Should non-randomised studies be included in reviews of interventions for vulnerable groups: a case study from domestic violence research

Jean Ramsay, Gene Feder (reviewers)
Barts and The London, UK
and
Geraldine Macdonald (group editor)
Cochrane Developmental, Psychosocial and Learning Problems Group

introduction

- debate about the place of non-randomised intervention studies (NRS) in systematic reviews
- this tends to focus on the evaluation of complex interventions at system level
- Cochrane review groups have varying policies on including NRS
- the policy of our Cochrane review group is that NRS should only be included if randomised trials are ethically inappropriate or technically impossible

our view about inclusion of NRS

our starting position as DV reviewers

- well-designed NRS are a legitimate source of evidence for evaluation of interventions
  - potentially greater external validity
  - more feasible

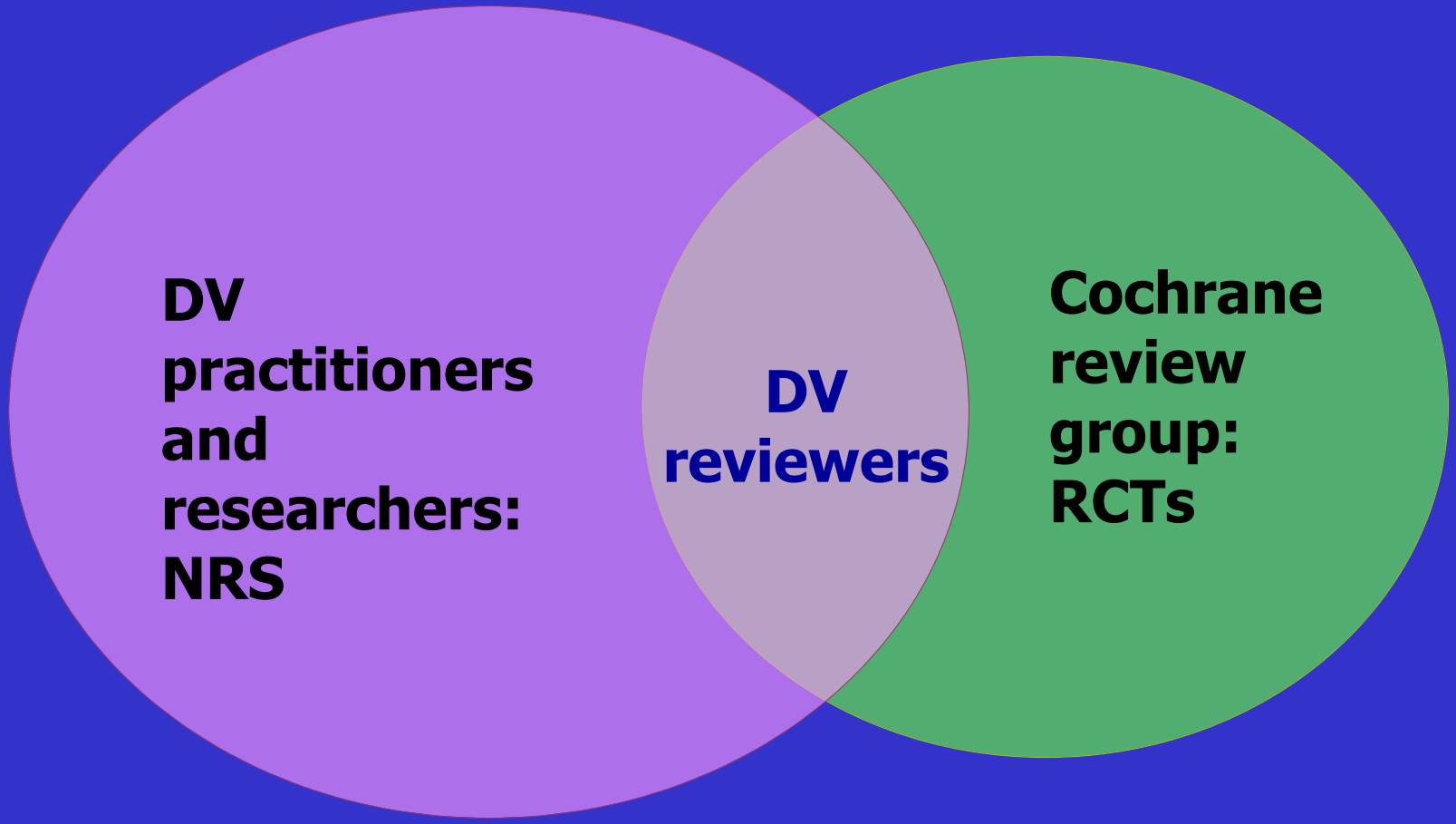
- wariness by DV researchers about RCTs means few such studies conducted

aim and objectives

- clarification of the debate about the inclusion of NRS in domestic violence research

- objectives
  - to summarise our debate with the editor of CDPLG on inclusion of NRS
  - to compare conclusions of a systematic review of advocacy interventions for women experiencing DV, including or excluding NRS

between a rock and a hard place



perceived ethical implications

- RCTs not ethical when recruited women are vulnerable and at serious risk of further abuse
  - randomisation perpetuates the abused woman's lack of power over her life and day-to-day decisions
  - random allocation to a control group is unacceptable when women are in dire need and require immediate help

perceived logistical implications

- recruitment difficulties linked to control groups
- contamination problems when clinicians or DV specialists care for both intervention and control groups
  - cluster randomisation is a solution but can present further problems
    - » increased sample size
    - » increased cost
- assumptions of RCTs about standardisation and adequate follow-up difficult to achieve

response of CDPLG: ethical issues

- perceived ethical problems arising from having a control group rather than randomisation
  - being in a control group ≠ no care

- is it ethical to assume an intervention is going to be beneficial and not harmful?
- increasing relevance by broadening study design criteria is meaningless if the studies are so biased that they come to erroneous conclusions

= unethical!

response of CDPLG: other issues

- logistical difficulties may be true, but "difficult" does not mean impossible, as evidenced by existing RCTs in this area
  - if RCTS for a specific DV intervention are not possible in all settings then separate reviews are needed

- other Cochrane groups may include both RCTs and NRS but this does not make it valid to do so

our decision on including NRS

- for the Cochrane review, limited the included study designs to RCTs only

- for UK Department of Health review, *all* studies that included some form of control data:
  - RCTs
  - matched group studies
  - `before and after' studies

advocacy review findings

- nine studies fulfilled the wider review inclusion criteria (4 RCTs, 2 matched group NRS, and 3 `before and after' NRS)
- RCTs and NRS were similar in relation to
  - settings (health, legal, community)
  - demography of women participants
- quality of study design and execution
  - RCTs and matched groups NRS were similar
  - all `before and after' studies rated poor

review findings

- numerous different outcomes measured therefore difficult to compare RCT versus NRS
- only outcome common to most studies was `further abuse'
- effect sizes only available or calculable for 2 of the NRS
  - but still not comparable

a soft place to land?

- clear that many of the logistical difficulties of conducting RCTs in this field can be overcome
- cluster randomisation removes the pressure from individual participants
- much of the resistance to RCTs by DV researchers is based on conflation of the implications of randomisation with the ethical challenge of control groups

challenges for DV researchers

- health care policy is increasingly based on less biased evidence and resources are allocated accordingly
- DV researchers and activists need a consensus on a minimum level of acceptable care for women allocated to control groups
- "normal care" is probably unethical
- "acceptable care" will include components that do not have a strong evidence base
- need to articulate questions about the additional effect of interventions

nevertheless …

- continuing dilemma about individual randomisation and we believe that NRS are a valid alternative (specific to vulnerable groups/participants)
- generic debate about *complementing* RCT's with well-designed NRS to improve external validity of evidence
  - other review groups have set an important precedent in including other controlled study designs

conclusion

need continuing Cochrane-wide debate on whether non-randomised studies should be included in reviews of interventions ……