

Impact of Language and Education on participant research attitudes and engagement in clinical research: The Type 1 Diabetes Bone Health Connection (T1D BEACON) Sub Study

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ABSTRACT

Patient participation in clinical research is critical to advance the field of medicine. Prior studies indicate that 11% of study sites fail to recruit participants and that 40% of participants do not understand what the study entails.^[1] Traditional language in recruitment materials tends to focus on study logistics, which does not convey direct relevance to the potential participant. We hypothesize that patient-centric language and use of health education materials during clinical research recruitment may positively impact research engagement and attitudes toward research. The T1D BEACON study is being implemented across MGH and BWH to evaluate factors affecting bone health in adults with type 1 diabetes (T1D), aiming to enroll 100 participants over two years. As a recruitment sub-study, we will compare impact of online recruitment materials utilizing traditional 'study-centric' language vs. 'patient-centric' educational language on research engagement. We will study the impact of receiving additional educational handouts vs standard study information letters alone on research attitudes using the validated Research Attitudes Questionnaire.^[2] Effective engagement, recruitment, and completion of the BEACON study will not only advance our scientific understanding of bone health and treatment approaches in T1D, but also has significant implications for effective research engagement practices across MGB.

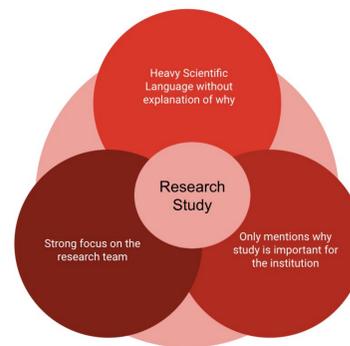
RESEARCH OBJECTIVE

Our overall objective is to understand whether a patient-centric approach and patient education can lead to an overall increase in participant engagement and better overall participant research attitudes.

METHODOLOGY

1. To understand how language impacts participant engagement, we will post a patient-centric and study-centric version of the recruitment material on Rally, a MGB clinical trials website.
2. To understand the impact of education on participant research attitudes, we will use fixed interval randomization to randomize participants to receive either:
 - (a) study recruitment letter
 - (b) study recruitment letter + educational handouts explaining the importance of bone health in type 1 diabetes

Study -Centric



- Makes it difficult for potential participants to understand the relevance of the study
- Emphasis on research team or institution's goals

ADULT VOLUNTEERS WITH AND WITHOUT TYPE 1 DIABETES NEEDED FOR BONE HEALTH STUDY

The Endocrine Unit at the Massachusetts General Hospital is performing a research study investigating the effect of type 1 diabetes on bone strength in adults. The goal of this research is to understand differences in underlying bone structure that may contribute to the increased hip fracture risk experienced among adults with type 1 diabetes.

Emphasis on institution's research study goals
Adults with type 1 diabetes who are 50 years and older are eligible to join the study. We are also recruiting adults without diabetes for a comparison group. Participation involves 2 visits to Massachusetts General Hospital over the course of 2 years. The visits include blood and urine tests, bone density scans, and medical history questionnaires. Each visit will last approximately 3 to 4 hours and volunteers will receive up to \$150 compensation. We hope that this research will allow us to design future treatments to strengthen bones in people with diabetes.

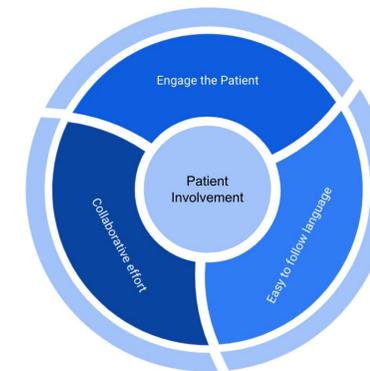
Heavy logistic focus

No engagement with patient

ANALYTIC PLAN

1. We will monitor the number of responses on the patient-centric versus study-centric language on Rally. Using the Chi-squared test, we will evaluate if there is a statistically significant difference between a particular approach and the number of Rally responses received.
2. We will compare patient attitudes towards medical research among the participants randomized to the groups with and without the additional educational materials about the research study during the recruiting phase. Patient attitudes towards medical research will be assessed by the Research Attitudes Questionnaire (RAQ),^[2] and will be compared between groups using independent t-tests.

Patient -Centric



- Asks for patient permission
- Engages potential participant
- Conveys relevance of study to participant
- Emphasis on collaboration

Do you have type 1 diabetes (T1D)?

We invite you to be part of the T1D Bone Health Connection study to understand and optimize bone and overall health in patients with type 1 diabetes.

Do you know that people with type 1 diabetes (T1DM) have an increased risk for bone fractures? Beyond bone health, this increased risk may impact overall health.

Collaborative effort
We invite you to learn more about the T1DM Bone Health Connection study as we collectively understand why people with T1DM have an increased risk of fractures, and how this risk impacts overall health.

Engagement with patient
We are inviting adults with type 1 diabetes who are 50 years and older to collaborate with us in a study at Massachusetts General Hospital. With your consent, volunteers and professionals will work together to collect blood and urine tests, bone density scans and medical history questionnaires to evaluate bone and overall health. The study participation will involve 2 visits to Massachusetts General Hospital over the course of 2 years for these assessments. Each visit will last approximately 3 to 4 hours and volunteers will receive up to \$150 compensation.

Patient Impact
This study will shed light on factors that influence bone health, and the connection to other health risks. We hope this research will provide a better understanding of bone health to design future treatments to improve care for people with T1D with diabetes. Your participation can make a difference.

Importance to patient

For each question below, please circle a number that corresponds to your view. The scale ranges from 1 (strongly disagree) to 5 (strongly agree).

1. I have a positive view about medical research in general.
strongly disagree 1 2 3 4 5 strongly agree
2. Medical researchers can be trusted to protect the interests of people who take part in their studies.
strongly disagree 1 2 3 4 5 strongly agree
3. We all have some responsibility to help others by volunteering for medical research.
strongly disagree 1 2 3 4 5 strongly agree
4. Society needs to devote more resources to medical research.
strongly disagree 1 2 3 4 5 strongly agree
5. Participating in medical research is generally safe.
strongly disagree 1 2 3 4 5 strongly agree
6. If I volunteer for medical research, I know my personal information will be kept private and confidential.
strongly disagree 1 2 3 4 5 strongly agree
7. Medical research will find cures for many major diseases during my lifetime.
strongly disagree 1 2 3 4 5 strongly agree

In evaluating participant attitudes, we will sum up the responses from the RAQ to present a final score. The final score can range from 7-35. A higher final score on this questionnaire indicates that a participant places higher value on medical research and a lower score indicates that they place a lower value on medical research.

CONCLUSIONS

- Currently, most clinical research recruitment materials follow a study-centric approach, focusing on the study logistics rather than on educating the potential participant about the topic of the research study.
- Additionally, many clinical sites face challenges in effectively recruiting patients to participate in their studies.
- Through studying the impact of language and education in the recruitment process, we hope to understand whether patient-centric approaches better engage broader populations in clinical research.

REFERENCES

1. Tufts Center for the study of drug development http://CSSD.TUFTS.EDU/NEWS/COMPLETE_STORY/%20PR_IR_JAN-FEB_2013
2. Rubright, J. D., Cary, M. S., Karlawish, J. H., & Kim, S. Y. (2011, March). Measuring how people view biomedical research: Reliability and validity analysis of the Research Attitudes Questionnaire. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3253733>