
Colin Binns, MBBS, PhD1 and Wah Yun Low, PhD2

In epidemiology and public health, there is ongoing debate about the level of research required to recommend a new intervention, or modify an existing program. Such is the strength of randomized controlled trials (RCTs) that the debate is now centered on whether there are any situations where a RCT is not warranted. The development of meta-analyses and the techniques of systematic reviews has only served to strengthen the preeminence of RCTs. One of the questions editors now look at when considering a paper for publication is its potential for incorporation into future meta-analyses.

The first known RCT in public health was in the late 18th century when Dr James Lind studied the effect of lime juice and the prevention of scurvy.1 Perhaps the earliest and best-known modern RCT was the Medical Research Council trial of streptomycin in the treatment of tuberculosis under the leadership of Sir Austin Bradford-Hill.2 Since then the RCT has become the “gold standard” with a synthesis of RCTs (meta-analyses and systematic reviews) providing the basis for evidence-based practice in public health and clinical medicine. The number of trials has grown rapidly, and there are now more than 600 000 controlled trials listed in the Cochrane database.

But in many situations RCTs have not been done. For example, there were no proper trials of insulin or penicillin before their first use, as there was simply not enough raw material available for a trial with an adequate sample size. The annual Christmas issue of the British Medical Journal (BMJ) always includes a selection of unusual and humorous articles that are worth reading. For the 2003 issue, Smith and Pell wrote an article on parachutes that has since been cited 600 times.3 They attempted a systematic review of the use of parachutes to prevent death after jumping out of an aircraft. They found that “no randomised controlled trials of parachute use were found, largely due to the infrequency of the injuries or deaths involved.”