

Original citation:

Froud, Robert J., Rajendran, Dévan, Patel, Shilpa, Bright, Philip, Bjørkli, Tom, Eldridge, Sandra, Buchbinder, Rachelle and Underwood, M. (Martin) M.D.. (2016) The power of low back pain trials : a systematic review of power, sample size, and reporting of sample size calculations over time, in trials published between 1980 and 2012. Spine.

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The power of low back pain trials: A systematic review of power, sample size, and reporting of sample size calculations over time, in trials published between 1980 and 2012

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- 1 Funding: Campus Kristiania, University of Warwick, Monash University, and
- 2 Barts and the London Charity. RB is funded by an Australian National Health and
- 3 Medical Research Council (NHMRC) Senior Principal Research Fellowship.

1

2 Abstract

3

4 Study design

5 A systematic review of non-specific low back pain (LBP) trials published

6 between 1980 and 2012.

7

8 Objectives

9 To explore what proportion of trials have been powered to detect different

10 bands of effect size; whether there is evidence that sample size in LBP trials is

11 increasing with time; what proportion of trial reports include a sample size

12 calculation; and whether likelihood of reporting sample size calculations is

13 increasing with time.

14

15 Summary of background data

16 Clinical trials should have a sample size sufficient to detect a minimally

17 important difference for a given power and type I error rate. An underpowered

18 trial is one within which probability of type II error is too high. Meta-analyses do

19 not mitigate underpowered trials.

20

21 Methods

22 Reviewers independently abstracted data on sample size at point of analysis,

23 whether a sample size calculation was reported, and year of publication.

24 Descriptive analyses were used to explore ability to detect effect sizes, and

1 regression analyses to explore the relationship between sample size, or
2 reporting sample size calculations, and time.

3

4 Results

5 We included 383 trials. Only one-third were powered to detect a standardised
6 mean difference of 0.5 or less. Average sample size was 153 people, which
7 increased only slightly (~ 4 people/year) from 1980 to 2000, and declined
8 slightly (~ 4.5 people/year) from 2005 to 2011 ($P < 0.00005$). Sample size
9 calculations were reported in only 41% of trials. The odds of reporting a sample
10 size calculation (compared to not reporting one) increased until 2005 and then
11 declined ($OR_{year} = 1.06$, $OR_{year^2} = 0.99$; $P < 0.00005$).

12

13 Conclusions

14

15 Trialists should make LBP trial samples sizes large enough to detect realistic
16 effect sizes, and report sample size calculations. It may be justifiable to power a
17 trial to detect only large effects in the case of novel interventions. Funders, peer-
18 reviewers, editors, and readers should be vigilant for and critical of
19 underpowered trials.

20

21

22 Key words

23

24 Back pain; Sample size; Sample size calculations; Power; Reporting; Ethics; Effect
25 sizes; Minimally important difference; Clinical trials; Systematic Review.

Key points

1. Only around one-third of trials are powered to detect an effect size of 0.5 or less. The vast majority (95%) do not have the power to detect realistic effect sizes.
2. Sample size in back pain trials has only increased by trivial magnitudes since 1980 and has been declining since 2005.
3. Sample size calculations are reported by only 41% of trials, and since 2005 the proportion reporting sample size calculations has fallen.
4. Except for cases in which novel interventions are being tested and a small sample size is clearly justified by design, it is imperative that back pain trial sample sizes are made larger, the required size is established *a priori* and is reported in publications.

1 Précis

2 Froud *et al* systematically reviewed non-specific low back pain trials published
3 between 1980 and 2012, and show most are not powered to detect realistic
4 effect sizes and that the majority do not report sample size calculations. They
5 discuss the ethical implications, possible mitigating circumstances, and outline a
6 strategy for improvement.

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1 Introduction

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5 Statistical tests in clinical trials generally test null hypotheses that differences
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8 between populations are zero.¹ Customarily, type I error rate (or alpha) is set at
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10 0.05, *i.e.* rejection of the null hypothesis if there is <5% probability it is true,
11
12 given the observed result. Also customarily, the power of the study, *i.e.* the
13
14 probability of detecting a difference if one truly exists in the population, is
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16
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18 usually set at 80% or 90%.

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22 The magnitude a study is powered to detect should be based on the population-
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25 difference that is perceived as worthwhile.² Non-specific low back pain (LBP)
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28 trials utilise many different outcome measures, in different units, but outcomes
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30
31 can be standardised by dividing the between-group difference by the standard
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33
34 deviation to produce a standardised effect size (ES).³⁻⁵ Conventionally, ESs of 0.2
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36 are considered small, 0.5 medium, and 0.8 large.⁶ Whether or not the magnitude
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39 can be considered worthwhile, at a population level, may depend on the cost of
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42 providing the treatment in question.^{7,8} Large, high-quality trials suggest that
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44
45 effective interventions may have a 'typical' ES of around 0.3.^{3,9,10}

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49 If a trial is underpowered then there is a greater risk of type II error; *i.e.* failing to
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52 detect a difference when one exists in the population.¹ Thus, assuming good
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55 internal validity, it is difficult to interpret outcomes in trials reporting null
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58 results, in cases where sample sizes are small. It has been suggested that in these
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61 cases meta-analyses of underpowered studies provide remedy.¹¹ However, LBP
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64 populations may often be too heterogeneous to permit sensible pooling in fixed
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1 effects models, and random-effects models make assumptions about population
2 distributions that may be unrealistic.¹²⁻¹⁵ Additionally, pooling of different
3 outcomes purporting to measure the same domains, with outcomes described in
4 terms of ES may be unsafe.¹⁶ Further, therapist-delivered interventions testing
5 the same basic intervention may be so dissimilar, and poorly specified, that it is
6 not possible to describe the intervention evaluated by the meta-analysis in a
7 manner that would allow replication.

8
9 There is a risk that underpowered trials have very limited value and contribute
10 little to the evidence base. There have been several calls to increase sample sizes
11 in trials over the past decades, and the importance of undertaking sample size
12 calculations has been emphasised.^{1,17-19} The impact that calls and checklists have
13 had on practice relating to power and reporting sample size calculations in back
14 pain trials is unclear.

15
16 Our aims were to explore: 1) what proportion of LBP trials have been powered to
17 detect bands of effect size ranging between small ($d=0.2$), 'typical' ($d=0.3$),
18 medium ($d=0.5$), or large ($d=0.8$); 2) whether there is evidence that sample size
19 in LBP trials is increasing with time; 3) what proportion of trial reports include a
20 sample size calculation, by year; and 4) whether the likelihood of reporting a
21 sample size calculation is increasing with time.

1 Materials and methods

2

3 Two reviewers (RF, SP) independently identified randomised controlled trials
4 (RCTs), published from 1980 inclusive, of interventions for non-specific low back
5 pain (nsLBP) from COST-B13's European Guidelines for the Management of Low
6 Back Pain (EGLBP) and from the systematic reviews reported in the EGLBP.²⁰
7 The EGLBP search was extended in two phases. In 2007, two reviewers (RF, SP)
8 searched from November 2002, when the COST-B13 search finished, to the end
9 of December 2006, using the Cochrane library, PubMed, Embase, HTA, and Lilacs
10 databases. In 2012, three reviewers (PB, DR, TB) searched from January 2007 to
11 January 2012, using PubMed, Embase, and the Cochrane library, within which
12 the majority of LBP trials are indexed. Supplemental Digital Content file 1 (PDF)
13 shows a typical search string. Table 1 shows inclusion and exclusion criteria.

We combined material from the EGLBP and extended searches, removing duplicates, and short-listing by title and abstract. Full-texts were obtained if the titles and abstract alone contained insufficient information for assessment against Table 1 criteria.

All five reviewers abstracted data from the LBP trials on numbers analysed for the primary outcome for the pre-specified main comparison, details of whether or not a sample size calculation was reported, and the year of publication. An outcome was identified as 'primary' if (1) the outcome was nominated as such; if no outcome was nominated, or if multiple outcomes were nominated, we used (2) the outcome measure on which the sample size calculation was based; if this was not reported, we identified (3) the first outcome measure referred to in the abstract; and if this was not identified, we used (4) the first outcome mentioned in the paper. This approach has been taken in several other methodological reviews.²¹⁻²³ We identified the primary end-point, or used the first follow-up time point in cases when this was not clear. Disagreements were resolved through discussion and, if necessary, with arbitration and a fourth reviewer (RF, SE, or MU). Reporting of sample size calculation was judged present if, as a minimum, it was reported how many participants were estimated as required to detect a given between-group difference, or if the latter was not reported, if the detectable between-group difference could be readily calculated from what was reported. The calculations needed to be *a priori* (*i.e. post hoc* power calculations were not counted).

1 For all data abstraction we used expert validation of 20% of papers, as has been
 2 done in other methodological reviews.²⁴ It was decided *a priori* that in the case of
 3 agreement being less than 80%, full independent abstraction would be
 4 undertaken. Validation disagreements were settled by arbitration involving an
 5 independent reviewer.

6
 7 For each trial, the average sample size by arm was calculated and compared to
 8 the threshold of participants needed to detect an ES of small (Cohen's $d=0.2$),
 9 small-to-medium ($d=0.3$), medium ($d=0.5$), or large ($d=0.8$), under the
 10 assumption of comparisons to groups of approximately equal size. Trials were
 11 categorised according to their ability to detect within these bands.⁴

12
 13 The proportion of trials reporting sample size calculations was calculated by
 14 year. To explore our objective of whether sample size is increasing with time, we
 15 used linear regression with a log-transformation of sample size to control for the
 16 heteroschedasticity (*i.e.* the changing variance) of sample size on year. To
 17 explore the likelihood of reporting a sample size calculation by time, we fitted a
 18 logit model, regressing reporting of sample size (binary) on year. Non-linear
 19 relationships between predictor and outcome variables were explored through
 20 fitting polynomial terms in predictor variables and log rank tests were used to
 21 test these terms for statistical significance ($\alpha=0.05$). Model fit was examined
 22 using residual plots, and in the case of the logit model, a combination of Pseudo
 23 R^2 , AIC, and residual plots. Locally weighted least squares (Lowess) smoothers
 24 were added if they aided interpretations of trends over time. All analyses were
 25 performed in Stata, version 12 (Statacorp, Texas).

Results

From our combined searches, we sifted a total of 7,066 hits, removing 4,398 of these based on titles and abstracts and 1,931 duplicates, and assessed 737 papers at full-text level. We rejected 354 papers that did not fit our inclusion criteria.^{10,25-377} We included 383 trials (Figure 1).³⁷⁸⁻⁷⁶⁰ **[Note: *this makes for a large reference list. References can be included with the supplemental digital content tables if preferred.***] Supplemental Digital Content file 2 (PDF) shows a table of the characteristics of included studies, and Supplemental Digital Content file 3 (PDF) shows a table of the characteristics of excluded studies.

Ability of trials to detect effect sizes

Across all trials, the average total sample size was 152.8 (IQR=126; range 12 to 2,594). Figure 2 shows histograms of average group size and logged average group size, with reference guidelines for ES detection ability. Table 2 shows the frequency of trials by ES detection category. The majority (67.1%) of trials were only powered to detect ES of greater than 0.5 (medium).

Sample size over time

A quadratic term in year was required to adequately model sample size over time (*i.e.* the relationship follows a quadratic curve rather than a line ($P<0.0005$)). Linear regression of sample size on *year* and *year*² explained 4.6% of the variance in sample size. For use in estimation, $\beta_{year}=-0.0131702$, $\beta_{year^2}=-0.0027846$ (centered around the average in *year*, of 2002.141), with a constant of 31.1585; $P<0.00005$). For example, the predicted log sample size for the year 2000 (*i.e.* the year with the largest sample sizes) is: $31.1585+(\underline{2000}^*$

0.0131702)+((2000-2002.141)²*-0.0027846)=4.82; *i.e.* a total sample size of around 124 people. Other years may be inserted into this equation, as required. Figure 3 shows a plot of the model with 95% CIs fitted, and a Lowess smoother, which more clearly highlights the turning point and fall in sample size after 2005.

The reporting of sample size calculations in general

Across the whole time period of interest, the proportion of trials in which a sample size calculation was reported is 41% (95%CI 36.3 to 46.4).

The likelihood of reporting sample size calculations by time

From the logit model, the odds ratio for reporting a sample size calculation by year is 1.093 (1.06 to 1.13), $P < 0.00005$, Pseudo $R^2 = 6.7\%$ (*i.e.* very strong evidence of an increase in odds of reporting sample size calculation of 9% per year). However, model fit is improved by adding quadratic term in year (*i.e.* the increase in odds of reporting sample size calculation curves over time), $P = 0.0001$. In the quadratic model, $\beta_{year} = 0.057851$ (OR=1.060, 95% CI 1.017 to 1.104), $\beta_{year^2} = -0.0099829$ (OR=0.990, 95% CI 0.984 to 0.996), $P < 0.00005$, and Pseudo $R^2 = 9.7\%$. For use in prediction (*i.e.* where $Pr = e^{xb} / (1 + e^{xb})$ and xb is the linear predictor), the constant, when *year* is unadjusted and *year*² is centered on its average, is -115.806. Figure 4 shows the proportion of trials reporting sample size calculations, by year, and weighted by the number of trials per year, with fitted values for the probability of reporting a sample size calculation. It shows 2005 marks a turning point toward deterioration in terms of the proportion reporting sample size calculations.

1

2 Discussion

3 *Main findings*

4 Only around one-third of trials are powered to detect an ES of 0.5 or less. Only
 5 around 5% of trials are powered to detect ‘typical’ magnitudes of 0.3 or less.
 6 There is evidence of an increase of sample size over time from 1980, but the
 7 increase is trivial, and slips into decline from 2005. Sample size calculations are
 8 reported in only 41% of trials published between 1980 and 2012. The likelihood
 9 of reporting sample size calculation increases by several percent each year, but
 10 begins to decrease after 2005.

11

12 *Implications*

13 Large, high quality trials of interventions for back pain that have convincingly
 14 demonstrated effectiveness, suggest a typical ES for LBP interventions is around
 15 0.3.^{3,9,10} However, between 1980 and 2012, 95% of published trials have not had
 16 sufficient power to detect such magnitudes. There is a culture of conducting
 17 underpowered trials in the field of nsLBP research that needs to be addressed –
 18 the distribution of sample size shown in Figure 2 needs to be right-shifted.
 19 Underpowered trials have limited utility and are ethically questionable.

20

21 As explained at the introduction, meta-analytic techniques do not mitigate
 22 underpowered trials, as even in random effects models assumptions must be
 23 made about the between-study heterogeneity that may often be invalid;
 24 especially in cases where heterogeneity may be due to methodological reasons

1 rather than clinical heterogeneity.¹⁵ That said, there might be a place for smaller
 2 trials. As many larger high-quality trials of interventions for low back pain
 3 demonstrate only small-to-moderate differences, a counter-argument can be
 4 made that continuing to do these will do little to progress the field. Smaller well-
 5 conducted trials of novel interventions that are only powered to detect larger
 6 effect sizes could indicate promising avenues for intervention development.
 7 However, in such cases there should be clear rationale for this and great care to
 8 describe the novel intervention for subsequent replication.

9
 10 Only 41% of trials even report sample size calculations. In 1992, Cohen pointed
 11 out that while there is no disagreement between methodologists on the utility of
 12 such calculations, progress over the last 25 years had been slow.¹ It is regrettable
 13 that in the back pain field, in the quarter-century that followed his observation,
 14 progress continues to be slow. From 2005, it has even deteriorated.

15
 16 As change must be affected at the level of individual trialists, the implications are
 17 that trialists, funders, peer-reviewers, and journal editors each have a role to
 18 play in helping to improve the situation.

19

20 *Comparisons to existing research*

21 Castellini *et al*, in 2016, reviewed RCTs of mechanical low back pain published
 22 after 1968.⁷⁶¹ Among 222 included studies, they found that 36% reported a
 23 sample size calculation, but only 16% reported what they deemed complete
 24 calculations. They found that both reporting and completeness of reporting
 25 improved between 1968 and 2013, and show a relative decline in the proportion

1 reporting sample size calculations since 2005. This is consistent with our data.
 2 Their point estimate that 36% report sample size calculations is slightly less than
 3 ours. We suggest the following possible reasons; 1) Castellini's work dates back
 4 to publications in the late 1960s, which predates several calls for improvements
 5 in sample size (although only eight trials (3.6%) predate 1980); 2) our sample is
 6 based on 58% more trials; 3) Castellini's search used the terms 'rehabilitation',
 7 so the population may have been slightly different to ours; and 4) we required *a*
 8 *priori* reporting of the number of participants required to detect a given
 9 between-group difference, as minimum criteria to judge reporting the
 10 calculation. While it is clear how Castellini judged completeness of reporting of
 11 sample size calculations, it is not clear whether minimal criteria were used to
 12 judge reporting of a basic sample size calculation.

13
 14 Moher *et al* reviewed 383 trials, published between 1975 and 1990, exploring
 15 their power to detect 25% and 50% relative differences if null results were
 16 reported.¹⁷ They found that 25% reported null results, and of these only 16%
 17 and 36% had the power to detect these magnitudes of difference. They observed
 18 that these percentages did not increase over time. Whilst our results are not
 19 directly comparable, we found that sample size in general has increased over
 20 time, albeit by a trivial amount, until 2005. Moher also found that in trials
 21 reporting null results, 32% reported sample size calculations, and that this
 22 increased from 0% in 1975 to 43%, in 1990. Since we did not separately explore
 23 reporting in trials reporting null results, our results are not directly comparable,
 24 although we also observed an increase over time, at least until 2005. Given both
 25 Moher's and our results, we note the implication that in 1990, the likelihood of

1 reporting a sample size calculation seems greater if the trial reported a null
2 result.

3 4 *Strengths and limitations*

5 This work provides a useful account of trends of sample sizes in back pain trials
6 and reporting of sample size calculations. It comes from a comprehensive review
7 of trials that were published between 1980 and 2012, during which time there
8 were several calls to ensure such trials had appropriate sample sizes.^{1,17-19}

9
10 One limitation of our work is that we did not consider the extent of the reporting
11 of sample size calculations or likelihood of reporting by positive or negative
12 results. This work was part of a larger systematic review addressing several
13 other methodological research questions and these aspects were not prioritized;
14 however, we acknowledge Castillini's and Moher's useful contributions here.^{17,761}

15
16 Caution should be noted in using the quadratic models for future prediction, as
17 trajectories of falls will be predicted to continue along the quadratic curve, which
18 peaked in 2000 and 2005, respectively. Should any authors like to update the
19 model we will be happy to share our data. We could have described our findings
20 descriptively, but model fitting was useful insofar as it demonstrates the trend
21 and the weight of evidence for the observations.

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25

1 *Conclusions*

2 That the vast majority (95%) of trials are not powered to detect realistic effect
3 sizes might be considered unethical, unless novel interventions are being tested
4 and the small size is clearly justified. Increases in sample sizes have been trivial,
5 and decline after 2005. The majority of authors still do not report sample size
6 calculations.

7
8 Trialists should plan to make the size of LBP trials large enough to detect
9 realistic effect sizes and report sample size calculations. It may be justifiable to
10 power a trial only to detect large effect sizes in the case of testing a novel
11 intervention. Funders, peer-reviewers, editors, and readers should be vigilant for
12 and critical of underpowered trials, especially if these report null results.

Conflicts of Interest and Source of Funding: RF and MU are directors and shareholders of Clinvivo Ltd, a company that provides health outcome data collection services. These services were not used in this study. Høyskole Kristiania received funding from University of Warwick and Monash University to complete this research. Barts and The London Charity provided funding for the first stage of this research.

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Tables

Table 1: Inclusion and exclusion criteria, and the order of their evaluation

| | |
|---------------------|--|
| | Inclusion criterion |
| | RCTs of nsLBP |
| Order of evaluation | Exclusion criteria |
| 1 | Non-English language reports |
| 2 | Studies that were not RCTs or presented insufficient information for us to determine whether randomisation was used to allocate participants |
| 3 | Reports that self-identified as pilot/feasibility studies |
| 4 | Cross-over designs (because of limited utility in the LBP field) |
| 5 | RCTs with mixed samples (<i>e.g.</i> neck or thoracic pain in addition to LBP), samples of participants with radiating leg pain, or referred pain extending past the knee, or samples including LBP specific pathology (<i>e.g.</i> cancer, ankylosing spondylitis, or disc herniation) or pregnancy |
| 6 | Trials using solely objective or psychological outcome measures |
| 7 | Non-inferiority designs |
| 8 | Follow-up studies with no new outcome measures, and multiple publications. In the case of multiple publications, we included the first published article and excluded subsequent publications |

RCT=Randomised controlled trial; nsLBP=Non-specific low back pain

Table 2: Trials' ability to detect different categories of effect size

| Ability to detect category of d | n -band (average arm guide) where power=80%, $\alpha=0.05$ | Number of trials in category | Proportion of trials in category (95% CI) |
|-----------------------------------|---|------------------------------|--|
| $d<0.2$ | $392<n$ | 3 | 0.8 (0.2 to 2.3) |
| $0.2<d<0.3$ | $174<n<393$ | 17 | 4.4 (2.6 to 7.0) |
| $0.3<d<0.5$ | $62<n<175$ | 106 | 27.7 (23.3 to 32.4) |
| $0.5<d<0.8$ | $23<n<63$ | 175 | 45.7 (40.6 to 50.8) |
| $0.8<d$ | $n<24$ | 82 | 21.4 (17.4 to 25.9) |

Figure legends

Figure 1 – The figure shows a flow chart of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions.

Figure 2 – The figure shows histograms of average group size and logged average group size, with reference guidelines for effect size detection thresholds (assuming comparison to another group of equal size). Referenced effect sizes can be detected only by trials to the right of each line.

Figure 3 – The figure shows fitted values with 95% CI, Lowess smother and residuals of log sample size on year of publication.

Figure 4 – The figure shows the proportion of trials reporting sample size calculations, by year, and weighted by the number of trials per year, with fitted values for the probability of reporting a sample size calculation.

Figure 1

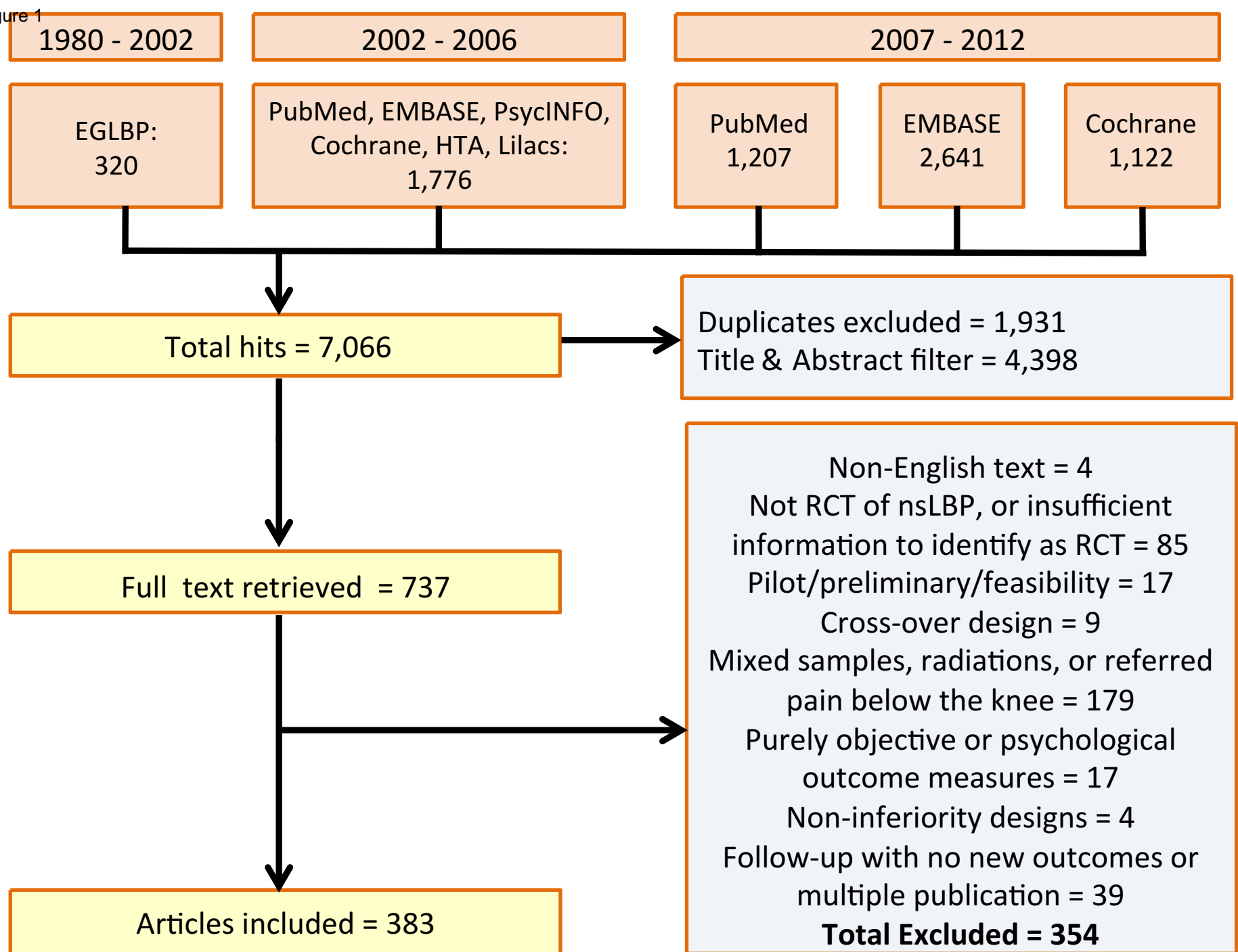


Figure 2

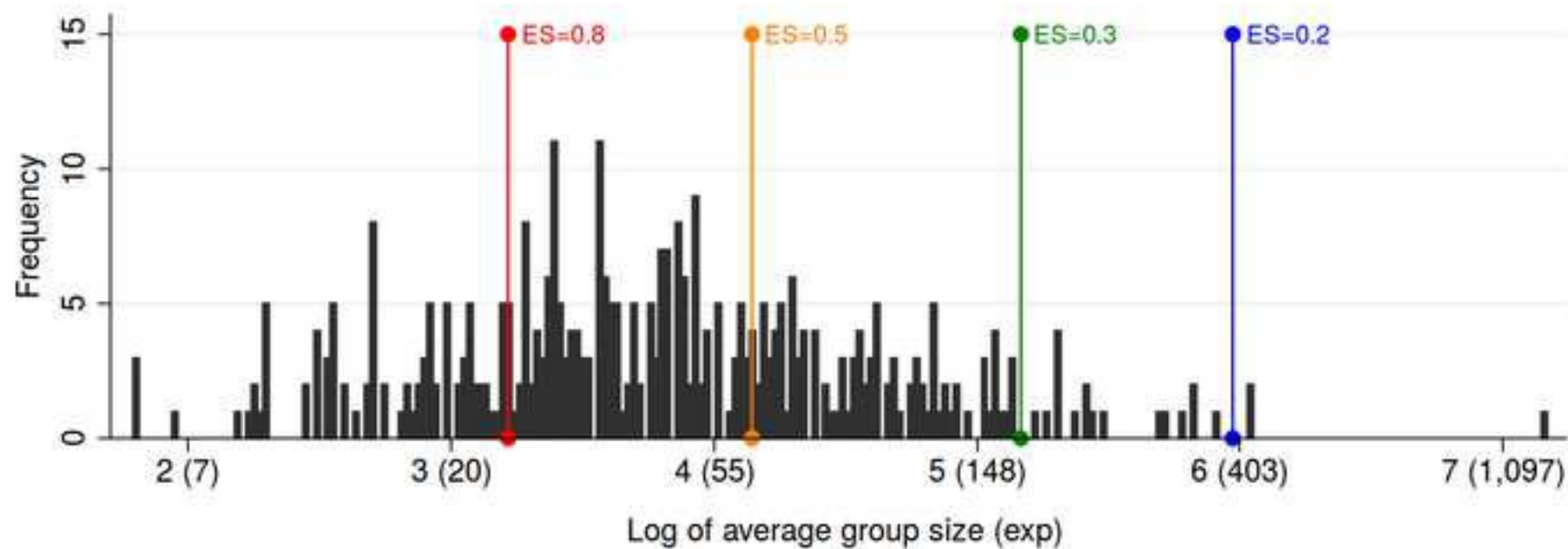
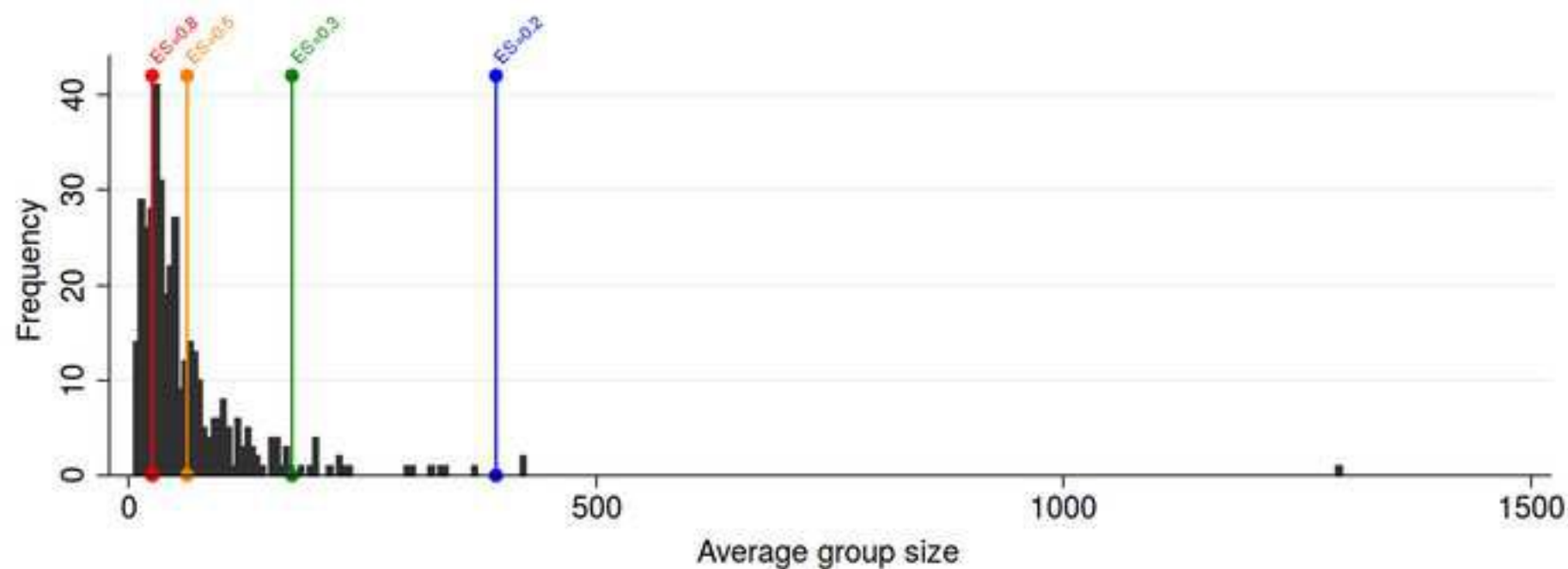


Figure 3

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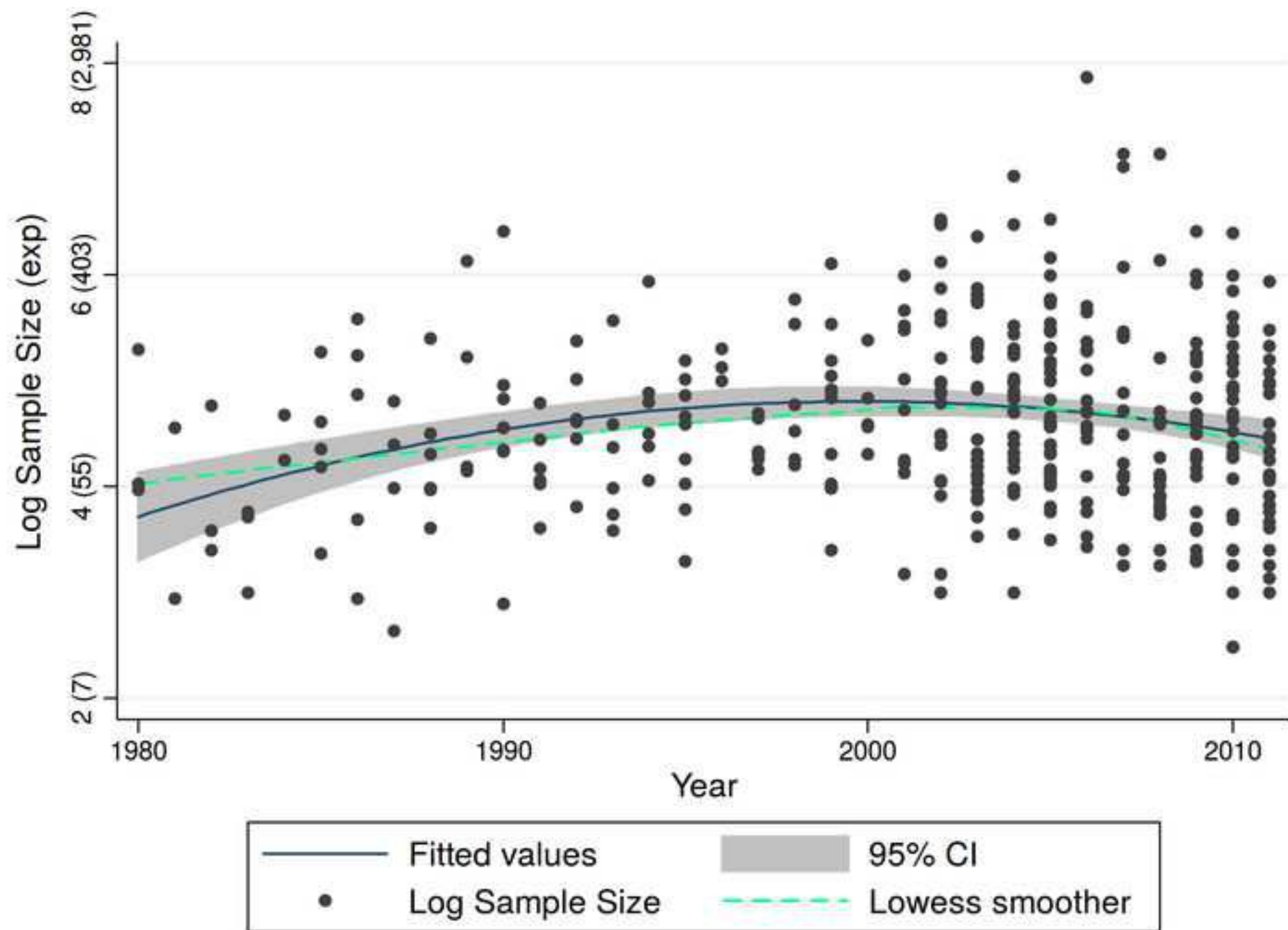
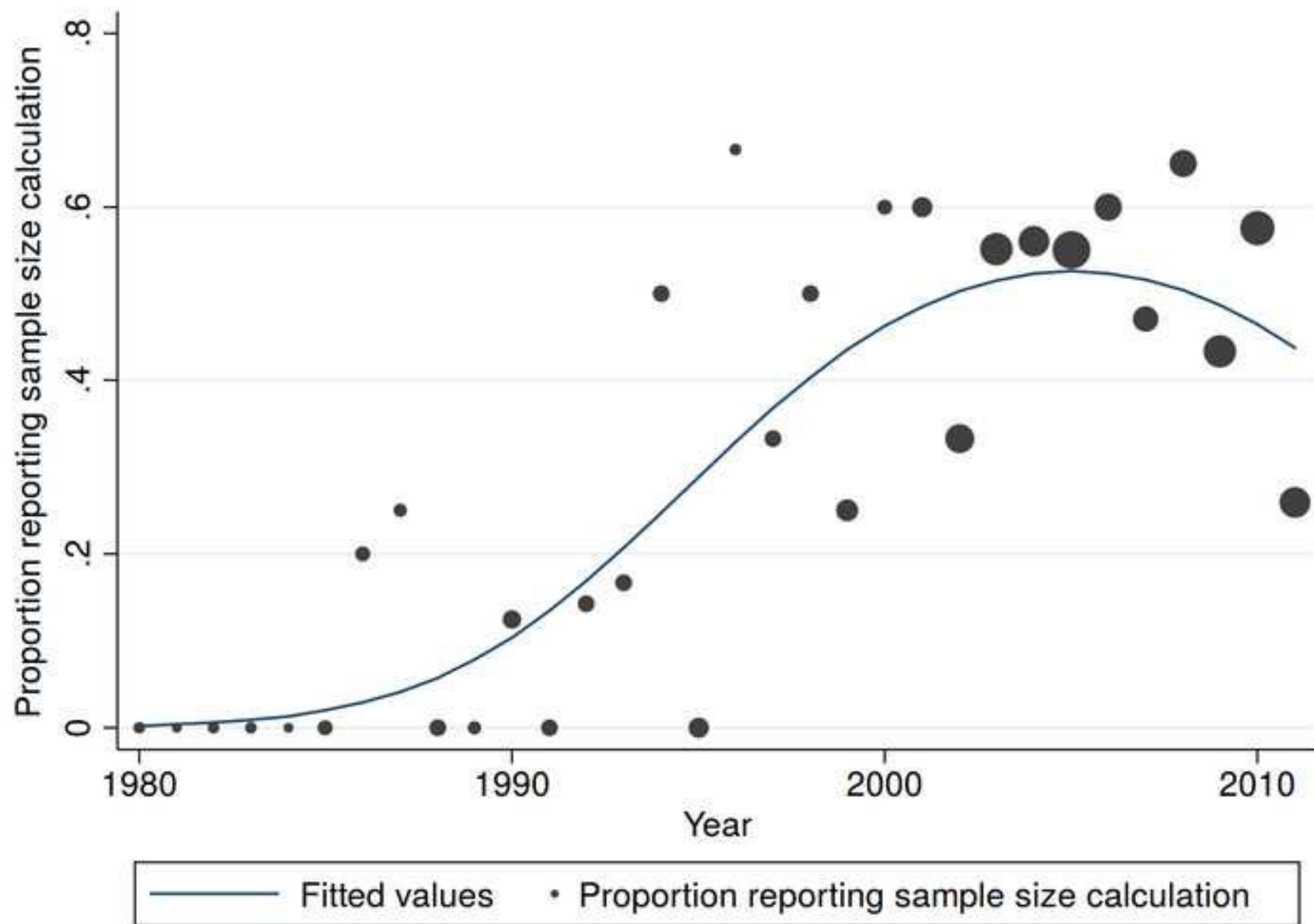


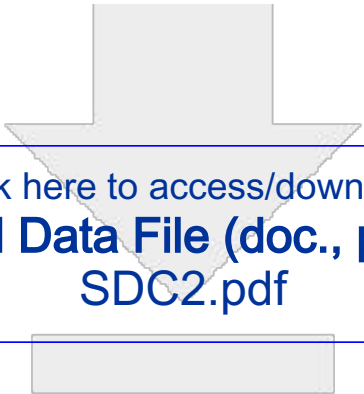
Figure 4





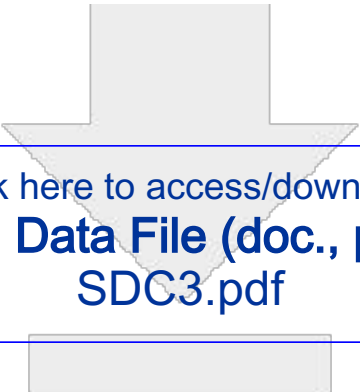
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