

Involvement of consumers in studies run by the Medical Research Council Clinical Trials Unit (MRC CTU): Results of a survey

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MRC CTU Consumer Involvement Group

- Set up in 2008 with the aim of providing support to consumer involvement across range of CTU research
- **“Consumer involvement”**
 - **Active** involvement of consumers in research not as subjects of that research
- **“Consumers”**
 - Patients, carers, service users, parents/guardians, community groups etc
 - Definition based on that of INVOLVE (www.invo.org.uk)

MRC CTU 2009 Survey: Methods

- In 2009, initiated a survey to
 - Establish a baseline of previous and current consumer involvement in CTU led research
 - Inform Unit-wide guidance on involvement
 - Provide evidence regarding impact of involvement
- Electronic questionnaire using [SurveyMonkey.com](https://www.surveymonkey.com)
 - Developed and tested April – October 2009
 - Distributed October 2009 (reminders January 2010)
 - Closed April 2010

MRC CTU 2009 Survey: Methods

- **Sampling frame:** All research studies included in MRC CTU progress report (published April 2009)
 - RCTs, non-randomised trials, systematic reviews
 - Different stages of research
 - Early development to completed and published
- Mixture of open and closed questions, e.g.
 - Did the trial involve consumers? If so,
 - Reasons for involving consumers
 - How consumers were identified and supported
 - Perceived benefits, challenges and impact of involvement

MRC CTU 2009 survey: Analyses

1. Quantitative analysis

- Proportion of studies with / without involvement
- Nature of involvement
- Change in the amount of involvement over time?
 - Ongoing vs. Completed studies

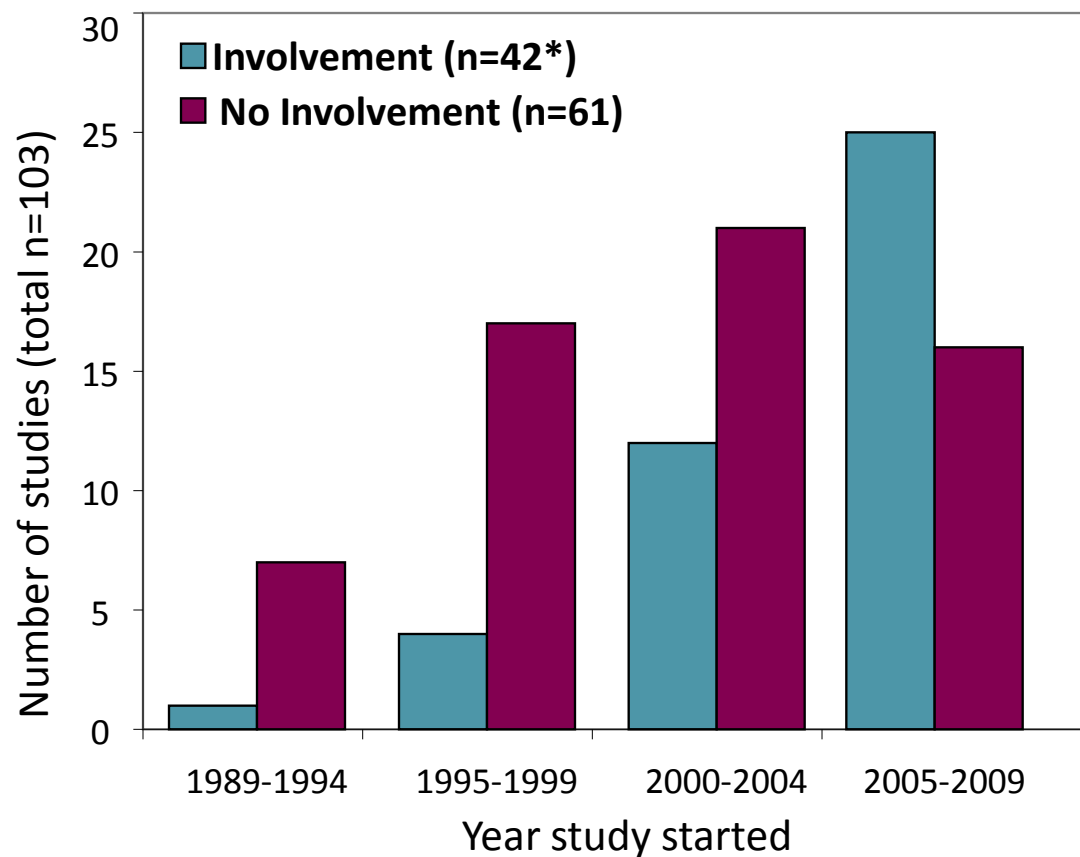
2. Qualitative analysis

- E.g. Benefits, challenges and perceptions of impact
- Emerging themes extracted from responses independently by members of the Consumer Involvement Group
- Key themes identified by consensus

Results: Description of included studies

- 160 studies included in survey
 - 138 (86%) completed questionnaires
 - Start dates from 1989-2009
 - Similar numbers of completed and ongoing (68 vs. 69)
 - Research types
 - 93 RCTs (67%)
 - 23 systematic reviews (17%)
 - 22 non-randomised or observational studies (16%)
 - Research areas
 - Cancer 69 (50%),
 - HIV 42 (30%)
 - Other diseases (e.g. arthritis, TB, blood transfusion medicine) 27 (20%)

Results: Change in involvement over time



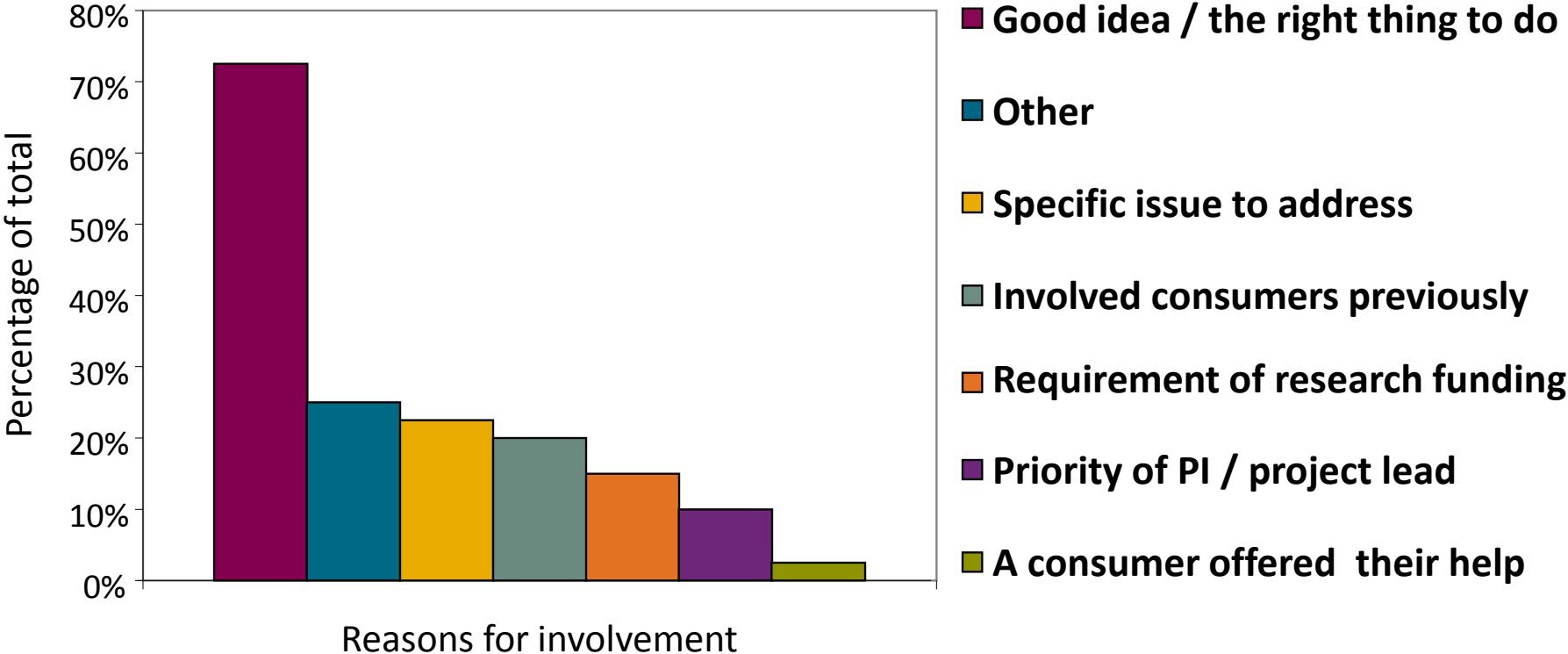
- 25 studies initiated 2005 - 2009 had involvement (vs. 16 without)
- All new RCTs in 2009 have involvement (n=4)
- Involvement in ongoing studies than in completed studies (40% vs. 23%, $p=0.037$)

*One study with involvement had an unknown start date

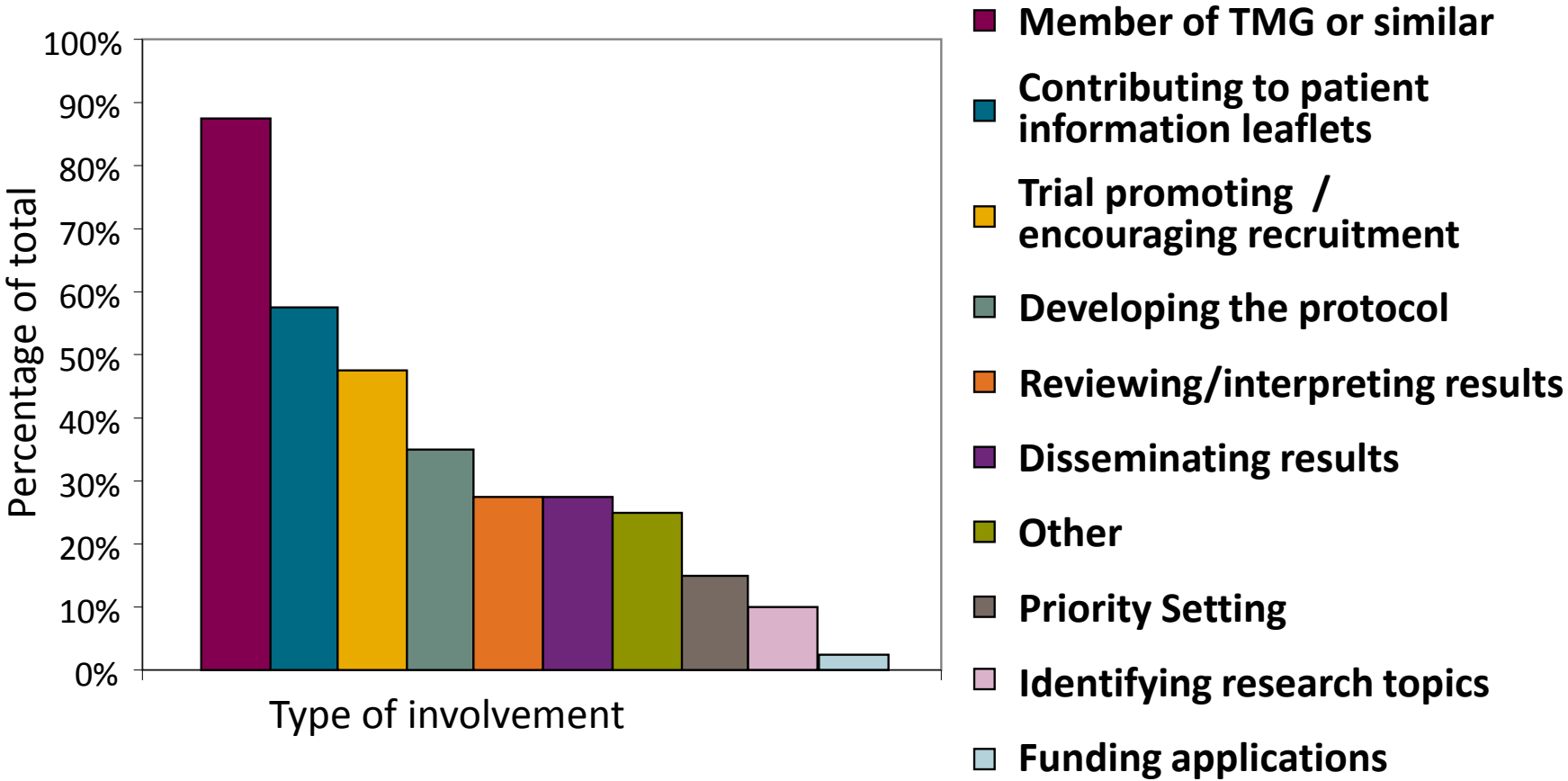
Results: Consumer Involvement

- 43 (31%) studies involved consumers
 - No involvement in 64 studies (46%)
 - Unknown 31 studies (23%)
- Of the 43 studies:
 - 34 (79%) were RCTs
 - 32 (75%) involved 1-2 consumers
 - Some involved considerably more e.g. in focus groups
 - Most involved consumers who were previously known to the clinical investigators or members of the research team e.g. through prior involvement in research projects
 - 1 study advertised opportunity

Results: Reasons for involvement



Results: Activities of consumers



Results: Improving the design of studies

- Studies had a more patient-centred approach
- Patients' experiences of treatment in particular were very valuable in trial design, e.g.
 - by providing insights into why patients may (or may not) consent to a study
 - potentially improving acceptability of the study design to patients considering entering the trial
 - may have also impacted indirectly to improve recruitment

Ideas as to why patients might consent to enter TRISST which offers different surveillance schedules rather than opting for chemotherapy

Trial design was far more acceptable to patients and their families and uptake was very high (76% of eligible patients joined)

Results: Improved promotion and dissemination

- Consumer involvement provided a direct “connection to patient communities” for promotion of the **RADICALS** trial
- Consumers in the **PREDICT** trial steering committee helped in the development of an educational *YouTube* video about obstructive sleep apnoea
- In the **MDP301** study, consumers were involved in peer education about the importance of adherence to the study treatment and HIV prevention in general
- Involving consumers, “hugely aided dissemination” at the end of the **DART** trial, as well as having been important in “uptake and acceptance” at the start of the trial.

Results: Better study documentation

- Researchers identified various study documents that had been affected by consumer involvement, including
 - protocol development,
 - patient information leaflets
 - writing study papers
 - funding applications

The consumers who sit on our committee are actively engaged with the trial and offer very useful comments on how patients / carers may view the trial and trial materials. They have also made a valuable contribution to our application for additional funding

It was useful to have someone with a non-scientific perspective commenting on the manuscript, e.g. questioning results or processes that we often take for granted. They were also very helpful when preparing a lay summary for dissemination to a wider audience

Results: Involvement in decision making

Our consumers were absolutely vital in helping us to come to a good decision (which was to wait a while and keep the drug in the trial)

We became involved in a piece of research that we hoped would provide information on late treatment effects. I'm not sure we would have done this if the consumers hadn't been involved.

Our consumers are also involved in helping us to decide how best to involve other consumers in our future meta-analyses

Results: Researchers feel more confident

Involvement led to researchers being more confident that studies were:

- targeting and responding to consumer needs
- addressing the most relevant issues as perceived by patients.
- appropriately dealing with concerns of patients and families

Researchers also suggested that working with people who had first hand experience of a disease had:

- led to a better understanding of the condition or treatments being studied
- put the research into context

Results: Difficulties and challenges

- Researchers also identified some challenges of consumer involvement:
 - additional resources or time required to involve consumers
 - consumers becoming too unwell during the course of the research to continue their involvement
 - difficulties attending meetings
 - difficult to know what to expect from the consumers
 - not knowing where to go for help or advice
- Most of those who had involved consumers had received no training on how best to involve consumers
 - many indicated that some support (e.g. guidelines or mentoring) may have been helpful

Conclusions

- Results for studies involving consumers show:
 - Most researchers involved consumers because it was a good thing to do!
 - Consumers were involved in a wide range of activities –
 - most commonly as part of a TMG or similar
 - Often researchers relied on consumers already known to them
 - More examples recently (2010/11) of new studies successfully recruiting new consumers through advertising opportunities

Conclusions

- Overall, 64 studies had no involvement
 - further 31 unknown – most likely to be none?
- Involvement has increased over time
 - **BUT** still room for improvement!!
- Lack of support / guidance *may be* hampering involvement?
- Impact on research is difficult to measure
 - Involvement generally perceived to be positive

Current and Future Work

- Consumer member on CTU Protocol Review committee ensures a minimum input at an early stage
- Consumer Involvement Group improving support within MRC CTU, e.g.
 - Recently updated Guidance Notes for trial staff
 - Leading on an update of the INVOLVE guidance for clinical trials and systematic reviews
 - Worked with consumers to develop an Induction Pack to support consumer members of TMGs
 - Developing a policy on Involvement for MRC CTU

Acknowledgements

We wish to thank:

- members of MRC CTU staff who completed and returned questionnaires, sometimes for many research studies,
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