

Supplementary file 5 – Power estimations of secondary outcomes

The below power calculations are based on a sample size of 350 participants as specified in the main document.

Days alive outside hospital

Using a minimal important difference of 3 days, a standard deviation of 9, a risk of type I error of 5%, and accounting for the fact that the data is expected not to be normal distributed, we will be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) of 82.1%.¹

The Atrial Fibrillation Effect on Quality-of-Life (AFEQT)

In previous trials the observed difference between groups was normally distributed with a standard deviation of 21.^{2,3} Using a minimal important difference of 7, we will be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) of 87.5%. The Type I error probability associated with this test of this null hypothesis is 5%.

Quality of life using the SF-36 questionnaire (mental component score)

In previous trials the observed difference between groups was normally distributed with a standard deviation 10.⁴⁻⁶ Using a minimal important difference of 4, we will be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) of 96%. The Type I error probability associated with this test of this null hypothesis is 5%.

Serious adverse events

We anticipate a failure rate among control of 20%. If we anticipate a relative risk reduction of 60%, we will be able to reject the null hypothesis with probability (power) of 90.2%. The Type I error probability associated with this test of this null hypothesis is 5%.

POWER ESTIMATIONS OF EXPLORATORY OUTCOMES

All-cause mortality

Prior data indicate that the mortality rate among controls is about 5%.⁷ If we anticipate a relative risk reduction of 10%, we will be able to reject the null hypothesis with probability (power) of 5.7%. The Type I error probability associated with this test of this null hypothesis is 5%.

Composite of all-cause mortality, stroke, myocardial infarction and cardiac arrest

Prior data indicate that this outcome occurs in controls in about 8%.^{7,8} If we anticipate a relative risk reduction of 10%, we will be able to reject the null hypothesis with probability (power) of 5.9%. The Type I error probability associated with this test of this null hypothesis is 5%.

Cardiac mortality

Prior data indicate that the failure rate among controls is 3.9%.⁷ If we anticipate a relative risk reduction of 10%, we will be able to reject the null hypothesis with probability (power) of 5.4%. The Type I error probability associated with this test of this null hypothesis is 5%.

Stroke

Prior data indicate that cardiac mortality among controls is 3.9%.⁷ If we anticipate a relative risk reduction of 10%, we will be able to reject the null hypothesis with probability (power) of 5.4%. The Type I error probability associated with this test of this null hypothesis is 5%.

Hospitalisation for worsening of heart failure

Prior data indicate that heart failure among controls is 27.4%.⁷ If we anticipate a relative risk reduction of 10%, we will be able to reject the null hypothesis with probability (power) of 9.0%. The Type I error probability associated with this test of this null hypothesis is 5%.

Number of hospital admissions

Prior data indicate that number of participant who are hospitalised is 27.4%.⁷ If we anticipate a relative risk reduction of 10%, we will be able to reject the null hypothesis with probability (power) of 9%. The Type I error probability associated with this test of this null hypothesis is 5%.

Six-minute walking distance

In previous trials the observed difference between groups was normally distributed with a standard deviation 75.⁹⁻¹¹ Using a minimal important difference of 40, we will be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) of 99.9%. The Type I error probability associated with this test of this null hypothesis is 5%.

Physical activity using trial accelerometer

Prior data indicates that the standard deviation among groups was 65 minutes pr. Day when measuring sedentary behaviour. Assuming a difference in groups of 20 minutes/day, we will be able to reject the null hypothesis with a probability of 81.9%. The type 1 error probability associated with this test of this null hypothesis is 5%.^{12 13}

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