Chapter 11

Training Programs for Improving Communication about Medical Research and Clinical Trials: A Systematic Review

Aurora Occa and Susan E. Morgan

Additional information is available at the end of the chapter

http://dx.doi.org/10.5772/intechopen.70188

Abstract

Objectives: The aim of this article is to provide recommendations on the structure, materials, and outcomes that should be adopted for communication training programs designed to improve clinical trial education for patients.

Methods: A systematic review of peer-reviewed articles was conducted. A total of 22 studies were included. Several dimensions were analyzed, such as program design, content development, pedagogical tools, content of the program, and the outcomes affected.

Results: The trainings described in the articles analyzed generally took the form of workshops and were developed by groups of heterogeneous experts. Trainings used a variety of educational materials and activities often developed by the research team hosting the training. The outcome measures and assessment methods were not consistent among the trainings, which hinders the ability to statistically synthetize findings.

Conclusions: Findings from the review point to a number of recommendations for the development of future clinical research communication training programs. Training programs should be developed by a team of experts with a range of expertise and should be organized in the form of workshops. Participants should be able to role-play newly acquired communication skills using standardized patients.

Keywords: clinical trials communication, training for recruiters, clinical trials recruitment, accrual, informed consent

1. Introduction

Clinical trials represent the first essential step toward the development of treatments targeting cancer and various diseases [1, 2], and allow researchers to Test the effectiveness of preventive

measures, treatments, screenings, and diagnostic techniques [3]. However, despite the evidence for the positive benefits of conducting clinical trials, and despite the overall agreement on the importance of clinical research (as evidenced by the Cancer Moonshot initiative and recent, highly funded efforts directed toward advancing precision medicine), researchers are limited by the low number of patients consenting to join clinical research studies [4, 5]. The most critical consequence of low accrual rates is that treatment effectiveness cannot be adequately assessed, even if a new regimen appears to be promising [6]. Research on the reasons for clinical trials' low accrual rates has identified several key barriers, which include a low rate of physicians' referral [7, 8]. Many physicians characterize discussions about research and clinical trials with patients as particularly challenging, a problem, which is rarely addressed, even by academic medical centers committed to the research enterprise [9].

Physicians are not the only professionals who face challenges when trying to communicate about clinical trials. In fact, clinical and medical research teams are typically composed of a heterogeneous group of professionals with specific skills and roles; these include study nurses, clinical research coordinators, research associates, nonstudy personnel, and professional recruiters [9]. Regardless of the role, however, good communication skills are necessary to meet the needs of both patients and PIs to ensure both information comprehension and accrual [10, 11]. Conversations with patients and their families intended to educate them about participation in clinical trials and research studies present unique challenges that differ significantly from typical exchanges in the provider-patient encounter. Discussions about clinical trial participation are quite challenging due to the uncertainty regarding the outcomes of clinical trials, and the complex nature of consent documents [12]. For example, a treatment recommendation that involves the possibility of enrolling in a clinical trial is fraught with uncertainty because patients are generally randomized into one of multiple treatment arms, and because the treatment itself is under study [13]. Thus, both the treatment outcomes and any possible side effects have yet to be defined. Additionally, recruiters (whether clinical research professionals, physicians, or study nurses) need to provide information through documents that are strictly governed by legal and ethical policies. The content and the structure of the consenting documents are complex and often difficult to understand for patients [14]. Many patients express concerns about the trustworthiness of the clinical research process and the experts involved [14, 15].

Because of the uncertainty associated with the treatment, the complexity of procedures and documents, the vulnerability of patients, and the often-negative attitudes of patients toward medical research, discussions about clinical trial participation can be difficult for both patients as well as clinical personnel. Because patients' intentions to enroll into a clinical trial are strongly related to the competency of communication by recruiters [16, 17], and because communication is a mediating variable in the decision process on whether or not enroll [14, 15, 18], it is essential for medical and clinical research professionals receive training on how to better communicate with patients about participating in clinical trials and research studies. Trainings specifically aimed at improving communication skills may help to increase the rate of patient accrual to clinical trials [10, 19].

Although there have been successful training programs focused on doctor-patient communication [20–25], there is little theoretical and empirical research on the best way to develop trainings for improving clinical trial communication. Previous studies of other types of communication training programs in health care environments have provided evidence that the structure of the training as well as the type of educational materials employed have dramatic consequences on

http://dx.doi.org/10.5772/intechopen.70188

the effectiveness of the trainings and the learning outcomes of participants [24, 26–28]. In the case of trainings to improve communication about clinical trials and research studies, there is no clear evidence about the best structure for trainings or the materials to be used. Therefore, this study aims to fill a gap in the literature by addressing the following research questions:

RQ1: How are clinical trials communication training programs structured?

RQ2: What type of content is included in communication skills training programs for those who recruit for clinical trials study?

RQ3: How are the outcomes of these trainings assessed?

2. Methods

2.1. Key terms and databases

A literature review was performed by using several databases, namely scholar.google.com, university library's database, MEDLINE, PsycINFO. The search terms used were "clinical trials training," "clinical trials recruiters training," "cancer trials training," "clinical trials recruiters' communication," and "clinical trials patients' recruitment." Second, an additional search was conducted by checking the references employed by the articles considered relevant for the purposes of the present study. This process yielded 22 articles on communication training programs designed to increase medical and nonmedical professionals' efficacy in recruiting potential participants for research studies and clinical trials.

2.2. Inclusion and exclusion criteria

In order to be included in this systematic review, the studies had to meet several criteria. First, they had to deliver and test educational trainings; second, participants in the trainings had to be health care professionals; third, the trainings had to provide instructions and educational materials or activities to improve clinical trial communication skills. After a careful review of the literature, 22 studies were found to be appropriate for the present systematic review. Further, in order to be considered in this systematic review, the studies had to meet the following inclusionary criteria: report on physicians' and medical personnel communication strategies to recruit patients; provide empirical evidence rather than theoretical assertions or recommendations (that is, qualitative or quantitative data had to be reported), and results had to be published in a peer-review journal.

2.3. Data extraction and analysis

Information from the studies selected for this project was summarized into tables and compared across studies. Key information that was retrieved included authors' names, year of publication, country where the trainings were conducted, journal in which the findings were published, theoretical background, methods adopted for the study, type of training, demographics, content development methodology, format of educational material, timing of the program, and learning assessment.

3. Results

From the search for relevant studies, the authors included a total of 22 studies conducted between 1998 and 2016. All of the articles included in the present study were published in peer-reviewed journals. The majority of the studies did not report using a theoretical framework as basis for the communication training program. Also, the majority of the studies did not provide exhaustive information about participants' demographics. When these data were available (7 studies out of 22), more participants were reported to be female, for a total of 275 females participating versus 212 total males participating. When data were available about the profession of participants (12 studies out of 22), Participants included 658 physicians, 373 nurses, 29 research coordinators, and only 1 person described as a professional recruiter, although all participants in these training programs were responsible for recruiting patients for clinical trials. Half of the studies assessed the effectiveness of training by using quasi-experimental designs; two of the remaining studies used survey as data collection methodology, and the other two studies used qualitative methodologies. Only 8 studies out of 22 reported whether the intervention was the first communication raining experience for participants, or not.

3.1. Design of training programs

With regard to the type of training developed and implemented, 18 studies out of the 22 analyzed employed a workshop format, while 1 training utilized coaching sections and peer-reviews [10]. Duration of the trainings varied across studies, ranging from a minimum of 3 hours, to a maximum of three days. Some trainings were spread over 2 days [29–31] or 3 days [46]. In the majority of the studies, participants selfselected into the training programs. Consistent with what has been observed in the literature on communication training in health care environments [32], the duration of the training programs seems to be an indicator of their effectiveness, with the longest trainings having the most positive outcomes. Information about the design of the trainings for each study is presented in **Table 1**.

3.2. Content development and pedagogic tools

The educational content of the trainings reviewed was varied, as was the source material used. Seventeen studies reported creating original content for their training, using source material that included the team's own original research, and collaborations with experts, such as oncologists, nurses, and clinical trials managers. One study explicitly reported the contributions of patients [30]. Another publication did not describe the process of developing the material, but reported that the training was done by instructors with previous experience in teaching communication skills to physicians. Similarly, the pedagogical tools adopted were varied. There was a general preference for the use of video materials, such as DVDs or videotaped scenarios, which were used in 10 training programs [29, 30, 33–40]. Other formats used included case studies, vignettes, instructional manuals, dummy referral letters, protocols, and didactic presentations. The majority of the trainings included role-playing activities, and/or review of real-world discussions among recruiters and patients (whether actual or standardized patients). In many cases, checklists were used to standardize the observation

Study	Design	Control group	Content development	Format educational material	Duration	Sensitive words explained
Fallowfield et al. [29]	Experiment	Yes	Authors, physicians and nurses	Workshop, five DVD-based scenarios + handbook, dummy referral letters outlining patients' histories, bibliography	8 h, 2 days	N/A
Jenkins et al. [30]	Experiment	N/A	Authors, recruiters physicians, nurses trial managers, and patients	Workshop, interactive exercise, didactic presentations, four DVD-based scenarios + handbook	8 h, 2 days	Yes, randomization and placebo
Fallowfield et al. [39]	Experiment	No	Authors	Workshop, exercise and activities: small groups critiques, SP*, video reviews; videotaped scenarios; case histories, comprehensive handbook; papers; annotated bibliography	3 day course	Yes
Brown et al. [37]	Survey and conversation	Yes	Previous research with experts from different fields	Workshop, strategies document, presentation of strategies, video model of ideal behavior, role-played (standardized patient)	1 day	N/A
Fallowfield et al. [40]	Experiment, survey and conversation	No	Authors	Workshop, exercise and activities: small groups critiques, SP, video reviews; videotaped scenarios; case histories, comprehensive handbook; papers; annotated bibliography	3 days or 1.5 days	No
Hietanen et al. [41]	Survey	No	Experts: oncologist-psychotherapists	Workshop, lecture, role-played with real patients	1 day	Yes, randomization
Mann et al. JAN. 2014	Interviews	Yes	Trial team	APEX trial protocol and research literature	N/A	Yes, randomization

Study	Design	Control group	Content development	Format educational material	Duration	Sensitive words explained
Paramasivan et al. T. 2011	Content, thematic, and conversation analysis	No	Previous research from the team	Workshop, lecture (face to face and teleconference)	N/A	Yes, randomization
Larson et al. [11]	Experiment	No	Authors and administrative offices	Workshop, lecture, vignettes, role-played	3 h	N/A
Cadman et al. [33]	Experiment	No	NIMH—no info on the development	Workshop, video, didactic lecture	N/A	No
Bernhard et al. [35]	Experiment	Yes	Authors based on the available literature	Workshop with didactic presentation and video, strategies document, feedback	7 h	No
Yap et al. [36]	Observation and interviews with patients	Yes	Authors using materials from previous projects	Workshop with didactic presentation, slides, pocket card, scientific article, audiotaped examples	N/A	Yes, randomization
Kendall et al. [43]	Quantitative: changes in recruitment rates	Yes	Not produced by authors. The source is unspecified (US based)	Didactic presentation and educational material	N/A	N/A
Jenkins et al. [31]	Experiment	No	Authors	Workshop with didactic presentation, trial planning, team-building exercise, role-playing, open discussion	1.5 days	N/A
Fallowfield et al. [44]	Experiment	No	Authors	Workshop	1 day	N/A
Donovan et al. [45]	Mixed method	No	Authors based on formative research	Workshop, document, feedback, role-playing	N/A	Yes, randomization
Mills et al. T 2014	Content and thematic analysis	No	N/A	Documents, individual and group discussions, role-play	N/A	Yes, randomization
Butow et al. HE 2015	Experiment	Yes	Authors using materials from previous projects	Workshop, video, role-play, individualized feedback	7 h	N/A

Study	Design	Control group	Content development	Format educational material	Duration	Sensitive words explained
Wuensch et al. EJoCC. 2011	Survey	No	Authors using formative research	Workshop, role-play, pocket card, feedback from experts & colleagues	17 h	Yes, randomization
Wells et al. [47]	Quasi-experiment	Yes	Authors using formative research	In-person and online training	N/A	N/A
Kimmick et al. [38]	Experiment	Yes	N/A	Educational symposium, lecture outline, videos, emails, checklists, case discussion seminar, bibliography, slides	N/A	No
Burnett et al. [48]	Experiment	No	Authors using formative research (literature review)	Workshop, reflective practice component	1 day	Yes, randomization

Table 1. Design and content of the training.

and analysis of such discussions. **Table 1** reports the role and profession of the people who developed the content and materials used in the trainings, as well as the formats used in each training.

3.3. Information conveyed

Several areas of focus for the trainings were reported. Six studies [10, 13, 29, 38, 42, 46], reported training participants on the importance of assessing the eligibility of patients for the clinical trials. Authors reported assessing participants' performance on how to offer the opportunity to participate in clinical trials (with the exception of [40], which does not explicitly mention it). Only six studies instructed participants how to address possible benefits and side effects associated with clinical trials participation [11, 29, 35, 37, 45, 46]. Generally, authors did not recommend different communication strategies for different phases of clinical trials. Seven trainings out of the 22 analyzed in this review instructed participants on how to check for patients' understanding of the information provided [10, 13, 29, 30, 34, 37, 42]. In this regard, Mann et al. [10] and Brown et al. [37] reported "summarizing" as a useful technique to check for patients' understanding. Other topics specifically addressed by the training programs included how to explain the aims of clinical trials [10, 13, 29, 30, 39, 41], the importance of informing patients about the voluntariness of their potential enrollment [10, 11, 29, 30, 33], or the importance of avoiding coercive behaviors and/or the importance of adopting a shared decision making process [34, 35, 37]. In some training, participants were instructed on strategies for clarifying key terms such as "randomization" and "placebo," which tend to be difficult for a large proportion of patients to understand or accept [10, 13, 30, 36, 39, 41, 42, 45, 46, 48]. Few studies explicitly addressed concerns and strategies to successfully deal with potential participants' struggle to manage uncertainty [29, 30, 36, 37, 42]. Ultimately, only 3 studies out of 22 specifically discussed the role that family members play in influencing patients' decisions on whether to enroll or not in clinical trials or provided training on how to better address family members' concerns [29, 30, 36, 40, 47]. A summary of the main information conveyed is shown in **Table 2**.

3.4. Assessments

Whether training programs had a concrete impact on the communication skills of the participants was assessed through several means. Consistent with the literature on trainings to improve physician-patient communication [27, 49, 50], one of the most widely adopted strategies (13 studies out of 22) consisted of an evaluation of audio recorded interactions of participants in the training programs with either real-world patients or standardized patients. Similarly, 16 studies reported having used self-assessments, although specific measures differed across studies. In one study [41], the self-assessment consisted in a qualitative description of the experience participants in the training program had when interacting with patients. Only three studies did not explicitly report any assessment of the outcomes [11, 38, 43]. Although similar methodologies were used, the outcomes of the trainings tended to differ significantly across studies. The strategies used to assess the communication trainings are shown in **Table 3**.

Study	Key information offered	Scenarios	Patient is suitable	Participation offered
Fallowfield et al. [29]	Scenarios portraying different trials, tumor sites, and patient characteristics; communicating risks; checking for understanding	Stressed person communication demands; talking about innovativeness of the treatment; interacting with family members; communication difficulties when dealing with failing tests; communication for Phase II; study retention	Yes	Yes
Jenkins et al. [30]	Scenarios portraying how to structure trial discussions; how to describe treatments available; process of randomization; checking for understanding	(1) Introduction to trials, concept of randomization, difficulties associated with trials (use of different perspectives); (2) adjuvant treatment and uncertainty; (3) distressed patients, dealing with questions; (4) dealing with patients with preference for a specific study arm	No	Yes
Fallowfield et al. [39]	Skills development; knowledge acquisition; personal awareness	N/A	No	Yes
Brown et al. [37]	Scenarios informing on shared decision making; structuring consultations, risks & benefits; checking for understanding; providing clear & comprehensive information; avoiding coercion	Patient with stage II breast cancer	N/A	Yes
Fallowfield et al. [40]	Breaking bad news; discussing therapeutic options; informed consent; talking with relatives; psychosocial concerns	N/A	N/A	N/A
Hietanen et al. [41]	Articles and checklist published on information about CT and informed consent	N/A	No	Yes
Mann et al. JAN. 2014	APEX trial protocol and research literature; checking for understanding	Interviews considered effective	Yes	Yes
Paramavisan et al. T 2011	Lecture (face-to-face and teleconference); checking for understanding	N/A	Yes	Yes
Larson et al. [11]	Personal experience; principles of ethical conduct; key elements of consent process; risks and benefits of participation; voluntary nature of research; purpose of research	N/A	No	No

Study	Key information offered	Scenarios	Patient is suitable	Participation offered
Cadman et al. [33]	Communication skills (style, use of plain language, body language, tone of voice, eye-contact); contextual elements (environment); relevant elements of informed consent; importance of relationship building	Mental health, but authors suggest that the video can be used to improve informed consent in general; study presentation; risks & benefits; alternative treatments; confidentiality & patients' rights; voluntariness of participation	No	N/A
Bernhard et al. [35]	Shared decision making; sequential information disclosure; clarity; disclosing controversial information; avoiding coercive communication	Breast cancer patients	N/A	N/A
Yap et al. [36]	Communication skills (positive and negative examples); importance of considering emotional preparedness of patients & family members; metaphors to explain randomization; stressed person communication demands; literacy concerns	Children and their family members	N/A	Yes
Kendall et al. [43]	Specifically tailored to the needs of the recruitment site	N/A	N/A	N/A
Jenkins et al. [31]	Team-specific involvement in research; patients' attitudes; problematic trials; interpersonal communication with team members; planning strategies; identification of potential issues in the patient sheet	Cancer teams in UK	N/A	Yes
Fallowfield et al. [44]	Tailored to the needs of the site; trials planning; quality of patient sheet; interpersonal communication; time management	Breast cancer teams	N/A	Yes (actual recruitment)
Donovan et al. [45]	Tips for recruitment; case studies; informed consent process; risks/benefits; importance of randomization	N/A	N/A	Yes
Mills et al. T 2014	Importance of eliciting and exploring treatments preferences; strategies to explain randomization; importance of balance of arms	N/A	Yes	Yes

Study	Key information offered	Scenarios	Patient is suitable	Participation offered
Butow et al. HE 2015	Shared decision making framework; correctly sequence information; ensure clarity; avoid coercion	Breast cancer trials	N/A	Yes
Wuensch et al. EJoCC 2011	Opening of discussion; disclosing risks and benefits; offering participation; clarifying meaning of randomization	Oncology clinical trials	Yes	Yes
Wells et al. [47]	Barriers, beliefs, social norms, myths of African Americans and Hispanics about clinical trial enrollment	Radiation therapy	No	No
Kimmick et al. [38]	Importance of mental status assessment; assess depression, cognition, comorbidity	Geriatric oncology clinical trials	Yes	No
Burnett et al. [48]	Importance of clinical trials; types of clinical trials; benefits; randomization; answer questions; provide screening recommendations, barriers	Nursing oncology clinical trials	N/A	N/A

Table 2. Information conveyed.

3.5. Improved outcomes

Clinical trial communication training programs influenced several outcomes. In seven studies, participants reported increased confidence in their ability to better interact with and educate patients. However, in terms of better communication of clinical trials, only a few studies reported strong effects [29, 30, 33, 36, 41], with only one article reporting modest but significant changes [39]. A study by Brown et al. [37] reported no significant improvement in participants' ability to provide clinical information, nor did they report differences in the way participants structured their consultations. However, the authors reported improvements in shared-decision making behaviors, and in refraining from using coercive behaviors [37]. Fallowfield et al. [40] demonstrated improvements in participants' communication and information provision skills as a result of the training, even if communication about clinical trials specifically was not significantly affected by training. In one study [10], participants reported increased knowledge of trial design, and an improved ability to adhere to the study protocol after receiving the training. Mills et al. [13] observed that after the training participants improved in their ability to address patients' preferences. Only three studies assessed and obtained improvements in accrual rates [38, 43, 47]. The positive changes associated with training participation are shown in **Table 3**.

Study	Audio-taped assessment	Patient simulator assessment	Participants generate list of optimal points	Strategies/key points document	Subjective assessment/survey	Outcomes considered
Fallowfield et al. [29]	Yes	Yes	Yes	Yes	Yes	Self-confidence; communication of trial entry; voluntariness; questions asking; discussion of symptom control; permit time for consideration; discussion of aims
Jenkins et al. [30]	Yes	Yes	Yes	Yes	Yes	Communication of trials; use of key words; check patient understanding; self-confidence
Fallowfield et al. [39]	Yes	Yes	N/A	N/A	Yes	Quality of the course material; expression of empathy; communication skills
Brown et al. [37]	Yes	Yes	No	Yes	Yes	Shared decision-making behavior; reduction of coercive behaviors. Patients' attitudes; Physicians' behavior
Fallowfield et al. [40]	Yes	Yes	No	No	Yes	Confidence; discussion of clinical trials; communication skills; self-awareness; improvement in the consent process
Hietanen et al. [41]	No but voice feedback	Yes	No	No	No but description of personal experience	Psychosocial reaction; interviewing techniques; patients' needs when receiving info about CT
Mann et al. JAN 2014	Yes	No	No	No	Yes	Protocol adherence; knowledge of trial design; acceptability of the training; communication skills

Study	Audio-taped assessment	Patient simulator assessment	Participants generate list of optimal points	Strategies/key points document	Subjective assessment/survey	Outcomes considered
Paramavisan et al. T 2011	No	No	N/A	Yes (tips)	Yes (from interviews)	Confidence; addressing patients' preferences/ concerns; knowledge of informed consent elements
Larson et al. [11]	N/A	Yes	N/A	N/A	N/A	Enthusiasm and surprise about the perceived improvement
Cadman et al. [33]	No	No	No	No	Yes	Knowledge of informed consent elements; communication; contextual factors
Bernhard et al. [35]	Yes	No	No	Yes	Yes	Reduction of patients' decisional conflict; patients' involvement; reduction of patients' anxiety
Yap et al. [36]	Yes	No	No	No	Yes, completed by patients	Adoption of a sequence approach; eliciting questions; clarifying concepts
Kendall et al. [43]	No	No	No	No	No	Accrual
Jenkins et al. [31]	No	No	No	No	Yes	N* of patients approached; professionals' involvement with the trial; awareness; confidence
Fallowfield et al. [44]	No	No but used role-play	No	No	Yes	Awareness of other members' roles; confidence; facilitation of the workshop; role-play; planning
Donovan et al. [45]	Yes	Yes	No	No	No	Use of right documents; completion of informed consent; accrual

Study	Audio-taped assessment	Patient simulator assessment	Participants generate list of optimal points	Strategies/key points document	Subjective assessment/survey	Outcomes considered
Mills et al. T 2014	Yes	No	No	No	No	Addressing patients' treatments' preferences; improvement in informed consent process
Butow et al. HE. 2014	Yes	Yes	No	No	Yes	Shared decision-making; high satisfaction
Wuensch et al. EJoCC. 2011	Yes	Yes	No	No	Yes	Acceptance of the training; relevance of the training; appreciation of the training
Wells et al. [47]	No	No	No	No	Yes	Accrual; knowledge; attitudes
Kimmick et al. [38]	No	No	No	No	No	Accrual; accrual per type of treatment
Burnett et al. [48]	No	No	No	No	Yes	Knowledge; attitudes; confidence; format of the workshop; atmosphere; usefulness; and quality of the workshop

Table 3. Assessment and improved outcomes.

http://dx.doi.org/10.5772/intechopen.70188

4. Discussion

This study presents a systematic review of published articles on trainings to improve communication about clinical trials with patients. From the review, it appeared that the majority of the trainings followed the format of a workshop, as also observed in a previous review [51]. The duration of the trainings ranged from 3 hours to 3 days. According to literature on communication training programs for physicians (not specifically aimed at improving clinical trial communication), the optimal length for a training workshop seems to be 3 days [32]. However, currently there are not enough data to confirm these results in a clinical trial communication context.

In the majority of the articles reviewed, the educational materials used in the trainings were developed through the collaborative efforts of several experts with diverse backgrounds, including oncologists, clinical trial coordinators, researchers, and nurses. Having an interdisciplinary team seems to be a common strategy for successfully developing trainings to improve clinical trial communication. In order to further enhance educational materials and messages' effectiveness, appeal, and clarity, it may be beneficial to include communication researchers in the team.

The pedagogical materials were quite varied across trainings; despite this, there seemed to be a preference for visual forms of communication such as videos and vignettes, and role-playing [52, 53]. Many training programs used checklists in order to help both participants and educators to assess the outcomes of recruiters-patient interactions (both when the conversation was reproduced in videos, as well as during role-playing). These checklists were described as useful educational tools by all the studies and should be included in future training protocols, even if specific details on the content of these checklists are only approximately reported in the articles. Trainings themselves focused on several topics. A portion of this information is consistent with the recommendations provided by the literature on clinical trials accrual [5, 9, 54]. However, the choice of topics differed across the trainings, and not all key areas were reported as having been covered. Research teams generally collected preliminary data to provide better targeted information; this strategy is consistent with recommendations from previous studies focusing on communication trainings for physicians [55, 56], which encouraged trainers to consider contextual factors and characteristics of the organizations in which participants operate. However, future programs should provide content that is consistent with research on the barriers faced by potential participants in order to develop well-design trainings that are geared toward effective patient education. A first step toward this goal would be establishing an agreement on the outcomes that should be obtained through communication trainings to improve clinical trial accrual. In addition, only few studies reported positive, significant changes in participants' recruiting skills, although all participants reported increased confidence and satisfaction with the training. This is in line with findings from Townsend et al. [51]. Unfortunately, the fact that outcomes differed by study hindered our ability to statistically analyze results from the entire body of literature.

The articles synthetized in this paper represent an important effort toward the improvement of patient education about participation in clinical trials and research studies, and potentially, an increase in accrual rates. However, despite having conducted an extensive literature search, only 22 studies were found as adequate to be included in this systematic review. In our opinion, this finding alone is sufficient to call for additional studies aimed at evaluating the efficacy

of trainings for improving clinical trial communication and subsequently, patient satisfaction with the enrollment/consent process as well as improved accrual rates for clinical trials.

This study contributes to the emerging literature on clinical trial communication, and to the literature addressing clinical trials planning processes. Despite its contributions, this systematic review presents certain limitations. Only peer-reviewed studies were included; there is the possibility that other teams have conducted training programs to improve clinical trial communication and have disseminated findings in formats other than peer-reviewed journals. Future reviews should search for such materials and include them in their analysis. In addition, only materials in English were included, but it is possible that studies have been published in other languages.

5. Conclusion

Despite the wide diffusion of communication trainings for physician and medical personnel, only a few studies were retrieved with regard to specific trainings on communication about clinical trials. These studies demonstrated significant impact on outcomes such as participants' satisfaction, self-confidence, and understanding of the design of clinical trials. However, few training demonstrated any significant improvement in participants' recruiting skills. In light of the urgency of the need to increase clinical trial accrual, improved communication training may be an effective way to support recruitment goals. Researchers should further define the most effective strategies to meet the educational needs of professional recruiters, research coordinators, and study personnel, with the ultimate goal of improving accrual rates and the quality of patients' experience while enrolled in clinical trials and research studies.

5.1. Practice implications

Training programs for improving communication with patients about participation in clinical trials and research studies should be developed based on the insights from several experts, including social scientists focused on communication. These trainings should be organized in the form of workshops, where participants can receive both didactic education and the opportunity to role-play new communication skills. Role-playing exercises may prove to be particularly effective with standardized patients, if such a resource is available. The use of checklists during observations of role-plays is recommended as an objective test of behavioral outcomes. The long-term outcomes of the training on patient satisfaction with the enrollment and consenting process as well as study accrual rates should be carefully defined and assessed.

Author details

Aurora Occa* and Susan E. Morgan

*Address all correspondence to: aurora.occa@gmail.com

Department of Communication Studies, School of Communication, University of Miami, Miami, USA

References

[1] Friedman DB, Kim SH, Tanner A, Bergeron CD, Foster C, General K. How are we communicating about clinical trials? An assessment of the content and readability of recruitment resources. Contemporary Clinical Trials. 2014;**38**:275-283. DOI: 10.1016/j.cct.2014.05.004

[2] Quinn GP, McIntyre J, Gonzalez LE, Antonia TM, Antolino P, Wells KJ. Improving awareness of cancer clinical trials among Hispanic patients and families: Audience segmentation decisions for a media intervention. Journal of Health Communication. 2013;**18**:1131-1147. DOI: 10.1080/10810730.2013.768723

[3] Langford A, Resnicow K, An L. Clinical trial awareness among racial/ethnic minorities in HINTS 2007: Sociodemographic, attitudinal, and knowledge correlates. Journal of Health Communication. 2010;**15**:92-101. DOI: 10.1080/10810730.2010.525296

[4] Haddad RI, Chan ATC, Vermorken JB. Barriers to clinical trial recruitment in head and neck cancer. Oral Oncology. 2015;**51**:203-211. DOI: 10.1016/j.oraloncology.2014.12.007

[5] Albrecht TL, Eggly SS, Gleason MEJ, Harper FWK, Foster TS, Peterson AM, Orom H, Penner LA, Ruckdeschel JC. Influence of clinical communication on patients' decision making on participation in clinical trials. Journal of Clinical Oncology. 2008;**26**:2666-2673. DOI: 10.1200/JCO.2007.14.8114

[6] Carter RE, Sonny SC, Brady KT. Practical considerations for estimating clinical trial accrual periods: Application to a multi-center effectiveness study. BMC Medical research Methodology. 2005;**5**:1-5. DOI: 10.1186/1471-2288-5-11

[7] Kaplan CP, Nápoles AM, Dohan D, Hwang ES, Melisko M, Nickleach D, Quinn JA, Haas J. Clinical trial discussion, referral, and recruitment: Physician, patient, and system factors. Cancer Causes & Control. 2013;**24**:979-988. DOI: 10.1007/s10552-013-0173-5

[8] Foley JF, Moertel CG. Improving accrual into cancer clinical trials. Journal of Cancer Education. 1991;**6**:165-173. DOI: 10.1080/08858199109528114

[9] Parreco LK, DeJoice RW, Massett HA, Padberg RM, Thakkar SS. Power of an effective clinical conversation: Improving accrual onto clinical trials. Journal of Oncology Practice. 2012;**8**:282-286. DOI: 10.1200/JOP.2011.000478

[10] Mann C, Delgado D, Horwood J. Evaluation of internal peer-review to train nurses recruiting to a randomized controlled trial–Internal Peer-review for Recruitment Training in Trials (InterPReTiT). Journal of Advanced Nursing. 2014;**70**:777-790. DOI: 10.1111/jan.12254

[11] Larson EL, Cohn EG, Meyer DD, Boden-Albala B. Consent administrator training to reduce disparities in research participation. Journal of Nursing Scholarship. 2009;**41**:95-103. DOI: 10.1111/j.1547-5069.2009.01256.x

[12] Krieger JL, Palmer-Wackerly A, Dailey PM, Krok-Schoen JL, Schoenberg NE, Paskett ED. Comprehension of randomization and uncertainty in cancer clinical trials decision making

among rural, Appalachian patients. Journal of Cancer Education. 2015;**30**:743-748. DOI: 10.1007/s13187-015-0789-0

[13] Mills N, Blazeby JM, Hamdy FC, Neal DE, Campbell B, Wilson C, Paramasivan S, & Donovan JL. Training recruiters to randomized trials to facilitate recruitment and informed consent by exploring patients' treatment preferences. Trials, 2014;**15**:1-13

[14] Albrecht TL, Ruckdeschel JC, Riddle DL, Blanchard CG, Penner LA, Coovert MD, Quinn G. Communication and consumer decision making about cancer clinical trials. Patient Education and Counselling. 2003;**50**:39-42. DOI: http://dx.doi.org/10.1016/S0738-3991(03)00078-8

[15] Albrecht TL, Blanchard C, Ruckdeschel JC, Coovert M, Strongbow R. Strategic physician communication and oncology clinical trials. Journal of Clinical Oncology. 1999;**17**:3324-3332

[16] Morgan SE, Mouton A, Occa A, Potter J. Clinical trial and research study recruiters' verbal communication behaviors. Journal of Health Communication. 2016;**21**:1-8. DOI: http://dx.doi.org/10.1080/10810730.2016.1157654

[17] Morgan SE, Occa A, Mouton A, Potter J. The role of nonverbal communication behaviors in clinical trial and research study recruitment. Health Communication. 2016;**32**:1-9. DOI: http://dx.doi.org/10.1080/10410236.2016.1140266

[18] Morgan SE, Mouton A. Improving patient accrual to research studies through communication design interventions. In: Harrison TH, Williams E, editors. Organizations, Communication, and Health. New York, NY: Routledge. 2015;82-100

[19] Fletcher B, Gheorghe A, Moore D, Wilson S, Damery S. Improving the recruitment activity of clinicians in randomised controlled trials: A systematic review. BMJ Open. 2012;**2**:e000496. DOI: 10.1136/bmjopen-2011-000496

[20] Cegala DJ. Patient communication skills training: A review with implications for cancer patients. Patient Education and Counselling. 2003;**50**:1-94. DOI: http://dx.doi.org/10.1016/S0738-3991(03)00087-9

[21] Cegala DJ, Lenzmeier BS. Physician communication skills training: A review of theoretical backgrounds, objectives and skills. Medical Education. 2002;**36**:1004-1016. DOI: 10.1046/j.1365-2923.2002.01331.x

[22] Cegala DJ, McClure L, Marinelli TM, Post DM. The effects of communication skills training on patients' participation during medical interviews. Patient Education and Counselling. 2000;**41**:209-222. DOI: http://dx.doi.org/10.1016/S0738-3991(00)00093-8

[23] van Dalen J. Communication skills in context: Trends and perspectives. Patient Education and Counselling. 2013;**92**:292-295. DOI: http://dx.doi.org/10.1016/j.pec.2013.05.020

[24] Berkhof M, van Rijssen HJ, Schellart AJ, Anema JR, van der Beek AJ. Effective training strategies for teaching communication skills to physicians: An overview of systematic reviews. Patient Education and Counselling. 2011;**84**:152-162. DOI: http://dx.doi.org/10.1016/j.pec.2010.06.010

[25] Ammentorp J, Sabroe S, Kofoed PE, Mainz J. The effect of training in communication skills on medical doctors' and nurses' self-efficacy: A randomized controlled trial. Patient Education and Counselling. 2007;**66**:270-277. DOI: http://dx.doi.org/10.1016/j.pec.2006.12.012

[26] Sarbaz M, Kimiafar K, Taherzadeh Z, Naderi H, Eslami S. Effect of modifying the information and training structure on the occupational safety of health care workers in exposure to blood and body fluids: A quasi-experimental study. American Journal of Infection Control. 2016;**45**:80-82. DOI: http://dx.doi.org/10.1016/j.ajic.2016.05.023

[27] Lane C, Rollnick S. The use of simulated patients and role-play in communication skills training: A review of the literature to August 2005. Patient Education and Counselling. 2007;**67**:13-20. DOI: http://dx.doi.org/10.1016/j.pec.2007.02.011

[28] Aspegren K. BEME Guide No. 2: Teaching and learning communication skills in medicine-a review with quality grading of articles. Medical Teacher. 1999;**21**:563-570

[29] Fallowfield LJ, Solis-Trapala I, Jenkins VA. Evaluation of an educational program to improve communication with patients about early-phase trial participation. The Oncologist. 2012;**17**:377-383. DOI: 10.1634/theoncologist.2011-0271

[30] Jenkins V, Fallowfield L, Solis-Trapala I, Langridge C, Farewell V. Discussing randomised clinical trials of cancer therapy: Evaluation of a Cancer Research UK training programme. British Medical Journal. 2005;**330**:1-6. DOI: 10.1136/bmj.38366.562685.8F

[31] Jenkins VA, Farewell D, Farewell V, Batt L, Wagstaff J, Langridge C, Fallowfield LJ, Teams Talking Trials Steering Committee. Teams talking trials: Results of an RCT to improve the communication of cancer teams about treatment trials. Contemporary Clinical Trials. 2013;**35**:43-51

[32] Stiefel F, Barth J, Bensing J, Fallowfield L, Jost L, Razavi D, Kiss A. Communication skills training in oncology: A position paper based on a consensus meeting among European experts in 2009. Annals of Oncology. 2010;**21**:204-207. DOI: 10.1093/annonc/mdp564

[33] Cadman ME, Murphy JH, Brintnall-Karabelas J, Squires C, Whorton K, Pao M. A training program for improving the informed consent discussion between clinical researchers and their subjects. Journal of Empirical Research on Human Research Ethics. 2014;**9**:71-75

[34] Butow P, Brown R, Aldridge J, Juraskova I, Zoller P, Boyle F,… Bernhard J. Can consultation skills training change doctors' behaviour to increase involvement of patients in making decisions about standard treatment and clinical trials: A randomized controlled trial. Health Expectations. 2015;**18**:2570-2583

[35] Bernhard J, Butow P, Aldridge J, Juraskova I, Ribi K, Brown R. Communication about standard treatment options and clinical trials: Can we teach doctors new skills to improve patient outcomes? Psycho-Oncology. 2012;**21**:1265-1274

[36] Yap TY, Yamokoski A, Noll R, Drotar D, Zyzanski S, Kodish ED, Multi-site Intervention Study to Improve Consent Research Team. A physician-directed intervention: Teaching and measuring better informed consent. Academic Medicine. 2009;**84**:1036-1042

[37] Brown RF, Butow PN, Boyle F, Tattersall MHN. Seeking informed consent to cancer clinical trials; Evaluating the efficacy of doctor communication skills training. Psycho-Oncology. 2007;**16**:507-516. DOI: 10.1002/pon.1095

[38] Kimmick GG, Peterson BL, Kornblith AB, Mandelblatt J, Johnson JL, Wheeler J,… Muss HB. Improving accrual of older persons to cancer treatment trials: A randomized trial comparing an educational intervention with standard information: CALGB 360001. Journal of Clinical Oncology. 2005;**23**:2201-2207

[39] Fallowfield L, Jenkins V, Farewell V, Saul J, Duffy A, Eves R. Efficacy of a Cancer Research UK communication skills training model for oncologists: A randomised controlled trial. The Lancet. 2002;**359**:650-656. DOI: 10.1016/S0140-6736(02)07810-8

[40] Fallowfield L, Lipkin M, Hall A. Teaching senior oncologists communication skills: Results from phase I of a comprehensive longitudinal program in the United Kingdom. Journal of Clinical Oncology. 1998;**16**:1961-1968

[41] Hietanen PS, Aro AR, Holli KA, Schreck M, Peura A, Joensuu HT. A short communication course for physicians improves the quality of patient information in a clinical trial. Acta Oncologica. 2007;**46**:42-48. DOI: 10.1080/02841860600849067

[42] Paramasivan S, Huddart R, Hall E, Lewis R, Birtle A, Donovan JL. Key issues in recruitment to randomised controlled trials with very different interventions: A qualitative investigation of recruitment to the SPARE trial (CRUK/07/011). Trials. 2011;**12**:1-15. DOI: 10.1186/1745-6215-12-78

[43] Kendall B, Städeli R, Schegg B, Olbrich M, Chen E, Harmelin-Kadouri R, Aurup P, Hildemann SK. Clinical Trial Educator program—A novel approach to accelerate enrollment in a phase III International Acute Coronary Syndrome Trial. Clinical Trials. 2012;**9**:358-366

[44] Fallowfield L, Langridge C, Jenkins V. Communication skills training for breast cancer teams talking about trials. The Breast. 2014;**23**:193-197

[45] Donovan JL, Lane JA, Peters TJ, Brindle L, Salter E, Gillatt D,… ProtecT Study Group. Development of a complex intervention improved randomization and informed consent in a randomized controlled trial. Journal of Clinical Epidemiology. 2009;**62**:29-36

[46] Wuensch A, Goelz T, Bertz H, Wirsching M, Fritzsche K. Disclosing information about randomised controlled trials in oncology: Training concept and evaluation of an individualised communication skills training for physicians COM-ON-rct. European Journal of Cancer Care. 2011;**20**:570-576

[47] Wells JS, Pugh S, Boparai K, Rearden J, Yeager KA, Bruner DW. Cultural competency training to increase minority enrollment into radiation therapy clinical trials—An NRG oncology RTOG study. Journal of Cancer Education. 2016;1-7

[48] Burnett C, Bullock L, Collins CA, Hauser L. Evaluation of a clinical cancer trial research training workshop: Helping nurses build capacity in Southwest Virginia. Public Health Nursing. 2016;**33**:565-572

[49] Colletti L, Gruppen L, Barclay M, Stern D. Teaching students to break bad news. The American Journal of Surgery. 2001;**18**:220-223. DOI: http://dx.doi.org/10.1016/S0002-9610(01)00651-1

[50] Haist SA, Wilson JF, Pursley HG, Jessup ML, Gibson JS, Kwolek DG, Stratton TD, Griffith CH. Domestic violence: Increasing knowledge and improving skills with a four-hour workshop using standardized patients. Academic Medicine. 2003;**78**:S24-26

[51] Townsend D, Mills N, Savović J, Donovan JL. A systematic review of training programmes for recruiters to randomised controlled trials. Trials. 2015;**16**:432

[52] Chant S, Jenkinson TIM, Randle J, Russell G. Communication skills: Some problems in nursing education and practice. Journal of Clinical Nursing. 2002;**11**:12-21. DOI: 10.1046/j.1365-2702.2002.00553.x

[53] Wilkinson S, Roberts A, Aldridge J. Nurse–patient communication in palliative care: An evaluation of a communication skills programme. Palliative Medicine. 1998;**12**:13-22. DOI: 10.1191/026921698675034697

[54] Fleisher L, Ruggieri DG, Miller SM, Manne S, Albrecht T, Buzaglo J, Collins MA, Katz M, Kinzy TG, Liu T, Mannig C, Charap ES, Millard J, Miller DM, Poole D, Raivitch S, Roach N, Ross EA, & Meropol NJ. Application support tools: The preparatory education about clinical trials (PRE-ACT) study. Patient Education and Counseling. 2014;**96**:63-71

[55] Uitterhoeve RJ, Bensing JM, Grol RP, Demulder PHM, van Achterberg T. The effect of communication skills training on patient outcomes in cancer care: A systematic review of the literature. European Journal of Cancer Care. 2010;**19**:442-457. DOI: 10.1111/j.1365-2354.2009.01082.x

[56] Baldwin TT, Ford JK. Transfer of training: A review and directions for future research. Personnel Psychology. 1988;**41**:63-105. DOI: 10.1111/j.1744-6570.1988.tb00632.x