Package: BI (via r-universe)

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Title Blinding Assessment Indexes for Randomized, Controlled, Clinical Trials

Description Generate the James Blinding Index, as described in James et al (1996) <https://pubmed.ncbi.nlm.nih.gov/8841652/> and the Bang Blinding Index, as described in Bang et al (2004) <https://pubmed.ncbi.nlm.nih.gov/15020033/>. These are measures to assess whether or not satisfactory blinding has been maintained in a randomized, controlled, clinical trial. These can be generated for trial subjects, research coordinators and principal investigators, based upon standardized questionnaires that have been administered, to assess whether or not they can correctly guess to which treatment arm (e.g. placebo or treatment) subjects were assigned at randomization.

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URL https://github.com/marcschwartz/BI

BugReports https://github.com/marcschwartz/BI/issues

Repository https://marcschwartz.r-universe.dev

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BI *Blinding Indices for Randomized, Controlled, Clinical Trials*

Description

Generate James (1996) and Bang (2004) Blinding Indexes to assess whether or not satisfactory blinding has been maintained in a randomized, controlled, clinical trial. These can be generated for trial subjects, research coordinators (RCs) and principal investigators (PIs), based upon standardized questionnaires that have been administered, to assess whether or not they can correctly guess to which treatment arm (e.g. placebo or treatment) subjects were assigned at randomization.

Usage

```
BI(x, weights = NULL, conf.level = 0.95,
   alternative.J = c("two.sided", "less", "greater"),
   alternative.B = c("two.sided", "less", "greater"),
   group.names = c("Treatment", "Placebo"))
```

Arguments

`x`	A 3 row by 2 column integer matrix of cross-tabulated counts based upon the blinding assessment questionnaire administered. See Details.
`weights`	A 3 row by 2 column numeric matrix of alternative cell weights to use for the James Blinding Index, in lieu of the default. See Details.
`conf.level`	A scalar numeric value defining the confidence level for the returned one-sided or two-sided confidence intervals for the indices.
`alternative.J`	A character vector indicating whether two-sided (the default) or one-sided confidence intervals for the James Index are to be returned. See the note below.
`alternative.B`	A character vector indicating whether two-sided (the default) or one-sided confidence intervals for the Bang Index are to be returned. See the note below.
`group.names`	A character vector indicating the treatment group (arm) names for the Bang Blinding Index

Details

The current implementation supports two treatment arms (e.g. Treatment and Placebo), with 3 possible treatment assignment guesses for each blinding survey respondent (e.g. Treatment, Placebo and Do Not Know).

The default internal weights for the James Index are `weights <- matrix(c(0, 0.5, 0.5, 0, 1, 1), nrow = 3, ncol = 2, byrow = TRUE)`, which are 0 for correct guesses, 0.5 for incorrect guesses and 1 for Do Not Know.

The reader is referred to the references indicated below, especially Bang et al 2004, Kolahi et al 2009 and Bang et al 2010, for more in-depth discussions of the indices, how they should be used, the nuances and caveats associated with each, and the use and timing of the associated blinding surveys.

The James Blinding Index (BI), which is not treatment arm specific, is a continuous value such that 0 <= James BI <= 1. If the index is 1, all responses are incorrect, and complete blinding is inferred, albeit, this may indicate unblinding in the opposite direction (e.g. opposite guessing). If the index is 0, all responses are correct, and complete unblinding is inferred. If the index is 0.5, then half of the guesses are correct and half of the guesses are incorrect, inferring random guessing. Unblinding may be claimed if the upper limit of the two-sided confidence interval is < 0.5.

The Bang Blinding Index (BI), which is calculated per treatment arm, is a continuous value such that -1 <= Bang BI <= 1. If the index is 1, all responses are correct, and complete unblinding is inferred. If the index is -1, all responses are incorrect, and complete blinding is inferred, albeit, this may indicate unblinding in the opposite direction (e.g. opposite guessing). If the index is 0, then half of the guesses are correct and half of the guesses are incorrect, inferring random guessing. In general, if -0.2 <= Bang BI <= 0.2, blinding is considered to be successful. Unblinding (or opposite guessing) may be claimed if the relevant limit of the one-sided confidence interval does not cover 0.

Value

A named list of length 2, each list element containing a matrix with the respective index and summary statistics.

`JamesBI`	The James Index result is a 1 x 4 matrix containing the overall index estimate, standard error, lower and upper limits of the confidence intervals.
`BangBI`	The Bang Index result is a 2 x 4 matrix containing the per arm index estimates, standard errors, lower and upper limits of the confidence intervals.

Note

IMPORTANT: Per Bang (2004), there is a preference for using one-sided confidence intervals for the Bang Index, whereas the James Index uses two-sided confidence intervals. Thus, while the default values for `alternative.J` and `alternative.B` are both `two.sided` to avoid potential confusion in the output, the reader will most commonly want to use the appropriate one-sided alternative for the Bang Index. In the case of one-sided confidence intervals, the non-relevant boundary will be fixed to the relevant extreme value of the index. In the case of the James BI, it will be 0 or 1, and in the case of the Bang BI, it will be -1 or 1.

There is an edge case for the James Index only, per James (1996) page 1425, and cited in Bang (2004) page 146, where the only positive (>0) counts in both arms are for Do Not Know. That is, the two (2) counts for the correct responses and the two (2) counts incorrect responses are all 0 (`all(x[1:2, ] == 0)`), while both counts for Do Not Know are positive (`all(x[3, ] > 0)`). In this case, the James Index is set to 1, the standard error is set to 0 and the confidence intervals are set accordingly.

There are other cases where the James Index and/or the Bang Index (for one or both arms) will be mathematically undefinable (NaN) and the output will reflect this. This will generally occur when divide by 0 scenarios are present for the internal calculations of each index. The specific details of each scenario can depend upon, for example, whether the default weights for the James Index are being used. In the case of the James Index, this will generally occur when the internal Kappa calculation cannot be performed due to a 0 value for `Pde` in the denominator. In the case of the Bang Index, this will generally occur, for example, when the only positve counts present are for Do Not Know in one or both arms.

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References

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Howick J, Webster RK, Rees JL, Turner R, Macdonald H, Price A, et al. TIDieR-Placebo: A guide and checklist for reporting placebo and sham controls. PLoS Med 2020;17(9)

Examples

```
## The format and ordering of the 3 x 2 'x' count matrix,
## and the 3 x 2 'weights' matrix, if specified, must be:
##               Treatment  Placebo
## Treatment     xxx        xxx
## Placebo       xxx        xxx
## Do Not Know   xxx        xxx

## where the rows are the assignment guesses by the surveyed party,
## and the columns are the actual assignments.

## CRISP example from Bang et al 2004 from table 7
## Note that the paper presents both limits for the one-sided
## intervals for the Bang Index.
x <- matrix(c(82, 27, 25, 29, 170, 83), nrow = 3, ncol = 2, byrow = TRUE)
BI(x)
BI(x, alternative.B = "greater")
BI(x, alternative.B = "less")

## Houweling 2014 et al examples from table 2
## Investigators
## Note that the paper presents both limits for the one-sided
## intervals for the Bang Index.
x <- matrix(c(48, 22, 4, 30, 330, 319), nrow = 3, ncol = 2, byrow = TRUE)
```

```
BI(x)
BI(x, alternative.B = "greater")
BI(x, alternative.B = "less")

## Research coordinators
## Note that the paper presents both limits for the one-sided
## intervals for the Bang Index.
x <- matrix(c(94, 52, 11, 44, 289, 284), nrow = 3, ncol = 2, byrow = TRUE)
BI(x)
BI(x, alternative.B = "greater")
BI(x, alternative.B = "less")

## Patients
## Note that the paper presents both limits for the one-sided
## intervals for the Bang Index.
x <- matrix(c(143, 104, 14, 57, 188, 175), nrow = 3, ncol = 2, byrow = TRUE)
BI(x)
BI(x, alternative.B = "greater")
BI(x, alternative.B = "less")
```

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