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The role of a communication intervention in shaping cancer clinical trial consultations: patient and provider experiences with the TrialTalk tool

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Abstract

PURPOSE

Evaluation of TrialTalk, a communication intervention, in a randomized controlled trial showed that patients who experienced TrialTalk (intervention group) were more likely to consent to trials compared to those who didn't (control group). This study seeks to explore how and why TrialTalk influenced patients' trial decisions and compare the decision-making consultation experiences of the two groups.

METHODS

Semi-structured interviews were conducted with a sample of patients with cancer and providers from both groups who underwent a decision-making consultation, including clinical trials. Interviews were transcribed verbatim and coded using an evidence synthesis–based model.

RESULTS

Interviews were conducted between February 2018 and April 2019. In total, 11 providers (8 in the intervention group and 3 in the control group), and 7 patients (4 in the intervention group and 3 in the control group) participated in the interviews. Seven themes were identified about the decision-making consultation, (1) delivering prognostic information and managing patient emotions, (2) describing treatment options and promoting patients' autonomy, (3) Improving patients' awareness and understanding of treatment options, (4) Gathering support and information after visit, (5) Recordkeeping and sharing information with other team members, (6) Deliberation and integrating patients' values and preferences, and (7) Making the decision. Concerns about TrialTalk intervention were noted.

CONCLUSION

This pilot study shows that both patients and providers had positive experiences with TrialTalk intervention. Using TrialTalk prompted providers to increase their use of several aspects of shared decision-making. Future research is needed to evaluate the impact of TrialTalk implementation on health outcomes.

Introduction

Rapid growth in cancer treatments and the uncertainty about the benefits and risks of these new therapeutics increase the demand on providers to demystify complex treatment information and help patients make decisions that align with their preferences and goals.[1] Discussing clinical trials in particular poses an additional challenge to cancer treatment consultations. Studies have shown that many physicians encounter difficulties in initiating and providing balanced information about cancer

clinical trials.[2] Not surprisingly, patients often fail to understand and recall information related to trials, leading to low clinical trial accrual.[3] This is concerning since the majority of patients don't enroll in trials and accruals historically ranged between 2–8% [4, 5]

Shared-decision making (SDM) is a collaborative approach that has shown promise in helping patients navigate high-stakes, preference-sensitive decision-making consultations. Consultations that follow an SDM approach were associated with a higher likelihood of patients' participation in cancer clinical trials. [6] SDM has also been linked with higher patient satisfaction with given information[7], lower decisional conflict [8], and better psychosocial outcomes.[9] While clinicians widely endorse SDM, they rarely receive formal SDM training [10].[11] Additionally, the use of patient decision aids in clinical practice remains low. [12–15] Poor SDM has been associated with worse patient-reported health, lower medication adherence, and greater utilization of healthcare services.[16]

Several interventions focused on clinical trial discussion have been developed and tested in the literature.[17, 18] However, they have been associated with mixed results and minor improvements in clinical trial accrual. Recognizing this gap, our team developed TrialTalk, a theory-based, communication intervention informed by real-world consultations, to help providers navigate cancer treatment discussions and engage patients in the decision-making process.[19, 20] TrialTalk was evaluated in a randomized controlled trial (RCT) in which providers assigned to the intervention group received TrialTalk training and had the option to apply the TrialTalk method in treatment discussions. On the other hand, providers in the control group didn't receive the training and provided usual care.[21] Findings show that a significantly higher proportion of patients in the intervention group consented to participate in clinical trials compared to the control group. A qualitative component was embedded in the RCT to uncover the experiences and perceptions of a subset of patients and providers from both groups. This would provide a deeper understanding of the mechanism by which TrialTalk shaped the treatment discussion and clinical trial decision and identify TrialTalk components that were valued by patients and providers.

Study objectives:

1. Explore patients' and providers' experiences with the decision-making consultations which involve clinical trial discussion and compare the experiences of intervention and control groups
2. Describe intervention patients and providers perceptions of TrialTalk intervention

Methods

Study design and participants

This is a qualitative descriptive study that involve interviews conducted with participants enrolled in an RCT published earlier.[21] The Consolidated Criteria for Reporting Qualitative Research (COREQ) was utilized to report the findings (see Appendix 1 for COREQ checklist).[22]

The study was conducted in UW-Health, an academic medical center located in an urban area. All oncologists, including medical, hematologic, radiation, and surgical oncologists, who provide consultations that involve therapeutic clinical trials were invited to participate in the RCT. Providers were recruited at division and research group meetings and through email invitations. Any provider who had sufficient knowledge of TrialTalk intervention that could influence the randomization process was excluded from participation. During the consent process, providers indicated their willingness to participate in an optional interview portion of the study.

Interested oncologists were asked to identify patients who experienced a decision-making conversation. The goal was to complete 20 paired interviews from each group with an equal distribution of patients who agreed to participate in a clinical trial and others who had declined participation. Clinic staff obtained permission from potential patients to be contacted by the research team for screening and consenting. To be eligible, patients had to be over 18, were seen in any UW oncology clinic, and participated in a treatment discussion with a participating oncologist that included a therapeutic clinical trial. Patients were excluded if they were non-English speakers, blind, or were offered phase 1 clinical trial due to their non-therapeutic nature.

TrialTalk Intervention

TrialTalk intervention design was informed by the conversation analysis of over a hundred audiorecorded treatment discussion consultations. [23, 24] TrialTalk includes conversational and diagrammatic aspects. The diagram is created by physicians in real-time on paper and personalized for each patient. It includes a description of diagnosis and prognosis, available treatment options, including best supportive care, standard-of-care treatment, and clinical trials. Physicians also record the expected benefits and toxicities for each option as well as one to two efficacy parameters to facilitate the comparison between different options (example of a TrialTalk diagram with instructions is shown in Fig. 1). At the end of the discussions, physicians indicate their recommended option on the diagram to let patients know their preferences for their unique situation. Patients are invited to take the diagram home to revisit discussed information and weigh their options with family and loved ones. The conversational aspect includes proven communication strategies to help providers navigate the prognostic and treatment discussion while constructing the diagram. Additional information about the intervention is published elsewhere.[21]

Data collection

One outreach specialist with training in qualitative research conducted the interviews. The interviews were semistructured and the guide was pilot-tested before study initiation. Interviews with oncologists explored how they explained prognosis, treatment options and outcomes, whether the patient enrolled in the TrialTalk study decided to enroll in a clinical trial or not, and the type of decision aids/visuals used. The interview took place at a time and private location of their choosing.

Patients participated in the interview at their next clinic visit or via telephone. Interviews were designed to elicit patients' memories of the decision-making conversation, their feelings about how the conversation went, and factors that went into the decision they made. Patients were asked to bring a copy of the decision tool with them to the interview or any handouts given to them by their oncologist and to discuss how they used these documents to aid their decision. For interview conducted over the phone, patients were asked to have these materials available during the interview. All interviews were scheduled within twelve weeks of the decision-making conversation for optimal recall and were audiorecorded and transcribed verbatim for later analysis (for the interview guide see Appendix 2).

Data analysis

A hybrid inductive-deductive thematic analysis was used to analyze interview transcripts and notes.[25] The strengths of this analysis are that it's grounded in established conceptual frameworks and models while allowing distinct themes to emerge. The codebook was guided by *Bomhof-Roordink et al* [26] summary of shared-making components, which were derived from a systematic review of 40 unique SDM models. The summary included 53 different elements clustered into 24 components (see Appendix 3 for more information about components and elements). The analysis was conducted by two coders trained in qualitative methods using NVivo software (BQ & AA). [27] First, one coder conducted a first pass on the transcripts to familiarize themselves with the data. Next, meaningful chunks in transcripts were coded systematically using the codebook. Emerging concepts were identified and analyzed using open coding and categorized under existing themes. New themes were created and added to the codebook if the inductive codes didn't fit under the model. Memoing was conducted extensively to justify the addition of the new codes. Two coders then analyzed all transcripts independently using the revised codebook while noting the similarities and differences between intervention and control accounts of the consultation and decision-making process. After the completion of coding, related SDM components were combined into higher-order themes using an iterative process among coders for ease of reporting.

Results

Interviews were conducted between February 2018 and April 2019. Recruitment goals were not met due to logistical issues and time constraints for physicians. In total, eleven providers were interviewed; 8 in the intervention group and 3 in the control group. Provider characteristics are shown in Table 1. Seven patients with varying cancer diagnoses participated in the interviews; 4 in the intervention group and 3 in the control group (Table 2). Interviews lasted for an average of 21 minutes: 2.9 seconds with providers and for 20 minutes: 41 seconds with patients.

Table 1
Characteristics of providers who participated in the interview

ID	Group	gender	Years of experience*	Specialty
03	intervention	female	13	breast
06	intervention	female	9	breast
07	intervention	female	9	breast
11	control	female	2	gastrointestinal
13	intervention	male	3	genitourinary
16	intervention	female	20	thoracic
19	control	male	2	hematology
22	intervention	male	2	lymphoma/myeloma
23	intervention	female	7	radiation oncology
25	control	male	NA	radiation oncology
26	intervention	female	5	gynecology
* at the time of consent				

Table 2
Characteristics of patients who participated in the interviews

ID	Group	Gender	Age	Cancer/ stage	CT type mentioned	CT enrollment decision	Physician ID
100	control	female	59	multiple myeloma	randomized without placebo	enrolled	19
188	intervention	female	47	breast/IIb	randomized without placebo	enrolled	3
198	intervention	male	60	follicular lymphoma/ IV	not randomized	enrolled	22
236	intervention	female	71	lung/ IV	not randomized	enrolled	16
290	intervention	female	62	breast/ IIb	randomized without placebo	declined	23
355	control	male	64	esophageal /III	randomized with placebo	declined	11
385	control	female	65	lung/ IIIa	randomized without placebo	enrolled	25

CT: clinical trial

Patients and providers' experiences with the decision-making consultations from the SDM lens are summarized below. Quotes are presented in Table 3. It's important to note that one provider in the intervention group (*Provider07*) reported not applying TrialTalk in practice and their view was represented below under TrialTalk concerns.

Delivering prognostic information and managing patient emotions

Using TrialTalk supported providers' role in breaking bad news and explaining prognostic information to patients. Recording the prognosis on TrialTalk diagram reinforced information about the severity of patients' conditions, as one provider described writing "high risk" on the diagram was a change in how they communicate prognostic information. As expected, providers noted patients were distressed and overwhelmed upon hearing their prognosis. However, walking through the diagram with patients helped ground patients and significantly alleviated their anxiety, with one provider noting that patients left the conversation feeling better than when coming in.

Providers in the control group focused on delivering prognostic information verbally and didn't allude to any specific communication strategy.

Describing treatment options and promoting patients' autonomy

A unique aspect of TrialTalk intervention was that it helped providers be more prepared for consultations. During the visit, providers in the intervention group reported that using TrialTalk helped them organize and streamline discussions of available treatment options. It shifted the conversation from primarily discussing the recommended treatment to sharing balanced, in-depth information about all possible treatment options along with pros and cons. Providers also noted that using TrialTalk increased the depth and breadth of information they provided about clinical trials as it forced them to "slow down" and spend more time going through nuanced details of trial participation.

All providers in the intervention group reported presenting three options on the diagram, in the following order: supportive care, standard of care, and clinical trials. According to providers, using TrialTalk reinforced patients' autonomy as they were not obliged to pursue standard of care treatment or clinical trials if these options didn't align with their goals and values.

Constructing three arrows on the diagram served as a reminder for providers to incorporate supportive care discussions in their consultations. Providers noted that explicit discussion of supportive care helped solidify patients' understanding of their prognosis as patients were able to visualize the outcomes when no treatment was received. The three arrows also prompted providers to introduce the clinical trial option even when no trial was available, or patients were not eligible, to mentally prepare patients for a potential clinical trial in the future. TrialTalk verbal strategies to discuss clinical trials were valued by several providers. Explaining the purpose of clinical trials as "trying to do something better" was considered an effective approach to clarify misconceptions about a challenging topic such as clinical trials.

In contrast, providers in the control group commonly described two options: standard of care followed by discussion of available clinical trials, which ranged from 1–2 trials. One provider specifically noted that they focused on the clinical trial option during their encounter with a study patient, as they offer the highest survival benefits for that patient. The limited number of providers who mentioned supportive care described it last, especially for patients with good prognosis. When discussing clinical trials, providers provided information about the purpose of trials, study design, treatment schedule, side effects, and how they compare to standard treatments. Some providers reported that they introduced the clinical trial option by highlighting their affiliation with an academic center, a setting in which clinical trials are commonly conducted and offered to patients. Concerning visual aids, some providers cited creating visuals in real-time to explain the mechanism of medications or describe different arms of clinical trials.

Improving patients' awareness of treatment options and outcomes

Patients appreciated the TrialTalk visual citing that it improved their awareness of all available options. This was particularly appreciated by patients with preferences for visuals and written information. Patients also valued the simple language used by providers to deconstruct complex information, which enhanced information processing and comprehension during a challenging conversation. Patients reported that TrialTalk reduced memory and cognitive burden.

When asked whether providers discussed efficacy parameters of treatment options, patients in the intervention group repeatedly referred to the diagram and were able to describe treatment's impact on survival or cancer control using percentages and absolute risk terms. Patients reported that the way information was delivered about clinical trials, their purpose, expectations, and impact on life helped them see the positives of enrolling in a trial, which factored in their decision to pursue one.

Patients in the control group were not fully aware of all available options. They were able to recall the one treatment recommended by their physician, suggesting they were not given a choice. Additionally, none of the patients recalled learning about efficacy parameters for their treatment options from their doctor. One patient could not remember relevant information about treatment endpoints, such as cancer recurrence rate, despite her physician mentioning they shared that information with her during the interview.

Gathering support and information after visit

Interviews with intervention patients revealed that TrialTalk diagram allowed them to revisit information discussed in their visit at home and process it at their own pace. Both patients and providers in the intervention group recognized the potential of TrialTalk visual in fostering patients' discussions of their prognosis and treatment options with their family and friends at home. These factors were deemed important to maximize patients' ability to make an informed, value-based decision. On the other hand, participants in the control group reported seeking additional information about their condition and treatment outcomes independently using the internet.

Recordkeeping and sharing information with other team members

This theme was exclusive to the intervention group. A few providers reported scanning the TrialTalk visual and uploading it to patients' medical records, which allowed efficient information sharing with other physicians, including primary care physicians. Having a permanent record of the treatment discussion was deemed helpful by some providers who referenced it in subsequent consultations when patients failed to remember what had been discussed earlier.

The impact of TrialTalk guided consultation extended to trial coordinators. Providers reported that clinical trial research nurses noticed that patients who received TrialTalk consultations had a better

understanding of clinical trials and were more receptive to engaging with them. These findings highlight that TrialTalk has the potential to improve interprofessional collaboration and prep patients for potential discussions with trial coordinators.

Deliberation and integrating patients' values and preferences

Interviews with providers from both groups revealed their shared commitment to exploring patients' goals and values and integrating them into the discussion. Notably, some providers in the intervention group reported a change in how they help patients weigh options, shifting from a focus on generic survival data to explaining how each option might influence important aspects of their lives.

While patients in both groups reported being involved in the decision-making process and their concerns and preferences were being heard and honored, patients in the intervention group reported a sense of partnership with the healthcare team.

Making the decision

There was not a consistent pattern in how patients in either group made decisions. While some deferred entirely to their providers and accepted their recommendations without hesitation, others took some time to weigh their options and gather information before making their decisions.

Provider endorsement of clinical trials and patients' interest in contributing to greater good were common reasons to pursue a clinical trial among intervention and control patients. Minor differences were noted in other factors. For example, intervention patients' decisions were based on effective information delivery by providers, trial accessibility, proven medication efficacy, and perceived survival benefits. On the other hand, control patients in this study were more concerned about trial impact on quality of life and financial burden, which was voiced by patients with advanced esophageal cancer and multiple myeloma. It's important to note that underlying differences in patients' cancer diagnoses and treatment goals (life prolonging vs curative) might have shaped patients' decision about whether to pursue a clinical trial or not.

Concerns about TrialTalk

Interestingly, patients in the intervention group didn't voice any negative remarks about TrialTalk visual or verbal strategies. Providers, on the other hand, described some challenges regarding using TrialTalk in their consultations, particularly in relation to the discussion of clinical trials. Some providers reported that TrialTalk might not be well-suited for certain trials, such as trials that involve preventative therapies or treatment deescalation. Deciding which trial to discuss when multiple trials were open was also a concern for some providers. One provider reported difficulty explaining side effects associated with experimental drugs given that their full risk profile had not yet been well established.

Some providers highlighted that TrialTalk would be more relevant for medical oncology consultations than for other specialties (e.g., hematology and radiation oncology). Others shared their discomfort in

discussing “no treatment” option in the context of curative cancer diagnoses and when several effective treatment options were available. Concerns about the time and preparation needed to construct the diagram during the visit were voiced by a couple of providers. To overcome some of the barriers described above, some providers did some adaptations to the TrialTalk methods, including refraining from discussing “no treatment option” for some consultations and deferring the decision entirely to patients by not indicating their preferred option on the diagram.

Table 3
Representative quotes from patients and providers

Theme	Group	Quote
Prognostic awareness and managing emotions	Intervention	" I'd say overall positive experience with using the tool to convey not just options, but also prognostic information and to think about those, think about that information and not just speak about it in a way a doctor would speak about prognosis, but speak about it in a way that can be used for comparisons and could be used, you know, in a tangible way for the patient to make a decision" **Provider22** "I am hospital-phobic, doctor-phobic, so until I really went through this with her, starting out, I would not have, if it weren't for her explaining it to me, I probably would not be doing this." **Patient188**
Describing treatment options and promoting patients' autonomy	Intervention group	"It makes you really come in more prepared I think that way" **Provider3** "And it also reminds me to talk about supportive care with every patient, which I really, really try and do. But because there's the three rows, I'm always going to hit on all of them, even if there's no clinical trials available… So you can still introduce the idea, even if you're not gonna deliver that day and that you've said supportive care before and they know what that means." **Provider26** "It helped, I think it, by forcing me to slow down and us discussing important aspects of the clinical trial in more depth, I hope that helped her to make the decision" **Provider16**
	Control group	"And I actually even draw little pictures for patients to describe to them why- why- what is immunotherapy, because people see it on TV all the time, but nobody really knows what it is" **Provider11**
Patients' awareness of treatment options	Intervention	"When he kind of broke it down and talked to me like I could understand it. Not all these big words and stuff, you know, like I don't understand and that…it was pretty self-explanatory" **Patient198** "Obviously, positive because the old me would never have done a clinical trial at all. So the way she talked about it and presented it, first my, I think my husband was there also, and we talked about it. And it seemed like a plus to try this, just to add it in and see, you know it just seemed like a good study to do, a good clinical study for me to participate in after her presentation, the way she presented it." **Patient188**
	Control	"I don't know what my other options really would be if I decide not to. I think I had to trust that I'm making the right choices about my options. If I had decided not to go on the medication or not to do the trial, I would just be limiting my, well, my life" **Patient100** **Interviewer**: So did he give you any information about like, how, how many other people were treated for this same kind

Theme	Group	Quote
		of cancer and how, how each option would work for you? **Patient385**: No. I got some of that information from, I believe it was the internet, who is obviously representing, you know, did a nice job. But that's where I think that information came from
Deliberation and exploring patient goals and values	Intervention	" to really spell out how each option relates to that patient particular goals, so they're talking about, "I want to keep working." How does each option help them keep working? Or I want to, you know, I want to be, if you have enough energy to play with my grandkids. Like, how do we make that happen? So I think its given me more concrete things, rather than talking about a five-year survival or something that I actually might feel quite abstract and not, cuz you can live for five years and feel real crappy." **Provider26** I felt like I could take as much time as I needed to ask questions. But I also felt really validated in terms of me as a person, and that I'm an equal member, maybe the most important member of the treatment team, and that my opinion matters." **Patient290**
	Control	"I think she was interested in like what, like I said, what she could do here versus what she could do close to home. And then she was concerned more, she was concerned a lot about, you know, her ability, once again, things like working and things, and could she drive herself and all those things. And those are not things [..] different, you know, between standard versus one of the trial options. Quite honestly, all of that is pretty similar except where I highlighted that they would have to get treatment here for the E1A11 trial." **Provider19**
Gathering information and support	Intervention	"And having things written down in a pretty easy, basic way, so they could go home and share it with family members. I think that patients found that particularly useful." **Provider26** "But it was nice that we could re-reference the diagram later at a different date too. Because I think, after that, we left the hospital that day, I think I had like seven different conversations with different people, so." **Patient198**
	Control	**Interviewer**: So you sought this out independently? **Patient100**: I did.
Recordkeeping and sharing information with other team members	Intervention	" I also think that the diagram also has like the research nurses that come to the room like after we talk to the patient about the study, so I think it makes their- their job easier, because they know like where to start from. And actually I had like- it's funny because like it happened twice, like the nurse actually mentioned that to me after- after she talked to the patient and left the room, so like the patient had a good understanding of what was going on, what treatments were available, and what was the study about." **Provider13**

Theme	Group	Quote
Making the decision	Intervention	“Because it seemed like they've already been giving it, is what she told me, I believe, that people with Stage IV already have been using this, so it's already something that's been given. It's not this brand new drug. It's something that's been given, and that it's FDA approved for them.” **Patient188** “Well, the biggest thing was that whatever we decided to do, once we did decide, is that I wasn’t ready to go anywhere yet. I wanted to spend as much time here with my kids and grandkids as I could. So that was the biggest thing for me.” **Patient198**
	Control	“and I explained them to her, she really knew where I was coming from - is quality of life. I mean, you know, another year of coming to [UNIVERSITY HOSPITAL 1], you know, for the first six months, once every other week, and then it’s once a month, and maybe not feeling well and, you know, all these things did weigh on me a lot.” **Patient355**
Concerns about TrialTalk	Intervention	“I mean, I find it difficult like for a patient with a newly diagnosed disease that there are several treatment options available, like to present like doing nothing as an option. Even in many cases like some diseases like the option is not- are not really great, it doesn’t work well, like the survival benefit is small, it’s very toxic but still I mean, most patients especially when they first come in they don’t want to hear like the option of doing nothing.” **Provider13** “Part of it is just the actual logistics of this, for me to carry a sheet of paper and remember to have it in clinic and then bring it in to the right patient’s rooms. It’s, yeah, I’m not going to step out to go get it and drawing it was just a little bit of a pain so I just kind of keep doing my own version of it.” **Provider7** “I know when [TrialTalk instructor] does the training, he talks about, “Try not to present more than one additional option,” honestly that was sometimes hard, because we occasionally had patients who had more than one clinical trial option, usually we try to pick the one we want to talk to them about, but it does sometimes creep in” **Provider6**

Discussion

The present pilot study highlights the experiences of patients and providers with clinical trial consultations and the role TrialTalk played in shaping these conversations. As the number of interviewed participants was small, findings should be interpreted with caution.

Interviews with providers from different oncology specialties revealed that TrialTalk improved the content and quality of decision-making consultations, which involve clinical trial discussions. Reports by intervention patients and providers indicate that providers increased their use of several aspects of shared decision-making as a result of using TrialTalk method such as providing structured and unbiased

information about prognosis and treatment options, promoting patients' awareness and understanding of their treatment options, fostering sense of autonomy, and facilitating deliberation with family and loved ones. These findings are critically important given that around a third of the patients misunderstand their prognosis and over half of patients overestimate their chances for cure.[28] [29] Additionally, studies have shown that patients tend to remember less than 40% of what has been discussed during the visit, which was attributed to poor patient-provider communication, information overload, and patients' emotional state during the visit.[30]. Without clear and accurate information about prognosis and treatment goals and allowing patients to revisit and process information at their pace, they would not be able to make truly informed decisions about next steps of their treatment.

Meaningful differences have been noted in how clinical trial discussions were discussed between two groups. Patients in the intervention group constantly described clinical trials as one of three options while patients in the control group expressed not being given a real choice and instead felt that trials were their only viable option. Not only does this approach dismiss patient agency and autonomy, but it also prompts patients to pursue clinical trials based on their feelings (fear, not having a choice, trust in physicians) rather than deliberate assessment of the benefits and risks of trials compared to other options on the table. This is consistent with other studies that explored patients' perception of clinical trial decision-making consultations. [31, 32] Intervention providers admitted that TrialTalk approach motivated them to allocate additional time to thoroughly discuss various aspects of clinical trials. The benefits of this comprehensive discussion reflected positively on subsequent clinical trial discussions that patients had following the consultations. Future studies should examine the perceptions and experiences of other staff involved in trial accrual such as research nurses and trial coordinators following TrialTalk implementation.

This study has several limitations. As the study was conducted in an academic medical center, in which clinical trial culture is more common, findings can't be generalized to other settings such community-based hospitals or centers located in rural areas. Interviewing a small sample of patients and providers from each group might have compromised data saturation. More effective recruitment methods are needed to maximize the number of enrolled participants and capture the full range of patients and providers' experiences. The inclusion of patients across different cancer diagnoses and stages increases the risk of heterogeneity bias. Additionally, interviews were scheduled within 12 weeks of the consultations which might have affected participants' recall of their experience. Finally, audiorecording conversations is needed to get deeper insights into the content, length, and communication style of providers from both groups when discussing treatment options, including clinical trials.

Conclusion

This pilot study shows that both patients and providers had positive experiences with TrialTalk. Implementing TrialTalk in cancer decision-making consultations has the potential to foster shared-decision making and improve patient comprehension of their treatment options, including clinical trials.

Declarations

Conflict of interest:

The authors declare they have no financial or non-financial interests to disclose.

Ethics approval:

The study was approved by The University of Wisconsin Minimal Risk Research Institutional Review Board (UW16060) and was performed in accordance with the ethical standards as laid down in the Declaration of Helsinki.

Consent to participate:

Informed consent was obtained from all individual participants included in the study.

Data availability statement

The data supporting this study's findings are available upon reasonable request from the corresponding author, subject to restricted access and with the permission of the University of Wisconsin-Madison.

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Author Contribution

Conceptualization: [Toby Campbell]; Methodology: [Toby Campbell]; Formal analysis and investigation: [Bonyan Qudah, Apoorva Anandan, Eileen McGuine]; Writing - original draft preparation: [Bonyan Qudah]; Writing - review and editing: [Toby Campbell, Bonyan Qudah]; Funding acquisition: [Toby Campbell]; Resources: [Toby Campbell]; Supervision: [Toby Campbell]

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Figures

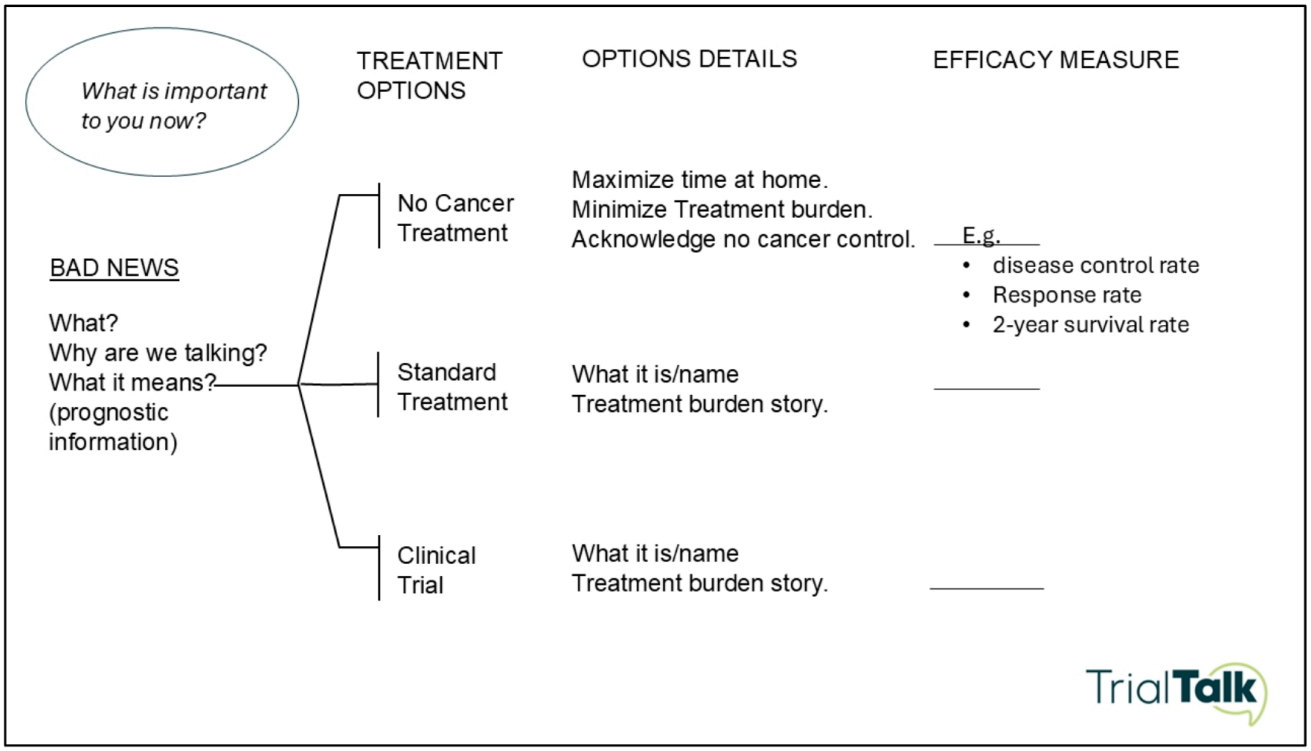


Figure 1

Outline of TrialTalk diagram

Supplementary Files

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