Sample Size Determination in Health Sciences Research

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Outlines

- Introduction
- General health research:
  - One sample
  - Two samples (independent, paired)
  - Correlation, Regression
- Validation:
  - Exploratory and Confirmatory Factor Analyses
  - Reliability
  - Agreeement
  - Sensitivity & Specificity

Software used

- Sample Size Calculator (web)

  https://wnarifin.github.io/ssc_web.html

Introduction

Why calculate?

- An important part of a research design & plan
- Determines:
  - ✔ Number of participants
  - ✔ Funding
  - ✔ Feasibility
  - ✔ Validity

Steps toward calculation

(1) Define the research **objective**

(2) Decide on the suitable **statistical analysis**

(3) Determine the **sample size**

Define objective

- Clearly define objective
- Outcome (dependent variables)?
- Predictors (independent variables)?
- Measurable

Statistical analysis

- Choose suitable statistical analysis based on:
  - objective itself – compare, estimate, correlate, validate ...
  - the scale of outcome & predictors
  - sample – independent / dependent
- Examples:
  - Independent *t*-test for ...
  - Chi-squared test for ...
  - Linear regression for ...
  - Logistic regression for ...

Sample size formula

- Choose suitable sample size formula / method
- Based on objective & chosen statistical analysis
- Estimation vs Hypothesis Testing
- Examples:
  - Confidence interval – estimation
  - Comparison of means – hypothesis testing

General

One mean

(1) Objective:

- Estimate mean of numerical outcome in a population e.g. BMI, weight etc
- "This study aims to estimate mean BMI among UiTM students."

One mean

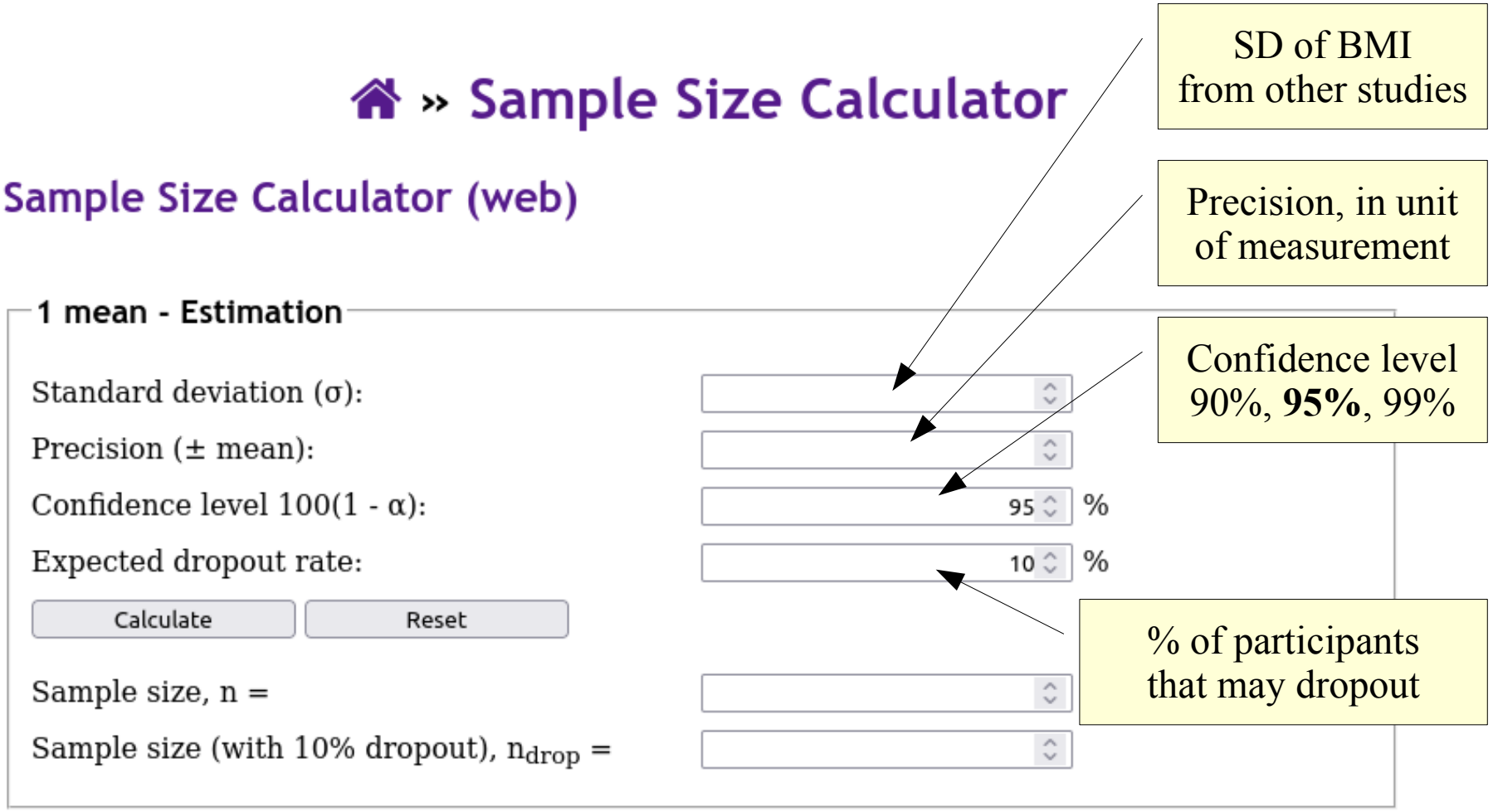
(2) Statistical analysis:

- Mean, 95% Confidence Interval (CI)

(3) Sample size method:

- Single mean – Estimation

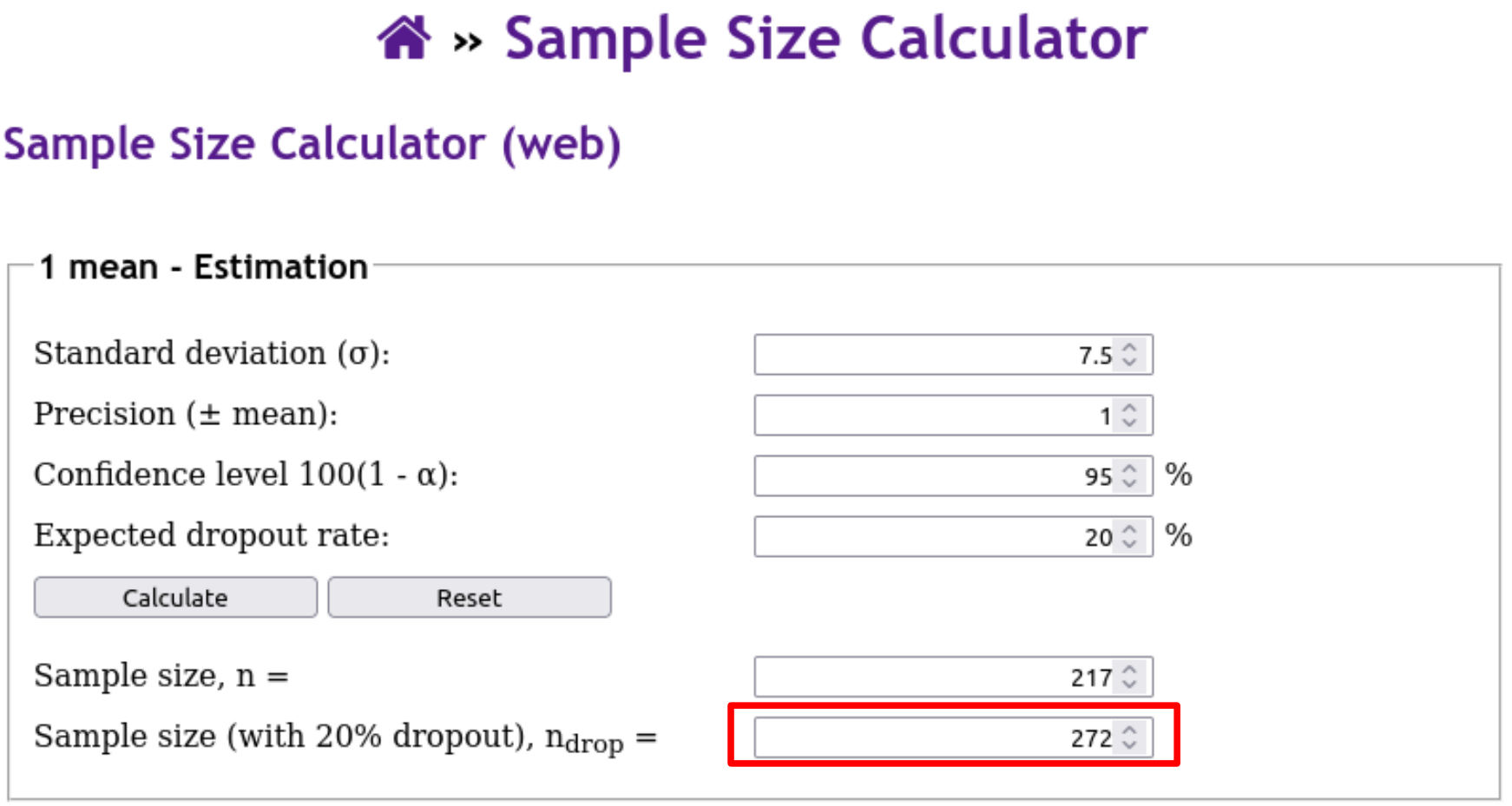
1. Means → Single Mean → 1 mean – Estimation



One mean

- Let say:
  - SD of BMI = 7.5kg/m^2
  - Precision = 1kg/m^2
  - 95% Confidence level
  - 20% dropout
- How many UiTM students should we sample?

One mean


» Sample Size Calculator
Sample Size Calculator (web)
1 mean - Estimation
Standard deviation (σ):
7.5
Precision (± mean):
1
Confidence level 100(1 - α):
95
%
Expected dropout rate:
20
%
Calculate
Reset
Sample size, n =
217
Sample size (with 20% dropout), n_drop =
272

One mean

- We have to sample 272 students to estimate mean BMI among UiTM students, with mean BMI ± 1kg/m^2, taking into account a 20% dropout rate.

One proportion

(1) Objective:

- Estimate % or proportion of categorical outcome in a population e.g. obesity, diabetes etc
- "This study aims to estimate prevalence of obesity among UiTM students."

One proportion

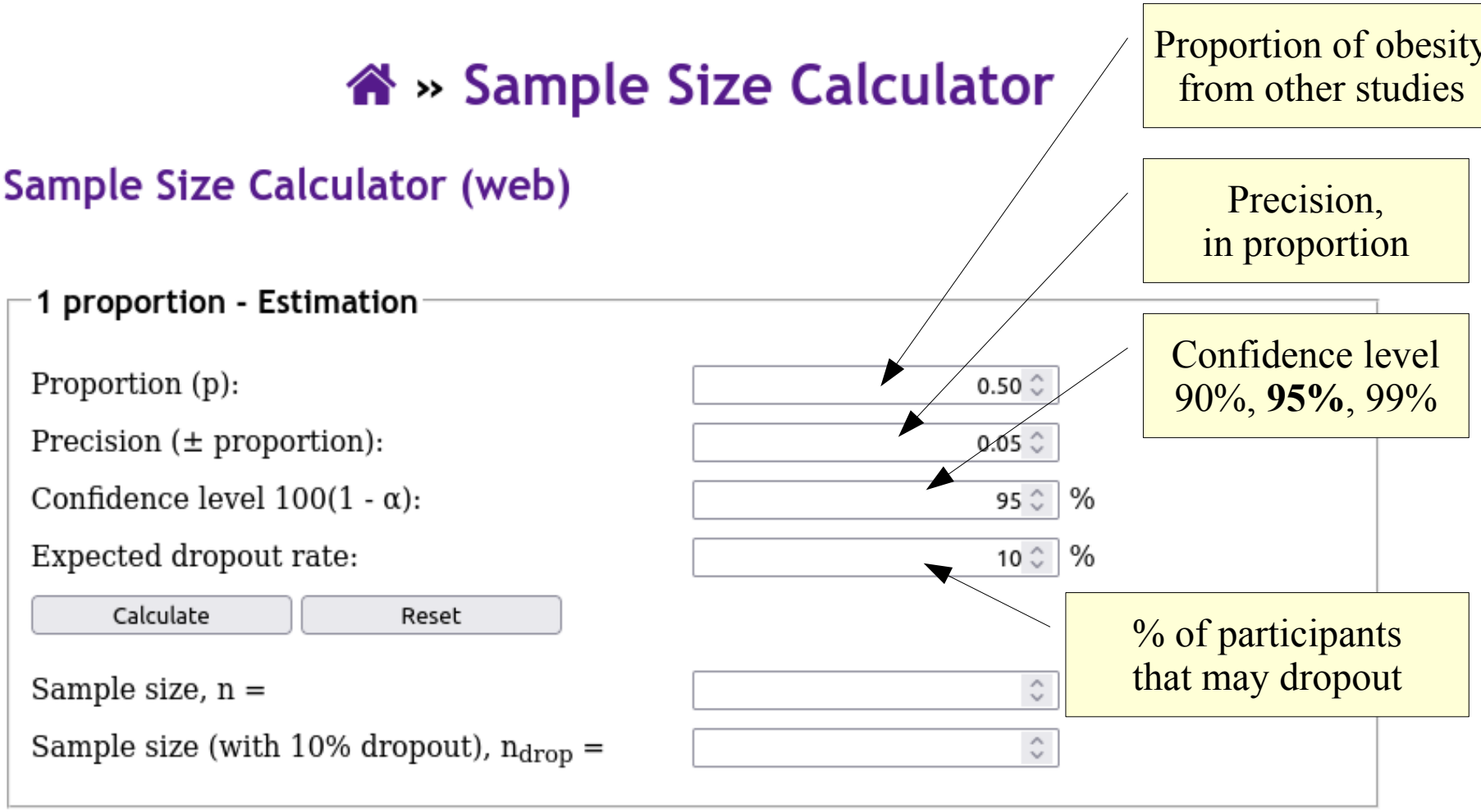
(2) Statistical analysis:

- Proportion, 95% Confidence Interval (CI)

(3) Sample size method:

- Single proportion – Estimation

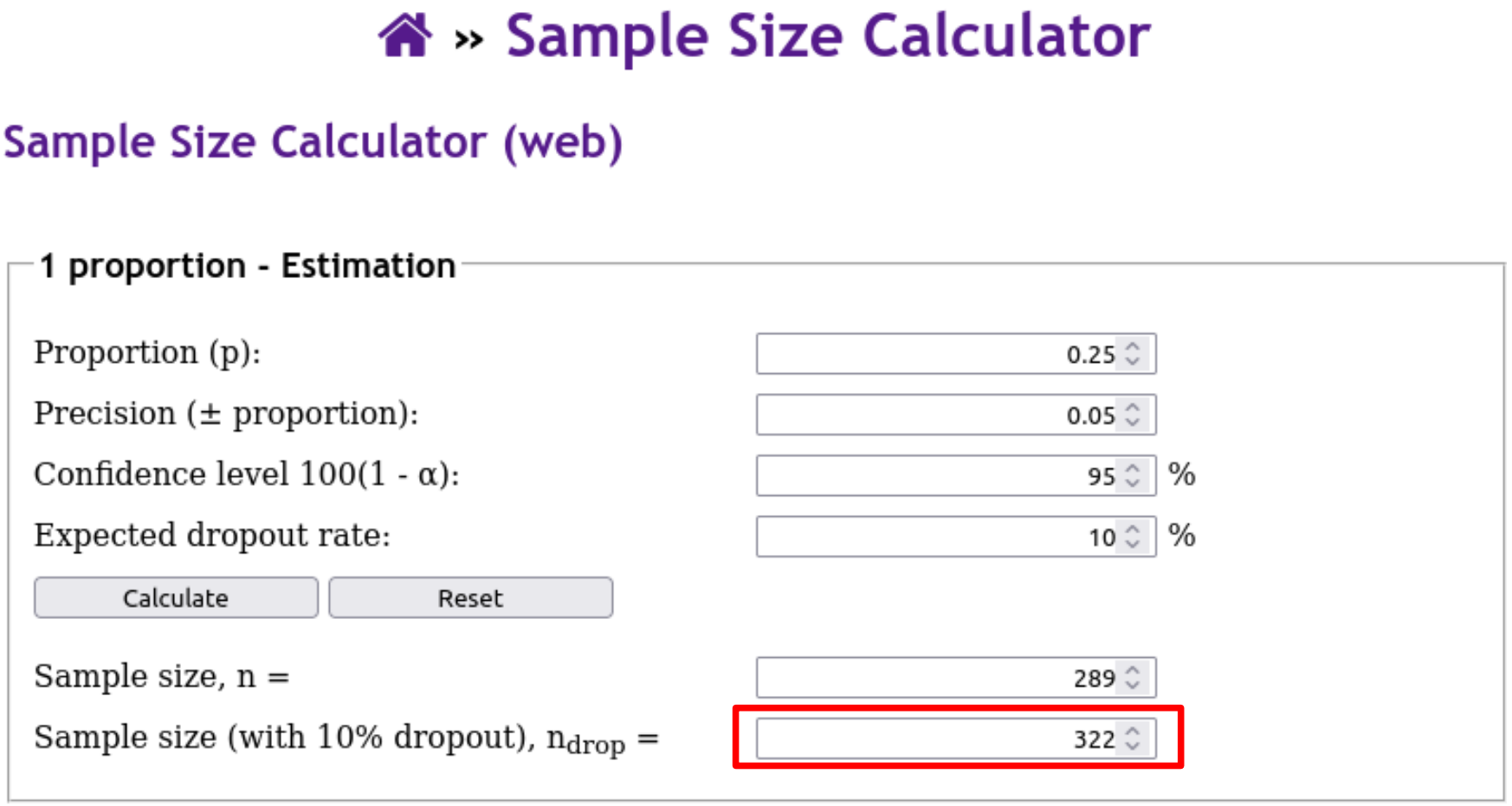
2. Proportions → Single proportion → 1 proportion – Estimation



One proportion

- Let say:
  - Prevalence of obesity = 25% = 0.25 (in proportion).
  - Precision = ±5% = 0.05 (in proportion).
  - 95% Confidence level.
  - 10% dropout (i.e. those who won't let you measure their weight and height).
- How many UiTM students should we sample?

One proportion



One proportion

- We have to sample 322 students to estimate prevalence of obesity among UiTM students, with % of obesity ± 5%, taking into account a 10% dropout rate.

Two means

(1) Objective:

- Compare means of a numerical outcome in two populations e.g. BMI, weight etc
- "This study aims to compare mean BMI between 1st and final year students."

Two means

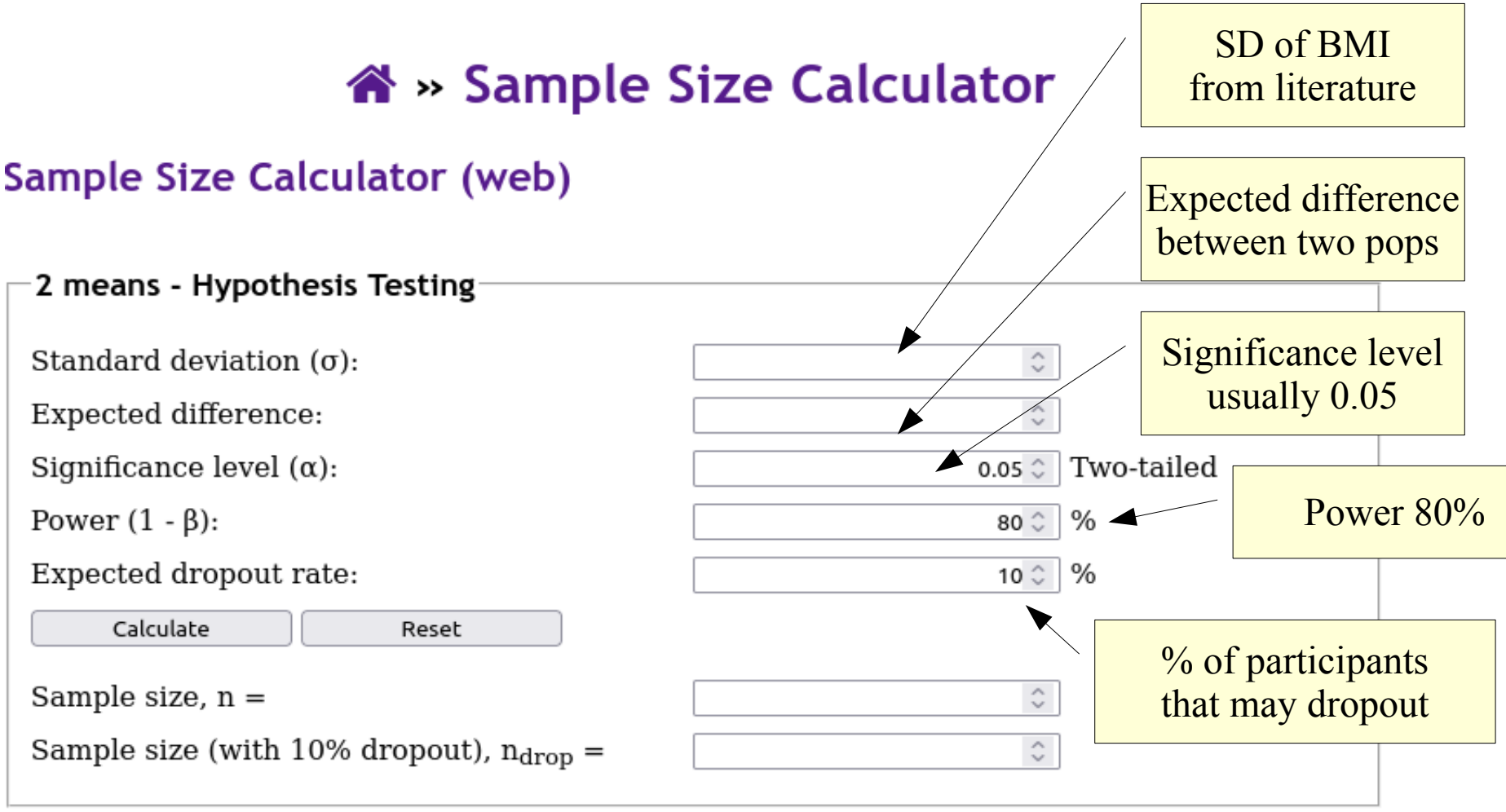
(2) Statistical analysis:

- Independent t-test

(3) Sample size method:

- Two means – Hypothesis testing

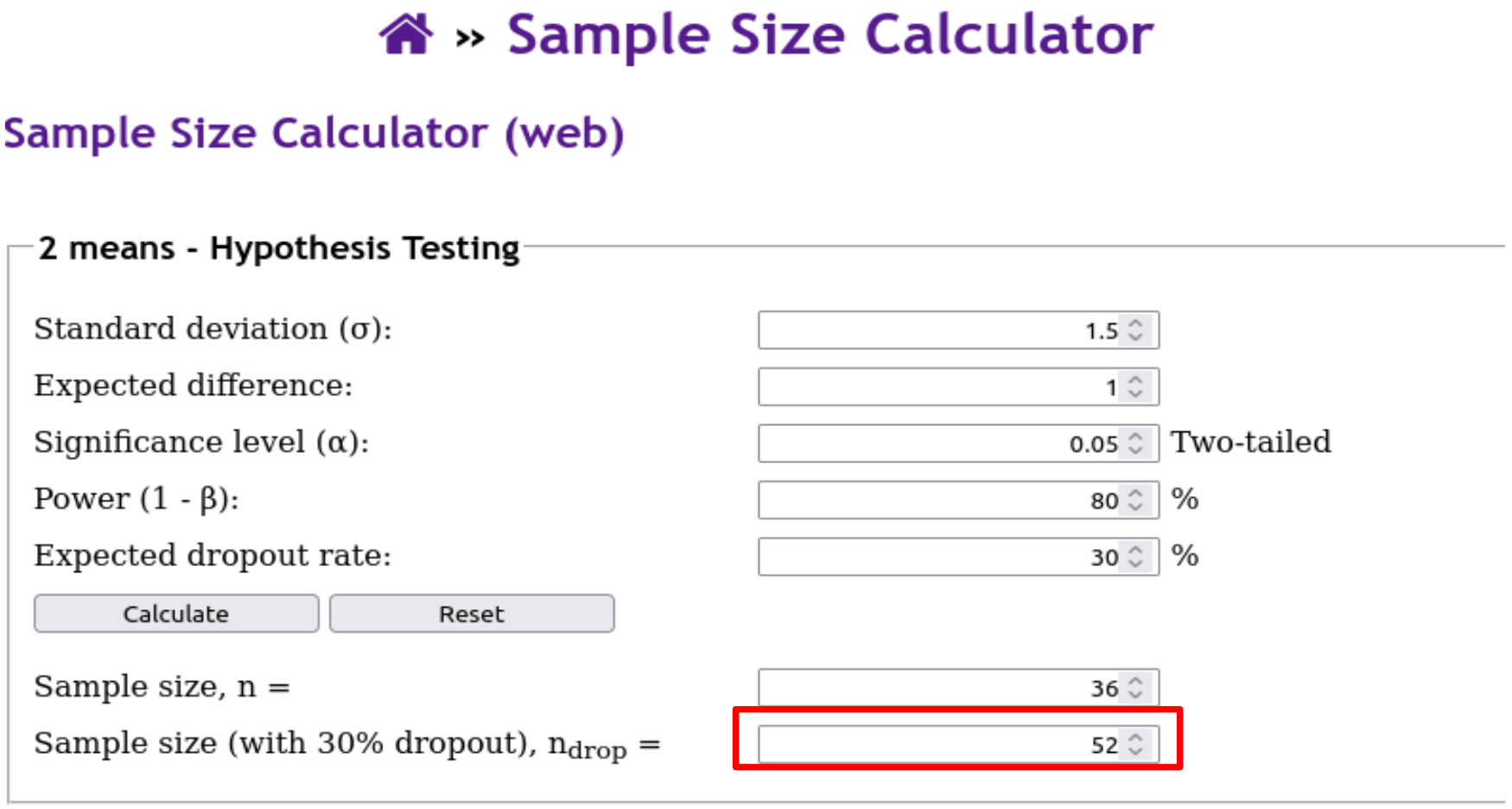
1. Means → Two-mean comparison (independent) → 2 means – Hypothesis Testing



Two means

- Let say:
  - Largest SD you could find from literature = 1.5
  - Expected Difference = 1 unit.
  - Significance level = 5% (0.05)
  - Leave Power = 80% – default value.
  - 30% dropout (i.e. as some weight themselves while only one foot was on the scale).
- How many students per group should we sample?

Two means


» Sample Size Calculator
Sample Size Calculator (web)
2 means - Hypothesis Testing
Standard deviation (σ): 1.5
Expected difference: 1
Significance level (α): 0.05 Two-tailed
Power (1 - β): 80 %
Expected dropout rate: 30 %
Calculate
Reset
Sample size, n = 36
Sample size (with 30% dropout), n_{drop} = 52

Two means

- We have to sample 52 1st year students and 52 final year students to make the comparison, expecting a difference of 1 unit BMI between the two, taking into account a 30% dropout rate.

Two proportions

(1) Objective:

- Compare % or proportion of categorical outcome in two populations e.g. obesity, diabetes etc
- "This study aims to compare prevalence of obesity between 1st and final year students."

Two proportions

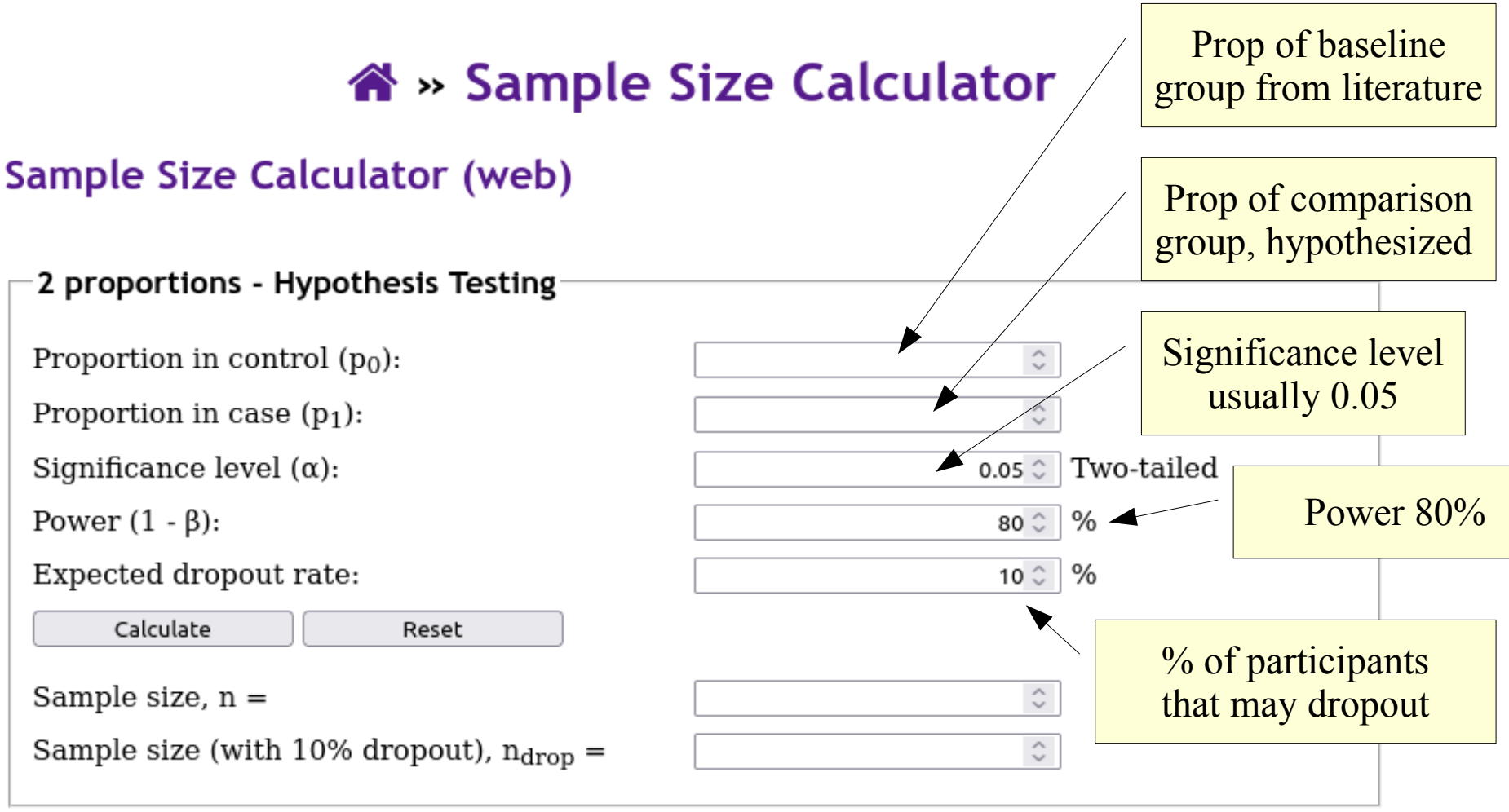
(2) Statistical analysis:

- Chi-squared test

(3) Sample size method:

- Two proportions – Hypothesis testing

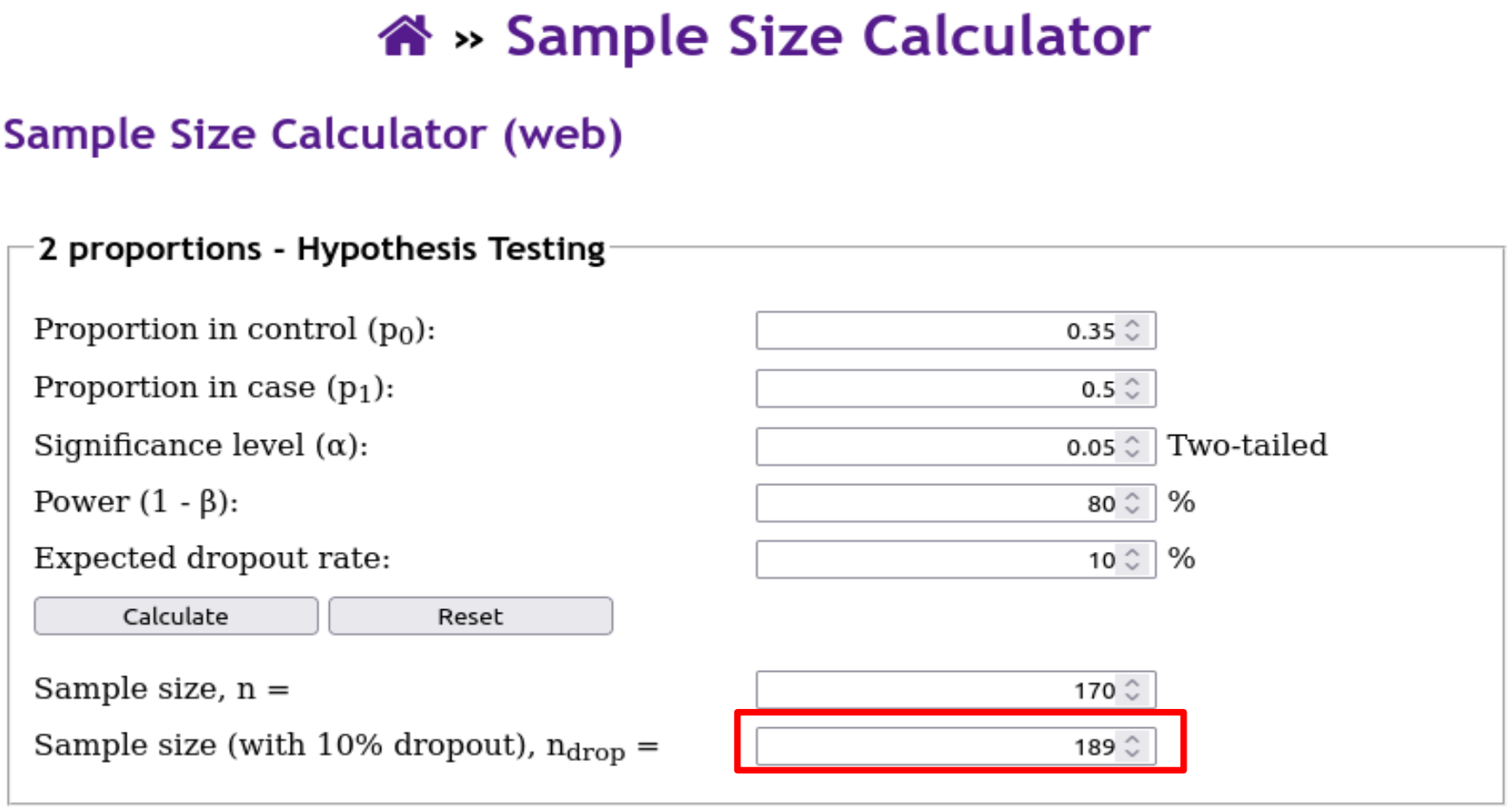
2. Proportions → Two-proportion comparison (independent) → 2 proportions – Hypothesis Testing



Two proportions

- Let's say:
  - p_0 = 35% = 0.35 (in proportion) → 1st year students as control.
  - p_1 = 50% = 0.5 (in proportion) → Hypothesized % for final year students.
  - Significance level = 5% (0.05)
  - Power = 80%
  - 10% dropout
- How many students per group should we sample?

Two proportions



Two proportions

- We have to sample 189 1st year students and 189 final year students to make the comparison, expecting a difference of 15% for % of obesity between the two, taking into account a 10% dropout rate.

Two means (paired)

(1) Objective:

- Compare means of a numerical outcome in a population, pre-post design e.g. weight before and after intervention
- "This study aims to compare mean weight before and after a weight loss program among students."

Two means (paired)

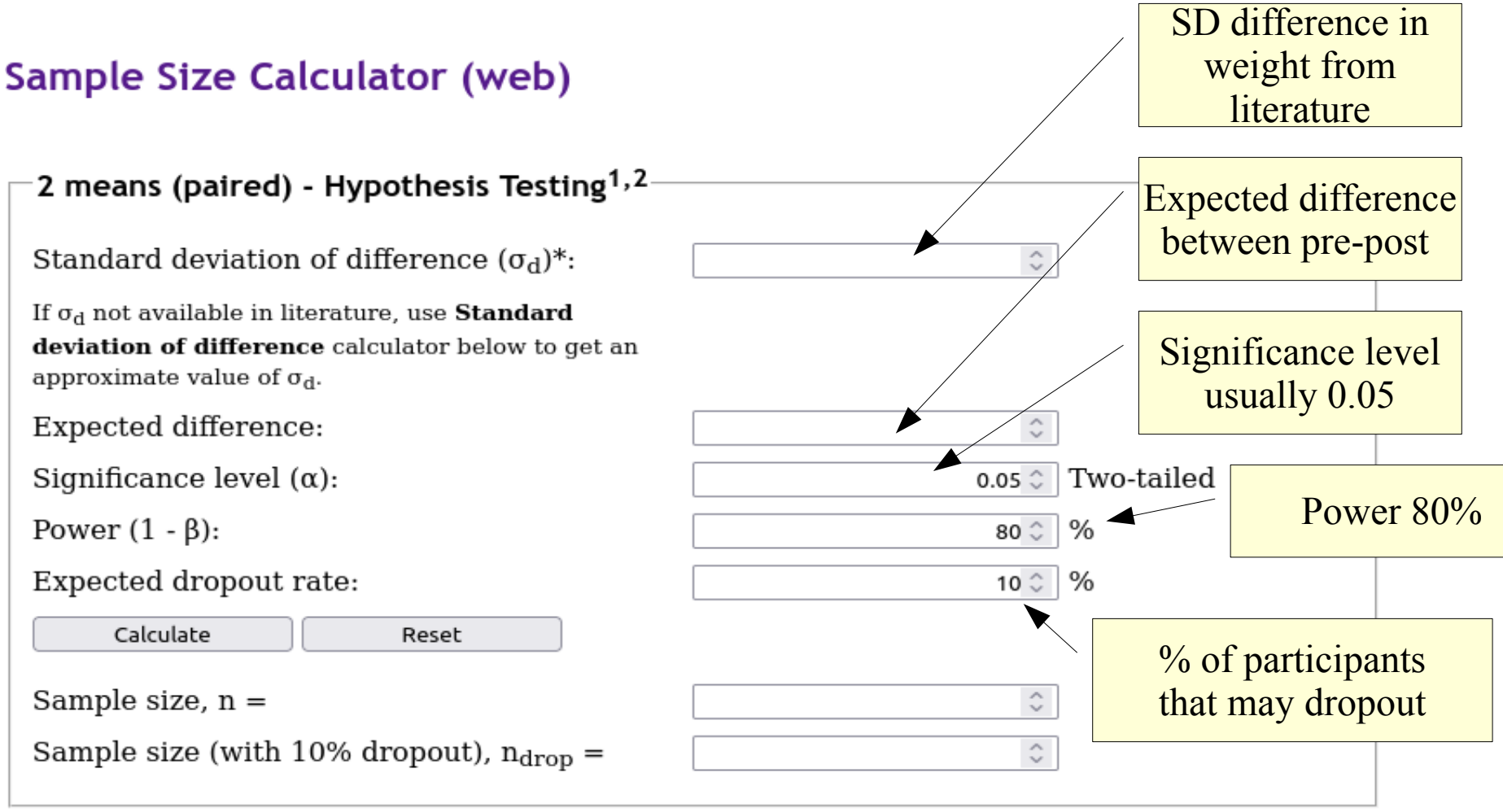
(2) Statistical analysis:

- Paired t-test

(3) Sample size method:

- Two means (paired) – Hypothesis testing

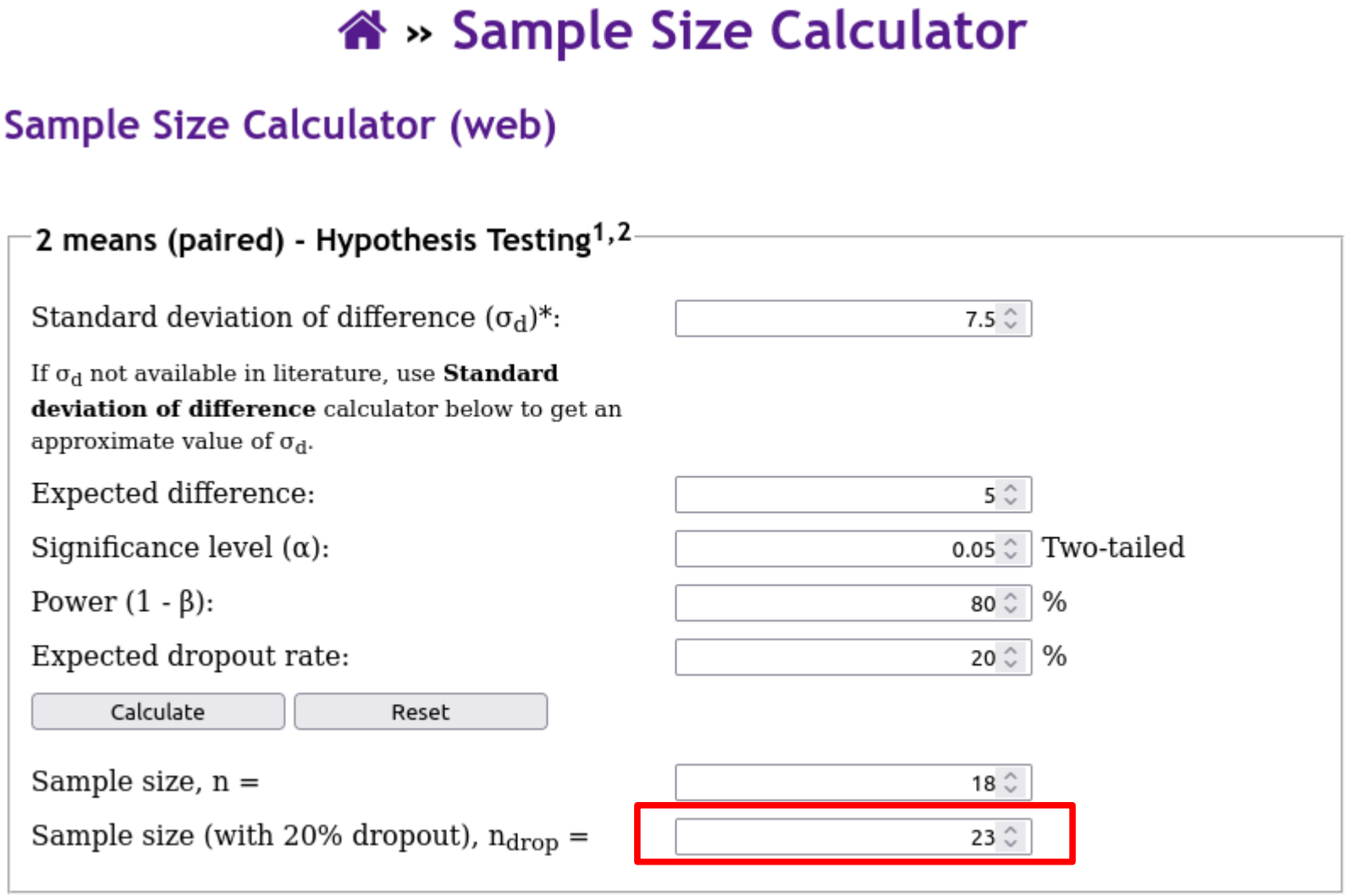
1. Means → Two-mean comparison (paired) → 2 means (paired) – Hypothesis Testing



Two means (paired)

- Let say:
  - SD of difference from literature = 2.5kg
  - Expected Difference = 5kg (post – pre weight)
  - Significance level = 5% (0.05)
  - Power = 80%
  - 20% dropout
- How many students should we sample?

Two means (paired)



Two means (paired)

- We have to sample 23 students to make the comparison, expecting 5kg change following the weight reduction program, taking into account a 20% dropout rate.

Two proportions (paired)

(1) Objective:

- Compare % or proportion of a categorical outcome in a population, pre-post design e.g. % vaccine uptake after before and after health promotion
- "This study aims to compare percentage of vaccine uptake among villagers before and after a vaccine awareness campaign."

Two proportions (paired)

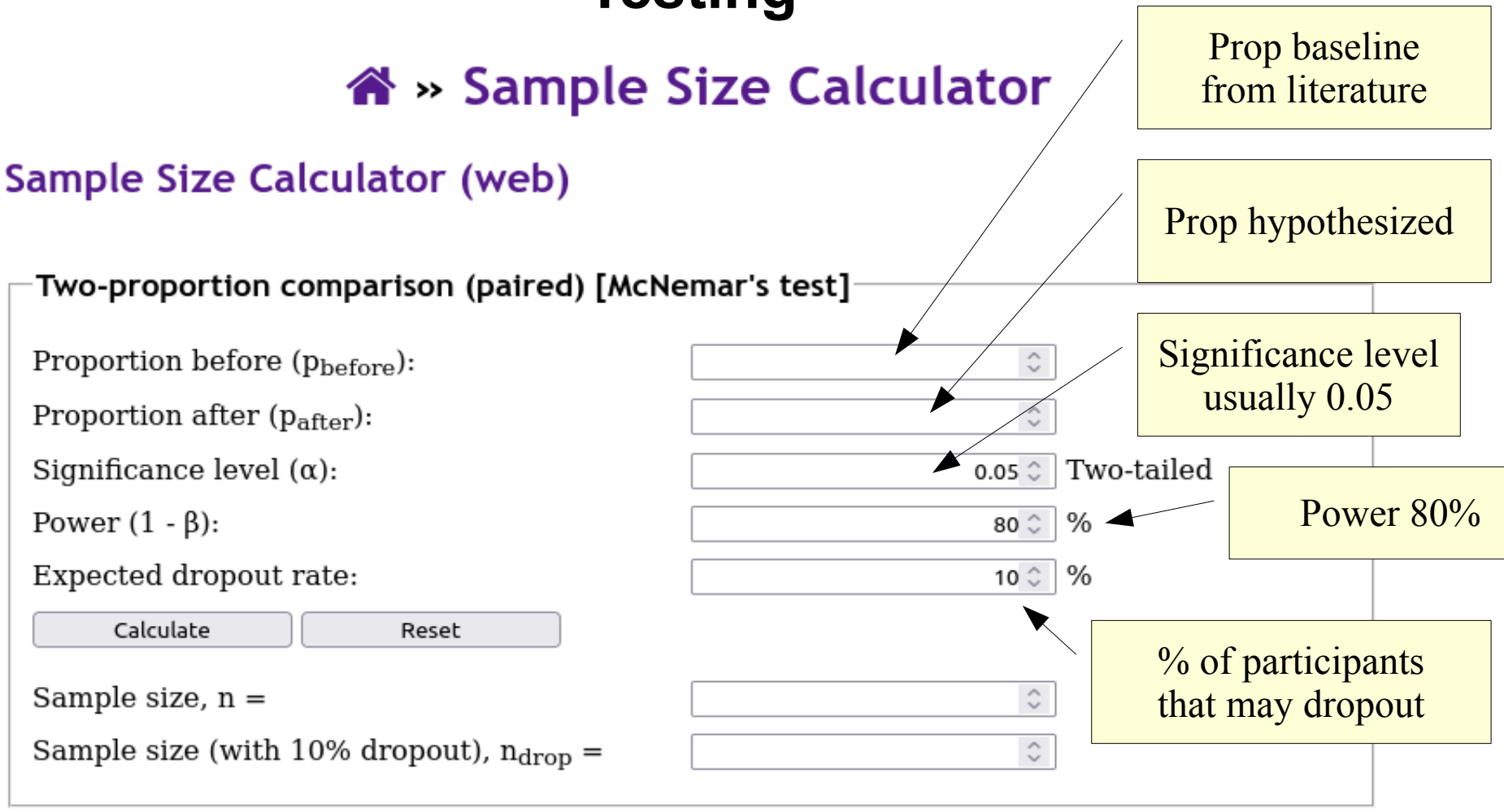
(2) Statistical analysis:

- McNemar's test

(3) Sample size method:

- Two proportions (paired) – Hypothesis testing

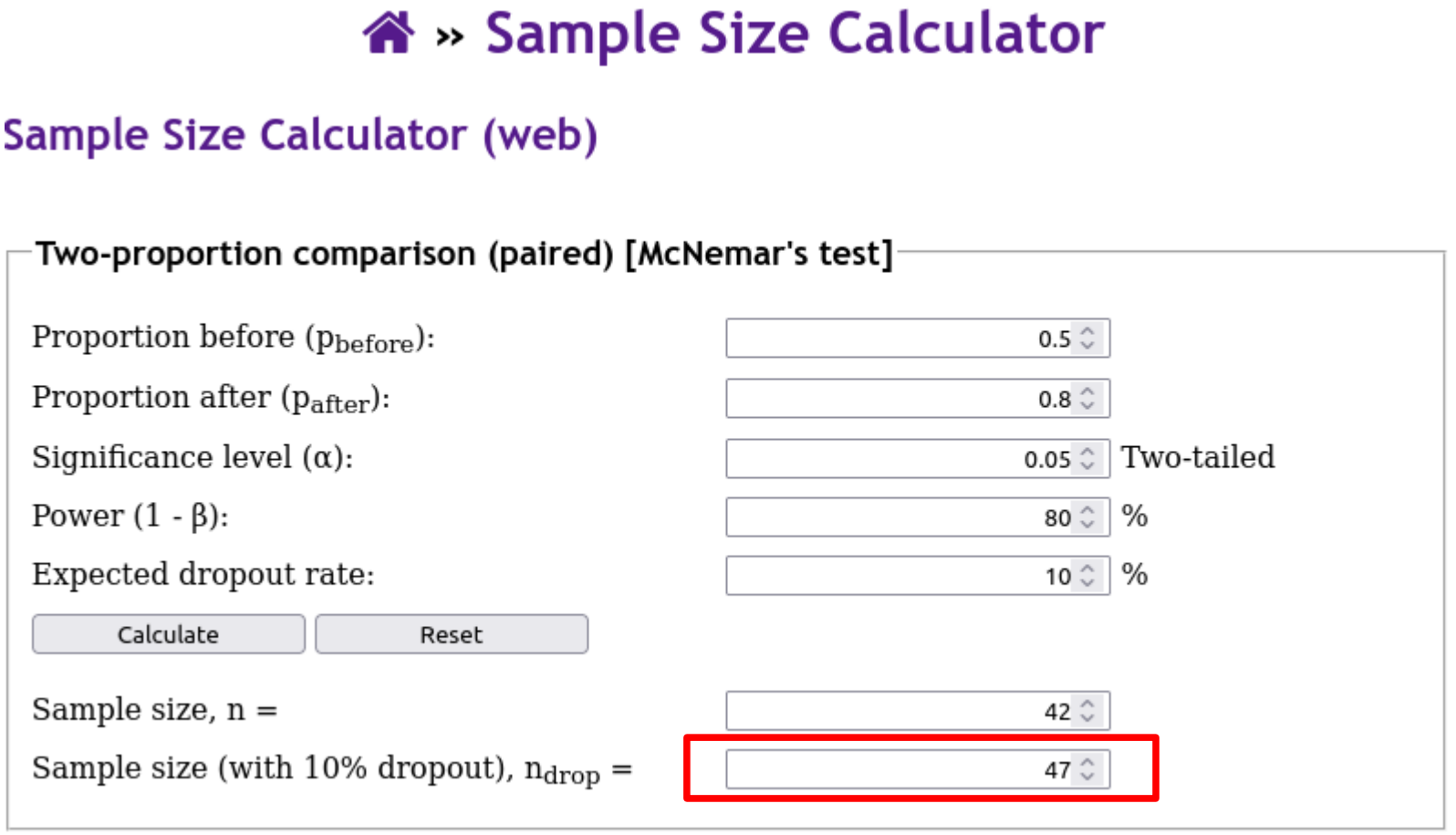
2. Proportions → Two-proportion comparison (paired) → 2 proportions (paired) – Hypothesis Testing



Two proportions (paired)

- Let's say:
  - p_{before} = 50% = 0.5 (in proportion) → before campaign
  - p_{after} = 80% = 0.8 (in proportion) → after campaign
  - Significance level = 5% (0.05)
  - Power = 80% (0.8)
  - 10% dropout
- How many villagers should we sample?

Two proportions (paired)



Two proportions (paired)

- We have to sample 47 villagers to make the comparison, expecting 30% change in vaccine uptake following the vaccine awareness campaign, taking into account a 10% dropout rate.

Correlation

(1) Objective:

- Determine correlation between two numerical outcomes e.g. between age and cholesterol level etc
- "This study aims to determine the correlation between age and cholesterol level among lecturers."

Correlation

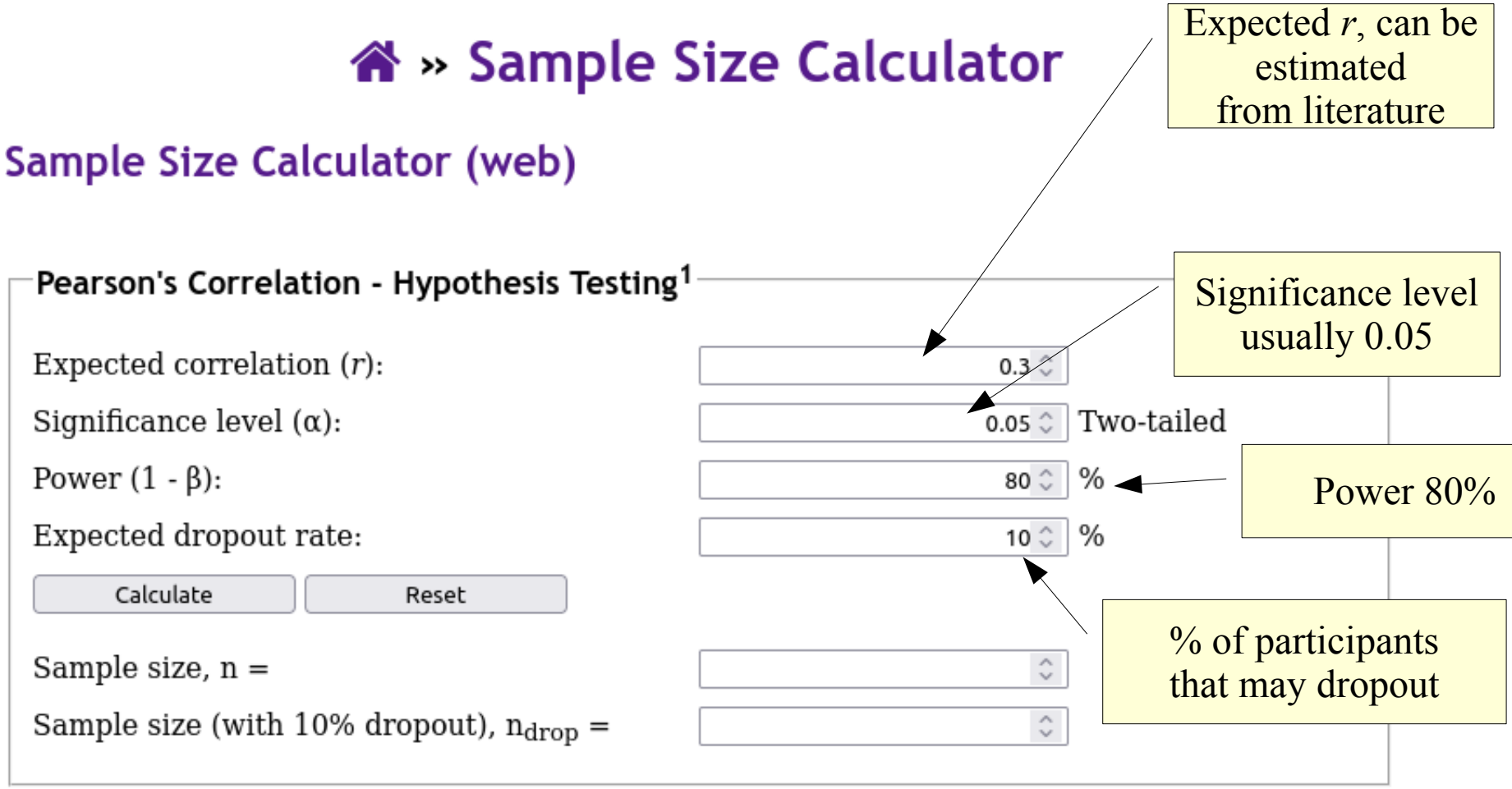
(2) Statistical analysis:

- Pearson's correlation coefficient

(3) Sample size method:

- Pearson's correlation – Hypothesis testing (H_0: $r = 0$)

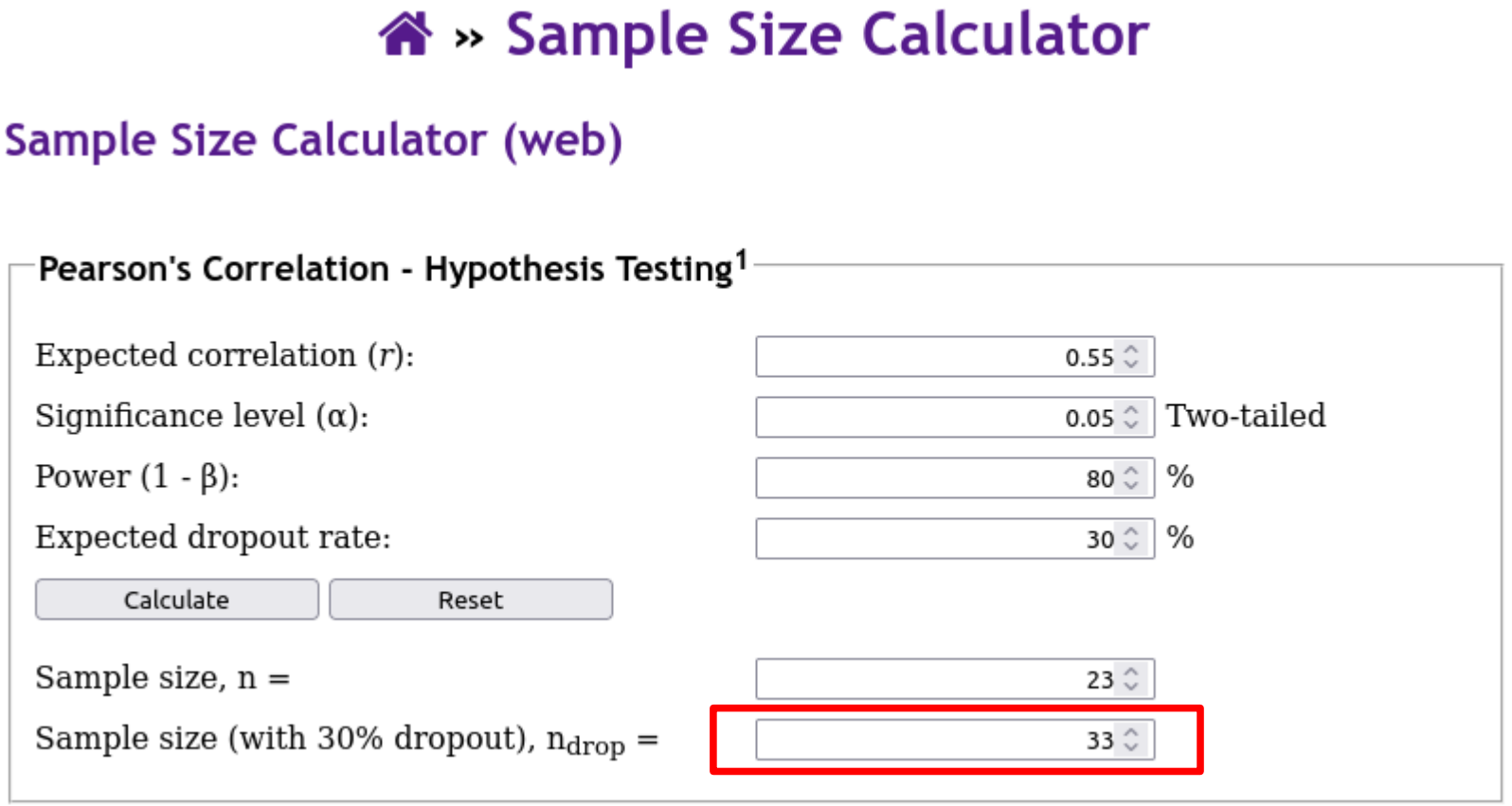
3. Pearson's correlation → Hypothesis Testing



Correlation

- Let say:
  - Correlation *r* that you expect, educated guess from literature = 0.55
  - Significance level = 5% (0.05)
  - Power = 80%
  - 30% dropout
- How many lecturers should we sample?

Correlation



Correlation

- We have to sample 33 lecturers to determine the correlation between age and cholesterol level, taking into account a 30% dropout rate.

Multivariable, numerical outcome

(1) Objective:

- Determine associated factors of a numerical outcome, e.g. predictors of cholesterol level etc
- "This study aims to determine the associated factors of cholesterol level among lecturers."

Multivariable, numerical outcome

(2) Statistical analysis:

- Multiple linear regression

(3) Sample size method:

- Rule-of-thumb – 10 subjects per independent variable*
  - $n = k \times 10$

*Norman, G. R., & Streiner, D. L. (2008). Biostatistics: the bare essentials. Ontario, Canada: BC Decker Inc.

Multivariable, numerical outcome

- Let's say:
  - 1 numerical outcome (cholesterol)
  - 3 numerical independent variables:
    - Age in years, BMI in kg/m^2, weekly physical activity in hours
  - 3 categorical independent variables:
    - Male = yes, no (binary)
    - Smoking = yes, no (binary)
    - Race = Malay, Chinese, Indian (3 levels)
  - 20% dropout
- How many lecturers should we sample?

Multivariable, numerical outcome

Independent Variables, k	Count
Age (numerical)	1
BMI (numerical)	1
Weekly physical activity (numerical)	1
Male (binary categorical)	1
Smoking (binary categorical)	1
Race (categorical, 3 levels → 2 dummy variables)	2
Total	7

Formula:

$$n = k \times 10$$

Independent variable count, k = 7

Sample size, n?

n = k x 10 = 7 x 10 = 70

n + 20% dropout?

n_{drop} = n / (1 – dropout proportion)
= n / (1 – 0.2)
= 70 / 0.8 = 87.5

Sample size is 88 (rounded up).

Multivariable, numerical outcome

- We have to sample 88 lecturers to investigate the associated factors of cholesterol level among lecturers, taking into account a 20% dropout rate.

Multivariable, binary outcome

(1) Objective:

- Determine associated factors of a binary outcome, e.g. predictors of hypertension (HPT)
- "This study aims to determine the associated factors of HPT among workers in ABC office."

Multivariable, binary outcome

(2) Statistical analysis:

- Multiple logistic regression

(3) Sample size method:

- Rule-of-thumb – 10 events-per-parameter*
  - Event, n_1 = number with outcome e.g. CAD = yes
  - Parameters = Indep. Variables + (Intercept + Interaction Terms)
  - Sample size, $n = n_1 + n_0$ (w/out outcome) = n_1 / p (prevalence)

*Hosmer, D., Lemeshow, S., & Sturdivant, R. (2013). Applied logistic regression (3rd ed.). Hoboken, New Jersey: John Wiley & Sons Inc

Multivariable, numerical outcome

- Let's say:
  - 1 binary outcome (HPT)
  - Prevalence of HPT, $p = 0.3$
  - 3 numerical independent variables:
    - Age in years, BMI in kg/m^2, weekly physical activity in hours
  - 3 categorical independent variables:
    - Male = yes, no (binary)
    - Smoking = yes, no (binary)
    - Race = Malay, Chinese, Indian (3 levels)
  - 30% dropout
- How many workers should we sample?

Multivariable, numerical outcome

Independent Variables, k	Count
Age (numerical)	1
BMI (numerical)	1
Weekly physical activity (numerical)	1
Male (binary categorical)	1
Smoking (binary categorical)	1
Race (categorical, 3 levels → 2 dummy variables)	2
Total	7

Formula:

$$n_1 = \text{parameters} \times 10$$

$$n_1 = (k + 1) \times 10$$

$$n = n_1 / p$$

1 intercept
0 interaction

Events, n_1?

$n_1 = (k + 1) \times 10 = (7 + 1) \times 10 = 80$

Sample size, n?

$n = n_1 / p = 80 / 0.3 = 266.7 \approx 267$

$n_{drop} = n / (1 - \text{dropout proportion})$

$= n / (1 - 0.3)$

$= 267 / 0.7 = 381.4 \approx 382$

Sample size is 382.

Multivariable, numerical outcome

- We have to sample 334 workers to investigate the associated factors of hypertension among workers in ABC office, taking into account a 20% dropout rate.

Validation

Exploratory factor analysis

(1) Objective:

- Explore internal structure validity / construct validity of a psychometric tool / questionnaire
- "This study aims to explore the internal structure validity of ABC-Q among students."

Exploratory factor analysis

(2) Statistical analysis:

- EFA

(3) Sample size method:

- Rule-of-thumb – 5 respondents / item*

*Costello, A. B., & Osborne, J. W. (2005). Best practices in exploratory factor analysis: Four recommendations for getting the most from your analysis. Practical Assessment Research & Evaluation, 10(7).

Exploratory factor analysis

- Let's say a researcher wants to validate a questionnaire with:
  - 40 items (variables)
  - 30% dropout
- How many respondents should he sample?

Formula:

$$n = k \times 5$$

$n = k \times 5 = 40 \times 5 = 200$

$n_{drop} = n / (1 - \text{dropout proportion}) = 200 / (1 - 0.3) = 287.7 \approx 288$

Sample size is 288.

Exploratory factor analysis

- We have to sample 288 students to explore the internal structure validity of ABC-Q among the students, taking into account a 30% dropout rate.

Confirmatory factor analysis

(1) Objective:

- Confirm internal structure validity / construct validity of a psychometric tool / questionnaire
- "This study aims to confirm the internal structure validity of ABC-Q among students."

Confirmatory factor analysis

(2) Statistical analysis:

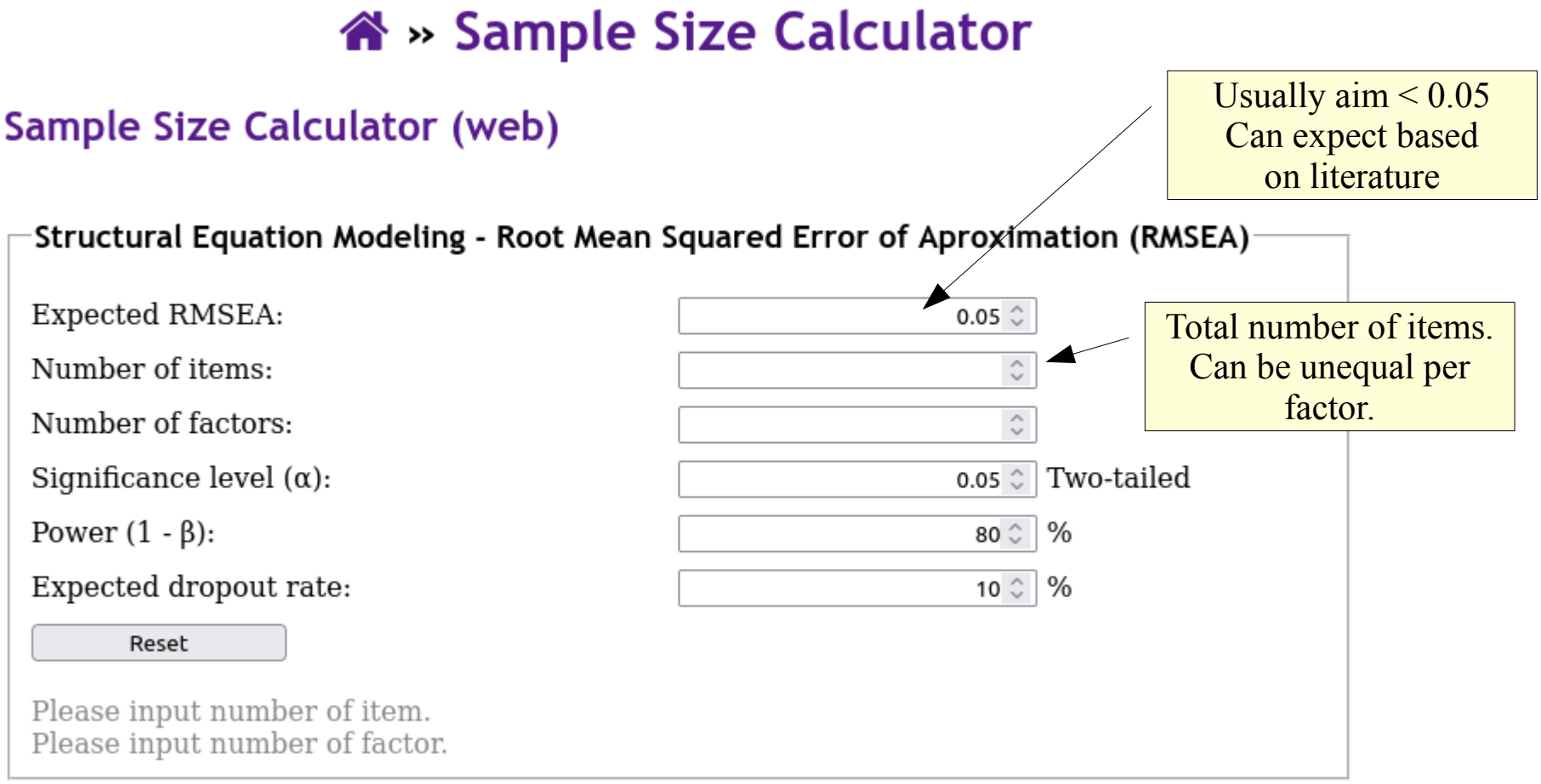
- CFA

(3) Sample size method:

- Rule-of-thumb – at least 200 respondents*
- RMSEA, CFI model fit indices – Hypothesis testing

*Kline, R. B. (2016). Principles and practice of structural equation modeling. 4th ed. New York: Guilford Publications.

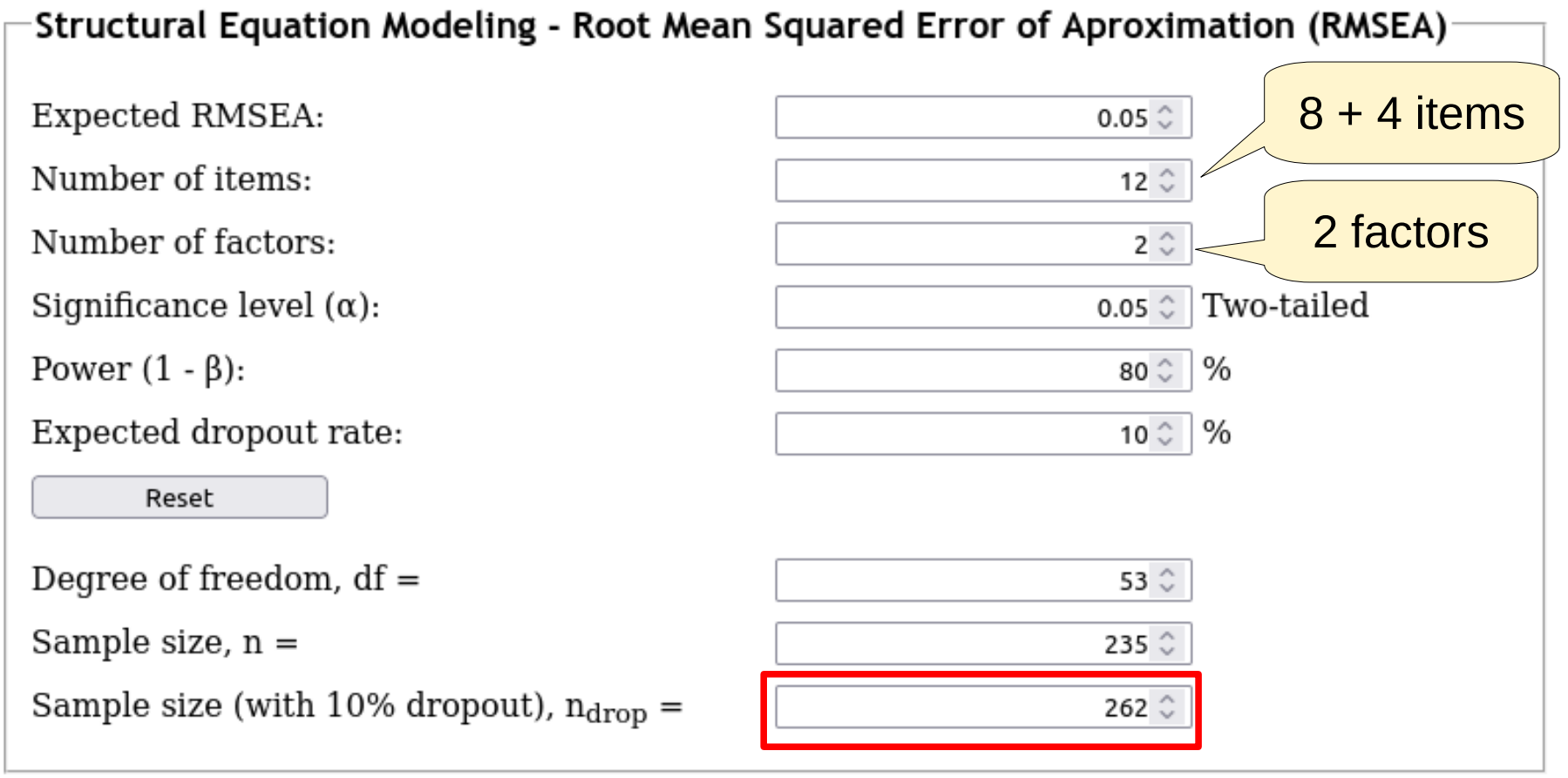
5. Structural Equation Modeling → RMSEA



Confirmatory factor analysis

- Let's say a researcher wants to validate a questionnaire with:
  - 2 factors
  - Factor 1: 8 items, Factor 2: 4 items
  - Acceptable RMSEA is set < 0.05.
  - 10% dropout
- How many respondents should he sample?

Confirmatory factor analysis

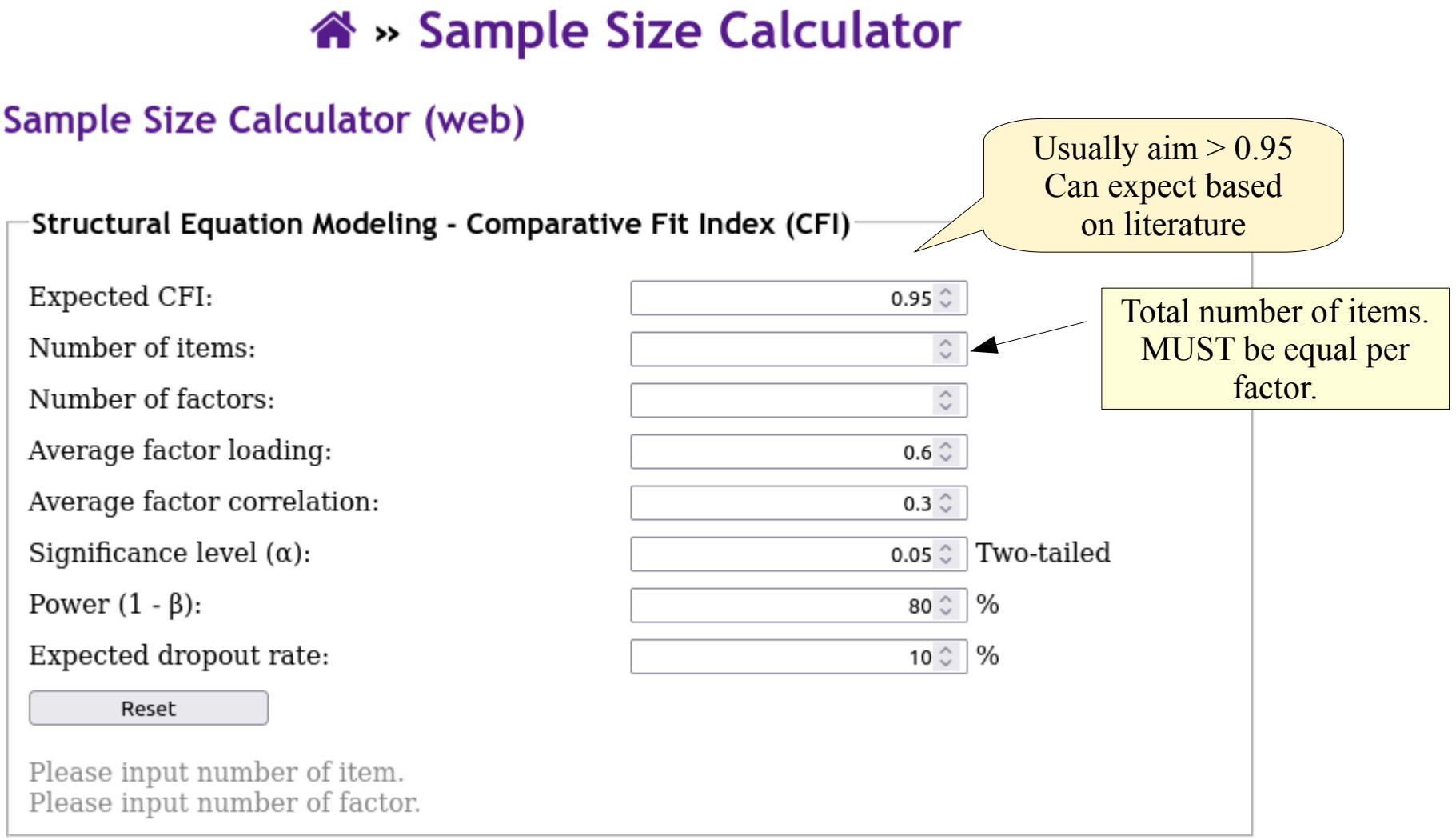


Confirmatory factor analysis

- We have to sample 262 students to confirm the internal structure validity of ABC-Q among the students, taking into account a 10% dropout rate.

5. Structural Equation Modeling → CFI

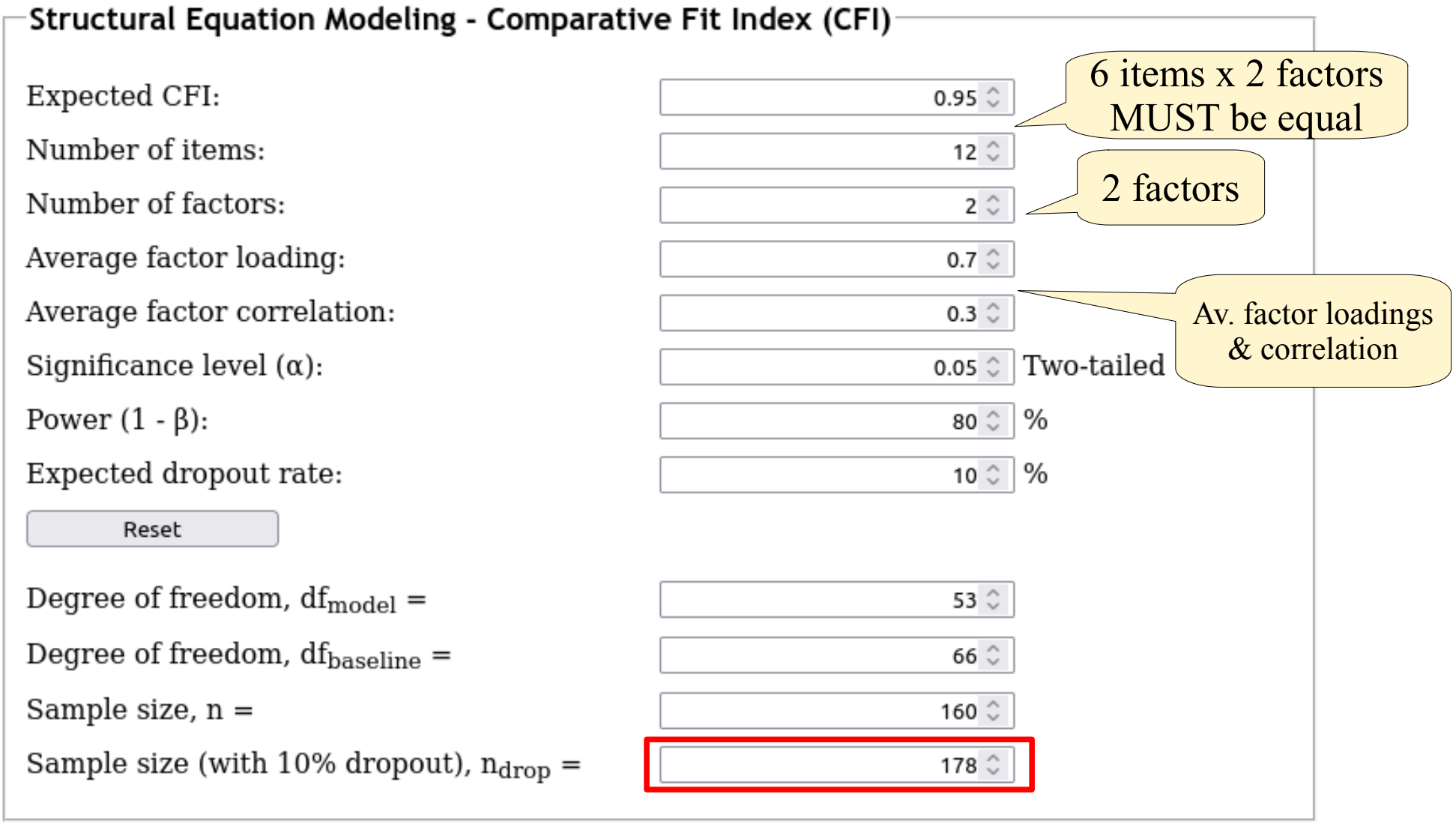
Requires equal number of items per factor



Confirmatory factor analysis

- Let's say a researcher wants to validate a questionnaire with:
  - 2 factors, 6 items each
  - Based on literature, average factor loading is around 0.7
  - Average factor-factor correlation around 0.3
  - Acceptable CFI > 0.95
  - 10% dropout
- How many respondents should he sample?

Confirmatory factor analysis

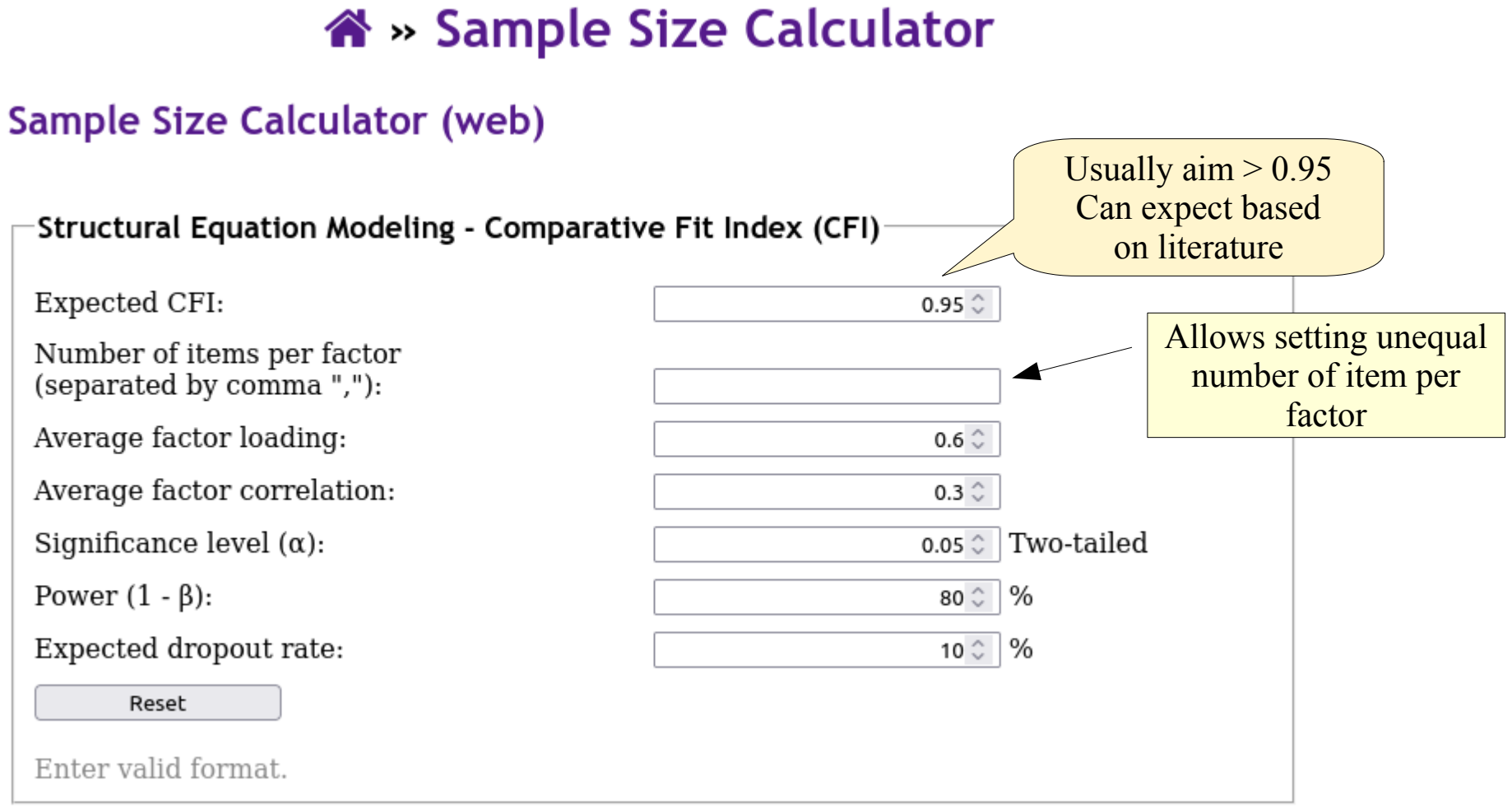


Confirmatory factor analysis

- We have to sample 178 students to confirm the internal structure validity of ABC-Q among the students, taking into account a 10% dropout rate.

5. Structural Equation Modeling → CFI (advanced)

Allows unequal number of items per factor



Confirmatory factor analysis

- Let's say a researcher wants to validate a questionnaire with:
  - 3 factors
  - Factor 1: 8 items, Factor 2: 4 items, Factor 3: 6 items
  - Based on literature, average factor loadings around 0.7
  - Average factor-factor correlation around 0.3
  - Acceptable CFI > 0.95
  - 10% dropout
- How many respondents should he sample?

Confirmatory factor analysis

Structural Equation Modeling - Comparative Fit Index (CFI)

Expected CFI:	0.95
Number of items per factor (separated by comma ","):	8, 4, 6
Average factor loading:	0.7
Average factor correlation:	0.3
Significance level (α):	0.05 Two-tailed
Power (1 - β):	80 %
Expected dropout rate:	10 %

Reset

Degree of freedom, df_{model} =	132
Degree of freedom, $df_{baseline}$ =	153
Sample size, n =	162
Sample size (with 10% dropout), n_{drop} =	180

Factor 1: 8 items
Factor 2: 4 items
Factor 3: 6 items

Av. factor loadings & correlation

Confirmatory factor analysis

- We have to sample 180 students to confirm the internal structure validity of ABC-Q among the students, taking into account a 10% dropout rate.

Cronbach's alpha

(1) Objective:

- Determine reliability of a psychometric tool / questionnaire
- "This study aims to determine the reliability of ABC-Q among students."

Cronbach's alpha

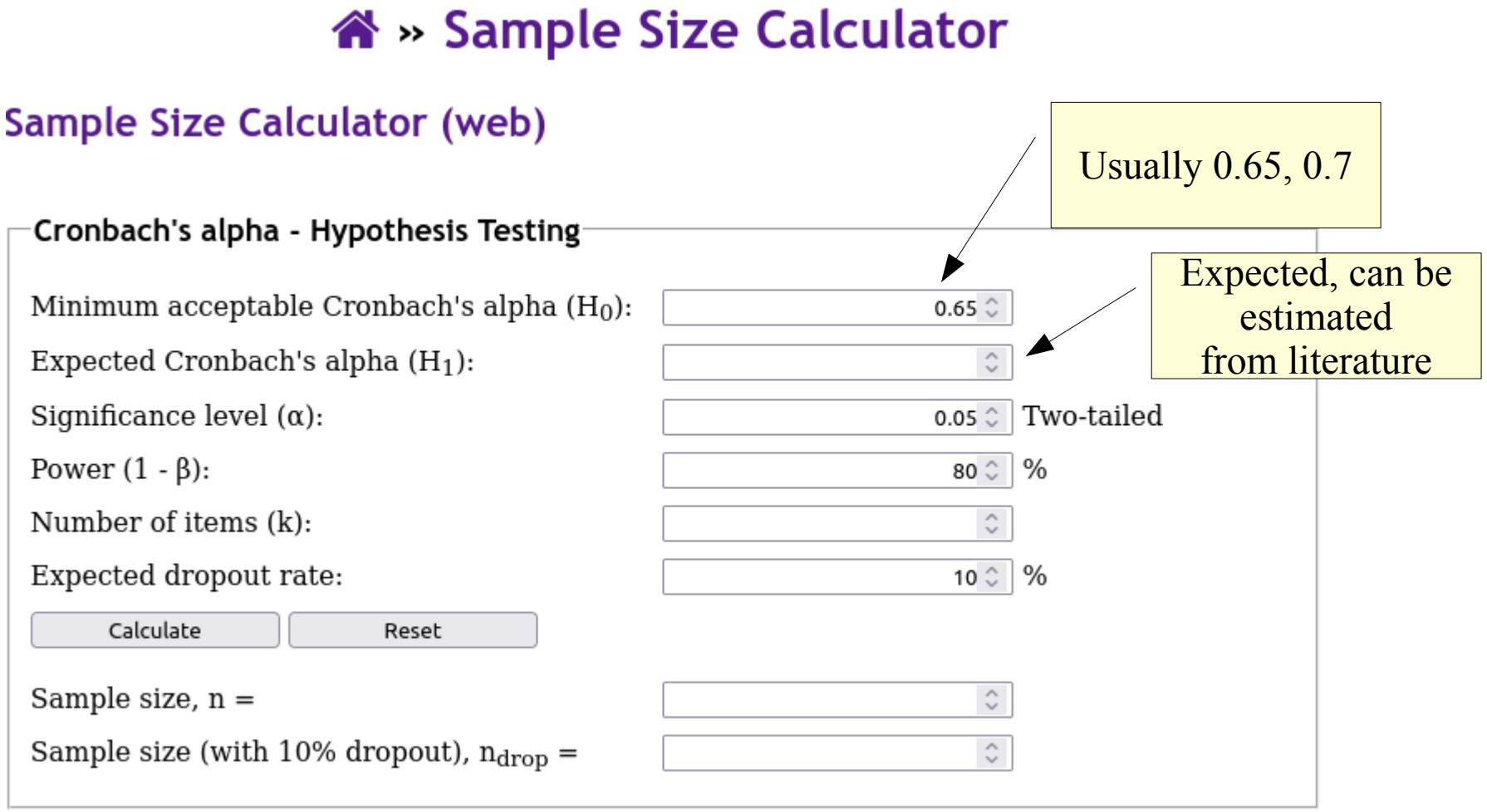
(2) Statistical analysis:

- Cronbach's alpha coefficient

(3) Sample size method:

- Cronbach's alpha coefficient – Hypothesis testing

4. Reliability → Cronbach's alpha coefficient



Cronbach's alpha

- Let's say a researcher wants to determine reliability of a questionnaire with:
  - Minimum acceptable Cronbach's alpha = 0.7
  - Expected Cronbach's alpha = 0.85
  - 2 factors
  - Factor 1: 8 items, Factor 2: 6 items
  - 20% dropout
- How many respondents should he sample?
  - Calculate for each factor, and take the largest.

Cronbach's alpha

Sample Size Calculator (web)

Cronbach's alpha - Hypothesis Testing

Minimum acceptable Cronbach's alpha (H_0):	0.7	
Expected Cronbach's alpha (H_1):	0.85	
Significance level (α):	0.05	Two-tailed
Power (1 - β):	80	%
Number of items (k):	8	
Expected dropout rate:	20	%

Calculate Reset

Sample size, n =	40
Sample size (with 20% dropout), n_{drop} =	50

Expected, can be from literature

8 items from Factor 1

Cronbach's alpha

Sample Size Calculator (web)

Cronbach's alpha - Hypothesis Testing

Minimum acceptable Cronbach's alpha (H_0):	0.7	
Expected Cronbach's alpha (H_1):	0.85	
Significance level (α):	0.05	Two-tailed
Power (1 - β):	80	%
Number of items (k):	6	
Expected dropout rate:	20	%

Calculate Reset

Sample size, n =	42
Sample size (with 20% dropout), n_{drop} =	53

Expected, can be from literature

6 items from Factor 2

Cronbach's alpha

- We have to sample 53 students to determine the reliability of ABC-Q among the students, taking into account a 20% dropout rate.

Intraclass correlation

(1) Objective:

- Determine test-retest reliability / interrater reliability of a numerical measure, i.e. consistency / agreement.
- "This study aims to determine the test-retest reliability of ABC-Q among students."
- "This study aims to determine the interrater reliability of new doctors in measuring blood pressure."

Intraclass correlation

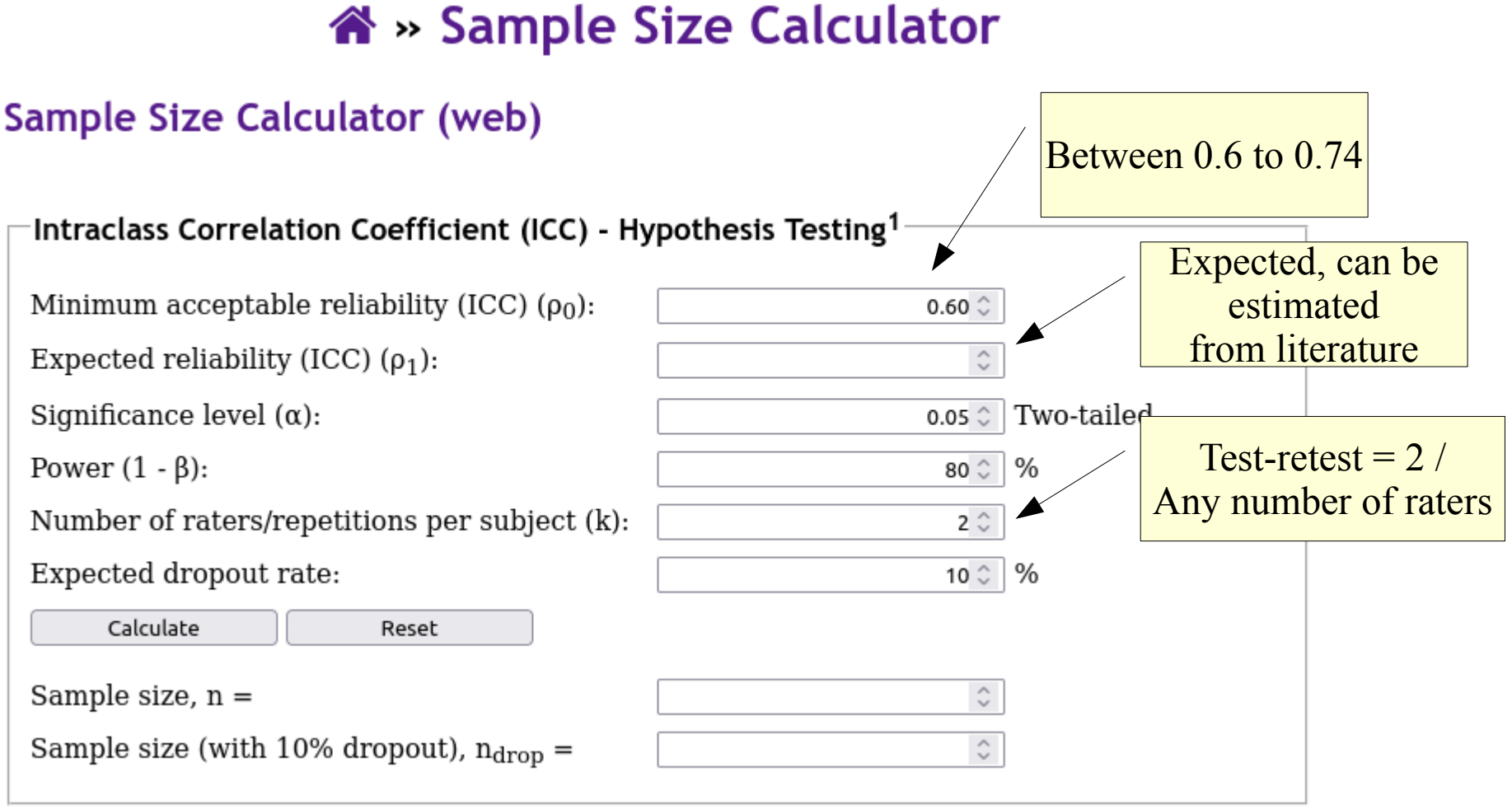
(2) Statistical analysis:

- Intraclass correlation coefficient (ICC)

(3) Sample size method:

- Intraclass Correlation Coefficient (ICC) - Hypothesis Testing

4. Reliability → Intraclass correlation coefficient (ICC) → ICC - Hypothesis Testing



Intraclass correlation - test-retest

- Let's say for test-retest reliability:
  - Minimum acceptable ICC = 0.7
  - Expected ICC = 0.85
  - Two occasions
  - 10% dropout
- How many respondents should he sample?

Intraclass correlation

» Sample Size Calculator

Sample Size Calculator (web)

Intraclass Correlation Coefficient (ICC) - Hypothesis Testing[1]

Minimum acceptable reliability (ICC) (ρ_0):	0.7	
Expected reliability (ICC) (ρ_1):	0.85	
Significance level (α):	0.05	Two-tailed
Power (1 - β):	80	%
Number of raters/repetitions per subject (k):	2	
Expected dropout rate:	10	%

Calculate Reset

Sample size, n =	53
Sample size (with 10% dropout), n_{drop} =	59

Expected, can be from literature

2 repetitions for test-retest

Intraclass correlation

- We have to sample 59 students to determine the test-retest reliability of ABC-Q among the students, taking into account a 10% dropout rate.

Intraclass correlation - interrater

- Let's say for interrater reliability:
  - Minimum acceptable ICC = 0.8 (set higher, measuring blood pressure correctly is a serious matter)
  - Expected ICC = 0.9
  - 5 doctors
  - 10% dropout
- How many doctors should he sample?

Intraclass correlation

» Sample Size Calculator

Sample Size Calculator (web)

Intraclass Correlation Coefficient (ICC) - Hypothesis Testing[1]

Set higher at 0.8

Minimum acceptable reliability (ICC) (ρ_0):	0.8	
Expected reliability (ICC) (ρ_1):	0.9	
Significance level (α):	0.05	Two-tailed
Power (1 - β):	80	%
Number of raters/repetitions per subject (k):	5	
Expected dropout rate:	10	%

Expected, can be from literature

5 doctors

Calculate Reset

Sample size, n =	33
Sample size (with 10% dropout), n_{drop} =	37

Intraclass correlation

- We have to sample 37 **patients** to determine the interrater reliability of 5 **doctors** in measuring blood pressure, taking into account a 10% dropout rate.

Kappa agreement

(1) Objective:

- Determine interrater reliability of a categorical measure, i.e. consistency / agreement.
- "This study aims to determine the interrater reliability of two radiologists in rating X-ray films for the presence of pneumonia among patients with shortness of breath."
- Rater = human rater / diagnostic test

Kappa agreement

(2) Statistical analysis:

- Kappa coefficient

(3) Sample size method:

- Kappa (2 raters) – Hypothesis testing

4. Reliability → Kappa coefficient → Kappa (2 raters) - Hypothesis Testing

» Sample Size Calculator

Sample Size Calculator (web)

Kappa (2 raters) - Hypothesis Testing[1]

Minimum acceptable kappa (κ_0):	0.6	
Expected kappa (κ_1):		
Proportion of outcome (p), e.g. *p* of heart disease:	0.5	
Significance level (α):	0.05	Two-tailed
Power (1 - β):	80	%
Expected dropout rate:	10	%

Calculate Reset

Sample size, n =

Sample size (with 10% dropout), n_{drop} =

Usually 0.6, Moderate agreement

Expected, can be estimated from literature

Kappa agreement

- Let's say a researcher wants to determine the agreement between two radiologists:
  - Minimum acceptable kappa = 0.6
  - Expected kappa = 0.9
  - Presence of pneumonia among patients with shortness of breath is 30% ($p = 0.3$)
  - 30% dropout
- How many patients should be sampled?

Kappa agreement

» Sample Size Calculator

Sample Size Calculator (web)

Kappa (2 raters) - Hypothesis Testing[1]

Minimum acceptable kappa (κ_0):	0.6	
Expected kappa (κ_1):	0.9	
Proportion of outcome (p), e.g. *p* of heart disease:	0.3	
Significance level (α):	0.05	Two-tailed
Power (1 - β):	80	%
Expected dropout rate:	30	%

Calculate Reset

Sample size, n =	66
Sample size (with 30% dropout), n_{drop} =	95

Expected, can be from literature

30% presence of pneumonia $p = 0.3$

Kappa agreement

- We have to sample 95 X-ray films of patients with shortness of breath to determine the interrater reliability of two radiologists in rating X-ray films for the presence of pneumonia, taking into account a 30% dropout rate.

Sensitivity & Specificity

(1) Objective:

- Estimate sensitivity and specificity of a diagnostic test, e.g. RTK-Ag for COVID-19
- "This study aims to determine sensitivity and specificity of a new COVID-19 self-test kit among exposed adults."

Sensitivity & Specificity

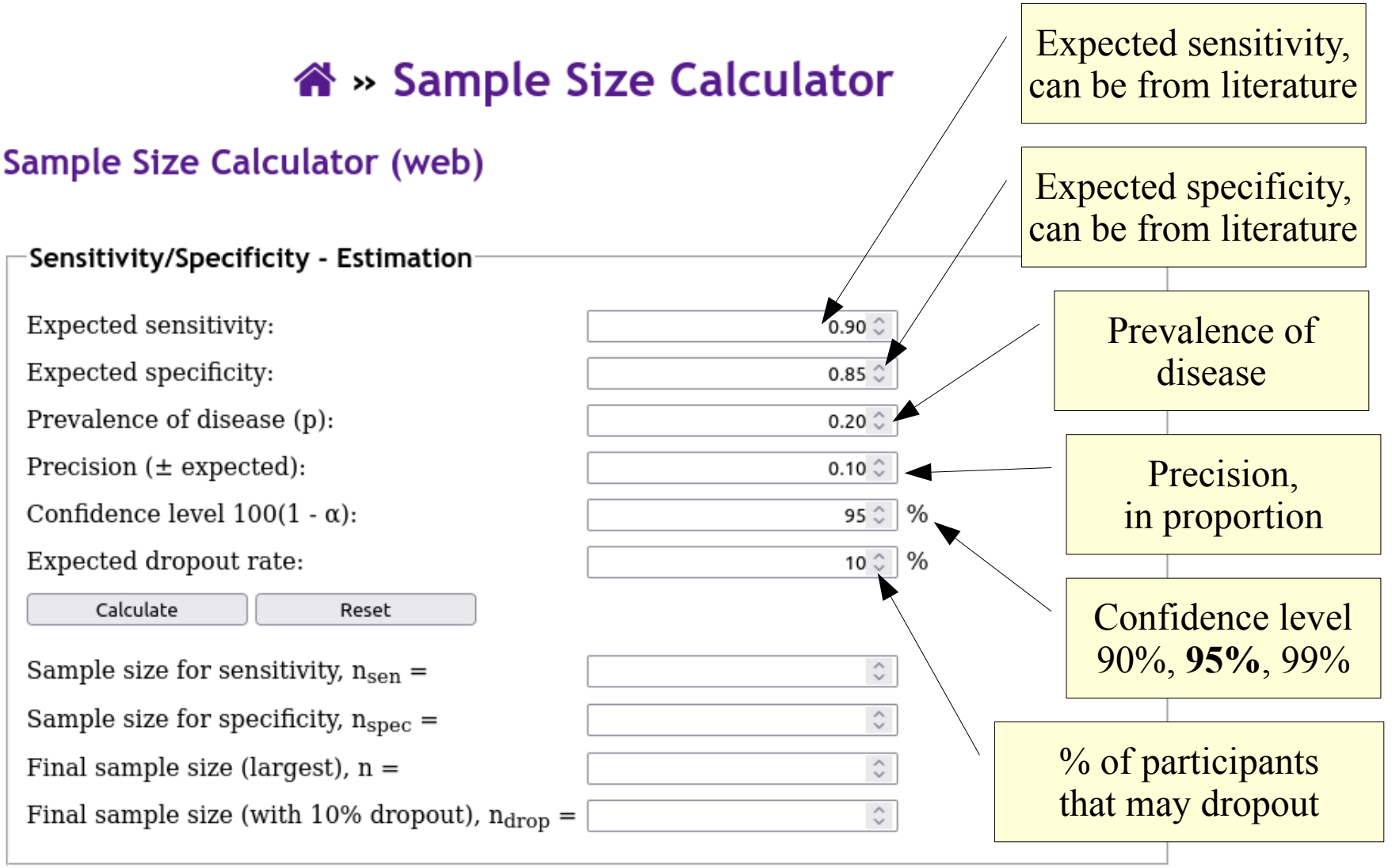
(2) Statistical analysis:

- Proportion, 95% Confidence Interval (CI)

(3) Sample size method:

- Sensitivity/Specificity – Estimation

2. Proportions → Sensitivity and specificity → Sensitivity/Specificity - Estimation

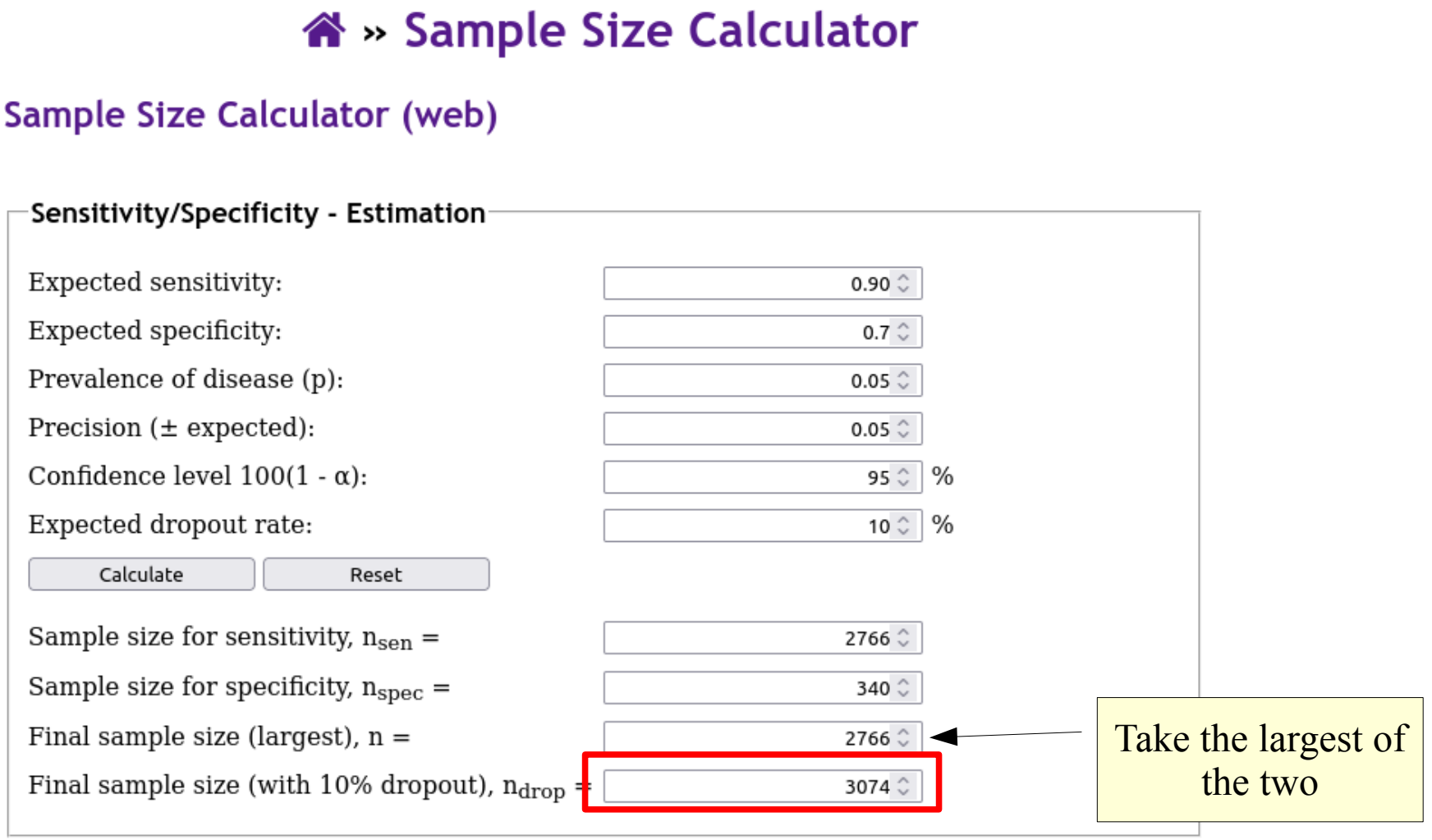


Sensitivity & Specificity

- Let say:
  - Expected Sensitivity = 0.9
  - Expected Specificity = 0.7
  - Prevalence of COVID-19* = 5% = 0.05 (in proportion)
  - Precision = ±5% = 0.05 (in proportion)
  - 95% Confidence level
  - 10% dropout
- How many exposed adults should we sample?

*based on positivity rate

Sensitivity & Specificity



Sensitivity & Specificity

- We have to sample 3075 patients to estimate both sensitivity and specificity of the new test kit among exposed adults, taking into account a 10% dropout rate.

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