**Sample Size Determination for Group Exercise vs. Personal Training in Colorectal CA Patients Study**

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**Rationale**

We have four scenarios for you to decide between based on your scientific understanding of the study. The four scenarios are focused on four speculated mean differences (delta) between the two arms, with the first one taken the mean difference from the paper by Courneya et al. 2016, and the second, third, and fourth are between the first mean difference and the observed difference in your own pilot study. We then calculated the required sample size under a range of standard deviation (sd) for each scenario with the smallest of 27.4 from the paper by Courneya et al. 2016 and the largest of 84.0 from your pilot study. All the calculations are based on an 80% statistical power.

**Scenario 1 (delta=10.5)**

**Standard deviation = 27.4**

Group sample sizes of 64 and 128 (192 total) achieve 80.2% power to reject the null hypothesis of equal means when the population mean difference is 10.5 with a standard deviation for both groups of 27.4 and with a significance level (alpha) of 0.050 using a one-sided two-sample equal-variance t-test. To account for a dropout rate of 15%, the personal training group would need to begin with 76 participants expecting 12 to dropout and the group training group start with 151 expecting 23 to dropout. Thus, a beginning recruitment total of 227 participants would expect to lose 35 by the end of the study.

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| --- | --- | --- | --- | --- |
|  | Sample Size | | | Total Sample Size required with a 15% attrition rate |
| sd | N1 | N2 | N |
| 27.4 | 64 | 128 | 192 | 227 |
| 28 | 67 | 134 | 201 | 237 |
| 29 | 72 | 144 | 216 | 255 |
| 30 | 77 | 154 | 231 | 273 |
| 33 | 93 | 186 | 279 | 329 |
| 42 | 149 | 298 | 447 | 527 |
| 51 | 219 | 438 | 657 | 774 |
| 60 | 303 | 606 | 909 | 1070 |
| 69 | 401 | 802 | 1203 | 1416 |
| 78 | 512 | 1024 | 1536 | 1808 |
| 84 | 594 | 1188 | 1782 | 2097 |

**Scenario 2 (delta=12.5)**

**Standard deviation = 28**

Group sample sizes of 46 and 92 (141 total) achieve 80.0% power to reject the null hypothesis of equal means when the population mean difference is 12.5 with a standard deviation for both groups of 28 and with a significance level (alpha) of 0.050 using a one-sided two-sample equal-variance t-test. To account for a dropout rate of 15%, the personal training group would need to begin with 56 participants expecting 9 to dropout and the group training group start with 111 expecting 17 to dropout. Thus, a beginning recruitment total of 167 participants would expect to lose 26 by the end of the study.

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|  | Sample Size | | | Total Sample Size required with a 15% attrition rate |
| sd | N1 | N2 | N |
| 27.4 | 46 | 92 | 138 | 164 |
| 28 | 47 | 94 | 141 | 167 |
| 29 | 51 | 102 | 153 | 180 |
| 30 | 54 | 108 | 162 | 192 |
| 33 | 66 | 132 | 198 | 234 |
| 42 | 106 | 212 | 318 | 375 |
| 51 | 155 | 310 | 465 | 548 |
| 60 | 214 | 428 | 642 | 756 |
| 69 | 283 | 566 | 849 | 999 |
| 78 | 362 | 724 | 1086 | 1278 |
| 84 | 419 | 838 | 1257 | 1479 |

**Scenario 3 (delta=15)**

**Standard deviation = 30**

Group sample sizes of 38 and 76 (114 total) achieve 80.2% power to reject the null hypothesis of equal means when the population mean difference is 15 with a standard deviation for both groups of 30 and with a significance level (alpha) of 0.050 using a one-sided two-sample equal-variance t-test. To account for a dropout rate of 15%, the personal training group would need to begin with 38 participants expecting 7 to dropout and the group training group start with 45 expecting 14 to dropout. Thus, a beginning recruitment total of 135 participants would expect to lose 21 by the end of the study.

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| --- | --- | --- | --- | --- |
|  | Sample Size | | | Total Sample Size required with a 15% attrition rate |
| sd | N1 | N2 | N |
| 27.4 | 32 | 64 | 96 | 114 |
| 28 | 33 | 66 | 99 | 117 |
| 29 | 36 | 72 | 108 | 128 |
| 30 | 38 | 76 | 114 | 135 |
| 33 | 46 | 92 | 138 | 164 |
| 42 | 74 | 148 | 222 | 263 |
| 51 | 108 | 216 | 324 | 383 |
| 60 | 149 | 298 | 447 | 527 |
| 69 | 197 | 394 | 591 | 696 |
| 78 | 251 | 502 | 753 | 887 |
| 84 | 291 | 582 | 873 | 1028 |

**Scenario 4 (delta=48.2)**

**Standard deviation = 84**

Group sample sizes of 29 and 58 (87 total) achieve 80.5% power to reject the null hypothesis of equal

means when the population mean difference is 48.2 with a standard deviation for both groups of

84.0 and with a significance level (alpha) of 0.050 using a one-sided two-sample equal-variance

t-test. To account for a dropout rate of 15%, the personal training group would need to begin with 35 participants expecting 6 to dropout and the group training group start with 69 expecting 11 to dropout. Thus, a beginning recruitment total of 104 participants would expect to lose 17 by the end of the study.

**Additional Comments**

If the similar study has shown vastly different variances in multiple studies, then one option in obtaining the variance of the study is to utilize a two-stage design with the variance estimated at the pre-defined first stage and adjust the sample size accordingly.