

# **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

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- 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](http://www.invo.org.uk))

# MRC CTU 2009 Survey: Methods

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- 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

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- **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

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## 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

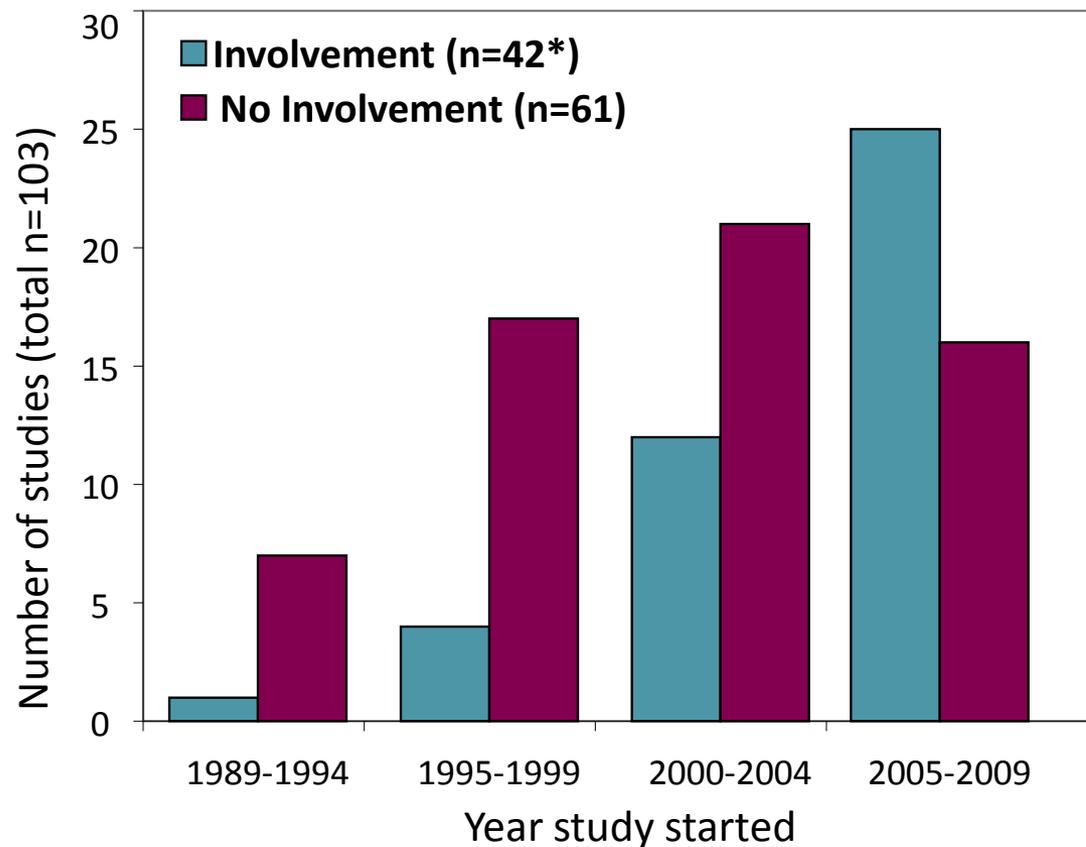
- E.g. Benefits, challenges and perceptions of impact
- Emerging themes extracted from responses independently by members of the Consumer Involvement Group
- Key themes identified by consensus

# Results: Description of included studies

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- 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

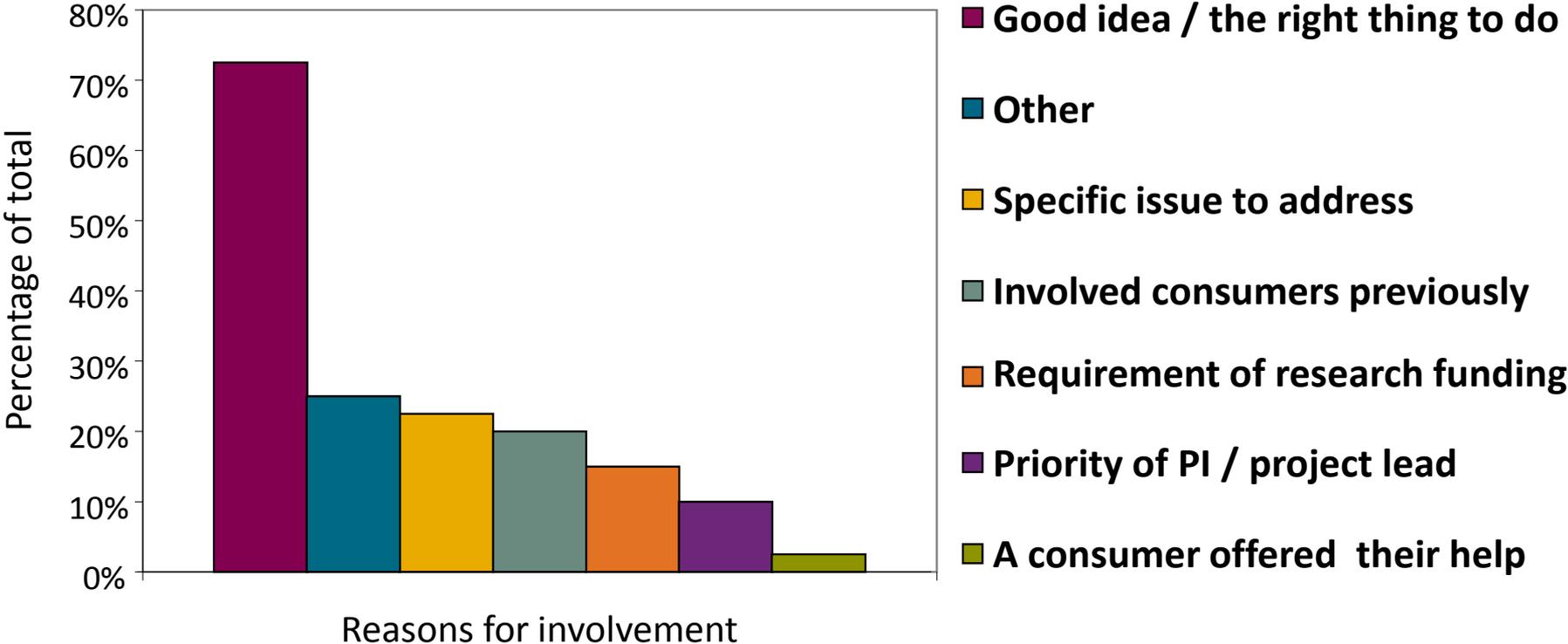
# Results: Consumer Involvement

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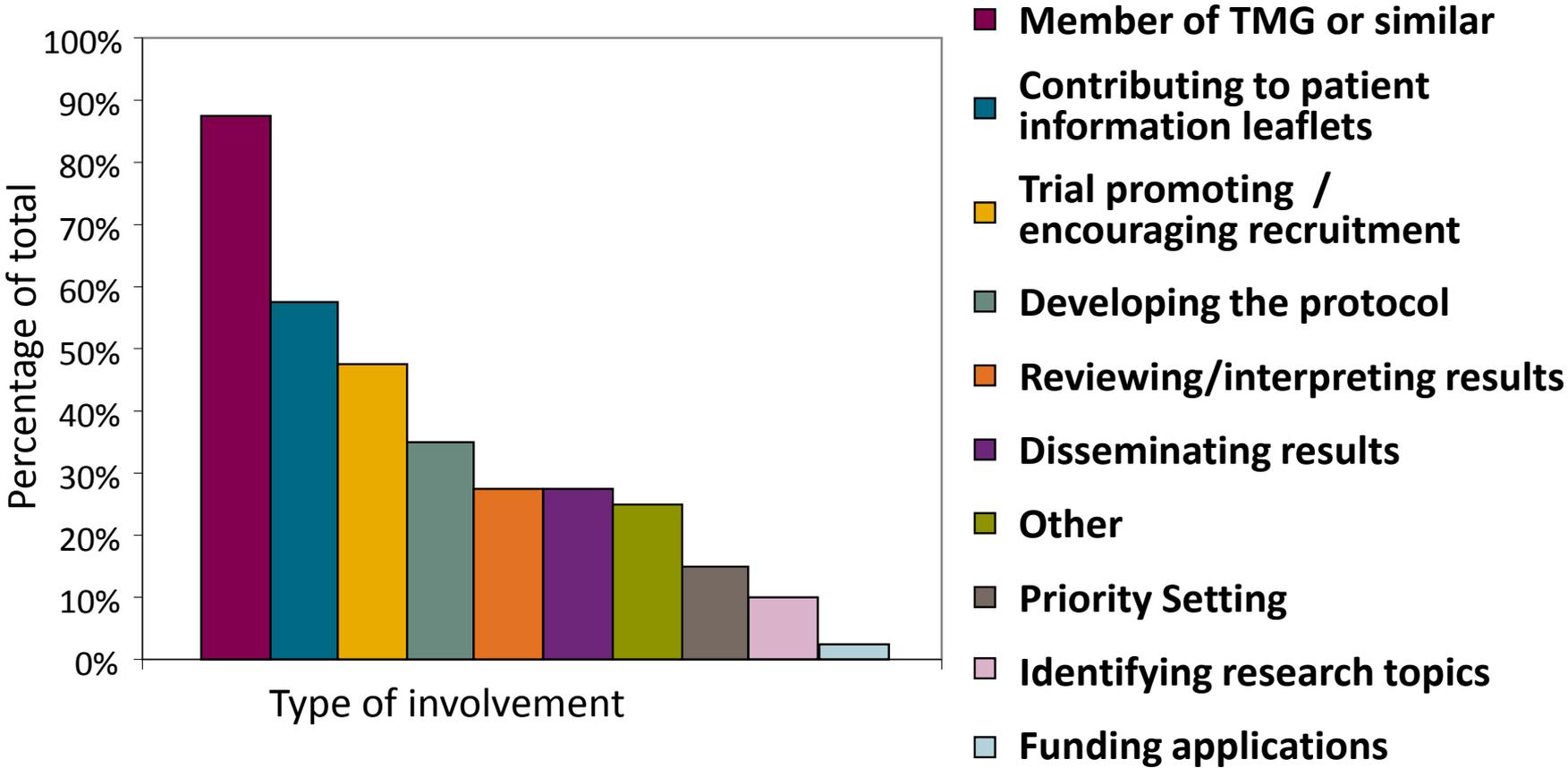
- 43 (31%) studies involved consumers
  - No involvement in 64 studies (46%)
  - Unknown 31 studies (23%)
- Of the 43 studies:
  - 34 (79%) were RCTs
  - 32 (75%) involved 1-2 consumers
    - Some involved considerably more e.g. in focus groups
  - Most involved consumers who were previously known to 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

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# Results: Activities of consumers



# Results: Improving the design of studies

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- 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

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- 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

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- 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

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*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

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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

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- 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

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- 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

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- 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

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- 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

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We wish to thank:

- members of MRC CTU staff who completed and returned questionnaires, sometimes for many research studies,
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- Former members of the CTU Consumer Involvement Group for their help in developing the questionnaire