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Development of Written Materials for Participants in an Alzheimer's Disease and Related Dementias Screening Trial

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Abstract

Given that participants' experiences in clinical trials include a variety of communication touchpoints with clinical trial staff, these communications should be designed in a way that enhances the participant experience by paying attention to the self-determination theoretical concepts of competence, autonomy, and relatedness. In this feature, we argue that clinical trial teams need to consider the importance of how they design their written participant communication materials, and we explain in detail the process our multidisciplinary team took to design written materials for the patient and family caregiver participants in our Alzheimer's disease and related dementias (ADRD) screening trial. This article concludes with suggested guidance and steps for other clinical trial teams.

Keywords

Alzheimer's disease, dementia, screening, caregivers, family, communication, self-determination theory, best practices

Introduction

Increasingly, a significant number of patients, particularly those receiving care at academic health centers, are simultaneously enrolled in clinical trials as research participants. While there are certain ethical and process-specific aspects of participating in a clinical trial that differ from being a patient, the distinction between patient and research participant is diminishing as more trials are being launched (1). And, while there is significant attention paid to ethical and patient-centered messaging around engagement, recruitment, informed consent, and retention of participants in clinical trials (2–4), little work has focused on the participant experience with communication materials within clinical trials—including correspondence about trial schedules, activities, and procedures, or other materials intended to communicate information for the trial.

Researchers should develop and design clinical trial communication with participants that not only adhere to the fidelity of the intervention, but that also are patient-centered through aligning with the appropriate information and literacy needs of the participant population, treating the patient with respect, and incorporating language that acknowledges the participants' autonomy in the trial. The expectation for clinical trials should be that information exchange and communication experiences of the participant are of the same high standards that we would hope to have for any high-quality clinical patient experiences. In this feature, we describe the process we took for accomplishing the goals of designing theoretically-based written participant communication materials to enhance the participant experience and provide important clinical information to participants in an accessible and engaging manner.

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Written Letters and Materials

One of the most important communication tools in clinical trials and practice is the use of written materials that are sent to participants/patients as a follow-up after a visit. The majority of this out-of-clinic communication focuses on delivering test and diagnostic results, which often includes complex medical information that patients and participants must comprehend and potentially act on—thus, these letters are essential for effective healthcare. Letters frequently resolve an episode of care or provide follow-up information from an initial visit; for example, letters remind patients about tests or labs they have completed in-person *and* relay the results of those tests (e.g., eye exam, Pap test, genetic test). Further, they reinforce information that was provided during the face-to-face encounter, including outlining "next steps" for the patient. This is important considering research indicating that between 40% and 80% of the medical information that providers deliver in face-to-face clinical encounters is immediately forgotten (5). Information recall is even more difficult for patients dealing with complex and distressing health information (5), and for those with diminished cognitive capabilities such as older adults (6).

Simultaneously, with the movement away from paternalistic medicine, patients are encouraged to be active participants in their treatment plans and that includes the role they can play within a clinical trial setting, which is often an important outcome variable. This active role requires that patients understand and are capable of acting on the written information they receive from their clinicians, despite only 12% of Americans having proficient health literacy (7) and more than one-fifth of adults possessing low literacy proficiency (8). In one study examining genetic counseling visit follow-up letters, for example, the average reading level of the letters was 11th grade, while more than half of Americans read below a 9th grade level (9). The problem is that written communication materials often must convey dense, difficult-to-understand information in a way that an average person can understand, while also motivating desired behavior, such as returning to a referring physician, scheduling more testing, or undergoing behavioral change at home to maintain their health—a monumental task in both contemporary medicine and clinical trials. Further complicating this task is that some clinical trials, such as the one described in this article, may focus on individuals with cognitive decline or impairment, which could further complicate literacy and recall abilities.

Interestingly, despite the importance of these written materials, there is little guidance on how to create participant written materials in a clinical trial setting when the materials are meant for information purposes and are not part of the intervention itself. In fact, there is quite a bit of focus on designing appropriate and effective communication which happens *prior* to the clinical trial, such as recruitment messages (10,11) and guidance on writing and assessing consent forms (12–16), as well as *after* the clinical trial, such as communication of study results to patients (17–19). However, missing from this list is a focus on the communication that happens between participants and researchers *during* the study. Therefore, we designed theoretically-based written participant communication materials to enhance the participant experience and provide important clinical information during the trial.

Designing Written Materials for COADS Trial

In this case study, we describe the development of written participant communication materials used in the implementation of the Caregiver Outcomes of Alzheimer's Disease Screening (COADS) Trial. The COADS Trial is a randomized controlled trial testing screening for Alzheimer's disease and related dementias (ADRD) on dyads of older primary care patients and their family members (20). The COADS trial has enrolled 1,809 dyads, who were randomized into one of three groups: the Screening Only group includes dyads where the patient received ADRD screening at baseline, in which both the patient and family member received disclosure of the screening results, with positive screen dyads receiving a list of local resources for diagnostic follow-up; the Screening Plus group, includes dyads where the patient received ADRD screening at baseline coupled with disclosure of the screening results, with positive screen dyads referred to a dementia collaborative care program for diagnostic evaluation and care management if the patient was determined to have mild cognitive impairment or ADRD; and Control, no screening. The COADS trial will measure the family member quality of life (primary outcome) and family member mood, anxiety, caregiver preparedness, and self-efficacy (secondary outcomes), congruence of depressive and anxiety symptoms between older adults and family members, and compare the effectiveness of two strategies for diagnostic evaluation and management after ADRD screening between the two groups randomized to screening (Screening Only vs. Screening Plus) at baseline, 6, 12, 18, and 24 months.

Per the COADS protocol, all patient–family member dyads in our study who were randomized to a screening group (Screening Only and Screening Plus) were notified of the results and possible follow-up actions. While the ADRD screening event *is* the intervention, the study team developed materials for the dyads that (1) communicated information about the patient's ADRD screening performance, (2) provided context for what the results meant, and (3) explained possible next steps for the patient–family member dyad. For the Screening Only group, the next steps were to follow-up with the patient's primary care provider (PCP) and in the Screening Plus group, the next step was a follow-up visit with the specialists at the dementia collaborative care program connected with our academic health center. This information was delivered through both mailed letters (which included an educational infographic about

Table 1. Theoretical Patient-Centered Constructs Reflected in Study Materials.

Theoretical Construct	Excerpt from Patient-Participant Materials
Competence	
Clear explanation of test purpose using plain language and simile.	"Brief screening test, like the one you took, measure the health of the brain. For example, we use test like these the same way we use blood pressure cuffs to measure heart health." (Also reflected in Infographic.)
Guidance for interpreting test result	"We are writing to let you know that your score on the brief screening test is lower than we would expect to see for someone like you." (Also reflected in Infographic.)
Readability Analysis	~6th grade reading level
Formatting	Size 12 font, use of white space, numbered lists, infographic to reinforce information
Autonomy	
Reminder of previous actions	"…you did a brief screening test with our research team on [DATE] where you answered some questions and were asked to remember a few words."
Suggestions for future actions	"We encourage you to discuss these screening results with your family and with your primary care physician." (Also reflected in Infographic.)
Empower Patient/Family Participation	Included outside links and phone numbers for follow-up care
Relatedness	
Acknowledgement of impact of test result news	"We understand that this may be concerning news."
Gratitude	"We thank you for being in our study."
Personalization/Use of Patient Name and Pronoun (Family Letter)	"We are writing to let you know that the [PATIENT'S NAME] score on the test is lower than we would expect to see for someone like [HIM/HER], indicating that [HE/SHE] may be experiencing problems with memory or thinking.

ADRD and screening designed by our team for this study) and script-guided phone calls. Because the results of the ADRD screening test could be understandably concerning, we designed our written materials to dyads that communicated information in a sensitive and supportive manner, accounted for literacy and information needs, and acknowledged the autonomy that the dyad had in this content.

Our team used Agile Science methodology to develop these written participant communication materials. Agile Science is an eight-step reproducible and scalable process that can be applied to any topic in public health or health care delivery to rapidly generate, test, and evaluate novel solutions (21).

First, we identified the key goals of the communication materials for the COADS trial dyads. These goals included:

1. Remind patients that the brief test they completed at baseline was a screening test for ADRD.
2. Provide dyads with their ADRD screening result (positive or negative).
3. Offer information about what an ADRD screening test is to assist with interpretation of results.
4. Cleary identify and suggest next steps/actions for patients and their families.
5. Frame written materials in a way that would balance worry and hope.

After the initial draft of the written materials was created, the team met to ensure that the materials were designed by theory and evidence-based strategies. Specifically, the team used the key constructs in self-determination theory (SDT).

SDT is a theoretical approach to behavior motivation that is useful in informing how we can treat patients in an ethical, patient-centered, and efficient way (22) SDT contends that individual motivation is informed by three psychological needs: competence, autonomy, and relatedness; when applied to patient care, this framework can inform how communication can be structured to address these needs in a meaningful way (22). Importantly, when these psychological needs are addressed in the healthcare context and the patient feels competent in understanding their situation, a sense of autonomy is developed to act in self-beneficial ways. Furthermore, the patient feels relational and emotional support from the provider and other clinic staff, encouraging the patient to engage in behaviors that promote their own health and well-being (23).

In addition to providing a theory-informed approach to motivating patient behavior, an examination of SDT demonstrates that it is solidly grounded in ethical considerations of patient care, such as the "adequate understanding" necessary to make meaningful choices (i.e., competence, autonomy) and an emphasis on empathic communication (i.e., relatedness) (24). The overall aim of the theory is compatible with an ethical approach to elevating the good and minimizing harm in patient care. Beyond that, the literature has consistently demonstrated the value of integrating SDT into a variety of clinic and health-related contexts to ensure positive patient outcomes (23,25–28). Therefore, we applied this theoretical model to our written participant materials in the

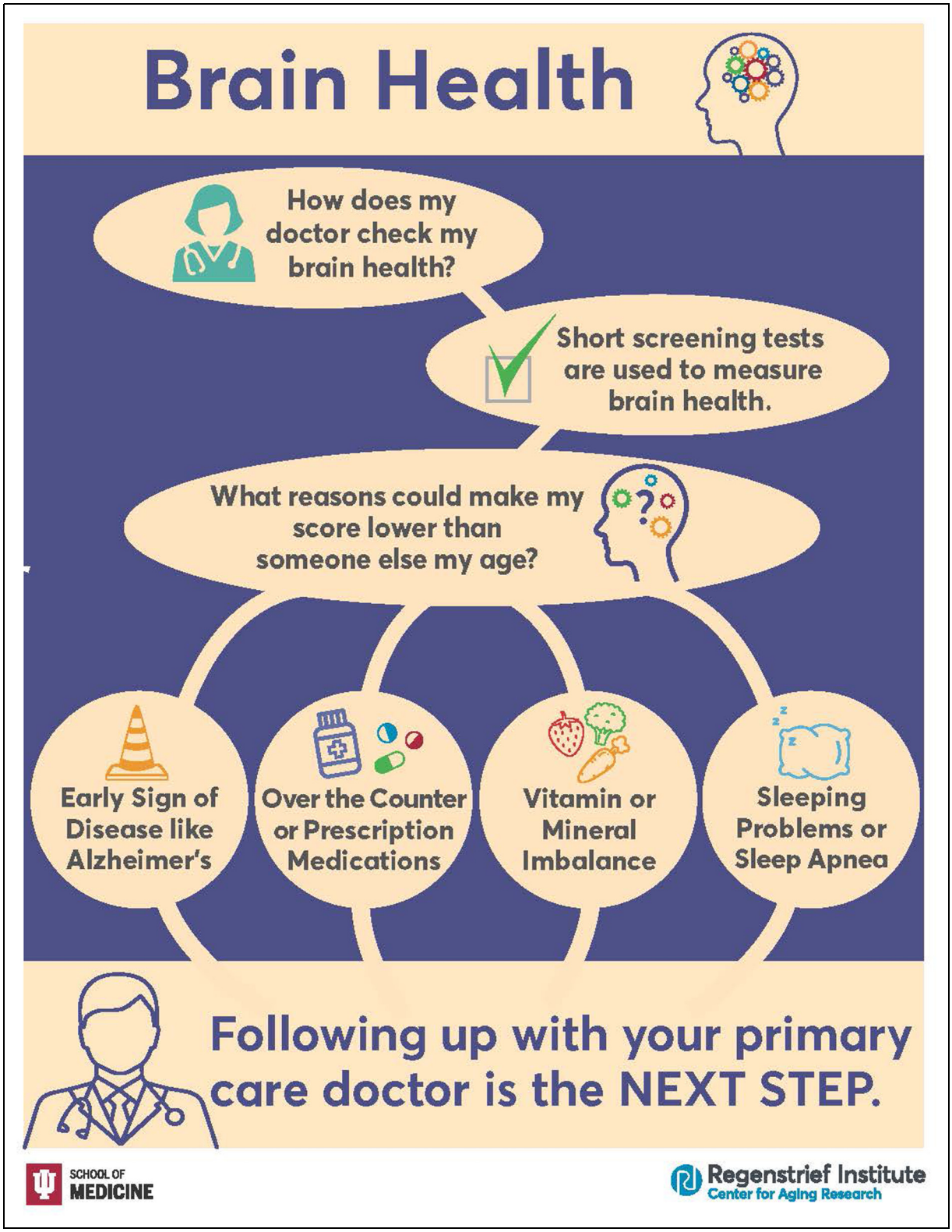

Figure 1. COADS Brain Health Infographic.

COADS trial. Rather than approaching these written materials as a transmission of information to the dyad (i.e., a relay of screening results), we integrated these three SDT psychological needs into our written trial materials.

Using the established goals identified by the team for the written materials and being guided by previous literature on the concepts of SDT, the team began editing the written materials. When integrating the concepts of SDT into our study materials, we carefully focused on each concept as an individual need, while also addressing the needs holistically and how they fit with the COADS project. To address competence, we used evidence-based tactics to ensure materials were easy to read and understand, and were formatted in ways to achieve optimal processing of complex information (e.g., bulleted lists, graphics, use of white space). For example, all written materials were put through a readability analysis to ensure a maximum sixth grade reading level when possible. We also developed a picture infographic that matched the text provided in the letter. To address autonomy, we focused on the importance of patients' sense of participation and control in their own care, such as highlighting the steps they have already taken and emphasizing the choices they have in their next steps for care. For example, we avoided language like "you must" and included choices for how a patient might want to follow up with the dementia collaborative care clinic or their primary care physician. When appropriate, we pointed patients and their families to outside resources to help them feel even more empowered, such as websites and organizations that focus on cognitive issues. To address relatedness, we focused on employing language that demonstrated empathy and connectedness such as personalization of letters (e.g., using their preferred name—"Dear Jimmy," instead of James –in both the greeting *and* throughout the letter) and incorporated expressions of gratitude and empathy. For example, in cases where a patient received positive ADRD screening test results indicating the potential for disease, we acknowledged that this "may be concerning news."

Throughout this process, members of the team shared drafts with healthcare providers and researchers connected to our project or from similar disciplinary backgrounds (e.g., aging research, medical communication studies), informally polled older adults in our own research networks about how we had worded and arranged information in the written materials, and had a research assistant meet with patrons at a local health fair to share initial drafts of the written materials and gather feedback. We met several times to discuss what we heard and learned from these encounters, and this process resulted in multiple iterations until a final set of materials was created. Table 1 lists examples of each SDT concept and examples of how we operationalized it within the written materials; Figure 1 shows the infographic we developed along with one of our patient letters used in the study.

Utilizing this approach in other clinical trial settings need not be a daunting task. In offering guidance to others interested in integrating this process into their clinical trial communication with participants, here are some key steps to help you get started:

1. Identify the objectives of each written patient material being used; compare those objectives to the existing letter or patient materials. This will help identify any communication and information gaps.
2. Use a free online readability analysis tool to evaluate the reading level of written patient materials. If higher than eighth grade, identify words, phrases, and sentences that can be simplified or explained in clearer, laymen's terms.
3. Approach the written materials like you would any face-to-face communication encounter—work to integrate word choices that convey relational support and connectedness. Try and empathize how the patient and their family would be feeling when reading these letters and materials.
4. Clearly identify what the medically appropriate next steps are for the patient and their family in the context of your clinical trial, explain why these next steps are important, and describe how the patient and their family can accomplish these actions. This could include, for example, not just indicating that they need follow-up lab work, but listing the lab location, phone number, and hours so that they can easily accomplish that goal.
5. Gather feedback from other clinicians, patients, and their families about the patient letters and materials that you use. This can be as simple as sending a draft over email or inviting patients and their families to a short focus group to review materials and offer their thoughts. Most importantly, be *responsive* to this feedback and work to make revisions based on what you've learned. (Note: make sure to remove any personal health information from the sample materials you use.)

Conclusion

With the decreasing distinction between "patient" and "research participant" due to the increasing number of clinical trials happening in the United States each year (29), there is a need for more clinical trial researchers to design their participant materials using evidence-based, theoretically-informed approaches that address competence, autonomy, and relatedness. In this article, we described the Agile Science process we took to achieve these goals and encourage others to do the same. Although this approach may seem obvious to some, the process we have outlined helps re-center the patient's needs in these written materials—a worthy goal in clinical trial research.

Author's Contributions

KJH, JAH, TB, MB, MS, and NF have all contributed to the planning and designing of the larger clinical trial. All authors have equally contributed to the writing and reading of this feature manuscript. All authors read and approved the final manuscript.

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Statement of Human and Animal Rights

This article does not contain any studies with human or animal subjects.

Statement of Informed Consent

There are no human subjects in this article and informed consent is not applicable.

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