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DISSEMINATING RESULTS TO CLINICAL TRIAL PARTICIPANTS: A QUALITATIVE REVIEW OF PATIENT UNDERSTANDING IN A POST-TRIAL POPULATION

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Disseminating results to clinical trial participants: a qualitative review of patient understanding in a post-trial population

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Structured Abstract

Objective: To identify the most appropriate format for results dissemination to maximise understanding

Design: Qualitative

Setting: Of the original 58 4-T Trial centres, 34 from the UK agreed to take part in this ancillary research.

Participants: All participants from these centres were eligible. 455 participants were sent questionnaires. 40 were completed and returned.

Primary & Secondary outcome measures: The low response rate meant that we were unable to make any firm conclusions about the patient preferred method of dissemination however we were able to comment on the level of understanding demonstrated by the trial participants.

Results: The returned questionnaires demonstrated broad satisfaction with the results letter circulated, general enthusiasm for the trial and a variable level of understanding of the results, however there was a high proportion of responders who were not clear on why the research was undertaken or what the results meant.

Conclusions: The low response rate is likely to reflect a biased cohort who were both enthusiastic about the research and who had a good experience during their three years in the trial. It is perhaps not surprising therefore that the overview is positive. That this population was still not fully informed about the purpose of the research would seem to confirm a low level of understanding amongst the general public which we suggest should be addressed during the consent process.

Trial Registration: Original 4-T Trial Registration ISRCTN51125379

Summary

Article Focus

* Investigation into participant satisfaction with method of dissemination and understanding of clinical trial results

* Exploration into reasons for participation in clinical trials

Key Messages

* Responders were broadly satisfied with their trial experience

* Responders did not demonstrate good understanding of results beyond their own treatment needs

* Responders reported a variety of reasons for taking part in the research including physician recommendation and altruism.

Strengths and Limitations

* The low response rate was disappointing, especially as it is likely that those who returned their questionnaires had a positive trial experience leading to a bias in the results

* That this motivated population still demonstrated limited understanding indicates that more needs to be done at the time of consent and during the trial

Objective

Clinical trial results are generally published solely within the healthcare community and rarely disseminated beyond scientific publications[1]. However, it is increasingly a requirement of ethical and regulatory approvals that the public is involved where possible in all stages of research, and that results are shared with the patients who took part. As a result of this interest in public and patient involvement it is now common for dissemination plans to form part of initial study proposals[1]. Researchers are therefore encouraged to share results with patients but there remains no consensus on the best method for doing this. Additionally, although patients participate willingly in clinical trials, it is not known if they are interested in knowing the results of the research to which they have contributed. It is also not known if they are aware of the reasons for the research. Previously we collected information retrospectively from clinical centres who held a patient event to share the one-year results from the three-year Treat to Target in Type 2 Diabetes (4-T) Trial[2] (Current Controlled Trials number, ISRCTN51125379). We discussed our experience and made suggestions for how the information collected could be used to inform further work in this area[3].

The 'coffee morning' approach was popular with patients, and staff did not find this onerous to organise, but whilst patients were aware of the implications for their personal future care, it remained unclear if patients fully understood the results of the study as a whole.

We decided to review patient understanding of the final results from the 4-T Trial which were also published and circulated to all participants. This open-label, multi-centre trial randomised 708 participants with type 2 diabetes which was suboptimally controlled with oral antihyperglycaemic therapy (glycated haemoglobin 7.0–10.0%) to the addition of a basal, biphasic or prandial insulin regimen. Patients were followed for three years and a second insulin formulation was added if glycaemic control remained inadequate. The final results concluded that patients initiated onto the long acting insulin detemir who

later added prandial doses of aspart achieved good glycaemic control with a lower risk of hypoglycaemia and less weight gain than patients initiated onto either the biphasic aspart or aspart insulins[4].

Design

Simultaneous to publication the 4-T centres were emailed a press release and letter detailing the headline trial results and were asked to forward a copy of the letter to all trial participants as soon as possible. Subsequently patients were invited to complete a questionnaire in which they were asked to assess the results letter they received, identify the main findings of the study from a given list and comment on the results in their own words. The questionnaires were returned in pre-paid envelopes to the 4-T Co-ordinating Centre in Oxford, where the responses were entered into a simple database. Free text responses were reviewed and categorised by two researchers.

Results

By the end of the 4-T trial 596 of the 708 originally randomised patients had not withdrawn consent, were still alive and in contact with sites. Of these, 455 (76%) from 34 (59%) of the 58 trial centres were invited to complete the questionnaire. 40 (9%) questionnaires were received by the Co-ordinating Centre. Responses are summarised in Tables 1-2.

Table 1: General Information about the 4-T Trial and medical research

	Yes	No	Unsure	Not Answered	Total
Did you understand the results presented in the letter	35	1	4	0	40
Were you satisfied with the information in the letter	39	1	0	0	40
Were you satisfied with the time you spent learning the results of the trial	37	1	1	1	40
Did you understand the results presented to you today	35	4	1	0	40
Do you understand the risks/benefits of each insulin in the trial	37	0	3	0	40
Do you know how to manage your diabetes in the immediate future	38	0	1	1	40

Was the information in the letter appropriate	36	1	3	0	40
Was the information in the letter useful	37	1	2	0	40
Was the 4-T trial experience as you expected	37	1	2	0	40
Would you take part in a similar trial again	34	1	3	2	40
Would knowing at the start of the trial that you would receive the results at the end influence your decision to take part in another trial	31	3	5	1	40
Did receiving these results improve your experience of the trial as a whole	34	2	3	1	40
Would you like to attend a coffee morning to learn more about the results of the 4-T Trial	19	10	10	1	40
Would you like to take part in a teleconference to learn more about the results of the 4-T Trial	5	18	15	2	40

Table 2: Reasons for taking part in the 4-T Trial and patient experience during the trial

Why did you take part in the 4-T Trial? (patients were invited to add free text and could specify more than one reason)	
Clinical Care team recommendation	17
Improving own control	15
Helping patients in the future	11
Care in trial better than standard	10
Improve personal control of diabetes	8
Wanted to find out more about diabetes	4
Needed insulin for treatment of diabetes	4
4-T was a 'no risk' trial	2
Wanted to share experiences of diabetes with others	2
Did you find anything unpleasant whilst in the trial? (patients were invited to add free text and were not limited to one negative)	
Nothing/No answer	28
Small inconveniences	7
- SMCG readings	3
- Attending clinic visits	3
- Weight gain	3

- Blood tests	1
Evidence of Understanding	
Different types of insulin are associated with different hypoglycaemia rates	17
Hypoglycaemia is a risk with insulin treatment	11
Insulin treatment was not associated with weight gain	10
Insulin treatment lowered blood glucose	6
Identified all correct responses and no incorrect responses	5

When asked to describe the results in their own words five patients specifically referred to the different effects of each insulin: (T40001D: "Different types of Insulin effect (sic) people in different ways."; T42001R: "This study has shown that although there are various different types of Insulin which are used to manage the patients HbA1c levels. They were seen to give different side effects such as differing weight gains for each type. Which then increases the need to increase insulin dosage to maintain levels and also varying amounts of hypoglycaemic episodes. Thus resulting in better info for GP's to judge which type is better for each individual patient."; T54007Y: "Study has shown differences in control of hypoglycaemia and weight gain between the different insulins but overall all three improved control and after 3 years all groups had a similar HbA1c value."). However, just one of these five (T54007Y) also answered appropriately to the pre-specified results.

Ten patients' assessments of the trial focused on how the trial had improved their personal diabetes control, one acknowledging a treatment effect of the second insulin formulation (T54002C: "although I had many hypo's in the earlier 2 years they did lessen towards the end; which also shows the use of the 2 insulins gives greater control.") and a further ten said the trial had led to a better understanding of diabetes in general.

Nine others responded with seven different explanations including a recognition that insulin treatment lowers blood glucose, that a computerised algorithm was used to control glucose levels (T42023R: "All the way through the study my glucose levels were fed into the computers and the amount of insulin increase was recorded, when the trial was over I had no knowledge of how to adjust the insulin for myself") and that research leads to improved medical care (T40005E: "That research can and does have benefits for users of insulin and future treatment decisions", T24008S: "The 4T study showed me and I hope others that with the help that I got will open their eyes as to what work has being done by people that care in study so much")

Five patients did not complete this section of the questionnaire.

Conclusion

Several 4-T centres did not want to take part in this ancillary research which limited the scope as we were only able to contact approximately half of the original participants. There were long delays in local approval processes which we believe contributed to the disappointing response rate. It is also apparent that the small number of patients who chose to complete the questionnaire felt well-informed about the trial and for the most part had a positive trial experience. This is likely to have influenced their decision to return the documents to Oxford therefore care should be taken to extrapolate these results to describe the general patient experience in 4-T.

As we found previously[3], patient comments clearly demonstrate appreciation for both trial and local clinical staff. As before, there is no evidence to support the argument that participants are not interested in receiving results[5] rather the opposite was true. This supports the need for researchers to share the full results and not just the information which will affect an individual's future care as has often been the case previously[5]. Another study disseminated results to patients by means of a teleconference[6] and this

was warmly received by the press[7]. We were keen to see if this would be widely received as an acceptable method for the 4-T patients. It is interesting to note the lack of interest expressed compared with the coffee morning option. This may be because some of these patients had a previous positive experience of a 4-T coffee morning at the end of the first year. It also may be related to the average age of the 4-T patient (61.7±9.8 years at randomisation) compared with the younger age group (~50years) of the Huntington disease trial.

Although most patients chose at least one of the correct options for the results of the trial, when asked to describe the findings in their own words we found patients' tended to focus on their individual care with over a quarter describing personal improvements in diabetes control. This correlates with the reasons why patients entered the trial (table 2), is consistent with other recent research[8] and indicates that the purpose of clinical research is not well understood by the public, and we suggest this should be better explained at the outset, and reinforced during trials.

Communication of scientific research to lay audiences is a key area for both academic and political communities. Science scepticism is common in developed nations yet only 25% of European and American public are considered 'scientifically literate'[9]. Researchers have a responsibility therefore to report their work; the Canadian Health Services Research Foundation recommends that when considering dissemination, information is "clear, simple…tailored for each audience based on knowledge user need"[10]. It is a requirement that trials registered with ClinicalTrials.gov publish results in the public domain and the 4-T results are available in full. We postulate however that these are not presented in a way that encourages lay review. Our research shows that patients are interested in the main results, and feel that they are able to understand them, if they are presented in an appropriate way.

Assessment of patient understanding based on information received in a results letter was positive but we feel there are some aspects which should be addressed to improve the knowledge base in this area. The 4-T model of providing results to participants via a social event was well received by participants and clinical centres and shows promise as a method of disseminating information. It remains to be seen if the interactive opportunities offered by local coffee mornings would lead to greater understanding of research in general.

The main 4-T Study was funded and sponsored by Novo Nordisk Ltd. This ancillary research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Data Sharing

Original data are available on request from the Diabetes Trials Unit. Please contact the corresponding author in the first instance.

Contributorship

JLD and HCP devised the study and wrote the protocol. JLD wrote the initial draft of the manuscript. Both authors take responsibility for the final content.

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None

Competing Interests

JLD has no competing interests. HCP has received payment from Novo Nordisk for sitting on advisory panels and also from Novo Nordisk, Eli Lilly, Sanofi and Boehringer Ingelheim for lectures and travel expenses.

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DISSEMINATING RESULTS TO CLINICAL TRIAL PARTICIPANTS: A QUALITATIVE REVIEW OF PATIENT UNDERSTANDING IN A POST-TRIAL POPULATION

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Disseminating results to clinical trial participants: a qualitative review of patient understanding in a post-trial population

Word Count: 1901

Structured Abstract

Objective: To identify the most appropriate format for results dissemination to maximise understanding of trial results

Design: Qualitative

Setting: Of the original 58 4-T Trial centres, 34 agreed to take part in this ancillary research.

Participants: All participants from these centres were eligible. 343 participants were sent questionnaires.

Primary & Secondary outcome measures: The low response rate meant that we were unable to make any firm conclusions about the patient preferred method of dissemination however we were able to comment on the level of understanding demonstrated by the trial participants.

Results: 40 (12%) questionnaires were returned from 15 centres. We received no questionnaires from over half of the centres. The questionnaires which were returned demonstrated broad satisfaction with the results letter, general enthusiasm for the trial and a variable level of understanding of the results, however there was a high proportion of responders who were not clear on why the research was undertaken or what the results meant.

Conclusions: The low response rate may be related to delays during the trial set-up process suggesting that interest in a study quickly wanes for both patients and centres. From this we deduce that rapid dissemination of results is needed if it is to have any impact at all. The responders are likely to reflect a biased cohort who were both enthusiastic about the research and who had a good experience during their three years in the 4-T trial. It is perhaps not surprising therefore that the overview is positive. That this population was still not fully informed about the purpose of the research would seem to confirm a low level of understanding amongst the general public which we suggest should be addressed during the consent process.

Trial Registration: Original 4-T Trial Registration ISRCTN51125379

Summary

Article Focus

* Investigation into participant satisfaction with method of dissemination and understanding of clinical trial results

* Exploration into reasons for participation in clinical trials

* Suggestions to improve patient response to post-study questionnaires

Key Messages

* Responders were broadly satisfied with their trial experience but rarely demonstrated good understanding of results beyond their own treatment needs

* Study interest seems to wane quickly for both patients and centres

* Results dissemination needs to form part of protocol development and circulated soon after the end of the trial

Strengths and Limitations

* The low response rate was disappointing, especially as it is likely that those who returned their questionnaires had a positive trial experience leading to a potential bias in the results

* That this motivated population still demonstrated limited understanding of the research indicates that more needs to be done at the time of consent and during the trial

Objective

Clinical trial results are generally published within the healthcare community and rarely disseminated beyond scientific publications[1]. However it is increasingly a requirement of research approvals that, wherever possible, the public is involved at all stages of research. It is desirable that results are shared with those who take part, but there remains no consensus on the best method of disseminating study findings. Additionally, although patients participate willingly in clinical trials, it is not known if they are aware of the purpose of their trial, or if patients are actually interested in the results. We have presented information collected retrospectively from clinical centres who had held a patient event to share interim results from the three-year Treat to Target in Type 2 Diabetes (4-T) Trial (ISRCTN51125379)[2] [3]. This experience informed the design of the current work.

This 'coffee morning' approach proved popular with patients, and staff did not find this onerous to organise, but whilst patients demonstrated awareness of the implications for their own future care, it remained unclear if patients fully understood the results of the study as a whole.

The 4-T trial was an open-label, multi-centre trial in which 708 type 2 diabetic participants with sub-optimal control (glycated haemoglobin 7.0–10.0%) using oral agents were randomized to the addition of a basal, biphasic or prandial insulin regimen. Patients were followed for three years and a second insulin formulation was added if glycaemic control remained inadequate. The final results concluded that patients initiated onto the long acting insulin detemir who later added prandial doses of aspart achieved good glycaemic control with a lower risk of hypoglycaemia and less weight gain than patients initiated onto either the biphasic aspart or aspart insulins[4]. Trial results were disseminated to all participants at the end of the study, and we decided to assess the level of understanding amongst those who took part, as well as their level of satisfaction with the trial experience.

Design

Simultaneously with peer-reviewed publication, the 4-T centres were emailed a press release and letter detailing the headline results and asked to forward a copy of the letter to all trial participants as soon as possible. Subsequently patients were invited to complete a questionnaire in which they were asked to assess the results letter, identify the main findings of the study from a given list and comment on the results in their own words. The questionnaires were returned in pre-paid envelopes to the Co-ordinating Centre where responses were entered into a simple database. Free text was reviewed and categorised by two researchers. The research was approved in the UK by Oxford REC B; ref 09/H0605/100 and by individual sites in Ireland.

Results

By the end of the 4-T trial 577 (81%) of the 708 originally randomised patients were still alive and had not withdrawn consent. Of these, 234 patients (41%) were ineligible as their home site did not take part in this results study. A total of 343 (59%) patients from 34 (61%) trial centres were invited to complete the questionnaire. 40 (12%) questionnaires were received from 15 (44%) sites. Responses are summarised in Tables 1 to 3. Responder demographics (Table 4) did not differ from the main trial.

Table 1: Patient satisfaction with the results letter

		Completely Dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Completely Satisfied	No Answer	Total
1	The time taken to learn the results of the study	1	0	4	20	15	0	40
2	The source of information given today	1	0	0	26	13	0	40

3	Satisfaction with the source of information	1	0	1	23	14	1	40

Table 2: General information about the 4-T Trial and medical research

		Strongly Disagree	**Disagree**	**Neither agree nor disagree**	**Agree**	**Agree Strongly**	**No Answer**	**Total**
4	I understood the results presented to me today	0	1	4	25	10	0	40
5	I understand the risks and benefits of each insulin	0	0	3	28	9	0	40
6	I understand what I need to do to continue with my diabetes medication	0	0	1	22	16	1	40
7	The information content of the patient results letter was about right.	0	1	3	31	5	0	40
8	The patient results letter was useful/informative?	0	1	2	32	5	0	40
9	Taking part in the 4-T trial was as I expected	1	0	2	24	13	0	40
10	I would participate in a similar study again	1	0	3	11	23	2	40
11	I would be more likely to take part in a clinical trial if I knew I would receive the results of the trial at the end	1	2	5	17	14	1	40
12	Receiving the study results improved the overall experience of taking part	1	1	3	18	16	1	40
13	I would have preferred to attend a coffee morning to learn the trial results	3	7	10	7	12	1	40
14	I would have preferred to take part in a telephone conference to learn the trial results	6	12	15	3	2	2	40

Table 3: Reasons for taking part in the 4-T Trial and patient experience during the trial

Why did you take part in the 4-T Trial? (patients were invited to add free text and could specify more than one reason)	
Clinical Care team recommendation	17
Improving own control	15
Helping patients in the future	11
Care in trial better than standard	10
Improve personal control of diabetes	8
Wanted to find out more about diabetes	4
Needed insulin for treatment of diabetes	4
4-T was a 'no risk' trial	2
Wanted to share experiences of diabetes with others	2
Did you find anything unpleasant whilst in the trial? (patients were invited to add free text and were not limited to one negative response)	
Nothing/No answer	28
Small inconveniences	7
- SMCG readings	3
- Attending clinic visits	3
- Weight gain	3
- Blood tests	1
Evidence of Understanding	
Different types of insulin are associated with different hypoglycaemia rates	17
Hypoglycaemia is a risk with insulin treatment	11
Insulin treatment was not associated with weight gain	10
Insulin treatment lowered blood glucose	6
*Identified **all** correct responses and **no** incorrect responses*	5

When asked to describe the results in their own words five patients referred to the different effects of each insulin (T40001D: “Different types of Insulin effect (sic) people in different ways.”; T42001R: “This study has shown that although there are various different types of Insulin which are used to manage the patients HbA1c levels. They were seen to give different side effects such as differing weight gains for each type. Which then increases the need to increase insulin dosage to maintain levels and also varying amounts of hypoglycaemic episodes. Thus resulting in better info for GP's to judge which type is better for each individual patient.”; T54007Y: “Study has shown differences in control of hypoglycaemia and weight gain between the different insulins but overall all three improved control and after 3 years all groups had a similar HbA1c value.”). However just one (T54007Y) also selected the appropriate options from those offered in the questionnaire.

Ten patients’ assessments of the trial focused on how the trial had improved their personal diabetes control, one acknowledging a treatment effect of the second insulin formulation (T54002C: “although I had many hypo's in the earlier 2 years they did lessen towards the end; which also shows the use of the 2 insulins gives greater control.”) and a further ten said the trial had led to a better understanding of diabetes in general. Nine others responded with seven different explanations including the recognition that insulin treatment lowers blood glucose, that a computerised algorithm was used to control glucose levels (T42023R: “All the way through the study my glucose levels were fed into the computers and the amount of insulin increase was recorded, when the trial was over I had no knowledge of how to adjust the insulin for myself”) and that research leads to improved medical care (T40005E: “That research can and does have benefits for users of insulin and future treatment decisions”, T24008S: “The 4T study showed me and I hope others that with the help that I got will open their eyes as to what work has being done by people that care in study so much”). Five patients did not complete this section of the questionnaire.

Table 4: Demographics of those who returned their questionnaire compared against the main 4-T Study

	Dissemination Study	**Main Study**	p-value (t-test)
Gender			
Number female N (%)	14 (35.0)	254 (35.9)	
Number male N (%)	26 (65.0)	454 (64.1)	
Total	*40*	*708*	0.91
Race			
Number white N (%)	37 (92.5)	635 (92.2)	
Number non-white N (%)	3 (7.5)	73 (7.8)	
Total	*40*	*708*	0.57
Age			
Mean (SD)	64.1(±8.2)	61.7(±9.8)	1.68

Conclusion

The disappointingly low response rate was a surprise, however we can suggest reasons for the apparent lack of interest. This additional research was developed towards the end of the main study and neither patients nor sites were expecting further involvement beyond their final 4-T visit. We also experienced long delays in local approval processes. We have no robust statistics, but many local R&D offices took a very long time to review the documents, some requiring us to re-submit more than once. We believe these delays directly impacted on the response rate since rather than being able to send the recruitment packs to 4-T patients soon after the trial results were published in October 2009, they were eventually circulated six to eight months later. For all patients this would have been almost twelve months after they had completed the trial; for many it would have been up to two and a half years after their final 4-T visit. It is possible patients felt disconnected from the trial, or that the results had little relevance to them at this late stage.

Interestingly 23 (41%) of the original 4-T centres declined to take part in this follow-on study. By the time they were asked to distribute recruitment packs many centres had archived their 4-T files and any loyalty they may have had towards 4-T is likely to have been supplanted by newer research studies. Additionally, we received no patient questionnaires from 19 (56%) of the 34 sites who did agree to take part, and it is possible the recruitment packs were not circulated. We have no detailed statistics on reasons for site refusal but anecdotally we can report that some were reluctant to distribute recruitment packs on behalf of the research team as there was no financial recompense. The study was also ineligible for the NIHR Research Network portfolio for the same reason. Whilst we appreciate that R&D offices have a responsibility to ensure their staff are adequately resourced, we feel that this low budget ancillary study is something that the network could have supported. With hindsight it may have been beneficial to convert the 4-T research sites to Patient Identification Centres and request permission from the National Information Governance Board for Health and Social Care to recruit via the central co-ordinating office.

Had we been able to contact patients directly we may have had better representation as we would have been able to include all 577 patients in the initial recruitment phase. We would also have been able to follow up non responders which we were unable to do through the sites, although this is recommended practice[5].

Although we initially intended to investigate patient understanding of trial results and the preferred method of receiving end of trial information, the low response rate makes it difficult to extrapolate findings to the wider population. It is clear that the most of the patients who completed the questionnaire felt well-informed about the trial and for the most part had a positive trial experience. This is likely to have influenced their decision to return the documents therefore care should be taken when interpreting these results.

As we found previously[3], patients clearly demonstrate appreciation for local clinical staff. Our results in table 1 suggests that although there is a cohort of patients who are not interested in the trial beyond their own treatment, the majority of patients thought receiving the results improved their trial experience. This supports the need to share the full results and not just information which will affect an individual's future care as has often been the case previously[6]. Another study disseminated results via teleconference[7] and this was warmly received by the press[8]. We were keen to see if this would be widely received as an acceptable method for 4-T patients. It is interesting to note the lack of interest expressed compared with the coffee morning option. This may be because some patients had a previous positive experience of a 4-T coffee morning. It also may relate to the age of 4-T patients, who were on average over ten years older than the Huntington disease patients. The Huntington patients may also have had greater levels of disability, which might constrain their choice of medium for results dissemination.

Although most patients chose at least one correct option for the trial results, when asked to describe the findings in their own words we found patients tended to focus on their individual care with over a quarter describing personal improvements in diabetes control. This correlates with the reasons why patients entered the trial (table 2), is consistent with other research[9, 10], and indicates that the purpose of clinical research is not well understood by the public. We suggest this should be better communicated at the outset, and then reinforced throughout the trial process.

Communication of scientific research to lay audiences is a priority for both academic and political communities. Scientific scepticism is common in developed nations, yet only 25% of European and American public are considered 'scientifically literate'[11]. Researchers have a responsibility to report their work and the Canadian Health Services Research Foundation recommends that when considering dissemination, information is "clear, simple…tailored for each audience based on knowledge user need"[12]. It is a requirement that trials registered with ClinicalTrials.gov publish in the public domain, and 4-T results are available via this website. We postulate however that the ClinicalTrials.gov template does not encourage lay review.

The 4-T model of providing results to participants via a social event was well received by patients and sites and shows promise as a method of sharing information. We believe this study illustrates that results dissemination plans should occur alongside protocol development forming part of the overall study and included in reimbursement calculations. We have perhaps also shown that interest in studies quickly wanes for both patients and centre staff so any dissemination is likely to be needed rapidly if it is to have any impact at all. It remains to be seen if the interactive opportunities offered by local coffee mornings would lead to greater understanding of research in general.

Data Sharing

Original data are available on request from the Diabetes Trials Unit, University of Oxford. Please contact the corresponding author in the first instance.

Contributorship

JLD and HCP devised the study and wrote the protocol. JLD wrote the initial draft of the manuscript. Both authors take responsibility for the final content.

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Competing Interests

JLD has no competing interests. HCP has received payment from Novo Nordisk for sitting on advisory panels and also from Novo Nordisk, Eli Lilly, Sanofi and Boehringer Ingelheim for lectures and travel expenses.

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Communicating Clinical Trial Results to Participants Questionnaire

Subject no: T ☐☐☐☐☐☐ **Questionnaire no:** 1

Initials: ☐☐☐ **Date** ☐☐/☐☐/☐☐☐☐

We are interested in your views on the information presented to you today. There are no right or wrong answers. Please answer each statement by CIRCLING a number on the scale provided to indicate how like you the statement is. If you make a mistake, please cross it out using a single line.

Please complete the questionnaire using a BLACK pen and not pencil.

THANK YOU

Communicating Clinical Trial Results to Participants Questionnaire

		Completely dissatisfied	Dissatisfied	Neither satisfied Nor dissatisfied	Satisfied	Completely satisfied
1.	The time taken to learn the results of the study	**1**	**2**	**3**	**4**	**5**
2.	The source of information given today	**1**	**2**	**3**	**4**	**5**
3.	Satisfaction with the source of information	**1**	**2**	**3**	**4**	**5**

		Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
4.	I understood the results presented to me today	**1**	**2**	**3**	**4**	**5**
5.	I understand the risks and benefits of each insulin	**1**	**2**	**3**	**4**	**5**
6.	I understand what I need to do to continue with my diabetes medication	**1**	**2**	**3**	**4**	**5**

		Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
7.	The information content of the patient results letter was about right.	**1**	**2**	**3**	**4**	**5**

Communicating Clinical Trial Results to Participants Questionnaire

		Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
8.	The patient results letter was useful/informative?	**1**	**2**	**3**	**4**	**5**
9.	Taking part in the 4-T trial was as I expected	**1**	**2**	**3**	**4**	**5**
10.	I would participate in a similar study again	**1**	**2**	**3**	**4**	**5**
11.	I would be more likely to take part in a clinical trial if I knew I would receive the results of the trial at the end	**1**	**2**	**3**	**4**	**5**
12.	Receiving the study results improved the overall experience of taking part	**1**	**2**	**3**	**4**	**5**
13.	I would have preferred to attend a coffee morning to learn the trial results	**1**	**2**	**3**	**4**	**5**
14.	I would have preferred to take part in a telephone conference to learn the trial results	**1**	**2**	**3**	**4**	**5**

Which statements do you believe best describes your understanding of the 4-T trial results?

Please <u>CIRCLE</u> any that apply

15.	The results of the 4-T study showed that adding insulin treatment lowers blood glucose levels	**1**
16.	The results of the 4-T study showed that hypoglycaemia (very low blood sugar levels) is a risk of taking insulin treatment	**2**
17.	The results of the 4-T study showed that different types of insulin are associated with different risks of hypoglycaemia	**3**
18.	The results of the 4-T study showed that insulin treatment is not associated with weight gain	**4**

Please Turn Over

19. Why did you take part in the trial in the first place?

20. What appealed about taking part in a clinical trial?

21. What didn't?

22. Please explain in your own words what the 4-T study has shown.