programme change anything? To answer, you need the right test for each question, and you need to say honestly when the answer is no.*

The trial tested a lifestyle health education programme, delivered over twelve weeks to university students, aiming to improve health literacy and healthy behaviours. The task was to analyse the trial data and report the answers to six questions.

02 WORDS USED IN THIS DOCUMENT

Word	What it means
Randomised controlled trial	A study in which people are assigned by chance to receive a programme or not, so the two groups start alike.
Intervention and control	The group that receives the programme, and the group that does not.
Health literacy	How well a person can find, understand and use health information.
Body mass index (BMI)	Weight divided by height squared, used as a rough measure of body size.
Normality check	A test of whether the data are close enough to a bell curve for t-tests and ANOVA to be used.
Independent t-test	Compares the averages of two separate groups.
Paired t-test	Compares the same people before and after.

Word	What it means
Effect size (Cohen's d)	How big the difference is, not only whether it is real. About 0.2 is small, 0.5 medium and 0.8 large.
Chi-square test	Compares proportions, such as the share of each group with asthma.

03 THE SIX QUESTIONS AND THE TEST CHOSEN FOR EACH

#	Question	Test	Why this test
1	Is health literacy after the programme different between campus A and campus B?	Independent t-test	Two separate groups, one score each
2	Did the programme change BMI, comparing intervention with control?	Independent t-test with Cohen's d	Two separate groups; the effect size shows how large the gap is
3	Did health literacy change among those who received the programme?	Paired t-test	The same people, measured before and after
4	Is the share with asthma different between the two groups?	Chi-square test	Both variables are categories
5	Is health literacy at the start different across three age groups (20 or under, 21 to 25, 26 or over)?	One-way ANOVA	Three or more groups, one score
6	Can age, sex and health literacy after the programme predict BMI after the programme?	Multiple linear regression	Several predictors of one numeric outcome

04 HOW EACH QUESTION WAS ANSWERED

THE SAME ROUTINE FOR EVERY QUESTION

1. Check the data for errors and missing values.
2. State the null hypothesis: that there is no difference or no effect.
3. Run the normality check, and choose the test that suits it.
4. Run the test and record the statistic, the degrees of freedom and the p-value.
5. Report the effect size where the test supports one.
6. Say whether the null hypothesis is rejected, and give the answer in a plain sentence that a programme manager can use.

> **An everyday example.** Suppose, for illustration only, that the control group's BMI averages 26 and the intervention group's averages 24, with a standard deviation of 4 in both. The difference is 2 and $2 \div 4 = 0.5$, a medium effect. A p-value would then say whether a gap of that size could easily be chance in a sample this size. These numbers are invented to show the reading. They are not from the trial.

05 WHAT A CAREFUL REPORT INCLUDES

- The group sizes next to every mean, so the reader can see how much data each result rests on.
- The p-value and the effect size together, since a result can be significant but small, or large but uncertain.
- A plain statement of what was not significant, because no difference is also an answer.
- A check that the text, the tables and the decisions agree with each other before the report is sent.

06 LIMITS OF THE DESIGN

With about 80 participants, the trial can find only fairly large effects. Groups of unequal size, and results on two campuses, reduce the comparability of the two arms. The regression in question 6 describes association in this sample and cannot show that age or sex causes a change in BMI.

07 OUTPUTS

A statistical analysis report that answers all six questions, with a table, a decision and a plain-language reading for each.

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