

Book

Testing times for clinical research

12 years ago I crossed the line between clinician and patient when, at the age of 33 years, I found out that I had breast cancer. At the time, I was doing a PhD about the problems of using randomised controlled trials (RCTs) to assess the effectiveness of treatments in my own discipline (orthodontics). During my research, I had become aware of the benefits of taking part in clinical trials and, ironically, the uncertainties about treating younger women with early breast cancer. So at the time of my diagnosis I asked my consultant if there were any RCTs that I could take part in. His response shocked me. He said that I “must not let academic niceties get in the way of the best treatment for me”. But what was the best treatment? I certainly didn’t know and also recognised that the profession was questioning what the optimum treatment was for early breast cancer in women younger than 50 years. So what was I to do?

After a traumatic weekend and a few phone calls, I succeeded in having my care transferred to another consultant at a nearby teaching hospital. He welcomed my request to enter a trial and recruited me into one that was assessing three different breast cancer treatments for women in my age-group. This chain of events led me to believe that it is desirable for people to understand the issues surrounding clinical trials before they became ill, rather than having to weigh up the “academic niceties” at the same time as coming to terms with their illness.

During the trial I did not know if the treatment I was taking was the best treatment option, but for me what was important was the taking part and not the winning. 12 years on, I know that I was not in the “winning” group of the trial, but in my own way I feel I have won. I am still alive, I have had two wonderful children

since I finished my treatment, and have seen the outcome of the trial I was in benefit two close friends with early breast cancer.

My experience made me welcome the message so forcefully argued by Imogen Evans, Hazel Thornton, and Iain Chalmers in *Testing Treatments: Better Research for Better Healthcare*. These authors bring together the

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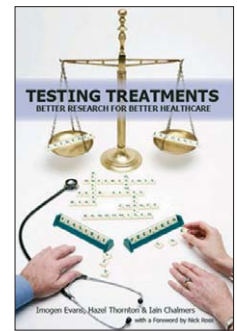
important issues involved in the introduction of new treatments. The aim of the book is to foster collaboration between patients and clinicians and to encourage researchers to develop clinical trials that ask questions that are relevant to both, that are ethically run, and that produce results which are disseminated and incorporated into clinical practice. *Testing Treatments* will inform patients, clinicians, and researchers alike.

As clinicians, we are encouraged to base our practice on sound evidence and to fully inform our patients of all treatment options. *Testing Treatments* will help us to achieve this goal: it makes us question how sound the evidence is in terms of why and how the research was done, which outcomes were assessed and reported, and who paid the bill. From a patient’s point of view, however, *Testing Treatments* may be a little disturbing: the inherent uncertainty of clinical trials is not something that every patient wants to embrace. For some patients, being asked to take part in a clinical trial may feel as if they are being asked to be a research guinea pig when all they want is to be

given the best treatment available. By contrast, other people seem willing to test out a new drug or treatment, which has not yet been fully assessed as being effective for their disease type or severity, if there is a chance that it might cure them.

How do we reconcile these, often conflicting, positions? How good are clinicians at accepting, admitting, and discussing uncertainty about which treatment is best for any particular patient? How good are patients at balancing the risks of their disease against the relative risks and benefits of the treatments on offer? Somehow we must come together to acknowledge these uncertainties and ensure that the most promising treatments are tested fairly, outcomes relevant to patients are measured, and that once found to be effective, an intervention—be it a drug, operation, or diagnostic test—is made available to those who would benefit from it.

Testing Treatments discusses these scenarios in a logical, upbeat, and accessible way. The book starts by quashing the notion that new always means better. The authors eloquently point out that this is not always so and explain how some treatments, which had been in common use, were found to be at best ineffective and at worst harmful when given a fair test against no treatment, a placebo, or an alternative intervention. They also reveal how the introduction of effective treatments has been delayed because nobody had kept track of the published results of clinical trials. The justifications for, and the theory behind, RCTs (fair tests) are explained in a lucid way. Examples are also provided of how selective reporting and a failure to keep abreast with the results of all trials can influence the perceived effectiveness of an intervention.



Testing Treatments: Better Research for Better Healthcare
Imogen Evans, Hazel Thornton, Iain Chalmers.
British Library, 2006. Pp 224.
£12.95. ISBN 0-7123-4909-X.

Testing Treatments gives new credence to the uncertain clinician. He is not someone whose knowledge is deficient, but rather is someone who acknowledges that there are uncertainties about what is best, tries to make sense of the available evidence, and is willing to express these uncertainties clearly and test them fairly. This particular message of the book really struck home for me, since it described a clinician who was the complete antithesis of the first consultant I saw. However, during my most recent consultation about my future treatment options, the first thing my current consultant did was to admit that there was uncertainty about how best to treat women in my situation. He then went on to explain about an RCT for which he was recruiting patients.

I could not believe my ears. How things had changed in 12 years. Perhaps I should not have been so surprised. I have seen an acceptance of uncertainty and an increase in published RCTs in my own speciality during this time.

Testing Treatments sets out a blueprint as to how we all—clinicians, patients, and researchers—can take clinical trials forward. As clinicians, we need to accept uncertainty, either individually or collectively, and realise that the treatments that we learnt were the most effective when we sat finals may not be today. We need to be willing to take part in clinical trials and invite our patients to participate in research that is appropriate to their situation. As patients, we need to realise that if we feel that we have the right to the

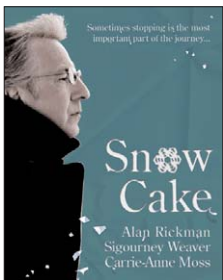
best treatment then we also have a responsibility to help find out what that might be and be willing to take part in clinical trials, if we think they are applicable, and are invited to do so. As researchers, we need to make trials that are worthwhile and relevant to participants. If we can truly collaborate, so that patients and potential patients are involved in the design of clinical trials, then hopefully people will welcome the opportunity to take part in these trials. I hope that *Testing Treatments* raises the awareness of all concerned about the need for fair tests of treatments so that better research can help to improve the health care that we all, at some stage in our lives, will receive.

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Binge Britain: Alcohol and the National Response
Martin Plant, Moira Plant. Oxford University Press, 2006. Pp 208. £19.95. ISBN 0-199-29941-2.



Snow Cake
Directed by Marc Evans, written by Angela Pell. Revolution Films and Rhombus Media, 2006. On general release in the UK from Sept 16, 2006.

In brief

Book Alcohol in the UK

A friend of mine's 14-year-old daughter has a scar on the bridge of her nose caused by an accident during an experimental alcohol binge. My friend's reaction? Good. Good that any time her daughter looks in the mirror she will be reminded of the harmful effects of binge drinking and may be discouraged. The harm caused to individuals and to society by binge drinking is forcefully laid out in *Binge Britain: Alcohol and the National Response*.

One of the most compelling parts of the book describes the political process by which the power of the drinks manufacturing lobby overcame the pleas of scientists, doctors, and the police to achieve an extension of drinking hours in the UK.

Moira and Martin Plant are clear about the way forward: health education messages are largely futile and often misinterpreted.

They argue that we need to stem the cheap supply of alcohol and to increase taxes on alcoholic drinks. Colin Blakemore, head of the UK's Medical Research Council, and others have recently called for a revision of the UK's current categorisation of drugs so that they would be classified by harm, not criminality. Alcohol would be number five above ecstasy, LSD, and cannabis. Read this book to understand why.

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Film Autism in a cold climate

Snow Cake stars Alan Rickman as Alex, a laconic Englishman who spends a life-changing week with the high-functioning but autistic Linda (Sigourney Weaver). Linda's interests include sparkly trinkets, trampolining, and eating snow (snow cakes, if you will). Alex enters Linda's meticulously organised life

after he is involved in the car crash that killed Linda's daughter. The action takes place in the wintry wilds of Northern Canada, the snow-covered landscape hauled into service as an uncomplicated metaphor for human isolation.

Rickman struggles gamely with the script's saccharine excesses. Possessed of a reserve the film itself would do well to cultivate, Rickman is dryly humorous and engaging. Although Weaver adeptly constructs the gestures and mannerisms of autism, the condition itself is presented as a form of extreme quirkiness, its rough edges conveniently smoothed away. The whole thing simply doesn't ring true; the film follows a course that is simultaneously predictable and contrived. The truth is: *Snow Cake* leaves you cold.

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