



HHS Public Access

Author manuscript

Nurs Res. Author manuscript; available in PMC 2025 January 01.

Published in final edited form as:

Nurs Res. 2024 ; 73(2): 166–171. doi:10.1097/NNR.0000000000000710.

Ensuring Intervention Fidelity of an Attention Control Arm in a Multi-Site Randomized Controlled Trial

Amy R. Newman, PhD, RN, CPNP-PC [Assistant Professor],

Marquette University College of Nursing and Children's Wisconsin, Milwaukee, Wisconsin

Karen M. Moody, MD, MS [Professor],

The University of Texas MD Anderson Cancer Center Houston, TX

Kerri Beckett, MD, MS [Assistant Professor],

Medical College of Wisconsin, Milwaukee, WI

Erin Connelly, APRN, CPNP-PC [Pediatric Nurse Practitioner],

Children's Healthcare of Atlanta and Emory University, Atlanta, Georgia

Cynthia Holladay, MPA [Clinical Research Coordinator],

Indiana University School of Medicine, Indianapolis, Indiana

Katie Parisio, DO [Assistant Professor],

Thomas Jefferson University and Nemours Children's Health, Wilmington, Delaware

Jonathan L. Powell, MD,

Thomas Jefferson University and Nemours Children's Health, Wilmington, Delaware

Angela Steineck, MD, MS [Assistant Professor],

Medical College of Wisconsin, Milwaukee, WI

Verna L. Hendricks-Ferguson, PhD, RN, FPCN, FAAN [Irene Riddle Endowed Chair & Professor]

Corresponding author: Amy R. Newman, PhD, RN, CPNP-PC, Marquette University College of Nursing, Clark 209, PO Box 1881, Milwaukee, WI, 53233 (amy.newman@marquette.edu).

Author Note

Amy R. Newman, PhD, RN, CPNP-PC, is Assistant Professor at Marquette University College of Nursing and Nurse Scientist at Children's Wisconsin, Milwaukee, WI.

Karen M. Moody, MD, MS, is Professor, Department of Pediatrics Patient Care, Division of Pediatrics and Department of Palliative Care and Rehabilitation Medicine, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX.

Kerri Beckett, MD, MS, is Assistant Professor and **Angela Steineck, MD, MS,** is Assistant Professor, Section of Pediatric Hematology/Oncology/Blood & Marrow Transplant, Department of Pediatrics, Medical College of Wisconsin, Milwaukee, WI.

Erin Connelly, APRN, CPNP-PC, is Pediatric Nurse Practitioner at Children's Healthcare of Atlanta and Emory University, Atlanta, GA.

Cynthia Holladay, MPA, is Clinical Research Coordinator, PResNet, Division of Children's Health Services Research, Department of Pediatrics, Indiana University School of Medicine, Indianapolis, IN.

Katie Parisio, DO, is Clinical Assistant Professor of Pediatrics and **Jonathan L. Powell, MD,** is Clinical Assistant Professor of Pediatrics, Thomas Jefferson University, Division of Hematology/Oncology and Palliative Medicine and Nemours Children's Health, Wilmington, DE.

Verna L. Hendricks-Ferguson, PhD, RN, FPCN, FAAN, is Irene Riddle Endowed Chair & Professor, Saint Louis University Trudy Busch Valentine School of Nursing, St. Louis, MO.

The authors have no conflicts of interest to report.

Ethical Conduct of Research: This study was reviewed and approved by the Indiana University Institutional Review Board (IRB) (IRB Number: 1904351083), which is the reviewing IRB for all study sites.

Clinical Trial Registration: This clinical trial is registered at [ClinicalTrials.gov](https://clinicaltrials.gov). The trial number is [NCT04330833](https://clinicaltrials.gov/ct2/show/study/NCT04330833) and the date of registration was April 2, 2020. The first study participants were enrolled on January 18, 2021.

Saint Louis University, Trudy Busch Valentine School of Nursing, St. Louis, MO

Abstract

Background: Intervention fidelity is a critical element of randomized controlled trials, yet reporting of intervention fidelity among attention control arms is limited. Lack of fidelity to attention control procedures can affect study outcomes by either over- or underestimating the efficacy of the intervention under examination.

Objectives: This brief report describes the approach researchers took to promote fidelity to the attention control arm of a National Institutes of Health-funded pediatric palliative care randomized controlled trial.

Methods: The Informational Meetings for Planning and Coordinating Treatment trial aims to determine the efficacy of a communication intervention that uses care team dyads (i.e., physicians partnered with nurses or advanced practice providers) to engage parents of children with cancer that have a poor prognosis in structured conversations about prognostic information, goals of care, and care planning. The intervention is compared to an attention control arm, which provides parents with structured conversations on common pediatric cancer education topics, such as talking with their child about their cancer, clinical trials, cancer treatment, side effects, etc. National Institutes of Health guidelines for assessing and implementing strategies to promote intervention fidelity were used to design (a) the attention control arm of a randomized controlled trial, (b) related attention control arm training, and (c) quality assurance monitoring.

Results: Attention control study procedures were designed to mirror that of the intervention arm (i.e., same number, frequency, and time spent in study visits). Cluster randomization was used to allocate care team dyads to one arm of the randomized controlled trial. Care team dyads assigned to the attention control arm participated in online training sessions to learn attention control procedures, the different roles of research team members, and quality assurance methods. Fidelity to attention control procedures is assessed by both the interveners themselves and a quality assurance team.

Discussion: Study design, training, and delivery are all critical to attention control fidelity. Baseline training often needs to be supplemented with booster training when time gaps occur between study start-up and implementation. Quality assurance procedures are essential to determine whether interveners consistently deliver attention control procedures correctly.

Keywords

attention control; communication; fidelity; methods; randomized controlled trials as topic

Randomized controlled trials (RCTs) are considered the gold standard for conducting intervention research as randomization helps to minimize selection bias and determine causal relationships between an intervention and specific outcomes (Hariton & Locascio, 2018). When designing an RCT, researchers must select the appropriate type of control group to compare to the intervention group. Traditionally, participants in the control group receive either no active treatment or the standard treatment. Attention control is an alternative to the traditional control group. Attention control groups (ACGs) receive the same dose of interpersonal interaction (e.g., time, intensity, and/or contacts) as the

intervention group but no other aspects of the intervention (Aycocock et al., 2018). This is done to control the attention participants receive, which may inadvertently affect study outcomes (Beal et al., 2009; LaFave et al., 2019).

A critical aspect of RCTs is validity, or the extent to which the study tests its underlying hypothesis. *Internal* validity refers to the degree to which differences in outcome variables can be correctly attributed to the intervention under investigation. One of the main threats to internal validity in RCTs is bias—in particular, performance bias. Performance bias occurs when participants or interveners do not adhere to the study protocol (Spieth et al., 2016). Internal validity, therefore, is enhanced by intervention or treatment fidelity. Intervention fidelity refers to the “extent to which core components of interventions are delivered as intended by the protocols” (Gearing et al., 2011, p. 78). Enhancing intervention fidelity has the effect of not only increasing internal validity but also external validity, as a high degree of intervention fidelity is needed for both study replication and generalizability. Much of the literature in this area has focused on strategies to ensure and measure fidelity to treatment interventions with limited discussion of fidelity to attention control conditions (Rhee et al., 2020). However, without examining attention control fidelity, RCT outcomes may unknowingly reflect either the unintended omission or addition of elements to the control group (Borrelli, 2011).

In the context of behavioral health interventions, a National Institutes of Health (NIH) workgroup established best practices and recommendations to enhance treatment fidelity. The strategies they describe fall into the following areas: (a) study design, (b) training of intervenors, (c) delivery of treatment, (d) receipt of treatment, and (e) enactment of treatment skills (Bellg et al., 2004). Guided by these NIH recommendations, the purpose of this paper is to describe the approach researchers took to promote fidelity to the attention control arm of an NIH-funded pediatric palliative care RCT. The study is registered on [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT0433083) (NCT0433083).

Overview of the Study

The Informational Meetings for Planning and Coordinating Treatment (IMPACT) trial is a single institutional review board-approved multisite, cluster RCT designed to evaluate the effect of interprofessional palliative care, communication intervention for parents of children under 18 diagnosed with cancers that have a poor prognosis (i.e., less than 25% chance of overall survival). Seven sites from around the United States are participating in the trial. All participating sites are academically affiliated, have pediatric oncology programs seeing, on average, 45 patients per year, and draw from large catchment areas. The IMPACT treatment intervention partners a physician with a registered nurse or advanced practice provider ([APP]; i.e., nurse practitioner or physician assistant) trained in serious illness communication and a structured approach to delivering diagnostic and prognostic information. These dyads will be hereafter referred to as “care team dyads.” The IMPACT treatment intervention is compared to an attention control arm, which consists of structured nurse or APP-delivered parent education based on a handbook developed by the National Cancer Institute ([NCI], 2015). This five-year RCT study aims to (a) increase parents’ receptivity to receive earlier hospice care; (b) decrease high-intensity medical interventions

and pain and emotional suffering in children at end of life (EOL); and (c) reduce parental distress and uncertainty. Pilot work examining the intervention's feasibility, acceptability, and preliminary efficacy has been previously published (Hendricks-Ferguson et al., 2017, 2021; Moody et al., 2020). Such work is integral to improving the EOL experiences of pediatric patients with poor prognosis cancers and their parents.

Study Design

When developing the IMPACT trial, the attention control arm was designed to parallel the IMPACT intervention arm in terms of timing, frequency, and length of intervention visits (see Table 1). However, the content of the IMPACT intervention differs significantly from the attention control arm, as does who delivers the content and how it is delivered. The IMPACT intervention applies evidence-based communication skill building (Back et al., 2003; Hendricks-Ferguson et al., 2017; Moody et al., 2020) to facilitate discussions regarding parent/family goals of care and the patient's prognosis. The focus of the attention control visits is considerably different. Attention control nurses or APPs provide parents education based on a list of topics generated from the NCI's handbook, *Children with Cancer: A Guide for Parents* (2015), avoiding discussions regarding palliative care, prognosis, and goals of care. If parents bring up any of these topics, they are provided with basic education based on the NCI handbook and encouraged to have further discussions with their primary care team outside of the study visits. Information related to topics of interest can be printed for parents to review.

For the IMPACT trial, cluster randomization was selected to prevent contamination across study arms and conditions (Magill et al., 2019). Each institution identified care team dyads within both their pediatric neuro-oncology and solid tumor subspecialty practices. The number of participating dyads at each site was determined by institution size and the anticipated number of potentially eligible patients. Number of dyads at each site ranged from two to three at the time of randomization. Randomization then occurred at the level of the subspecialty practice at each site (i.e., neuro-oncology vs. solid tumor) based on subspecialty, clinicians' reported experiences with palliative care/EOL communication skills training, and number of patients seen annually by the pediatric oncology subspecialty practice (Chaudhary & Moulton, 2006). Once randomized, care team dyads within each subspecialty practice only deliver the intervention to which they were randomized (i.e., if a neuro-oncology dyad was randomized to the IMPACT intervention arm, they provide the IMPACT intervention to all their patients who are enrolled in the study).

Training Providers

The lead authors (i.e., PhD-prepared faculty with pediatric oncology and RCT experience) developed a standard training curriculum to prepare nurses and APP interveners in the attention control arm. As nurses from five different institutions across the U.S. needed to be trained to deliver the attention control arm and a limited grant budget, the investigators chose to create an online training experience. All standardized training materials—including study-related documents and recordings of training sessions—were made available to interveners in a secure, university-approved, cloud-based storage platform, allowing easy access to all study and training materials. The didactic training incorporated active learning strategies,

including role play, active listening exercises, and a video demonstration of the attention control procedures to enhance online learning. Three 2-hr training sessions were developed based on the amount of information to be presented. The first session focused on reviewing the study protocol with an emphasis on describing attention control procedures, accessing study and training materials, and reviewing patient and family education best practices. The second session focused on describing roles of the different research team members, including the study's multiple principal investigators (mPIs), site PIs, and project managers; reviewing attention control logistics (e.g., scheduling of sessions, recording of sessions, etc.); and engaging in role-play activities. The third session focused on attention control fidelity and quality assurance (QA) processes and the role of the nurse or APP, data entry, and identification and reporting of adverse events. Following training, the nurse and APP interveners were asked to complete an anonymous evaluation of the online training procedures via a secure online data management platform (i.e., Qualtrics; see Figure 1). Survey results demonstrated that the nurses and APPs found online education to be an effective way to receive the required information and training; as a result, they felt equipped and confident in their abilities to perform attention control procedures.

Delivery of Attention Control

A protocol outlining attention control procedures was created to promote attention control fidelity in the IMPACT trial. In addition, a script was created for interveners to use as a reference when conducting study visits. All visits are audio-recorded to determine skill acquisition and ensure that study visits are delivered per protocol. Also, following each of the first three visits an intervener performs, the intervener completes a standardized QA checklist to ensure they performed attention control procedures according to the study protocol. Interveners continue to perform self-assessment until they have consistently documented at least 80% fidelity according to the checklist. To monitor for protocol-delivery skill drift (i.e., unintentionally omitting or adding components of the intervention as time from initial training increases; Bellg et al., 2004), a QA team randomly reviews 25% of all attention control visits by listening to the audio recordings to ensure adherence to the study protocol. The QA team is led by the mPIs, who have trained PhD-prepared nurses and PhD-level nursing students to audit study visits. Also, if more than 2 months lapse between attention control visits, the intervener repeats self-assessment with the QA checklist. Interveners can also review the three recorded training sessions, as needed, to help them prepare and deliver any of their future visits with parents. Finally, feedback from and to the interveners is provided at regular intervener meetings with the attention control arm team leaders. Additional feedback for interveners not meeting or maintaining competency based on QA spot checks is offered privately by the attention control arm team leaders, with booster training provided as needed.

Discussion

Study design, intervener training, and intervention delivery are all critical aspects of RCT implementation to ensure fidelity. Previous reports have focused primarily on design and training for treatment intervention delivery with less emphasis on attention control; however, design and training for an attention control arm must be equally as rigorous. Rigor is critical

to ensuring that significant differences in outcomes (if present) can be attributed to specific elements of the treatment intervention versus the less specific elements of the ACG (Guidi et al., 2018). Here, we have described our success in designing an attention control arm and an effective training program on attention control procedures to promote fidelity.

Several lessons were learned from our virtual attention control training as part of a multisite study. One related to the challenges in scheduling training sessions with nurses and APP interveners, who were employed full-time, worked different schedules, and lived in different time zones. We recommend that investigators plan extra time into their training timeline to allow for scheduling training dates for interveners at multiple data-collection sites and inclusion of several different cohorts to facilitate training. Further, all time zones should be considered and clearly communicated in bold print when sending training invitations. Additionally, we recommend sending reminders to trainees with a note about time zone differences before all training dates.

Although we provided standardized and comprehensive training resources (e.g., NCI parent-education handbook, research team role descriptions, QA checklists, attention-control protocol policies and procedures), time elapsed between training and implementation at different study sites. In light of this, we recognized that nurses and APPs needed additional training time to remain competent and confident in attention control procedures. To meet this need, virtual booster training sessions were woven into regularly scheduled attention control team meetings, and the nurses and APPs were reminded and encouraged to review any of the three previously recorded training sessions to prepare for future visits with parents. Ongoing assessment and feedback are provided to interveners to ensure fidelity of planned attention control procedures, i.e., to avoid intervention drift.

Of note, a few additional challenges were identified from using a virtual platform to conduct planned training sessions to promote attention control fidelity. First, not all nurses and APPs were familiar with using online videoconferencing technology. Additionally, some nurses and APPs did not have web cameras on their work computers, which did not allow viewing of their participation during training sessions and limited active engagement. Therefore, when planning training sessions, investigators should include extra training time to orient interveners in using web-based videoconferencing technology and consider including funds for purchasing web cameras for hospital-employed team members as part of site budgets. Finally, when conducting a longitudinal RCT (e.g., 5 or more years in duration), intervener turnover should be anticipated, which requires additional training and time on the part of the study team. Having previously recorded training sessions available can facilitate efficient and timely onboarding of new study team members.

Finally, when implementing an attention control arm using clinician interveners, potential ethical issues must be taken into consideration and addressed during training. Several months into participant enrollment, nurse interveners (particularly advanced practice nurses) described the challenges of balancing their role as the intervener with that of also being the patient's provider. Nurses felt uncomfortable, awkward, and conflicted not addressing or discussing palliative care when it might otherwise have been suggested naturally. Challenges that may come into play when clinicians function as research interveners include role

confusion experienced by the participant, tension between clinical responsibilities and research demands, and therapeutic misconception (Judkins-Cohn et al., 2014). Therapeutic misconception occurs when the participant overestimates the personal benefits they may experience from research participation based on their relationship with the clinician-intervener. Potential ethical challenges should be identified in advance and incorporated into study training. Interveners are then aware of potential conflicts and better prepared to address them. In addition, regular research team meetings can provide a forum for discussion, debriefing, and guidance from the study team leaders (Park et al., 2014).

Conclusion

Optimizing intervention fidelity is critical to ensuring valid and reliable outcomes from RCTs. Strategies to enhance intervention fidelity involve ensuring robust study design, including thoughtful selection of the control arm, training of interveners, and consistent delivery of the study arms (treatment and control). We have described our approach to promoting intervention fidelity in the context of a multisite RCT with a focus on the design, training, and delivery of an attention control arm. Our attention control training was unique in that it occurred in the virtual environment, allowing us to provide reflection and insight for future researchers considering intervention training in an online environment.

Acknowledgement:

Research reported in this publication was supported by the National Cancer Institute of the National Institutes of Health under Award Number R01CA235632. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. A. Steineck received funding through an ASCO Conquer Cancer Career Development Award. The authors thank Dr. Joan Haase, PhD, RN, FAAN (Professor Emerita, Indiana University School of Nursing), for her mentorship. The authors thank Dr. Susan Perkins, PhD (Professor of Biostatistics & Health Data Science, Indiana University School of Medicine), one of the multiple principal investigators, for her support and comments on the approach to randomization. The authors thank Michelle Mravec-Arthur, BSN, RN (Doctoral Student, Indiana University School of Medicine), for her support in initial manuscript development. The authors thank the nurses, physicians, and advance practice providers who serve as the interveners for the attention control arm of the study: Janie Avila, MSN, APRN, FNP-C, CPON (Advanced Practice Provider, MD Anderson Cancer Center), Dr. W. Thomas Cash, MD, MSc (Pediatric Hematologist/Oncologist, Aflac Cancer and Blood Disorders Center of Children's Healthcare of Atlanta), Jonathan Cunningham, MPAS, PA-C (Advance Practice Provider, MD Anderson Cancer Center), Dr. Nathan Dahl, MD (Pediatric Hematologist/Oncologist, Children's Hospital Colorado), Lauren Everingham, MSN, APRN, CPNP-PC (Advance Practice Provider, Nemours Children's Health), Dr. Molly Hemenway, DNP, RN, CPNP-PC/AC (Advance Practice Provider, Children's Hospital Colorado), Dr. Anna Janss, MD, PhD (Pediatric Neuro-Oncologist, Aflac Cancer and Blood Disorders Center of Children's Healthcare of Atlanta), Dr. Tobey MacDonald, MD (Pediatric Neuro-Oncologist, Aflac Cancer and Blood Disorders Center of Children's Healthcare of Atlanta), Dr. Jean Mulcahy-Levy, MD (Pediatric Hematologist/Oncologist, Children's Hospital Colorado), Heather Meador, MSN, APRN, CPNP-PC/AC, CPHON (Advance Practice Provider, MD Anderson Cancer Center), Dr. Sarah Mitchell, MD (Pediatric Hematologist/Oncologist, Aflac Cancer and Blood Disorders Center of Children's Healthcare of Atlanta), Danielle Morley, BSN, RN, CPHON (Cancer Care and Fertility Preservation Coordinator, Nemours Children's Health), Kelly Pergande, BSN, RN, CPHON (Solid Tumor Nurse Clinician, Children's Wisconsin), Christie Powell, MSN, RN, CPNP (Advance Practice Provider, Aflac Cancer and Blood Disorders Center of Children's Healthcare of Atlanta), Dr. Zsila Sadighi, MD (Pediatric Neuro-Oncologist, MD Anderson Cancer Center), Silvia Saenz, BSN, RN (Registered Nurse, MD Anderson Cancer Center), Shelby Winzent-Oonk, PA-C (Advance Practice Provider, Children's Hospital Colorado), and Dr. Wafik Zaky, MD (Pediatric Neuro-Oncologist, MD Anderson Cancer Center). The authors thank the members of the quality assurance team Nancy Dias, PhD, RN, CNE (Assistant Professor, East Carolina University College of Nursing), Stacy Crane, PhD, RN, CPON (Assistant Professor, UTHouston Cizik School of Nursing), and Savannah Blalock, BSN, RN (Doctoral Student, East Carolina University College of Nursing).

References

- Aycock DM, Hayat MJ, Helvig A, Dunbar SB, & Clark PC (2018). Essential considerations in developing attention control groups in behavioral research. *Research in Nursing & Health*, 41, 320–328. 10.1002/nur.21870 [PubMed: 29906317]
- Back AL, Arnold RM, Tulsy JA, Baile WF, & Fryer-Edwards KA (2003). Teaching communication skills to medical oncology fellows. *Journal of Clinical Oncology*, 21, 2433–2436. 10.1200/JCO.2003.09.073 [PubMed: 12805343]
- Beal CC, Stuijbergen A, Volker D, & Becker H (2009). Women's experiences as members of attention control and experimental intervention groups in a randomized controlled trial. *Canadian Journal of Nursing Research*, 41, 16–31.
- Bellg AJ, Borrelli B, Resnick B, Hecht J, Minicucci DS, Ory M, Ogedegbe G, Orwig D, Ernst D, & Czajkowski S (2004). Enhancing treatment fidelity in health behavior change studies: Best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychology*, 23, 443–451. 10.1037/0278-6133.23.5.443 [PubMed: 15367063]
- Borrelli B (2011). The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials. *Journal of Public Health Dentistry*, 71, S52–S63. 10.1111/j.1752-7325.2011.00233.x
- Chaudhary MA, & Moulton LH (2006). A SAS macro for constrained randomization of group-randomized designs. *Computer Methods and Programs in Biomedicine*, 83, 205–210. 10.1016/j.cmpb.2006.04.011 [PubMed: 16870302]
- Gearing RE, El-Bassel N, Ghesquiere A, Baldwin S, Gillies J, & Ngeow E (2011). Major ingredients of fidelity: A review and scientific guide to improving quality of intervention research implementation. *Clinical Psychology Review*, 31, 79–88. 10.1016/j.cpr.2010.09.007 [PubMed: 21130938]
- Guidi J, Brakemeier E-L, Bockting CLH, Cosci F, Cuijpers P, Jarrett RB, Linden M, Marks I, Peretti CS, Rafanelli C, Rief W, Schneider S, Schnyder U, Sensky T, Tomba E, Vazquez C, Vieta E, Zipfel S, Wright JH, & Fava GA (2018). Methodological recommendations for trials of psychological interventions. *Psychotherapy and Psychosomatics*, 87, 276–284. 10.1159/000490574 [PubMed: 30007961]
- Hariton E, & Locascio JJ (2018). Randomised controlled trials—The gold standard for effectiveness research. *BJOG: An International Journal of Obstetrics and Gynaecology*, 125, 1716. 10.1111/1471-0528.15199 [PubMed: 29916205]
- Hendricks-Ferguson V, Newman AR, Brock KE, Haase JE, Raybin JL, Saini S, & Moody KM (2021). COMPLETE (Communication Plan Early Through End of Life): Development of a research program to diminish suffering for children at end of life. *Journal of Pediatric Nursing*, 61, 454–456. 10.1016/j.pedn.2021.08.010 [PubMed: 34452795]
- Hendricks-Ferguson VL, Pradhan K, Shih C-S, Gauvain KM, Kane JR, Liu J, & Haase JE (2017). Pilot evaluation of a palliative and end-of-life communication intervention for parents of children with a brain tumor. *Journal of Pediatric Oncology Nursing*, 34, 203–213. 10.1177/1043454216676836 [PubMed: 27920233]
- Judkins-Cohn TM, Kielwasser-Withrow K, Owen M, & Ward J (2014). Ethical principles of informed consent: Exploring nurses' dual role of care provider and researcher. *Journal of Continuing Education in Nursing*, 45, 35–42. 10.3928/00220124-20131223-03 [PubMed: 24369754]
- LaFave SE, Granbom M, Cudjoe TKM, Gottsch A, Shorb G, & Szanton SL (2019). Attention control group activities and perceived benefit in a trial of a behavioral intervention for older adults. *Research in Nursing & Health*, 42, 476–482. 10.1002/nur.21992 [PubMed: 31647125]
- Magill N, Knight R, McCrone P, Ismail K, & Landau S (2019). A scoping review of the problems and solutions associated with contamination in trials of complex interventions in mental health. *BMC Medical Research Methodology*, 19, 4. 10.1186/s12874-018-0646-z [PubMed: 30616508]
- Moody K, Hendricks-Ferguson VL, Baker R, Perkins S, & Haase JE (2020). A pilot study of the effects of COMPLETE: A communication plan early through end of life, on end-of-life outcomes in children with cancer. *Journal of Pain and Symptom Management*, 60, 417–421. 10.1016/j.jpainsymman.2020.03.033 [PubMed: 32315752]

- National Cancer Institute. (2015). Children with cancer: A guide for parents. NIH Publication No. 15–2378. National Institutes of Health. Retrieved from <https://www.cancer.gov/publications/patient-education/guide-for-parents>
- Park T, Usher K, & Foster K (2014). The challenges of conducting a nurse-led intervention in a randomized controlled trial with vulnerable participants. *Nursing Research and Practice*, 2014, 394237. 10.1155/2014/394237 [PubMed: 24876952]
- Rhee H, Grape A, Tumiel-Berhalter L, Wicks M, Sloand E, & Butz A (2020). Fidelity of a peer-led asthma self-management intervention and its attention control in a multisite study of urban adolescents. *Research in Nursing & Health*, 43, 195–205. 10.1002/nur.22001 [PubMed: 31793688]
- Spieth PM, Kubasch AS, Penzlin AI, Illigens BM, Barlinn K, & Siepmann T (2016). Randomized controlled trials – A matter of design. *Neuropsychiatric Disease and Treatment*, 2016, 1341–1349. 10.2147/NDT.S101938

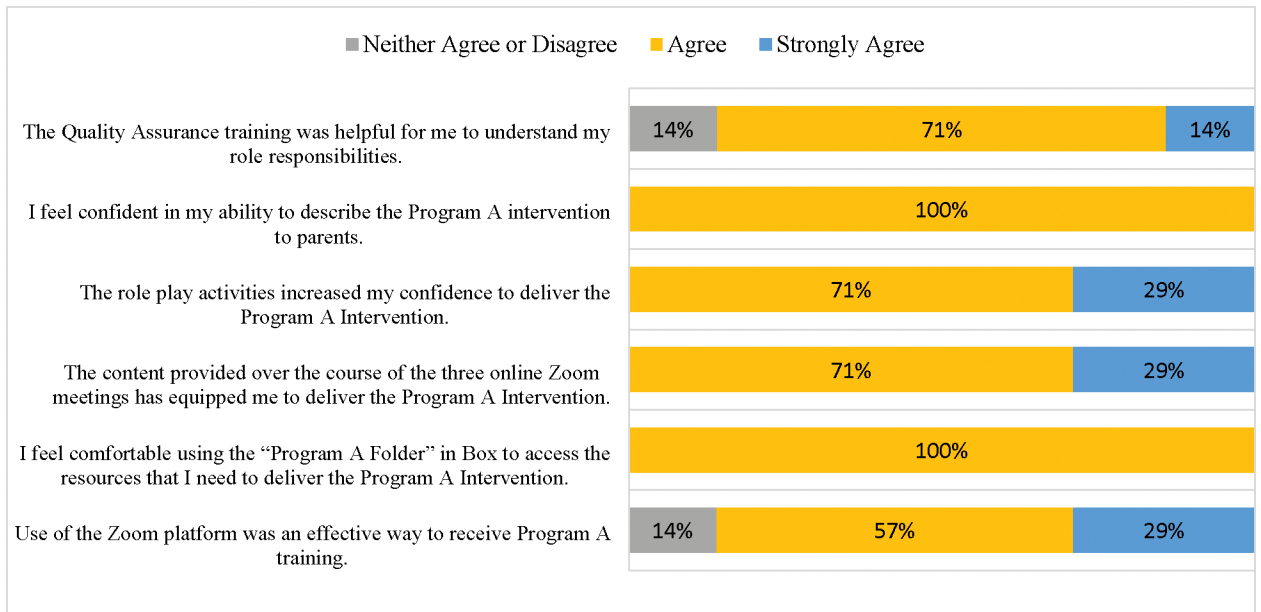


Figure 1.
IMPACT Trial: Program A Training Evaluation

Note. "Program A" is the attention control arm of the study. A total of 7 nurses/advance practice providers completed the survey. None of the respondents selected "Disagree" or "Strongly Disagree" for any of the items. All values do not add to 100% due to rounding on some items.

Table 1

IMPACT Trial Study Schema

Cluster Randomize Care Team Dyads	
Program A: Attention Control	Program B: IMPACT Intervention
Parent(s)/Child recruit, enroll, consent/assent post diagnosis or first relapse	Parent(s)/Child recruit, enroll, consent/assent post diagnosis or first relapse
T1: Baseline data prior to Session 1	T1: Baseline data prior to Session 1
Session 1: After T1 baseline data collection.	Session 1: After T1 baseline data collection.
Session 2: Approx. 1–4 mos. after Session 1	Session 2: Approx. 1–4 mos. after Session 1
Session 3: Approx. 1–4 mos. after Session 2	Session 3: Approx. 1–4 mos. after Session 2
T2: Post-intervention data approx. 1–3 weeks after Session 3	T2: Post-intervention data approx. 1–3 weeks after Session 3
T _F : Follow-up data approx. every 1–4 mos. after T2	T _F : Follow-up data approx. every 1–4 mos. after T2
T _{EOS} : Post-death or end-of-study	T _{EOS} : Post-death or end-of-study

Note. T=time point; F=follow-up; EOS=end of study; mos.=months