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Communicating the results of research: how do participants of a cardiac rehabilitation RCT prefer to be informed?

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Abstract

Objective To determine the preferred means by which participants in a study of cardiac rehabilitation wish to be informed of the study's results.

Design Postal questionnaire survey of participants in a randomized controlled trial.

Setting Cornwall, southwest England.

Participants Patients recruited to the Cornwall Heart Attack Rehabilitation Management Study (CHARMS).

Method Participants recruited to CHARMS who were alive 3 years and 9 months after the trial was completed were contacted by letter and invited to return a reply slip with four short questions indicating how they would prefer to be informed about the published results of the study.

Results In March 2008, 191/230 participants originally recruited to CHARMS were still alive. General practitioners deemed 166/191 (88%) survivors medically appropriate to be contacted through a postal survey, and 154/166 (93%) participants responded to the invitation to participate in the follow-up survey. 86% (143/166) of participants indicated that they wished to be informed about the results: 115 (80%) of these elected to receive information by letter and 25 (18%) of these preferred to attend a meeting. Men older than 65 years predominated in this latter group. Women respondents preferred to receive the study results by letter; none preferred communication by email or the web.

Conclusion Survivors of acute myocardial infarction who participated in a RCT of cardiac rehabilitation wanted to receive a summary of the aggregate study results. Participants had preferences regarding how they would wish to be informed about the results of the study. Most participants preferred to be informed by letter or email, but some preferred the interaction of a group or a meeting.

Introduction

Patients are not usually informed about the results of studies in which they have participated.[1] In the United Kingdom (UK), accepted best practice is for patients and the public to be involved in all stages of research – a process enshrined in *Best research for best health*.[2] A recent review of studies about communicating results to participants indicated that trial participants 'want aggregate and clinically significant individual study results made available to them.[3]

The main debate about providing participants with summaries of the aggregate results of clinical studies can be found in studies relating to oncology,[1,4] which suggest that researchers have a moral obligation to inform participants of the results as a matter of respect for human dignity and to avoid treating people simply as a means to an end in scientific research. Research ethics boards overwhelmingly support the offer of providing research results to participants,[5,6] yet there is no agreed mechanism on whether, or how, to do this. In one survey, only 30% of researchers had formal plans to communicate their findings to participants.[4] Partridge *et al.*[7] reported that although 72% of clinicians believed participants wanted to know the outcomes of studies, only 25% had provided participants with summaries of the results.

Reasons for clinicians' reticence to share results included concerns about the negative emotional effect on participants and patients' difficulty in understanding the results. Partridge *et al.*[1] reported that participants in a trial in oncology that was stopped early were offered the option of receiving the negative results. Of the 95 participants, 85 (90%) opted to receive the results; most chose to receive written communication, although telephone and 'in person' options were also available. By contrast, $< 20\%$ of the 11 154 participants in the UK-based role of antibiotics in curtailing labour and early delivery (ORACLE) trial wanted a summary of the results.[8] An editorial that accompanied the publication of this large study commented on patients' lack of interest in receiving the results and suggested reasons such as the limited options offered (participants were not given the option of personal communication) and the fact that the consent process was not explicit.[6] This editorial endorsed the view that offering results to research participants should be an ethical obligation.

Published evidence on how best to inform patients involved in cardiac research of the results of the study in which they participated is lacking. Between 2000 and 2004, we conducted a randomized trial – the Cornwall Heart Attack Rehabilitation Management Study (CHARMS) – to determine if there was any difference in outcomes when patients who survived a heart attack followed a hospital-based or home-based (*Heart Manual*) cardiac rehabilitation programme.[9,10] The study involved a comprehensive cohort design, thus including both randomized and patient preference arms.[9,10] After our results were published, we wanted to determine how patients would like to be informed of our findings.

Methods

We conducted a postal questionnaire survey of the people who had participated in CHARMS. After obtaining approval from the Cornwall and Plymouth Research Ethics Committee (reference number 07/H0203/197), participants were contacted by letter and invited to return a reply slip with four short questions to indicate their preferred method (if any) of being informed about the published results (Questionnaire S1). A lay summary leaflet of the research results was prepared with the help of two patients with cardiac disease. Participants were then informed of the results of CHARMS through their preferred means of communication and a second postal survey was conducted using a satisfaction questionnaire.

Data collection

We checked the hospital's computerized system for patient administration to ascertain the participants' contact details and vital status. We sent each general practitioner the journal

abstract from the main study publication[9] and asked them to complete a short reply slip to confirm the participant's vital status and whether they were well enough to be invited to participate in a follow-up study. The lead investigator (HD) sent suitable participants a letter, which explained that we would like to share the study results with them. The correspondence included a participant information sheet and a consent form. We asked participants to complete a reply slip that gave them the option of receiving the results as a written summary by mail or e-mail, via a website, or through attendance at an oral presentation. A stamped addressed envelope was provided for return of the reply slip.

Participants who opted to be informed by written mail or e-mail were sent a written summary of the study findings based on the published journal abstract, which was suitable for lay readers.[9] Participants who elected to attend an oral presentation were given the same information at a meeting held by the principal investigator (HD) and the research nurse (JW) at the Royal Cornwall Hospital site in Truro. After being informed of the results, we assessed the satisfaction of the respondents by conducting another postal survey to find out how they were affected by the results – for example, did they make the right choice of method of receiving the results.

Analysis

Participants' responses were entered into an Excel spreadsheet, along with relevant demographic data. We tested comparisons between groups [men vs. women, age groups (younger or older than 65 years), the type of rehabilitation received (home-based or hospital-based), and whether participants had been randomized in CHARMS or had chosen their intervention (preference group)] using the chi-squared test or Fisher's exact test as appropriate and across the three methods of notification using univariate and multivariate ordinal logistic regression. Data were analysed with SPSS software (version 15) and STATA software (version 10).

Results

In March 2008, 191 survivors remained from the 230 participants recruited to CHARMS.[9] General practitioners deemed 166/191 (88%) survivors appropriate to be contacted in a postal survey. Overall, 154/166 (93%) participants responded to our reply slip with four short questions and 12 patients explicitly declined to participate. In total, 86% (143/166) of participants indicated that they wished to be informed about the results of CHARMS.

Table 1 summarizes the characteristics of the participants and non-participants in this

Table 1 Characteristics of survey participants and non-participants

Characteristic	Survey participants (%)	Non-participants[1] (%)	*P* value
Total (*n* = 230)			
Age (years) (SD)	68.5 (10.2)	69.3 (11.9)	0.578*
Gender			
Men (*n* = 188)	112 (78)	76 (87)	
Women (*n* = 42)	31 (22)	11 (13)	0.113
Home or hospital			
Home (*n* = 132)	79 (55)	53 (61)	
Hospital (*n* = 98)	64 (45)	34 (39)	0.413
Randomized or preference			
Randomized (*n* = 104)	67 (47)	37 (43)	
Preference (*n* = 126)	76 (53)	50 (57)	0.585

All *P* values are Fisher's exact *P* test, except where indicated by * (independent samples *t* test).
[1]Includes 39 participants who had died, 25 participants who were deemed unsuitable by their general practitioners and 12 respondents who declined to participate.

follow-up study. No statistically significant differences were seen between participants and non-participants with respect to age, gender, method of rehabilitation (home-based or hospital-based), or whether they had been randomized or had chosen their intervention (preference groups).

Table 2 shows how the participants wished to be informed about the study results, with comparison between gender, age group (younger or older than 65 years), the type of rehabilitation received (home or hospital), and whether participants were randomized or chose their intervention (preference group). A higher proportion of the hospital rehabilitation group wanted to be informed of the research results compared with the home rehabilitation group (64 (99%) vs. 79 (89%), $P = 0.025$). Overall, 115 (80%) respondents chose to be informed in writing by letter and 25 (18%) wished to attend a meeting (men older than 65 years predominated in this group). Women respondents preferred to receive their information by letter – none of the women chose e-mail or the web ($P = 0.009$ and $P = 0.026$ when adjusted for age, type of rehabilitation and whether participants were randomized or chose their intervention). 14 participants elected to be informed by more than one method. More participants younger than 65 years chose to receive the results by e-mail than older participants ($P < 0.001$ and $P = 0.120$ when adjusted for gender, type of rehabilitation and whether participants were randomized or chose their intervention).

The overwhelming majority of participants (96%) were happy with the method by which they received their results and the same proportion (96%) were pleased that they were informed. Between 87 and 96% reported that they found the results interesting, relevant to them and easy to understand. Only 9% of patients indicated that they were upset by the results. Overall, 93% of patients felt that taking part in this research study was valuable or very valuable. In terms of satisfaction, there was no significant difference between genders, age groups (<65 years or >65 years), whether patients were in the randomized or preference arms or followed the hospital or home based rehabilitation programme.

Comments received from some participants reflected individual feelings about the process of informing study participants. One said:

Table 2 How respondents of CHARMS wished to be informed of the study results

	Method of notification (%)[1]		
Participants	Letter	Meeting	E-mail/web
Total (n = 143)	115 (80)	25 (18)	17 (12)
Gender			
Men	85 (76)	23 (21)	17 (15)
Women	30 (97)	2 (7)	0
P value	0.009	0.106	0.024
Age (years)			
<65	39 (74)	6 (11)	15 (28)
>65	76 (84)	19 (21)	2 (2)
P value	0.130	0.174	<0.001
Home or hospital			
Home	66 (83)	10 (13)	12 (15)
Hospital	49 (77)	15 (23)	5 (18)
P value	0.397	0.121	0.203
Randomized or preference			
Randomized	51 (76)	13 (19)	7 (10)
Preference	64 (84)	12 (16)	10 (13)
P value	0.291	0.661	0.797

All P values are calculated using Fisher's exact P test.
[1]Fourteen participants asked to be informed by more than one method.

> I felt the leaflet I received gave adequate information about the research. I did not really want to attend a meeting, as for me it would have probably brought back unhappy memories of my heart attack. Each time I pass the hospital it takes me back to when I was in CCU [coronary care unit] back in Sept[ember] 2001. It certainly changed my life but seven years on I am carrying on an almost normal life. I am very grateful to everyone involved for saving my life and for continued research, which hopefully will benefit other heart patients. It was good for me to read that home rehab[ilitation] was just as good as attending hospital based rehabilitation.

Others said:

> My only criticism is that there seems to have been a long gap between completing the research and contacting me. I had thought that I had been forgotten.

> It is encouraging to know that research is being constantly done in order to improve rehabilitation after having a heart attack.

Discussion

Survivors of acute myocardial infarction who participated in a randomized controlled trial of cardiac rehabilitation wanted to receive a summary of the aggregate study results. Participants had preferences about how they wished to be informed about the results of the study. The vast majority of participants wished to be informed by letter or e-mail, but some preferred the interaction of a group or meeting. This is in keeping with the results of studies reported in a recent review.[3] Our results also indicate that there is a very high satisfaction rate when patients are involved in being informed about their study results.

We believe this is the first study reported in a peer-reviewed scientific publication from the UK involving people with acute myocardial infarction that has made a comprehensive attempt to inform participants of the results of the controlled trial in which they participated. None of the studies analysed in the most recent review of studies about communicating the results of clinical research to participants included trials of adult populations with cardiovascular disease (Table 3).[3] The authors of this review admit, however, that they conducted a narrative rather than systematic review of studies on communicating research results, and they did not state exactly how they conducted their literature review.[3] One recent publication not included in the latter review reported findings from parents of children with cancer and adolescents with cancer and another in people involved in a randomized controlled trial for Huntingdon's disease.[18,19]

We obtained a much higher response rate than the ORACLE study [143/166 (86%) vs. 1524/8941 (17%)].[8] This high response rate may be attributed to the following: we offered participants more than one way of obtaining the study results, our study had a strong local geographical identity and our study population was much smaller.

Our results concur with those of Partridge *et al.*,[1] who reported that 90% of women involved in a trial of surgery for breast cancer chose to receive the results of the study. Other studies have also reported similar findings and are in contrast with the much larger ORACLE study.[8,13,15] Given that the ORACLE study and the study by Partridge *et al.* involved only women, our study has explored the issue of gender when informing adult patients of the results of their study.[1,8] No other study has reported on age or gender differences in as much detail. One study that has considered the issue of informing participants in relation to gender mainly involved the parents of children with retinoblastoma and reported no statistically significant differences between the genders.[15] Our findings suggest that men older than 65 years prefer to be informed at meetings and that women prefer not to be informed through electronic means of communication. We were unable to determine any differences in the responses of participants originally placed within the randomized or preference arms. If the original trial had shown a difference in favour of the randomized or preference arms, however, the impact of our results may have been less positive.[9]

Table 3 Overview of nine studies in which aggregate results were offered to participants

Study	Year	No of patients	Population	Comment
Elbourne[11]	1987	247	Pregnant women allowed access to their obstetric records	99/247 women mentioned looking forward to receiving study results in response to an open-ended question about their feelings regarding enrolment
Bunin *et al.*[12]	1996	109	Mothers of paediatric patients with brain tumours	Mothers of patients rated the importance of study results as 4.5/5 on Likert scale
Snowdon *et al.*[13]	1998	24	Parents of infants in a clinical trial of extracorporeal membrane oxygenation (ECMO)	Qualitative description that parents of infants in trial 'felt strongly they should be sent the trial results'
Partridge *et al.*[14]	2003	51	Women in a trial of treatment for breast cancer	96% of respondents wanted to be informed of trial results
Schulz *et al.*[15]	2003	382	Children who survived retinoblastoma and parents of affected children	1.4% of respondents would have preferred not to receive results regarding their risk of developing future cancers
Fernandez *et al.*[16]	2005	20	Adolescents with cancer and parents of children with cancer	90% of participants wished to receive the results of research in which they participated
Partridge *et al.*[1]	2005	94	Women in a treatment trial for ductal carcinoma *in situ*	90% of participants elected to receive results related to the early closure of the trial
Dixon-Woods *et al.*[8]	2006	8,941	Women in a randomized controlled trial of antibiotics during pregnancy	20% of participants requested trial results Many of those who requested aggregate results also wanted information regarding their treatment allocation
Fernandez *et al.*[17]	2007	40	Adolescents with cancer and parents of children with cancer	100% of 30 parents and 10 adolescents wanted to receive study results regardless of implication. More than 95% felt they had 'strong' or 'very strong' rights to receive study results
Dorsey *et al.*[19]	2008	217	Men and women with mild to moderate Huntingdon's disease	89% of participants reported high satisfaction with site telephone call but only 50% were satisfied with the sponsor's press release
Fernandez *et al.*[18]	2009	495	Parents of children with cancer and adolescents with cancer	94% parents felt that they had a right to see the results of research and had specific preferences of how and what information should be communicated

Adapted and updated from Shalowitz and Miller.

Limitations of the study

We had a relatively small study population and our participants were recruited from a single rural centre with a stable population. Our findings thus may not be generalizable to other population groups. Although our findings are in agreement with those of other studies,[15] they involved cancer patients of a much younger age and dealt with issues that may not be applicable to patients with coronary heart disease. For example, in paediatric oncology, the patients involved in trials with poor outcomes preferred the information to be communicated personally, not just by a leaflet.[17]

We offered participants only the aggregate results, not their individual results. Shalowitz and Miller reported that participants in some trials were keen to receive both individual and aggregate results.[3] Some researchers recently questioned the putative obligation to disclose research results to participants and claim there is ambiguity regarding what information participants are given.[20] Miller *et al.*[20] suggest that, on the basis of their review of policy guidance, more work needs

to be done on the 'conceptual development' of this process before all researchers are ethically obliged to offer study results to participants.

Our short reply slip did not allow us to explore the reasons for decision making. A further qualitative study, similar to the qualitative study that was nested in CHARMS,[21] could have explored the reasons why participants chose a particular method of disclosure and would be a useful next step in this research.

Implications for further research

The studies discussed in this article, including our own, suggest that participants of research should be offered the results of the study to which they have contributed.[2] These findings need to be replicated in a wide range of disease areas and in larger numbers before this is made standard practice on both ethical and patient preference grounds. Given the vast number of multicentre trials that are conducted, it should be possible to offer participants the study results in the future in the original informed consent process.[2,6,22] A large study would help to inform a systematic approach on how best to inform participants and would also assess the outcomes of sharing results. However, the workload and cost implications of this kind of patient involvement in research should be considered at the outset, should be included in the protocol and should be part of the funding application,[3,22] and the cost of communicating results to participants should not be used as an argument for not informing participants.[3,22]

We accept that care needs to be exercised when informing patients in situations in which adverse outcomes have been common. Further research on how to inform vulnerable participants in research in a 'respectful and supportive manner' should be encouraged, as recommended by the Department of Health and the chairs of research ethics boards.[5,23]

Contributors

HD conceived the original idea of informing the CHARMS participants of the results of the study. HD, JC, RT, PHE and JW wrote the paper. SN was involved in collating the data from the survey and data input. CP, SN, and RT analysed the data. HD is guarantor for this study.

Competing interests

None declared.

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References

1 Partridge AH, Wong JS, Knudsen K *et al*. Offering participants results of a clinical trial: sharing results of a negative study. *Lancet*, 2005; **365:** 963–964.
2 Department of Health. Best Research For Best Health: A New National Health Research Strategy. London: Stationery Office, 2006.
3 Shalowitz DI, Miller FG. Communicating the results of clinical research to participants: attitudes, practices, and future directions. *PLoS Medicine*, 2008; **5:** e91.
4 Rigby H, Fernandez CV. Providing research results to study participants: support versus practice of researchers presenting at the American Society of Hematology annual meeting. *Blood*, 2005; **106:** 1199–1202.
5 Department of Health. Research Governance Framework for Health and Social Care. London: Stationery Office, 2005.
6 MacNeil SD, Fernandez CV. Offering results to research participants. *British Medical Journal*, 2006; **332:** 188–189.
7 Partridge AH, Hackett N, Blood E *et al*. Oncology physician and nurse practices and attitudes regarding offering clinical trial results to study participants.

Journal of the National Cancer Institute, 2004; **96:** 629–632.
8 Dixon-Woods M, Jackson C, Windridge KC, Kenyon S. Receiving a summary of the results of a trial: qualitative study of participants' views. *British Medical Journal*, 2006; **332:** 206–210.
9 Dalal HM, Evans PH, Campbell JL *et al.* Home-based versus hospital-based rehabilitation after myocardial infarction: a randomized trial with preference arms – Cornwall Heart Attack Rehabilitation Management Study (CHARMS). *International Journal of Cardiology*, 2007; **119:** 202–211.
10 Taylor RS, Watt A, Dalal HM *et al.* Home-based cardiac rehabilitation versus hospital-based rehabilitation: a cost effectiveness analysis. *International Journal of Cardiology*, 2007; **119:** 196–201.
11 Elbourne D. Subjects' views about participation in a randomized controlled trial. *Journal of Reproductive and Infant Psychology*, 1987; **5:** 3–8.
12 Bunin GR, Kazak AE, Mitelman O. Informing subjects of epidemiologic study results. Children's Cancer Group. *Pediatrics*, 1996; **97:** 486–491.
13 Snowdon C, Garcia J, Elbourne D. Reactions of participants to the results of a randomised controlled trial: exploratory study. *British Medical Journal*, 1998; **317:** 21–26.
14 Partridge AH, Burstein HJ, Gelman RS, Marcom PK, Winer EP. Do patients participating in clinical trials want to know study results? *Journal of the National Cancer Institute*, 2003; **95:** 491–492.
15 Schulz CJ, Riddle MP, Valdimirsdottir HB, Abramson DH, Sklar CA. Impact on survivors of retinoblastoma when informed of study results on risk of second cancers. *Medical and Pediatric Oncology*, 2003; **41:** 36–43.
16 Fernandez CV, Taweel S, Kodish E, Weijer C. Disclosure of research results to research participants: a pilot study of the needs and attitudes of adolescents and parents. *Paediatrics and Child Health*, 2005; **10:** 332–334.
17 Fernandez CV, Santor D, Weijer C *et al.* The return of research results to participants: pilot questionnaire of adolescents and parents of children with cancer. *Pediatric Blood and Cancer*, 2007; **48:** 441–446.
18 Fernandez CV, Gao J, Strahlendorf C *et al.* Providing research results to participants: attitudes and needs of adolescents and parents of children with cancer. *Journal of Clinical Oncology*, 2009; **27:** 878–883.
19 Dorsey ER, Beck CA, Adams M *et al.* Communicating clinical trial results to research participants. *Archives of Neurology*, 2008; **65:** 1590–1595.
20 Miller FA, Christensen R, Giacomini M, Robert JS. Duty to disclose what? Querying the putative obligation to return research results to participants. *Journal of Medical Ethics*, 2008; **34:** 210–213.
21 Wingham J, Dalal HM, Sweeney KG, Evans PH. Listening to patients: choice in cardiac rehabilitation. *European Journal of Cardiovascular Nursing*, 2006; **5:** 289–294.
22 Partridge AH, Winer EP. Informing clinical trial participants about study results. *Journal of the American Medical Association*, 2002; **288:** 363–365.
23 MacNeil SD, Fernandez CV. Attitudes of research ethics board chairs towards disclosure of research results to participants: results of a national survey. *Journal of Medical Ethics*, 2007; **33:** 549–553.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Questionaire S1. Cornwall Heart Attack Rehabilitation Management (CHARMS).

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