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EDITORIAL

Registration of clinical trials submitted for publication in *International Psychogeriatrics*

When we manage our patients both they and we would like to know that the interventions we prescribe have been tested and shown to be safe and effective for the uses to which they are put. The most powerful tool to determine the utility of specific interventions in the discipline of medicine is the double-blind placebo-controlled randomized clinical trial (RCT). Some of the complex problems encountered in psychogeriatrics do not lend themselves to straightforward yes or no outcomes, and some of the multifaceted interventions developed for the management of common psychogeriatric syndromes are difficult to test using standard RCT design, especially with regard to effective blinding and appropriate control conditions (Llewellyn-Jones *et al*. 1999; Haynes, 1999; Ames, 1999). Nevertheless, there are specific interventions for which RCT data have been very useful in refining treatment guidelines and advice (e.g. Doody *et al*., 2001) and, where this is the appropriate trial design, RCTs comprise the "gold standard" by which to assess the efficacy of a treatment or "management package".

The conclusions we draw about the usefulness of specific treatments are limited by the available data, which usually means trials published in peer-reviewed medical journals. Unfortunately, some clinical trials which might inform clinical practice never get published and their results are inaccessible. In the field of psychogeriatrics, two examples are the failure to publish some (apparently negative) trials of novel antipsychotics in the treatment of psychosis in dementia and/or behavioral and psychological symptoms of dementia (BPSD) (Ames *et al.*, 2005), and the non-appearance in the peer-reviewed literature of the results of several studies conducted in the 1990s, of the putative Alzheimer's disease treatment, lazabemide (like selegiline and rasagiline, an inhibitor of monoamine oxidase B). Such failures are deplorable, as patients and investigators signed up to these studies in good faith, with the intention of advancing knowledge, not conditionally on the basis that publication would proceed only if the results were positive. Meta-analyses to inform clinical practice in key areas, such as the usefulness of antipsychotics to treat psychosis of dementia and/or BPSD, or the efficacy of monoamine oxidase B inhibitors in the treatment of neurodegenerative disorders, will reach flawed conclusions if they include only the results of positive published trials and exclude those of negative unpublished ones.

Mindful of the potential consequences of the systematic concealment of the results of negative treatment trials, the International Committee of Medical Journal Editors (ICMJE) has resolved (De Angelis *et al.*, 2004) that their 11 member journals will require that all trials submitted for consideration for publication be registered in a public trials registry, effective 1 July 2005 for new trials, 13 September 2005 for trials that commenced enrollment before 1 July 2005. Having considered the issues at length at its September 2005 meeting in Stockholm, the editorial panel of *International Psychogeriatrics* unanimously agreed that this journal should impose the same condition upon authors submitting trials for publication here. Our instructions to contributors (available at www.journals.cambridge.org/jid_IPG) have been amended to reflect this fact, and from 31 December 2006 we will no longer review any trial submitted to us unless it was registered in an appropriate registry from the date it commenced recruitment or, if recruitment started before December 2006, we will require that it was registered on or before 30 November 2006. A number of trial registries are now in existence and, like our ICMJE colleagues, we ask that registries used be free to access, searchable, identify trials with a unique number, have minimal or no registration cost, validate registered information, include details to identify the trial and investigator, include the status of the trial, and disclose the research question, methodology, intervention, funding and sponsorship. We will also be requiring a copy of the trial protocol as a separate file and a checklist and flowchart in accordance with the CONSORT guidelines (www.consort-statement.org) to be sent in with each submitted manuscript reporting clinical trial results.

Our instructions to contributors and the CONSORT guidelines give comprehensive information about these requirements, but if potential authors have queries about the new rules they should contact the editor on ipaj-ed@unimelb.edu.au. As a *quid pro quo* for the implementation of these new requirements, and to encourage the publication of trials with negative as well as positive results, I pledge that for the remainder of my editorship, no paper reporting a clinical trial with negative results will be rejected purely because of the lack of any positive finding. I encourage those readers who have in their possession the unpublished negative results of any clinical trial to submit them to *International Psychogeriatrics* for assessment before the end of our amnesty period on 30 November 2006. If all medical journals insist on registration of all clinical trials published in their pages prior to patient recruitment, and treat trials with negative outcomes as being no less worthy than those with positive ones, we can hope to see the day when medical practice in general and the practice of psychogeriatrics in particular will be as "evidence-based" as it ought to be.

DAVID AMES
Editor-in-Chief
International Psychogeriatrics
Melbourne, Australia
Email: ipaj-ed@unimelb.edu.au

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