MRC Clinical Trials Unit

UCL

Show RESPECT: Sharing trial results with participants

Annabelle South, on behalf of the Show RESPECT study team

17/10/2022 | PCPH Seminar

Smarter Studies
Global Impact
Better Health

Outline

1. Background
2. Show RESPECT methods
3. Patients' perspectives on receiving trial results (highlights)
4. Site staff views on sharing results with participants
5. What factors influence participant satisfaction with how the results are shared?
6. Discussion and Recommendations

Background

- **~90% of trial participants want to be told overall results**
- **90% of clinical trials in UK have not told participants about findings**

  (UK HRA Research Transparency Report 2021)
- **Many barriers to sharing results, including:**
  - Lack of resources
  - Practical challenges
  - Little high quality evidence on how best to do this

My motivation for this study

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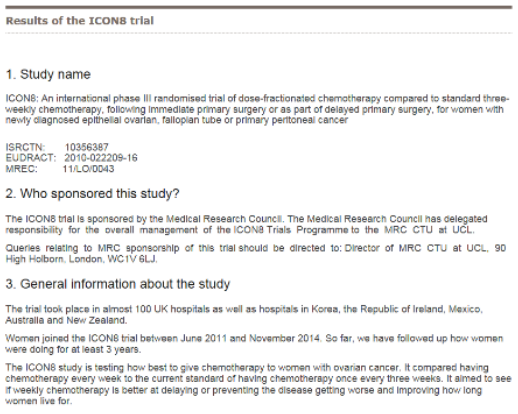
Show RESPECT methods

Show RESPECT design



Results of the ICON8 trial

1. Study name

ICON8: An international phase III randomised trial of dose-fractionated chemotherapy compared to standard three-weekly chemotherapy, following immediate primary surgery or as part of delayed primary surgery, for women with newly diagnosed epithelial ovarian, fallopian tube or primary peritoneal cancer

ISRCTN: 10356387
EUDRACT: 2010-022209-16
MREC: 11/LO/0043

2. Who sponsored this study?

The ICON8 trial is sponsored by the Medical Research Council. The Medical Research Council has delegated responsibility for the overall management of the ICON8 Trials Programme to the MRC CTU at UCL.

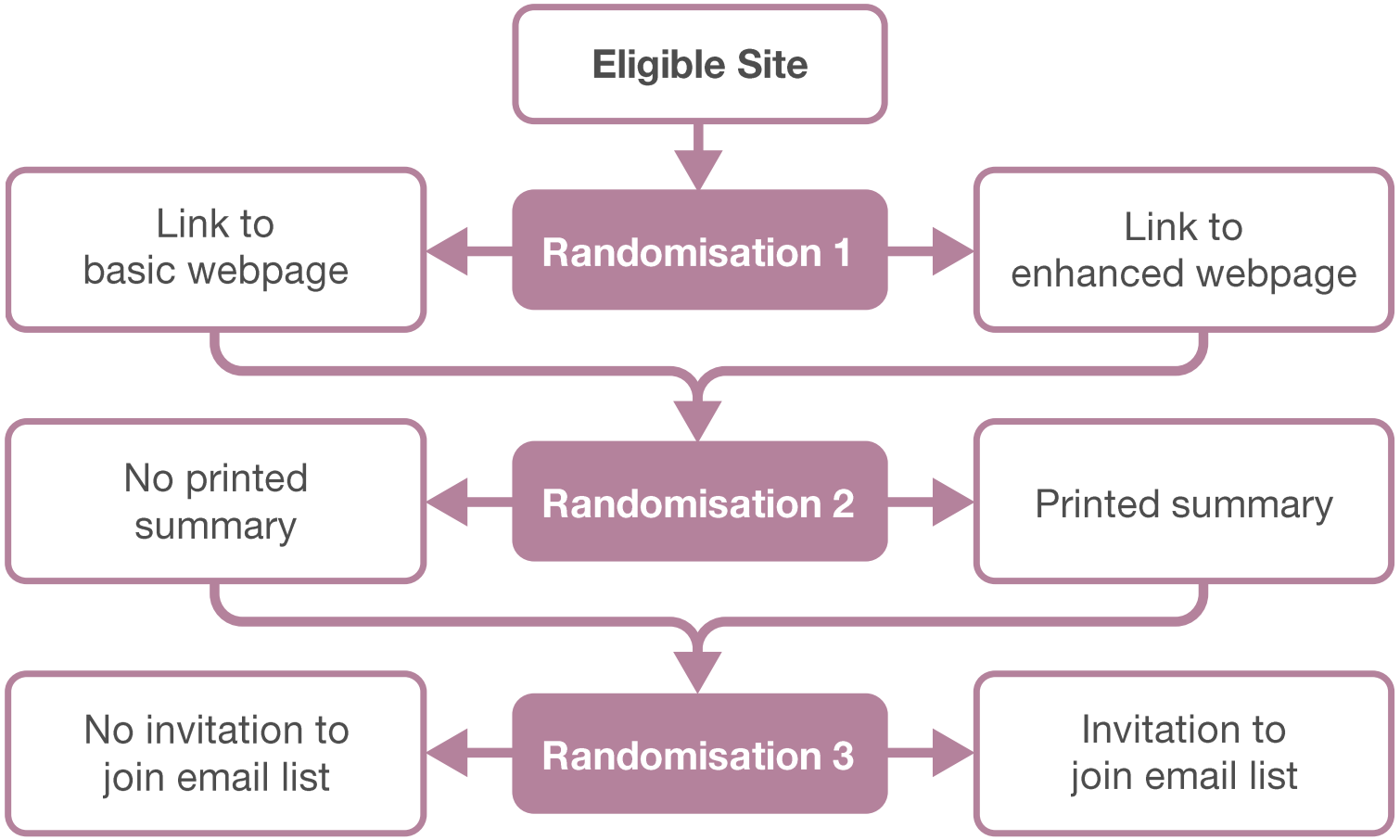
Queries relating to MRC sponsorship of this trial should be directed to: Director of MRC CTU at UCL, 90 High Holborn, London, WC1V 6LJ.

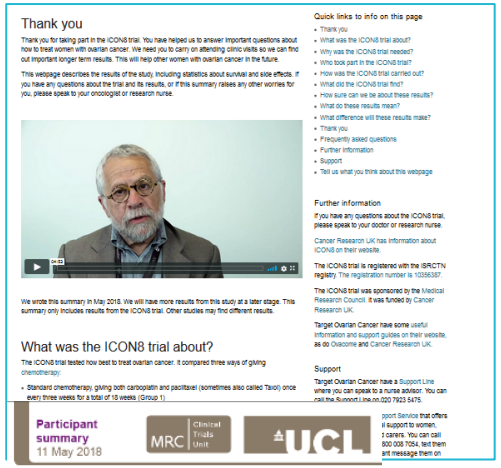
3. General information about the study

The trial took place in almost 100 UK hospitals as well as hospitals in Korea, the Republic of Ireland, Mexico, Australia and New Zealand.

Women joined the ICON8 trial between June 2011 and November 2014. So far, we have followed up how women were doing for at least 3 years.

The ICON8 study is testing how best to give chemotherapy to women with ovarian cancer. It compared having chemotherapy every week to the current standard of having chemotherapy once every three weeks. It aimed to see if weekly chemotherapy is better at delaying or preventing the disease getting worse and improving how long women live for.





Thank you

Thank you for taking part in the ICON8 trial. You have helped us to answer important questions about how to treat women with ovarian cancer. We need you to carry on attending clinic visits so we can find out important longer term results. This will help other women with ovarian cancer in the future.

This webpage describes the results of the study, including statistics about survival and side effects. If you have any questions about the trial and its results, or if this summary raises any other worries for you, please speak to your oncologist or research nurse.

Quick links to info on this page

- Thank you
- What was the ICON8 trial about?
- Why was the ICON8 trial needed?
- Who took part in the ICON8 trial?
- How was the ICON8 trial carried out?
- What did the ICON8 trial find?
- How sure can we be about these results?
- What do these results mean?
- What difference will these results make?
- Thank you
- Frequently asked questions
- Further information
- Support
- Tell us what you think about this webpage

Further information

If you have any questions about the ICON8 trial, please speak to your doctor or research nurse.

Cancer Research UK has information about ICON8 on their website.

The ICON8 trial is registered with the ISRCTN registry. The registration number is 10356387.

The ICON8 trial was sponsored by the Medical Research Council. It was funded by Cancer Research UK.

Target Ovarian Cancer have some useful information and support guides on their website, as do Ovacome and Cancer Research UK.

Support

Target Ovarian Cancer have a Support Line where you can speak to a nurse advisor. You can call the Support Line on 020 7923 5475.

We wrote this summary in May 2018. We will have more results from this study at a later stage. This summary only includes results from the ICON8 trial. Other studies may find different results.

What was the ICON8 trial about?

The ICON8 trial tested how best to treat ovarian cancer. It compared three ways of giving chemotherapy:

- Standard chemotherapy, giving both carboplatin and paclitaxel (sometimes also called Taxol) once every three weeks for a total of 18 weeks (Group 1)

Participant summary
11 May 2018

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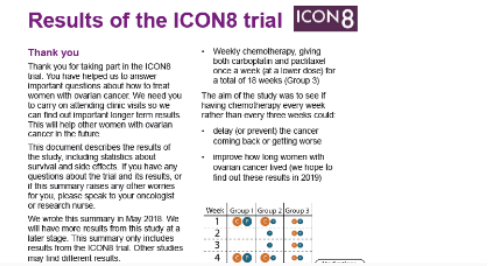

Results of the ICON8 trial

ICON8

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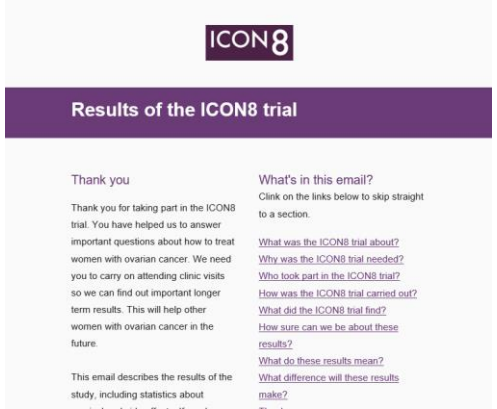
- Weekly chemotherapy, giving both carboplatin and paclitaxel once a week (at a lower dose) for a total of 18 weeks (Group 3)

The aim of the study was to see if having chemotherapy every week rather than every three weeks could:

- delay (or prevent) the cancer coming back or getting worse
- improve how long women with ovarian cancer lived (we hope to find out these results in 2019)



ICON8

Results of the ICON8 trial

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This email describes the results of the study, including statistics about

What's in this email?

Clink on the links below to skip straight to a section.

What was the ICON8 trial about?
Why was the ICON8 trial needed?
Who took part in the ICON8 trial?
How was the ICON8 trial carried out?
What did the ICON8 trial find?
How sure can we be about these results?
What do these results mean?
What difference will these results make?

ICON8

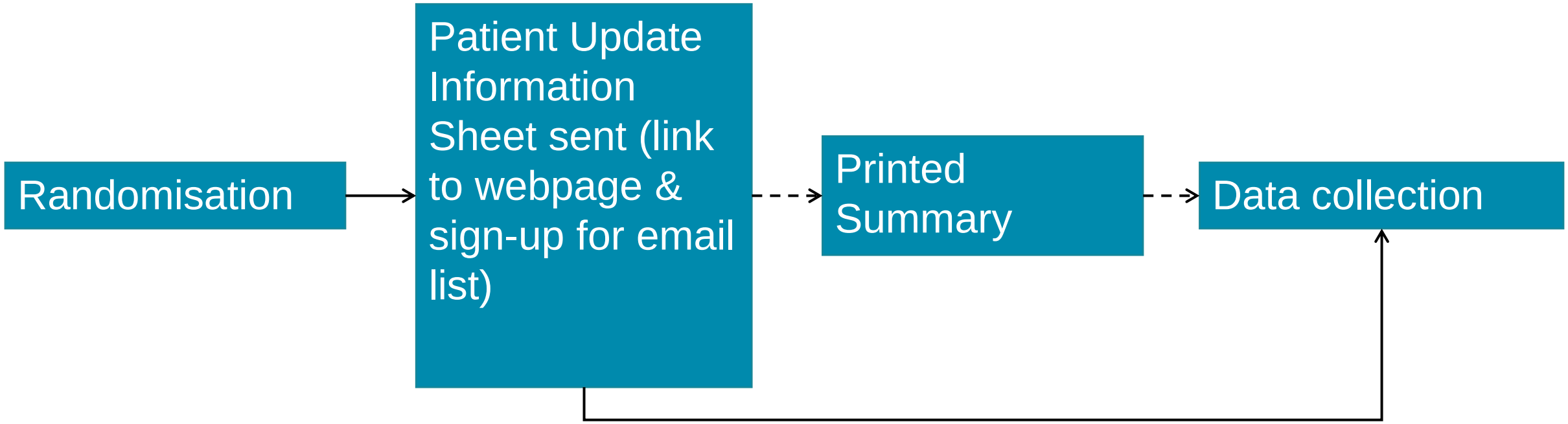
Ovarian cancer trial

Should chemotherapy be given every 3 weeks or weekly? (2 different weekly schedules)

Found no difference in progression-free survival between the arms

~1500 women took part (mostly from UK)

Process


Randomisation
Patient Update Information Sheet sent (link to webpage & sign-up for email list)
Printed Summary
Data collection

Data collection from site staff

- **Questionnaires completed by site staff:**
  - Immediately after sending out the Patient Update Information Sheet (or Printed Summary, if applicable)
  - 2-3 months later

(both timepoints were before Show RESPECT patient results were known)

- **Semi-structured interviews carried out with site staff**

Qualitative methods

Semi-structured interviews

- with patients
- with site staff (nurses, doctors and trial coordinators) involved in sharing results with participants

- Thematic analysis
- Triangulation between the data sets ‘following the thread’

Interviewees

Patient interviewees	13
Reported satisfaction	
Very unsatisfied, quite unsatisfied or neither satisfied nor unsatisfied	5
Quite satisfied or very satisfied	5
Highest level of education	
A levels or lower	6
Degree or higher	6
Frequency of internet use	
Less than once a week	2
More than once a week	10

Site staff interviewees	11
Job role	
Medical	2
Nursing	5
Administrative	4
Randomisation	
Site randomised to posted printed summary	6
Site not randomised to posted printed summary	6
Number of participants at site	
≤5	2
6-11	5
≥12	4

RESULTS: Patients

PLOS MEDICINE

OPEN ACCESS PEER-REVIEWED

RESEARCH ARTICLE

Testing approaches to sharing trial results with participants: The Show RESPECT cluster randomised, factorial, mixed methods trial

Annabelle South, Nalinie Joharatnam-Hogan, Cara Purvis, Elizabeth C. James, Carlos Diaz-Montana, William J. Cragg, Conor Tweed, Archie Macnair, Matthew R. Sydes, Claire Snowdon, Katie Gillies, Talia Isaacs, Barbara E. Bierer, Andrew J. Copas

Version 2 Published: October 4, 2021 • https://doi.org/10.1371/journal.pmed.1003798

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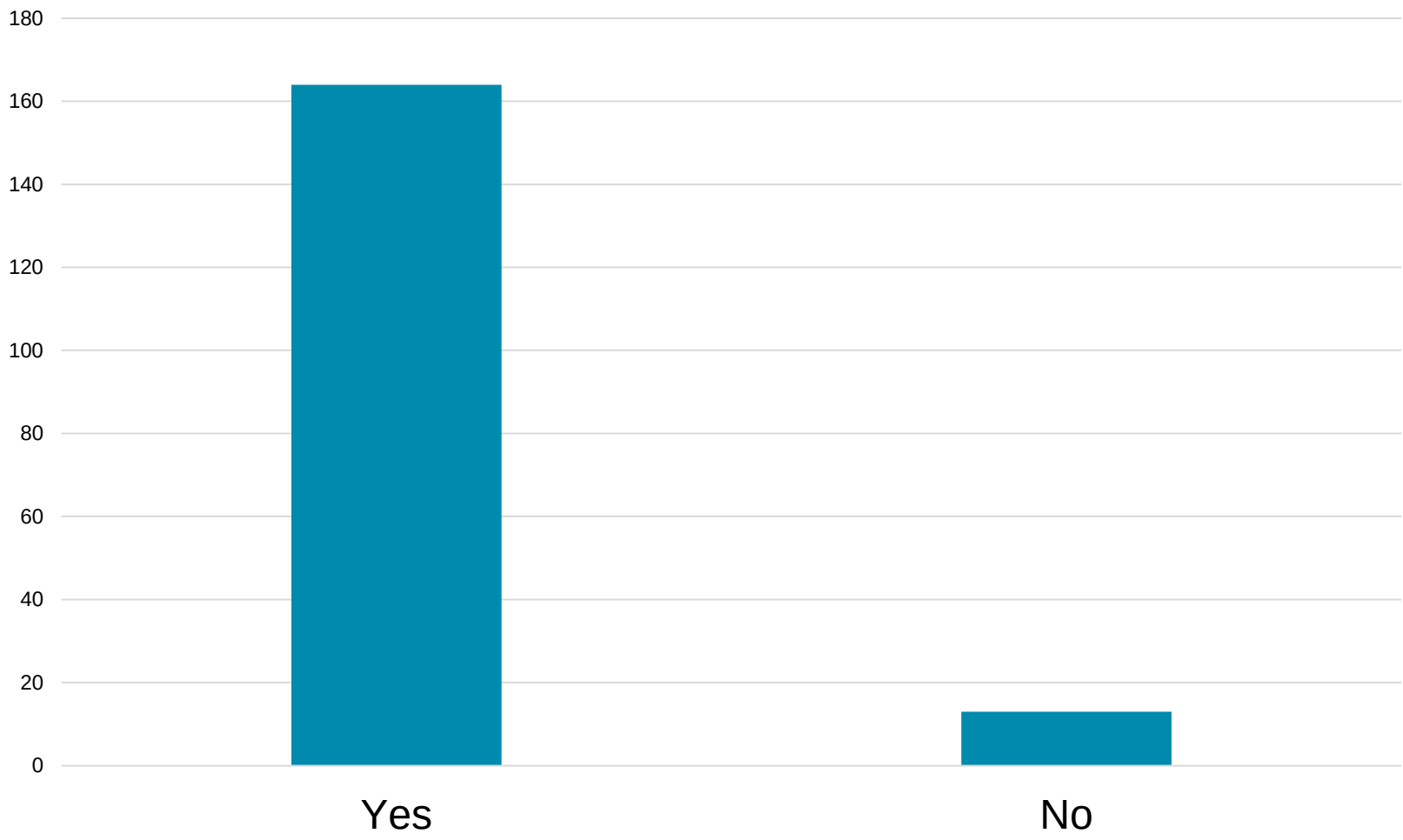
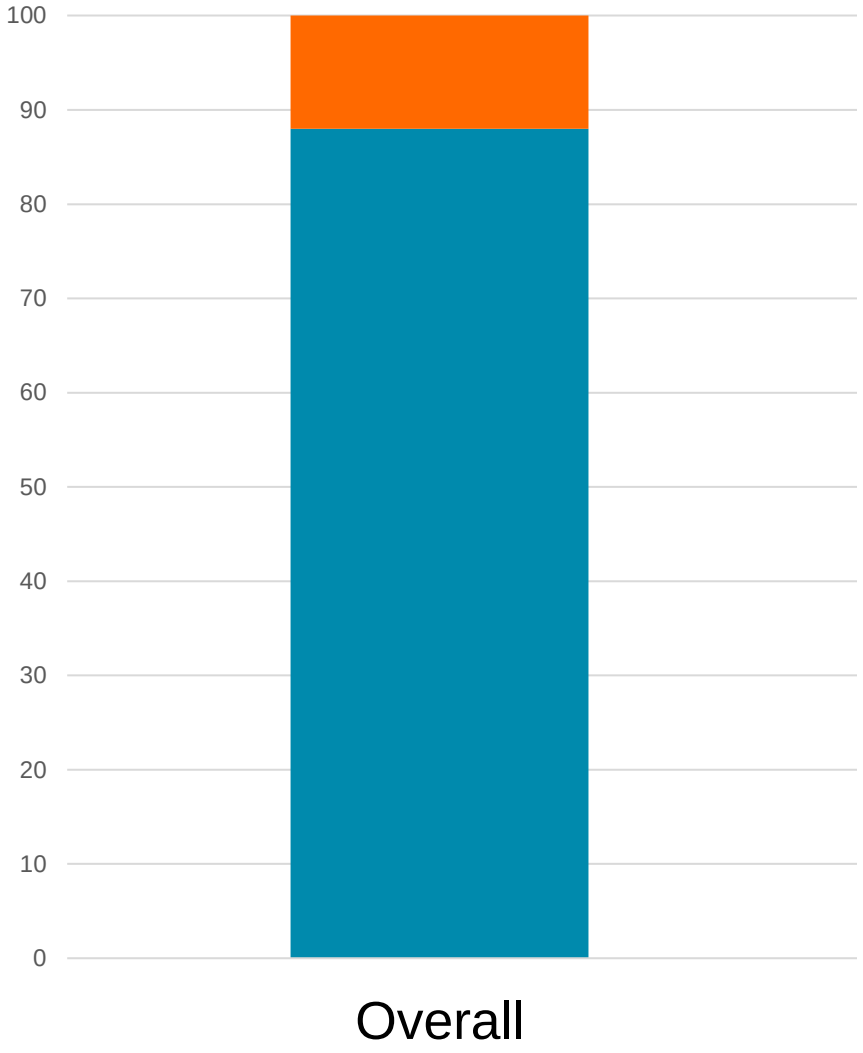
Baseline characteristics of respondents (patients)	
Age: Mean (IQR)	67 (62-74)
ICON 8 arm	**N (%)**
Standard treatment	57 (32)
Dose fractionated paclitaxel	61 (34)
Dose fractionated carboplatin & paclitaxel	62 (34)
Highest level of education	
A level or below	137 (77)
Degree or higher	41 (23)
English as first language	172 (97)
Use of internet or email	
Less than daily	71 (40)
Daily	108 (60)

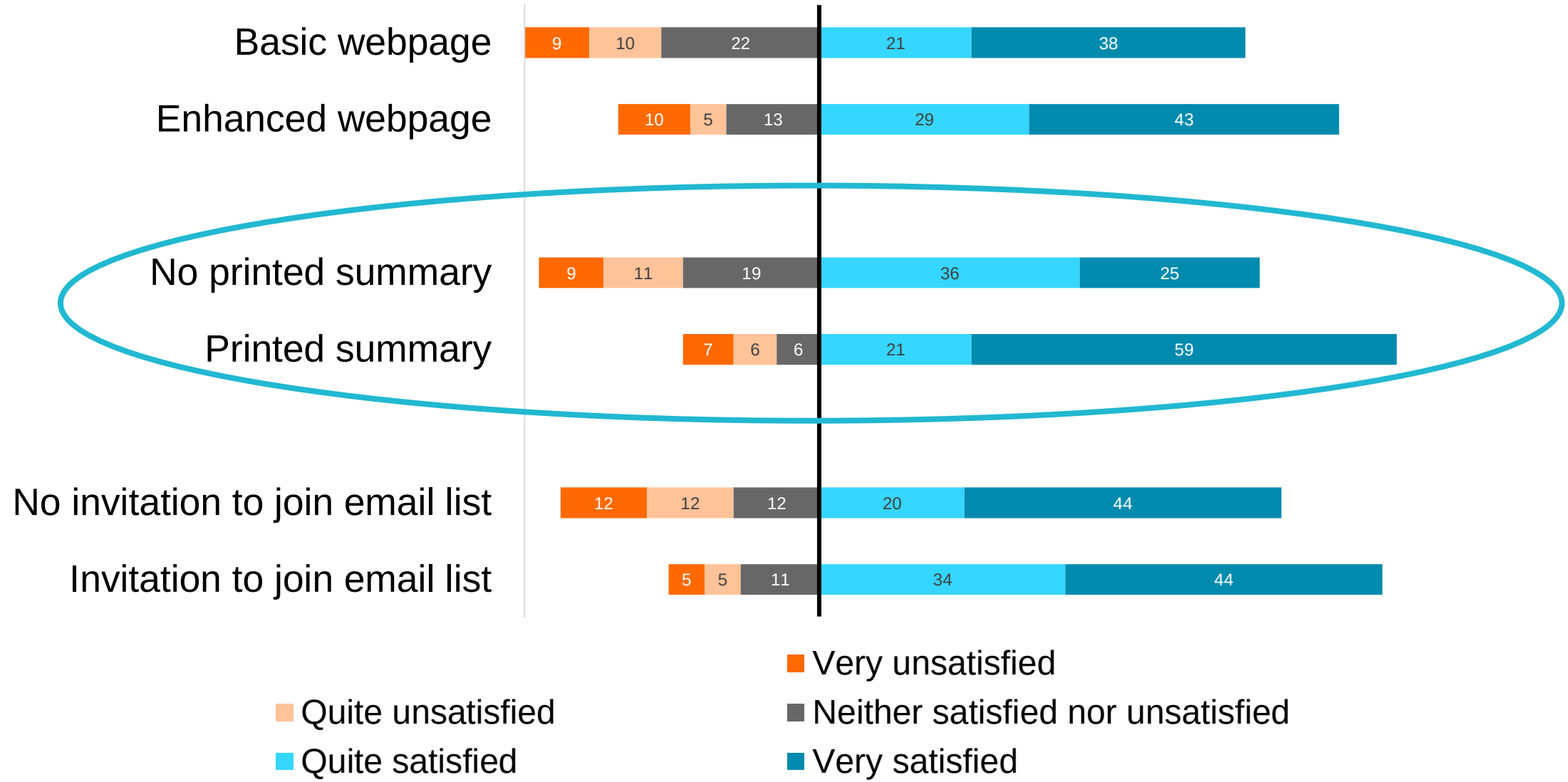
Did participants want to know the results?



Proportion of women who wanted to hear the results who did



Patient satisfaction with how the results were shared



Adjusted ordinal odds ratio: 3.15 (1.66 to 5.98) p<0.001

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Site staff views on sharing results with participants

Site staff views on sharing results

Strong support for principle of offering results to all participants

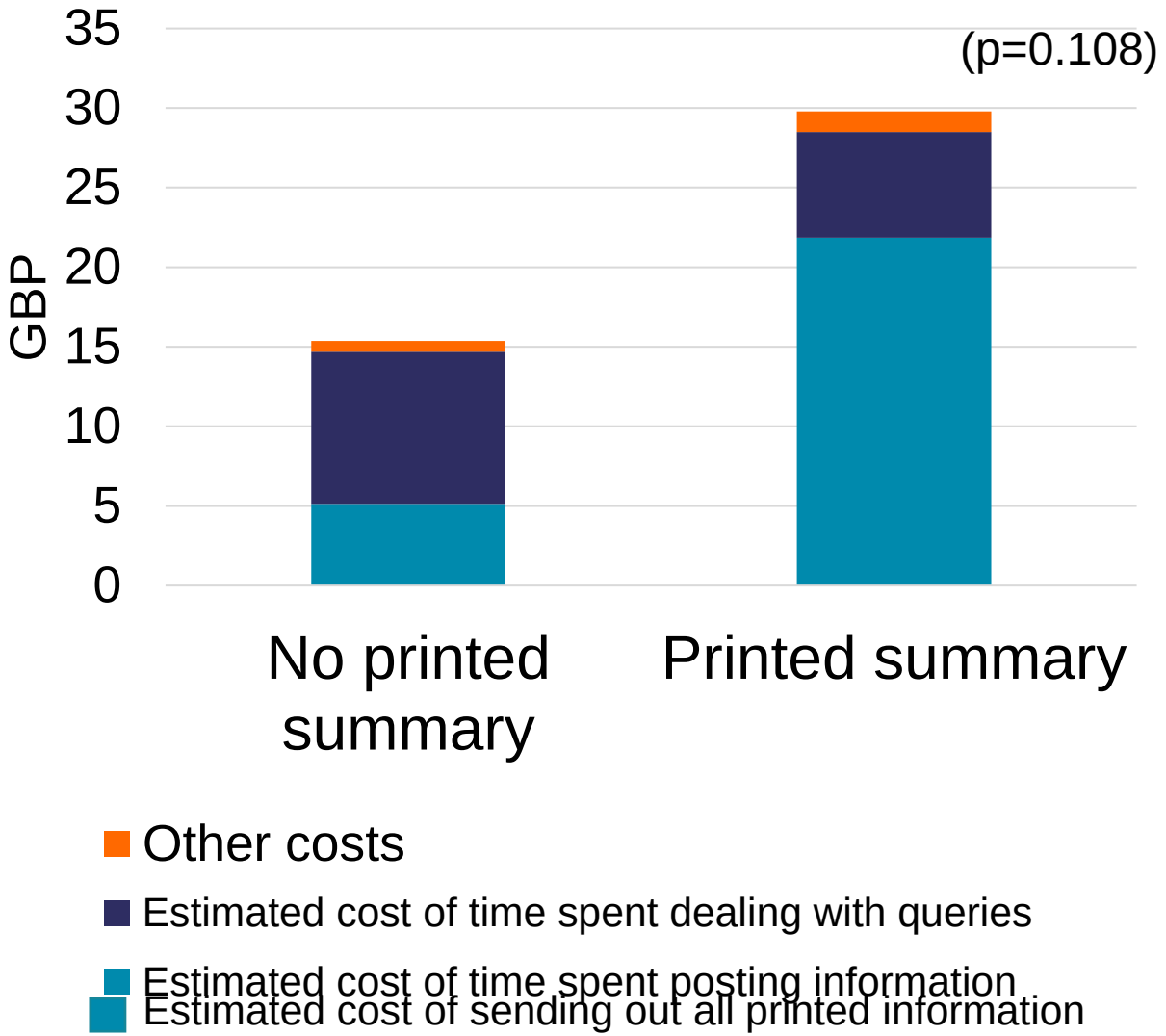
Motivation for sharing results linked to participants' motivation for joining trials

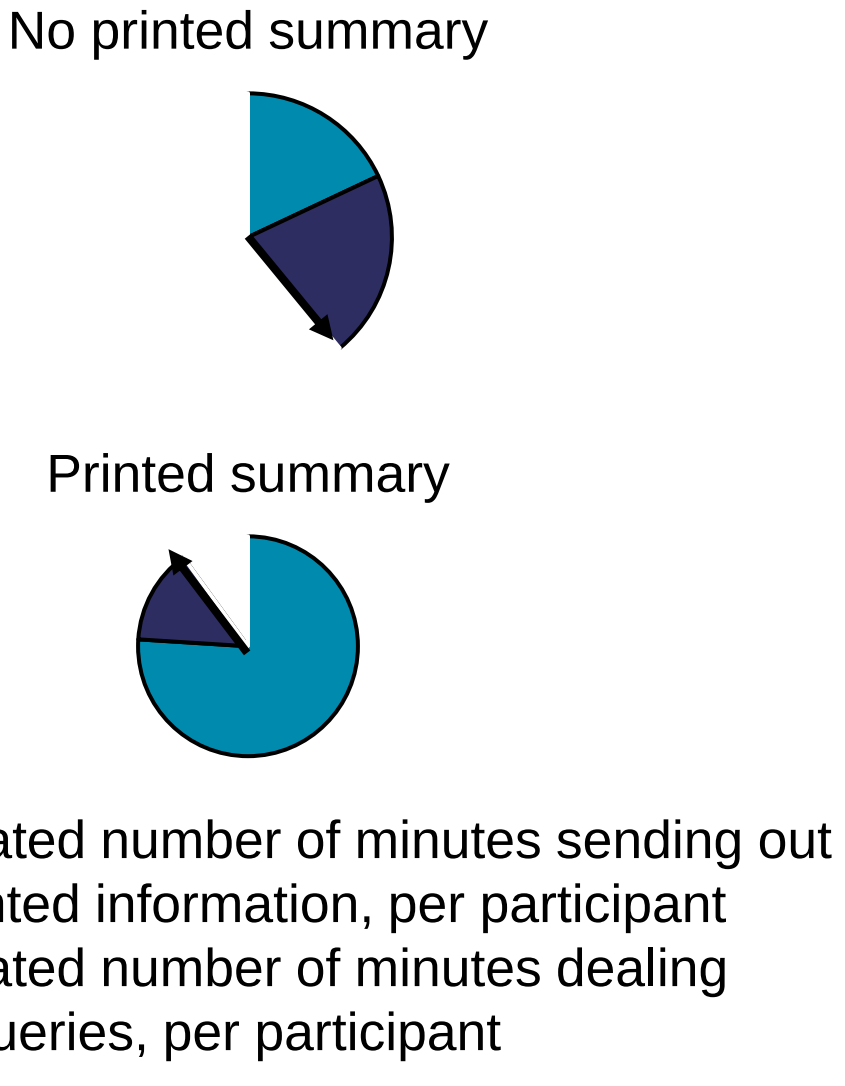
Benefits of sharing results with participants:

- Showing respect and valuing participants' contribution
- Increasing awareness of benefit of research
- Help participants process their trial experience

Most had no experience of systematically sharing trial results, prior to Show RESPECT

Resources required from sites to share results

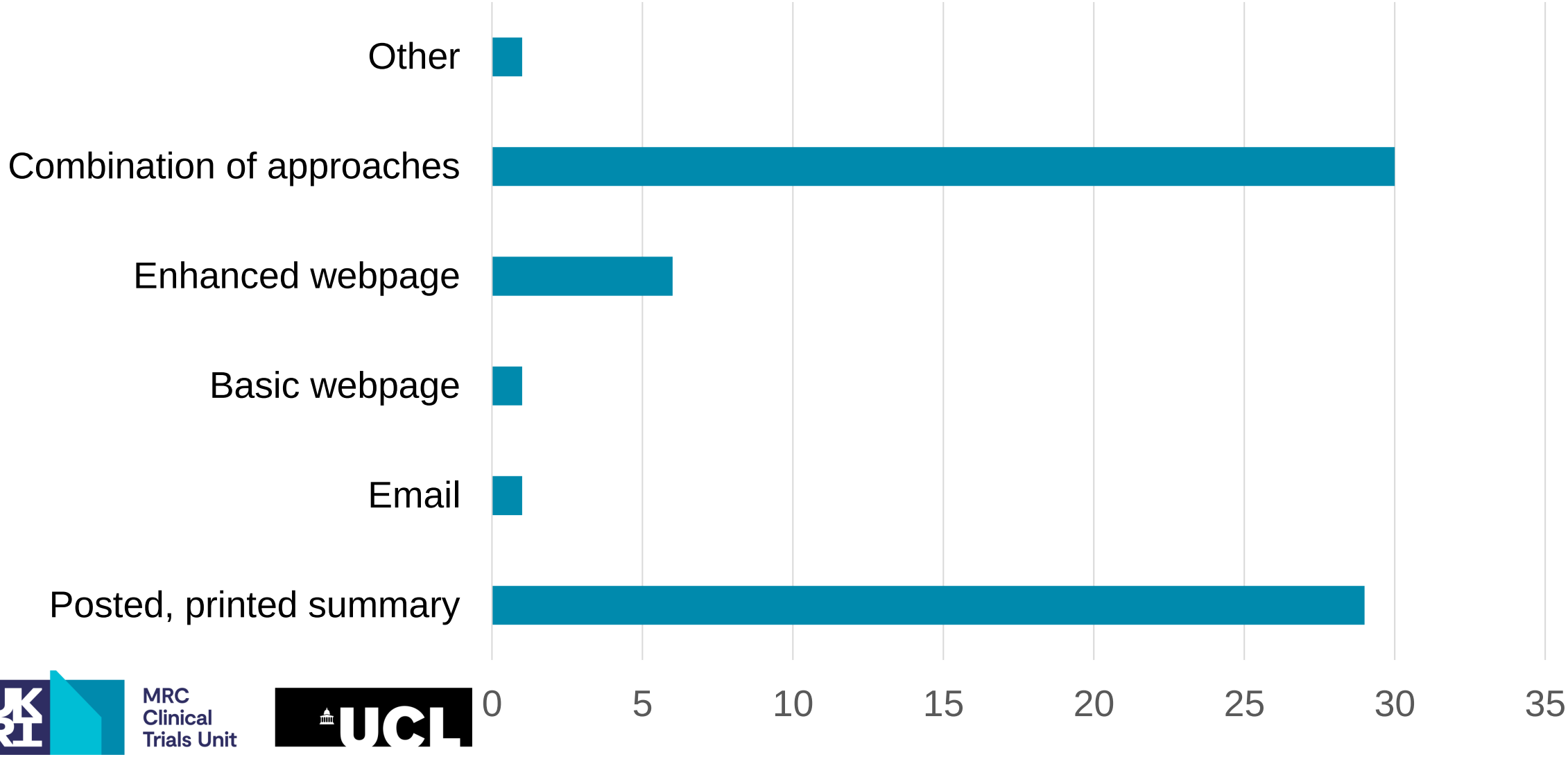




Time and costs to the Clinical Trials Unit

	Development time (hours)	Testing/ reviewing time (hours)	Distribution time (hours)	Total (hours)	Approximate cost of time (GBP)
Patient Update information Sheet	17	9.5	9.5	36	1545
Basic webpage	4	9.5	n/a	13.5	564
Enhanced webpage	11	9.5	n/a	20.5	872
Printed Summary	11.5	13	2	26.5	1182
Email list	22	17	2	41	1695
Total	**65.5**	**58.5**	**13.5**	**119.5**	**5858**

How do site staff prefer to share results with participants?



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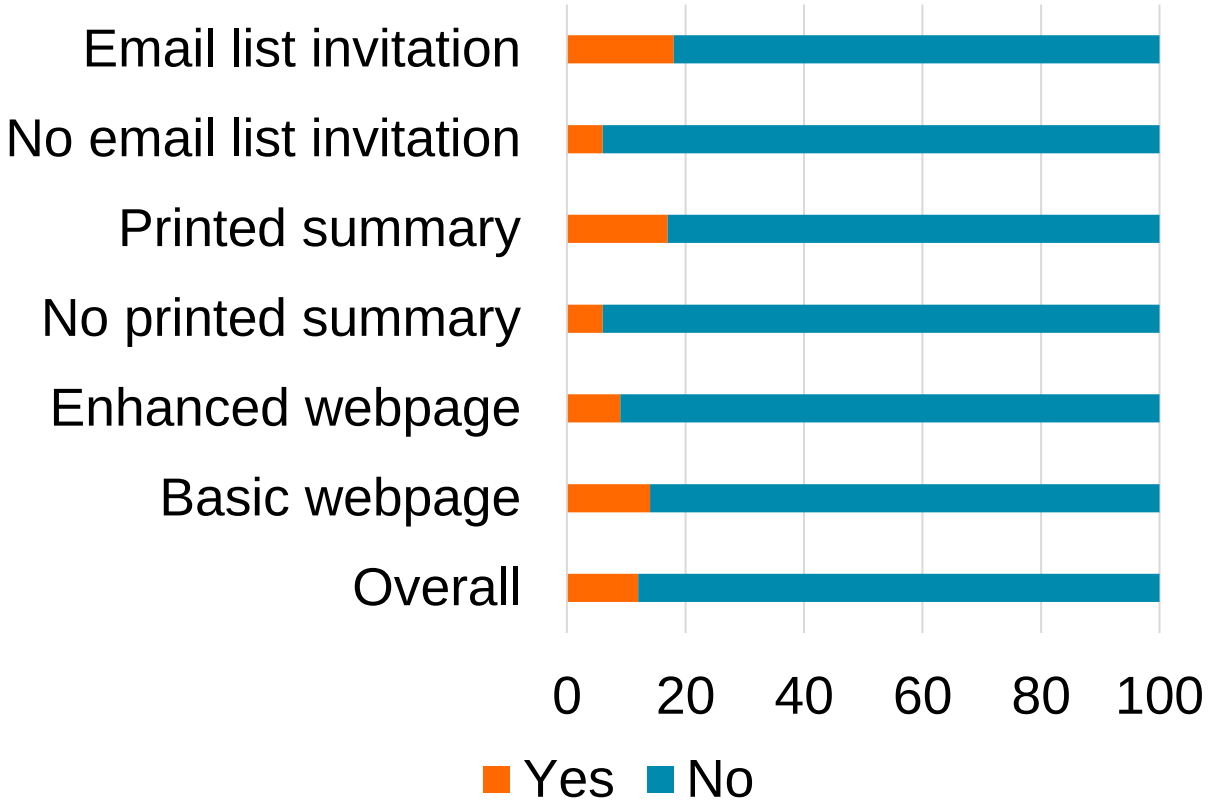
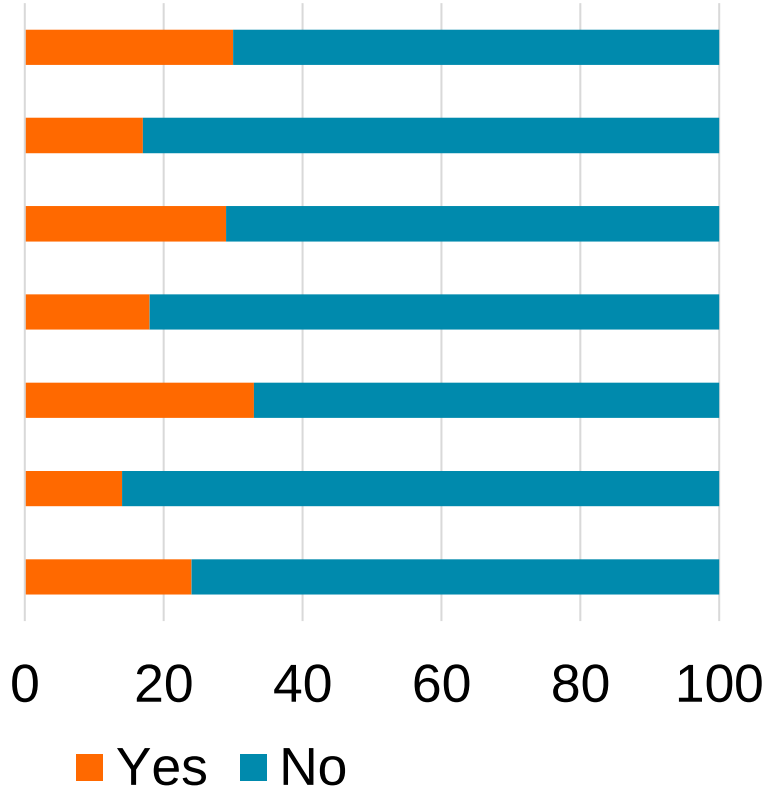
Challenges and concerns

Any concerns about how you shared the results?

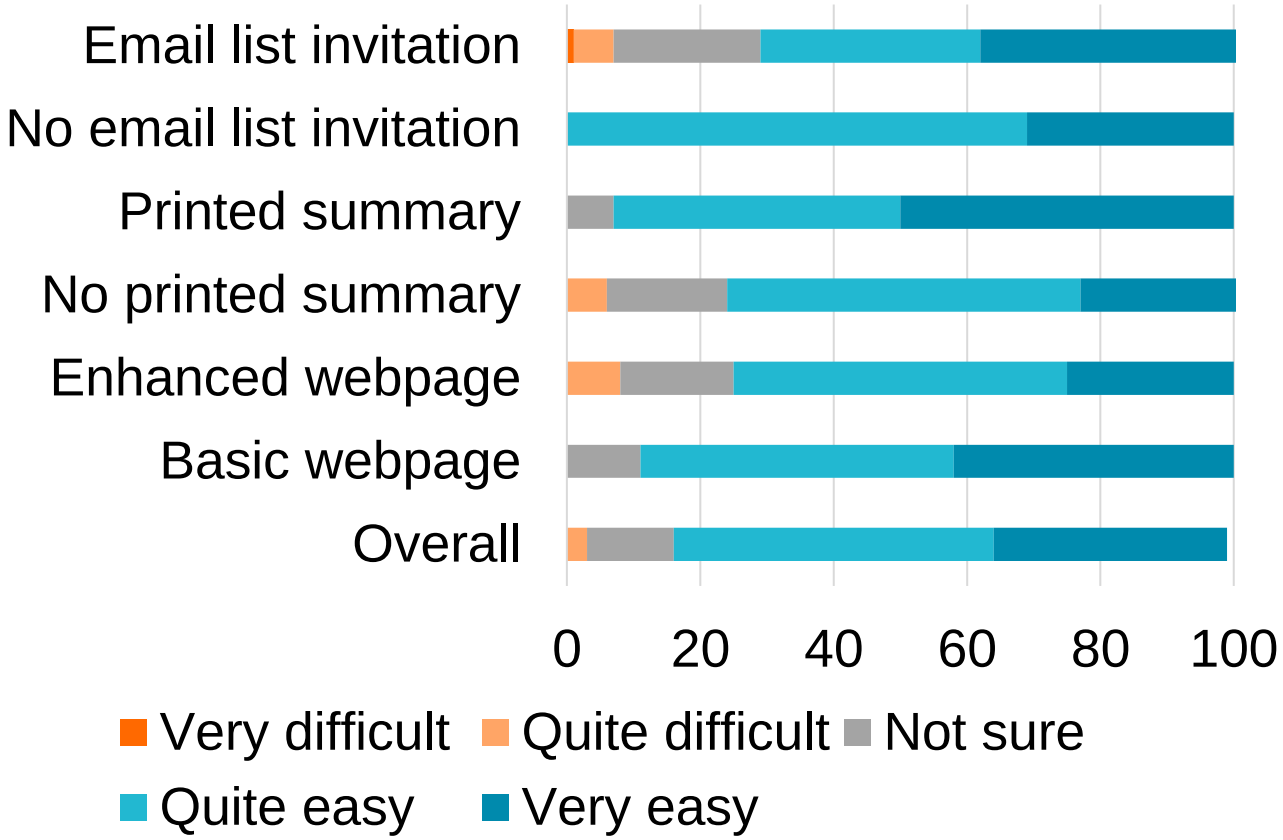


Did you find anything challenging about sharing the results?

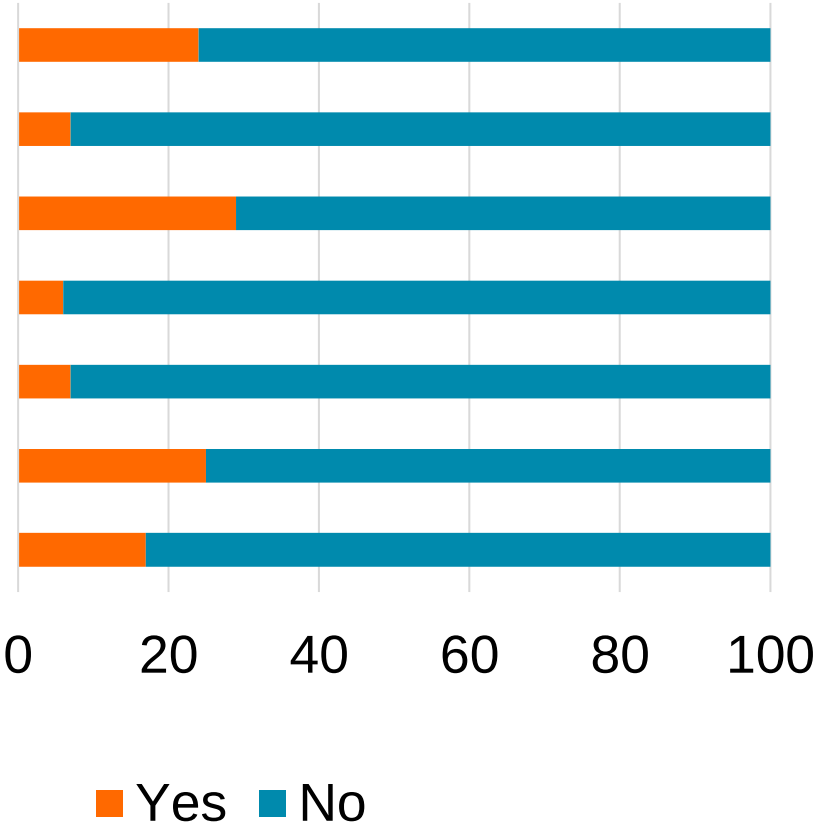


Dealing with queries and upset participants

How easy was it to help with queries?

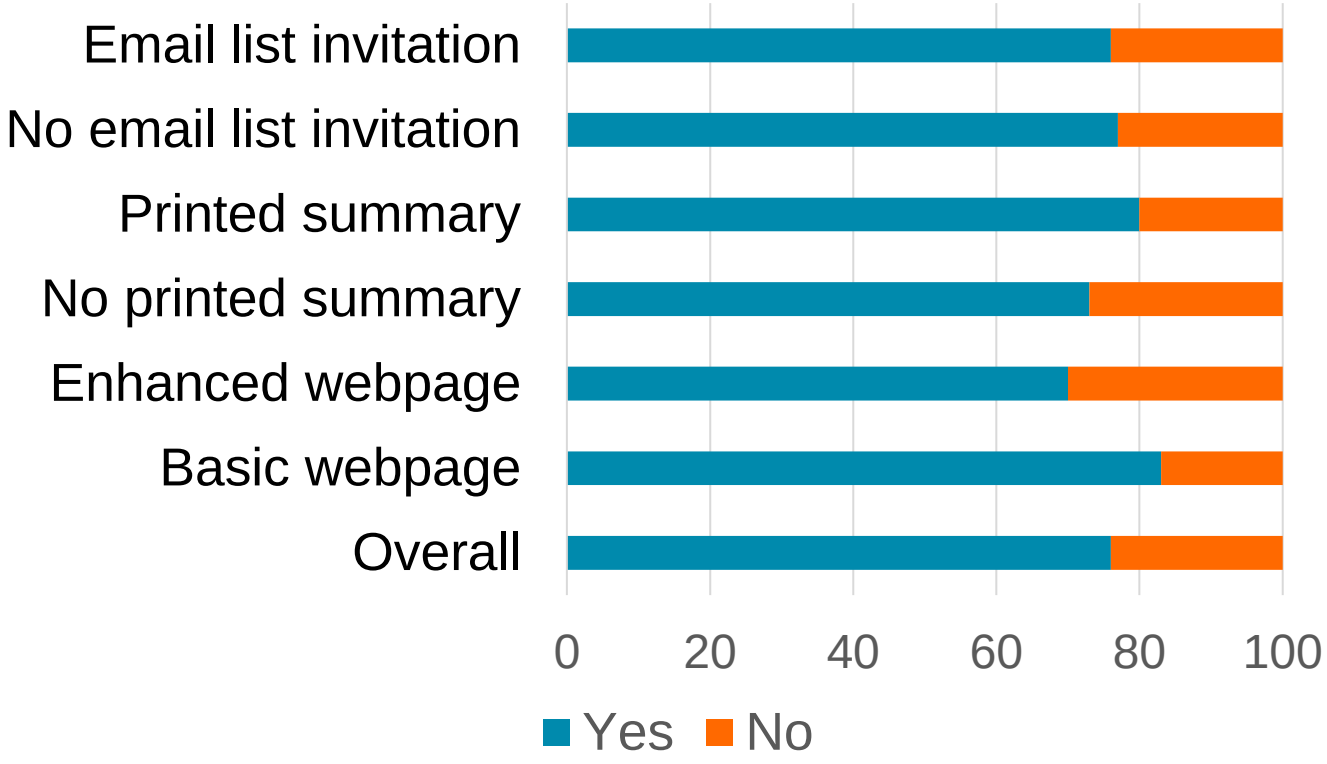


Do you remember any participants being upset?

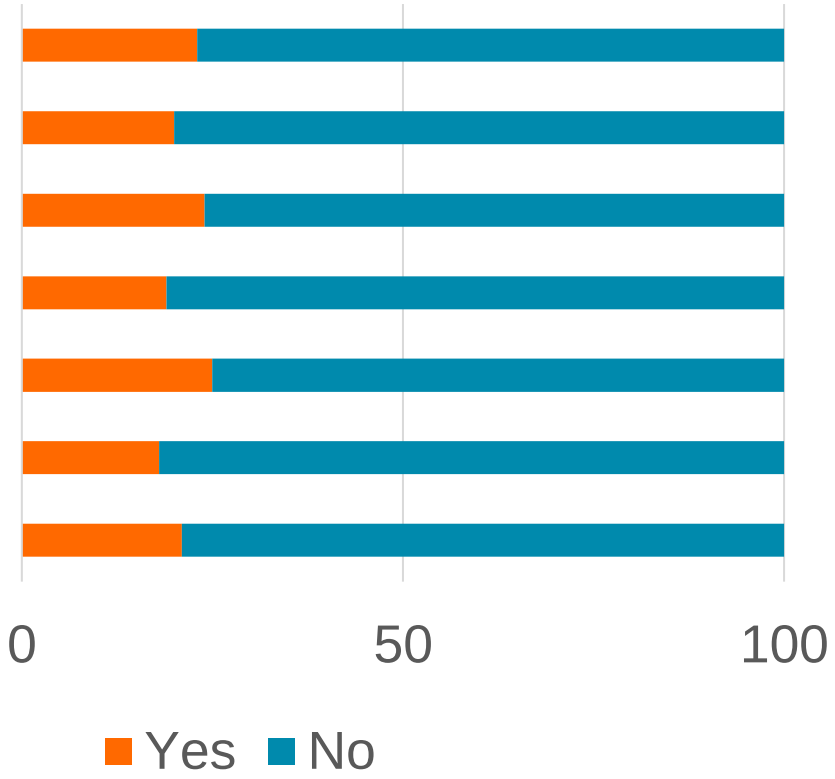


Sharing results in future trials

Should the way you shared results with participants be the standard approach for other trials?



Would you do anything different for future trials?



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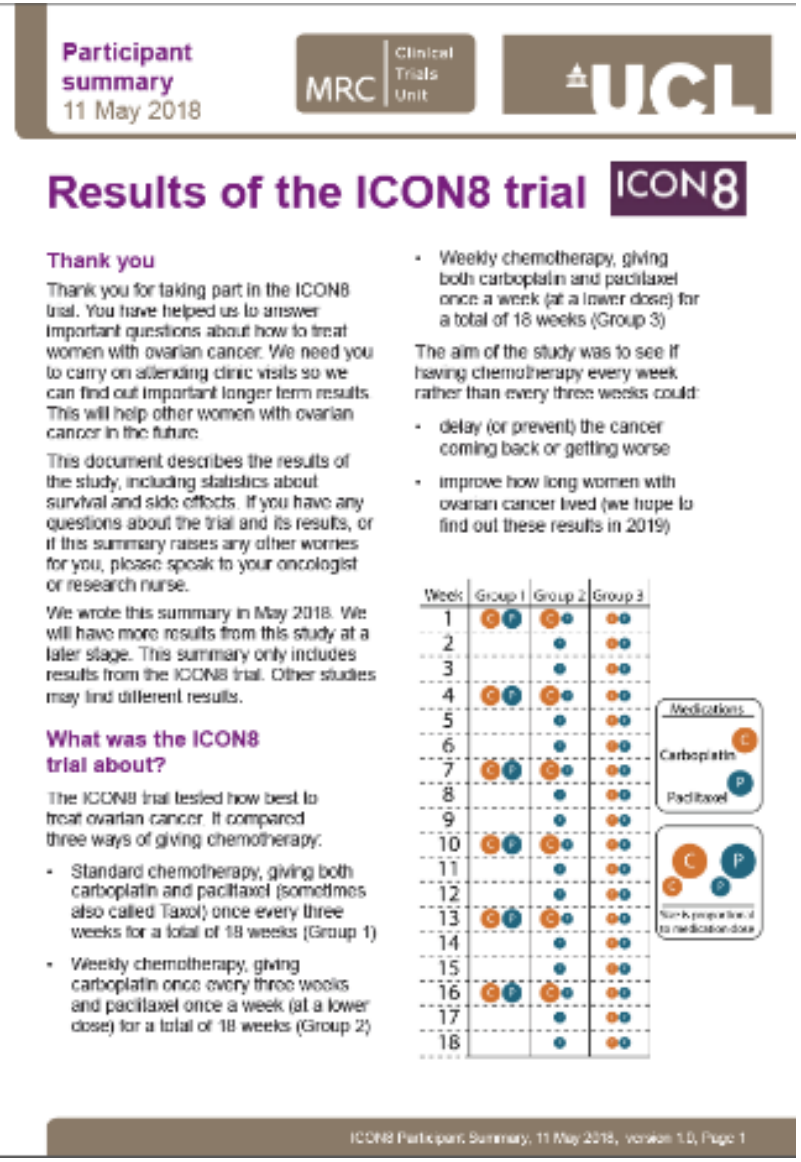
What factors influence participant satisfaction with how results are shared?

Participant characteristics influence the appropriateness of different communication approaches



Participant summary
11 May 2018

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Results of the ICON8 trial

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- Standard chemotherapy, giving both carboplatin and paclitaxel (sometimes also called Taxol) once every three weeks for a total of 18 weeks (Group 1)
- Weekly chemotherapy, giving carboplatin once every three weeks and paclitaxel once a week (at a lower dose) for a total of 18 weeks (Group 2)
- Weekly chemotherapy, giving both carboplatin and paclitaxel once a week (at a lower dose) for a total of 18 weeks (Group 3)

The aim of the study was to see if having chemotherapy every week rather than every three weeks could:

- delay (or prevent) the cancer coming back or getting worse
- improve how long women with ovarian cancer lived (we hope to find out these results in 2019)

ICON8 Participant Summary, 11 May 2018, version 1.0, Page 1

Printed summaries viewed as being easy to access for all participants:

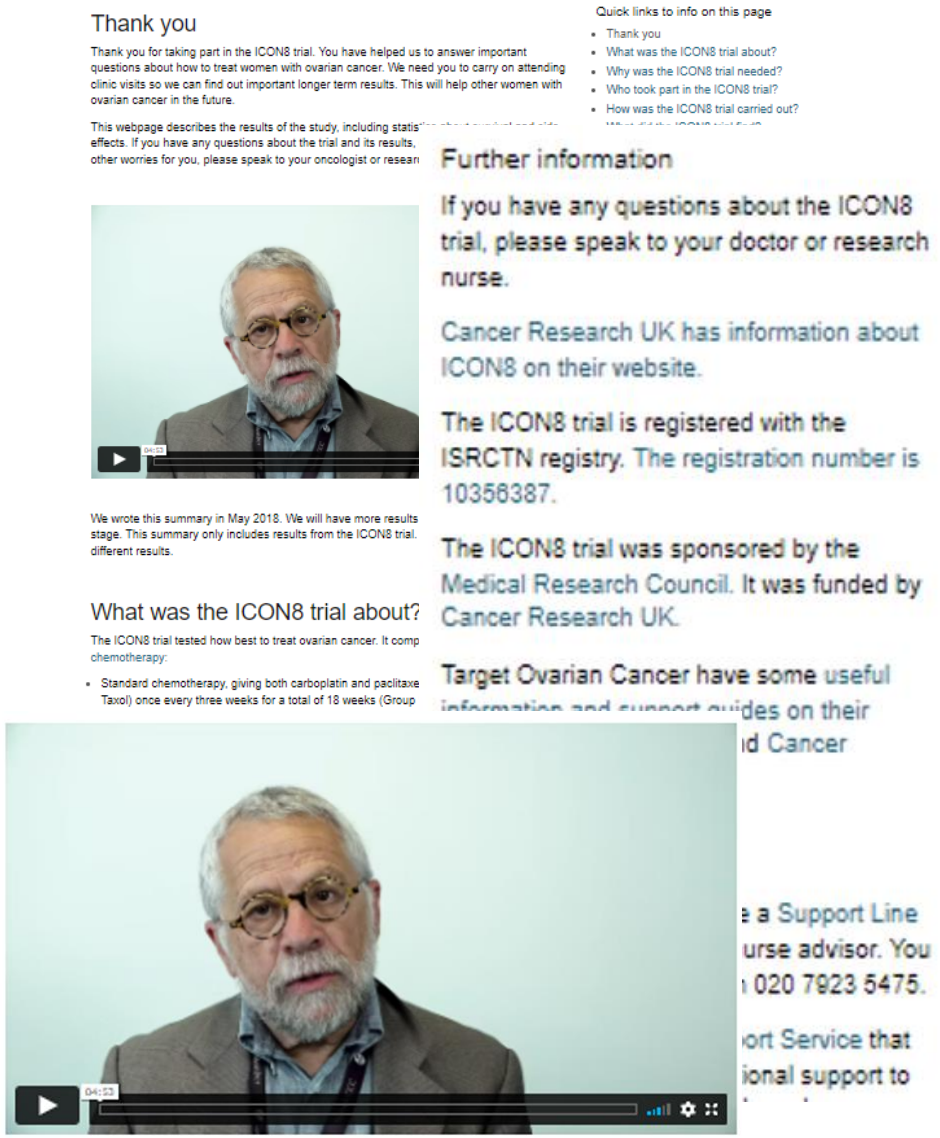
- Particularly for older patients
- Or those who aren't comfortable with internet use

Easy to file for further reference
Easy to show to others

"Like my mum, for instance, in her 80s, she wouldn't have access to this [webpage], so she would only want… She would only be able to have posted results, really."

GMI02: Patient, medium site

Participant characteristics influence the appropriateness of different communication approaches



Links to further info & support, and FAQ section useful:

- For those who like lots of information
- For those with less access to support

Video helpful for those who aren't keen on reading

"I think making results as accessible as possible and making sure that there is a facility for this to be a two-way process, within reason, is important. I would hope that most trial participants would be able to do that with their treating oncologist and research nurse, but if they're not, I think having the ability to do that with the trials unit, and the trial team, is important."

HLCLI02: Clinician, large site

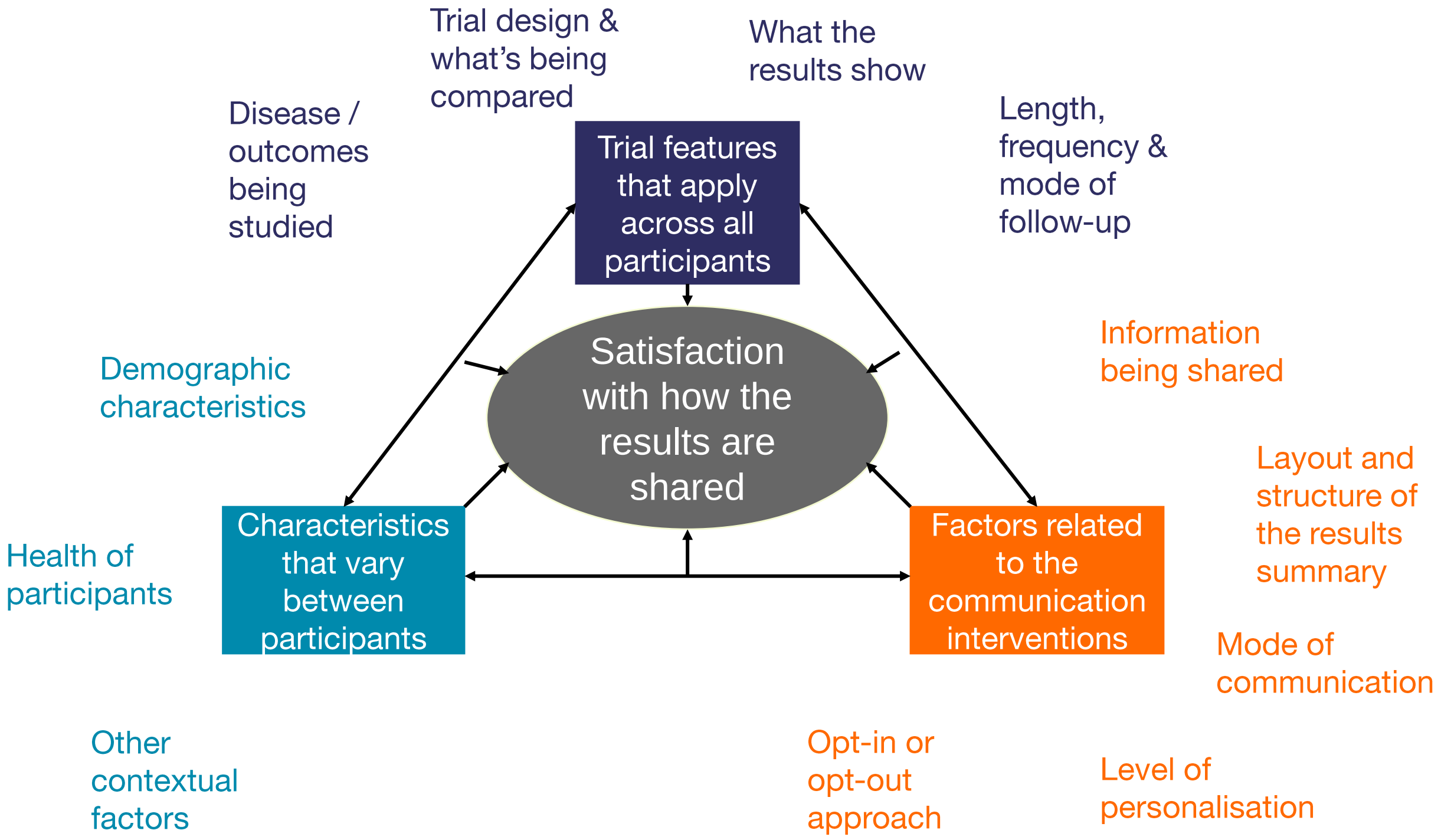
The nature of the trial (results) affects how results should be shared

More personal approaches may be needed:

- If results are complex or upsetting (eg to those in inferior arm)
  - Maybe less important for less serious conditions

Some degree of personalisation may be needed in trials where close relationships develop between participants and site staff

“I sent it by itself, but just because I didn’t know the patients. I want a cover letter to be quite personal, and so I wasn’t comfortable writing a cover letter to patients I didn’t particularly know. And then I didn’t want it to be generic, I feel like they probably deserve a bit more than that.” *CLTCI04: Trial Coordinator, large site*


Trial design & what's being compared
What the results show
Disease / outcomes being studied
Length, frequency & mode of follow-up
Trial features that apply across all participants
Satisfaction with how the results are shared
Information being shared
Demographic characteristics
Layout and structure of the results summary
Characteristics that vary between participants
Factors related to the communication interventions
Health of participants
Mode of communication
Other contextual factors
Opt-in or opt-out approach
Level of personalisation

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Discussion & Recommendations

Limitations

- Only carried out within one trial context
- Not powered to detect differences in site staff outcomes
- Only able to explore a limited range of factors
  - Need further research in other settings

Implications for other studies

Site staff want to share results with participants, but need to be supported to do so

Importance of logs and following up with sites

How do we balance the constraints of sites with large numbers of participants vs the demand from patients?

HRA currently developing guidance on sharing results with participants

Recommendations for researchers (1)

- How results will be shared with participants must be considered from the planning stage of studies
- When deciding how to share results with participants, consider the following factors: who the trial population is, the information to be communicated, who should share the results, the resources available for doing this, the tools and process for sharing results, and timing of communication

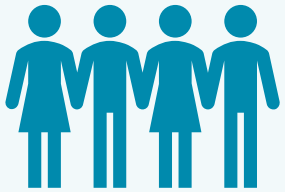
Recommendations for researchers (2)

- Participants should be offered choice over whether to receive results or not
- Patient and public involvement is essential
- Plans for sharing overall trial results should take into consideration whether this is likely to raise questions about individual results or randomised allocation, how these questions will be dealt with and by whom

Conclusions: Patients

- Participants want to be offered trial results
- Patient Update Information Sheet followed by Printed Summary (Opt-out) was best approach tested for patient populations like those in ICON8

Conclusions: patients



No one-size-fits-all approach to sharing results with participants

Need to consider

Participant characteristics

How the results may affect them emotionally

What they may want to do with the results

Context of relationships developed with site staff during the trial

Conclusions: site staff

- Site staff strongly support sharing results with participants
- The approaches tested in the Show RESPECT study were feasible to implement for site staff
- Sending out printed results summaries takes time, but site staff prefer this approach to purely electronic means of communication for this patient population
- Site staff were keen to be able to share results systematically with participants in future trials

Thank you

Andrew Clamp; Rick Kaplan; Liz James; Adrian Cook; Babasola Popoola; Francesca Schiavone; Jonathan Badrock; Cara Purvis; Sierra Santana; Carlos Diaz-Montana; Andrew Copas; Nalinie Joharatnam-Hogan, Archie MacNair; Ania Sperdon; Will Cragg; Conor Tweed; Matt Sydes; Katie Gillies; Barbara Bierer; Amanda Hunn; Jane Oakley; Eva Burnett; Julia Bailey; Talia Isaacs; Claire Snowdon
PPI contributors
Patients and staff of: Musgrove Park Hospital: Northampton General Hospital; York Hospital; Queen Elizabeth the Queen Mother; Queen's Hospital (Romford); Nottingham University Hospital; Peterborough City; North Devon District Hospital; Norfolk & Norwich University Hospital; Royal United Hospital; Dorset County Hospital; Airedale General Hospital; Great Western Hospital; Royal Cornwall Hospital; George Eliot Hospital; Royal Berkshire Hospital; Mount Vernon / Lister; Royal Marsden Sutton/ Chelsea; Velindre; Royal Devon & Exeter; Broomfield Hospital; St Bartholomews Hospital; Clatterbridge; Christie Hospital; Royal Derby Hospital; Ipswich Hospital; Hinchingbrooke Hospital; Warwick Hospital; Torbay District General Hospital; Bedford Hospital; Maidstone Hospital; Cheltenham General Hospital; Royal Shrewsbury Hospital; Southend University Hospital; Hammersmith Hospital; Royal Lancaster Infirmary; University Hospital Coventry & Warwickshire; Weston Park Hospital; Huddersfield Royal Infirmary; Addenbrookes Hospital; Castle Hill Hospital; St James' University Hospital; St George's Hospital

UKRI MRC Clinical Trials Unit

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