Package 'reappraised'

July 23, 2025

Title Statistical Tools for Assessing Publication Integrity of Groups

of Trials Version 0.1.1 **Description** Takes user-provided baseline data from groups of randomised controlled data and assesses whether the observed distribution of baseline p-values, numbers of participants in each group, or categorical variables are consistent with the expected distribution, as an aid to the assessment of integrity concerns in published randomised controlled trials. References (citations in PubMed format in details of each function): Bolland MJ, Avenell A, Gamble GD, Grey A. (2016) <doi:10.1212/WNL.000000000003387>. Bolland MJ, Gamble GD, Avenell A, Grey A, Lumley T. (2019) <doi:10.1016/j.jclinepi.2019.05.006>. Bolland MJ, Gamble GD, Avenell A, Grey A. (2019) <doi:10.1016/j.jclinepi.2019.03.001>. Bolland MJ, Gamble GD, Grey A, Avenell A. (2020) <doi:10.1111/anae.15165>. Bolland MJ, Gamble GD, Avenell A, Cooper DJ, Grey A. (2021) <doi:10.1016/j.jclinepi.2020.11.012>. Bolland MJ, Gamble GD, Avenell A, Grey A. (2021) <doi:10.1016/j.jclinepi.2021.05.002>. Bolland MJ, Gamble GD, Avenell A, Cooper DJ, Grey A. (2023) <doi:10.1016/j.jclinepi.2022.12.018>. Carlisle JB, Loadsman JA. (2017) <doi:10.1111/anae.13650>. Carlisle JB. (2017) <doi:10.1111/anae.13938>. License MIT + file LICENSE **Encoding UTF-8** RoxygenNote 7.2.3 **Imports** boot, broom, data.table, dplyr, epitools, flextable, ggplot2, ggpubr, magrittr, officer, purrr, readxl, rlang, stats, tidyr, utils, vcd, vcdExtra **Depends** R (>= 2.10) LazyData true Suggests knitr, rmarkdown VignetteBuilder knitr NeedsCompilation no **Author** Mark Bolland [aut, cre, cph] (ORCID:

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anova_fn

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Description

Creates plots of distribution of p-values for differences in baseline means calculated using Carlisle's montecarlo anova method.

Usage

```
anova_fn(
  df = anova_data,
  method = "alt",
  seed = 0,
  sims = -1,
  btsp = 500,
  title = "",
  verbose = TRUE
)
```

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Arguments

df	dataframe generated from load_clean function
method	"orig" is adapted from original code; "alt" avoids using loops in the code (see details)
seed	the seed to use for random number generation, default $0 = \text{current}$ date and time. Specify seed to make repeatable.
sims	number of simulations, default -1 = function selects based on number of variables and sample size
btsp	number of bootstrap repeats used to generate 95% confidence interval around AUC
title	optional title for plots
verbose	TRUE or FALSE indicates whether progress bar and comments show and prints plot

Details

Method is from Carlisle JB, Loadsman JA. Evidence for non-random sampling in randomised, controlled trials by Yuhji Saitoh. Anaesthesia. 2017;72:17-27.

R code is in appendix to paper. This function is adapted from that code.

The function has two methods. The published code selects each variable from each study then generates simulations for that variable using a row-wise approach with several loops. The adapted method is method = "orig". The method = "alt" generates all the simulations at once and initially I thought was considerably faster, but in practice the time savings are small.

The results from the two approaches will not be identical even if the same random number seed is used because they use the generated random numbers in different orders but the p-values generated differ by about <0.1. Usually the differences are close to 0.01 (although this depends on the number of simulations- more simulations = smaller differences). The code that generates the p-value for each variable from the simulated means is essentially the same.

Returns a list containing 3 objects and (if verbose = TRUE) prints the plot anova_ecdf

Value

list containing 3 objects as described

- anova_ecdf = plot of cumulative distribution of calculated p-values compared to the expected uniform distribution
- anova_pvalues = plots of distribution of calculated p-values and AUC, as for pval_cont_fn()
- anova all results = list containing
 - anova_data = data frame of baseline data, with calculated p-values
 - anova pvals = plot of distribution of calculated p-values from anova pvalues
 - anova_auc = plot of AUC of calculated p-values from anova_pvalues

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Examples

```
# load example data
anova_data <- load_clean(import= "no", file.cont = "SI_pvals_cont",anova= "yes",</pre>
format.cont = "wide")$anova_data
# run function (takes only a few seconds)
anova_fn(seed=10, sims = 100, btsp = 100)$anova_ecdf
# to import an excel spreadsheet (modify using local path,
# file and sheet name, range, and format):
# get path for example files
path <- system.file("extdata", "reappraised_examples.xlsx", package = "reappraised",</pre>
                    mustWork = TRUE)
# delete file name from path
path <- sub("/[^/]+$", "", path)
# load data
anova_data <- load_clean(import= "yes", anova = "yes", dir = path,</pre>
     file.name.cont = "reappraised_examples.xlsx", sheet.name.cont = "SI_pvals_cont",
     range.name.cont = "A:O", format.cont = "wide")$anova_data
```

cat_all_fn

Compares observed and expected distribution of all categorical (binomial) variables

Description

Creates plots of observed to expected numbers and ratios for the binomial variables and/or compares reported and calculated p-values for the variables

Reference: Bolland MJ, Gamble GD, Avenell A, Cooper DJ, Grey A. Distributions of baseline categorical variables were different from the expected distributions in randomized trials with integrity concerns. J Clin Epidemiol. 2023;154:117-124

Usage

```
cat_all_fn(
  df = cat_all_data,
  comp.pvals = "no",
  fisher.sim = "y",
  fish.n.sims = 10000,
  binom = "no",
  two_levels = "no",
  del.disparate = "yes",
  excl.level = "yes",
  seed = 0,
```

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```
title = "",
  verbose = TRUE
)
```

Arguments

df	data frame generated from load_clean function
comp.pvals	"yes" or "no" indicator whether reported and calculated p-values should be compared
fisher.sim	"yes" or "no" indicator whether to allow fisher test to simulate p-values for $>2*2$ tables
fish.n.sims	number of simulations to use in Fisher test, default 10,000
binom	"yes" or "no" indicator whether observed to expected distributions of binomial variables should be calculated
two_levels	"yes" or "no" indicator whether variables with more than 2 levels should be collapsed to 2 levels
del.disparate	if yes, data in which the absolute difference between group sizes is $>20\%$ are deleted
excl.level	"yes" or "no" indicator whether one level of a variable should be deleted. Deleted level is chosen randomly using seed parameter.
seed	seed for random number generator, default $0 = \text{current}$ date and time. Specify seed to make repeatable.
title	title name for plots (optional)
verbose	TRUE or FALSE indicates whether progress bar and comments show and flextable or plot or both are printed

Details

Returns a list containing objects described below and (if verbose = TRUE) prints the flextable cat_all_diff_calc_rep_ft and/or graph cat_all_graph depending on options chosen

Value

list containing objects as described

if p-value comparison used:

- cat_all_pvals = data frame of data for comparison of reported and calculated p-values
- cat_all_diff_calc_rep_ft = flextable of comparison of reported and calculated p-values
- cat_all_diff_calc_rep_data = data frame used to make flextable
- cat_all_diff_thresh_ft = flextable of comparison of reported and calculated p-values when only threshold given
- cat_all_diff_thresh_data = data frame used to make flextable for p-value thresholds

if comparing categorical variables used

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• cat_all_graph = plot of observed to expected numbers and differences between groups, top panels are the absolute numbers, bottom panels are the differences between trial arms in two arm studies

- cat_all_graph_pc = plot of observed to expected numbers expressed as percentages and differences between groups, top panels are the percentages, bottom panels are the differences between trial arms in two arm studies
- cat_all_data_abs = data frame of data for absolute numbers
- cat_all_data_df = data frame of data for difference between groups in two arm studies
- cat_all_dataset_abs = data frame of dataset used for all trials
- cat_all_dataset_df = data frame of dataset used for two arm trials
- cat_all_all_graphs list containing
 - abs = plot for absolute numbers only
 - df = plot for difference between groups in two arm studies only
 - pc = plot for percentages only
 - all_pc = composite plot of percentages and absolute numbers
 - individual_graphs list of 6 individual plots making up composite figures

```
# load example data
cat_all_data <- load_clean(import= "no", file.cat = "SI_cat_all", cat_all= "yes",</pre>
format.cat = "wide")$cat_all_data
# run function comparing p-values only (takes only a few seconds)
cat_all_fn (comp.pvals = "yes")$cat_all_diff_calc_rep_ft
# run function comparing distribution of binomial variables only
# to speed example up limit to 12 2-arm trials with 20 variables
# (takes close to 5 secs)
cat_all_data <- cat_all_data [1:41, c(1:8,10:11,13:15)]</pre>
cat_all_fn (binom = "yes", two_levels = "yes", del.disparate = "yes",
excl.level = "yes", seed = 10)$cat_all_graph
# to import an excel spreadsheet (modify using local path,
# file and sheet name, range, and format):
# get path for example files
path <- system.file("extdata", "reappraised_examples.xlsx", package = "reappraised",</pre>
                   mustWork = TRUE)
# delete file name from path
path <- sub("/[^/]+$", "", path)
# load data
```

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```
cat_all_data <- load_clean(import= "yes", cat_all = "yes", dir = path,
    file.name.cat = "reappraised_examples.xlsx", sheet.name.cat = "SI_cat_all",
    range.name.cat = "A:N", format.cat = "wide")$cat_all_data</pre>
```

cat_fn

Compares observed and expected distribution of a categorical (binomial) variable

Description

Creates plots of observed to expected numbers and ratios for the specified binomial variable

Usage

```
cat_fn(
   df = cat_data,
   x_title = "",
   prefix = "",
   del.disparate = "yes",
   title = "",
   verbose = TRUE
)
```

Arguments

df data frame generated from load_clean function

x_title name of the variable for use on the x-axis

prefix letter for variable columns in data frame

del.disparate if yes, data in which the absolute difference between group sizes is >20% are deleted

title title name for plots (optional)

verbose TRUE or FALSE indicates whether to print plot

Details

An example is for trial withdrawls in Bolland 2021

Bolland MJ, Gamble GD, Avenell A, Cooper DJ, Grey A. Participant withdrawals were unusually distributed in randomized trials with integrity concerns: a statistical investigation. J Clin Epidemiol 2021;131:22-29.

Returns a list containing 4 objects and (if verbose = TRUE) prints the plot cat_graph

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Value

list containing 4 objects as described

• cat_graph = plot of observed to expected numbers and differences between groups, top panels are the absolute numbers, bottom panels are the differences between trial arms in two arm studies

- cat_data_abs = data frame of data for absolute numbers
- cat_data_df = data frame of data for difference between groups in two arm studies
- cat_all_graphs = list containing
 - abs = plot for absolute numbers only
 - df = plot for difference between groups in two arm studies only
 - individual_graphs list of 4 individual plots making up composite figures

Examples

```
# load example data
cat_data <- load_clean(import= "no", file.cat = "SI_cat", cat= "yes",</pre>
format.cat = "wide", cat.names = c("n", "w"))$cat_data
# run function (takes only a few seconds)
cat_fn(x_title= "withdrawals", prefix="w", del.disparate = "yes")$cat_graph
# to import an excel spreadsheet (modify using local path,
# file and sheet name, range, and format):
# get path for example files
path <- system.file("extdata", "reappraised_examples.xlsx", package = "reappraised",</pre>
                    mustWork = TRUE)
# delete file name from path
path <- sub("/[^/]+$", "", path)
# load data
cat_data <- load_clean(import= "yes", cat = "yes", dir = path,</pre>
    file.name.cat = "reappraised_examples.xlsx", sheet.name.cat = "SI_cat",
    range.name.cat = "A:G", cat.names = c("n", "w"), format.cat = "wide")$cat_data
```

cohort_fn

Compares proportions of matching summary statistics in different cohorts

Description

Creates flextable of probability of matching mean, SD, and mean and SD for each variable in different cohorts in the specified number of simulations

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Usage

```
cohort_fn(
  df = cohort_data,
  seed = 0,
  sims = -1,
  n_vars = 10,
  popn = "",
  title = "",
  verbose = TRUE
)
```

Arguments

df	data frame generated from load_clean function
seed	the seed to use for random number generation, default $0 = \text{current}$ date and time. Specify seed to make repeatable.
sims	number of simulations, default -1 = function selects based on number of variables and sample size.
n_vars	restrict analyses to variables in at least (>=) this number of cohorts, default = 10 (ie variable has mean in 10 or more cohorts).
popn	if dataset contains studies in different sub-populations, code this in cohort_data\$population and studies are subsetted if match in this variable. 'All' overrides this and uses all data regardless of information in this variable.
title	title name for plots (optional)
verbose	TRUE or FALSE indicates whether progress bar and comments show and flextable is printed

Details

Reference data is from Bolland 2021

Bolland MJ, Gamble GD, Avenell A, Grey A. Identical summary statistics were uncommon in randomized trials and cohort studies. J Clin Epidemiol 2021;136:180-188.

Returns a list containing 6 objects and (if verbose = TRUE) prints the flextable cohort_ft

Value

list containing 6 objects as described

- cohort_ft = flextable of results
- cohort_graph = plot of observed to expected numbers of matches per cohort for mean; SD; and mean and SD
- all_graphs = list containing
 - all_graphs = all plots on single plot
 - both_graphs = list of 3 plots row by row used to form all_graphs
 - individual_graphs= list of 6 individual plots used to form all_graphs

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- cohort_cohort_data = data frame used to generate results data
- cohort_prob_data = data frame used to make flextable
- cohort_oe_data= data frame used to make observed to expected plots

Examples

```
# load example data
cohort_data <- load_clean(import= "no", file.cont = "SI_cohort", cohort= "yes",</pre>
format.cont = "long")$cohort_data
# run function (takes close to 5 seconds)
cohort_fn(seed=10, sims = 100)$cohort_ft
# to import an excel spreadsheet (modify using local path,
# file and sheet name, range, and format):
# get path for example files
path <- system.file("extdata", "reappraised_examples.xlsx", package = "reappraised",</pre>
                     mustWork = TRUE)
# delete file name from path
path <- sub("/[^/]+$", "", path)
# load data
cohort_data <- load_clean(import= "yes", cohort = "yes", dir = path,</pre>
     file.name.cont = "reappraised_examples.xlsx", sheet.name.cont = "SI_cohort",
     range.name.cont = "A1:F101", format.cont = "long")$cohort_data
```

final_digit_fn

Compares proportions of final digits from summary statistics

Description

Creates graph of proportion of final digits for summary statistics of specified variables

Usage

```
final_digit_fn(
   df = generic_data,
   vars = "",
   dec.pl = "no",
   dec.pl.vars = "",
   title = "",
   verbose = TRUE
)
```

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Arguments

df	data frame generated from load_clean function
vars	vector of the summary statistics to be used
dec.pl	"yes" or "no" indicator whether columns for decimal places are included (yes) or should be calculated (no)
dec.pl.vars	vector of the names of the columns for decimal places for each statistics
title	title name for plots (optional)
verbose	TRUE or FALSE indicates whether print plot

Details

This approach is still in development and needs validation and discussion about its place in integrity assessment.

Requires data frame containing columns for study, variable (named var), summary statistic(s) (named with single letter eg m or s), and optional columns for decimal places for each statistic (named dp_* eg dp_m, dp_s). Data can be imported using the generic option of load_clean function

Returns a list containing 5 objects and prints the plot digit_graph

Value

list containing 5 objects as described

- digit_graph = plot of proportions of final digits
- digit_ft = flextable of results
- digit_table = data frame of results
- digit dataset = data frame of data set used to generate results data
- digit data = results of analyses used to generate results data

```
path <- sub("/[^/]+$", "", path)

# load data
generic_data <- load_clean(import= "yes", generic = "yes", dir = path,
    file.name.cont = "reappraised_examples.xlsx", sheet.name.cont = "SI_pvals_cont",
    range.name.cont = "A1:051", gen.vars.del = c("p"),
    format.cont = "wide")$generic_data</pre>
```

load_clean

Load data then clean and format it

Description

Function loads and cleans data for the nine functions

Usage

```
load_clean(
  import = "yes"
  file.cont = ""
  file.cat = "",
  dir = "",
  file.name = "",
  pval_cont = "no",
  match = "no",
  cohort = "no",
  anova = "no",
  dir.cont = "",
  file.name.cont = "",
  sheet.name.cont = "Sheet1",
  range.name.cont = "",
  format.cont = "wide",
  cat = "no",
  sr = "no",
  cat_all = "no",
  pval_cat = "no",
  cat.names = c("n"),
  dir.cat = "",
  file.name.cat = "",
  sheet.name.cat = "Sheet1",
  range.name.cat = "",
  format.cat = "wide",
  generic = "",
  gen.vars.keep = "",
  gen.vars.del = "",
  verbose = TRUE
)
```

Arguments

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import	'yes' indicates import excel file. 'no' indicates takes dataset already loaded into R as data frame
file.cont	If import = 'no', name of data frame containing continuous data
file.cat	If import = 'no', name of data frame containing categorical data
dir	If import = 'yes', path to location of excel file for continuous and categorical data
file.name	If import = 'yes', file name of excel file containing continuous and categorical data
pval_cont	'yes'/'no' indicating if data will be used for pval_cont_fn. Only data for 1 continuous data function can be loaded with each run of this function.
match	'yes'/'no' indicating if data will be used for match_fn. Only data for 1 continuous data function can be loaded with each run of this function.
cohort	'yes'/'no' indicating if data will be used for cohort_fn. Only data for 1 continuous data function can be loaded with each run of this function.
anova	'yes'/'no' indicating if data will be used for anova_fn. Only data for 1 continuous data function can be loaded with each run of this function.
dir.cont	If import = 'yes', path to location of excel file for continuous data
file.name.cont	If import = 'yes', file name of excel file containing continuous data
sheet.name.con	
	Sheet name containing continuous data
range.name.con	
J	
-	Range of cells containing continuous data. Can be in format 'a1:b20' or 'a:b'
format.cont	Range of cells containing continuous data. Can be in format 'a1:b20' or 'a:b' 'wide'/'long' indicating continuous data is in wide or long format
-	Range of cells containing continuous data. Can be in format 'a1:b20' or 'a:b'
format.cont	Range of cells containing continuous data. Can be in format 'a1:b20' or 'a:b' 'wide'/'long' indicating continuous data is in wide or long format 'yes'/'no' indicating if data will be used for cat_fn. Only data for 1 categorical
format.cont	Range of cells containing continuous data. Can be in format 'a1:b20' or 'a:b' 'wide'/'long' indicating continuous data is in wide or long format 'yes'/'no' indicating if data will be used for cat_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for sr_fn. Only data for 1 categorical
format.cont cat	Range of cells containing continuous data. Can be in format 'a1:b20' or 'a:b' 'wide'/'long' indicating continuous data is in wide or long format 'yes'/'no' indicating if data will be used for cat_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for sr_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for cat_all_fn. Only data for 1 categor-
format.cont cat sr cat_all	Range of cells containing continuous data. Can be in format 'a1:b20' or 'a:b' 'wide'/'long' indicating continuous data is in wide or long format 'yes'/'no' indicating if data will be used for cat_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for sr_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for cat_all_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for cat_all_fn. Only data for 1 categorical data function indicating if data will be used for cat_all_fn. Only data for 1 categorical data function indicating if data will be used for cat_all_fn. Only data for 1 categorical data function indicating if data will be used for cat_all_fn.
format.cont cat sr cat_all pval_cat	Range of cells containing continuous data. Can be in format 'a1:b20' or 'a:b' 'wide'/'long' indicating continuous data is in wide or long format 'yes'/'no' indicating if data will be used for cat_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for sr_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for cat_all_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for cat_all_fn. Only data for 1 categorical data function can be loaded with each run of this function.
format.cont cat sr cat_all pval_cat cat.names	Range of cells containing continuous data. Can be in format 'a1:b20' or 'a:b' 'wide'/'long' indicating continuous data is in wide or long format 'yes'/'no' indicating if data will be used for cat_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for sr_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for cat_all_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for cat_all_fn. Only data for 1 categorical data function can be loaded with each run of this function. names of variables to be used in cat_fn and sr_fn
format.cont cat sr cat_all pval_cat cat.names dir.cat	Range of cells containing continuous data. Can be in format 'a1:b20' or 'a:b' 'wide'/'long' indicating continuous data is in wide or long format 'yes'/'no' indicating if data will be used for cat_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for sr_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for cat_all_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for cat_all_fn. Only data for 1 categorical data function can be loaded with each run of this function. names of variables to be used in cat_fn and sr_fn If import = 'yes', path to location of excel file for categorical data If import = 'yes', file name of excel file containing categorical data
format.cont cat sr cat_all pval_cat cat.names dir.cat file.name.cat	Range of cells containing continuous data. Can be in format 'a1:b20' or 'a:b' 'wide'/'long' indicating continuous data is in wide or long format 'yes'/'no' indicating if data will be used for cat_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for sr_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for cat_all_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for cat_all_fn. Only data for 1 categorical data function can be loaded with each run of this function. names of variables to be used in cat_fn and sr_fn If import = 'yes', path to location of excel file for categorical data If import = 'yes', file name of excel file containing categorical data
format.cont cat sr cat_all pval_cat cat.names dir.cat file.name.cat sheet.name.cat	Range of cells containing continuous data. Can be in format 'a1:b20' or 'a:b' 'wide'/'long' indicating continuous data is in wide or long format 'yes'/'no' indicating if data will be used for cat_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for sr_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for cat_all_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for cat_all_fn. Only data for 1 categorical data function can be loaded with each run of this function. names of variables to be used in cat_fn and sr_fn If import = 'yes', path to location of excel file for categorical data If import = 'yes', file name of excel file containing categorical data Sheet name containing categorical data
format.cont cat sr cat_all pval_cat cat.names dir.cat file.name.cat sheet.name.cat range.name.cat	Range of cells containing continuous data. Can be in format 'a1:b20' or 'a:b' 'wide'/'long' indicating continuous data is in wide or long format 'yes'/'no' indicating if data will be used for cat_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for sr_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for cat_all_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for cat_all_fn. Only data for 1 categorical data function can be loaded with each run of this function. names of variables to be used in cat_fn and sr_fn If import = 'yes', path to location of excel file for categorical data If import = 'yes', file name of excel file containing categorical data Sheet name containing categorical data Range of cells containing categorical. Can be in format 'a1:b20' or 'a:b'
format.cont cat sr cat_all pval_cat cat.names dir.cat file.name.cat sheet.name.cat range.name.cat format.cat	Range of cells containing continuous data. Can be in format 'a1:b20' or 'a:b' 'wide'/'long' indicating continuous data is in wide or long format 'yes'/'no' indicating if data will be used for cat_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for sr_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for cat_all_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for cat_all_fn. Only data for 1 categorical data function can be loaded with each run of this function. names of variables to be used in cat_fn and sr_fn If import = 'yes', path to location of excel file for categorical data If import = 'yes', file name of excel file containing categorical data Sheet name containing categorical data Range of cells containing categorical. Can be in format 'a1:b20' or 'a:b' 'wide'/'long' indicating categorical data is in wide or long format
format.cont cat sr cat_all pval_cat cat.names dir.cat file.name.cat sheet.name.cat range.name.cat format.cat generic	Range of cells containing continuous data. Can be in format 'a1:b20' or 'a:b' 'wide'/'long' indicating continuous data is in wide or long format 'yes'/'no' indicating if data will be used for cat_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for sr_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for cat_all_fn. Only data for 1 categorical data function can be loaded with each run of this function. 'yes'/'no' indicating if data will be used for cat_all_fn. Only data for 1 categorical data function can be loaded with each run of this function. names of variables to be used in cat_fn and sr_fn If import = 'yes', path to location of excel file for categorical data If import = 'yes', file name of excel file containing categorical data Sheet name containing categorical data Range of cells containing categorical. Can be in format 'a1:b20' or 'a:b' 'wide'/'long' indicating categorical data is in wide or long format 'yes'/'no' indicating if data to be loaded for generic use

Details

Function can load continuous or categorical data. Continuous data can be used for comparison of baseline p-values (pval_cont_fn), matching summary stats within a trial (match_fn), matching summary stats in different cohorts (cohort_fn), or comparing means of baseline p-values (anova_fn). Categorical data can be used for comparisons of observed with expected distributions for single variable (cat_fn), for group numbers in trials using simple randomisation (sr_fn), for all variables (cat_all_fn), and for comparison of baseline p-values (pval_cat_fn).

There is one function in development that allows assessment of proportion of final digits in summary statistics (final_digit_fn). This function works using summary statistics but could be adapted to use on raw continuous or categorical data.

Only 1 continuous and/or 1 categorical data set allowed per load to avoid clashes

Data can be imported from a file (import = "yes") or taken from an existing data frame, import = "no"

If loading from an existing data use file.cont and file.cat

If loading from common directory or file, can use dir and file.name rather than more specific dir.cont, dir.cat, file.name.cont, or file.name.cat.

Comments about each indicator: pval_cont

loads continuous data for pval_cont_fn, outputs as list of 1 containing named data frame pval_cont_data.

format should be study, variable or var, n, m, s, p. Can be in any order. n = sample size, m = mean, s = standard deviation, p = baseline p value (can omit if not reported)

```
can be in wide or long format wide: study, var, n1, n2, n3 ..., m1, m2, m3 ... s1, s2, s3..., p long: study, var, group, m, s, n, p group or g or grp required for long format separators (eg n1 n_1 n.1) are stripped and replaced
```

match

loads continuous data for match_fn, outputs as list of 1 containing named data frame match_data

remainder is same as for pval_cont above.

only difference between pval_cont and match is that match allows for missing mean or SD whereas pval_cont does not

format should be study, variable or var, n, m, s. Can be in any order. n = sample size, m = mean, s = standard deviation

```
can be in wide or long format wide: study, var, n1, n2, m1, m2, s1, s2, p long: study, var, group, m, s, n
```

```
group or g or grp required for long format separators (eg n1 n_1 n.1) are stripped and replaced
```

cohori

loads continuous data for cohort_fn, outputs as list of 1 containing named data frame cohort_data

same as pval_cont but allows a lookup variable for variable names

format should be study, variable or var, n, m, s, p. Can be in any order. n = sample size, m = mean, s = standard deviation

```
can be in wide or long format wide: study, var, n1, n2, n3 ..., m1, m2, m3 ... s1, s2, s3... long: study, var, group, m , s, n
```

group or g or grp required for long format separators (eg n1 n_1 n.1) are stripped and replaced

lookup table is var_name_final, var_name_orig and allows you to specify a list of all variables names (var_name_orig) from all studies and a lookup table of standardised names (var_name_final) allowing different names in different studies to be standardised

has optional variable 'population' which can be used to subset the data if trials in different populations are reported

anova

loads continuous data for anova_fn, outputs as list of 1 containing named data frame anova_data

same as for pval_cont above but allows for optional value for decimal place

format should be study, variable or var, n, m, s, p. Can be in any order. n = sample size, m = mean, s = standard deviation, d= decimal place of mean (if omitted, this is calculated automatically in anova_fn)

```
can be in wide or long format wide: study, var, n1, n2, n3 ..., m1, m2, m3 ... s1, s2, s3..., d long: study, var, group, m , s, n , d
```

group or g or grp required for long format separators (eg n1 n_1 n.1) are stripped and replaced

cat

loads categorical data for cat_fn, outputs as list of 1 containing named data frame cat_data

```
format should be study, n, v. Can be in any order, n= group size, v= number with characteristic
can be in wide or long format
wide: study, n1, n2, n3 ..., v1, v2, v3...
long: study, group, n, v
group or g or grp required for long format
use cat.names to name variable eg c("n", "v"), c("n", "g") ...
separators (eg n1 n_1 n.1) are stripped and replaced
sr
loads categorial data for sr_fn, outputs as list of 1 containing named data frame sr_data
as for cat but only requires study and n
format should be study, n. n= group size
can be in wide or long format
wide: study, n1, n2, n3 ...
long: study, group, n
group or g or grp required for long format
separators (eg n1 n_1 n.1) are stripped and replaced
cat all
loads categorical data for cat_all_fn, outputs as list of 1 containing named data frame cat_all_data
format should be study, var or variable, n, N, level, stat, recode, p. Can be in any order, n = number
with characteristic, N = group size, p = baseline p value (can omit if not reported), can use "ns" for
not significant or "<" or ">" to indicate threshold (eg "<0.05")
optional level - number for level of variable (eg y/n = 1,2; high/med/low = 1,2,3)
optional recode- for variables with >2 levels to tell how to recode into 2 groups
optional stat: statistical test used for p-value: chisq - Chisquare, chisqc- Chisquare with correction,
fisher- Fisher's exact, midp - midp -calculated using two different methods, lr- likelihood ratio, mh
- Mantel-Haenszel test
can be in wide or long format
wide study, var, n1, n2, n3, ... N1, N2, N3... p, stat, level, recode
long study, var, group, n, N, p, stat, level, recode
group or g or grp required for long format
if variable has 2 levels, only 1 required, other will be calculated.
```

separators (eg n1 n_1 n.1) are stripped and replaced pval cat loads categorical data for pval_cat_fn, outputs as list of 1 containing named data frame pval_cat_data as for cat_all but recode variable is not generated format should be study, var or variable, n, N, p. Can be in any order, n = number with characteristic, N = group size, p = baseline p value (can omit if not reported), can use "ns" for not significant or "<" or ">" to indicate threshold (eg "<0.05") optional level - number for level of variable (eg y/n = 1,2; high/med/low = 1,2,3) optional stat: statistical test used for p-value : chisq - Chisquare, fisher- Fisher's exact can be in wide or long format wide study, var, n1, n2, n3, ... N1, N2, N3... p, stat, level long study, var, group, n, N, p, stat, level group or g or grp required for long format if variable has 2 levels, only 1 required, other will be calculated. separators (eg n1 n_1 n.1) are stripped and replaced generic loads data for use generic use, outputs as list of 1 containing named data frame generic_data use cont suffixes for file details: dir.cont (or dir), file.name.cont (or file.name), sheet.name,cont, range.name.cont) format should be study, var or variable, variable names optional gen.vars.keep = vector of variables to keep optional gen.vars.del = vector of variables to delete can be in wide or long format wide study, var, a1, a2..., b1, b2 ... long study, var, group, a, b, group or g or grp required for long format

separators (eg n1 n_1 n.1) are stripped and replaced no data checking or other transformations take place

18 match_fn

Value

list containing a named data frame containing data in suitable format for appropriate function as described in Details

Examples

match_fn

Compares proportions of matching summary statistics within two-arm randomised trials

Description

Creates flextable of matching summary statistics by significant figures with Reference data

Usage

```
match_fn(df = match_data, verbose = TRUE)
```

Arguments

df data frame generated from load_clean function

verbose TRUE or FALSE indicates whether to print flextable

match_fn 19

Details

Reference data is from Bolland 2021

Bolland MJ, Gamble GD, Avenell A, Grey A. Identical summary statistics were uncommon in randomized trials and cohort studies. J Clin Epidemiol 2021;136:180-188.

Returns a list containing 6 objects and (if verbose = TRUE) prints the flextable match_ft_all

Value

list containing 6 objects as described

- match_ft_all = flextable of matches with reference data
- match_ft = flextable of matches (no reference data)
- ref_match_ft = flextable of reference data
- match_match_data = data frame of results used in calculations
- match_table = data frame of matches used to make flextable
- ref_table = data frame of reference data used to make flextable

```
# load example data
match_data <- load_clean(import= "no", file.cont = "SI_pvals_cont", match= "yes",</pre>
format.cont = "wide")$match_data
# run function (takes only a few seconds)
match_fn()$match_ft_all
# to import an excel spreadsheet (modify using local path,
# file and sheet name, range, and format):
# get path for example files
path <- system.file("extdata", "reappraised_examples.xlsx", package = "reappraised",</pre>
                    mustWork = TRUE)
# delete file name from path
path <- sub("/[^/]+$", "", path)
# load data
match_data <- load_clean(import= "yes", match = "yes", dir = path,</pre>
     file.name.cont = "reappraised_examples.xlsx", sheet.name.cont = "SI_pvals_cont",
     range.name.cont = "A:O", format.cont = "wide")$match_data
```

20 pval_cat_fn

pval_cat_fn	Compares observed and expected distribution of p-values for categor-
	ical variables

Description

Creates plots of calculated p-value distribution and AUC (area under curve)

Usage

```
pval_cat_fn(
   df = pval_cat_data,
   seed = 0,
   sims = -1,
   btsp = 500,
   title = "",
   stat = "chi_midp",
   stat.override = "no",
   fisher.sim = "y",
   fish.n.sims = 10000,
   method = "mix",
   verbose = TRUE
)
```

Arguments

df	data frame generated from load_clean function
seed	the seed to use for random number generation, default $0 = \text{current}$ date and time. Specify seed to make repeatable.
sims	number of simulations, default -1 = function selects based on number of variables.
btsp	number of bootstrap repeats used to generate 95% confidence interval around AUC
title	optional title for plots
stat	statistical test to be used 'chisq', 'fisher', 'midp' or 'midp.epitools' (from epitools package), 'midp.sas' (as calculated in SAS), or combinations -if chisq is not appropriate because expected cells<5, use second test: 'chi_fish', 'chi_midp' or 'chi_midp.epi','chi_midp.sas'
stat.override	if 'yes' then test specified in stat will be used rather than values for stat in data frame
fisher.sim	"yes" or "no" indicator whether to allow fisher test to simulate p-values for $>$ 2*2 tables
fish.n.sims	number of simulations to use in Fisher test, default 10,000

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method 'sm', 'mix', or 'ind'. 'ind' does test on individual data, 'sm' summarises data

and then does test on summary data, 'mix' does 'ind' for fisher and 'sm' for others. Duration varies with size of studies, test, and number of simulations.

Experiment before running large simulations.

verbose TRUE or FALSE indicates whether progress bar and comments show and prints

plot

Details

See also Bolland MJ, Gamble GD, Avenell A, Grey A, Lumley T. Baseline P value distributions in randomized trials were uniform for continuous but not categorical variables. J Clin Epidemiol 2019;112:67-76.

Returns a list containing 3 objects and (if verbose = TRUE) prints the plot pval_cat_calculated_pvalues

Value

list containing 3 objects as described

- pval_cat_calculated_pvalues = plots of calculated p-value distribution and AUC
- pval_cat_reported_pvalues = plots of reported p-value distribution and AUC (if p-values were reported)
- all_results = list containing
 - pval_cat_baseline_pvalues_data = data frame of all results used in calculations
 - pval_cat_reported_pvalues= plot of reported p-value distribution
 - pval_cat_auc_reported_pvalues = AUC of reported p-values
 - pval_cat_calculated_pvalues = plot of calculated p-value distribution
 - pval_cat_auc_calculated_pvalues= AUC of calculated p-values

pval_cont_fn

```
pval_cat_data <- load_clean(import= "yes", pval_cat = "yes", dir = path,
    file.name.cat = "reappraised_examples.xlsx", sheet.name.cat = "SI_cat_all",
    range.name.cat = "A:n", format.cat = "wide")$pval_cat_data</pre>
```

Description

Creates plots of calculated p-value distribution and AUC (area under curve)

Usage

```
pval_cont_fn(df = pval_cont_data, btsp = 500, title = "", verbose = TRUE)
```

Arguments

df	data frame generated from load_clean function
btsp	number of bootstrap repeats used to generate 95% confidence interval around AUC

title optional title for plots

verbose TRUE or FALSE indicates whether progress bar and comments show and prints

plot

Details

Reference data is from (Carlisle 2017, Bolland 2021)

Carlisle JB . Data fabrication and other reasons for non-random sampling in 5087 randomised, controlled trials in anaesthetic and general medical journals. Anaesthesia 2017;72:944–52 .2017

Bolland MJ, Gamble GD, Grey A, Avenell A. Empirically generated reference proportions for baseline p values from rounded summary statistics. Anaesthesia 2020;75:1685-1687.

See also Bolland MJ, Gamble GD, Avenell A, Grey A, Lumley T. Baseline P value distributions in randomized trials were uniform for continuous but not categorical variables. J Clin Epidemiol 2019;112:67-76.

and Bolland MJ, Gamble GD, Avenell A, Grey A. Rounding, but not randomization method, non-normality, or correlation, affected baseline P-value distributions in randomized trials. J Clin Epidemiol 2019;110:50-62.

Returns a list containing 4 objects and (if verbose = TRUE) prints the plot pval_cont_calculated_pvalues

pval_cont_fn 23

Value

list containing 4 objects as described

- pval_cont_calculated_pvalues = plots of calculated p-value distribution and AUC
- pval_cont_reported_pvalues = plots of reported p-value distribution and AUC (if p-values were reported)
- pval_cont_ft_diff_calc_rep_p = flextable of distribution of differences in calculated and reported results
- all_results = list containing
 - pval_cont_baseline_pvalues_data = data frame of all results used in calculations
 - pval_cont_diff_calc_rep_p = data frame of differences between calculated and reported p-values
 - pval_cont_reported_pvalues= plot of reported p-value distribution
 - pval_cont_auc_reported_pvalues = AUC of reported p-values
 - pval_cont_calculated_pvalues = plot of calculated p-value distribution
 - pval_cont_auc_calculated_pvalues= AUC of calculated p-values

```
# load example data
pval_cont_data <- load_clean(import= "no", file.cont = "SI_pvals_cont", pval_cont= "yes",</pre>
format.cont = "wide")$pval_cont_data
# run function (takes only a few seconds)
pval_cont_fn(btsp=100)$pval_cont_calculated_pvalues
# to import an excel spreadsheet (modify using local path,
# file and sheet name, range, and format):
# get path for example files
path <- system.file("extdata", "reappraised_examples.xlsx", package = "reappraised",</pre>
                    mustWork = TRUE)
# delete file name from path
path <- sub("/[^/]+$", "", path)
# load data
pval_cont_data <- load_clean(import= "yes", pval_cont = "yes", dir = path,</pre>
     file.name.cont = "reappraised_examples.xlsx", sheet.name.cont = "SI_pvals_cont",
     range.name.cont = "A1:051", format.cont = "wide")$pval_cont_data
```

24 SI_cat_all

SI_cat

Example of 20 observations for categorical analysis

Description

Sample from Sato/Iwamoto dataset of 35 studies with withdrawal data see Bolland MJ, Gamble GD, Avenell A, Cooper DJ, Grey A. Participant withdrawals were unusually distributed in randomized trials with integrity concerns: a statistical investigation. J Clin Epidemiol 2021;131:22-29.

Usage

SI_cat

Format

A data frame with 20 rows and 8 variables:

study study ID

n1, n2, n3 number of participants in each group

w1, w2, w3 number of withdrawals in each group

SI_cat_all

Example of 50 variables from different studies for categorical (cat_all_fn) analysis

Description

Sample from Sato/Iwamoto dataset of 31 studies with categorical data

Usage

SI_cat_all

Format

A data frame with 106 rows and 14 variables:

study study ID

var variable

level level of variable

recode value to recode level two if collapsing variable to two levels

levels_no total number of levels for each variable

group number of trial arms

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n1, n2, n3 number of participants with characteristic in each group

N1, N2, N3 number of participants in each group

p reported p-value

stat reported statistical test used to calculate p-value

SI_cohort

Example of 100 observations for cohort analysis

Description

Sample from Sato/Iwamoto dataset of 226 baseline variables in 34 cohorts see Bolland MJ, Gamble GD, Avenell A, Grey A. Identical summary statistics were uncommon in randomized trials and cohort studies. J Clin Epidemiol 2021;136:180-188.

Usage

SI_cohort

Format

A data frame with 100 rows and 6 variables:

study study ID

var variable name

n number of participants in group

m mean of variable

s sd of variable

group number of group

SI_pvals_cont

Example of 50 observations for p-value analysis

Description

Sample from Sato/Iwamoto dataset of 500 baseline variables in 41 trials for details see Bolland MJ, Avenell A, Gamble GD, Grey A. Systematic review and statistical analysis of the integrity of 33 randomized controlled trials. Neurology 2016;87:2391-2402.

Usage

SI_pvals_cont

26 sr_fn

Format

A data frame with 50 rows and 15 variables:

```
study study ID
var variable name
n1,n2,n3,n4 size of group 1, 2, 3, 4
m1,m2,m3,m4 mean of variable for group 1, 2, 3, 4
s1,s2,s3,s4 sd of variable for group 1, 2, 3, 4
p reported p-value
```

sr_fn

Compares observed and expected distribution of difference in numbers of participants between groups in two-arm randomised trials

Description

Creates plot of observed to expected numbers and ratios for differences in numbers of participants between trial groups

Usage

```
sr_fn(
    df = sr_data,
    br = "no",
    block = data.frame(study = "", fbsz = "", n_fb = "", df = ""),
    title = "",
    verbose = TRUE
)
```

Arguments

df	data frame generated from load_clean function
br	block randomisation: 'yes' or 'no'. If 'no' runs function as if all trials used simple randomisation. If 'yes' performs simple calculations as if block randomised
block	an additional option for studies using block randomisation. block is a data frame containing columns named study (for study id); fbsz (for the final block size); n_fb (for number of participants in the final block); df (the difference between groups)
title	title name for plots (optional)
verbose	TRUE or FALSE indicates whether progress bar and comments in block randomisation function show and whether to print plot

sr_fn 27

Details

An example is for Sato and Iwamoto trials in Bolland 2016

Bolland MJ, Avenell A, Gamble GD, Grey A. Systematic review and statistical analysis of the integrity of 33 randomized controlled trials. Neurology 2016;87:2391-2402.

Returns a list containing 4 objects and (if verbose = TRUE) prints the plot sr_graph

Value

list containing 4 objects as described

- sr_graph = plot of observed to expected numbers for differences between numbers of participants in trial groups
- sr_graph = plot of observed to expected numbers and ratios for differences between numbers of participants in trial groups
- sr_individual_graphs = list containing 2 plots making up composite figure
- sr_data = data frame containing data for plots

```
# load example data
sr_data <- load_clean(import= "no", file.cat = "SI_cat", sr= "yes",</pre>
format.cat = "wide")$sr_data
# run function (takes only a few seconds)
sr_fn()$sr_graph
# to import an excel spreadsheet (modify using local path,
# file and sheet name, range, and format):
# get path for example files
path <- system.file("extdata", "reappraised_examples.xlsx", package = "reappraised",</pre>
                    mustWork = TRUE)
# delete file name from path
path <- sub("/[^/]+$", "", path)
# load data
sr_data <- load_clean(import= "yes", sr = "yes", dir = path,</pre>
   file.name.cat = "reappraised_examples.xlsx", sheet.name.cat = "SI_cat",
   range.name.cat = "A:D", format.cat = "wide")$sr_data
# function has an additional option for block randomisation.
# If studies are block randomised and the final block size is known,
# the number of participants in the final block can be determined.
  The distribution of differences between groups for the final block
  can be compared to the expected distribution
# Few studies provide all these details so it seems unlikely this function
# would get used often
```

28 sr_fn

Example takes only a few seconds to run

```
 \begin{split} sr\_fn(br = "yes", \ block = \ data.frame(study = c(1,2,3,4,5,6,7,8,9,10), \\ fb\_sz= \ c(2,4,6,8,10,12,8,8,6,14), \ n\_fb = c(1,1,4,5,7,8,4,6,2,10), \\ df=c(1,1,0,1,3,4,2,2,0,0)))\$sr\_graph \\ \end{split}
```

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