



Iterative development and pilot testing of an intervention fidelity monitoring plan for the enhanced, electronic health record-facilitated pragmatic clinical trial: Implications for training and protocol integrity

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ABSTRACT

Fidelity monitoring is the degree to which a clinical trial intervention is implemented as intended by a research protocol. Consistent implementation of research protocols supported with extant fidelity monitoring plans contribute rigor and validity of study results. Fidelity monitoring plans should be comprehensive yet practical to accommodate the realities of conducting research, particularly a pragmatic clinical trial, in dynamic settings with heterogeneous patient populations. The purposes of this paper are to describe the (1) iterative development and implementation of protocols for intervention fidelity monitoring, (2) pilot testing of the fidelity monitoring plan, (3) the identification of interventionist training deficiencies, and (4) opportunities to enhance protocol rigor for a cancer symptom management intervention delivered through the electronic health record patient portal and telephone as part of a complex, multi-component pragmatic clinical trial to uncover training deficits and bolster protocol integrity. The intervention focuses on prominent symptoms reported among medical oncology patients including sleep disturbance, pain, anxiety, depression, low energy (fatigue) and physical function. In this pragmatic trial, the role of interventionist is a registered nurse symptom care manager (RN SCM). A three-part fidelity monitoring plan with checklists audit: Part-1 RN SCM role training activities in research components, clinical training components, and protocol simulation training; Part-2 RN SCM adherence to the intervention core components delivered over the telephone; and Part-3 maintenance of adherence to core intervention components. The goal is $\geq 80\%$ adherence to components of each of the three checklists. An initial pilot test of the fidelity monitoring plan was conducted to evaluate the checklists and the RN SCM adherence to core protocol components. RN SCM skills and training deficits were identified during the pilot phase, as were opportunities to improve protocol integrity. Overall, approximately 50% of the audited RN SCM telephone calls had $\geq 80\%$ fidelity to the core components. There remains on-going need for RN SCM training and skill building in action planning. The content presented in this paper is intended to begin to fill the gap of fidelity monitoring plans for complex interventions tested in pragmatic clinical trials and delivered remotely in an effort to strengthen protocol integrity.

1. Introduction

Intervention fidelity monitoring is essential for the success of any

clinical trial. Broadly defined, fidelity monitoring is the degree to which an intervention was implemented as intended by the research protocol [1]. Fidelity monitoring plans ensure rigor of clinical trial protocols to

Abbreviations: EHR, Electronic health record; RN, Registered Nurse; SCM, Symptom Care Manager; E2C2, Enhanced Electronic Health Record-facilitated Cancer Symptom Control; SPADE, Sleep disturbance, Pain, Anxiety, Depression, Energy (fatigue); SMART, Specific-Measurable-Achievable-Relevant-Time limited.

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enhance confidence that the intervention was delivered as intended, especially when multiple interventionists are involved. Development and consistent implementation of research protocols and fidelity monitoring plans contribute to the internal validity (interpretation) and external validity (generalizability) of the study's findings [2]. The core of fidelity monitoring is developing clear protocols for intervention delivery (i.e., manuals), assessing adherence to key aspects of the research protocols, and intervening when adherence is inconsistent.

Healthcare interventions are increasingly delivered remotely via technology-based, tele-health and mobile application-based platforms. This increases patient access but presents a unique set of challenges for fidelity monitoring, including the way in which interventionists navigate protocols and the procedures for the auditor to observe intervention delivery for fidelity monitoring. The training, monitoring, and re-training of interventionists is essential to promote and ensure fidelity, rigor, and intervention validity regardless of the setting in which the research protocol is delivered. In the delivery of complex interventions in pragmatic trials (i.e., real world conditions), though, the need for fidelity is balanced against the need for practical and responsive implementation adaptations [3,4]. Regular review of protocol fidelity in these cases serves not only as a method of ensuring adherence to delivery of core intervention components but as an opportunity to identify the need for refinements. Attention to how the protocol is being implemented and on-going responsiveness to the needs of those involved is consistent with the intent of the pragmatic trial approach.

The purposes of this paper are to describe: (1) the iterative development and implementation of protocols for intervention fidelity monitoring, (2) pilot testing of the fidelity monitoring plan, (3) the identification of interventionist training deficiencies, and (4) opportunities to enhance protocol rigor for a cancer symptom management intervention delivered through the electronic health record (EHR) patient portal and telephone as part of a complex, multi-component pragmatic clinical trial. The intervention focuses on symptoms that are common among individuals with cancer including sleep disturbance, pain, anxiety, depression, and low energy (fatigue) (SPADE) as well as physical function. Background information is first presented on the parent pragmatic clinical trial and the role of the protocol interventionists.

2. Materials and methods

2.1. Parent clinical trial background and setting

The intervention and associated fidelity monitoring plan described here is a primary component of the Enhanced, EHR-facilitated Cancer Symptom Control (E2C2) Pragmatic Clinical Trial (UM1 CA233033, 09/21/2018–06/30/2023; A. Cheville, PI). The E2C2 clinical trial was funded under the National Cancer Institute funding opportunity announcement (RFA-CA-19-035) to facilitate implementation and evaluation of symptom monitoring and symptom management systems for persons with cancer and cancer survivors. The settings for the E2C2 clinical trial are the Mayo Clinic campus in Rochester, Minnesota (MN) and the Midwestern regions of Mayo Clinic facilities located in Southwest MN, Southeast MN, Northwest Wisconsin (WI) and Southwest WI.

The aims of this trial are to evaluate the effectiveness and implementation of a remotely delivered cancer symptom monitoring and management system that uses two empirically supported levels of care, based on patient-reported symptom questionnaires completed at home through the patient portal or at the time of an oncology appointment and captured in the EHR. Level 1 provides low-touch, automated, self-management support for patients reporting moderate SPADE symptoms or limitations in physical function (or both). Level 2 provides registered nurse-managed collaborative care for patients reporting more intense (severe) symptoms or functional limitations (or both). The intervention also includes EHR-embedded clinical decision support tools for care teams. Using a stepped-wedge design, disease-specific oncology

care teams are cluster randomized inclusive of clinician teams who care for medical oncology patients across all phases of cancer care in community care settings and clinics within an academic medical center. The overall goal of this trial is to provide evidence for the impact of the E2C2 intervention on the management of SPADE symptoms and functional limitations, as well as outcomes of healthcare utilization, adherence to cancer treatment, and survival. Details of the E2C2 protocol are published elsewhere [5].

2.2. E2C2 registered nurse symptom care manager role and competencies

The Registered Nurse Symptom Care Manager (RN SCM) is a unique role created for the purposes of this pragmatic trial. The RN SCM role combines research responsibilities with clinical nursing practice skills. RN SCM patient contact is accomplished remotely either via the electronic health record portal (messaging) or the telephone. Per the research protocol, the RN SCM serves as the interventionist providing support and resources to patients who report severe symptoms. Guideline concordant, evidence-based structured algorithms guide each patient interaction, along with nursing judgment integral to assessment and planning of care such as when to notify medical providers of an urgent patient development.

The RN SCM job description was based upon the role of a clinical RN within the division of medical oncology. It is preferred that candidates for the RN SCM role have clinical practice experience in the oncology setting, ability to work independently, excellent communication and teaching skills, as well as attention to details. As the E2C2 pragmatic trial is clinically focused, the RN SCM role reports up through the department of nursing, rather than a medical oncology research department. This approach has the benefit of ensuring that the RN SCM has a thorough understanding of the role and is fully integrated into the clinical practice. Further, there is immediate access to existing educational structures, course offerings, and training.

Training to the RN SCM role consists of educational requirements of the Department of Nursing as well as the research requirements of the institution and the funding agency supporting this pragmatic trial. For the research component of the RN SCM role, training was required in Good Clinical Practices and the Protection of Human Research Subjects.

2.3. Development of RN symptom care manager intervention protocols

Clear protocols are a necessary component for intervention research and for future replicability. The RN SCM symptom management protocols were developed by a group of multidisciplinary experts in oncology, palliative care and pain management, nursing, social work, psychiatry, physical therapy, and pharmacy. Algorithms were developed for each of the SPADE symptoms and physical function based on cancer care guidelines and most recent evidence base (e.g., American Society of Clinical Oncology and National Comprehensive Cancer Network guidelines). Algorithms were then reviewed by core members of the E2C2 research team, including the RN SCMs. Algorithms underwent several iterations to ensure they could be consistently and usefully implemented to guide symptom assessment and management by the RN SCMs during patient interactions. Details on the individual symptom management algorithms are available elsewhere [5].

2.4. Development of the fidelity monitoring plan for a complex intervention

E2C2 is a complex intervention (i.e., several interacting components, multiple behaviors targeted, and some tailoring allowed) [6] designed for use in heterogeneous cancer patient populations. The fidelity monitoring plan addresses delivery of the RN SCM component, which is the core of the collaborative care model. While RN SCMs are provided with evidence-based algorithms, they are also tasked with responding to unique patient needs across the cancer care trajectory and using their

own clinical experience and judgment. It is imperative that each RN SCM implement the protocol as intended. Likewise, it is necessary that the monitoring plan provides a way to assess fidelity to guideline-concordant treatment algorithms and the more dynamic process of engaging patients in conversations about symptoms. The development of a fidelity monitoring plan should consider (a) who will provide ratings on what aspects of fidelity; (b) at what frequency and at what intervals, with what mode of data collection; and, (c) with what standard of fidelity in mind [7]. Specifically for this pragmatic trial, these fidelity monitoring considerations were operationalized as (a) the role of the RN SCM with patients as audited by a PhD-prepared nurse co-investigator, (b) the recorded telephone interactions between the RN SCMs and medical oncology patients as the data sources, (c) frequency of auditing as described in each part of the monitoring plan, and (d) a standard of $\geq 80\%$ adherence to key components of the fidelity monitoring plan based on previous clinical trial experience [8]. Additional recommendations for fidelity monitoring plans include striving to achieve a balance between rigor and pragmatic value [9], which are dependent on the goals of a specific clinical trial. The latter recommendation was especially important in this pragmatic trial given the large volume of patients across heterogeneous medical oncology and community oncology settings.

The fidelity monitoring plan for the CONNECT primary palliative care clinical trial described by Robbins-Welty and colleagues [10] was selected as the model for the E2C2 fidelity monitoring plan based on similarities between the E2C2 and CONNECT RN interventionist roles. The CONNECT investigators developed and utilized a 3-part fidelity monitoring plan with accompanying checklists: (1) Part 1-Pre-intervention training and development, (2) Part 2-Monitoring protocol delivery, and (3) Part 3- Maintenance of protocol fidelity. Adapted from the CONNECT plan, the three parts of the E2C2 fidelity monitoring plan are described below.

2.4.1. E2C2 RN symptom care manager fidelity monitoring plan

2.4.1.1. Part 1: Pre-intervention training and development. The first part of the E2C2 fidelity monitoring plan is focused on training activities for any nurse recruited for the RN SCM role. This includes formal training in institutional research practices, such as human subjects training; review of the trial protocol, which provides a detailed overview of the study approach, the evidence behind the intervention, and the research methods; and attendance at training sessions developed for the clinical champions in each of the medical oncology trial settings. The objective is to ensure interventionists' *clinical work* can be reliably conducted in the context of a research study, and that the RN SCMs understand how their role fits within the larger E2C2 intervention. RN SCMs also visit clinical sites and get familiar with the operations of the clinical areas whose patients will be a part of the intervention.

Pre-E2C2 training and development is also focused on how to deliver core components of intervention delivery, e.g., EHR reports and patient education materials available for symptom management. Throughout orientation, the orientee engages in self-learning and self-audits in aspects of the research protocol, as well as role-specific functions including symptom assessment, EHR navigation, and portal interaction with patients. Orientees also receive training on how to interact with oncology care team members as part of the collaborative care model and how to access resources to promote patient engagement in symptom self-management.

Self-reported preparedness was assessed at the initiation of training and orientation, and then again at the completion of the training period (Table 1). Each orientee received the pre-questionnaire (Part 1) via email and completed it electronically. Each RN SCM reported on a scale of 1 (not well prepared) to 5 (very well prepared) how well prepared she/he felt in core aspects of the E2C2 protocol symptom management intervention prior to training and then again after training completion.

Table 1

RN SCM Perceived Pre-Post Training Preparedness Self-Assessment Ratings (N = 5) Directions: On a scale of 1–5 (1 = Not well prepared, 3 = Somewhat prepared, 5 = Very well prepared) how prepared do you feel you were/are to.

Question:	Mean (SD)
1. Establish rapport with a patient?	
Before the training?	3.6 (.55)
After the training?	4.2 (.44)
2. Explain your role as the RN Symptom Care Manager?	
Before the training?	3.2 (.83)
After the training?	4.2 (.44)
3. Focused review of patient's EHR prior to any interaction?	
Before the training?	3 (.77)
After the training?	3.6 (.55)
4. Assess patient views about his or her severe symptom(s)?	
Before the training?	2.6 (.55)
After the training?	3.8 (.44)
5. Assess what a patient has tried to manage a severe symptom(s)?	
Before the training?	2.8 (.83)
After the training?	4.2 (.44)
6. Provide emotional support?	
Before the training?	3.4 (.55)
After the training?	4.0 (.44)
7. Administer the appropriate instrument(s) to track symptom management of severe symptom(s)?	
Before the training?	2.8 (.83)
After the training?	3.4 (.89)
8. Appropriate triage to primary care team or more urgent treatment?	
Before the training?	2.6 (.89)
After the training?	3.8 (1.1)
9. Identify and assess symptom needs?	
Before the training?	2.8 (.44)
After the training?	3.8(1.1)
10. Help patients to focus on symptom goals?	
Before the training?	3.0(.7)
After the training?	3.8 (.83)
11. Consider patient's barrier(s) to symptom management?	
Before the training?	3 (.7)
After the training?	4 (.7)
Question:	Mean (SD)
12. Use focused assessment skills to address a patient's symptoms?	
Before the training?	2.8 (.44)
After the training?	4.2 (.44)
13. Complete a patient interaction log?	
Before the training?	2.6 (.54)
After the training?	3.6 (.89)
14. Use evidence-based symptom algorithm(s) to address severe symptom(s)?	
Before the training?	2.2 (.44)
After the training?	3.8(.83)
15. Help a patient to identify self-care resources?	
Before the training?	2.6(.54)
After the training?	4.2 (.44)
16. Elicit a patient's readiness to take action to engage in self-management of symptom(s)?	
Before the training?	2.8 (.44)
After the training?	3.8 (.83)
17. Comfort navigating portal and Epic environment?	
Before the training?	2.4(1.1)
After the training?	3.6(1.1)
18. Elicit patient's adherence to symptom management plan?	
Before the training?	2.6(.54)
After the training?	3.8(.83)
19. Elicit patient's utilization of recommended/provided self-management resources?	
Before the training?	2.8(.44)
After the training?	3.8(.83)
20. Help a patient to talk with his or her provider about severe symptoms?	
Before the training?	3(.71)
After the training?	4.2(.44)
21. Access and utilize resources to facilitate patient interactions?	
Before the training?	2.6(.55)
After the training?	3.6(.55)
22. Comfort with motivational interviewing?	
Before the training?	3(.71)
After the training?	3.6(1.5)
23. Take appropriate action for Red Flag patient symptom(s)?	
Before the training?	3(.71)
After the training?	4(.0)

(continued on next page)

Table 1 (continued)

Question:	Mean (SD)
24. Comfort with utilization of behavioral strategies to engage patient during remote interactions?	
Before the training?	2.8(1.1)
After the training?	3.75(.5)

COMMENTS:

Greatest challenge was learning the Epic environment, navigation, and documentation; no motivational interview training.

A comments section was included for the RN SCMs to convey input on areas that required further training or skill development ([Appendix A](#)).

2.4.1.2. Part 2: Monitoring protocol delivery. Part 2 of the E2C2 intervention fidelity monitoring plan is focused on the core elements being tested as conceptualized in the grant application and research protocol ([Appendix B](#)). The role of fidelity auditor is performed by a PhD-prepared nurse co-investigator. The sources of data being monitored are the recorded phone calls between patients and RN SCM adherence to delivery of core elements of the E2C2 intervention protocol.

The protocol fidelity monitoring checklist is used to ascertain whether the key components of the RN SCM interventionist role are adhered to during the patient phone call. A minimum of 10 recorded patient telephone calls per RN SCM are assessed for intervention protocol fidelity by the auditor. If $\geq 80\%$ adherence to the checklist items is achieved during monitoring of the first 10 RN SCM-patient interactions, then 10% of the subsequent individual RN SCM-patient interactions are monitored throughout the protocol implementation phase of E2C2. If $< 80\%$ adherence to the fidelity monitoring checklist items is realized during initial monitoring, feedback is provided to the RN SCM with suggestions to achieve target adherence. Then, another 10 interactions of recorded patient phone calls are monitored. Monitoring of any individual RN SCM continues until the desired goal of $\geq 80\%$ adherence to protocol intervention fidelity is achieved. Feedback and/or booster training in any aspect of the E2C2 intervention protocol to achieve the desired fidelity standard is provided by a member of the research team or an auditor to an individual RN SCM who may be deficient in one or more component(s) of the fidelity monitoring plan.

The core elements of fidelity monitoring contained in the Part-2 checklist are centrally focused on action planning, motivational interviewing techniques, behavior change principles, and framing of questions in an open-ended format to facilitate patient engagement in self-management as well as active participation in goal setting. Fidelity monitoring focuses on the RN symptom care management role and expectations for assessing symptoms by actively engaging patients to begin participation in and to take ownership for self-management of one or more SPADE symptoms or physical function. To facilitate patient engagement in symptom self-management, several resources are available. For example, to objectively measure physical activity with a verbalized goal to walk for 20 min three times per week, a patient may be provided a pedometer and an activity log. The activity log can be completed electronically or in paper format. An auditor will listen specifically for elements of active engagement such that each goal is based on each individual patient's preferences that are specific, measurable, achievable, personally relevant and time limited to foster empowerment and active engagement.

2.4.1.3. Part 3: Maintenance of protocol fidelity. Lastly, part 3 of the E2C2 fidelity monitoring plan focuses on each RN SCM's maintenance of adherence to core principles of the pragmatic trial intervention protocol over time ([Appendix C](#)). The data source remains the recorded telephone calls of each RN SCM's interactions with medical oncology patients as audited by one of the research team co-investigators. After an individual RN SCM attains and maintains $\geq 80\%$ adherence to the protocol components monitored in part-2 of the fidelity monitoring plan, fidelity

maintenance is conducted every 3 months with ten randomly selected recorded telephone calls by the respective auditor. More frequent fidelity maintenance monitoring is conducted if concerns are apparent and/or adherence drops below 80%. Identification of any E2C2 intervention component(s) requiring 'booster training' inform the development and implementation of a re-training plan. Re-training goals and timeline to achieve $\geq 80\%$ adherence to the protocol are mutually agreed upon.

3. Results

Between August 2019 and October 2020, five RN SCMs completed the pre-post self-assessment questionnaires. Between September 2019 and December 2020, approximately 20 recorded intervention calls per RN SCM were reviewed to inform our fidelity monitoring pilot test. Results for Part 1 and Part 2 of this test are reported below. Part 3-maintenance ([Appendix C](#)) is on-going and not reported here.

3.1. Part 1

RN SCM self-assessments prior to and after completion of training and orientation (Part 1) to this unique nursing role revealed low perceived preparedness and training gaps. Self-reported preparedness for the RN SCM role pre-protocol implementation ranged from a mean of 2.2 (not prepared) to 3.6 (somewhat prepared) ([Table 1](#)). The higher pre-training scores were reported for psychosocial skills of establishing rapport and providing emotional support to patients. Lower perceptions of role preparation were reported for specific aspects of the research protocol such as assessing and managing severe symptoms guided by the symptom algorithms. As summarized in [Table 1](#), the level of reported perceived preparation in the RN SCM role and functions increased across all essential training and core protocol areas after completion of orientation activities.

The self-assessment also illuminated gaps in the RN SCM role training. These identified gaps led to the development of additional training or other resources to facilitate each RN SCM to feel prepared to fully engage in the role. For example, information and resources for the immediate engagement of patients for developing individualized, specific action plans was notably absent. Motivational Interviewing was also identified as a training gap and was identified as one area for on-going skill acquisition. Simulation ([Appendix A](#)) has not been implemented as a core training component in orientation to the RN SCM role as it was not considered valuable.

3.2. Part 2

All RN SCM intervention calls were recorded with participant permission for quality assurance purposes inclusive of fidelity monitoring. The RN SCM protocol delivery intervention fidelity monitoring checklist (Part-2) represents several iterations and revisions over several months after the initial implementation of the E2C2 intervention protocol ([Appendix B](#)). As with any clinical trial, amendments were made to the protocol and the symptom algorithms based on early experiences implementing the research protocol. Adherence to protocol delivery was based on the protocol as written at the time of the recorded call.

During the first round of pilot testing, adherence to protocol delivery intervention fidelity components was consistently $< 80\%$ among the RN SCMs. However, the auditors noted several challenges related to how the E2C2 intervention delivery was designed, rather than skills deficits. The first challenge identified was that the patient telephone calls focused on and were prominently driven by the steps contained in each severe symptom algorithm. There was confusion among patients as to the role of the RN SCM with that of the primary medical oncology provider. Subsequently, the symptom algorithms used to guide telephone interactions with patients were revised to immediately and more explicitly highlight the specific role of the RN SCM from those of the medical

oncology care team. Other revisions to the symptom algorithms included streamlining protocols, consistent language among each of the SPADE/physical function symptom algorithms to promote patient engagement in action planning, and to reduce non-productive, lengthy telephone conversations.

Intervention fidelity monitoring also uncovered a critical issue in study procedures. It was discovered during telephone interactions with patients that many had not received or did not recall receiving baseline study materials (Mayo Clinic *My Guide to Cancer Symptoms*); a key resource for patients to engage in symptom self-management. This was due to a few factors, including receiving several mailings from Mayo Clinic or preference for receiving this important source of information in an electronic format. To remedy this issue, the protocol was amended so that RN SCMs query patients regarding the receipt of this essential symptom management material in telephone scripts and the Part-2 checklist.

Two main areas were identified for improving adherence to protocol delivery fidelity through a combination of RN SCM skill development and operational improvements: use of open-ended questions and skill development for action planning to promote patient-centered engagement in symptom management. Reminders to use open-ended questions to engage patients in symptom management were added to the Part-2 fidelity checklist. Specifically, conversation suggestions were added to the checklist to guide the RN SCM in patient-centered engagement for both symptom management and action planning. To engage patients and promote ownership for self-management, it is imperative that each patient identify which of the five SPADE symptoms or physical function is personally most salient or bothersome. It is vitally important that action planning commence during the first telephone contact to engage patients in symptom self-management. Unfortunately, action planning was absent early on during intervention protocol delivery. To remedy this gap, additional resources were provided to the RN SCMs for establishing individualized action plans during the first patient encounter. Tips and prompts were provided to guide the immediate development of specific-measurable-achievable-relevant-time limited (SMART) goals to empower patients to begin symptom self-management and to track symptom improvement over time.

The second round of pilot testing adherence to protocol delivery intervention fidelity revealed improvements and areas for further development. With the streamlining of the respective symptom algorithms and a consistent approach to guide the patient interaction has brought clarity to the RN SCM role. These improvements immediately place the focus of the phone call on the RN SCM's role to assess one severe symptom at a time and work with the individual patient to establish goals.

Approximately 50% of the recorded RN SCM-patient phone call interactions contain elements of action planning and simple SMART goals to guide engagement in self-management. The auditors have held video meetings with the RN SCMs reviewing the key components of action planning and goal setting. Emphasis is also placed on returning feedback to the respective RN SCM after each batch of 10 audited calls has been completed. On-going work and strategies to strengthen skills in goal setting, motivational interviewing and action planning are underway. Plans include role play to build skills and confidence in action planning.

4. Discussion

Despite the growth of technology-based healthcare interventions, few trials report intervention fidelity protocols, or the adherence to fidelity protocols [11], limiting assessment of intervention validity. There is an even greater paucity of literature reporting the fidelity of pragmatic trials that assess the remote delivery of complex interventions. The aim of this paper was to begin to fill these gaps by reporting how this study team developed, tested, and iteratively refined a fidelity monitoring plan for a remote, EHR-delivered intervention deployed with heterogeneous cancer patient populations in a pragmatic clinical trial, as well

as training of interventionists.

The overall goal of any intervention fidelity monitoring plan is to maintain scientific rigor yet be pragmatic in implementation. Our experience suggests challenges in several key areas, but it also highlights the benefits of incorporating assessment and feedback into the monitoring plan in order to refine the intervention and its implementation in practice. First, the RN SCMs utilize evidence-based symptom management algorithms to help patients develop a plan for managing their symptoms. Monitoring fidelity of an intervention that incorporates multiple symptom management algorithms that change over time has been a challenge. Iterative revisions to the fidelity monitoring checklists have been necessary based on changes to the algorithms and through pilot testing of the fidelity monitoring plan. Feedback and experiences from members of the research team and the RN SCMs have greatly informed this pragmatic trial's fidelity monitoring checklists and fidelity monitoring plan. Together, iterative pilot testing and revisions with the fidelity monitoring plan have contributed to research protocol integrity by streamlining telephone scripts to avoid lengthy, unfocused interactions with patients. Further, protocol enhancements have resulted in contributions to rigor and integrity of the pragmatic trial intervention.

Second, according to the intervention protocol, during interactions between patients and RN SCMs, the focus of the conversation is on one severe symptom, although patients may have multiple severe symptoms. To provide flexibility in addressing patient needs and reduce deviation from the symptom(s) of focus, changes to the protocol were made to allow for focus on one primary symptom and another secondary symptom during patient interactions. The Part-2 protocol fidelity monitoring checklist can be used as a prompt or guide for the RN SCM to focus on the most bothersome, severe symptom first while acknowledging a patient's additional symptom(s).

Length of interactions between patients and RN SCM's vary significantly but are guided by the patient's individual needs. Patients have important information to share about their cancer treatment and symptom experience; those conversations can be lengthy, and the patients' experiences often do not fit neatly into a set algorithm. Listening carefully to these messages is an important, albeit time consuming, component of establishing trust and rapport. Establishing initial rapport is critical for a continued patient-nurse relationship, and some patients need time to feel heard and validated. Often, the patient will bring up other important information in the discussion that enhances understanding of the patient and their symptoms that enhances the RN SCM's ability to develop an individualized treatment plan. The importance of active listening and allowing the patient to tell her/his story must be balanced with clinical demands and available resources, which can be a challenge in any setting. They may also need to be balanced with the cost of intervention delivery. Although oncology nurses are typically involved in symptom management, the RN SCM is a relatively new role focused on empowering patients to participate in symptom management to improve quality of life.

Engaging the RN SCM interventionists in fidelity monitoring during the role training phase proved to be beneficial. Completion of training and skill self-assessment revealed important deficits in motivational interviewing and action planning. We continue to work on ways to engage RN SCMs more directly in fidelity monitoring and in skill building to enhance their confidence in performance of the important E2C2 interventionist role.

Finally, there are challenges with deploying and assessing interventions like this, which are related to patient self-efficacy or acceptability. Not all patients are comfortable using the patient portal, have reliable internet access, or a device to complete the ePRO assessments, which may result in missing data and/or lack of receipt of educational materials. A recent article on intervention fidelity with technology-based interventions evaluated whether the interventionist ensured that all received information was clear and understood [12]. Our evaluation includes an assessment of whether patients can

summarize goals that are mutually set during the telephone interaction. However, additional evaluation of whether patients are able to access, understand, and apply information received through the portal would enhance fidelity monitoring and may be considered in future checklist revisions. Likewise, not all patients are ready or able to engage in self-management strategies [13] or action planning. Patient activation is one key factor in whether people engage in recommended strategies and can change behavior over time [14]. Assessing patient activation may further inform overall fidelity to intervention protocols designed to promote symptom self-management.

4.1. Limitations

The following limitations of our fidelity monitoring plan and checklists have been identified. First, our 3-part fidelity monitoring checklists are limited to key E2C2 components delivered by the RN SCMs as defined by the parent grant’s specific aims. The fidelity auditors provide summary feedback on monitoring results to the RN SCMs. The auditors do not contribute to the RN SCMs job performance or annual review, which is the responsibility of the clinical supervisor. Secondly, for those patients who are struggling with symptom management, the RN SCMs may make referrals to other professionals such as social workers or health coaches. As such, fidelity monitoring is not completed on these supplemental roles to improve outcomes for individuals undergoing cancer treatment or cancer survivors. Methods for assessing patient participation in self-management strategies recommended through written information and during virtual interactions would strengthen the fidelity monitoring plan [15]. Lastly, the impact of the global COVID-19 pandemic is evident. It is difficult to separate the impact of pandemic angst from a patient’s willingness to engage with the RN SCM in self-management of SPADE symptoms/physical function

and action planning to achieve adherence with the fidelity monitoring plan goals.

4.2. Summary and conclusions

The content presented in this paper is intended to begin to fill the gap in the absence of fidelity monitoring plans reported in the literature, specifically for fidelity monitoring of complex interventions tested in pragmatic clinical trials delivered in a remote or virtual format. Careful attention to the dynamic nature of pragmatic clinical trials resulted in several iterations of the fidelity monitoring plan reported here, requiring adaptation to changes from both the interventionists and the auditors.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Part 1-RN Symptom Care Manager (RN SCM) Pre-E2C2 Training and Simulation Activities

Research and Clinical Training	Yes	No	Comments
Complete CITI and GCP training			
Review E2C2 Research Protocol			
Symptom Sage Training attendance			Specify:
Completion Dept. of Nursing Orientation (as applicable)			
Completion of structured orientation curriculum			
Motivational Interviewing training			
Self-management education resources			
E2C2 Participating Sites visits			Specify:
Clinical shadowing			Specify:
Grand Rounds attendance			Specify:
Other			Specify:
E2C2 Simulation Training			
Cancer symptom self-management materials received by all patients			
Contacts patient in a timely manner based on symptom alert(s)			
Utilizes 4 question script to guide patient greeting for symptom ≥ 7			
Correctly implements RN SCM protocols and algorithms			
Care team alert for severe and/or persistent symptoms			
Correctly identifies “Red Flag” symptoms			
Orders appropriate questionnaire series for algorithm			
Follow-up in 4 weeks if patient desires			
Accesses and utilizes patient-specific resources			
Refers patient to site-specific resources			

Appendix B. Part-2 RN Symptom Care Manager (RN SCM) Protocol Delivery Intervention Fidelity Monitoring

Level 1 Self-management (all medical oncology patients)	Yes	No	Comments
Inquires if patient received <i>My Guide to Cancer Symptoms</i> education materials			
LEVEL 2: Severe Symptom(s) ≥ 7			
Identifies self & reason for phone call by referencing severe SPADE-specific symptom(s) reported by patient ≥7			Specify symptom:

(continued on next page)

(continued)

Level 1 Self-management (all medical oncology patients)	Yes	No	Comments
Identifies one severe SPADE symptom to focus on at a time Implements standardized algorithm script for each ≥7 SPADE symptom			<i>Which symptom would you like to work on? Which symptom can I help you with today?</i> Utilizes specific, needs- and preference-matched components of the symptom algorithm
Screens for presence of reported “Red flag” symptoms (pain, physical function) and follows contact hierarchy (ED, E2C2 MD, Care Team) Discusses next steps and follow-up plan with patient & primary Care Team or E2C2 physician Implements RN SCM protocol & algorithms for each symptom (a–i) a) Utilizes motivational interviewing and positive reinforcement to elicit patient responses b) Solicits cooperation to develop and document Action Plan for symptom management. Refer to MC4119–20 c) Queries patient’s values; recommends specific, needs- and preference-matched components of a Symptom Toolkit as part of Action Plan d) Utilizes Patient Resources link on E2C2 intranet site What’s Important to you? Setting Goals & Making Changes . Refer to MC7638PFrev1117 e) Uses “Teach Back” with patient to review Action Plan content and goal(s) f) Verbally summarizes conversation with patient including a portal message and steps patient will take to engage with Action Plan			Specify: Records Red Flag symptom(s) follow-up/resolution plan Uses open-ended questions as much as possible <i>I would like to assist you with _____ today. I have several resources I can suggest to help you manage ___ symptom.</i> Action Plan consists of specific and measurable simple goal(s) Refer to “How to self-manage” supplemental document SMART Goals: S-Specific, M-Measurable, A-Achievable, R-Relevant, T-Time-limited E.g.: “Today we discussed you will omit any caffeinated beverages after 1pm each day for the next week. Each morning you will record sleep quality on your log. You will let me know how you are doing with this plan.”
Level 2 Continued g-i g) Conveys date to patient for discussion at Care Management conference h) Encourages patient to monitor/track own results from Brief Symptom & Function scores by suggesting a specific resource i) Conveys to patient 1-week follow-up communication with a Follow-up questionnaire(s) for each severe symptom via portal or phone call	YES	NO	Cancer Symptom & Function Log [Refer to MC4119-17] Portal-based Symptom Tracker available on E2C2 intranet site
Follow-up Patient Phone Call Improvement of symptom(s)? Revise Action Plan as needed. Ascertain content and frequency patient utilizes symptom toolkit content. If not utilizing symptom toolkit, encourage with specific goal. Queries patient if keeping own <i>symptom management log</i> . Encourage keeping own symptom log. Consider referral to Health Coach for complex behavioral change and/or patient with low self-confidence to implement (fatigue, physical function, sleep) Follow-up phone call or portal message at 4-weeks if patient desires ; Review Action Plan ; revise as needed	YES	NO	Use of positive reinforcement. Action Plan goal(s) specific, measurable, and individualized Positive reinforcement. Encourage utilization of a symptom management log in portal or own copy. Refer to h above. Describe specific action and follow-up plan: Specify if patient desires follow-up and when. Use of positive reinforcement.
Delivery of protocol content inconsistent with principles of the intervention or outside the scope of the intervention.			

Comments:

Appendix C. Part 3-RN Symptom Care Manager (RN SCM) E2C2 Protocol Intervention Fidelity Maintenance

Level 1 Self-management (all patients)	Yes	No	Comments
Patient received <i>My Guide to Cancer Symptoms</i> education booklet Patient preferred communication mode identified Monthly SPADE symptom & function assessments pushed through portal			Specify: electronic, telephone, remote, other?
LEVEL 2: Severe Symptom(s) ≥ 7 Only Identify symptom needs using open-ended questions Other:			
E2C2 Re-Training <i>Specify:</i>			
E2C2 Component Booster Training <i>Specify:</i>			
Discuss next steps with RN SCM			
Delivery of content inconsistent with principles of the intervention/outside the scope of the intervention.			

Comments:

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