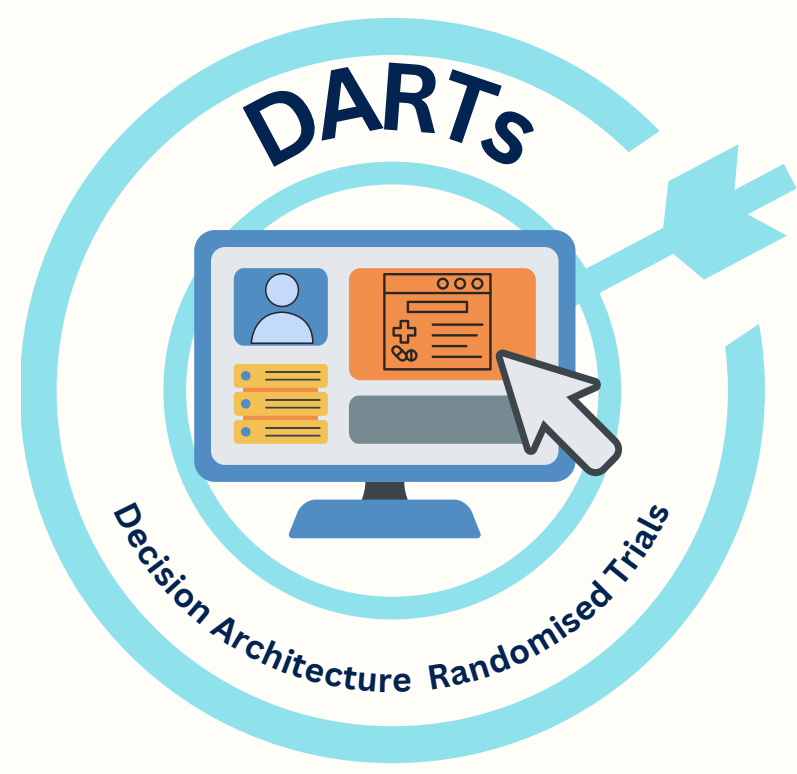


From Advisory Group to Citizens’ Assembly: co-producing deliberation in trial methodology research

Authors: Judit Kovacs¹, Richard Hooper¹, Stephen Chapman², Clare Relton¹

1. Wolfson Institute of Population Health, Queen Mary University of London, UK
2. University of Leeds, UK



A new pragmatic trial design - What informed consent approaches are acceptable to the public?

Decision Architecture Randomised Trials (DARTs) may be a very efficient and scalable solution to deliver studies of standard-of-care interventions (Flory et al., 2024).



However, DART’s informed consent requirements require further study before the design can be widely implemented (Flory et al., 2024).

To explore publicly legitimate informed consent approaches for DARTs, we are conducting a **Citizens’ Assembly** in East London.

A Citizens’ Assembly may be better than existing PPI approaches to address complex or ethically sensitive topics, such as informed consent (Vrydagh, 2023).

We have established **Advisory Group workshops** to co-design key Assembly features and pilot planned activities.

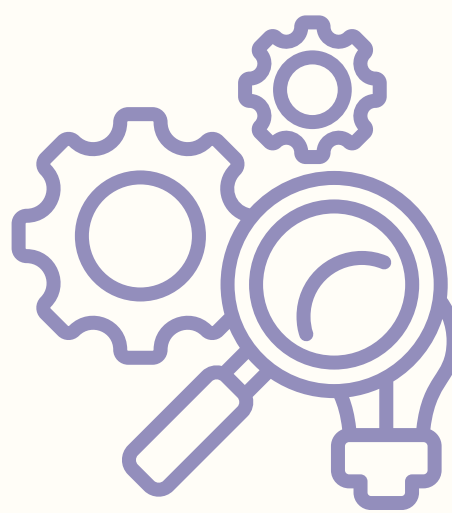
Patient and Public Involvement (PPI) in trials methodology research



PPI is essential for improving the quality and democratic nature of trials methodology research (Tudur Smith et al., 2014).



PPI approaches should enable the public to learn, ask questions and engage in informed discussions.



Compared with intervention studies, methodology research is more complex, less tangible to the public, and its impacts are less immediately visible (Stewart, 2019).

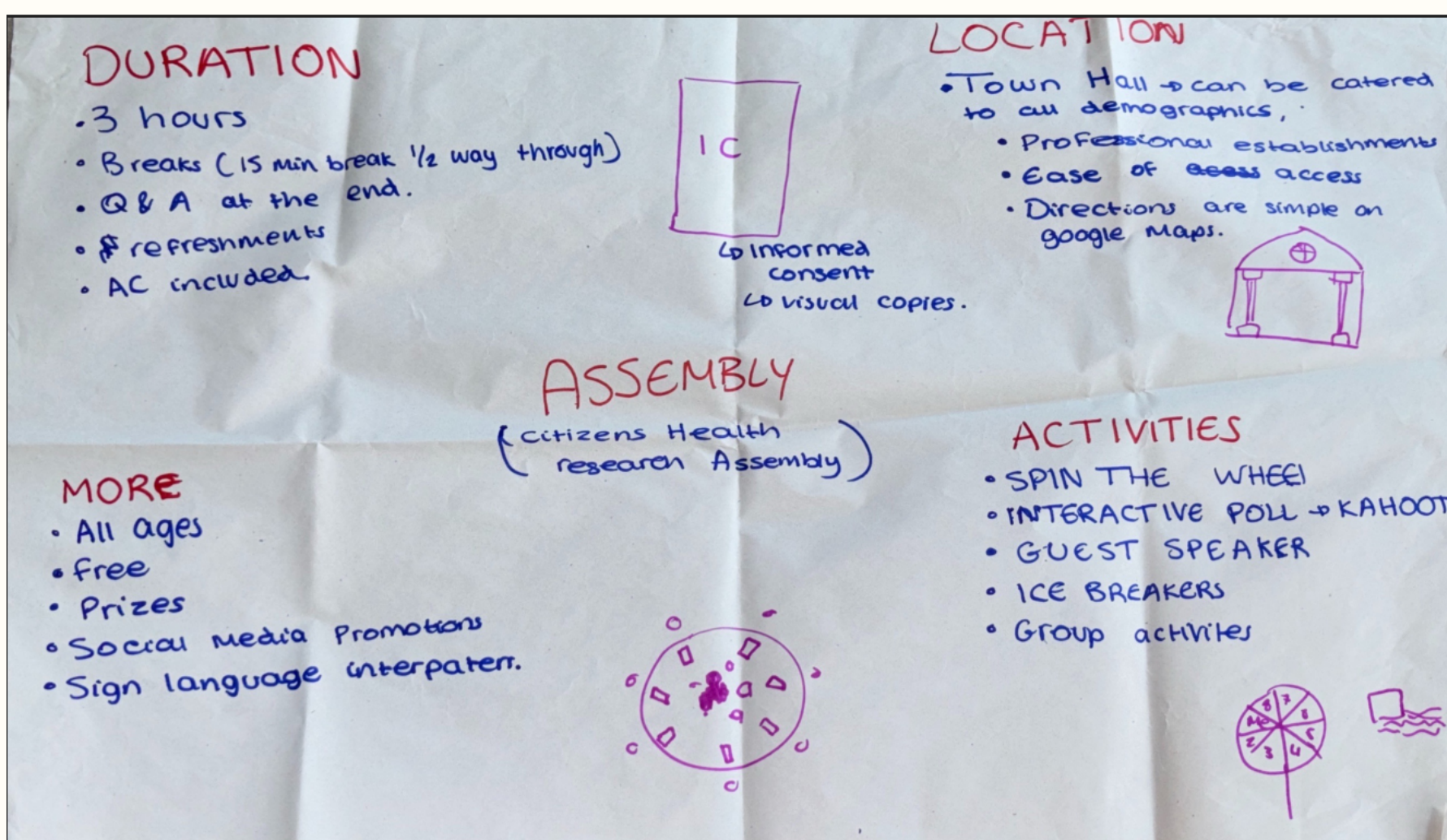


Citizens' Assembly is a promising approach already used to address a wide range of policy issues, but it has not yet been applied to trials methodology research.

Our Advisory Group Workshops

Workshop activities

1. Welcome and ice-breakers
2. Introduction
3. Clinical trials overview
4. Interactive demonstrations
5. Informed consent scenarios
6. Mind-mapping activity



- 13 East London adults
- Recruitment was conducted through community organisations
- 2 x 5-hours workshops were held at Queen Mary University of London
- Participants were paid £100 for their contribution.

Findings



Highly educated sample not representative of the wider population: several Advisors had healthcare backgrounds or were pursuing their second degree.



Payment was a key motivator, it was repeatedly highlighted as a reason for participating



Staying on topic was challenging, discussions often shifted towards personal stories.



Advisors valued learning and better being able to understand what happens “behind the scenes” in clinical trials.

Key takeaways

- **Broader recruitment will be essential to reach more diverse participants.**
- **Learning was reciprocal:** the workshops offered opportunities for Advisors to learn about trials while researchers gained insights that shaped the Assembly.
- **PPI in trials methodology presents distinct challenges:** complex concepts should be made accessible while balancing storytelling, reason-giving and group dynamics.
- **Who participates shapes what PPI can contribute:** limited diversity may constrain the perspectives and values represented.

Interested in PPI, trials methodology research & informed consent?



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3. Stewart, D. C., Bower, P., Woolfall, K., & Gillies, K. (2019). Actively Involving Patients/Public with Trials Methodology Research (TMR).
4. Vrydagh, J. (2023). Citizens' assemblies: An introduction. In M. Reuchamps, Vrydagh, J., & Welp, Y. (Ed.), De Gruyter Handbook of Citizens’ Assemblies. De Gruyter Brill