De-implementing Fall Prevention Alarms in Hospitals

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The Ohio State University Consent to Participate in Research Coaching Sessions Interviews

Study Title: De-Implementing Fall Prevention Alarms in Hospitals

Protocol Number: OSU IRB 2022B0262

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Sponsor: National Institute on Aging

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate.

Your participation is voluntary.

Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate.

Purpose:
The overall purpose of the study is to identify strategies to safely reduce use of fall prevention alarms in hospitals. Your participation in this study will provide information on the feasibility, acceptability and appropriateness of not only the practice of reducing fall prevention alarms, but also in the process of how your organization approached the reduction (e.g., educational strategies, audits, etc). You are being asked to participate in this study because you are a member of your hospital's De-Implementation Team and partake in the Coaching Sessions with the Fuld Institute staff.

Procedures/Tasks:
Each hospital will be randomized to the amount of Coaching Sessions: Low-Intensity or High-Intensity.

Low-Intensity Coaching Group:
- Initial 2 hour orientation course
- Monthly coaching sessions of 90 minute duration
- Access to web-based, synchronous 'office hours' for group discussion on progress and for troubleshooting barriers.

High-Intensity Coaching Group:
- Initial 4-hour orientation course
- Weekly coaching sessions x 4 weeks (each session at 90 minutes), then
- Monthly one-on-one coaching sessions (each session at 90 minutes)
- Access to on-call coaching assistance

- Access to web-based, synchronous 'office hours' for group discussion on progress and for troubleshooting barriers.

External coaching is a commonly used strategy to change practice among multiple collaborative sites where implementation requires customization to the site. Each study hospital, including yours, receives regularly scheduled coaching sessions with a doctorally prepared coach from the Helene Fuld Institute at the Ohio State University. Coaches serve as skill builders who train organizational personnel in quality improvement processes and develop proficiency in fall prevention.

Each coaching session will be conducted online using Zoom videoconferencing. Each hospital team will be composed of interprofessional team members (e.g., physicians, nurses, physical therapists, respiratory therapists, pharmacists, occupational therapists, speech language pathologists) who are responsible for leading the efforts to safely reduce fall prevention alarms.

Coaches will a) solicit team discussion on barriers and facilitators to the alarm de-implementation and implementing alternative fall prevention strategies, b) guide team strategies for addressing barriers, and c) assist the team in determining an action plan for addressing barriers and enhancing facilitators.

A research team member will coordinate a time to meet via a secure Zoom meeting link at a time that is best for you and your team. Coaching sessions will be audio recorded via Zoom, saved electronically as an audio file on a secure, single sign-on server, and transcribed verbatim. The purpose of the recordings are to ensure the coaches follow the standardized process for conducting the sessions across multiple sites over multiple sessions.

Duration:
Coaching sessions will vary in length and number depending upon whether you are in the Low-Intensity or High-Intensity group as indicated in the description under Procedures/Tasks. Initial sessions will take two (Low-Intensity) or 4 (High Intensity) hours while ongoing sessions typically last 1 ½ hours.

Coaching sessions are scheduled at regular intervals during the 30 months of the study.

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

Risks and Benefits:
There are no known physical or psychologic risks to being in the study.

You will not receive any benefit from study participation, but your opinions and experiences will contribute to a better understanding of what strategies are most beneficial in terms of safely reducing fall prevention alarms.

As we are using the Internet (secure ZOOM room), there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you. While data may be coded, it will exist for an extended period of time, which could be affected if there is a data breach. Your data will be stored on a password protected database.

Confidentiality:
We will work to make sure that no one sees your online responses without approval. But, because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify your site and potentially identify you since data are aggregated at the site level.

External collaborators from the University of Florida, Moffitt Cancer Center, and Children's Mercy Hospital Kansas, who are part of the research investigator team funded by the National Institute on Aging, will have access to the data.

Also, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information; and
- The sponsor, if any, or agency (including the Food and Drug Administration for FDA-regulated research) supporting the study.
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Future Research:
Your de-identified information may be used or shared with other researchers without your additional informed consent.

Incentives:
You will not be paid to participate in this study.

Participant Rights:
You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By agreeing to participate, you do not give up any personal legal rights you may have as a participant in this study.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

Contacts and Questions:
For questions, concerns, or complaints about the study, or you feel you have been harmed as a result of study participation, you may contact Dr. Molly McNett via email at mcnett.21@osu.edu.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251 or hsconcerns@osu.edu.

Providing consent

I have read (or someone has read to me) this page and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study. I am not giving up any legal rights by agreeing to participate.

To print or save a copy of this page, select the print button on your web browser.

Please click the button below to proceed and participate in this study. If you do not wish to participate, please close out your browser window.