



Intervention to improve recruitment to randomised controlled trials

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Outline

- Problematic nature of RCT recruitment
- Synthesis of research on recruitment in six RCTs
- Details of the components of the recruitment intervention
- Pilot in further RCT



Recruitment in pragmatic RCTs

- Increasing concerns about RCTs
 - ❖ Failing to start
 - ❖ Requiring additional support
 - ❖ Being underpowered or biased
- Systematic reviews identified
 - ❖ Clinician and patient barriers; logistical issues
 - ❖ Small number of effective strategies
 - Financial inducements, telephone reminders
 - ❖ Treweek et al 2010 Cochrane Collaboration
 - “there is a clear gap in knowledge with regard to effective strategies aimed at recruiters”



Intervention development: ProtecT trial

- Controversial topic of prostate cancer
- No reliable RCTs of treatment for PSA detected prostate cancer
- Previous trials had failed
- Trial of radical surgery, radiotherapy, monitoring “couldn’t be done”
 - ❖ “Treatments too different”:
 - ❖ “Men would not accept randomisation”
 - ❖ Surveys of practice showed polarisation

BUT – everyone agreed it had to be done!



ProtecT randomisation rates



Date	Eligible	Randomised
May 2000	30	10 (33%)
August 2000	45	23 (51%)
Novem 2000	67	39 (58%)
January 2001	83	51 (61%)
May 2001	155	108 (70%)

Donovan JL et al. *BMJ*2002; 325: 766-770.



ProtecT recruitment intervention

- ProtecT intervention components
 - ❖ Reviews of poorly performing centres
 - ❖ Training - all recruiters
 - ❖ Feedback - individuals
 - ❖ Documents - 'tips'

- Lessons learned
 - ❖ Presentation of information to patients was crucial
 - Order, content, balancing, explaining randomisation
 - ❖ Interpretation of terminology by participants was even more crucial
 - Random, watchful waiting



Donovan J et al. *Journal of Clinical Epidemiology* 2009; 62: 29-36.



Quartet study

- (ProtecT) complex intervention applied to five other RCTs
 1. Different protocols of follow up after primary cancer treatment
 2. Laser v. radiotherapy for throat cancer
 3. Drugs or CBT for post-natal depression
 4. Three different combinations of drugs for fever in children in primary care
 5. Policy for expedited return to work for those with mental health problems



Quartet study conclusions



- Intervention was able to uncover reasons for recruitment difficulties in each RCT
 - ❖ Complicated recruitment pathways
 - ❖ Recruiters often could not explain study details simply
 - ❖ Patients expressed strong treatment preferences
 - ❖ Clinicians worried about patient eligibility
 - ❖ Nurse-recruiters worried about role-conflict
- Each RCT required a dedicated plan to tackle recruitment difficulties, with some generic aspects

De Salis I, Donovan J. *Contemporary Clinical Trials* 2008; 29: 663-670.



Final recruitment intervention

- Phase 1: data collection
 - ❖ Evidence and protocol
 - ❖ Views and actions of PI, CI, TMG, recruiters
 - ❖ Eligibility/recruitment pathways
- Phase II: plan of action
 - ❖ Specific issues in RCT
 - ❖ Training for generic aspects e.g. preferences, presentation of study information
 - ❖ Individual feedback to recruiters on specific issues



Intervention applied to SPARE RCT



- Data collection (three months)
- Five key challenges identified
 - ❖ Recruiters had difficulty articulating design simply
 - ❖ Complicated recruitment pathways; difficult comm.
 - ❖ ‘Loaded’ terminology in study information
 - ❖ Small numbers of patients were eligible
 - ❖ Strong treatment preferences
- Plan of action implemented
 - ❖ Acceptable
 - ❖ Lack of eligible patients proved unsurmountable

Paramasivan S, Donovan J. *Trials* 2011; 12: 78



Conclusions

- Intervention using qualitative research methods can identify origin of recruitment difficulties
- Plan of action, with training and feedback is acceptable and can make improvements
- Proposal to evaluate intervention robustly in RCT in development, but difficult ...

