THE EVIDENCE DEBATE

The Cochrane Collaboration, now twenty years old, conducts systematic reviews of randomised controlled trials (RCTs) of health-care interventions. But how relevant is the RCT to the addictions field? RCT is on trial here with **Tim Leighton** and **Ed Day**.

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There is no doubt that for many kinds of intervention the meta-analysis of high quality randomised controlled trials (RCTs) is a route to more certain knowledge about their efficacy than any other review method.

However there is a rising chorus of discontent about the evidence in the drug and alcohol fields, particularly about psycho-social interventions such as "talking therapies" and complex social programmes such as therapeutic communities and mutual help organisations. This discontent is very far from anti-scientific in character: it is not coming from people who don't like the conclusions of the reviews because they challenge their beliefs or self-interest. Rather the voices are from among the most experienced and respected scientists in the field, each has related but different reasons for arguing that this evidence hierarchy has serious limitations.

The main arguments involve the research design itself and its relationship to real-world settings, the assumption that psychosocial interventions are technological, involving specific, theory-based active ingredients that can be packaged and tested, the question as to how causality can be established scientifically, the quality and quantity of the trials in specific areas, and whether or not the emphasis on RCTs is a problem for innovative and evolving treatments. Many of these arguments have been presented clearly and convincingly in the literature, but one aspect of the problem has yet to be properly articulated.

This is the very narrow, de-socialised view of science which maintains that truth about causality can only be established with controlled experiments. The main problem is that psychosocial interventions and programmes *do not have causal powers in themselves.* The causes of change in participants and recipients of such interventions are processes of changing reasoning (including emotional reasoning) and making use of resources offered. These causal powers are known to realist social scientists as 'mechanisms' and these are activated or inhibited according to a variety of contexts. This simple truth explains the baffling and contradictory results of apparently similar trials and the notorious failure, well-known to criminologists and health promotion researchers for example, of experimentally verified programmes and interventions to generalise to other social and cultural contexts. Different social contexts and positions provide different reasons to people to act.

What a significant positive result from an RCT of a psycho-social intervention actually tells us is that for this particular sample in this particular context the intervention studied was more effective than something else in activating change mechanisms. And this would be great if further trials revealed a consistent picture, but they very seldom do, so the solution is seen to lie in pooling and selecting for quality in the hope that a forest plot will reveal a significant trend. But what if the contexts and populations are different in the various studies? And could it not be that a study

in which CBT say, is found to be superior to Motivational Interviewing (MI), and another in which the reverse is found, both have something important to tell us about how interventions succeed or otherwise? Simply putting these and other studies into the mincer of meta-analysis squeezes out the significance of ground level variation in outcomes which is likely to be crucial in the application and contextual adjustment of interventions required to improve their effectiveness. As Ray Pawson has pointed out, the outputs of meta-analyses are means of means of means of means!

The Cochrane Review by Smedslund et al. (2011) on MI concludes that practitioners may be confident that doing MI is probably better than doing nothing, but that the evidence is not strong enough to conclude that MI is any more effective than a range of other things. As well as the usual recommendation for more trials, this review goes on to say: "This is a field where there is no lack of randomised controlled trials. Perhaps it is time to move from only studying whether MI works to also studying how it works, that is to study the mechanisms behind MI." The answer to finding out what is likely to work might not be more or better designed RCTs even when such studies are practical or viable. There is a large literature on mechanisms which has been accumulating since the 1970s. This literature has in my view been pushed aside by the dominant and perhaps simple minded idea that evidence from reviews of RCTs is the gold standard and the sole source of the truth about effectiveness. The value and utility of a good RCT is not in doubt, but the limitations of this method are hiding in plain sight, and it is time for the field to explore and understand these.

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If we want to know if an intervention is effective at achieving a specific outcome, we could simply deliver the intervention and observe the outcomes. However, even if it is successful, how would we know whether it was the intervention that caused the result or some other factor? Furthermore, we know that people that put themselves forward for a particular intervention are systematically different to those that do not. They may be more motivated to make a change for example, or have higher levels of social support encouraging them to attend. This is likely to mean that any positive effects of the intervention will be exaggerated. Both factors are examples of 'bias', or systematic errors or deviations from the truth in results or inferences. Bias can lead to both under- and over-estimations of the true effect of the intervention.

The solution is to use a randomised controlled trial (RCT). This type of research experiment is an attempt to ensure that the people receiving both interventions are as closely matched as possible. In its simplest form, all people that are eligible are randomly divided into two groups, one of which gets the normal current intervention and the other gets the new intervention. By *randomly* assigning people to groups we can eliminate the possibility that external factors affect the results and demonstrate that any differences in the pre-specified outcome between the two groups are a result of differences in the interventions.

RCTs are now the universal means of assessing which of two medical treatments works best. RCTs are used in areas as diverse as business strategy, international development work, public policy, and even the criminal justice system. However, Cochrane's major contribution was the recognition that such valid evidence was not usually accessible to decision-makers. The sheer quantity of research available from a rapidly increasing range of sources meant that it was difficult for anyone to keep up, and reviews of the literature were crucial. However, these also need to follow scientific principles in their preparation, as otherwise the views of experts (presented in textbooks) often ignore evidence for effective treatments and continue to recommend ineffective ones.

Reviews conducted under the banner of the Cochrane Collaboration respond to this challenge by identifying, appraising and synthesising research-based evidence and presenting it in an accessible format. Transparent and consistent procedures are used to find, evaluate and synthesize the results of relevant research. Procedures are explicitly defined in advance, in order to minimize bias and to ensure that the exercise can be replicated by anyone else that wishes to do so. Furthermore, RCTs may be expensive and difficult to organise at a practical level, and so may be 'underpowered', i.e. lacking sufficient numbers of participants to detect small but potentially important differences in outcomes. A systematic review can overcome this by using statistical methods (meta-analyses) to combine the results of a number of smaller studies to effectively make one larger one.

The work of the Cochrane Collaboration is not a panacea for all ills, and the RCT may be less useful in conditions where the intervention and the outcome cannot be clearly defined and measured. However, I would argue that the 20th birthday is a cause for celebration for two main reasons. Firstly, the inclusion of drug and alcohol problems as a topic area is important to raise the profile of the problem and to challenge the stigma often associated with addiction. The Drugs and Alcohol Group was registered with the Collaboration in January 1998. As of March 2013, 66 reviews had been completed, covering treatments from acamprosate to Alcoholics Anonymous.

Secondly, the egalitarian nature of the Collaboration and its procedures should reassure clinicians and clients alike. When RCTs were first introduced in medicine they were strongly resisted by some clinicians, many of whom believed that their personal expert judgement was sufficient to decide whether a particular treatment was effective. Likewise in the case of addiction there is a danger that experts by experience may 'prescribe' the pathway to recovery that worked for them, regardless of whether it works for another individual. Both groups may be right, but such confident predictions about treatment made by experts have also proved to be wrong in the past e.g. the failure of the 'Scared Straight' programme for deterring juvenile offenders. A Cochrane systematic review strives to present the whole picture, and do so in a way that invites critique and improvement. This puts vested interests to one side, and can only benefit the consumer.