Contemporary Clinical Trials Communications 11 (2018) 95–98

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc

Researchers' experiences with and perceptions of returning results to participants: Study protocol

Pearl A. McElfish[a,*], Rachel S. Purvis[b], Christopher R. Long[a]

[a] College of Medicine, University of Arkansas for Medical Sciences Northwest, 1125 N. College Ave., Fayetteville, AR, 72703, USA
[b] Office of Community Health and Research, University of Arkansas for Medical Sciences Northwest, 1125 N. College Ave., Fayetteville, AR, 72703, USA

ARTICLE INFO

Keywords:
Dissemination
Research results
Health research
Research participants

ABSTRACT

Background: Health research participants want to receive the results from research studies in which they have participated, and health research funding agencies encourage the returning of results to research participants. However, researchers rarely return results to research participants. This study protocol aims to fill the significant gap in knowledge that exists regarding experiences, perceptions, and challenges health researchers have with returning results to research participants.

Design: The study will use a mixed-methods concurrent triangulation design that will collect qualitative and quantitative data in one simultaneous phase to allow researchers to utilize each type of data to corroborate the findings from the other. The research team developed a mixed-methods survey to assess the experiences, perceptions, and challenges health researchers have with returning results to research participants.

Method: The survey includes both quantitative and qualitative (open-ended) questions and will be implemented online and will take approximately 10–15 min for respondents to complete. The survey is divided into four topics areas, which include respondents': 1) general opinion of returning results to participants in health research studies, 2) experiences with a specific study in which they did not return results to participants, 3) perceptions of specific challenges they face in returning results to participants, and 4) demographic characteristics and professional background information.

Summary: The study to be conducted will address knowledge gaps related to researchers' experiences, perceptions, and challenges with returning research results. The study is an important step toward pragmatic solutions that can improve researchers' ability to return results to participants.

1. Introduction

Health research participants report that they want to know the results of the studies in which they have participated [1–6]. Some institutional review boards (IRBs) and research ethics boards require researchers to provide plans for returning study results to participants in their study protocols [7–9]. Additionally, health research funding agencies, such as the Agency for Healthcare Research and Quality (AHRQ) and the Patient-Centered Outcomes Research Institute (PCORI), acknowledge the need to increase the returning of research results to nonacademic audiences [10,11].

Despite these factors encouraging dissemination of results to research participants, results are rarely returned to people who have participated in the research [12,13]. Long et al. found that only approximately 33% of 3381 participants from a wide range of studies received results [13]. Even among community-based participatory research (CBPR) studies, which has been highlighted as an effective way to engage participants, a systematic review of 101 journal articles found that only 48% of CBPR studies reported returning the results of their research to participants beyond traditional peer-reviewed publications [14]. Health researchers state that they are supportive of returning research results to participants [7,14–18]. However, researchers acknowledge that they often fail to return research results to participants [13,14,16,17].

Prior research suggests that returning results to participants may be impeded by researchers' uncertainty on how to best implement the dissemination of results to participants [19]. However, very little is known about what impediments researchers face in returning results to

Abbreviations: IRBs, Institutional review boards; AHRQ, Agency for Healthcare Research and Quality; PCORI, Patient-Centered Outcomes Research Institute; CBPR, Community-based participatory research; CTSA, Clinical and Translational Science Award

* Corresponding author. Northwest Arkansas Region, College of Medicine, Department of Internal Medicine, University of Arkansas for Medical Sciences Northwest, 1125 N. College Ave., Fayetteville, AR, 72703-1908, USA.
E-mail address: pamcelfish@uams.edu (P.A. McElfish).

https://doi.org/10.1016/j.conctc.2018.06.005
Received 16 February 2018; Received in revised form 5 June 2018; Accepted 13 June 2018
Available online 15 June 2018

participants. Few studies have examined researchers' experiences and perceptions in returning results to study participants. The limited studies available focus on documenting the perspectives of specific types of researchers, such as oncologists. For example, a 2004 study that surveyed 796 health care oncology providers found the three most reported challenges to sharing results were concerns about: the potential negative emotional effect on participants (60%), participants' difficulty understanding results (54%), and consumption of resources, including money and clinician time to complete dissemination (39%) [16]. Beyond that one article, little is known about the reasons why researchers are not returning study findings to participants, and this lack of knowledge has been cited as a significant gap in knowledge.

In 2013, after reviewing research on dissemination strategies, AHRQ documented significant gaps in knowledge exists regarding returning of research results and called for additional research [20]. Despite research funders increased emphasis on returning results to participants, much remains unknown regarding researchers' experiences, perceptions, and challenges with participant-level dissemination. It is important to address these knowledge gaps because returning results to participants is a crucial component in advancing translational science. The study to be conducted responds to AHRQ's report and will characterize researchers' experiences, perceptions, and challenges with participant-level dissemination. This paper describes the protocol of a mixed-methods study designed to understand researchers' experiences with and perceptions of participant-level dissemination.

2. Methods

The study is approved by the University of Arkansas for Medical Sciences (UAMS) Institutional Review Board (#205983).

2.1. Study aims

The primary aim of the study is to understand and document researchers' previous experiences with and perceptions of returning results to participants. A secondary aim of the study is to understand and document the challenges that researchers encounter when attempting to return research results to participants.

2.2. Study design

The study will use a mixed-methods concurrent triangulation design. A mixed-method concurrent triangulation design collects qualitative and quantitative data in one simultaneous phase and allows researchers to use each type of data to corroborate findings from the other [21–27]. In a mixed-method concurrent triangulation design, study data is analyzed separately and then combined during the interpretation phase. This method will allow us to cross-validate and confirm study findings to provide a more complete illumination of the research question. The mixed-method concurrent triangulation design will allow us to overcome the inherent weaknesses of using qualitative or quantitative methods separately [21–27].

Using the mixed-method concurrent triangulation design, the research team developed a mixed-methods survey to assess the experiences, perceptions, and challenges health researchers have with participant dissemination. After the survey was initially drafted, the research team reviewed the content questions and discussed revisions. The survey went through four rounds of revision and refinement before a final draft was approved by consensus of the researchers.

The survey will be implemented online using Research Electronic Data Capture (REDCap) [28]. The survey takes approximately 10–15 min for respondents to complete. The survey is divided into four topic areas that will measure respondents': 1) general opinion of returning results to participants in health research studies, 2) experiences with a specific study in which they did not return results to participants, 3) perceptions of specific challenges they face in returning results to participants, and 4) demographic characteristics and professional background. Among the specific challenges that will be evaluated by survey respondents are: 1) financial challenges, 2) ethical concerns, 3) logistical/methodological/skill-related challenges, and 4) systemic challenges (e.g., lack of career-related incentives to disseminate results to participants).

Surveys will collect quantitative and categorical data from respondents for each of the four topic areas. Closed-ended single- and multiple-response items, yes/no items, and percentage slider items are used for respondents to report their experiences and perceptions of returning study results.

In addition, eight open-ended survey items will collect qualitative data. The open-ended items will allow researchers to provide in-depth responses about their perceptions and experience regarding returning results to participants and to describe specific challenges that they encountered with participant-level dissemination. The open-ended items will ask respondents to: 1) explain why they believe results should always be returned to participants, 2) explain why they are not sure whether or not results should always be returned to participants, 3) describe reasons why they believe results should not always be returned to participants, 4) describe the reason (s) they did not return a study's aggregated results to the participants, 5) describe any financial challenges that have discouraged them from returning results to research participants, 6) describe any ethical concerns that have discouraged them from returning results to research participants, 7) describe any logistical/methodological/skill-related challenges that have discouraged them from returning results to research participants, and 8) describe any systemic challenges that have discouraged them from returning results to research participants (see Table 1).

Table 1
Open-ended survey questions.

Themes	Open-ended survey questions
Why results should be returned	• Please take a few sentences to explain why you believe results should always be shared with participants.
Why results should not be returned	• Please take a few sentences to explain why you are not sure whether or not results should always be shared with participants. • Please take a few sentences to describe reasons why you believe results should NOT always be shared with participants.
Challenges to returning results to research participants	• Please briefly describe the reason(s) why you did not share the study's aggregated results with the participants. For example, please describe any actual (or anticipated) barriers you encountered. • Please take 1–2 sentences to describe any financial barriers that have discouraged you from disseminating results to research participants. • Please take 1–2 sentences to describe any ethical concerns that have discouraged you from disseminating results to research participants. • Please take 1–2 sentences to describe any logistical/methodological/skill-related barriers that have discouraged you from disseminating results to research participants. • Please take 1–2 sentences to describe any systemic barriers that have discouraged you from disseminating results to research participants.

The survey concludes with items assessing the respondents' demographic characteristics and professional backgrounds. Characteristics to be assessed include gender, age, academic degrees held, and history of obtaining funding for scientific research projects. This will allow us to understand heterogeneity of participants and responses. The final item on the survey provides a blank in which respondents can input an email address if they would like the research team to send them a summary of the aggregate survey results.

The research team comprises a group of eleven researchers affiliated with four universities with Clinical and Translational Science Award (CTSA) programs. The CTSA program is a national network comprised of medical research centers that collaborate on ways to improve the translational research process in an effort to increase patient access to innovative treatment and is funded by the National Institutes of Health's (NIH) National Center for Advancing Translational Sciences (NCATS) [29]. Respondents will be recruited from universities in the United States through the CTSA principal investigator network. Additionally, principal investigators of Prevention Research Centers from approximately twenty universities will be included in recruitment efforts. Prevention Research Centers are a network of twenty-six academic research centers in twenty-four states that study how people and communities can avoid or reduce the risks for chronic illnesses like heart disease, obesity, and cancer [30].

An overview of the study will be emailed to principal investigators at each university along with a request for principal investigators' assistance in recruiting researchers who fit the inclusion criteria at their respective institutions. A survey invitation template will be provided with this initial email so that the principal investigators can invite researchers at their respective institutions to participate. The email template will explain that the study aims to explore researchers' experiences and perceptions with returning study results to participants in health research. The email invitation will also provide the inclusion criteria and a link to the online survey. Once the study link is accessed by researchers, they will have the opportunity to confirm their eligibility based on the inclusion criteria, to consent, and to provide their responses to the survey. No compensation will provided to researchers who complete the survey. Two weeks after the initial email invitation is sent to principal investigators, a second email will be sent to request they send another reminder invitation to their investigator networks. Recruitment will continue for up to six months after the initial recruitment e-mail is sent. Based on: 1) the research team's prior experience with online survey recruitment and analyses [13], 2) an intention to capture a diversity of experiences across research areas, and 3) the need to capture sufficient responses to facilitate adequately-powered comparisons when effect sizes are uncertain and possibly negligible, the target sample size is 450 researchers who meet the inclusion criteria.

To participate in the study, respondents must be age 18 or older. They are required to self-report as health researchers with a faculty or post-doctoral appointment at an academic medical institution, and they must conduct research that includes consent of human subjects. Both community engaged and non-community engaged researchers from academic medical institutions will be recruited.

2.3. Data analysis

Quantitative data analysis of the survey results will include descriptive as well as inferential statistical techniques, including correlation, *t*-tests, and non-parametric tests. Given the descriptive nature of the study aims (i.e., to document and understand researchers' experiences, perspectives, and challenges with sharing results), the analytic strategy will focus on presenting results of item-level descriptive analyses, with an emphasis on frequencies and proportions. For example, we will present: 1) descriptive summaries of respondents' attitudes toward returning results to participants in health research studies, 2) respondents' responses to items about a specific study in which they did not return results to participants, and 3) the degree to which respondents' report facing specific challenges in returning results to participants. Inferential analyses will focus on comparing groups of respondents who may be expected to have different attitudes and experiences from one another (e.g., comparisons between respondents who self-identify as community-engaged researchers vs. those who do not). For these analyses, alpha will be set at .05 two-tailed, and effect size indicators will be included. If the target sample size of 450 is met, reporting of inferential comparisons will emphasize results with non-negligible effect sizes or that aid interpretation of other reported results.

For each descriptive and inferential analysis, each respondent's data will be included if she or he responded to the relevant items, regardless of the amount of missing data for that respondent on other items. However, there will be no attempt to impute missing responses for any items. For each analysis, the number of included respondents will be reported.

Three researchers with qualitative research experience will code the text of the open-ended questions for emergent themes. In order to assess the large number of open-ended responses, a coding template is the most appropriate and effective strategy to analyze the text [31,32]. The initial coding template will categorize responses based on three priori themes: 1) researchers' prior experiences with returning research results, 2) researchers' perceptions of returning research results, and 3) challenges researchers encountered with returning research results. As the data is coded, emergent themes will be identified and incorporated into the template. The data will then be extracted from the open-ended responses and incorporated into the codebook in order to provide illustrative excerpts from the responses for each theme or domain they best represent. Two confirmation coders will then review the data. Finally, the research team will confirm that the data and illustrative excerpts are applied to the correct domain by critically reviewing each analytic product to ensure rigor and reliability. Any discrepancies in interpretation will be discussed and resolved via consensus of the three coders.

2.4. Implementation and dissemination plan

A summary of the aggregate survey results, as well as any subsequent scientific publications based on the research, will be distributed throughout the CTSA network. Additionally, any respondents who indicate that they wish to receive results and provide a contact email will be sent a summary of the aggregate survey results. Study findings can inform the creation of policies, tools, and trainings by research institutions to help researchers overcome challenges to returning results to participants. Funding agencies may also use the study's findings to develop new policies and procedures for grantees as well as provide access to tools that grantees can utilize to help them return results to participants beyond peer-reviewed journal publications.

3. Summary

While health researchers and funding agencies emphasize the importance of disseminating results to participants [10,11], researchers report that they rarely share results beyond peer-reviewed publications [12–14]. The study will have significant implications for researchers, research institutions, and research funders because it will address knowledge gaps related to researchers' experiences, perceptions, and challenges related to returning results to participants. Study results will provide new information about health researchers' attitudes toward results sharing across their entire research programs, specific instances when researchers feel results sharing is (or is not) appropriate, and the extent to which researchers encounter specific barriers mentioned in existing literature on the ethics and practice of research dissemination. Conducting this study is a necessary step toward pragmatic solutions that can improve research dissemination to participants—and, eventually, broader audiences—and thereby increase the effectiveness of translational health research.

Acknowledgments

This project was supported by a Translational Research Institute (TRI) grant (#1U54TR001629-01A1) through the National Center for Advancing Translational Sciences of the National Institutes of Health (NIH) grant (1U54TR001629-01A1). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

References

[1] M. Dixon-Woods, C. Jackson, K.C. Windridge, S. Kenyon, Receiving a summary of the results of a trial: qualitative study of participants' views, BMJ 332 (7535) (2006) 206–210.
[2] A.H. Partridge, J.S. Wong, K. Knudsen, R. Gelman, E. Sampson, M. Gadd, K.L. Bishop, J.R. Harris, E.P. Winer, Offering participants results of a clinical trial: sharing results of a negative study, Lancet 365 (9463) (2005) 963–964.
[3] C.V. Fernandez, J. Gao, C. Strahlendorf, A. Moghrabi, R.D. Pentz, R.C. Barfield, J.N. Baker, D. Santor, C. Weijer, E. Kodish, Providing research results to participants: attitudes and needs of adolescents and parents of children with cancer, J. Clin. Oncol. 27 (6) (2009) 878–883.
[4] A. Baylor, C. Muzoora, M. Bwana, A. Kembabazi, J.E. Haberer, L.T. Matthews, A.C. Tsai, P.W. Hunt, J.N. Martin, D.R. Bangsberg, Dissemination of research findings to research participants living with HIV in rural Uganda: challenges and rewards, PLoS Med. 10 (3) (2013) 4.
[5] S.B. Trinidad, E.J. Ludman, S. Hopkins, R.D. James, T.J. Hoeft, A. Kinegak, H. Lupie, R. Kinegak, B.B. Boyer, W. Burke, Community dissemination and genetic research: moving beyond results reporting, Am. J. Med. Genet. 176 (7) (2015) 1542–1550.
[6] R. Purvis, T. Abraham, C. Long, M. Stewart, T. Warmack, P. McElfish, Qualitative study of participants' perceptions and preferences regarding research dissemination, AJOB Empir. Bioeth. 8 (2) (2017) 69–74.
[7] C.V. Fernandez, E. Kodish, S. Shurin, C. Weijer, Offering to return results to research participants: attitudes and needs of principal investigators in the Children's Oncology Group, J. Pediatr. Hematol. Oncol. 25 (9) (2003) 704–708.
[8] C.V. Fernandez, C. Skedgel, C. Weijer, Considerations and costs of disclosing study findings to research participants, CMAJ (Can. Med. Assoc. J.) 170 (9) (2004) 1417–1419.
[9] M. Markman, Providing research participants with findings from completed cancer-related clinical trials: not quite as simple as it sounds, Cancer 106 (7) (2006) 1421–1424.
[10] Patient-Centered Outcomes Research Institute, What We Mean by Engagement, (2015) http://www.pcori.org/funding-opportunities/what-we-mean-engagement , Accessed date: 27 July 2015.
[11] D. Carpenter, V. Nieva, T. Albaghal, J. Sorra, Development of a planning tool to guide research dissemination, in: K. Henriksen, J.B. Battles, E.S. Marks, D.I. Lewin (Eds.), Advances in Patient Safety: from Research to Implementation (Volume 4: Programs, Tools, and Products, Agency for Healthcare Research and Quality, Rockville, MD, 2005, pp. 83–91.
[12] D.I. Shalowitz, F.G. Miller, Communicating the results of clinical research to participants: attitudes, practices, and future directions, PLoS Med. 5 (5) (2008) e91.
[13] C.R. Long, M.K. Stewart, T.V. Cunningham, T.S. Warmack, P.A. McElfish, Health research participants' preferences for receiving research results, Clin. Trials 13 (6) (2016) 582–591.
[14] P.G. Chen, N. Diaz, G. Lucas, M.S. Rosenthal, Dissemination of results in community-based participatory research, Am. J. Prev. Med. 39 (4) (2010) 372–378.
[15] A.H. Partridge, E.P. Winer, Informing clinical trial participants about study results, J. Am. Med. Assoc. 288 (3) (2002) 363–365.
[16] A.H. Partridge, N. Hackett, E. Blood, R. Gelman, S. Joffe, S. Bauer-Wu, K. Knudsen, K. Emmons, D. Collyar, R.L. Schilsky, E.P. Winer, Oncology physician and nurse practices and attitudes regarding offering clinical trial results to study participants, J. Natl. Cancer Inst. 96 (8) (2004) 629–632.
[17] H. Rigby, C.V. Fernandez, Providing research results to study participants: support versus practice of researchers presenting at the American Society of Hematology annual meeting, Blood 106 (4) (2005) 1199–1202.
[18] P.M. Wilson, M. Petticrew, M.W. Calnan, I. Nazareth, Does dissemination extend beyond publication: a survey of a cross section of public funded research in the UK, Implement. Sci. 5 (2010) 61.
[19] F.A. Miller, R. Christensen, M. Giacomini, J.S. Robert, Duty to disclose what? querying the putative obligation to return research results to participants, J. Med. Ethics 34 (3) (2008) 210–213.
[20] L. McCormack, S. Sheridan, M. Lewis, V. Boudewyns, C.L. Melvin, C. Kistler, L.J. Lux, K. Cullen, K.N. Lohr, Communication and Dissemination Strategies to Facilitate the Use of Health-related Evidence, Agency for Healthcare Research and Quality, Rockville, MD, 2013, pp. 1–520.
[21] M. Bergman, Advances in Mixed Methods Research: Theories and Applications, SAGE Publications Ltd, London, 2008.
[22] J.W. Creswell, Research Design: Qualitative, Quantitative, and Mixed Methods Approaches, fourth ed., SAGE, 2013.
[23] J.W. Creswell, V.L. Plano Clark, Designing and Conducting Mixed Methods Research, second ed., SAGE, 2010.
[24] J. Creswell, V. Plano Clark, M. Gutmann, W. Hanson, Advanced mixed methods research designs, in: A. Tashakkori, C. Teddlie (Eds.), Handbook of Mixed Methods in Social and Behavioral Research, SAGE, Thousand Oaks, CA, 2003, pp. 209–240.
[25] R. Johnson, A. Onweugbuzie, L. Turner, Toward a definitions of mixed methods research, J. Mix. Methods Res. 1 (2) (2007) 112–133.
[26] R. Johnson, A. Onwuegbuzie, Mixed methods research: a research paradigm whose time has come, Educ. Res. 33 (7) (2004) 14–26.
[27] J.E. Sale, L.H. Lohfeld, K. Brazil, Revisiting the quantitative-qualitative debate: implications for mixed-methods research, Qual. Quantity 36 (1) (2002) 43–53.
[28] P. Harris, R. Taylor, R. Thielke, J. Payne, N. Gonzalez, J. Conde, Research electronic data capture (REDCap)–a metadata-driven methodology and workflow process for providing translational research informatics support, J. Biomed. Inf. 42 (2) (2009) 377–381.
[29] National Institutes of Health National Center for Advancing Translational Sciences, Clinical and translational science award (CTSA), https://ncats.nih.gov/ctsa/about , Accessed date: 15 February 2018.
[30] Centers for Disease Control and Prevention, Prevention Research Centers. https://www.cdc.gov/prc/index.htm. (Accessed February 15, 2018.
[31] N. King, C. Cassell, G. Symon, Using templates in the thematic analysis of text, in: C. Cassell, G. Symon (Eds.), Essential Guide to Qualitative Methods in Organizational Research, Sage Publications, Thousand Oaks, CA, 2004.
[32] S. Nadin, C. Cassell, Using data matrices, in: C. Cassell, G. Symon (Eds.), Essential Guide to Qualitative Methods in Organizational Research, Sage Publications, Thousand Oaks, CA, 2004.