

# Show Results to Participants Engaged in Clinical Trials: Basic results summary

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## Objectives

To test three hypotheses evaluating which method of communicating trial results leads to the greatest participant satisfaction. The hypotheses were that satisfaction rates would be higher using:

- 1) an Enhanced Webpage compared to a Basic Webpage
- 2) a Printed Summary sent by post on an opt-out basis compared to no Printed Summary
- 3) An invitation to join an Email List compared to no invitation being issued

## Design

A cluster randomised 2 by 2 by 2 factorial study within a trial, testing different approaches to communicating results to trial participants. Each cluster was a UK secondary or tertiary care centre that was part of the ICON8 ovarian cancer trial (ISRCTN10356387). Allocations were not blinded, although patients were not aware that patients at other sites were being offered results using a different approach.

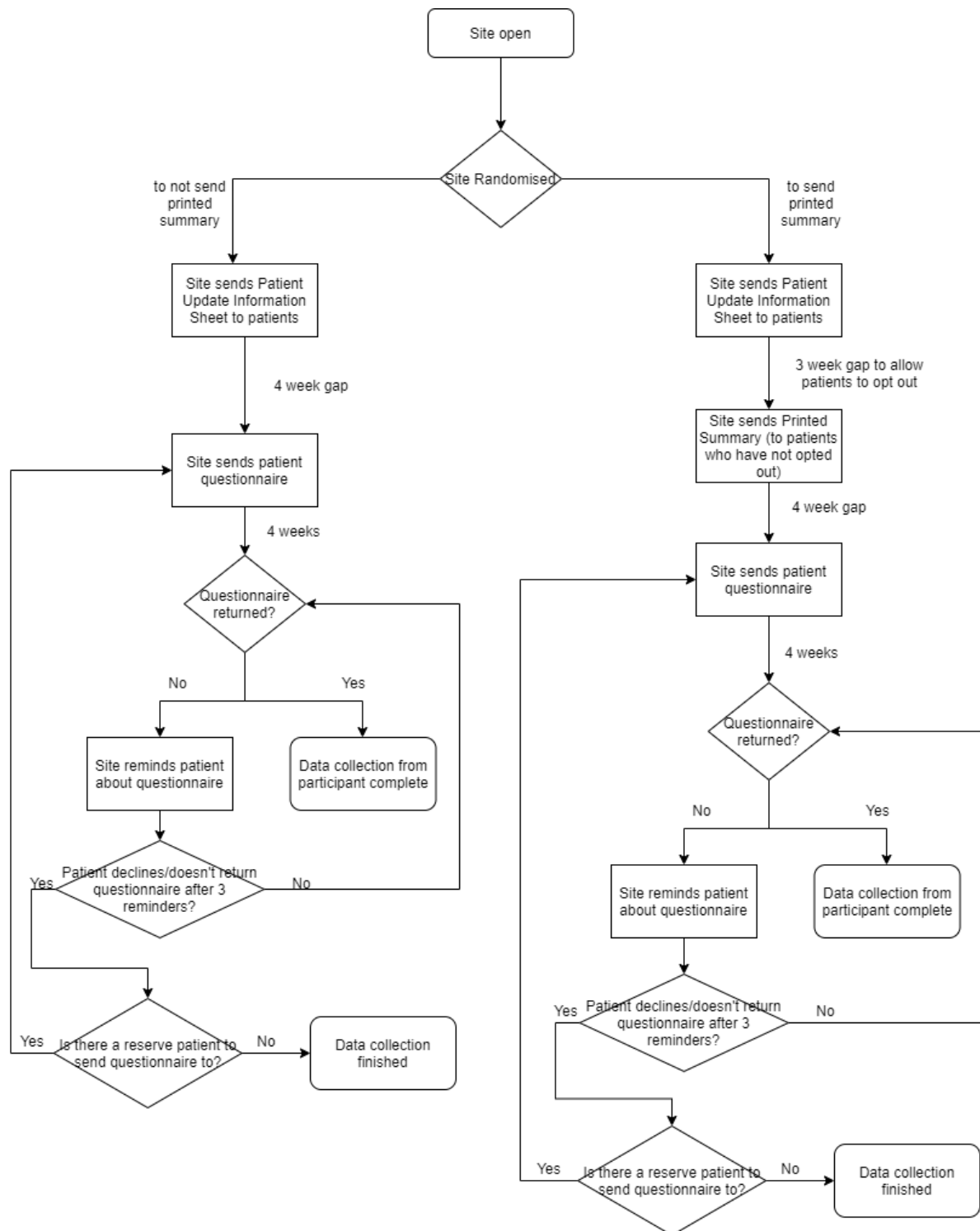
## Interventions process

Figure 1 shows the intervention and data collection process. All eligible ICON8 participants at sites participating in Show RESPECT were sent a Patient Update Information Sheet (PUIS). This thanked them for taking part in ICON8 and informed them that the results were available, and how to access them (depending on which interventions their site was randomised to). This included a link to the allocated webpage, and, if randomised to the email list invitation, a link to sign-up to the email list. For sites randomised to the Printed Summary intervention, the PUIS informed patients that they would be sent a Printed Summary of the results in three weeks' time, unless they opted out. After the three weeks had elapsed, the Printed Summaries were sent to patients at these sites who had not opted out. The content of the interventions was not tailored to the ICON8 arm the participant had been in.

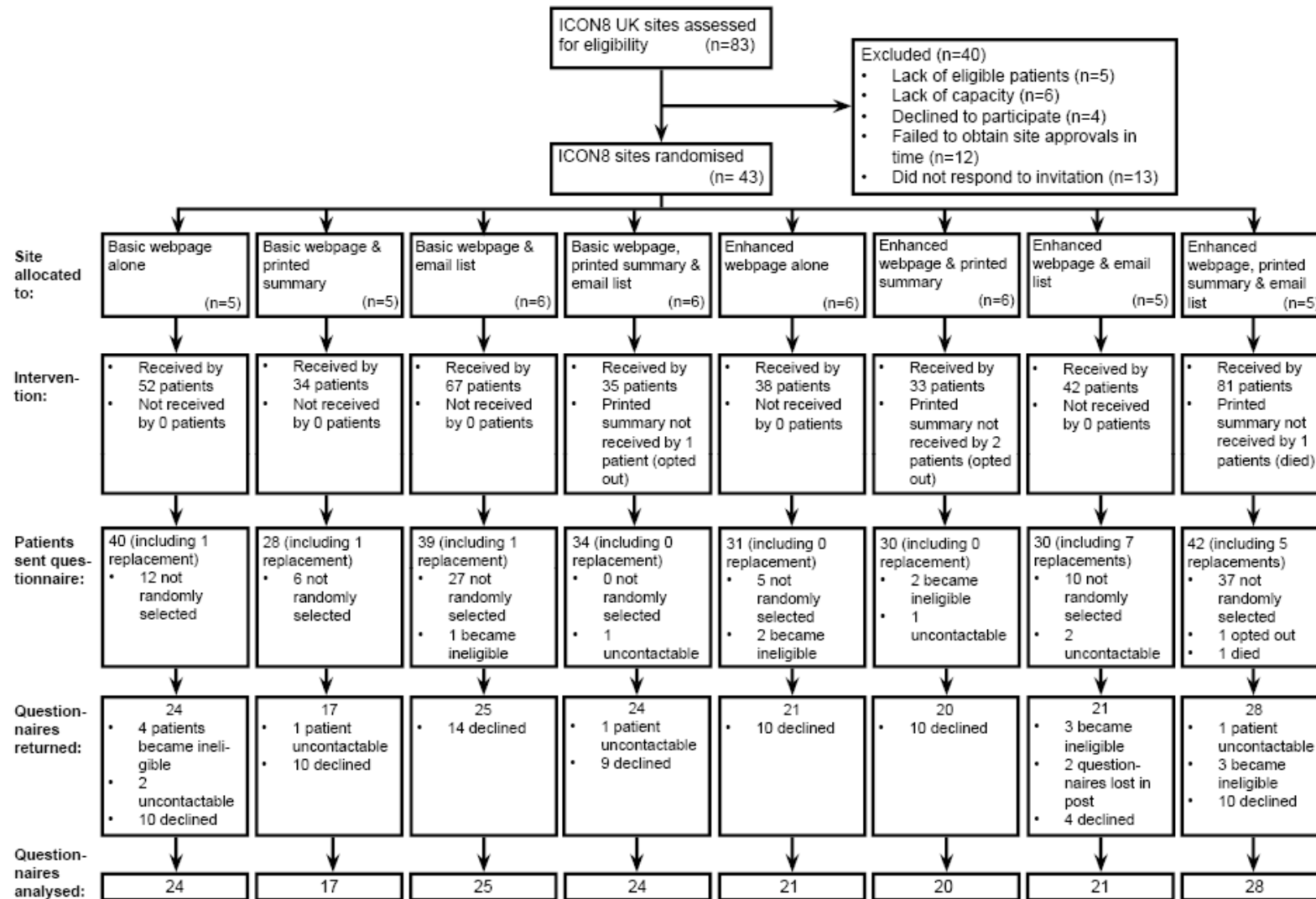
## Data Collection

Four weeks after the PUIS (for sites randomised to no Printed Summary) or the Printed Summary was sent to patients (for sites randomised to the Printed Summary), the patient feedback questionnaire was posted to patients. At small sites ( $\leq 5$  eligible participants), these questionnaires were sent to all eligible patients. At medium (6-12 eligible participants) and large sites ( $> 12$  eligible participants), questionnaires were sent to 6 (for medium-sized sites) or 12 (for large sites) randomly selected eligible patients. A randomly ordered reserve list was drawn up for sites with more eligible patients than were initially sent questionnaires. If a patient from the initial sample declined to take part, or did not return their questionnaire after three reminders, the next patient on the reserve list was sent a questionnaire (see Figures 1 and 2).

**Figure 1: Intervention and data collection process**



**Figure 2: Consort Diagram**



**Table 1: Baseline characteristics of all eligible participants at trial sites**

(NB. Not all of these participants were sent the questionnaire – see protocol for further details).

	Webpage		Printed summary		Email list	
	Basic webpage	Enhanced webpage	No printed summary	Printed summary	No invitation	Invitation
<b>Age</b>						
Mean (IQR)	67 (61-74)	66 (58-73)	66 (59-73)	67 (60-74)	67 (61-74)	66 (59-73)
≤70 years	115 (58%)	121 (63%)	125 (62%)	111 (60%)	90 (57%)	146 (63%)
> 70 years	82 (42%)	71 (37%)	78 (38%)	75 (40%)	68 (43%)	85 (37%)
<b>ICON8 arm</b>						
A	58 (29%)	67 (35%)	63 (31%)	62 (33%)	50 (32%)	75 (32%)
B	73 (37%)	62 (32%)	72 (35%)	63 (34%)	53 (34%)	82 (35%)
C	66 (34%)	63 (33%)	68 (33%)	61 (33%)	55 (35%)	74 (32%)

**Table 2: Baseline Characteristics of participants who returned the questionnaire**

	Webpage		Printed summary		Email list		Overall
	Basic webpage	Enhanced webpage	No printed summary	Printed summary	No invitation	Invitation	
<b>Total</b>	<b>90</b>	<b>90</b>	<b>91</b>	<b>89</b>	<b>82</b>	<b>98</b>	<b>180</b>
<b>Age</b>							
Mean (IQR)	67 (61-74)	68 (62-74)	67 (61-74)	68 (62-74)	68 (63-75)	67 (61-73)	67 (62-74)
	<b>n (%)</b>	<b>n (%)</b>	<b>n (%)</b>	<b>n (%)</b>	<b>n (%)</b>	<b>n (%)</b>	<b>n (%)</b>
≤70 years	52 (58)	51 (57)	52 (57)	51 (57)	43 (52)	60 (61)	103 (57)
>70 years	38 (42)	39 (43)	39 (43)	38 (43)	39 (48)	38 (39)	77 (43)
<b>ICON8 arm</b>							
Standard treatment	26 (29)	31 (34)	29 (32)	28 (31)	25 (30)	32 (33)	57 (32)
Dose fractionated paclitaxel	33 (37)	28 (31)	32 (35)	29 (33)	28 (34)	33 (34)	61 (34)
Dose fractionated carboplatin & paclitaxel	31 (34)	31 (34)	30 (33)	32 (36)	29 (35)	33 (34)	62 (34)
<b>Highest level of educational attainment</b>							
No qualifications	14 (16)	24 (27)	25 (27)	13 (15)	19 (23)	19 (20)	38 (21)
GCSE or equivalent	28 (31)	29 (33)	26 (29)	31 (36)	32 (40)	25 (26)	57 (32)
A-level or equivalent	25 (28)	17 (19)	18 (20)	24 (28)	17 (21)	25 (26)	42 (24)
Undergraduate degree	11 (12)	13 (15)	11 (12)	13 (15)	8 (10)	16 (16)	24 (13)
Postgraduate degree	11 (12)	6 (7)	11 (12)	6 (7)	5 (6)	12 (12)	17 (10)
<b>English as first language</b>							
Yes	82 (93)	90 (100)	85 (96)	87 (98)	78 (98)	94 (96)	172 (97)
No	6 (7)	0 (0)	4 (4)	2 (2)	2 (3)	4 (4)	6 (3)
<b>Use of internet or email</b>							
Never	17 (19)	9 (10)	13 (14)	13 (15)	11 (13)	15 (15)	26 (15)
Once per month at most	3 (3)	4 (4)	4 (4)	3 (3)	6 (7)	1 (1)	7 (4)
More than once per month, but not as often as every week	1 (1)	10 (11)	6 (7)	5 (6)	0 (0)	11 (11)	11 (6)
Once per week or more, but not as often as every day	10 (11)	17 (19)	15 (17)	12 (13)	16 (20)	11 (11)	27 (15)
Every day	58 (65)	50 (56)	52 (58)	56 (63)	49 (60)	59 (61)	108 (60)

## Outcome measures<sup>1</sup>

**Table 3: Primary outcome: Participant's satisfaction with the way they found out the results of ICON8**

	Webpage				Printed summary				Email list				Overall n (%)
	Basic webpage n (%)	Enhanced webpage n (%)	Unadjusted OR <sup>2</sup> (95% CI) p-value	Adjusted OR <sup>3</sup> (95% CI) p-value	No printed summary n (%)	Printed summary n (%)	Unadjusted OR <sup>2</sup> (95% CI) p-value	Adjusted OR <sup>3</sup> (95% CI) p-value	No invitation n (%)	Invitation n (%)	Unadjusted OR <sup>2</sup> (95% CI) p-value	Adjusted OR <sup>3</sup> (95% CI) p-value	
Reported satisfaction with how the results were communicated													
Very unsatisfied	7 (9)	8 (10)	1.39 (0.75 to 2.59) p=0.295	1.47 (0.78 to 2.76) p=0.235	6 (9)	6 (7)	3.27 (1.74 to 6.16) p<0.001	3.15 (1.66 to 5.98) p<0.001	8 (12)	4 (5)	1.33 (0.71 to 2.47) p=0.373	1.38 (0.72 to 2.63) p=0.327	12 (8)
Quite unsatisfied	8 (10)	4 (5)			7 (11)	5 (6)			8 (12)	4 (5)			12 (8)
Neither satisfied nor unsatisfied	17 (22)	11 (13)			12 (19)	5 (6)			8 (12)	9 (11)			17 (12)
Quite satisfied	16 (21)	24 (29)			23 (36)	17 (21)			13 (20)	27 (34)			40 (28)
Very satisfied	29 (38)	36 (43)			16 (25)	48 (59)			29 (44)	35 (44)			64 (44)

<sup>1</sup> NB. Outcome measures from Site staff and CTU staff data have not yet been analysed. We will post an update with these results when they are available.

<sup>2</sup> Odds ratio from ordinal regression, assuming proportional odds. Adjusted for strata, randomisation phase (early vs late) and clustering. OR>1 indicates greater satisfaction, OR<1 indicates less.

<sup>3</sup> Odds ratio from ordinal regression, assuming proportional odds. Adjusted for age, education level and internet use as well as strata, randomisation phase (early vs late) and clustering OR>1 indicates greater satisfaction, OR<1 indicates less.

**Table 4: Secondary outcomes**

	Webpage				Printed summary				Email list				Overall n (%)	
	Basic webpage n (%)	Enhanced webpage n (%)	Unadjusted OR <sup>4</sup> (95% CI) p-value	Adjusted OR <sup>5</sup> (95% CI) p-value	No printed summary n (%)	Printed summary n (%)	Unadjusted OR <sup>4</sup> (95% CI) p-value	Adjusted OR <sup>5</sup> (95% CI) p-value	No invitation n (%)	Invitation n (%)	Unadjusted OR <sup>4</sup> (95% CI) p-value	Adjusted OR <sup>5</sup> (95% CI) p-value		
The information told me everything I wanted to know <sup>6</sup>														
Strongly disagree	0 (0)	3 (4)	2.13 (1.13 to 4.00) p=0.019	2.15 (1.13 to 4.07) p=0.019	0 (0)	3 (4)	1.32 (0.70 to 2.46) p=0.391	1.32 (0.70 to 2.48) p=0.394	1 (1)	2 (3)	1.12 (0.60 to 2.10) p=0.728	1.11 (0.58 to 2.12) p=0.759	3 (2)	
Slightly disagree	5 (7)	2 (3)			1 (2)	6 (7)			3 (4)	4 (5)			7 (5)	
Neither agree nor disagree	16 (23)	10 (13)			15 (23)	11 (14)			13 (19)	13 (16)			26 (18)	
Slightly agree	21 (30)	13 (17)			20 (31)	14 (17)			16 (24)	18 (23)			34 (23)	
Strongly agree	28 (40)	48 (63)			29 (45)	47 (58)			34 (51)	42 (53)			76 (52)	
The information was easy to understand <sup>6</sup>														
Strongly disagree	2 (3)	4 (5)	0.92 (0.47 to 1.81) p=0.817	1.05 (0.53 to 2.08) p=0.895	1 (2)	5 (6)	1.60 (0.82 to 3.11) p=0.167	1.66 (0.84 to 3.27) p=0.144	2 (3)	4 (5)	0.85 (0.43 to 1.66) p=0.627	0.79 (0.39 to 1.59) p=0.500	6 (4)	
Slightly disagree	4 (6)	1 (1)			2 (3)	3 (4)			3 (4)	2 (3)			5 (3)	
Neither agree nor disagree	10 (14)	8 (11)			12 (18)	6 (7)			8 (12)	10 (13)			18 (12)	
Slightly agree	10 (14)	16 (21)			14 (22)	12 (15)			10 (15)	16 (20)			26 (18)	
Strongly agree	44 (63)	47 (62)			36 (55)	55 (68)			44 (66)	47 (59)			91 (62)	
I found the results upsetting														
Strongly disagree	40 (59)	35 (49)	1.26 (0.66 to 2.41) p=0.485	1.24 (0.65 to 2.39) p=0.514	35 (55)	40 (53)	1.21 (0.64 to 2.30) p=0.564	1.31 (0.68 to 2.51) p=0.421	39 (61)	36 (47)	1.68 (0.87 to 3.23) p=0.123	1.54 (0.79 to 3.00) p=0.206	75 (54)	
Slightly disagree	5 (7)	7 (10)			6 (9)	6 (8)			4 (6)	8 (11)			12 (9)	
Neither agree nor disagree	11 (16)	19 (26)			15 (23)	15 (20)			14 (22)	16 (21)			30 (21)	
Slightly agree	7 (10)	9 (13)			8 (13)	8 (11)			2 (3)	14 (18)			16 (11)	
Strongly agree	5 (7)	2 (3)			0 (0)	7 (9)			5 (8)	2 (3)			7 (5)	

<sup>4</sup> Odds ratio from ordinal regression, assuming proportional odds. Adjusted for strata, randomisation phase (early vs late) and clustering. OR>1 indicates greater agreement, OR<1 indicates less agreement with the statement.

<sup>5</sup> Odds ratio from ordinal regression, assuming proportional odds. Adjusted for age, education level and internet use as well as strata, randomisation phase (early vs late) and clustering. OR>1 indicates greater agreement, OR<1 indicates less agreement with the statement.

<sup>6</sup> For producing the odds ratios for this variable, the strongly and slightly disagree categories were merged.

	Webpage				Printed summary				Email list				Overall n (%)	
	Basic webpage n (%)	Enhanced webpage n (%)	Unadjusted OR <sup>7</sup> (95% CI) p-value	Adjusted OR <sup>8</sup> (95% CI) p-value	No printed summary n (%)	Printed summary n (%)	Unadjusted OR <sup>7</sup> (95% CI) p-value	Adjusted OR <sup>8</sup> (95% CI) p-value	No invitation n (%)	Invitation n (%)	Unadjusted OR <sup>7</sup> (95% CI) p-value	Adjusted OR <sup>8</sup> (95% CI) p-value		
How willing are you to take part in future research? <sup>9</sup>														
Very unwilling	1 (1)	2 (3)	0.77 (0.37 to 1.62) p=0.494	0.80 (0.38 to 1.70) p=0.567	3 (5)	0 (0)	1.11 (0.54 to 2.30) p=0.777	1.09 (0.52 to 2.28) p=0.827	2 (3)	1 (1)	0.72 (0.34 to 1.51) p=0.380	0.70 (0.33 to 1.53) p=0.375	3 (2)	
Quite unwilling	1 (1)	1 (1)			1 (2)	1 (1)			1 (1)	1 (1)			2 (1)	
Not sure	6 (8)	4 (5)			2 (3)	8 (10)			3 (4)	7 (9)			10 (7)	
Quite willing	9 (13)	16 (21)			13 (20)	12 (15)			10 (15)	15 (19)			25 (17)	
Very willing	54 (76)	52 (69)			47 (71)	59 (74)			51 (76)	55 (70)			106 (73)	
How likely are you to recommend taking part in research to others? <sup>10</sup>														
Very unlikely	3 (4)	3 (4)	1.13 (0.55 to 2.31) p=0.739	1.17 (0.56 to 2.44) p=0.671	5 (7)	1 (1)	1.28 (0.63 to 2.62) p=0.491	1.23 (0.59 to 2.57) p=0.579	2 (3)	4 (5)	0.82 (0.40 to 1.69) p=0.594	0.77 (0.36 to 1.65) p=0.507	6 (4)	
Quite unlikely	1 (1)	1 (1)			0 (0)	2 (3)			1 (1)	1 (1)			2 (1)	
Not sure	6 (8)	1 (1)			2 (3)	5 (6)			4 (6)	3 (4)			7 (5)	
Quite likely	11 (15)	17 (23)			15 (22)	13 (16)			11 (16)	17 (21)			28 (19)	
Very likely	51 (71)	53 (71)			45 (67)	59 (74)			49 (73)	55 (69)			104 (71)	
I am glad I found out the trial results <sup>11</sup>														
Strongly disagree	0 (0)	2 (3)	0.79 (0.38 to 1.65) p=0.533	0.84 (0.40 to 1.75) p=0.638	0 (0)	2 (3)	1.69 (0.81 to 3.50) p=0.161	1.69 (0.81 to 3.53) p=0.162	1 (2)	1 (1)	0.80 (0.39 to 1.67) p=0.555	0.76 (0.36 to 1.62) p=0.475	2 (1)	
Slightly disagree	1 (1)	1 (1)			0 (0)	2 (3)			0 (0)	2 (3)			2 (1)	
Neither agree nor disagree	7 (10)	7 (9)			9 (14)	5 (6)			5 (8)	9 (11)			14 (10)	
Slightly agree	12 (17)	13 (17)			14 (21)	11 (14)			13 (20)	12 (15)			25 (17)	
Strongly agree	50 (71)	52 (69)			43 (65)	59 (75)			47 (71)	55 (70)			102 (70)	
I regret finding out the trial results <sup>12</sup>														
Strongly disagree	53 (79)	48 (68)	1.51 (0.74 to 3.01) p=0.253	1.41 (0.68 to 2.92) p=0.354	45 (70)	56 (76)	0.93 (0.46 to 1.88) p=0.850	0.94 (0.46 to 1.91) p=0.856	48 (76)	53 (71)	1.51 (0.74 to 3.08) p=0.253	1.51 (0.72 to 3.16) p=0.279	101 (73)	
Slightly disagree	3 (4)	9 (13)			7 (11)	5 (7)			7 (11)	5 (7)			12 (9)	
Neither agree nor disagree	9 (13)	12 (17)			10 (16)	11 (15)			8 (13)	13 (17)			21 (15)	
Slightly agree	2 (3)	1 (1)			2 (3)	1 (1)			0 (0)	3 (4)			3 (2)	
Strongly agree	0 (0)	1 (1)			0 (0)	1 (1)			0 (0)	1 (1)			1 (1)	

<sup>7</sup> Odds ratio from ordinal regression, assuming proportional odds. Adjusted for strata, randomisation phase (early vs late) and clustering. OR>1 indicates greater willingness/likelihood/agreement, OR<1 indicates less.

<sup>8</sup> Odds ratio from ordinal regression, assuming proportional odds. Adjusted for age, education level and internet use as well as strata, randomisation phase (early vs late) and clustering OR>1 indicates greater willingness/likelihood/agreement, OR<1 indicates less.

<sup>9</sup> For calculating the odds ratios, the very unwilling, quite unwilling and not sure were merged for this variable



	Webpage				Printed summary				Email list				Overall n (%)
	Basic webpage n (%)	Enhanced webpage n (%)	Unadjusted OR <sup>13</sup> (95% CI) p-value	Adjusted OR <sup>14</sup> (95% CI) p-value	No printed summary n (%)	Printed summary n (%)	Unadjusted OR <sup>13</sup> (95% CI) p-value	Adjusted OR <sup>14</sup> (95% CI) p-value	No invitation n (%)	Invitation n (%)	Unadjusted OR <sup>13</sup> (95% CI) p-value	Adjusted OR <sup>14</sup> (95% CI) p-value	
It was easy to find the trial results													
Strongly disagree	5 (7)	3 (4)	1.34 (0.71 to 2.53) p=0.373	1.75 (0.90 to 3.42) p=0.100	3 (5)	5 (6)	1.15 (0.61 to 2.18) p=0.662	1.37 (0.71 to 2.66) p=0.345	5 (8)	3 (4)	0.81 (0.42 to 1.54) p=0.511	0.70 (0.36 to 1.38) p=0.306	8 (6)
Slightly disagree	5 (7)	4 (5)			7 (11)	2 (3)			4 (6)	5 (6)			9 (6)
Neither agree nor disagree	14 (21)	7 (9)			6 (9)	15 (19)			6 (9)	15 (19)			21 (15)
Slightly agree	8 (12)	19 (25)			14 (22)	13 (16)			11 (17)	16 (20)			27 (19)
Strongly agree	36 (53)	43 (57)			34 (53)	45 (56)			39 (60)	40 (51)			79 (55)

<sup>10</sup> For calculating the odds ratios, the very unlikely, quite unlikely and not sure were merged for this variable

<sup>11</sup> For calculating the odds ratios, the strongly disagree, slightly disagree and neither agree nor disagree categories were merged for this variable

<sup>12</sup> For calculating the odds ratios, the neither agree nor disagree, slightly agree and strongly agree categories were merged for this variable

<sup>13</sup> Odds ratio from ordinal regression, assuming proportional odds. Adjusted for strata, randomisation phase (early vs late) and clustering. OR>1 indicates greater agreement, OR<1 indicates less agreement with the statement.

<sup>14</sup> Odds ratio from ordinal regression, assuming proportional odds. Adjusted for age, education level and internet use as well as strata, randomisation phase (early vs late) and clustering. OR>1 indicates greater agreement, OR<1 indicates less agreement with the statement.

**Table 5: Proportion of respondents who reported finding out the results, of those who said they wanted to learn of the results**

	Webpage		Printed summary		Email list		Overall
	Basic webpage n/N (%)	Enhanced webpage n/N (%)	No printed summary n/N (%)	Printed summary n/N (%)	No invitation n/N (%)	Invitation n/N (%)	n/N (%)
Number of respondents who reported finding out the results, of those who said they wanted to learn of the results	71/80 (89)	74/84 (88)	67/81 (83)	78/83 (94)	65/74 (88)	80/90 (89)	145/164 (88)

**Proportion of respondents who reported not wanting to find out the results who did find out the results:** 0/13 (0%)

**Respondents' preferred way to receive the results:** data to follow

**Other ways respondents' would have liked to receive the results:** data to follow

**Reported uptake of the interventions:** data to follow

**Adverse events:** 8 respondents' questionnaire responses met the threshold to trigger the study clinician to inform site teams of potential concern (Strongly agreed or slightly agreed with 'I found the results upsetting to hear about', and answered at least one other question negatively).