

## Acupuncture for Chronic Headache RCT Data

### Introduction to Data Set

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### Summary

Andrew Vickers, PhD (<https://www.mskcc.org/profile/andrew-vickers>) published an article in 2006 (Whose data set is it anyway? Sharing raw data from randomized trials; see reference below) that argued “data sharing should come to be seen as an inherent part of conducting a randomized trial...” As part of the article, he released the data set from an acupuncture trial on which he was PI (data is open and still available to download in Excel format – link below). This data set combined with the original primary report of that randomized trial and protocol paper for the trial provide a rich, real data example that can be used to create a variety of different classroom exercises. Some ideas:

- Composition of datasets, best practices for data documentation and sharing
- Descriptive statistics and table/figure creation
- Basic inference (confidence intervals, p-values)
- ANCOVA (*primary analysis used in RCT*) and related issues (ANCOVA vs ANOVA, etc)
- Handling of missing data
- Power and sample size
- Design issues (selection of comparison group, blinding, etc)

### Abstract

This data set contains data obtained from "Acupuncture for chronic headache in primary care: large, pragmatic, randomized trial", Andrew J Vickers, Rebecca W Rees, Catherine E Zollman, Rob McCarney, Claire M Smith, Nadia Ellis, Peter Fisher and Robbert Van Haselen, 2004 Mar 27;328(7442):744.

### Background

Chronic headaches (migraines and tension-type headaches), in addition to being miserable for its sufferers, are a significant public health challenge due to their associated costs (health, economic, and social). Available medications benefit some, while others seek alternative, non-pharmacologic, approaches.

### Objective

This randomized controlled trial aimed to determine the effect of acupuncture therapy vs. no acupuncture therapy on headache, health status, days off sick, and resource use in patients with chronic headaches. These measures were assessed at randomization, 3 months post-randomization, and 1 year post-randomization.



## **Subjects & Variables**

This dataset is a HIPAA de-identified. It consists of measurements of 13 variables on 401 consenting study participants at 36 sites.

## **Key Articles**

- *Primary report of Acupuncture RCT (publicly available):*  
Vickers, A. J., Rees, R. W., Zollman, C. E., McCarney, R., Smith, C. M., Ellis, N., ... Van Haselen, R. (2004). Acupuncture for chronic headache in primary care: large, pragmatic, randomised trial. *BMJ (Clinical Research Ed.)*, 328(7442), 744. PMID: [PMC381326](#)  
*Note that the main paper has an e-appendix that provides sensitivity analysis results for missing data which was substantial*
- *Design Paper for RCT (requires personal or institutional subscription):*  
Vickers, A., Rees, R., Zollman, C., Smith, C., & Ellis, N. (1999). Acupuncture for migraine and headache in primary care: A protocol for a pragmatic, randomized trial. *Complementary Therapies in Medicine*, 7(1), 3–18. PMID: [10361566](#). Available through ScienceDirect:  
<http://www.sciencedirect.com/science/article/pii/S0965229999800533>
- Project Report submitted to Funding Agency (NHS R&D Health Technology Assessment Programme; *Publicly available report*) → *This report contains much more detail than the primary publication about study details*  
[http://www.journalslibrary.nihr.ac.uk/data/assets/pdf\\_file/0008/64943/FullReport-hta8480.pdf](http://www.journalslibrary.nihr.ac.uk/data/assets/pdf_file/0008/64943/FullReport-hta8480.pdf)
- *Data from RCT (publicly available):*  
Vickers, A. J. (2006). Whose data set is it anyway? Sharing raw data from randomized trials. *Trials*, 7, 15. PMID: [PMC1489946](#)



## **Supplementary/Relevant Articles**

- Vickers, A. J. (2004). Statistical reanalysis of four recent randomized trials of acupuncture for pain using analysis of covariance. *Clin J Pain*, 20(5), 319–323. PMID: [15322438](#)
- Vickers, a. J., & Altman, D. G. (2001). Statistics Notes: Analysing controlled trials with baseline and follow up measurements. *Bmj*, 323(7321), 1123–1124. PMCID: [PMC1121605](#)
- Vickers, A. (2003). How many repeated measures in repeated measures designs? Statistical issues for comparative trials. *BMC Medical Research Methodology*, 3(1), 22. PMCID: [PMC280679](#)
- Vickers, A. J. (2001). The use of percentage change from baseline as an outcome in a controlled trial is statistically inefficient: a simulation study. *BMC Med Res Methodol*, 1, 6. PMCID: [PMC34605](#)
- Vickers, A. J. (2002). Placebo controls in randomized trials of acupuncture. *Eval Health Prof*, 25(4), 421–435. PMID: [12449085](#)
- Hrynaszkiewicz, I., Norton, M. L., Vickers, A. J., & Altman, D. G. (2010). Preparing raw clinical data for publication: guidance for journal editors, authors, and peer reviewers. *Trials*, 11, 9. PMCID: [PMC2825513](#)
- Hrynaszkiewicz, I., & Altman, D. G. (2009). Towards agreement on best practice for publishing raw clinical trial data. *Trials*, 10, 17. PMCID: [PMC2662833](#)

