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Motivating first-time, group O blood donors to return: Rationale and design of a randomized controlled trial of a post-donation telephone interview

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Abstract

First-time blood donors are essential to the US donor pool, providing nearly a third of all donations. Unfortunately, there are a wide variety of obstacles to repeat donation and new donors are extremely difficult to retain. Because each donor experiences a unique set of deterrents, we developed a post-donation interview based on motivational interview principles in order to flexibly address individual barriers. The primary aim of this randomized clinical trial is to examine retention of first-time, group O blood donors who are randomly assigned to receive either a telephone-delivered interview with motivational and action planning components or a standard-of-care control call approximately six weeks after their donation. Measures of donation attitude, perceived behavioral control, intention, and motivational autonomy will be measured before and after the telephone contact using online surveys, and donation attempts will be tracked for one year using blood center donor databases. We hypothesize that, compared to controls, donors who receive the telephone interview will be more likely to make a donation attempt over the following year. In addition, we will examine possible mechanisms of action of the interview using key predictors of donation behavior as described by Self Determination Theory (i.e., motivational autonomy) and the Theory of Planned Behavior (i.e., attitude, perceived behavioral control, and intention). Results of this intervention may help to support a novel strategy to enhance retention of selected blood donors in an effort to better meet the nation's blood supply needs.

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Keywords

clinical trial; blood donation; motivational interview; implementation intention

1. Introduction

First-time blood donors are essential to the US donor pool, providing nearly a third of all donations.[1] Unfortunately, new donors are extremely difficult to retain. Less than half provide a second donation,[2–4] and only 2% of first-time donors under the age of 20 become committed donors.[3] As a result, the nation's blood supply is highly reliant on first-time donors who must constantly be replaced. In addition to enormous ongoing recruitment costs, failure to retain first-time donors has important health implications as repeat blood donors are less likely to be deferred for poor health[5] and to test positive for blood-borne infectious dieseases.[6] Collection from experienced donors also promotes donor safety as they are half as likely as first-time donors to experience adverse events during donation (e.g., syncope).[7] Additionally, because experienced donors have known blood types it is possible to more efficiently target retention efforts to address changing demands in the need for specific blood products. Finally, our ability to increase and retain eligible donors will be a vital determinant of the future blood supply as our population ages. In sum, more creative and effective approaches are needed to increase donor retention, and particularly within their first year of giving as the number of donations within this critical period is positively related to long-term commitment.[3]

Research has identified a wide variety of deterrents to donor retention (e.g., perceived inconvenience, negative past experiences, fear, low perceived control).[8] Because each donor experiences a unique set of deterrents, we developed a post-donation interview based on motivational interview principles to flexibly address individual barriers. Our interview encourages donors to reflect upon their unique motivations for giving and how the act of donating is consistent with what matters to them most. In a pilot study we demonstrated that donors who completed the interview at one month post-donation reported more positive attitudes towards donation and greater confidence as a donor.[9] Further, compared to the no-call control group, donors who received the intervention were significantly more likely to donate in the subsequent year.

The current project extends this pilot study in several important respects. First, we will examine the ability of a telephone-delivered post-donation interview to target retention of first time, group O donors. It would be particularly efficacious to increase retention of individuals with O RhD negative (O-) blood, who represent just 7% of the US population, as red blood cells from these "universal donors" can be transfused to anyone in an emergency when there isn't time for blood typing or if the matching blood type is in short supply. To allow us to generalize our findings beyond one specific donor group, we will recruit both O RhD positive (O+) and O- donors. Second, because our pilot study demonstrated that the relationship between intention and behavior was imperfect (i.e., many of those with increased donation intentions failed to follow through), we have added an implementation intention intervention component to the interview. Implementation intention is a form of

action planning that has been shown to enhance behavioral follow-through among those who express an intention to engage in a wide variety of health-promoting behaviors, including blood donation.[10–12] Third, our current project examines the effects of our interview in a larger and more diverse sample of blood donors. The purpose of this paper is to describe the specific aims and design of the current project.

2. Design and Methods

2.1. Hypotheses

The primary aim of this study is to examine retention of first-time, group O blood donors who are randomly assigned to receive either a telephone-delivered interview with motivational and action planning components or a standard-of-care control call. We hypothesize that, compared to controls, donors who receive the telephone interview will be more likely to make a donation attempt in the next year. In addition, we will examine possible mechanisms of action of the interview using key predictors of donation behavior as described by Self Determination Theory[13] (i.e., motivational autonomy) and the Theory of Planned Behavior[14–16] (i.e., attitude, perceived behavioral control, and intention).

2.2 Study design

This multi-site study will be conducted by Ohio University (Athens, OH, USA), New York Blood Center (New York, NY, USA), and Hoxworth Blood Center (Cincinnati, OH, USA). We will recruit first-time, group O donors two to four weeks after their donation using the donor databases of New York Blood Center and Hoxworth Blood Center. Eligible donors will be contacted via email and invited to participate in the study. Interested donors will complete a baseline assessment immediately after providing informed consent, and then be randomly assigned to either the Interview group (where they will receive a telephone call based on motivational interview and implementation intention principles) or to the Control group (where they will receive a standard donor recruitment telephone call focusing on date of next eligibility and an offer of information to schedule a donation). Telephone contact will be made approximately six weeks after the initial donation. This time frame has been chosen to be prior to each donor's next date of eligibility (i.e., whole blood donors can give blood every 8 weeks), to allow enough time for post-call assessments to be conducted prior to the next possible donation, and to allow flexibility in a potential donation plan (i.e., when, where, and how) for those in the interview group who engage in implementation intention. Approximately one week later, donors will be contacted to complete the online post-call assessment. Outcome measures assessed in the baseline and post-call surveys will include donation attitudes, perceived behavioral control, intention, and motivations, and will be administered via Qualtrics (Qualtrics, Provo, UT, USA). Finally, donation attempts will be tracked for one year using the respective blood center donor database. We hypothesize that there will be enhanced retention among donors who receive the telephone interview, relative to the control group, and that this will be mediated by increases in positive donation attitude, perceived behavioral control, intention, and intrinsic motivation. The study protocol was approved by the Institutional Review Boards of Ohio University, New York Blood Center, and the University of Cincinnati and is registered with ClinicalTrials.gov (NCT02274064).

2.3. Participant screening, recruitment, and randomization

Two to four weeks after their first donation, group O blood donors who are at least 18 years of age and are eligible to donate again will be identified by the blood centers using their donor databases. The potential sample will include those who provided a whole blood or automated red cell (2RBC) donation and who will become eligible to donate again in the next 112 days (the minimum time interval required for 2RBC donors). Donors deferred for longer than 112 days will not be considered eligible for the study. Eligible donors will be contacted by the blood centers via email with information about the study and an invitation to participate. For those interested in participating, the email will contain a link to a website where they can read about the study in greater detail and obtain contact information if they have any questions. Those who agree to participate can complete the consent process online and then proceed to provide their contact and demographic information and to complete the baseline surveys (described below).

Participants will be randomly assigned to either the interview group or the control group using block randomization within gender to ensure a relatively equal distribution of participants of both sexes in each group.

2.4. Baseline assessment

The online baseline surveys will be available to the participant immediately upon enrolling in the study. Participants will begin by providing demographic and contact information and then, as described in Table 1, will complete a series of surveys related to Self Determination Theory (i.e., motivational autonomy)[13], the Theory of Planned Behavior (i.e., donation attitude, subjective norm, perceived behavioral control, and intention)[16–23], as well as other exploratory measures (e.g., decisional balance[24], moral norm[17,20,23,25,26], anticipated regret[20,25,26], and donation anxiety[25,26]).

2.5. Intervention

Approximately six weeks after their first donation, study participants will receive a telephone call from a trained interviewer. All calls will be recorded to permit treatment fidelity assessment and ongoing interviewer supervision.

2.5.1. Interview group—Participants in the Interview group will receive a telephone call that follows a script informed by the principles of motivational interviewing and implementation intention. Both components of the intervention will be delivered during the same call because the motivation to form an action plan will be maximally encouraged by the preceding emphasis on motivations for donation and coping strategies to address perceived barriers. The call will include a discussion of the donor's initial motivations; future donation intentions; donation barriers; perceived importance of donation and donation confidence; personal goals and values relating to donation; individualized coping strategies that they develop with the interviewer; and when, where, and how implementation intentions that they formulate. Based on our pilot study, we expect the average interview to last 15 minutes or less.

2.5.2. Control group—Participants randomly assigned to the Control group will receive a telephone call that follows the standard donor recruitment script currently in use by the collaborating blood centers. These calls focus on thanking the donor for their previous donation, reminding them of their next date of eligibility, and offering telephone and internet contact information to schedule a donation. We expect the average control call to last 3 minutes or less.

2.6. Post-intervention assessment

2.6.1 Post-call survey assessment—One week following their telephone call (approximately seven weeks after their first donation), participants in both groups will receive a reminder email/text with a link to the website where they can repeat the same surveys included in the baseline assessment. To encourage participation and retention, participants will be offered a $50 incentive for completing the baseline assessment, telephone call, and post-call assessment. In addition, participants will also be sent reminder emails and/or text messages to complete the online questionnaires if they have been available for longer than a week and not completed.

2.6.2. One-year follow-up—Because all blood donors receive unique identification codes, the blood center donor databases can be used to track all instances of subsequent donation attempts. Consistent with our previous studies, we will track subsequent donation attempts for one year after the date of next eligibility (i.e., 8 weeks after their first donation). It should be noted that donors who intend to donate may be turned away at the donor health screening (e.g., due to low hemoglobin); hence, both donation attempts and completed donations will be recorded. At the one year follow-up we will also contact all participants (by telephone, text, and/or email) to make a direct inquiry about their donation attempts in the preceding year. This communication will ensure that we have information from participants who may have moved from the blood center catchment areas. Finally, during the one year follow-up all participants will receive the usual messaging and recruitment that is provided by the blood centers, including possible email, text message, social media and/or telephone calls.

2.7. Process evaluation

Interviewers will be Master's level graduate students in clinical psychology who will complete an 8-hour training session that includes: (1) education about blood donation, including common motivators and barriers, (2) motivational interviewing techniques adapted for blood donors, and (3) development of implementation intentions. Training will include lecture, discussion, and role-play using the interview telephone script and the control telephone script. This training session will be provided by licensed clinical psychologists (JLF and CRF).

To allow for ongoing assessment of treatment fidelity, all interviews will be audio recorded, transcribed, and coded by independent raters blind to the treatment hypotheses to assess fidelity to the telephone interview scripts. Coding will follow the principles outlined in the Motivational Interviewing Treatment Integrity (MITI) Code, version 3.1.1 with an equivalent system developed for implementation intention. MITI is a behavioral coding system that has

been developed to assess treatment fidelity in clinical trials and to provide structured feedback to clinicians using motivational interviewing. Interviews will be coded for adherence to the telephone interview script as well as in terms of adherence to motivational interview principles such as asking permission, affirmations, participant control, empathy, and being non-directive and non-confrontational.

Regular group supervision meetings, led by licensed clinical psychologists (JLF and CRF), will be conducted with the telephone interviewers using audio recordings, independent treatment fidelity ratings, and interviewer self-reports to provide appropriate guidance and to help maintain fidelity to the treatment protocol. Interviewers whose overall index of adherence falls below 90% will be required to pursue additional training before continuing.

2.8. Sample size calculation

Sample size estimates were calculated based on the minimum sample required to examine 1) intervention effects on retention of first-time donors using a Cox proportional hazards survival analysis and 2) potential mediators of intervention effects using path analysis. A Cox proportional hazards survival analysis will be conducted on the number of days to first return (i.e., a donation attempt) with the principal predictor variable being group membership. At our blood centers the one-year return rate for first-time donors is 33.8%. Based on the results of our prior pilot study,[9] which demonstrated a 22% increase in donor return rate for the treatment group, in the present study we would need 144 donors (72 per group) to achieve a power of at least 80% at $\alpha = 0.05$. To calculate the sample size needed for the path analysis, a Monte Carlo simulation was conducted with data from previous studies used to estimate the path coefficients among the variables in the proposed model. This analysis indicated that we would need 420 donors (210 per group) to achieve at least 80.7% power for the proposed path analyses. Accordingly, to ensure sufficient power for both sets of analyses and to allow for up to 10% participant attrition in the one-year follow-up data, we will recruit participants until a total of 466 donors (233 per group) have completed the post-intervention assessment.

2.9. Statistical analysis plan

All analyses will first be conducted on an intent-to-treat basis using all participants, and will then be repeated for the subset of participants who completed the telephone interview.

2.9.1. Intervention effects on retention of first-time donors—First, a Fisher's exact test will be conducted to compare the proportion of participants in each group who attempt to donate. We hypothesize that compared to Controls, donors in the Interview group will be more likely to make a donation attempt in the next year. Next, a Cox proportional hazards survival analysis (or a Kaplan-Meier nonparametric survival analysis in the event that the assumptions of the Cox survival analysis are not met) will be used to examine the number of days to the first return donation. The principal predictor variable will be group membership. As appropriate, we will also include covariates of age, gender, race, and ethnicity.

2.9.2. Potential mediators of intervention effects—Path analyses will be used to examine potential mediators of the intervention effect, including donor attitude, perceived

behavioral control, intention, and autonomy. In our hypothesized model, these variables can be both dependent and independent variables; hence, we will conduct a path analysis to model the relationship among the variables to examine 1) the effect of the telephone interview on attitude and perceived behavioral control and 2) the combined influence of attitude and perceived behavioral control on donation intention directly and donation attempts indirectly. We hypothesize that compared to Controls, donors in the Interview group will have larger increases in donation attitude and perceived behavioral control which will contribute to enhanced intention and actual donation attempts. In line with recent integrations of Self-Determination Theory and the Theory of Planned Behavior,[27–29] we will also conduct a path analysis to examine autonomy as a potential mediating factor between the intervention and Theory of Planned Behavior constructs of attitude, perceived behavioral control, intention, and donation attempts. Baseline levels of autonomy, attitude, perceived behavioral control, and intention will be included as covariates if they differ significantly between groups.

3. Discussion

Nearly 16 million units of blood are collected in the US each year to satisfy the constant demand for transfusions. According to the most recent national survey data available, our annual blood supply is donated by just 4.5% of the population, dropping from 5.4% in just the last three years.[1] Although the *overall* blood supply is currently adequate, this does not guarantee that there is a sufficient supply of the specific blood products that patients need. For example, shortages are reported for group O- red blood cells, group AB plasma and platelets, and antigen negative red blood cell products to prevent or treat alloimmunized patients. In addition to these current challenges, future shortages of needed blood products are more likely as older adults receive more transfusions and our population is aging. Unfortunately, the donor pool is aging along with the general population and this is reflected in a steadily increasing mean age of repeat donors.[30] A growing imbalance between supply and demand is also possible as our population becomes more diverse, as ethnic and racial minorities are substantially underrepresented in the donor pool. Recent efforts to expand the donor pool by recruiting younger donors have resulted in higher numbers of initial donations;[30] however, retention of new donors has been a significant problem. The majority of these donors do not return to provide a repeat donation, and less than 8% go on to become committed blood donors.[2–4] As a result, our blood supply is highly reliant on first-time donors (who provide 30.9% of all donations),[1] but these new donors must constantly be replaced because they typically fail to return.

The Theory of Planned Behavior,[31,32] the most widely used model to explain behavioral motivations, has consistently demonstrated an ability to predict blood donation intention and behavior.[14,15,17,19,20,22,25,26,33–36] This model has been shown to predict up to 86% of the variance in blood donation intention and 70% of the variance in donation behavior.[14,15,22,26,34,35] In the context of blood donation, *attitude* represents a basic evaluative judgment of giving blood, *subjective norm* refers to the perception of social pressure to donate blood, and *perceived behavioral control* reflects a combination of self-efficacy (confidence in one's ability to engage in the behavior) and controllability (perception of control over the behavior). Regression and structural equation models have

demonstrated that perceived behavioral control is typically the strongest individual predictor of donation intention, followed by donation attitude.[14,15,19,20,22,26,34–36] Subjective norm is a significant predictor in some studies, but not others.[14,15,19,20,22,26,34–36] Consistent with the Theory of Planned Behavior, first-time donors who fail to provide a repeat donation may hold less positive attitudes toward donation and/or perceive that they have limited ability to cope with the donation process. These issues may have been present prior to their initial donation or may have arisen as a result of their donation experience. In either case, a strategy designed to address individual attitudes and perceived barriers that may exist after an initial donation offers the potential to greatly impact donor retention rates among this large contingent of the donor pool.

This study's intervention draws on principles of motivational interviewing and action planning to address the unique barriers of individual donors. Motivational interviewing is a well-established set of clinical techniques that build upon intrinsic motivation as a means of promoting behavioral commitment. Existing research supports the efficacy of motivational interviewing as a tool for resolving ambivalence and increasing motivation towards the adoption of a variety of health-promoting behaviors, including lifestyle changes to modify diabetes risk, interventions to promote treatment adherence, and adoption of diet and exercise regimens.[37–42] The scripted telephone interview designed for the current protocol applies many of the principles and techniques of motivational interviewing with the goal of helping recent blood donors increase their intrinsic motivation and resolve any ambivalence regarding a repeat donation. In particular, the interview helps the donor explore reasons for and against making a future donation using empathy and non-directive problem solving, encourages the donor to reflect upon how current behavioral choices address larger life goals or the fulfillment of core values, and supports the donor's self-efficacy in the ability to engage in another donation.

To enhance the likelihood that positive changes in motivation as a result of the interview translate to subsequent donation, the interview script also includes an action planning component. Interviewers will use an implementation intention technique that has been demonstrated to be an effective means of bridging the gap between intention and a variety of health-promoting behaviors (e.g., adherence to medical screening, exercise, and healthy eating[43–47]). Implementation intentions are simple if-then plans that facilitate the translation of goal intentions into behavioral action (e.g., "If I am in situation *X*, then I will do *Y*"). These if-then plans are believed to enhance accessibility of mental representation of the external cue and to strengthen the association of the external cue and the behavioral response. Hence, subsequent cue exposure can trigger an automated response that requires minimal conscious thought and effort. Moreover, if-then plans have been shown to promote desired behavior by shielding ongoing goal-striving from potentially interfering internal thoughts, feelings, or physiological reactions.[45] While some encouraging data regarding the role of implementation planning in the blood donation context has been reported,[10–12] these studies used a written questionnaire format with pre-defined barriers. However, as noted above, successful application of the implementation technique crucially depends on identifying unique individual barriers and the development of specific, personalized if-then plans that will facilitate performance of the behavior in the face of these deterrents.[46,48] To our knowledge, this protocol will be the first in the context of blood donation to include an

open-ended discussion designed to ascertain personally-relevant barriers and foster individually-tailored implementation intentions; hence, this will be a novel and important contribution of the proposed study.

Of additional theoretical relevance to the current proposal, self-determination theory has increasingly been used as a model to understand the benefit of motivational interviewing approaches such as our telephone interview.[49,50] This convergence has occurred because of considerable conceptual overlap, and particularly the shared view regarding the central role of autonomy support in both self-determination theory and motivational interviewing. For example, our interview process involves a series of open-ended questions designed to honor and enhance individual autonomy in making a future donation decision (as opposed to applying pressure or encouragement to donate again). Specific topics include 1) individual motivations for giving, 2) the relationship between past donation behavior and personal goals/values, and 3) donation importance and confidence rulers (i.e., a motivational interviewing technique to enhance commitment). By including an assessment of donor autonomy, this study will be the first to our knowledge to examine motivational autonomy as a potential mediator of return donation behavior.

While this study will yield important information regarding the efficacy of this novel intervention to increase donor retention, there are some design limitations. Because collection of follow-up donation data does not require any action on the part of participants (i.e., data are collected directly from blood center databases), there can be no loss of data due to this form of drop-out. However, attrition may occur if participants move or donate outside of the blood center catchment area or donate to another collection center in their area. To address this issue we will supplement our follow-up data with direct donor contact to help ensure that we reach donors who may have moved or donated elsewhere. Importantly, there is no reason to expect that this form of donor attrition would vary in a systematic fashion between groups; hence our analyses will provide a conservative estimate of donor retention. Another concern is that, as in any study, those who volunteer may differ from those who do not. To address this issue, participants in the protocol will be compared to all first-time group O donors in the same year at each of our blood centers. This analysis will be used to determine whether our sample is representative of typical first-time group O donors with regard to demographic characteristics (e.g., age, height, weight, sex, race, and ethnicity) and experience of complications (e.g., syncopal reactions, bruising, etc.) during their initial donation. In addition, we will compare the one-year retention data from the participants in the Control group to the overall retention rate for first-time group O donors (and first-time donors as a whole) in the same year at each blood center to determine if retention in the Control group has been enhanced or suppressed by mere participation in the study.

In sum, the current study develops and tests a promising, theoretically-driven approach to targeted donor retention that focuses on the unique motivators and barriers faced by individual donors. Although this study is specifically aimed at retention of first-time, group O donors, the findings can be easily translated to promote retention of other donor groups based on evolving patient needs. As such the findings have the potential to dramatically improve the safety and stability of the nation’s blood supply.

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Table 1

Survey measures to be completed by participants at baseline (approximately 3 weeks post-donation) and after telephone contact (approximately 7 weeks post-donation).

Measure	Description	Sample item	Response Anchors
Blood donor identity Survey	An 18-item measure of six different regulatory styles, ranging from unmotivated to donate to increasing levels of autonomous motivation to donate (i.e., non-regulation to intrinsic regulation).	"Donating blood is consistent with my life goals."	(1) Not at all true to (7) Very true
Blood donation attitude	A 6-item measure of attitudes towards blood donation that yields a total score as well as subscale scores cognitive attitude (evaluative judgments) and affective attitude (emotional reactions).	"For me, donating blood within the next 8 weeks would be…"	(1) Unpleasant to (7) Pleasant
Blood donation subjective norm	A 6-item measure of perceived social pressure or expectations of significant others that one will donate blood within the next 8 weeks.	"The people who are most important to me think I should give blood in the next 8 weeks."	(1) Disagree to (7) Agree
Blood donation perceived behavioral control	A 6-item measure of one's confidence and perceived ability to donate blood within the next 8 weeks.	"How confident are you that you will be able to donate blood within the next 8 weeks?"	(1) Not very confident to (7) Very confident
Blood donation intention	A 3-item measure of one's intention to donate blood within the next 8 weeks.	"I plan to donate blood in the next 8 weeks."	(1) Disagree to (7) Agree
Blood donation decisional balance	A 12-item measure of the pros and cons of blood donation, which contains three subscales – Pros, Physical Cons, and Eligibility Cons.	"I may be helping somebody in my community."	(1) Not at all important to (5) Extremely important
Blood donation moral norm	A 3-item measure of perceived moral correctness associated with the act of donating blood.	"I feel a moral obligation to give blood."	(1) Strongly agree to (7) Strongly Disagree
Blood donation anticipated regret	A 3-item measure of negative feelings associated with failing to act in accordance with one's intention to donate within the next 8 weeks.	"If I do not donate blood within the next 8 weeks, I will regret it."	(1) Very unlikely to (7) Very likely
Blood donation anxiety	A 3-item measure of anxiety expected during blood donation.	"If I donate blood I will feel nervous."	(1) Not at all to (7) Very much