

POWER CALCULATIONS FOR RCT

METHOD A: Dichotomous outcomes, proportions at 6 months.

For 80% power		
Success rate @ 6 months		Sample Size
Index Group	Control Group	Each Group
0.80	0.10	10
0.70	0.10	12
0.60	0.10	17
0.50	0.10	24
0.40	0.10	38
0.80	0.15	11
0.70	0.15	14
0.60	0.15	21
0.50	0.15	32
0.40	0.15	57
0.80	0.20	13
0.70	0.20	18
0.60	0.20	27
0.50	0.20	44
0.40	0.20	91
0.80	0.25	15
0.70	0.25	22
0.60	0.25	35
0.50	0.25	66
0.40	0.25	165
0.80	0.30	18
0.70	0.30	28
0.60	0.30	48
0.50	0.30	103
0.40	0.30	Too many

The figures in bold are what is achievable with a sample size of 21 or less.

The differences for which larger samples are required, I submit, are not worth demonstrating.

A 40% success rate indicates that something terribly wrong is happening with the paradigm. Therefore, it is not worth proving against a control rate of 10%, 15%, 20% or more.

I might be impressed with 50% vs 15%, but that will require 32 patients.

I would not consider 50% vs 20% or more a sufficient vindication of the paradigm; and so, not worth the effort of 44 patients in each group.

Any other considerations get overtaken by method B.

METHOD B: Survival analysis.

For 80% power		
With 6 month follow-up		
Median survival (months)		Sample Size
Index Group	Control Group	Each Group
3	1	13
4	1	9
5	1	7
3	1.5	34
4	1.5	18
5	1.5	12
4	2	36
5	2	21
5	2.5	38
With 9 months follow-up		
6	1	5
6	1.5	9
6	2	14
6	2.5	23
6	3	37
With 12 months follow-up		
3	1	13
3	1.5	33
4	1	8
4	1.5	17
4	2	33
5	1	6
5	1.5	11
5	2	19
5	2.5	34
6	1	5
6	1.5	9
6	2	14
6	2.5	22
6	3	35
7	1	4
7	1.5	7
7	2	11
7	2.5	16
7	3	24
7	3.5	36

The longer-lasting the outcome in the index group, and the shorter the outcome in the control group, you can get away with less than 20 patients in each group. If the index outcome is really good, and the control outcome is lousy (< 2months survival), you can score with less than 10 patients.