



From trials to treatments

Randomised controlled trials

Alejandro R. Jadad

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Alejandro Jadad's *Randomised Controlled Trials* is a little book that tries to do a lot. In 123 pages of text the author sets out to provide not only an introduction to the design and reporting of randomized controlled trials (RCTs) but also guidance on quality assessment, meta-analysis and the role of RCTs in policy formulation.

In his introduction Jadad notes that his motivation for writing the book came from a desire to have a satisfactory single-source treatment of the RCT and its role in health care decision-making. The book is aimed at busy readers who want to become conversant with the basic principles of the RCT, the cornerstone of evidence-based care. Only about half of the book is devoted to traditional issues relating to the strengths and weaknesses of trials; the remainder deals with broader issues of evidence-based health care. Jadad has set a difficult course for himself, not only in terms of the breadth of his subject, but also in terms of his target audience. Although he explains that, after considering the needs of both doers and users, he decided to produce "an introductory guide for busy readers," the tension of that choice is evident. The lack of certain caveats (e.g., concerning methods of randomization) and the inclusion of certain topics (e.g., whether or not to contact authors of trial reports in doing a meta-analysis) are surprising for an introductory guide. Although the inclusion of the latter can be considered a bonus, the exclusion of the former is somewhat troubling.

Section headings in the form of pertinent questions provide helpful signposts for the reader. In the first chapter,

on RCT basics, we encounter fundamental questions such as: "What is a clinical trial?" and "How can randomisation be achieved?" Although this format is highly effective, there are problems with the corresponding content. Under the heading, "Are the elements of RCTs very different from other studies?," there is no mention of the ethical issues that arise when we intervene and randomly assign patients to different arms of a trial rather than simply observe the result of systematic treatment choices. The section on the means of achieving randomization offers suggestions about how to use coin-flipping and die-tossing as means of randomization without alerting readers to the fact that, although these methods serve as useful pedagogic models, in practice they are to be avoided.

Even though the book is aimed at busy readers it would have been in their best interest to leave a little more flesh on the bare bones. Without it, the risks of a nasty poke are not negligible. In the discussion of what is often called "randomized consent" (in the section "What is a trial with Zelen's design?") readers are cautioned about the potential pitfalls of this study design. They

should probably also be alerted to the fact that the National Institutes of Health has declared the original version of this study design unacceptable.¹

The book comprises eight chapters. Those dealing with RCTs per se concentrate on aspects of design and reporting. There is an entertaining and informative catalogue of potential biases, some unique to RCTs, some common to other research strategies, and several chapters oriented explicitly to important issues in evidence-based health care.

These include a discussion about how to judge whether a trial's results are likely to be useful to the reader's particular circumstances, a very good treatment of reviews, meta-analyses and guidelines, and an examination of the links between information and decisions. Jadad has a great deal of experience in the study of evidence-based health care and has made major contributions to RCT quality assessment. This comes through clearly in the good

practical advice he give us. But his discussions on the steps from individual trials to health care decision are the book's greatest strength. Unfortunately, the title of the book gives readers no indication of what they have to look forward to in these chapters.

Some additional fine-tuning is in order. I was a bit taken aback when I looked up "ethics" in the index and was referred to pages with nary a mention of the topic. Other pages that should have been referenced were not. Similarly I was surprised to find that the occasional reference had gone missing.



Fred Sebastian

Is *Randomised Controlled Trials* a useful addition to the literature? Unequivocally, yes. It provides a good survey of important issues in evidence-based health care, is easy to read, and is organized in a manner that helps the reader target specific areas of interest. Does it fill the gap the author alludes to in the introduction by providing “a single

source that could help [the reader] really understand what RCTs [are] about, their strengths and limitations, and how to use them while making health care decisions”? Not really. If one wanted to pursue that goal, a second edition with an expanded treatment of some of the basic topics would be a step in the right direction.

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Lifeworks

Modern optics

Let us record the atoms as they fall upon the mind in the order in which they fall, let us trace the pattern, however disconnected and incoherent in appearance, which each sight or incident scores upon the consciousness.

— Virginia Woolf, “Modern Fiction,” 1925

The National Gallery of Canada’s summer crowd-pleaser this year is *Monet, Renoir and the Impressionist Landscape*, a selection of 70 canvases from the extensive Impressionist collection of the Museum of Fine Arts in Boston. This survey of French landscape painting from the 1850s to the end of the 19th century attests to the depth of the Boston collection, even if the definition of “landscape” is somewhat strained by the inclusion of Renoirs that in another context would be called portraits. But there is no need to quibble here.

Those in the mood for a bolus dose of Impressionist dazzle might find this show rather studious. The exhibition is framed by a roomful of paintings representing the precursors to Impressionism, and by another roomful of works by contemporaries of the Impressionists who found acceptance through the official Salons rather than via the harder (or higher) road of the Salon des Refusés. But this contextualization illustrates how Impressionism was not a unitary movement. It was the product of an infusion of ideas from a number of sources, and those ideas took a different shape in each practitioner. The flecked application of paint by the Dutch marine artist Jongkind, whom the young Claude Monet met in 1861, showed the way for the rendering of



Camille Pissarro, *Morning Sunlight on the Snow, Éragny-sur-Epte*, 1894–5. Oil on canvas, 82.3 cm × 61.5 cm



Pierre-Auguste Renoir, *Woman with a Parasol and Small Child on a Sunlit Hillside*, 1874–6. Oil on canvas, 47.0 cm × 56.2 cm

light in a raw form, as if to replicate the moment of sensation that precedes the moment of perception. What Virginia Woolf proposed some years later for writing, the Impressionists accomplished in the representation of light.

The Impressionists' famed dedication to painting *en plein air*, where nuances of light and colour could be viewed with a new immediacy, was in part a legacy of the Barbizon painters who preceded them by roughly a generation. And their interest in landscape as a subject was both a revival of and a departure from earlier, classical traditions. But not all the Impressionists were equally committed to landscape, and not all were equally happy in the open air. Pissarro, the Impressionist who more than any other stayed the course, exhibiting at all eight Impressionist group exhibitions from 1874 to 1886, said that "the unity that the human mind gives to vision can only be found in the studio. It is there that our impressions, scattered as they are at first, become coordinated."¹ Perhaps he was making a virtue of necessity, for by the time he made this remark Pissarro's chronic dacryocystitis was forcing him

indoors, away from wind and dust.² Degas' preference for working in the studio may have been related to his sensitivity to light, perhaps as a result of macular

degeneration.³ But it is the arch-impressionist Monet whose failing eyesight is the most well-known, and whose love of painting outdoors never faltered. We picture him in his last years, in his garden at Giverny, tormented by his distorted perception of colour as he struggled to produce his *Waterlilies*, the tribute to the glory of France exacted from him by the statesman George Clemenceau.⁴ In the end, Monet's art transcended the affliction of his eyes. His paintings are a tribute to the glory of subjectivity.

Monet, Renoir and the Impressionist Landscape continues at the National Gallery in Ottawa until August 27.

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Claude Monet, *Grainstack (Sunset)*, 1891. Oil on canvas, 73.3 cm × 92.6 cm

Room for a view

Our man in Havana

The usual mishmash of uncontrollable circumstances found me on June 28 in Havana, discussing with colleagues over dinner the remarkable success of the Cuban health care system. Quite suddenly, at around 8 pm, the entire corps of waiters and chefs fled the dining room, and dinner and conversation came to a halt.

I followed the staff to the bar, where the attraction was, of course, a CNN newscast in Spanish of a small white airplane landing at Havana's José Martí airport and the subsequent appearance, before relatives and schoolchildren waving small Cuban flags, of little Elian Gonzalez and his father. As they watched, the hotel staff variously applauded, cried, and smiled with quiet pride at this victory for Cuban identity.

Cubans have some cause for their national pride. The World Bank ranks Cuba among the "lower middle income" nations, that is, among those with a per capita GNP of US\$761–\$3030 (www.worldbank.org/data/). Economically, this places Cuba somewhere in the bottom third of nations. Yet, even with a rapidly increasing population (now 11 million), Cuba ranks near the top in terms of health. Life expectancy at birth is 76 years, and the infant mortality rate of 6.4 per 1000 live births is lower than that of the United States and is surpassed, with very few exceptions, only by the most affluent countries.

This success appears to arise from two interrelated factors: a goal-driven health care system with an almost exclusive emphasis on primary and secondary prevention, and a motivated and abundant corps of doctors, nurses and other health care workers.

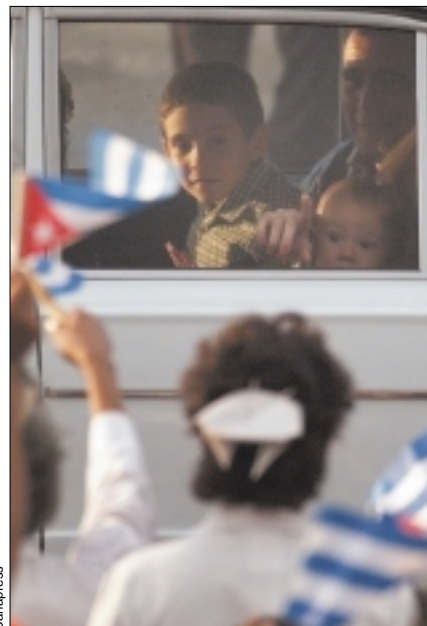
The Cuban health care system is actually, not just theoretically, based on primary care. Although centrally planned, administration is decentralized to the municipal level. Each of Cuba's 169 municipalities has a hospital with specialists in the major disciplines, several primary care centres and between

20 and 40 family medicine clinics, each of which is staffed by a solo physician and a nurse who live in the clinic or nearby and care for approximately 130 families in the vicinity. The result is that these physicians and nurses get to know each and every one of their families. This, coupled with a set of standard forms for record-keeping, leads to outstanding primary and secondary prevention. Vaccination rates are over 99%, and screening rates are also high.

Central planning seems to be working. But the good results in health care also stem from an ample supply of health care providers who, in spite of low wages, appear to be well trained and dedicated to their work. There are 21 faculties of medicine in the country, which boasts 65 000 practising physicians, of whom 30 000 are family doctors. By my calculation, this works out to 1 doctor for every 180 inhabitants. (In Canada, this ratio is 1 per 541.)

I write this as I attend the inaugural meeting of the International Society for Equity in Health. Cuba has certainly achieved equity — both of income and of health. But what about efficiency? The current system is anchored in the ideals of the Cuban Revolution, which led to the overthrow of the Batista regime in 1959. Many leaders and directors of the health care system appear to be in their 50s or 60s, and most, such as Dr. Cosme Ordoñez, the influential director of a major clinic in Havana, participated in the revolution. Ordoñez was captain of his high school basketball team, which also included Fidel Castro. During the revolution, while his wealthy family fled, Ordoñez stayed to bring about fundamental changes in the organization of health care, including the abolition of the equivalent of a College of Physicians and its replacement with a syndicate of health care workers.

The rhetoric of Cuba's leaders is peppered with the catchwords of that era: "comradeship," "revolutionary



Elian Gonzalez watches from a car as schoolchildren welcome his arrival in Havana on June 28, 2000.

Public Health Ministry," "peasants, workers and students," and so on. "Efficiency" and "competition" are not part of that vocabulary.

But the Cold War has ended and the US blockade on medical equipment and supplies is likely to be relaxed. With this will come money and investment and, eventually, more wealth for the average Cuban. The enthusiasm and altruism of Cuba's physicians and health care workers will be strained by an increasing desire for affluence and growing disparities in income. From my limited vantage point, I doubt that the Cuban health care system can be maintained at its current low level of efficiency. Once the usual targets are gone, the rhetoric will be less persuasive. One can only imagine that Cuba's remarkable health care system will be tested over the next few years. I hope its spirit and altruism survive.

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