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Building the evidence base for how we communicate trial results: the Show RESPECT study

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25 September 2018

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Hubs for Trials
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London Hub

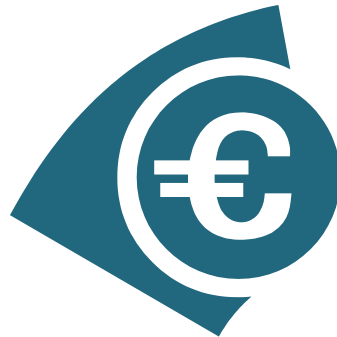
Communication of trial results is essential

1. Compliance with relevant regulations

2. Transparency



3. Reputation



4. Impact



But how can we do this effectively?

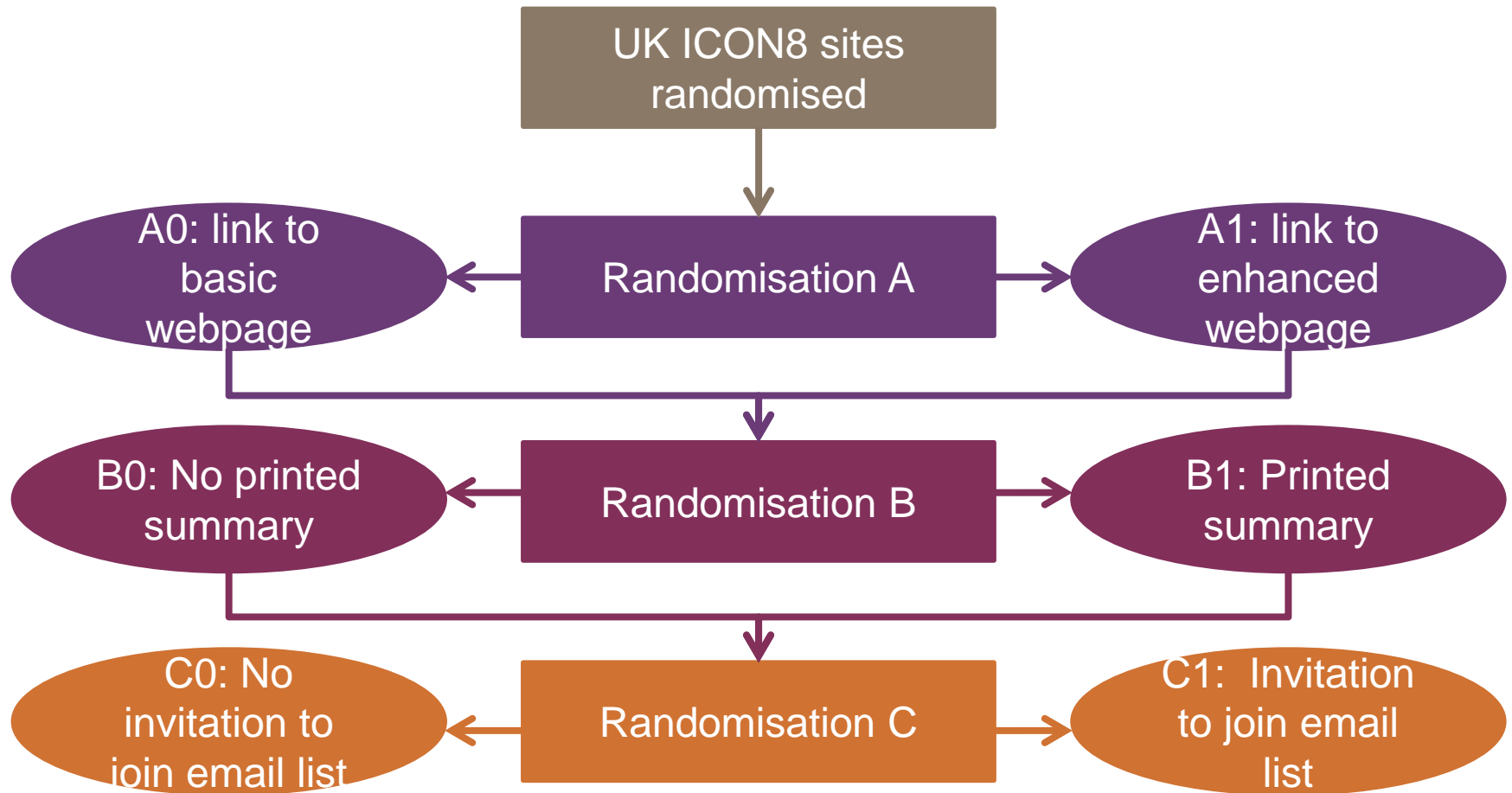


The Show RESPECT study

Show RESults to Participants Engaged in Clinical Trials

- A cluster randomised factorial trial of different ways to communicate results
- Within ICON8 (ovarian cancer trial)
- >37 sites in UK
- Mixed methods study:
 - Quantitative data from site staff & sample of participants
 - Qualitative interviews with participants & site staff

Study schema



Outcomes from participants

Primary outcome

- Reported satisfaction with how the results were communicated to them

Secondary outcomes

- Reported comprehension, results told everything they wanted to know, upset, willingness to take part in future research, likelihood of recommending taking part in research, glad or regret finding out results
- Uptake of interventions, Ease of finding out results, proportion finding out results, preferences

Outcomes from site & CTU staff

Process

- Time taken, concerns, challenges, queries, costs, delivery

Other

- Preferred methods, views on future approach

Where are we now?

- Ethics approval received
- Sites being set-up
- Randomise first batch of sites within the next month
- If study within ICON8 is successful, hope to run within other trials

Conclusions

- Communicating trial results effectively is vital
- Evidence base on how to do it is weak
- Show RESPECT seeks to generate evidence on how to communicate trial results to trial participants
- Many other questions around results communication
- Not easy
- We owe it to patients & society to communicate trial results effectively

Thanks

- To the patients who helped us design the study
- The team at the MRC CTU at UCL: Cara Purvis, Conor Tweed, Carlos Diaz Montana, Andrew Copas, Nalinie Joharatnam, Ania Spurdens
- The ICON8 team: Babasola Popoola, Liz James, Rick Kaplan, Adrian Cook
- Show RESPECT site staff
- The Study Steering Group: Barbara Bierer, Katie Gillies, Talia Isaacs, Amanda Hunn, Katie Scott, Katie-Jane Plumb, Claire Snowdon, Eva Burnett, Will Cragg, Matt Sydes