

NEUWRITE NORDIC

(<https://neuwrinenordic.org/>)

Participant Work

Column

Nearly Everyone Recovered— Or Was it Just a Few?

by Jussi Valtonen



Mikko Kakela

Originally published (<https://www.laakarilehti.fi/mielipide/lahes-kaikki-toipuivat-vai-aika-harva/?public=3ef4c1178c0f9a0f10e997ee57023a89>) on 15 Sep 2023 in Finnish Medical Journal (Lääkärilehti). Reproduced here in machine translation for NeuWrite Nordic participants.

Imagine a study where those who were ill were given a homeopathic remedy. If the treatment didn't help, the remedy would be changed, possibly many times. The goal would be to

determine how many would recover in a year in this way. Criteria for recovery would be agreed upon in advance.

Researchers would report that 67 percent had recovered. This figure would be frequently repeated in the field.

However, imagine that upon closer scrutiny of the results, it was discovered that the criteria had been quietly changed to non-blinded criteria. Additionally, those who had dropped out of the study and even people who met the "recovered" criteria before treatment had been creatively counted as recovered. The researchers themselves had financial ties to the companies selling the same remedies.

Honest opinion: How convinced would you be of the remedy's effectiveness? How impartial would you consider the study?

I believe that many of us would be rather skeptical of what appears to be bias.

Unfortunately, this example is not about homeopathy. It is from the largest-ever antidepressant study, funded by the National Institute of Mental Health, known as STAR*D. It involved 4,041 patients and cost \$35 million. The researchers were leading professors in the field.

The goal was to determine how many depressed individuals would benefit from antidepressants within 12 months if treatment was optimally administered and medication was changed when necessary, even up to four times. The study was important not only because of its thorough treatment but also due to the representative sample of patients, who were people truly seeking help.

"Due to the lack of controlled research data, the results will have significant public health implications because they are obtained from representative participant groups/conditions," the researchers wrote.

The results garnered a lot of attention. They were published in the *American Journal of Psychiatry* and the *New England Journal of Medicine*.

"After four optimized, well-targeted treatments, about 70% of patients recovered," declared a scientific editorial. The same figure was quoted by NIMH's (former) director Thomas Insel. Even last year, 16 years after the results were published, the *New York Times* reiterated that "nearly 70% of patients were symptom-free after the fourth treatment."

However, psychologist Ed Pigott was puzzled by the results. Pigott had used the same primary outcome measure in his own research. He wanted to compare his results to NIMH's large representative sample. But when he looked at the results, Pigott couldn't find the most important primary outcome measure anywhere. It wasn't reported at all. He wondered where it had gone.

Pigott wanted to find out what had happened. He obtained the research data.

The frequently quoted result of 70% recovery is misleading, according to an analysis by Pigott and his colleagues, which was published in *BMJ Open* this summer.

The results were inflated by changing the originally reported primary outcome to another—a non-blinded clinical assessment that was said to be used only as a support for treatment. Additionally, people who had met healthy criteria before treatment were counted as recovered with medication. Dropouts were also counted as having recovered with medication, even though dropping out of treatment often indicates that the patient did not benefit from it.

Only 35% actually recovered, according to the new analysis. (Without a placebo control, it is not known what portion of this is explained by the placebo effect and spontaneous recovery.)

If the results had been reported as pre-registered 17 years ago, the medication-centric treatment model for depression would likely have faced substantial criticism, the researchers note. Over the years, people might have also asked what would work better.

NeuWrite Nordic ry | 2024