

Package ‘swdpwr’

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Type Package

Title Power Calculation for Stepped Wedge Cluster Randomized Trials

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Description To meet the needs of statistical power calculation for stepped wedge cluster randomized trials, we developed this software. Different parameters can be specified by users for different scenarios, including: cohort and cross-sectional settings, binary and continuous outcomes, marginal (GEE) and conditional (mixed effect model) methods, different link functions (identity, log, logit links), with and without time effect of treatment, etc. The methods included in this package: Zhou et al. (2020) <doi:10.1093/biostatistics/kxy031>, Li et al. (2018) <doi:10.1111/biom.12918>. Supplementary documents can be found at: <<https://publichealth.yale.edu/cmips/research/software/swdpwr/>>. The Shiny app for swdpwr can be accessed at: <https://jiachenchen322.shinyapps.io/swdpwr_shinyapp/>.

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`swdpwr-package`*Power Calculation for Stepped Wedge Cluster Randomized Trials*

Description

This package includes a function `swdpower` that accounts for power calculation for stepped wedge cluster randomized trials.

Details

Package: `swdpwr`
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Previous literature and development of software focused mainly on continuous outcomes and obtained approximation results for binary outcomes. This package implemented new methods of power calculation for stepped wedge designs with binary outcomes and also incorporated procedures for continuous outcomes. The function `swdpower` can accommodate both cross-sectional and cohort settings by specifying three levels of correlation parameters, and includes scenarios under both conditional method (mixed effect model) and marginal method (GEE), different link functions (identity, log, logit links), with or without time effect, etc. With this package, investigators can obtain more accurate calculation of statistical power, that will help a lot in the design and analysis of stepped wedge cluster randomized trials. Other supplementary documents can be found at: <https://publichealth.yale.edu/cmips/research/software/swdpwr/>. The Shiny app for `swdpwr` can be accessed at: https://jiachenchen322.shinyapps.io/swdpwr_shinyapp/.

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References

Zhou X, Liao X, Kunz L M, et al. A maximum likelihood approach to power calculations for stepped wedge designs of binary outcomes[J]. *Biostatistics*, 2020, 21(1): 102-121.

Li F, Turner E L, Preisser J S. Sample size determination for GEE analyses of stepped wedge cluster randomized trials[J]. *Biometrics*, 2018, 74(4): 1450-1458.

swdpower

*A function of power calculation for Stepped Wedge Design Studies***Description**

This function performs power calculations for stepped wedge cluster randomized trials under different scenarios.

Usage

```
swdpower(
  K,
  design,
  family = "binomial",
  model = "conditional",
  link = "identity",
  type = "cross-sectional",
  meanresponse_start = NA,
  meanresponse_end0 = meanresponse_start,
  meanresponse_end1 = NA,
  effectsize_beta = NA,
  sigma2 = 0,
  typeIerror = 0.05,
  alpha0 = 0.1,
  alpha1 = alpha0/2,
  alpha2 = NA
)
```

Arguments

K	number of participants at each time period in a cluster
design	I*J dimensional data set that describes the study design (control 0, intervention 1), I is the number of clusters, J is the number of time periods
family	family of responses, specify family="gaussian" for continuous outcome and family="binomial" for binary outcome, with default value of "binomial"
model	choose from conditional model (model="conditional") and marginal model (model="marginal"), with default value of applying conditional model
link	choose link function from link="identity", link="log" and link="logit", with default value of identity link
type	choose the study type, specify type="cohort" for closed cohort study and type="cross-sectional" for cross-sectional study, with default value of cross-sectional study
meanresponse_start	the anticipated mean response rate in the control group at the start of the study
meanresponse_end0	the anticipated mean response rate in the control group at the end of the study, with default value equals to meanresponse_start (no time effects)

meanresponse_end1	the anticipated mean response rate in the intervention group at the end of the study
effectsize_beta	the anticipated effect size, just omit this parameter if you don't need to specify it. In all scenarios, you can choose to specify the three parameters about mean responses without specifying this effect size, or alternatively specify meanresponse_start, meanresponse_end0 and this effect size. For continuous outcomes, users can conduct power calculations by only specifying this parameter without the above three parameters about mean responses (as the power is dependent just on it), then calculation will be implemented assuming scenarios without time effects. If you would consider scenarios with time effects and continuous outcomes, please specify meanresponse_start, meanresponse_end0 (donot require accurate information, just make sure they are not equal) and this effectsize_beta.
sigma2	marginal variance of the outcome (only needed for continuous outcomes and should not be an input for binary outcomes), with default value of 0.
typeIerror	two-sided type I error, with default value of 0.05
alpha0	within-period correlation, with default value of 0.1
alpha1	between-period correlation, with default value of alpha0/2
alpha2	within-individual correlation, should not be an input under cross-sectional designs although it is numerically identical to alpha1 in this scenario by definition

Value

The object returned is a list, which includes the design matrix and a summary table of this design (including the power)

Examples

```
library(swdpwr)
#a cross-sectional design with 12 clusters, 3 periods and binary outcomes applying conditional model
#alpha2 should not be specified, as the current version does not support power calculation using
#conditional models with binary outcomes in a cohort design
#create a 12*3 matrix which describes the study design,
#0 means control status, 1 means intervention status
dataset = matrix(c(rep(c(0,1,1),6),rep(c(0,0,1),6)),12,3,byrow=TRUE)

#specify meanresponse_start, meanresponse_end0 and meanresponse_end1
swdpower(K = 30, design = dataset, family = "binomial", model = "conditional", link = "logit",
type = "cross-sectional", meanresponse_start = 0.2, meanresponse_end0 = 0.3,
meanresponse_end1 = 0.4, typeIerror = 0.05, alpha0 = 0.01, alpha1 = 0.01)

#specify meanresponse_start, meanresponse_end0 and effectsize_beta
swdpower(K = 30, design = dataset, family = "binomial", model = "conditional", link = "logit",
type = "cross-sectional", meanresponse_start = 0.2, meanresponse_end0 = 0.3, effectsize_beta = 0.6,
typeIerror = 0.05, alpha0 = 0.01, alpha1 = 0.01)

#a cohort design with 8 clusters, 3 periods and continuous outcomes applying marginal model
#sigma2 should be specified, as continuous outcomes require marginal variance in calculation
```

```
#create a 8*3 matrix which describes the study design,  
#0 means control status, 1 means intervention status  
dataset = matrix(c(rep(c(0,1,1),4),rep(c(0,0,1),4)),8,3, byrow=TRUE)  
  
#specify meanresponse_start, meanresponse_end0 and meanresponse_end1  
swdpower(K = 24, design = dataset, family = "gaussian", model = "marginal", link = "identity",  
type = "cohort", meanresponse_start = 0.1, meanresponse_end0 = 0.2, meanresponse_end1 = 0.4,  
sigma2 = 0.095, typeIerror = 0.05, alpha0 = 0.03, alpha1 = 0.015, alpha2 = 0.2)  
  
#specify effectsize_beta only, then the program runs assuming no time effects  
swdpower(K = 24, design = dataset, family = "gaussian", model = "marginal", link = "identity",  
type = "cohort", effectsize_beta=0.3, sigma2 = 0.095, typeIerror = 0.05, alpha0 = 0.03,  
alpha1 = 0.015, alpha2 = 0.2)
```

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