

Quantified Self & single-subject design research (N-of-1)

Dr. Martijn de Groot

BeyondRCT Conference

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Ken u zelf

- Hippocrates (400 v. Chr.)
- Sanctorius van Padua (16^{de} eeuw) – 30 jaar lang eten/drinken
- Lifelogging & Personal Informatics (20^{ste} eeuw)
- Quantified Self (2007)



Gary Wolf



Kevin Kelly

Opening (and Swallowing) A Can of Worms to Treat My Crohn's Disease

Sean Ahrens, BS¹

Editor's Note: This article discusses the experience, ingenuity, and determination of Sean Ahrens, a young patient with Crohn's disease who took it upon himself to treat his longstanding, symptomatic Crohn's disease with pig whipworm eggs. Reading this story will make some of you uncomfortable. You might question whether this work belongs in a medical journal or sends the wrong message to readers. However, we recognize that this topic is controversial and that N=1 reports cannot and should not change practice. The purpose of this story is not to encourage the use of pig whipworm or to demonstrate its efficacy (or lack thereof). We firmly believe that patients are uniquely qualified to provide insights into how they view their illnesses, weigh risks and benefits, and ultimately achieve self-efficacy. Stories like this are important for us to acknowledge and understand, even if they do not change our practice.

Am J Gastroenterol 2016; 111:918–920; doi:10.1038/ajg.2016.193; published online 24 May 2016



Sean's Health Report

Consistency

- Solid
- Soft Serve
- Mushy Pile
- Water

Blood?

Choose ▾

Gut Pain

- Discomforting
- Disruptive
- Eruptive
- Debilitating

SUBMIT

Figure 2. Google form created for a smartphone to record symptoms every day: gut pain, bowel movements, and presence of blood in stool.

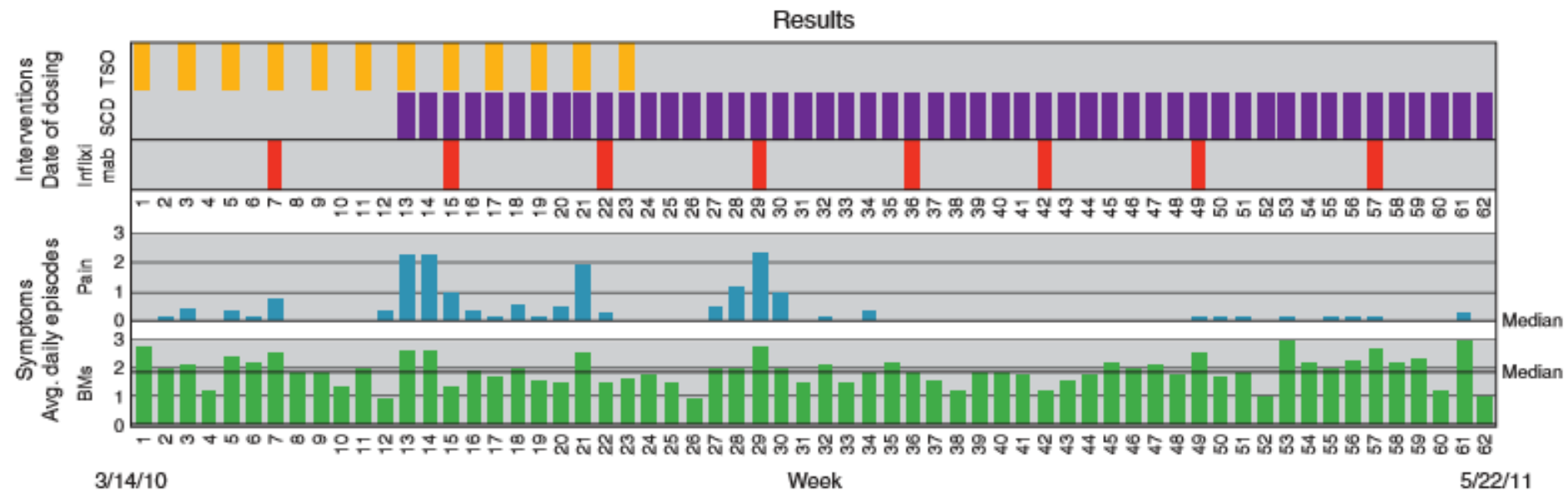
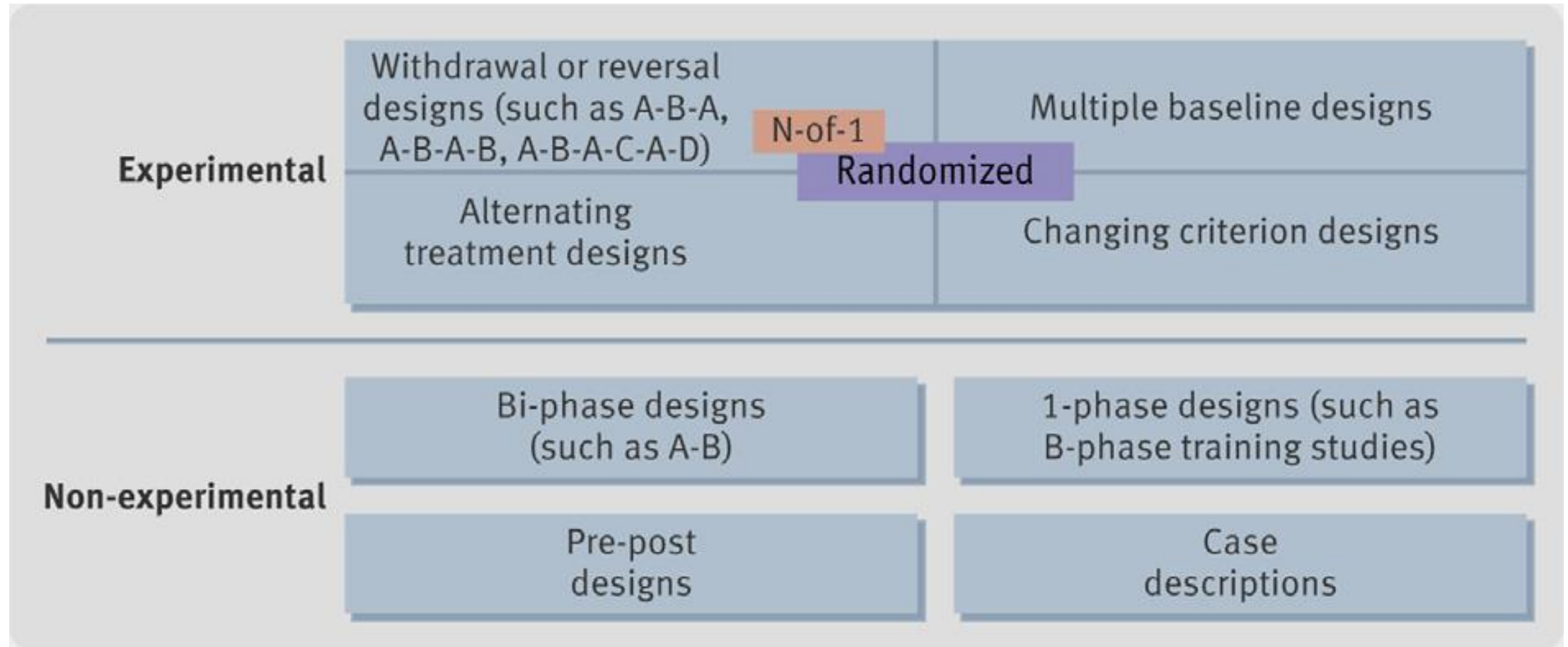


Figure 3. Symptom data over the 62-week collection period. Note, the visualization here summarizes pain and bowel movements into average daily counts and does not include or show their “consistency” or “intensity.” BMs, bowel movements; SCD, Specific Carbohydrate Diet; TSO, *Trichuris suis ova*. Note: Due to normal human circumstances of forgetting to log entries, episodes of pain and bowel movements carry some error of under-report.

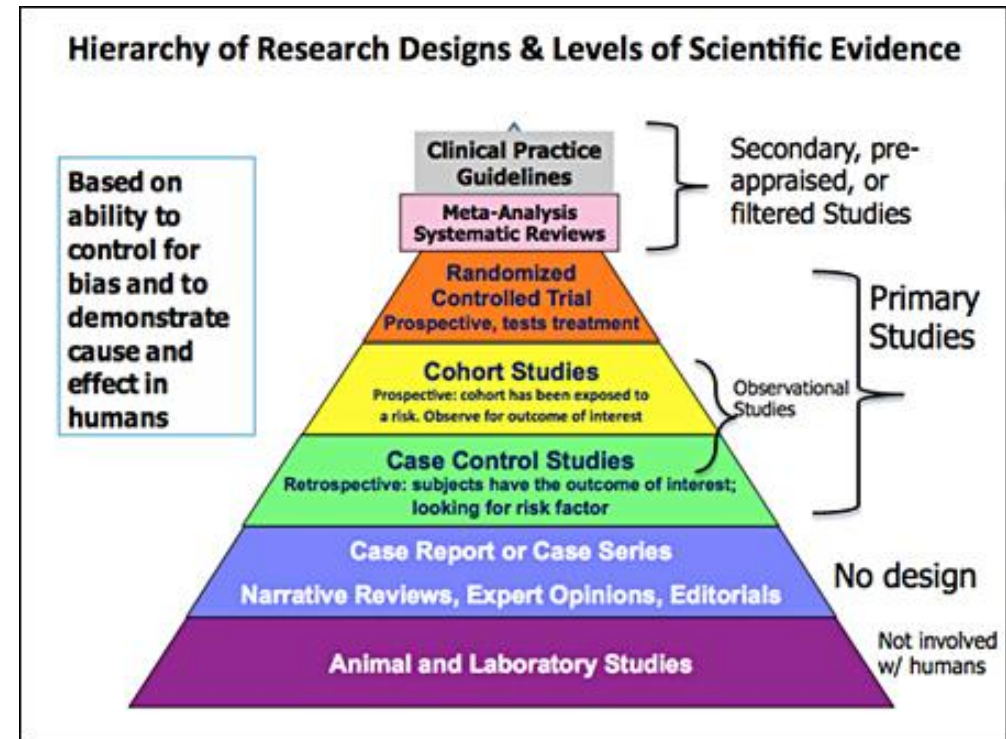
Why did I get better? Was it the pig whipworms (TSO)? Was it the SCD? Was it the natural course of the disease (i.e., Was I going to return to normal from my flare regardless of these interventions)? I do not know. I do not have the statistical power to tell you. Maybe TSO was responsible but had a highly lagging effect. I suspect that one or both of the interventions (TSO and SCD—and I am leaning toward SCD) assisted in my return to health. However, I cannot tell you that for sure. I am actually not entirely sure if it is possible to be conclusive in an experiment of one person. I do believe that if I had more baseline health data before starting the experiment, it would have helped these analyses. I am not sure, however, that it would make them conclusive.

N-of-1



Type 1 evidence if... (Oxford CEBM)

- One single person (patient)
- Two or more pairs of treatment period
- One for the intervention, one for the comparator
- Ideally double blinded (both patient and healthcare provider)
- Formal outcome assessment



N-of-1 failed as research practice in medicine

- Failure to show convincing benefits over standard clinical practice in several RCT's
- Generalisability limited to smaller groups of people
- Prospective protocol registration (hardly happens now)
- Incomplete reporting
- Marked variability in quality

ORIGINAL ARTICLE

Reporting quality of N-of-1 trials published between 1985 and 2013:
a systematic review

Jiang Li^{a,b,c}, Wei Gao^d, Salima Punja^e, Bin Ma^{a,b}, Sunita Vohra^f, Naihua Duan^{g,h},
Nicole Gablerⁱ, Kehu Yang^{a,b,*}, Richard L. Kravitz^{j,*}

- Consolidated Standards of Reporting Trials (CONSORT)
- Adherence to a recently published set of reporting guidelines (CONSORT Extension for N-of-1 Trials [CENT])
- The results show that there is considerable room for improvement in n-of-1 trials reporting.
- N=112 eligible studies:
 - 12 (10%) excellent (score >90% of CENT checklist items)
 - 56 (50%) good (50-90%)
 - 44 (39%) poor (<50%)

Personal meaning from personal data

Not everything that is important can be measured,
not everything that can be measured is important.



Dr. Martijn de Groot

martijndegr00t@hotmail.com

@grootm75

