Reviewer's report

Title: Conducting research in individual patients: lessons learnt from two series of N-of-1 trials

Version: 1 Date: 29 May 2006

Reviewer: Janet Pope

Reviewer's report:

General

--------------------------------------------------------------------------------
Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

--------------------------------------------------------------------------------
Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

--------------------------------------------------------------------------------
Discretionary Revisions (which the author can choose to ignore)

Their experience is recommended from 2 small trials they have done and not from a summary of the literature. However, there is likely generalizability of their comments for Family Practitioners that may want to do these studies.

Some overall recommendations could be stressed:
These trials are only good with meds that are rapidly acting and stop rapidly (in order to decrease the carryover effects).
Patient outcomes may be different, but could be homogeneous as you could ask each patient their preference in each couplet of treatment (first, second or neither) and this usually takes into consideration their benefit to side effects profile and benefit is patient centred.

There are 3 problems with N of 1 trials
It is difficult to get a placebo, so unblinded trials may have a role (not usually done to date).
Most doctors will not do any statistics, so patient preference is a good surrogate (with overall a win for a drug if 2 of 3 cycles prefer it or 3 of 5, etc, unless if pt will not go further as they are convinced one is superior or more toxic or inferior to the other and that achieves the outcomes of the individual study) and this would allow for variable cycles in one patient and another “there is no point of going to further cycles if objectives are met already.
Later the results are not acted on. Another trial (NSAID for OA, Pope et al) followed the patients after the trial was completed and at 3 months, there were many who returned to treatment even if it was not preferred during the N of 1 trials.

What next?: Accept after discretionary revisions

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No

Declaration of competing interests:

No, I declare I have no competing interests.