Case Study One

Obesity - Can a New Drug Help?

Obesity is known to be a major health risk throughout Europe and the United States leading to a number of possibly life threatening diseases. Developing a successful treatment for obesity is therefore important as a reduction in weight can greatly reduce the risk of illness for the individual. A sustained weight loss of 5 - 10% of initial body weight reduces the health risks associated with obesity. Diet and exercise are useful in weight control but may not always be successful in the long term. An integrated programme of diet, exercise and drug treatment may be beneficial for obese patients.

The data available for analysis arises from a study which aimed to investigate whether or not a new drug, used as part of a regime of diet, exercise and drug treatment, could assist in weight reduction for obese individuals.

The Clinical Trial

The study is an example of a *clinical trial* commonly used to assess the effectiveness of a new treatment. Clinical trials are subject to rigorous controls to ensure that individuals are not unnecessarily put at risk and that they are fully informed and give their consent to take part in the study. As giving any patient a treatment may have a psychological effect, many studies will compare a new drug to a dummy treatment (a *placebo*) where, to avoid bias, neither the patient nor the doctor recording information will know whether the individual patient is on the new treatment or placebo as the tablets / capsules look identical. This approach is known as double-blinding. Bias could also occur if the treatment given to an individual patient was based on their characteristics, e.g. if the more overweight patients were given the new treatment rather than the placebo they would have a greater chance of some weight loss. To avoid such bias the decision as to which individuals will receive the new treatment and which will receive the placebo must be made using a process known as *randomisation*. Using this approach each individual has the same chance of being given either the new treatment or the placebo.

The Patients in the Study

Patients taking part in this study were healthy adults (aged 18 to 65 years) and were between 30% and 80% above their ideal body weight. Rigorous criteria were defined to ensure that only otherwise-healthy individuals took part.

Patients received either the new drug or placebo for an eight week period and body weight was recorded at the start (Week 0 - known as *baseline*) and at Week 8. Information recorded for each patient included age (years), gender, height (cm), family history of obesity (yes/no), motivation rating (some/moderate/great), number of previous weight loss attempts and age of onset of obesity (1: ≤ 11 years, 2: 12 - 17 years, 3: ≥ 18 years).

The Data

The table shown overleaf (Table 1) gives, for each patient, the individual data, Week 0 and Week 8 weights, and a code (1 = placebo, 2 = new drug) which identifies whether the patient received the placebo or the new drug.

Previous studies of combined exercise, diet and drug regimes suggest that weight loss over an eight week treatment period varies approximately according to a Normal distribution with standard deviation 2.57 kg.

Measuring Outcome

To assess whether or not the new treatment is of any value, two possible measures can be considered:

1. Change in weight =
   Weight at Week 8 – Weight at Week 0
2. Did the patient achieve a greater than 5% reduction in weight?

Questions of Interest

In examining the results of this study the following questions are relevant.

i. What are the characteristics of the patients involved?
ii. Are the patients in the two groups similar at the start of the study?
iii. Is there any difference in terms of outcome for patients in the two treatment groups?

Table 1

The Study Data

Patient Number	Age (years)	Gender (M/F)	Height (cm)	Family History? (Y/N)	Motivation Rating 1: some 2: moderate 3: great	Previous Weight Loss Attempts	Age of Onset 1: ≤ 11 2: 12 - 17 3: ≥ 18	Weight at Week 0 (kg)	Weight at Week 8 (kg)	Treatment Group 1 = placebo 2 = new drug
101	43	F	162	Y	1	3	1	91.3	90.2	1
102	39	F	159	Y	3	5	1	88.8	87.0	2
103	48	F	163	Y	2	2	3	87.0	81.8	2
104	35	F	171	N	2	6	3	114.0	110.5	1
105	55	F	164	Y	2	3	3	107.4	103.5	2
106	48	F	162	Y	3	5	2	89.2	90.2	1
107	62	F	157	Y	3	1	2	84.1	84.0	1
108	53	F	165	Y	2	7	1	90.0	87.6	2
109	44	F	161	Y	2	1	1	95.4	95.0	1
110	45	F	168	Y	2	7	3	97.3	93.6	1
111	54	F	171	Y	1	3	3	108.1	100.9	2
112	40	F	168	Y	2	1	3	101.5	101.9	1
113	40	F	170	N	2	1	3	83.4	75.0	2
114	50	F	164	Y	2	5	2	102.2	96.3	1
115	39	F	154	Y	2	1	3	84.0	82.6	1
116	40	F	169	Y	1	7	3	103.7	95.7	2
117	44	F	169	N	2	1	1	99.2	99.2	2
118	44	M	177	Y	2	2	2	126.0	123.2	2
119	38	M	171	Y	1	1	1	103.7	95.5	2
120	42	M	175	N	2	4	3	117.9	117.0	1
121	53	M	177	Y	2	3	3	112.4	111.8	1
122	52	F	166	Y	1	3	3	85.0	80.0	2
123	35	F	159	N	2	1	3	83.8	77.9	2
124	60	F	157	N	1	2	3	73.8	74.8	1
125	61	F	152	N	1	2	3	67.7	66.1	1
126	49	F	171	Y	1	1	2	106.9	103.7	2
127	49	F	177	Y	1	2	3	102.5	102.0	1
128	38	F	156	N	2	1	1	81.5	78.9	2
129	42	F	158	Y	2	3	2	79.5	82.2	1
130	38	M	177	Y	2	3	3	103.0	97.2	2
131	41	M	182	Y	1	3	3	127.5	124.7	2
132	27	M	175	N	2	1	2	101.6	100.3	1
133	46	M	180	Y	1	3	3	106.0	101.0	1
134	42	M	177		1	4	3	112.8	111.2	1
135	53	M	173	N	1	2	3	98.4	95.0	1
136	59	M	183	Y	1	1	3	114.9	105.3	2
137	31	M	175	N	2	2	3	103.4	96.0	2