Registration of unpublished trials: a call to authors

THE British Journal of General Practice (BJGP) is inviting its readers to send information about unpublished randomized controlled trials. This is part of a collaborative effort, with more than 100 medical journals throughout the world, to report and register unpublished trials. The venture is being coordinated by Ian Roberts (Institute of Child Health, London).

Randomized controlled trials are acknowledged as being the foundation of safe and effective care, providing unbiased estimates of treatment efficacy and effectiveness. The BJGP has made a contribution to published trials in general practice.² However, it has been demonstrated that a large proportion of trials — possibly up to a half of all trials that receive ethical committee approval — are never submitted for publication.³ Publication bias is a hazard for medical research as it can lead to patients being harmed in several ways. First, they may be denied effective forms of health care: to detect moderate but clinically important treatment effects, pooling of individual trials into systematic reviews may be required; unpublished trials are an important source for properly conducted systematic reviews.4 Secondly, patients may be subjected to ineffective or harmful treatments: trials showing positive treatment effects are more likely to be published,3 and systematic reviews based solely on published studies are more likely to give false positive conclusions (e.g.magnesium in the treatment of myocardial infarction and aspirin in the prevention of pre-eclampsia).⁵ Lastly, patients may be asked to participate in new trials that have been designed to address questions that have already been answered.⁶

We appreciate that general practitioners involved with research have many constraints on their time, and that trials may go unreported for a variety of reasons. For example, if a trial produces a 'negative' result the author may feel that it will not be of interest to medical journals. Sometimes recruitment and conduct of a trial is problematic and may prolong the writing up of a study or jeopardize its feasibility. Investigators may move jobs or may discover a recently published study on the same subject and conclude that their results are redundant. Lastly, medical journals are more likely to publish trials demonstrating positive or significant findings.³

Investigators with unpublished trial data are urged to register

their trial by writing to the address below. Registration can be undertaken by anyone able to provide the registration information, even if they cannot provide the actual trial data. A degree of duplicate registration is anticipated. The information will be made available by listing the trial details on a web site, and in other ways as appropriate. So far there have been over 35 trial registrations with data on more than 5000 randomized patients (Roberts I, personal communication). We are unable to estimate the total number of unreported trials, but we are confident of a good response.

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Unpublished trial registration

Register any controlled trial that has not been published in full, including trials that have been published only as an abstract. Please complete one form for each trial being registered.

Contact details Surname:	Forename(s):
Postal address:	Tel (with regional codes): Fax (with regional codes): Email:
Trial details Approximate number of participants in the trial: Type of participant (e.g. people with clinical depression,	women at risk of breast cancer):
Type of intervention (e.g. steroids versus placebo):	
Type of intervention (e.g. steroids versus placebo).	versus

Please send registration details to: Dr Tom Fahey, Division of Primary Health Care, Canynge Hall, Whiteladies Road, Bristol BS8 2PR. (Fax: 0117 928 7340. Email: tom.fahey@bris.ac.uk.)