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Intervention

Development of a cancer clinical trials multi-media intervention: *Clinical Trials: Are they Right for You?*

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ABSTRACT

Objective: To describe processes used to develop a multi-media psycho-educational intervention to prepare patients for a discussion about cancer clinical trials (CTs).
Methods: Guided by a Steering Committee, formative research was conducted to develop an informative and engaging tool about cancer CTs. Twenty-three patients and caregivers participated in formative in-depth interviews to elicit information about perceptions of cancer CTs to inform production of a new media product.
Results: Formative research revealed participants had concerns about experimentation, held beliefs that cancer CTs were for patients who had no other treatment options, and wanted a balance of information about pros and cons of CT participation. The value of physicians as credible spokespersons and the use of patients as role-models were supported. Using iterative processes, the production team infused the results into creation of a multimedia psycho-educational intervention titled *Clinical Trials: Are they Right for You?*
Conclusion: An intervention, developed through an iterative consumer-focused process involving multiple stakeholders and formative research, may result in an engaging informative product.
Practice implications: If found to be efficacious, *Clinical Trials: Are they Right for You?* is a low-cost and easily disseminated multimedia psycho-educational intervention to assist cancer patients with making an informed decision about cancer CTs.

1. Introduction

Cancer clinical trials (CTs) test promising approaches for preventing, diagnosing, and treating cancer. However, according to the National Cancer Institute (NCI), only 3% of eligible adult cancer patients participate in CTs [1]. Many factors can impact cancer patients' participation in CTs. Some patients report they are not well informed about CTs [2,3]. In fact, research shows patients who have already participated in a CT often still lack information about the purpose, side effects, and potential benefits [4,5]. In addition, research suggests many individuals with cancer are unwilling to participate in CTs due to negative perceptions and misunderstandings about the trial process or research in general [2,6,7]. Patients may believe a CT has no benefit to them [2], fear giving up control over treatment decisions [2,8,9], and worry about treatment side effects [2,6,8,10]. Some patients are not comfortable with research, randomization, and recruitment processes, including the possibility of being given a placebo [2,6,7,11–14]. In previous work conducted within the Moffitt Cancer Center (MCC) Thoracic Oncology Program, data showed that in addition to lack of knowledge, some patients held misconceptions and inaccurate information about cancer CTs [4,15].

From a patient's perspective, the decision to enter a CT is complex because of lack of information, negative perceptions about research, and multiple situational, personal and literacy demands associated with participating in a trial [6,16]. These beliefs could likely interfere with decision making about participation in a cancer CT such that patients could not make a truly informed decision. Patients must weigh risks of participation against benefits [16]. To this end, making an informed decision requires patients to have an accurate understanding of both the CT under consideration, and also the research process as a whole. Many patients prefer to make their decision regarding participation in a CT with their doctor [5]. In fact, trusting a

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physician and physician's recommendation of participation in a CT are key factors in trial participation [13,17–20]. If patients' concerns are not addressed adequately by health professionals, they may decline or regret participation in a cancer CT [7,21]. Thus, innovative communication interventions are required to facilitate informed decision-making [6] and to prepare individuals for a discussion of CTs.

There have been numerous efforts to improve communication about CTs published in peer-reviewed literature including interventions to increase awareness about cancer CTs through positive messaging [4,15,22–28]. CT communication interventions include educational brochures [15,25,26], fliers and patient letters [4,23], websites [15], newspaper advertisements [23], and audiovisual materials [24–27]. Of these, audiovisual materials offer several advantages for patients who may be offered a clinical trial during a visit with an oncologist. They demonstrate high acceptability and portability to patients [29], show good potential for dissemination, and, unlike written materials or websites, may be preferred by individuals with low literacy because they do not require that a patient have reading skills [30]. In addition, patients can review them with family and friends who are unable to attend meetings with clinical and research staff [29,31]. Unlike decision aids, which help patients evaluate benefits, harms, and scientific uncertainty for participating in a specific CT as compared to other options, priming materials serve to prompt a patient who may be approached to participate in CTs at any point in their cancer experience [32]. A recent review of studies which involved multimedia educational aids for CTs found video- or computer-based multimedia tools led to better understanding of information related to medical evaluation or management when compared to routine methods of providing information [33].

A media intervention provided prior to a medical consultation that includes a CT discussion may be valuable in priming patients to talk to their doctor about CTs [34]. In other words, providing cancer patients with a balanced and informative message prior to CT recruitment has the potential to change expectations about the consultation and reduce negative attitudes towards CTs, leading to greater involvement and satisfaction with a decision [35]. The creation of a consumer-designed media intervention may illuminate patients' understanding of trials and improve their awareness. Therefore, the purpose of the present study is to describe processes used to develop a multi-media psycho-educational intervention (MPI) about cancer CTs inspired by a consumer-focused approach from social marketing as informed by the first two stages of the NCI's Health Communication Model [36]. The social marketing approach used in the NCI's Health Communication Model works to identify unique health communication/information needs of a segmented audience through formative research [36]. In contrast, other models may focus on changing behavioral intentions or increasing a behavior [36]. The two stages of the NCI's Health Communication Model used in the present study entail planning and strategy development through formative research, and developing and pretesting concepts, messages, and materials [36]. The present paper describes methodologies and systematic steps used to create an English-language MPI titled *Clinical Trials: Are they Right for You?*

2. Methods

2.1. Phase 1: planning and strategy development

A Steering Committee (SC) was convened to guide MPI development. The SC was comprised of 15 members, including faculty and staff at MCC, and a community representative. A smaller 9-person MPI production team worked on the logistical aspects of conducting formative research, developing the creative brief and script, and working with the media production company. The MPI production team included a cancer survivor and family members of cancer patients and survivors.

The MPI production team examined peer-reviewed literature on strategies used by others to improve understanding and participation in cancer CTs, including communication and media strategies. In addition to reviewing the peer-reviewed literature, the MPI production team conducted an exhaustive search of PubMed, the NIH clearinghouse, and Google to find existing videos designed to explain cancer CTs. The MPI production team reviewed the five published videos and found them to be lengthy, specific to the institution that developed them, and heavily laden with complex terminology at a high literacy level. Due to limitations in the five published videos, the production team determined it was necessary to create a new MPI that would appeal to the specific intended audience (newly diagnosed cancer patients and family members). Formative data were then required to tailor the media to our segmented audience, as suggested in a social marketing approach [36]. We retained three of the five videos that were the most public health-oriented for use in the formative research phase.

Following the review of previous research and media, the SC agreed to develop a media aid that could serve as a tool for making a decision about CTs. An easy-to-understand MPI (DVD and companion booklet) could be an appropriate communication channel for providing useful and engaging information about cancer CTs because of its wide acceptability and ease of use. The SC developed the following MPI aims: (1) to prime the target audience for future decision making about cancer CTs; (2) to dispel/address current myths and misperceptions about CTs; and (3) to increase efficacy about future cancer treatment decision making. The SC used a social marketing audience segmentation approach, which involves identifying the unique characteristics of population segments with different informational needs and focusing intervention resources in a manner likely to maximize the intervention [37]. The SC identified the initial intended audiences for the MPI to include: any adult who had a cancer diagnosis or suspected cancer diagnosis; family members who may search for information or treatment options for a cancer patient; cancer patients seeking a second opinion; cancer patients who had previously declined a CT; and patients whose cancer progressed despite treatment.

2.1.1. Formative research

Based on SC feedback, formative research was conducted to develop a MPI that was appealing to cancer patients who may be offered a CT at any point in their cancer treatment experience. The research was conducted using in-depth interviews which assessed perceptions of CTs, experience with CTs, and perceptions of previous CT educational videos. Using an approach from previous research [4,15], the SC met regularly to develop an interview guide that would identify factors influencing cancer patients' willingness to consider a CT and examine preferred MPI communication elements, such as format, tone, messaging, spokesperson, and length (interview guide available upon request).

2.1.1.1. Sample. Using a purposeful sampling strategy, participants were either approached in person in waiting rooms of MCC or were referred by oncologists and contacted by telephone. At the initial contact, potential participants were offered participation in an in-depth interview about cancer CTs. The goal was to obtain a sample of patients and caregivers who had different experiences with CTs (e.g., participated in a CT, declined participation in a CT, had never been offered a CT), and who represented a mix of demographic backgrounds and cancer types. To be included, patients and caregivers had to be: (1) 18 years or older; and (2) capable of