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Year 2007 *Paper* 28

Assessment of Sample Size and Power for the Analysis of Clustered Matched-Pair Data

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Abstract

This paper outlines how one can determined the sample size or power of a study design that is based on clustered matched-pair data. Detailed examples are provided.

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As a review, the following 2 x 2 table is used to summarize the results of a study based on K clusters of matched-pair data:

Table 1. McNemar's-Like Table for K Clusters of Matched-Pair Data.

Procedure 2	Procedure 1		
	Success	Failure	
Success	$\sum_{k=1}^{K} a_k$	$\sum_{k=1}^{K} b_k$	$\sum_{k=1}^{K} (a_k + b_k)$
Failure	$\sum_{k=1}^{K} c_k$	$\sum_{k=1}^{K} d_k$	
	$\sum_{k=1}^{K} (a_k + c_k)$		$\sum_{k=1}^{K} n_k$ = N

The following table is used to summarize the data for non-clustered matched-pair data:

Table 2. McNemar's Table for Non- Clustered Matched-Pair Data.

Procedure 2	Procedure 1		
	Success	Failure	
Success	a	b	a+b
Failure	c	d	a+b+c+d= N
	a+c		

Procedure to determine sample size of a study design that is based on clustered matched-pair data.

1. Initially assume that a non-clustered design will be used.
2. Specify the design parameters for the proposed study.
    a. $\alpha = 0.05$, two-sided
    b. power = 80%
    c. proportion of matched-pairs with Procedure 1 [Success], Procedure 2 [Success] = 0.03
    d. proportion of matched-pairs with Procedure 1 [Success], Procedure 2 [Failure] = 0.07
    e. proportion of matched-pairs with Procedure 1 [Failure], Procedure 2 [Success] = 0.02
    f. proportion of matched-pairs with Procedure 1 [Failure], Procedure 2 [Failure] = 0.88
3. Calculate the sample size required for a non-clustered design based on these design parameters (You can use nQuery).
    a. Results of nQuery: n (number of matched-pairs) = 262
4. Next, we need to specify a design parameter associated with the clustered study design: Intra-class correlation (ICC)
    a. ICC (ρ) is the correlation between pairs of subjects chosen at random from the same cluster.
        i. $\rho = \dfrac{\sigma_B^2}{\sigma_B^2 + \sigma_W^2}$
            1. where σ_B^2 is the between cluster variability
            2. where σ_W^2 is the within cluster variability
    b. the size of the ICC is generally larger for smaller clusters
        i. households $\sim$ 0 to 0.3 (large)
        ii. postcodes $\sim$ 0 to 0.05 (medium)
        iii. health districts $\sim$ 0 to 0.001 (small)
        iv. actual ICC usually not known at the design stage unless you have pilot data or published ICC's.
5. Once the ICC is specified, we need to compute the Inflation Factor (IF) aka Design Effect (Deff).
    a. The IF (Deff) is a multiplier that tells us how much more the total sample size N needs to be increased in order to maintain the design parameters specified in the non-clustered study design (Refer to 2. above).
    b. IF = 1+ (n-1)*ICC
        i. where n = (average sample size per cluster)
        ii. where ICC is the intra-class correlation
    c. So even when the ICC is small, the IF is substantial if n is large!
    d. When n = 1 (no clustering), IF (Deff) = 1, otherwise > 1.
    e. The power of a clustered design can be increased when one:
        i. increases the number of clusters (more effective)
        ii. increases the sample size per cluster (less effective; not much gain in power after 50 subjects per cluster!)
6. Determine the total sample size N required for the clustered design:
    a. Compute IF (Deff)
        i. the design parameters specified in 2.a. through 2.f. are used
        ii. the ICC is assumed to be 0.001, 0.05, 0.3
        iii. the non-clustered total sample size is 262 (Refer to 3.a. above)
        iv. the assumed number of clusters is 20 (i.e., average n per cluster is 13.1)
            1. IF = 1+ (13.1-1)*0.3 = 4.63
            2. IF = 1+ (13.1-1)*0.05 = 1.605
            3. IF = 1+ (13.1-1)*0.001 = 1.0121
    b. Compute the total sample size N required for the clustered design
        i. IF = 4.63, then N =1213.06 = 1214 $\rightarrow$ 93 clusters of size 13.1
        ii. IF = 1.605, then N = 420.51 = 421 $\rightarrow$ 32 clusters of size 13.1
        iii. IF = 1.0121, then N = 265.17 = 265 $\rightarrow$ 20 clusters of size 13.1

Example of power reduction when the effect of clustering is not accounted for in the sample size.

The design parameters for the proposed study.

α = 0.05, two-sided
power = 80%
proportion of matched-pairs with Procedure 1 [Success], Procedure 2 [Success] = 0.03
proportion of matched-pairs with Procedure 1 [Success], Procedure 2 [Failure] = 0.07
proportion of matched-pairs with Procedure 1 [Failure], Procedure 2 [Success] = 0.02
proportion of matched-pairs with Procedure 1 [Failure], Procedure 2 [Failure] = 0.88

The sample size required for a non-clustered design based on these design parameters:
n (number of matched-pairs) = 262

The assumed number of clusters is 20 (i.e., average n per cluster is 13.1)

IF = 1+ (13.1-1)*0.3 = 4.63
IF = 1+ (13.1-1)*0.05 = 1.605
IF = 1+ (13.1-1)*0.001 = 1.0121

The total sample size N required for the clustered design if you want to maintain the design parameters specified:

IF = 4.63, then N =1213.06 = 1214 → 93 clusters of size 13.1

IF = 1.605, then N = 420.51 = 421 → 32 clusters of size 13.1

IF = 1.0121, then N = 265.17 = 265 → 20 clusters of size 13.1

Power of the clustered design if the design parameters are held the same but the IF has not been applied:

ICC= 0.3 (large), IF = 4.63, then Power = 21%
ICC= 0.05 (medium), IF = 1.605, then Power = 57%
ICC= 0.001 (small), IF = 1.0121, then Power = 79%

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Personal Communication from Valerie L. Durkalski (durkalsv@musc.edu) regarding the use of the ICC for sample size determination when considering clustered matched-pair data, June 7, 2004.