Motivations to Transplant Registry Participation

Intervention Protocol

NCT ID # Pro2022000536

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THE STATE UNIVERSITY
OF NEW JERSEY

INTERVENTIONAL
RESEARCH PROTOCOL TEMPLATE
(HRP-503a)

STUDY INFORMATION

- **Title of Project:**
  Motivations for Stem Cell Transplant Registry Participation
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- **Protocol Version and Date:**
  v3 6.8.23

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1.0 Research Design

1.1 Purpose/Specific Aims

The current study seeks to understand factors that influence college students' likelihood of participating in the National Marrow Donor Program (NMDP)/Be the Match for bone marrow and stem cell donations. The secondary aim is to compare emotional and rational approaches to encouraging participation in the registry and how these approaches may impact intentions to participate in the NMDP.

A. Objectives

1. The study will describe the role of demographic, personality, and psychosocial factors in attitudes towards participating in the National Marrow Donor Program.
2. Two strategies for increasing motivation (emotional appeal or factual data on racial/ethnic disparities in representation on the registry) for enrollment will be tested.
3. Strategies for enrollment will be compared by Race and Ethnicity to understand the best approaches to recruiting diverse students into the registry program.

B. Hypotheses / Research Question(s)

Approximately 12,000 patients need a bone marrow transplant each year to treat their cancer or other hematologic condition, but only about 30% of these patients find matches within their families (National Marrow Donor Program, 2013). The NMDP maintains a list of potential donors through the "Be the Match" organization which often runs donor drives on college campuses. Bone marrow donors are matched on genetic similarities, making race and ethnicity an important component in finding a match between a patient and a potential donor. Donors registered with Be the Match are 67% White, making it more difficult for individuals of color to find good matches, which may delay transplants and ultimately impact survival and the success of transplants. Thus, diversity is an important component of enrolling potential donors in the transplant registry. Because the student body of Rutgers Camden is diverse and within the age range targeted to join the NMDP, understanding psychological factors that contribute to participation and the most effective strategies to cultivate enrollment intentions is an important step towards enhancing the diversity of the donor registry and improving health outcomes for patients of color.

1. It is hypothesized that students who report high levels of altruism will be more likely to report an intention to enroll in the stem cell transplant registry.
2. It is hypothesized that students who report high levels of knowledge about stem cell transplants will be more likely to report an intention to enroll in the stem cell transplant registry.
3. It is hypothesized that high altruistic students will be more likely to enroll when presented with an emotional appeal.
4. It is hypothesized that high knowledge students will be more likely to enroll when presented with a factual appeal.
5. It is hypothesized that the rational appeal which focuses on health disparities will result in a higher likelihood of enrollment for students of color as compared to white students.
6. It is hypothesized that self-esteem will differ between individuals who do and do not indicate an intention to enroll in the registry.

1.2 Research Significance

Previous international research has demonstrated that the potential to save lives is the most motivating factor in the decision to enroll in bone marrow registries while the biggest barriers are lack of information on the process and risks (Bart et al., 2014).Qualitative research supports that personality characteristics

such as altruism are important influences on intentions to register with NMDP and to later donate (Kaster et al., 2014) and altruism is described as central to the decision-making process in those who have gone through with donations (BIllen, Madrigal, Scior, Shaw & Strydom, 2017). However, when examining the relationship between altruism and intentions to enroll in the NMDP in a sample of medical students, altruism was not related to intentions (Narayaman et al., 2016). Self-esteem has also been implicated in charitable donations (Surana & Lomas, 2014) and bone marrow donors report more positive sense of self post-donation (Butterworth el al., 1993), but self-esteem has not been examined as a correlate of decision making to participate in bone marrow registries. Thus, the role of personality characteristics in motivating participation in the NMDP are unclear but may be important correlates to consider.

Knowledge about the bone marrow and stem cell donation process and how this information is communicated also appear to be important factors in whether participants enroll in the registry. Research in college students studying medically related fields has demonstrated that students hold many misconceptions about the donation process and those students with lower knowledge were less likely to indicate an intention to enroll (Vasconellos Nunes, & Feller, 2011). Further, knowledge about the process is generally higher in medical students who are enrolled in the registry (Narayaman et al., 2016). As knowledge is generally low even among students with medically-oriented training, understanding how to best communicate about the NMDP to a general college audience is important. Specifically, emotional appeals have been found to be more effective in motivating participation in transplant registries when compared to rational approaches that presented statistics and facts about the transplant process (Studts et al., 2010). Emotional appeals that help participants envision specific patients and the positive outcomes of their donation may be especially important in increasing the likelihood that an enrolled individual follows through with the donation when asked (Vekaria et al., 2020). What is not known though is how a rational appeal that includes information regarding the need for diversity may affect participation, especially in individuals from diverse backgrounds. To date, these different approaches to communicating information about bone marrow registries have not been studied in diverse college students.

Demographic factors, such as race and ethnicity, are also important predictors as evidenced by the lower likelihood of finding a match for individuals of color suggesting a need for greater diversity in the registry (National Marrow Donor Program, 2013). Older research suggests that a willingness to donate does not differ between African Americans and White individuals, but White individuals may be more familiar with the registry, which in turn leads to greater participation rates (Onitilo et al., 2004). Women may also be more willing to register (Studts, et al., 2010), although this predictor is not consistent across all studies (Monaghan et al., 2020). Family cancer history is also an important factor in the likelihood of participating (Studts, et al., 2010).

Our student body at Rutgers University Camden is very diverse and typically within the age range targeted by Be the Match, making it an important group to understand demographic, personality, and message communication factors that contribute to the likelihood of participation in the registry.

1.3 Research Design and Methods

A. Research Procedures

This study is a randomized controlled trial that will randomize participants to receive either an emotional appeal about a child with cancer who needs a bone marrow transplant or a rational appeal using data on the racial/ethnic disparities within the transplant registry. (See Appendix A for condition prompts).

Participants will be recruited through the Psychology Subject Pool through the SONA system which will then link students to the study measures in Qualtrics. Participants will be asked their age to confirm eligibility to participate (students must be between 18-35) and eligible students will be presented with the consent form in Qualtrics. Participants will then be asked to complete measures of demographic information, personality/psychological characteristics, and transplant-related knowledge, intentions, and attitudes. All participants will then be given background information on bone marrow transplants (See Appendix A for text).

Randomization: Students will be randomized by sex in Qualtrics to the emotional presentation condition or the rational presentation condition. The emotional condition will tell the story of a fictional pediatric patient with cancer who needs a transplant. The rational condition will describe the facts about the need for diversity in the registry (See Appendix A for condition prompts).

After being presented with the rational or emotional appeal, participants will again be asked their intentions to register, their motivations for registering, and their mood.

B. Data Points

Study data will include demographic information and responses to questionnaires given during the survey in Qualtrics.

C. Study Duration

Participation will last approximately 30 minutes.

D. Endpoints

The study will continue to collect data until a sufficient sample size is accrued.

1.4 Preliminary Data

N/A

1.5 Sample Size Justification

Prior research has demonstrated an effect size of w=0.38 (medium effect) between an emotional and rational appeal, thus we expect a medium effect size (Studts et al., 2010). In order to compare the effect of the two conditions (emotional/rational) by race/ethnicity (White, African-American, Latinx considered as the primary groups represented, recognizing there will be others) we will need 300 participants to have 85% power to detect a medium effect with a p-value of 0.05. To be conservative and ensure we have a large enough sample of each race/ethnicity group, we will seek to enroll 400 students.

1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables

The primary independent variable will be group (emotional or rational condition).

Emotional Appeal: Participants will be presented with a short vignette about a child undergoing cancer treatment and needing a bone marrow transplant in order to survive cancer. A publicly available animation of a teddy bear and hospital tools is also included in this condition.

Rational Appeal: Participants will be presented with data regarding the importance of considering race/ethnicity when looking for a bone marrow transplant donor and the likelihood of finding a match based on the patient's racial/ethnic background. An infographic depicting this information was created for this study.

Secondary Independent Variables: Additionally, demographic factors (race/ethnicity, sex, age), Altruism, Self-Esteem and Knowledge will be tested as secondary independent variables.

A full list of study measures is included in Appendix B.

Construct/Measure Name	Description
Demographics	(8) items will be used to assess the demographics of the student population.
Altruism	The Self-rated Altruism Scale (20 items) assesses altruistic behavior. Specifically, the questions refer to certain altruistic actions that students have partaken in and their frequency of said activities (Rushton, Chrisjohn, & Fekken, 1981).
Self-Esteem	The Rosenberg Self-Esteem Scale (10 items) tests the self-worth of an individual by testing the negative and positive feelings about ones' self using a 4-point Likert scale (Rosenberg, 1965).
Social Desirability	The Marlowe Crown Social Desirability Index short form (13 items) will be used to assess how much student responses are influenced by demand characteristics of participating in research (Fischer & Fick 1993).
Healthcare Distrust	The Healthcare Distrust Scale (10 items) assesses the level of trust participants have in the healthcare system. Specifically, the scale covers the positive and negative aspects of the healthcare system and how trust impacts choices (Rose et al., 2004).
Knowledge	This knowledge measure tests (12 items) misconceptions about the bone marrow registry and will be used to assess the general knowledge of the population we are administering the survey in to see the depth of knowledge regarding the research topic. This survey will also assesses opinions of participants regarding the process of going through a bone marrow transplant (Vasconellos 2011).
History of transplant/donation	Previous research by Narayanan et al., (2016) has included these 15 items to assess an individual's familiarity with the transplant and donation process.
Motivations to donate	Participants are asked to rank order 11 possible reasons that they may decide to register for the transplant registry (Bart et al., 2014). Participants will complete this measure before and after the Emotional/Rational condition presentation.
Attitudes towards bone marrow transplant	Participants will be asked 9 questions about their attitudes towards joining the bone marrow registry and donating stem cells at a later date. This measure has been used in previous research (Narayanan et al., 2016).
Ambivalence	The Simons Ambivalence Scale is a 7-item scale developed to assess feelings about solid organ donation(Gardner, 1987). The measure has been modified for stem cell donor participation (Fingerut et al., 2020) and 4 of the 7 items will be used in the current study.

B. Dependent Variables or Outcome Measures

The primary dependent variable is intentions to register in the bone marrow transplant registry.

Secondary Dependent Variables: Participants will be asked about how factual and how emotional they perceived the appeal they received is to determine if the manipulation worked. We will also ask about their current mood again.

Construct/Measure	Description
Intentions to register	Participants will be asked 2 questions about whether they will register and the rate the likelihood of registering. They will be asked these questions before and after the experimental manipulation.
Manipulation Check	Participants will be asked to rate how emotional and how factual the appeal they received was on a 1-7 scale.
Mood	Participant mood will be assessed pre/post survey, asking participants to rate their current mood on a 1-10 scale.

1.7 Drugs/Devices/Biologics

A. Schedule and Administration
N/A

B. Drug/Device Accountability and Storage Methods
N/A

1.8 Specimen Collection

A. Primary Specimen Collection
N/A

B. Secondary Specimen Collection
N/A

1.9 Data Collection

A. Primary Data Collection

- **Location**: Data will be collected online using the secure Qualtrics survey platform
- **Process of Data Collection**: Participants will log into Qualtrics from their own device and complete survey data remotely. We will review collected data on a weekly basis for completion.
- **Timing and Frequency**: Data collection will take place during a single session during the 2022-2023 and 2023-2024 school year.
- **Procedures for Audio/Visual Recording**: N/A
- **Study Instruments**: The survey instruments have been used in previous research studies. All measures are listed in section 1.6 and copies of all measures have been uploaded to the eIRB application (Appendix B).
- **Ethnographic Studies, Interviews, Or Observation**: N/A
- **Subject Identifiers**: No identifying information will be collected from the participants. Students log into the SONA system which manages participation credit without the research team having to collect any identifiable information from participants.

B. Secondary Data Collection

N/A

1.10 Timetable/Schedule of Events

This is a single visit study; thus all study procedures will happen after consent in one session.

2.0 Project Management

2.1 Research Staff and Qualifications

Dr. Lauren Daniel is a Clinical Psychologist in the Department of Psychology and Health Sciences at Rutgers Camden. Her research focuses on cancer research and how psychosocial factors influence health behaviors and quality of life.

2.2 Research Staff Training

All persons assisting with the research will maintain active CITI Training Certifications.

2.3 Other Resources

The study will draw on the students in the Psychology Subject Pool which is maintained by the Department of Psychology. Because the study is conducted online, there are no additional physical resources needed. There are no additional medical or psychological resources needed because the study poses no reasonably foreseeable risks to subjects.

2.4 Research Sites

Data will be collected and stored online in the secure Qualtrics Server hosted by Rutgers University.

3.0 Multi-Center Research

N/A

4.0 Subject Considerations

4.1 Subject Selection and Enrollment Considerations

A. Method to Identify Potential Subjects

Potential subjects for the study will be identified by their current enrollment in Introduction to Psychology (50:830:101) or Method and Theory of Psychological Research (50:830:255).

B. Recruitment Details

The study will be posted to the Psychology Subject Pool which is hosted on the website SONA, maintained by the Psychology Department. Students are given the opportunity to participate in research as part of their class experience and receive class credit for participation. No additional recruitment will take place.

C. Subject Screening

Describe whether and how individuals will be screened for eligibility and by whom.

- **Inclusion Criteria**
  Students enrolled Introduction to Psych (101) and Method and Theory (255) who are between the ages of 18-35 will be eligible to participate. Students will be asked to confirm that they are in the specified age range in Qualtrics before completing the informed consent form.
- **Exclusion Criteria**
  Students under 18 years of age or over 36 or older will be excluded.

D. Privacy Protections

This study will not collect any identifiable participant data. Sona creates a unique randomly generated participant ID that is used in Qualtrics to collect data. The Sona system will separately maintain participant email addresses for the purpose of assigning class credit, but this will not be linked to the data collected in Qualtrics. When a student completes the survey in Qualtrics, they are returned to the Sona system so that they may receive class credit. Researchers will only identify data by the unique randomly generated participant ID.

4.2 Obtaining Identifiable Information About Non-Subjects

N/A

4.3 Number of Subjects

A. Total Number of Subjects

It is expected that 500 students will be screened to accrue 400 complete subjects needed to analyze the hypotheses of this study.

B. Total Number of Subjects If Multicenter Study

N/A

C. Feasibility

The Psychology Subject Pool typically has between 500-700 students in the fall and 200-300 students in the spring, making recruiting feasible in one-two school years.

4.4 Consent Procedures

A. Consent Process

- **Location of Consent Process**
  The consent process will take place in Qualtrics after participants confirm eligibility. Participants will be required to agree to the document by checking a box in order to access the survey tools.
- **Ongoing Consent**
  N/A
- **Individual Roles for Researchers Involved in Consent**
  Researchers will develop the informed consent document but will not otherwise be directly involved in obtaining consent from participants.
- **Consent Discussion Duration**
  Participants will be given the consent form at the beginning of the study and will be allowed to consider participation for as long as possible. Contact information will be available for the principal investigator should the participant have questions or concerns regarding the study or its procedures.
- **Coercion or Undue Influence**
  The consent document will clearly state that participation in the study is voluntary. Additionally, course instructors will make clear to students that participation is voluntary and students will be given an alternative assignment for course credit should they not want to participate in research.
- **Subject Understanding**
  Before a subject can access the study survey tools, they will be required to indicate that they understand the nature of the study and consent to participate.
- **Protecting Privacy**
  Surveys will be completed online on the students' electronic devices, no one will know of their participation.

B. Waiver or Alteration of Consent Process

- **Waiver or Alteration Details**

N/A

- **Destruction of Identifiers**
  N/A
- **Use of Deception/Concealment**
  Participants will be given general details about the study activities and potential risks; however they will not be provided with specific hypotheses of the study. Specifically, the participants will be told that the study is interested in learning about students' knowledge and attitudes about participating in the NMDP, but students will only view one of the potential conditions (rational or emotional) to understand if these different methods differentially impact intentions to participate in the registry. Omitting information about the specific hypotheses is necessary to fairly test hypotheses and avoid demand characteristics.
  a. **Minimal Risk Justification**
     This study is minimal risk because we will be providing students with very brief information about the reasons individuals may decide to participate in the NMDP. This information is like that provided to encourage participation in other donation programs such as blood donation that is regularly broadcasted on radio and television advertisements.
  b. **Alternatives**
     Any alternative that involves divulging true purpose would not allow a fair test of the hypotheses.
  c. **Subject Debriefing**
     All participants will be provided with links to learn more about the Be the Match program at the end of the study. Participants will also be given the opportunity to ask questions of the research team through the PI's email address.

C. Documentation of Consent

- **Documenting Consent**
  Subjects' consent to participate in the study will be documented in their survey results, as they will be required to indicate that they understand the study and consent to participate before they are able to access the survey tools.
- **Waiver of Documentation of Consent (i.e., will not obtain subject's signature)**
  Subject's will indicate "I agree" or "I do not agree" in the online consent form, therefore a waiver of the documentation of consent is requested.

4.5 Special Consent Populations

A. Enrolling Minors-Subjects Who Are Not Yet Adults

- **Parental Permission**
  We will only enroll students who are 18 or older
- **Non-Parental Permission**
  N/A
- **Assent Process**
  N/A
- **Documentation of Assent**
  N/A
- **Reaching Age of Majority During Study**
  N/A

B. Enrolling Wards of the State

N/A

- **Research Outside of NJ Involving Minors**
  N/A

C. Enrolling Non-English-Speaking Subjects
N/A

- **Process for Non-English-Speaking Subjects**
  N/A
- **Short Form Consent for Non-English Speakers**
  N/A

D. Enrolling Adults Lacking Decision-Making Capacity (Surrogate Consent)
N/A

- **Assessing Adult Capacity to Consent**
  N/A
- **Selecting a Surrogate & Consent Process**
  N/A
- **Subject Assent**
  N/A
- **Selecting a Witness to the Surrogate Consent Process**
  N/A
- **Removing a Subject**
  N/A

E. Special Consent Considerations
The following steps will be taken to ensure that students do not feel coerced by faculty to participate in the research:

a. Students will be offered alternate assignments to participation in research, thus not participating will not affect their course grade.
b. Students will be able to select participation based on the study title and brief study description. Thus, they can elect not to participate in this specific study.
c. Language has been added to the consent form explaining that participation is voluntary and that deciding to take part in the study or withdrawing will not impact their standing in their psychology courses.

4.6 Economic Burden and/or Compensation for Subjects

A. Expenses
Participants will not incur any direct or indirect costs because of their participation in the study.

B. Compensation/Incentives
Participants will not receive any direct or indirect compensation or incentives for participation in this study.

C Compensation Documentation
N/A

4.7 Risks of Harm/Potential for Benefits to Subjects

A. Description of Risks of Harm to Subjects

- **Reasonably Foreseeable Risks of Harm**

The foreseeable risks associated with participating in this study are due to the study content being related to cancer and other blood-based conditions. Participants may find it distressing to read about a child with cancer in need of a bone marrow transplant.

- **Risk of Harm from an Intervention on a Subject with an Existing Condition**
  There are no documented risks to participation in this type of study.
- **Other Foreseeable Risks of Harm**
  Participation will be kept confidential and anonymous. Researchers will not have access to study names or identifying information.
- **Observation and Sensitive Information**
  N/A

B. Procedures which Risk Harm to Embryo, Fetus, and/or Pregnant Subjects
N/A

C. Risks of Harm to Non-Subjects
N/A

D. Assessment of Social Behavior Considerations
N/A

E. Minimizing Risks of Harm
Participants will be told the purpose of the study before consent, including that we are trying to learn about what motivates individuals to donate bone marrow/stem cells for patients with cancer and blood-based health conditions. Should they be uncomfortable with this study content they can elect not to participate. Further, should participants become uncomfortable while answering any questions or while reading about the reasons patients need a transplant, they can skip questions or stop participation at any time. Finally, participants will be provided with the principal investigator's contact information should they need to discuss the study content further.

- **Certificate of Confidentiality**
  N/A
- **Provisions to Protect the Privacy Interests of Subjects**
  N/A

F. Potential Direct Benefits to Subjects
There are no direct benefits for participating in the study, although their participation may help increase diverse enrollment in the NMDP in the future.

5.0 Special Considerations

5.1 Health Insurance Portability and Accountability Act (HIPAA)
N/A

5.2 Family Educational Rights and Privacy Act (FERPA)
N/A

5.3 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations)
Rutgers-Camden undergraduate students will be enrolled and the study and a considered a vulnerable population because of the potential for students to feel coerced by faculty and instructional staff.

A. Special Populations
Following the procedures for using students as subjects in the Rutgers Research HSPP the following steps will be taken to reduce the possibility for students to feel coerced into participation.

1) The Principal Investigator teaches one section of Method and Theory but will not recruit in class. Students will be given the opportunity to select which studies they would like to

participate in and will not be penalized in any way for participating or not participating in this specific study.
2) Students in the Psychology Subject Pool will be given an alternate assignment should they elect to not participate in research.
3) Students' grades will not be impacted if they do not consent to participation or if they choose to withdraw from the study. This will be explained to students as part of the consent process.

5.4 General Data Protection Regulation (GDPR)
N/A

5.5 NJ Access to Medical Research Act (Surrogate Consent)
N/A

6.0 Data Management Plan

6.1 Data Analysis
Data will be analyzed using ANOVAs and multivariate linear regression models.

6.2 Data Security
Survey data will be collected using Qualtrics, a secure online platform. There will be no identifiable information collected within the Qualtrics system. Participation credit is assigned through a separate system that manages the Psychology Subject Pool (SONA) and will not be linked to participant data except by time stamp if needed to later assign credit.

6.3 Data and Safety Monitoring

A. Data/Safety Monitoring Plan
N/A

B. Data/Safety Monitoring Board Details
N/A

6.4 Reporting Results

A. Individual Subjects' Results
N/A

B. Aggregate Results
Results of the research will be made available to participants upon request. All results will be presented on the sample. No individual results will be shared or published.

C. Professional Reporting
The research team will publish results and present them at academic conferences. The findings may also inform future studies regarding participation in the NMDP.

D. Clinical Trials Registration, Results Reporting and Consent Posting
This trial will be registered with ClinicalTrials.gov.

6.5 Secondary Use of the Data
Any data published in papers and/or presentations will be made available to researchers upon request. Data will not contain identifiers.

7.0 Research Repositories – Specimens and/or Data

N/A

8.0 Approvals/Authorizations

N/A

9.0 Bibliography

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