University of Basel

Department of Clinical Research

University Hospital Basel

Data Analysis Plan: 10 things to remember

Clinical Research Update Seminar

Marco Cattaneo, 25 October 2022

writing a Statistical Analysis Plan (SAP)

1. what?
2. when?
3. why?
4. how?

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   (it's in the name: a plan for the statistical analysis)
2. when?
3. why?
4. how?

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   (the main conceptual question: it is often required, but why?)

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   (since it is a plan: before the statistical analysis)

3. why?
   (the main conceptual question: it is often required, but why?)

4. how?
   (the main practical question: what should it include and how detailed?)

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SAP examples: SICS-I and CanCovDia

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> *If the blind review suggests changes to the principal features stated in the protocol, these should be documented in a protocol amendment. Otherwise, it will suffice to update the statistical analysis plan [...].*
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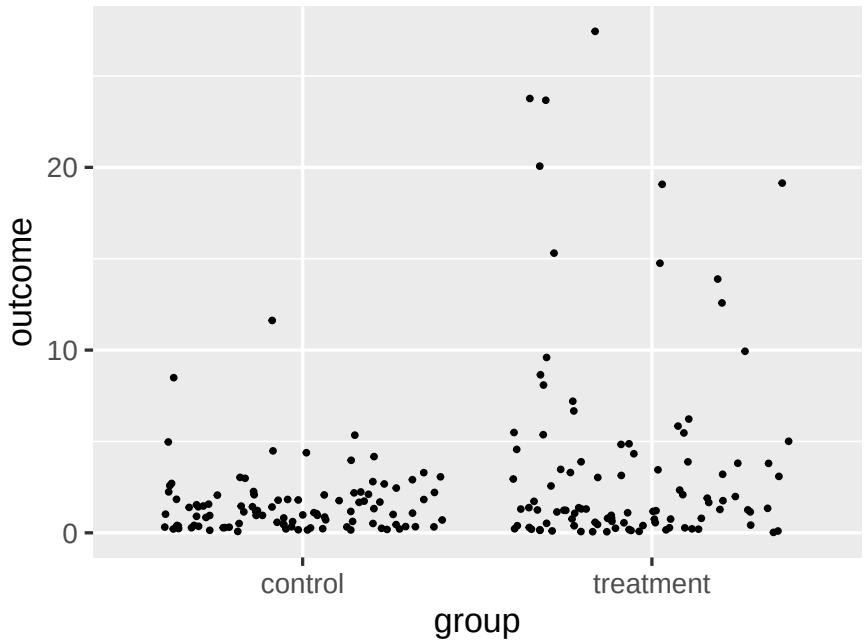
personal experience: on average preparing the dataset (IDA), writing the SAP, and performing the analysis each take roughly the same time

why?



testing the difference in average outcome between two groups (100 patients each):

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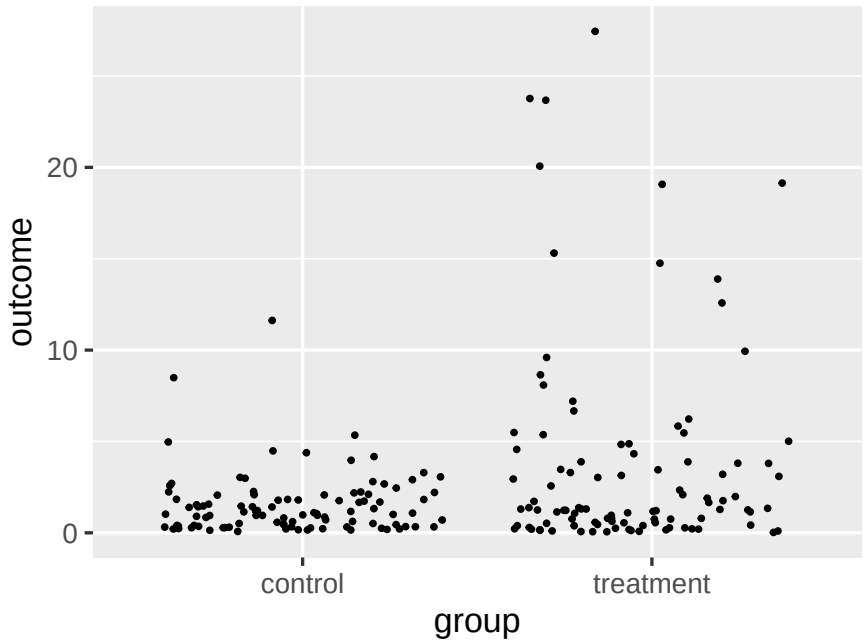

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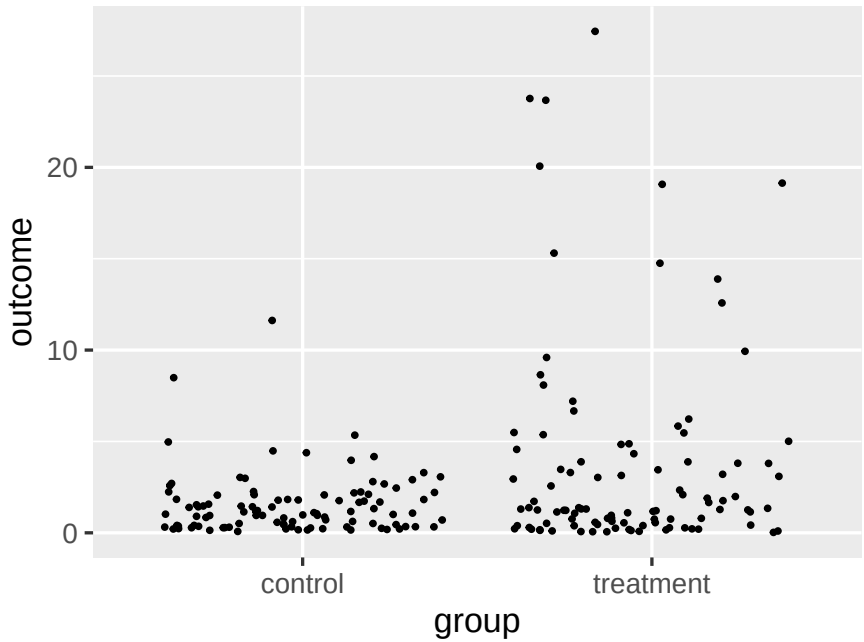

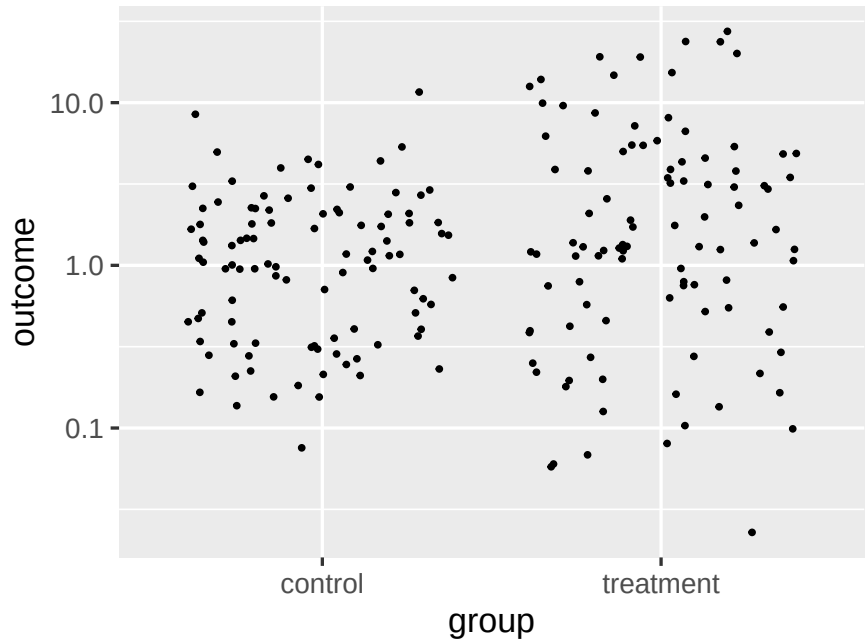

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- Welch's t-test for difference in mean log-outcome: $p=0.051$

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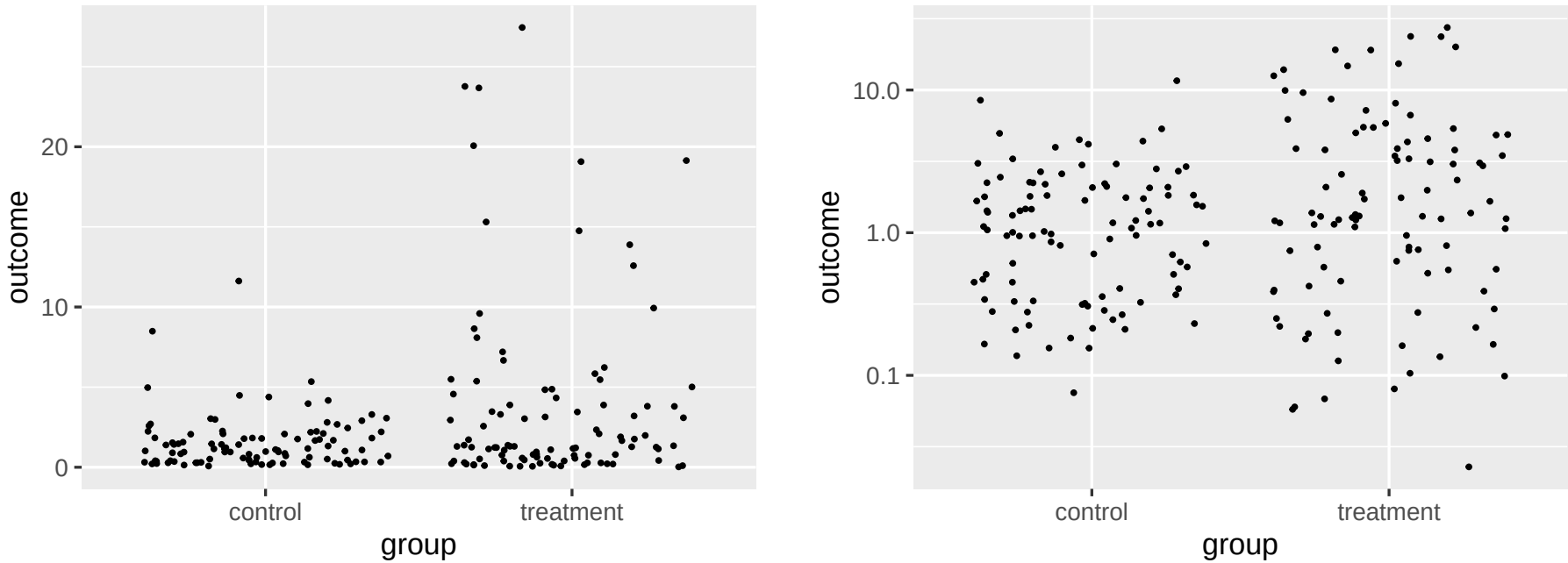

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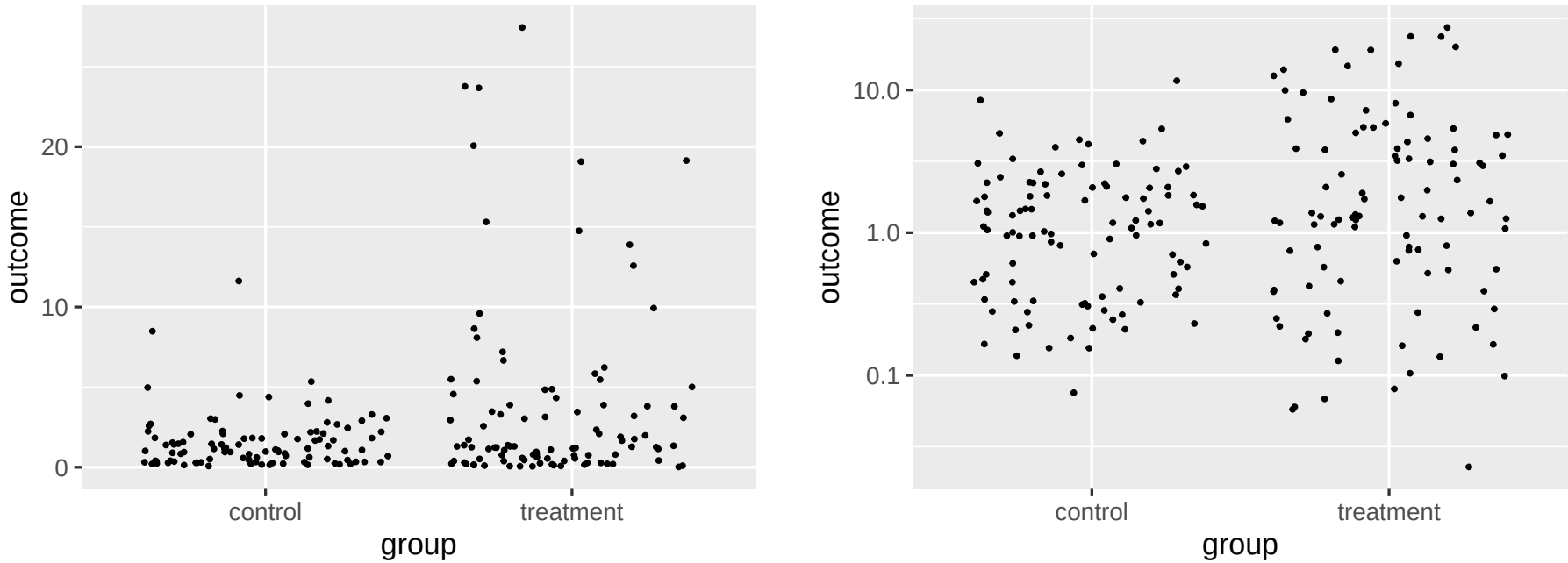

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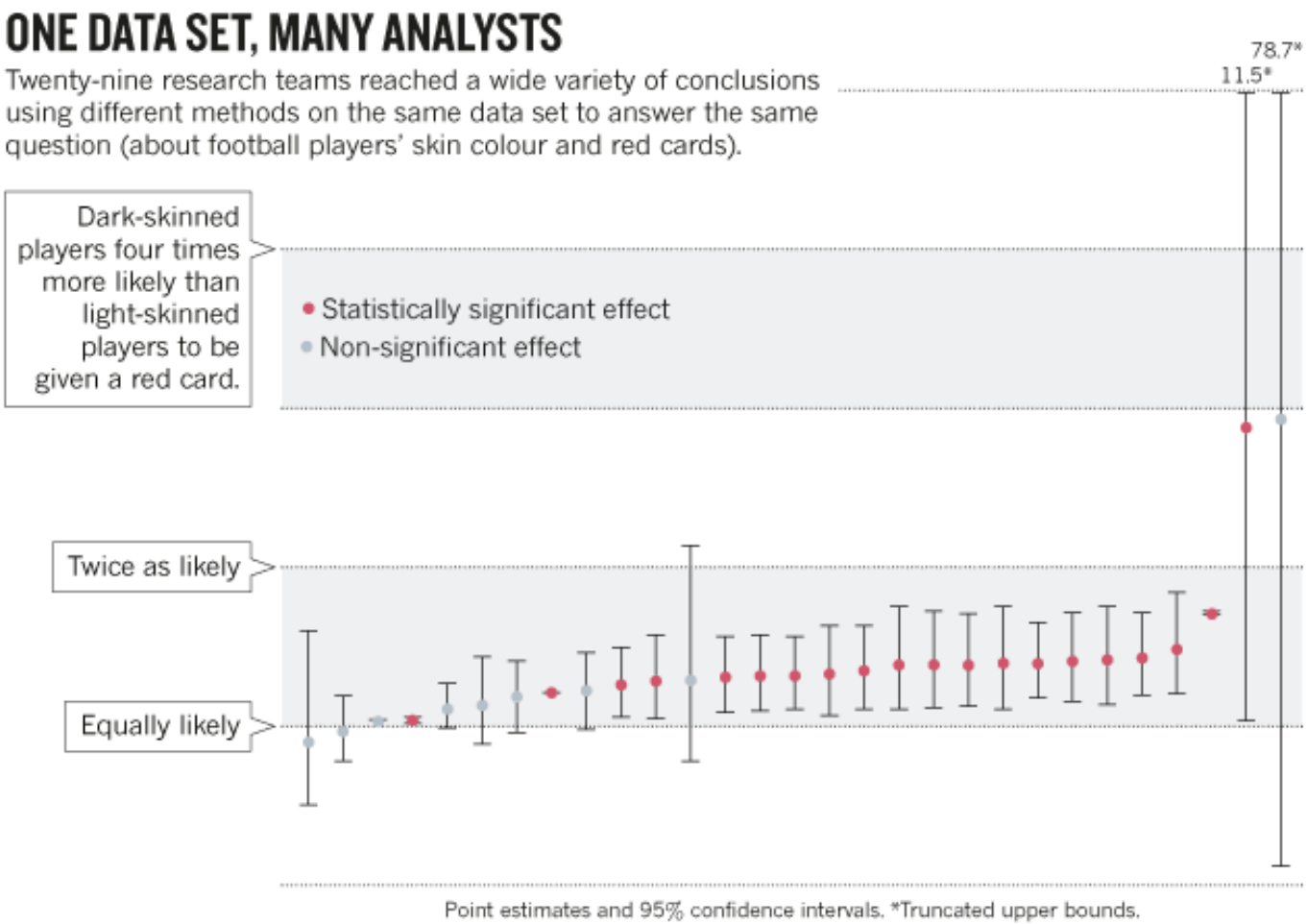
- Wilcoxon rank-sum test for difference in (log-)outcome distribution: p=0.046
- Mood's test for difference in median (log-)outcome: p=0.158

why?

Silberzahn and Uhlmann: Many hands make tight work [Nature, 2015]:



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- in particular, *p-hacking* (analyzing a question in different ways until a statistically significant result is obtained) and *data dredging* (analyzing many questions and selecting the statistically significant results) lead to too many false positive results (**multiple testing problem**)

why?

baseline characteristics of a randomized controlled trial [PLOS One, 2015]: 1 false positive in 23 tests (expected: 1 in 20)

Variable	MIT (N = 13)	HIIT (N = 15)	p-Value
Age (yrs)	20.0 (1.5)	20.0 (1.5)	0.7321
African-American	6 (46%)	2 (13%)	0.0957
Weight (kg)	89.7 (15.8)	94.3 (12.1)	0.4049
BMI (kg/m^2)	29.0 (3.4)	30.0 (3.1)	0.4215
Percent fat (%)	29.49 (5.08)	34.08 (6.45)	**0.0454**
VO_2 Peak (ml/kg/min)	34.95 (6.46)	35.72 (6.22)	0.7505
Peak Power (watts)	1022.4 (179.8)	891.0 (296.6)	0.1638
Resting Metabolic Rate (kcal/day)	1806.3 (215.3)	1835.4 (232.5)	0.7339
Total cholesterol (mg/dL)	163.0 (26.6)	169.3 (25.4)	0.5268
Triglycerides (mg/dL)	128.3 (103.7)	122.5 (55.9)	0.8228
HDL-cholesterol (mg/dL)	50.1 (9.2)	46.9 (10.6)	0.3985
LDL-cholesterol (mg/dL)	90.6 (16.8)	100.1 (19.4)	0.1762
Large VLDL Particles	5.18 (8.6)	3.3 (2.9)	0.5157
Medium VLDL Particles	25.81 (25.5)	24.55 (18.3)	0.8068
Small VLDL Particles	23.53 (11.5)	25.73 (16.3)	0.2355
Large HDL Particles	5.14 (2.7)	4.11 (2.2)	0.1665
Medium HDL Particles	11.63 (5.3)	13.75 (3.6)	0.6737
Small HDL Particles	15.53 (4.9)	12.91 (3.4)	0.355
SBP (mm Hg)	126.5 (12.7)	129.5 (9.7)	0.4890
DBP (mm Hg)	71.2 (6.9)	68.8 (7.0)	0.3727
Insulin Sensitivity (S_I)	4.57 (3.20)	3.60 (1.89)	0.3504
HOMA-IR	2.73 (1.55)	2.73 (1.33)	0.9990
QUICKI	0.3397 (0.0349)	0.3363 (0.0271)	0.7814

Table 2: Baseline characteristics of the two treatment groups. Values are Mean (SD) or N (%). Continuous variables were compared with a two-sample t-test with a Satterthwaite adjustment. Categorical variables were compared using Fisher's exact test. Boldface values indicate significance differences ($P < 0.05$).

doi:10.1371/journal.pone.0138853.t002

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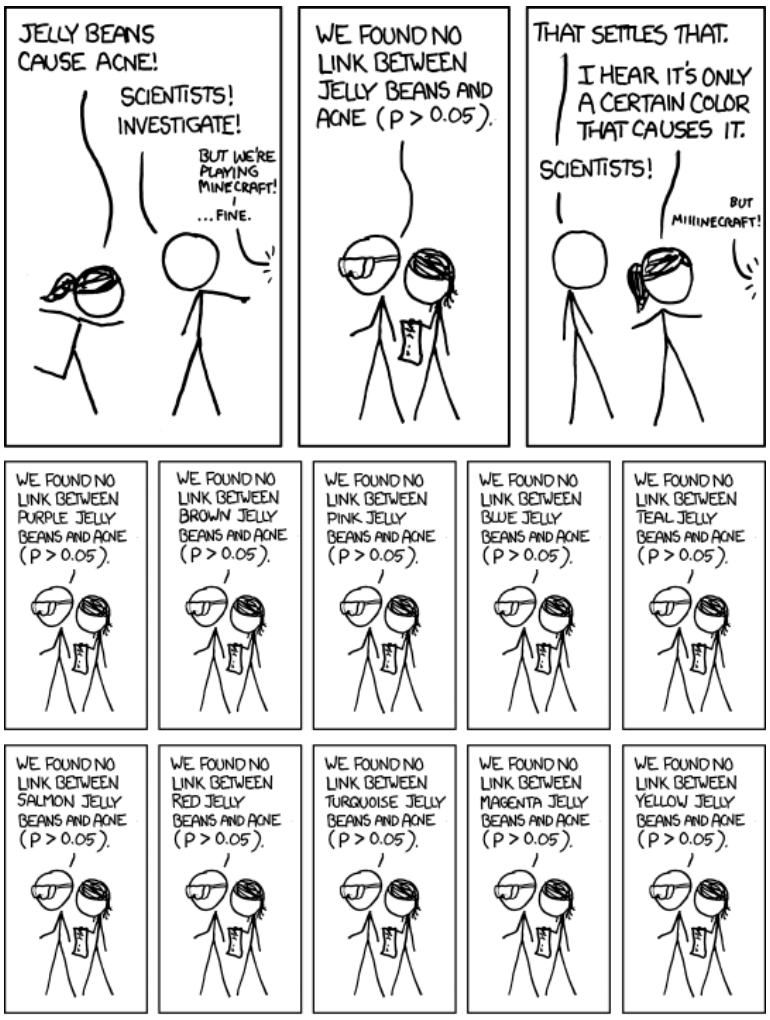

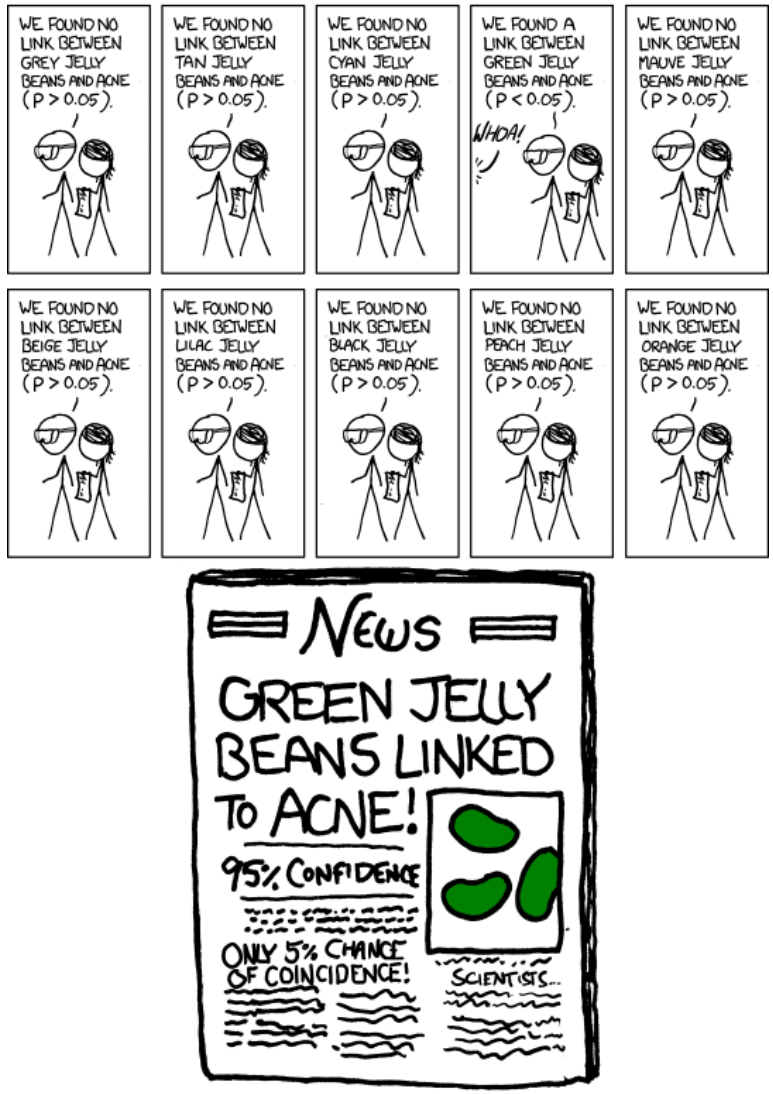

xkcd.com/882

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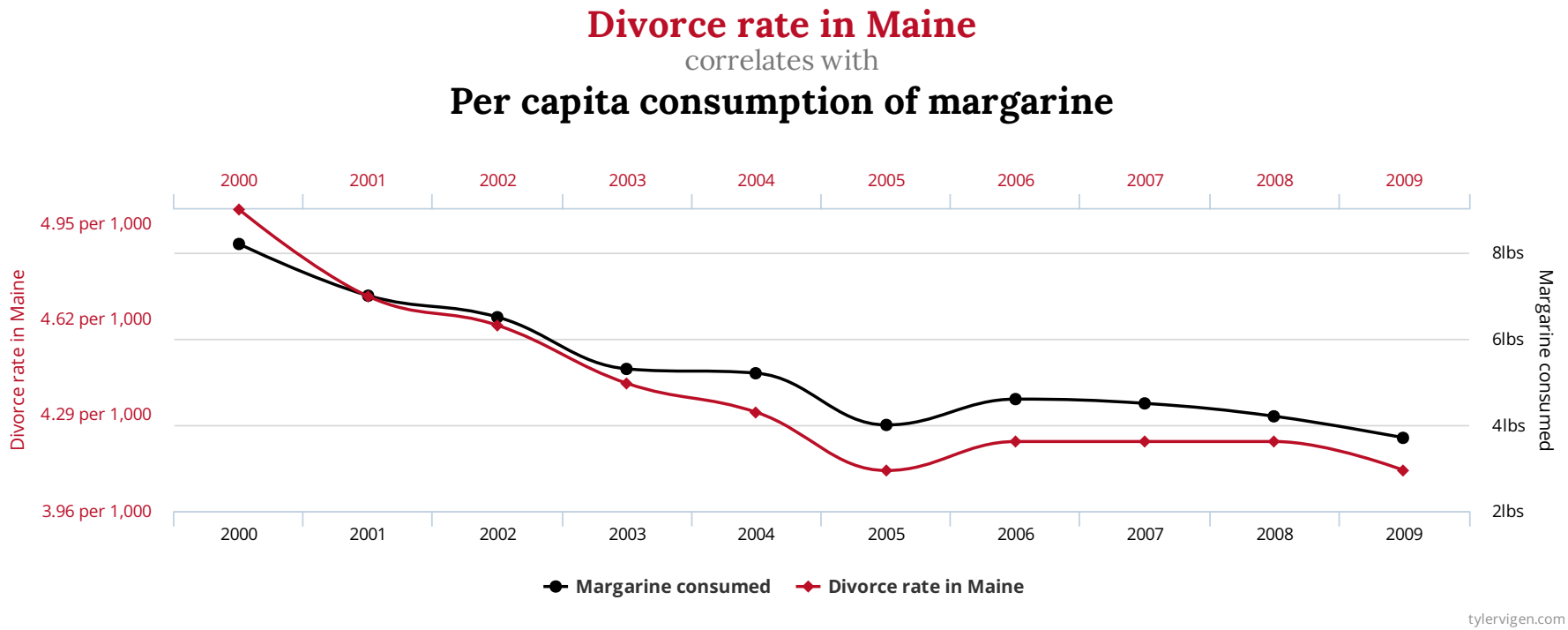
Divorce rate in Maine
correlates with
Per capita consumption of margarine
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
4.95 per 1,000
4.62 per 1,000
4.29 per 1,000
3.96 per 1,000
Divorce rate in Maine
8lbs
6lbs
4lbs
2lbs
Margarine consumed
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tylervigen.com

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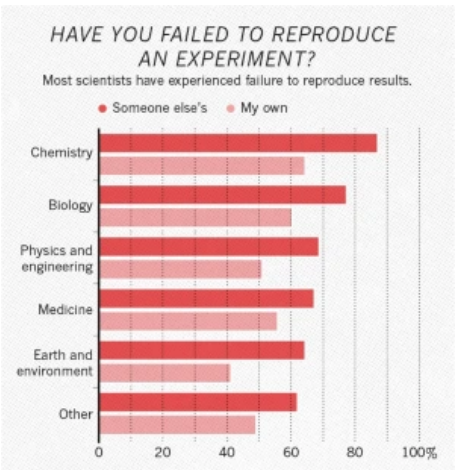
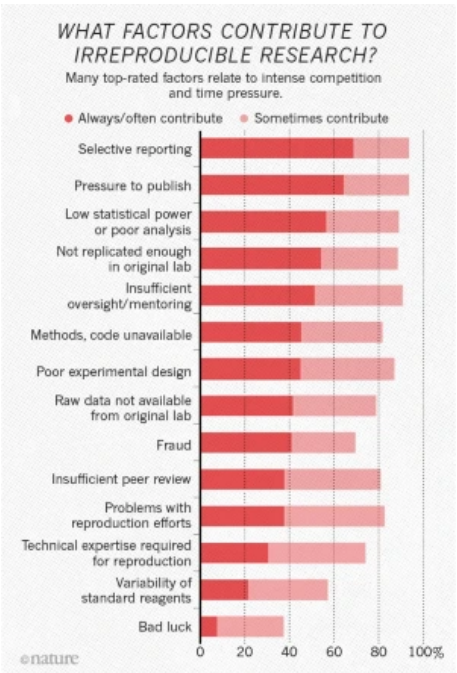
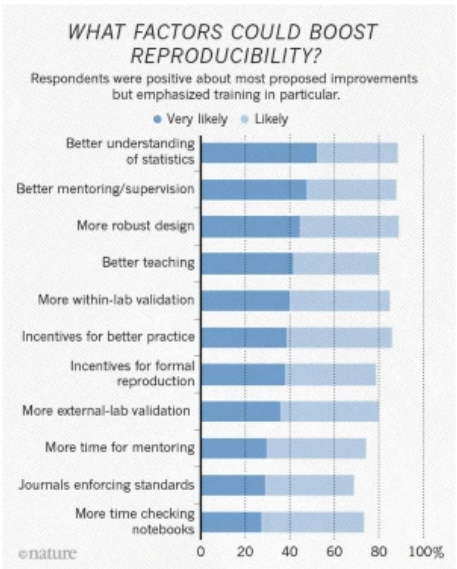
Baker: Is there a reproducibility crisis? [Nature, 2016]:







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- the only real drawback of SAPs for observational studies is costing time and resources for results that may anyway be of limited credibility

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- plan of how baseline characteristics will be summarized and possibly of which information will be included in a CONSORT flow diagram

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    - non-inferiority or equivalence margins
    - checks of model assumptions and alternative analysis methods
    - sensitivity and supplementary analyses
    - subgroup analyses
- description of planned exploratory analyses, which can be quite vague (but pre-specified exploratory analyses are usually considered a bit more credible than exploratory analyses tout court)

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- however, there are practical reasons opposing too much details:

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SAP examples again: SICS-I and CanCovDia

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10. *if you torture the data enough, nature will always confess* [Coase, 1982]

University of Basel

Department of Clinical Research

University Hospital Basel

Thank you
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