

Package ‘crctStepdown’

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Title Univariate Analysis of Cluster Trials with Multiple Outcomes

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Description Frequentist statistical inference for cluster randomised trials with multiple outcomes that controls the family-wise error rate and provides nominal coverage of confidence sets. A full description of the methods can be found in Watson et al. (2023) <[doi:10.1002/sim.9831](https://doi.org/10.1002/sim.9831)>.

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Imports fastglm, Rcpp, ggplot2, ggpubr, methods, stringr, lme4, reshape2

Depends R (>= 3.0.2)

Suggests testthat

NeedsCompilation yes

Author Sam Watson [aut, cre] (ORCID: <<https://orcid.org/0000-0002-8972-769X>>)

Maintainer Sam Watson <s.i.watson@bham.ac.uk>

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Contents

| | |
|---------------------------------|---|
| confint_search | 2 |
| est_null_model | 3 |
| gen_rand_order | 4 |
| outname_fit | 5 |
| permutation_test_impl | 5 |
| perm_dist | 6 |
| qscore_impl | 7 |

| | |
|--------------------------|----|
| setParallelCRT | 7 |
| simpleLM | 8 |
| stepdown | 8 |
| twoarm_sim | 10 |

| | |
|--------------|-----------|
| Index | 12 |
|--------------|-----------|

| | |
|----------------|---|
| confint_search | <i>Confidence interval search procedure</i> |
|----------------|---|

Description

Search for the bound of a confidence interval using permutation test statistics

Usage

```
confint_search(
  start,
  b,
  n,
  nmodel,
  Xnull_,
  y,
  tr_,
  new_tr_mat,
  invS,
  family,
  family2,
  Z,
  type,
  nsteps = 1000L,
  weight = TRUE,
  alpha = 0.05,
  verbose = TRUE
)
```

Arguments

| | |
|--------|---|
| start | Numeric value indicating the starting value for the search procedure |
| b | Numeric value indicating the parameter estimate |
| n | Integer indicating the sample size |
| nmodel | Integer. The number of models |
| Xnull_ | Numeric matrix. The covariate design matrix with the treatment variable removed |
| y | Numeric vector of response variables |
| tr_ | Numeric vector. The original random allocation (0s and 1s) |

| | |
|------------|---|
| new_tr_mat | A matrix. Each column is a new random treatment allocation with 1s (treatment group) and 0s (control group) |
| invS | A matrix. If using the weighted statistic then it should be the inverse covariance matrix of the observations |
| family | A statsfamily object |
| family2 | A string naming the link function |
| Z | Matrix. Random effects design matrix describing cluster membership |
| type | String. Either "rw" for Romano-Wolf, "b" or "br" for bonferroni, "h" or "hr" for Holm, or "none" |
| nsteps | Integer specifying the number of steps of the search procedure |
| weight | Logical indicating whether to use the weighted (TRUE) or unweighted (FALSE) test statistic |
| alpha | The function generates $(1-\alpha)*100\%$ confidence intervals. Default is 0.05. |
| verbose | Logical indicating whether to provide detailed output. |

Value

The estimated confidence interval bound

| | |
|----------------|-----------------------------|
| est_null_model | <i>Estimates null model</i> |
|----------------|-----------------------------|

Description

Given an lme4 model object and the value of the treatment effect parameter under the null hypothesis, the function returns a glm or lm object fitted under the null model with no cluster effects. For linear models (lmer) the value of the null is subtracted from the value of the outcome for those in receipt of the treatment and an lm model is fitted with no treatment effect. For generalised linear models (glmer) the model is refitted as a glm model with the treatment effect specified as an offset.

Usage

```
est_null_model(fit, data, tr_var = "treat", null_par)
```

Arguments

| | |
|----------|--|
| fit | An lme4 model object |
| data | The data frame used to fit model fit |
| tr_var | A string indicating the name of the column in data that is a binary indicator for whether the observation was under the treatment (1=treatment, 0=control) |
| null_par | Numeric the value of tr_var parameter under the null hypothesis |

Value

An lm or glm model fit under the null model

Examples

```

out <- twoarm_sim()
data <- out[[1]]
fit1 <- lme4::glmer(y1 ~ treat + (1|cl) ,
  data=data,
  family="poisson")

fit2 <- lme4::glmer(y2 ~ treat + (1|cl),
  data=data,
  family="poisson")
fitlist <- list(fit1,fit2)
nullfitlist <- list()
for(i in 1:length(fitlist)){
  nullfitlist[[i]] <- est_null_model(fitlist[[i]],
    data,
    tr_var = "treat",
    null_par = 0)
}

```

gen_rand_order

Function to generate a stepped-wedge cRCT randomisation allocation

Description

Function to generate a stepped-wedge cRCT randomisation allocation. Assumes a baseline and endline period in which no clusters and all clusters have the intervention, respectively.

Usage

```
gen_rand_order(nJ, nT)
```

Arguments

| | |
|----|-----------------------|
| nJ | Number of clusters |
| nT | Number of time points |

Value

A data frame with columns cl and t indicating the time

Examples

```
gen_rand_order(10,7)
```

| | |
|-------------|--|
| outname_fit | <i>Extracts the dependent variable name from glm, lm, or mer model</i> |
|-------------|--|

Description

Extracts the dependent variable name from glm, lm, or mer model

Usage

```
outname_fit(fit)
```

Arguments

fit A fitted model object of class glm, lm, or *merMod

Value

A string with the name of the dependent variable from the model

Examples

```
out <- twoarm_sim()
data <- out[[1]]
fit1 <- lme4::glmer(y1 ~ treat + (1|c1) ,
                  data=data,
                  family="poisson")
outname_fit(fit1)
```

| | |
|-----------------------|--|
| permutation_test_impl | <i>Generates realisations of the permutational test statistic distribution</i> |
|-----------------------|--|

Description

Generates realisations of the permutational test statistic distribution from a given matrix of permutations

Usage

```
permutation_test_impl(
  resids,
  tr_mat,
  xb,
  invS,
  family2,
  Z,
  weight,
```

```

  iter = 1000L,
  verbose = TRUE
)
```

Arguments

| | |
|---------|---|
| resids | A numeric vector of generalised residuals |
| tr_mat | A matrix. Each column is a new random treatment allocation with 1s (treatment group) and 0s (control group) |
| xb | A numeric vector of fitted linear predictors |
| invS | A matrix. If using the weighted statistic then it should be the inverse covariance matrix of the observations |
| family2 | A string naming the link function |
| Z | A matrix with columns indicating cluster membership |
| weight | Logical value indicating whether to use the weighted statistic (TRUE) or the unweighted statistic (FALSE) |
| iter | Integer. Number of permutation test iterations. |
| verbose | Logical indicating whether to report detailed output |

Value

A numeric vector of quasi-score test statistics for each of the permutations

| | |
|-----------|-------------------------------------|
| perm_dist | <i>Extracts the test statistics</i> |
|-----------|-------------------------------------|

Description

Extracts the test statistics from the output of the permute function. Returns the largest value from a specified subset of rows, each row is the test statistic from a different null hypothesis.

Usage

```
perm_dist(out, positions)
```

Arguments

| | |
|-----------|--|
| out | Array output by the permute function |
| positions | Vector indicating which rows of out to use |

Value

Vector of numeric values of length ncol(out)

| | |
|-------------|---|
| qscore_impl | <i>The quasi-score statistic for a generalised linear mixed model</i> |
|-------------|---|

Description

Generates the quasi-score statistic for a generalised linear mixed model

Usage

```
qscore_impl(resids, tr, xb, invS, family2, Z, weight = TRUE)
```

Arguments

| | |
|---------|---|
| resids | A numeric vector of generalised residuals |
| tr | A numeric vector of 1s (treatment group) and -1s (control group) |
| xb | A numeric vector of fitted linear predictors |
| invS | A matrix. If using the weighted statistic then it should be the inverse covariance matrix of the observations |
| family2 | A string naming the link function |
| Z | A matrix with columns indicating cluster membership |
| weight | Logical value indicating whether to use the weighted statistic (TRUE) or the unweighted statistic (FALSE) |

Value

A scalar value with the value of the statistic

| | |
|----------------|---|
| setParallelCRT | <i>Disable or enable parallelised computing</i> |
|----------------|---|

Description

By default, the package will use multithreading for many calculations if OpenMP is available on the system. For multi-user systems this may not be desired, so parallel execution can be disabled with this function.

Usage

```
setParallelCRT(parallel_, cores_ = 2L)
```

Arguments

| | |
|-----------|---|
| parallel_ | Logical indicating whether to use parallel computation (TRUE) or disable it (FALSE) |
| cores_ | Number of cores for parallel execution |

Value

None, called for effects

| | |
|----------|---|
| simpleLM | <i>A very basic linear model solver</i> |
|----------|---|

Description

Returns the OLS parameter estimates and fitted values. Used internally for quick fitting of null models.

Usage

```
simpleLM(y_, X_)
```

Arguments

| | |
|-----------------|------------------------------------|
| <code>y_</code> | A vector of outcome values |
| <code>X_</code> | The design matrix of fixed effects |

Value

A list with the parameter values and fitted values

| | |
|----------|---|
| stepdown | <i>Conduct the randomisation-based stepdown procedure</i> |
|----------|---|

Description

For a set of models fit with lme4, base R, or glmmrBase, the function will conduct the randomisation tests and generate p-values for the null hypotheses of no treatment effect that controls the family-wise error rate, and generates a 100(1-alpha)% confidence set for the treatment effect model parameters.

Usage

```
stepdown(
  fitlist,
  tr_var = "treat",
  cl_var = "cl",
  data,
  alpha = 0.05,
  plots = TRUE,
  n_permute = 1000,
  nsteps = 1000,
```

```

    type = "rw",
    rand_func = NULL,
    confint = TRUE,
    sigma = NULL,
    ci_start_values = NULL,
    verbose = TRUE
  )

```

Arguments

| | |
|------------------------------|--|
| <code>fitlist</code> | A list of models fitted with lme4, base R (lm or glm), or glmmrBase. All models should be fit using the same data frame. |
| <code>tr_var</code> | String indicating the name of the column in data that is a binary indicator for whether the observation was under the treatment (1=treatment, 0=control) |
| <code>cl_var</code> | String specifying the name of the column identifying the clusters/cluster-time |
| <code>data</code> | A data frame containing the data used to fit the models in fitlist |
| <code>alpha</code> | Numeric. 100(1-alpha)% confidence intervals are calculated. Default is 0.05 |
| <code>plots</code> | Logical indicating whether to plot permutational distributions and confidence interval search during running of function. Default is TRUE |
| <code>n_permute</code> | Number of permutations of the randomisation test to run |
| <code>nsteps</code> | Number of steps of the confidence interval search process |
| <code>type</code> | Method of correction: options are "rw" = Romano-Wolf randomisation test based stepdown, "h" = Holm standard stepdown, "h" = Holm stepdown using randomisation test, "b" = standard Bonferroni, "br" = Bonerroni using randomisation test, or "none" = randomisation test with no correction. |
| <code>rand_func</code> | String of the name of a function that re-randomises the clusters. The function must take the arguments nJ for the number of clusters and nT for the number of time periods. The function should produce a data frame that identifies the clusters in the treatment group under the new randomisation scheme. The data frame can either have a single column with name cl_var or two columns of cl_var and t identifying the cluster ID and time period a cluster joins the treatment group. If NULL then clusters are randomised in a 1:1 ratio to treatment and control |
| <code>confint</code> | Logical indicating whether to run the confidence interval search process |
| <code>sigma</code> | optional, list of estimated covariance matrices of the observations from the models in fitlist. If provided then the weighted q-score statistic is used. |
| <code>ci_start_values</code> | Optional list. The list should contain named vectors "upper" and/or "lower" that provide a set of starting values for the upper and/or lower confidence interval searches, respectively. Alternatively, a named scalar scale can be provided such that the starting values of the confidence interval search procedure are $est \pm scale * SE$. |
| <code>verbose</code> | Logical indicating whether to provide detailed output |

Value

A data frame with the point estimates, p-values, and confidence intervals

Examples

```

out <- twoarm_sim()
data <- out[[1]]
  fit1 <- lme4::glmer(y1 ~ treat + (1|cl) ,
  data=data,
  family="poisson")

fit2 <- lme4::glmer(y2 ~ treat + (1|cl),
  data=data,
  family="poisson")
stepdown(fitlist=list(fit1,fit2),
  data=data,
  n_permute = 100,
  nsteps=100,
  plots=FALSE,
  verbose=TRUE)

```

twoarm_sim

Simulates data from a two-arm parallel cluster randomised trial

Description

Simple simulation of two Poisson distributed outcomes for a two-arm parallel cluster randomised trial with no baseline measures. A log-linear model is specified $y \sim \text{Poisson}(\lambda)$ with $\lambda = \exp(\mu + \beta \cdot D + \theta)$ where D is the treatment effect indicator equal to one in clusters with the treatment and zero otherwise, and $\theta \sim N(0, \sigma^2)$ is the cluster random effect. Used for testing error rates of the methods.

Usage

```

twoarm_sim(
  nJ = c(7, 7),
  N = 20,
  mu = rep(1, 2),
  beta = c(0, 0),
  sig_cl = rep(0.05, 2)
)

```

Arguments

| | |
|----|---|
| nJ | Vector of two integers with the number of clusters in treatment and control arms |
| N | Number of individuals per cluster |
| mu | Vector of two numeric values with the intercept terms for the two models on the log scale |

| | |
|--------|---|
| beta | Vector of two numeric values that are the treatment effect parameters in the two models |
| sig_cl | Vector of two values equal to the variance of the random effect in each model |

Value

A list consisting of: (1) data frame with the cluster IDs (cl), treatment effect indicators (treat), and two outcomes (y1, y2), and (2) the values of the treatment effect parameters used in the simulation.

Examples

```
out <- twoarm_sim()
data <- out[[1]]
```

Index

confint_search, 2
est_null_model, 3
family, 3
gen_rand_order, 4
outname_fit, 5
perm_dist, 6
permutation_test_impl, 5
qscore_impl, 7
setParallelCART, 7
simpleLM, 8
stats, 3
stepdown, 8
twoarm_sim, 10