

SAP - Weight gain

Please note this is not the only SAP possible for this example.

Population

Old people admitted to hospital (would have been useful to have a definition of what was meant by 'old').

Primary objective

To investigate the effectiveness of a nutritional supplement in reducing or reversing weight loss.

Secondary objective

None specifically mentioned, but given that time of stay was also recorded as well as weight on entering hospital and that there were three nutritional groups identified, it might be reasonable to suggest a further objective would be to examine the effect of length of stay as well as weight on entry on weight loss.

Data collection

Old people routinely admitted to hospital (120 of them), categorised by nutritional group, within each group, randomly allocated to either receive or not the supplement. Patients observed for a maximum of 6 weeks, or until they were discharged.

Variables under consideration

Weight on entry

Nutritional group

Weight of discharge or 6 weeks whichever is shorter – **Secondary response variable**

Length of stay (in weeks)

Received or did not receive supplement

Weight Gain – **Primary response variable** (computed as Weight on discharge – weight on entry)

Missing data procedures

None mentioned, though one would guess that missing data might be an issue.

Summaries to be presented.

Boxplots of weight gain by nutritional group and by supplement

Descriptive statistics by nutritional group and supplement

Scatterplot of weight gain by length of stay

Models to be fitted

Primary objective:

General linear model (2-way ANOVA),

WG~group+supplement+group:supplement

Fit full model and then test to see if possible to simplify by dropping interaction term, significance set at 5%. Check residuals after final model for constant variance, normality.

Other models that could be considered:

Weightatend~ weight(beg)+group+supplement+possible interactions

Weightatend~ weight(beg)+length of stay+ group+supplement+possible interactions