

Quantitative Results Report Write-up **Study Protocol and Assessment Guidance Notes**

1. Study Background:

The dataset is from a hypothetical study on 175 participants who were approached in the screening waiting area of the Cancer Genetics Service for Wales (CGSW), during May 2019.

The aim of the study was to explore which of two leaflets developed as interventions to try and reduce distress levels (Intervention Leaflet 1 or Intervention Leaflet 2) had the greatest impact on individuals waiting to learn whether they are at increased risk of developing an inherited cancer. The interventions are based upon psychological coping theory and encourages individuals to restrict consideration of the issues related to their risk for a set time (e.g., 10-15 minutes) each day, and to actively distract from intrusive thoughts at all other times. The two intervention leaflets differed slightly to each other, to assess whether phrasing and type of activities documented had any bearing on the amount of distress being reported.

Data was collected on gender, age, marital status, education level at Baseline. Data from the Impact of Events (IES) scale was collected at three key time points (Time 1: Baseline - Upon referral to genetic risk assessment, Time 2: Whilst waiting for genetic risk assessment information, and Time 3: One-month post-risk information).

Raw scores on the IES required recoding (see copy of questionnaire). This has already been completed and only these recoded variables have been provided in the dataset, along with appropriate total IES scale scores at each of the three timepoints.

2. Design

A fully powered MRC Phase III randomised controlled trial aimed to assess the effectiveness of two different leaflet interventions in reducing distress in individuals undergoing cancer genetic risk assessment across Wales.

3. Study Groups

Intervention Leaflet 1 Group: Upon referral, participants randomised into the intervention leaflet 1 group received the study information pack and the standard distress reduction intervention leaflet sent out by the Cancer Genetics Service for Wales (CGSW) to new referrals.

Intervention Leaflet 2 Group: Upon referral, individuals randomised into the intervention leaflet 2 group received the study information pack and a new intervention coping with distress leaflet.

4. Data collection

Measures

Demographics (Baseline, Time 1 only): gender/age/marital status/education level

Cancer-specific distress: (Time 1, 2, and 3): The Impact of Event Scale (IES; Horowitz et al., 1979) adapted for familial cancer, consisting of 15 items capturing the frequency of participants' intrusive thoughts about their risk of developing cancer, and attempts to avoid these thoughts. The IES allows the calculation of a total score and separate intrusion and avoidance subscales scores. According to Horowitz (Horowitz (1982) and personal communication, 1999; 2004), scores on the global IES can be broken down into the following categories: low distress (scores below 8.5), medium distress (scores between 8.5 and 18) and high distress (scores of 19 or more).

5. The dataset and Write-up

The dataset has already been screened and cleaned for errors and outliers.

However, checks for normality and assumptions for each of the analyses are still required and should be appropriately reported.

1. Familiarise yourself with the data variables and scoring using the SPSS data input sheet, study Codebook, and information contained within the questionnaire that have been provided to you on Moodle.
2. Provide a brief explanation to the background of the study at the beginning of your write-up, based upon the information provided above.
3. Conduct in SPSS and then report in your write-up, the descriptives for demographics and scale scores.
(Do **not** put SPSS tables/charts in the write-up, you must create your own).
4. Conduct in SPSS and then report in your write-up, the test of Normality on the IES data at each of the three timepoints (total scores).
5. Conduct in SPSS and then report in your write-up, the Reliability Analysis on the IES scores at each of the three time points (individual items).
6. Conduct in SPSS and then report in your write-up, an appropriate t-test on the Baseline (Time 1) IES scores between the two leaflet groups to ensure there are no prior significant differences in distress levels.

7. Identify the appropriate type of ANOVA to conduct based on the research question: i.e., to examine distress levels between the **two** intervention groups (between-subjects) over the **three** time-points (within-subjects).
8. Carry out the appropriate analysis and correctly report this (interaction and main effects), including relevant statements about whether the data has met the assumptions for the analysis (ensure to read values from relevant alternative rows if assumptions have not been met).
9. Conduct and correctly report any necessary post-hoc pairwise comparisons (including a statement as to whether any alpha corrections were employed – e.g., LSD, Bonferroni).
10. Interpret the findings as you would in the results section of an APA journal and provide a brief concluding paragraph about the potential value of the two intervention leaflets on levels of distress in those undergoing genetic risk assessment.
(Include reference to overall distress levels reported from the sample data in line with relevant category thresholds of low, medium, and high distress).

Word count – 2,000 words

You must include a reference list and all outputs as an appendix to your written report.