BRIEF REPORT

Implementing motivational interviewing to improve endocrine therapy adherence among breast cancer patients: a qualitative process evaluation of the getset pilot intervention

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Abstract

Background This study evaluates the implementation of the GETSET (Guiding Endocrine Therapy Success through Empowerment and Teamwork) pilot, a motivational interviewing (MI) intervention aimed at improving endocrine therapy (ET) adherence among patients with breast cancer.

Methods Using the Consolidated Framework for Implementation Research (CFIR), qualitative interviews were conducted with site staff ($N=2$), patients ($N=4$), and counselors ($N=2$).

Results The thematic analysis identified facilitators such as high-quality materials, ease of scheduling sessions, and effective communication among staff. However, barriers included lack of personalization and systemic issues like understaffing.

Conclusions The study underscores the need to adapt implementation of behavioral interventions in a healthcare setting to improve ET adherence. As this was a process evaluation of a pilot study, future work should evaluate the barriers and facilitators to a larger clinical trial to identify if the same strategies should be refined.

Keywords Process evaluation · Endocrine therapy · Medication adherence · Interviews

Introduction

Hormone receptor positive (HR +) breast cancer is the most common form of breast cancer, with a generally favorable prognosis but a long possible time course of recurrence and a lengthy duration of treatment [1]. Following surgery, and in some cases, chemotherapy and radiation therapy, oral endocrine therapies (ET) such as tamoxifen or aromatase inhibitors (AI), are prescribed for 5–10 years due to their significant benefits in reducing recurrence and death [2, 3]. Yet, ET is commonly underutilized. Utilization is defined as non-initiation, non-adherence, or non-persistence of ET [4–8].

Underutilization of ET is associated with several factors. Multiple studies have identified a higher risk of ET non-adherence among Black women [2, 5, 6, 9–11]. The reasons for this disparity have been identified at multiple levels, including systemic, clinical, interpersonal, and intrapersonal [12]. In addition, medical mistrust resulting from historical events including the Tuskegee Syphilis Study, reduces trust in the healthcare system, thereby reducing adherence among Black women [10, 13]. Communication has also been linked to lack of adherence, as Black women more commonly report that their informational needs are not met compared to White women [11].

Clinical and behavioral barriers have also been identified as reasons for under-utilization across patients using ET. A systematic review noted that the side effects of ET are often strongly associated with its use, including body image and sexual concerns [14, 15]. Lack of perceived benefit of the drug has also been shown to be related to reduce ET

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adherence [16]. While it is important for research to address the systemic and interpersonal factors of ET utilization including access to care and patient–provider communication, the goal of the present study is to evaluate strategies patients can use now to improve their adherence and reduce recurrence, rather than focus on utilization more globally. Behavioral interventions that address patient-level barriers to ET adherence are needed.

Our team recently published the findings of a pilot study (GETSET—*Guiding Endocrine Therapy Success through Empowerment and Teamwork*), testing a behavioral intervention using motivational interviewing (MI) to improve ET adherence [17]. MI is an individualized and patient-centered counseling intervention that promotes health behavior change and has been successful in other medication adherence contexts [18–24]. It may be well-suited to address the contributors to ET non-adherence, so an evaluation on the barriers and facilitators to using MI is needed. Here, we report data from a process evaluation of GETSET, the goal of which was to better understand the implementation of GETSET using qualitative interviews from site staff, counselors, and patients who participated in the pilot study. Findings from this analysis can inform the development of implementation strategies for future population-based Motivation Interviewing (MI) intervention studies aimed at promoting medication adherence among patients with cancer from diverse backgrounds.

Methods

The GETSET pilot

GETSET is an MI intervention to improve ET adherence among breast cancer patients that was implemented through the University of North Carolina's Cancer Care Network. This intervention consisted of a total of 5 sessions with a counselor over 6 months, with the first session conducted in-person (i.e., 60–90 min) and the subsequent 4 conducted over the telephone (i.e., 30–60 min). Counselors were study personnel (e.g., research assistant and study coordinator) who were trained through a 2-day MI workshop. Counselors used an interview guide to direct sessions and patients used a corresponding workbook to aid them through sessions. Patients also had access to an educational video developed with patient and clinician input. These sessions included person-centered goal setting, identifying support networks and strategies, and others described in our previous work [17]. The GETSET pilot intervention was conducted between 2016 and 2018. Forty-six patients consented to participate, with 35 reaching the target of at least three (out of five) MI sessions. Overall, majority of participants reflected high feasibility and acceptability in using the intervention [17].

Additional information on the GETSET pilot study design and outcomes, including the patient workbooks and counselor guides for MI sessions, are described elsewhere [17]. All study procedures were approved by the UNC Institutional Review Board (IRB# 13-0736).

Interview guide development

To capture the perceptions of GETSET implementation among implementing staff and patients, semi-structured interview guides were developed by a multi-disciplinary team of health services researchers, oncologists, and behavioral scientists. The interview guides used the Consolidated Framework for Implementation Research (CFIR) 1.0 [25], and were tailored to include relevant questions based on the interview participant's role (patient, site staff, or counselor). CFIR was chosen as it is one of the most commonly utilized comprehensive multilevel implementation determinants frameworks [25]. It has been used widely, and there are also a multitude of resources and materials that allow researchers to categorize and label qualitative responses into themes [26, 27]. Our interview guide and codebook were developed in part using the CFIR interview guide tool accessible on the CFIR website, which comprises 39 constructs under 5 domains of implementation: intervention characteristics, outer setting, inner setting, individual characteristics, and process (Supplementary Material 1) [25]. Each of these domains focuses on a specific aspect of implementation: (1) the quality, complexity, and adaptability of the characteristics of the intervention itself (i.e., **intervention characteristics**), (2) the environment and external context of the organization implementing the intervention (i.e., **outer setting**), (3) the active moving system of communication and culture within the organization (i.e., **inner setting**), (4) the interplay and behaviors of those implementing the intervention (i.e., **individual characteristics**), and (5) planning, engaging, executing, and reflecting on the process of implementation (i.e., **process**) [16]. Not all questions were asked to interviewees, as interviewers focused on questions relevant to the individuals' experience. For example, patients were not asked about settings or structure of the implementation site.

Process evaluation recruitment and data collection

After completing the GETSET pilot, key team members conducted qualitative interviews to understand the implementation determinants of the GETSET pilot. Three groups of individuals were recruited: GETSET site staff who were most involved in recruitment at the site ($N=2$), patients who received the GETSET intervention ($N=4$, P1 & P2: White, Non-Hispanic; P3: Black/African American, Non-Hispanic; P4: Black/African American, Non-Hispanic), and all counselors in the pilot who delivered the GETSET interventions

(N = 2). All 46 patients from the pilot were contacted, but only 4 responded to indicate interest in an additional follow-up interview. Patients who indicated interest in the additional interview were re-consented using an IRB-approved addendum to the original intervention consent form. Site staff were not consented as the interviews were deemed non-human subjects research by the UNC IRB. Site staff was a broader category that included staff from the local sites who aided in implementation, including UNC healthcare leadership. These individuals were those that were most involved in patient recruitment. Counselors were not local site staff but were intentionally part of the research team to enhance neutrality.

Site staff and counselor interviews were conducted by JS and SD, were on average 30 min, and were conducted 3 months post-intervention in October 2018. Patient interviews were conducted by CS and SD 10 months post intervention, were completed by May 2019, and on average lasted 20 min. All interviews were semi-structured, which allowed for further probing of relevant questions. These interviews were conducted over the phone and audio recorded. An established transcription service company transcribed interviews immediately upon completion.

Qualitative analysis

Qualitative data were coded and analyzed using a deductive thematic analysis approach in Dedoose [21]. The deductive codebook was informed by the CFIR domains and subdomains. The CFIR qualitative rating methods were used to rate agreement with CFIR determinants across participant types (i.e., site staff, counselors, intervention recipients).[27] To maximize the reliability of how codes were applied, one transcript from each participant type was chosen and double coded by SD, VD, and CE. Coding of each double-coded transcript was then reviewed by the coders for consensus and codebook fit. No tiebreakers were used, and consensus was defined as unanimous agreement on each coding decision. During the consensus process, the codebook and associated definitions were altered to better fit the data and produce reliability between coders. Once the codebook was finalized, the remaining transcripts were divided among coders and coded.

Results

A total of N = 8 interviews were conducted with site staff (SS), counselors (C), and patients who took part in the GETSET pilot. Qualitative analysis revealed implementation barriers and facilitators across 10 sub-domains of CFIR. Each is summarized and Table 1 includes illustrative quotes from each theme.

Relative advantage, ease of use, and quality of GETSET

When interviewees were asked about how GETSET compared to other interventions, most indicated that other adherence interventions were not personalized or that this had not been done in their clinic before.

SS2: *"I've never really done medication adherence. I know that it can be a difficult aspect just because sometimes patients forget. Even I forget to take my own medicines."*

C1: *"I think endocrine-therapy adherence in a clinical setting is really just 'here's some information about how you can deal with side effects' … but it's not personalized to each patient at all."*

The ease of using GETSET was discussed among patients, particularly regarding scheduling phone calls and meetings with the counselor. P1: *"We scheduled [the session] ahead of time and it could be rescheduled … it was not a problem"*.

Counselors also noted that, despite the initial adjustment period in understanding the counseling structure, they found it easy to administer. C1: *"from my standpoint as a counselor it was pretty straightforward, and it followed a very nice pattern each time that allowed me to know what to expect and [patients] to know what to expect."*

Counselors noted the quality of intervention supplements, including the informational video, but did have suggestions for improvement. C2: *"It wasn't just a video that was slapped together … It was speaking to the women's experience."* *"(patients) would have liked to have seen some younger women … around the ages of 30 and 40 represented."*

Lack of GETSET adaptability

Counselors noted that the guides used for MI sessions were not personalized to patients, and patients suggested flexibility in the interview process.

P2: *"I think some flexibility in the interview process or in the intervention based on need … maybe not going on as long or being more focused so you're not going through all of this with them …That it's modified depending on the time."*

C1: *"the counseling guides [were] not written in a way that were—made them always really relevant for every patient."*

Relational connections and implementation climate within healthcare facilities

Counselors noted how communication among staff helped with improving continuity and quality of MI.

C2: *"Being realistic in terms of when we needed to increase our [counseling] staff in order to accommodate …*

Table 1 Qualitative themes and illustrative quotes of applicable CFIR domains

CFIR Domains	Sub-Domains	Illustrative quotes	
		Barriers	Facilitators
Innovation characteristics	Relative Advantage		P3: "being informed is an awesome thing. Even though you think you know everything … it was good to have that book."
	Complexity		SS2: "It didn't require much on our sides. … It wasn't too time consuming or problematic for me"
	Design Quality and Packaging		P3: "I grew up in the era where we had books. We could write. We could turn pages. We could fold pages down. That's what I did with that book."
	Adaptability	P3: "The only thing I would change about that book is those resources. Make sure they're within the vicinity of a person that's able to get there. … If the resources are not locally available, they shouldn't be in there. I know that would be that you'd have to write a book for every locale, but maybe that would be a need to put the resources in the area."	P4: "… everybody was accommodating. They did adapt to my needs, I gather that's answering that question, because the staff met up with me when I had an appointment, they came to my room"
Inner setting	Structural Characteristics	SS4: "we don't have enough staff, and so trying to get studies to move forward efficiently, and get to just the starting point, that process can often drag on way too long. In part, it's because it roadblocks with me sometimes, because I'm diluted in doing too many different things."	C1: "I felt like [we] all had a [really] positive relationship and a really productive working relationship. We stayed in contact with each other on a very regular basis. We had weekly meetings and updates on how things were going."
	Relational Connections		C2: "[Implementers were] willing and open to listen to insights that I was gathering as I was going through the process from "soup to nuts" of training, all the way through to my last counseling session"
Process	Engaging	C1: "our quote/unquote recruitment material, or advertisement of some sort, might've been helpful. Because it is a lot to process, and people have to think about whether it would be something that might be helpful for them"	
	Executing	SS3: "I mean, one person having to do all the sessions for one study, I think is gonna cause a scheduling issue"	P4: "everything at the time was as beneficial as it coulda been. I think the program at the time was geared to give me information, give me resources, give me the opportunity to ask questions. I did appreciate the program for that."
	Reflecting and Evaluating	C2: "Traditionally, counseling sessions, especially when you're dealing with an acute issue—you're usually seeing someone once a week, maybe every other week—so remembering to do something once a month can be difficult"	C2: "seeing how their insight and their experience could help to make adaptations and just giving you some insight in terms of what they [think] about as it currently stands … would be really great."

P Patient; *SS* Site Staff; *C* Counselor; *MI* Motivational Interviewing

so that there could be some continuity in terms of the quality and the integrity of the intervention itself by providing ample trainings and feedback sessions and things of that sort. Also, having a lot of time to communicate with the [counselor] team ….”

Additionally, interviewees noted that because clinical leadership was engaged in the implementation process, providers perceived GETSET as compatible with their structure, which reduced barriers to knowledge about the intervention and resulted in smoother implementation.

SS1: *“Our physicians here were very behind it. They thought it was a great thing to support these women through their first year. Usually, if you can get them through their first year, to be more adherent, and more aware of the importance of taking this medicine, they'll take it long-term. They were very much in favor of it.”*

Structural characteristics of implementation setting

Counselors and staff noted that pre-established communication channels and note-taking were helpful in making implementation efficient.

SS4: *“we have the infrastructure set up to make sure that we don't have surprises in that everybody knows who's taking care of which patient.”*

However, one staff member noted that under-staffing could be a future barrier that might hinder initiating GETSET.

SS4: *“we don't have enough staff, and so trying to get [GETSET] to move forward efficiently, and get to just the starting point, that process can often drag on way too long. In part, it's because it roadblocks with me sometimes, because I'm diluted in doing too many different things.”*

Engaging patients

When engaging patients, counselors noted that advertisements would be helpful to recruit patients to the intervention for future implementation of this intervention in other settings.

C1: *“advertisement of some sort, might've been helpful. Because it is a lot to process, and people have to think about whether it would be something that might be helpful for them.”*

Executing GETSET

Patients noted that having access to resources and materials, including the GETSET workbook designed for patient use, helped them complete the GETSET program.

P3: *“I would read through the material. I would write down some of the things that [MI] would call for. It really caused me to think about my priorities because there are*

sections in there where you had to prioritize things happening in your life.”

Counselors felt that GETSET was implemented according to plan but noted that keeping the plan flexible would be helpful for future use.

C2: *“it seems like we were definitely following our plan and stuck to that. Adaptations were necessary based on feedback from the clinic. Administrators were necessary related to the physicians and their insight on a particular patient, who had difficulties or challenges, where we may have needed to either delay the recruitment or wait to start their counseling or continue their counseling.”*

Reflecting on and evaluating GETSET

Counselors and site staff noted that the overall implementation of GETSET was successful. While site staff noted short positive statements (*“it worked well”*), counselors did have suggestions for improvements (see Table 1). One counselor did, however, note that feedback from patients aided in the implementation process:

C2: *“seeing how [the patient's] insight and their experience could help to make adaptations and just giving you some insight in terms of what [the patient] [thinks] about as it currently stands … would be really great.”*

Discussion

This analysis examines the facilitators and barriers to implementing MI (GETSET) to improve ET adherence among breast cancer survivors. To our knowledge, this is the first CFIR-based analysis of MI implementation focused on cancer medication adherence, and incorporating the patients' perspective, which is often excluded from similar evaluations.

Facilitators to Implementation

Interviews identified multiple facilitators to implementing GETSET. Namely, we found that our intervention addressed an area of support that is lacking: improving ET adherence. Facilitators also included advertisements, maintaining high quality materials and ensuring ease of use, as well as establishing good communication lines throughout the organization.

These facilitators are consistent with other studies. One evaluation of implementing a behavioral intervention to improve exercise and nutrition among adolescent and young adult cancer survivors found that access to high quality tools and resources aid in creating a healthy lifestyle [28]. Other medication adherence studies showed that improving patient

knowledge and having a supportive system facilitates implementation and improves treatment adherence [29].

Previous work has also shown that not having good lines of communication established can hurt intervention implementation. One scoping review found that when implementing medication adherence interventions, lack of communication was essential in facilitation [30]. In addition, a very complex intervention design can also be a barrier [29]. Our study found that ease of use is a facilitator when properly addressed. These studies showed that by addressing factors previously identified as barriers, they can become facilitators in the implementation of medication adherence interventions.

Barriers to implementation

Barriers to implementation were also identified. Specifically, clinic understaffing, lack of GETSET guide adaptability, and lack of interview flexibility were identified. There is an opportunity in MI to not increase the hours spent by overworked staff, as it can be administered by any appropriately trained staff member and does not require clinical training [31]. Our interviewees also noted barriers that, if addressed, would be facilitators to implementation. Particularly, improving flexibility of GETSET (e.g., choice of topics, frequency of contacts, and timing) could help overcome individual-specific barriers as seen in other studies [30].

Limitations and future directions

While our interviews identified critical themes to implementation, we also acknowledge some limitations.

First, CFIR 2.0 was published after completion of this manuscript and includes an updated structure with new domains of implementation evaluation, including the patient's perceived effectiveness of the intervention [26]. Our study focused on the patients' interpretations of implementation, as suggested by CFIR 1.0 [25].

Second, this study was conducted within one healthcare system that included an academic hospital and five community hospital clinics, and therefore, its generalizability may be limited. Future work should investigate using MI to improve medication adherence nationwide and conduct process evaluations of implementation at multiple healthcare institutions.

Third, as this was a smaller pilot study, only 8 interviewees participated, and patients were interviewed more than 10 months following study participation. This could impact the accuracy and saturation of information and could limit comparisons of responses by role. Researchers should also investigate how the diversity in implementation staff or counselors may impact these processes as well, as this was not collected in our study. Future work

should interview more key participants in a closer range of time to increase saturation and evaluate the differences and similarities in the responses.

Conclusions

This process evaluation suggests that the engaging patients with advertisements, maintaining high quality materials and ensuring ease of use, as well as establishing good communication lines throughout the organization are facilitators in implementing GETSET in a healthcare setting. Areas identified for improvement in implementing GETSET were understaffing in the clinic, lack of adaptability in making the GETSET guides relevant to each patient, and lack of flexibility in the interviews themselves. This study supports implementing and evaluating MI on a wider scale by considering the barriers and facilitators to using MI to improve ET adherence. Future interventions should ensure that the intervention design maintains its appeal and assess if the implementation setting has strong communication lines. In addition, these evaluations should use CFIR 2.0 to capture the patients' perspective of effectiveness. Overall, this study supports the notion that strong implementation structures are needed to effectively deliver patient-centered behavioral interventions, such as MI, to improve ET adherence.

Declarations

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