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**Cancer-Related Fatigue: Referral to Physical Therapy as a Collaborative Treatment
Approach**

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In partial fulfillment of the requirements for the Doctor of Nursing Practice Degree

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Abstract

Purpose

The purpose of this project was to determine if referral of patients with cancer-related fatigue to physical therapy as an intervention would improve patient fatigue levels and quality of life, and to develop and implement a change in policy and procedure within a select healthcare system for health care providers to adequately address cancer-related fatigue.

Background

Cancer-related fatigue is one of the most commonly reported symptoms among individuals diagnosed with cancer and is often exacerbated by cancer treatment; however, cancer-related fatigue remains undertreated despite the negative impact it has on quality of life (Thong et al., 2020; Gerber, 2016). With the number of individuals being diagnosed with cancer and death rates from cancer declining, it is imperative cancer-related fatigue is adequately assessed and treated.

Methods

To gather additional supporting evidence and using a pre- and post-intervention survey design, adults diagnosed with cancer and cancer-related fatigue were recruited from outpatient oncology clinics affiliated with a large healthcare system in Atlanta, Georgia. Self-reported fatigue and quality of life were assessed pre and post participant completion of 4-6 weeks of physical therapy prescribed for the treatment of fatigue. Strategies to improve health care provider assessment and treatment of cancer-related fatigue were outlined including the implementation of a computer-based work rule engine to be integrated into the EHR system to

increase compliance of providers in addressing cancer-related fatigue. Steps to achieve a system-wide change in policy and procedure related to the assessment and treatment of cancer-related fatigue also were outlined.

Significance

Three participants completed the initial study for the project. Due to a small sample size, analysis of data was limited. Trends in results suggest a decrease in fatigue levels and increase in quality of life of participants who complete 4-6 weeks of physical therapy for cancer-related fatigue.

Conclusion

Referring patients to physical therapy as a treatment plan for cancer-related fatigue may be an effective and efficient way to improve this symptom and positively impact patient quality of life. Implementing a system-wide change in current policy and procedure could simplify the process of assessment and treatment of cancer-related fatigue and increase health care provider compliance in addressing this debilitating symptom.

Keywords: Cancer-related fatigue, physical therapy, cancer fatigue, treatment protocol

Cancer-Related Fatigue: Referral to Physical Therapy as a Collaborative Approach to Treatment

According to the American Cancer Society (n.d.), in 2022, it is estimated there will be 1,918,030 individuals in the United States newly diagnosed with cancer. It is also predicted there will be over 58,970 patients newly diagnosed with cancer in the state of Georgia in 2022 (American Cancer Society, n.d). Statistics from the National Cancer Institute (n.d.) indicate the number of individuals dying from cancer is trending downward in the United States. The current 5-year survival rate of those diagnosed with cancer is 67.4%. This number reflects patients with all cancer types (National Cancer Institute, n.d.).

Cancer-related fatigue is one of the most commonly reported symptoms among individuals diagnosed with cancer and is often exacerbated by cancer treatment; however, cancer-related fatigue remains undertreated despite the negative impact it has on quality of life (Thong et al., 2020; Gerber, 2016). With the number of individuals being diagnosed with cancer and death rates from cancer declining, it is imperative cancer-related fatigue is adequately assessed and treated.

Problem Statement

Cancer-related fatigue has been documented as a significant concern among individuals diagnosed with cancer. Pearson et al. (2015) conducted an electronic survey assessing the knowledge base of health care providers who treat patients diagnosed with cancer regarding cancer-related fatigue. Results of this survey showed that while over half of the participants

reported having a cancer-related fatigue screening process, less than one fourth reported using a clinical guideline or conducting a more in-depth fatigue assessment with patients. Smith et al. (2019) found up to half of patients with cancer-related fatigue in their study reported not receiving advice regarding fatigue from their health care providers. In a systematic review and meta-analysis, Al Maqbali et al. (2020) noted up to half of all patients diagnosed with cancer report experiencing cancer-related fatigue. Studies have also found the level of fatigue experienced by most patients with cancer is described as moderate to severe (Wang et al., 2014). Having a moderate to severe level of fatigue has been shown to have a profoundly negative impact on quality of life affecting factors such as mood, relationships with others, and ability to work (Charalambous & Kouta, 2016; Roila et al., 2018).

With the significant impact cancer-related fatigue has on quality of life, and patients living longer after being diagnosed with cancer, it is imperative this symptom is fully addressed. While there is no gold standard for evaluating and treating cancer-related fatigue, guidelines for treatment have been outlined by the National Comprehensive Cancer Network (NCCN) (Al Maqbali et al., 2020). These guidelines suggest several treatment modalities; however, they do not address which modalities are most effective or provide a standard of care for reducing cancer-related fatigue. Therefore, the treatment for cancer-related fatigue is left up to provider preference. Evidence from a review of current literature supports exercise and physical activity as being highly effective for the management of cancer-related fatigue (Al Maqbali et al., 2020; Mustian et al., 2017). Exercise is also an intervention recommended by the NCCN as an effective treatment option. Referral to physical therapy by health care providers of patients suffering from cancer-related fatigue may be a means of addressing this symptom while enhancing quality of life. Evidence-based treatment protocols are lacking and, thus, are needed to

ensure cancer-related fatigue is adequately assessed and treated system wide. Developing and implementing system-wide policy and procedure changes to assist health care providers in assessing and ordering appropriate treatment for cancer-related fatigue may lead to improvements in patient quality of life.

Purpose Statement

No standard of care or treatment protocol for cancer-related fatigue exists. The lack of an evidence-based treatment protocol leads to inadequate and under-treatment of a significant symptom that negatively impacts quality of life. Therefore, it is imperative this symptom be addressed using current evidence as a foundation. Evidence from a recent review of literature supports physical therapy as a possible beneficial treatment intervention for cancer-related fatigue. Therefore, the purpose of this project was to obtain additional evidence to determine the effectiveness of physical therapy on decreasing cancer-related fatigue and, thus, increasing patient quality of life. In addition, a protocol to be integrated into a system-wide electronic health record (EHR) system for use by health care providers in referring patients who are on active cancer treatment as well as those who are on cancer surveillance and who report cancer-related fatigue, to physical therapy as an intervention was needed. Integrating this protocol in the form of a work rule engine or algorithm into the EHR would prompt the health care provider to address cancer-related fatigue at the time of diagnosis. The work rule engine would prompt the provider to simply click the desired intervention, such as referral to physical therapy, which would lead to a referral order and scheduling prompt. This would allow the provider to establish and document a diagnosis and intervention efficiently and accurately for treatment of the significant patient symptom of cancer-related fatigue.

Current practice could be improved by the implementation of a research-based treatment protocol for cancer-related fatigue. Referring patients to physical therapy would encourage interprofessional collaboration which could lead to improvements in practice and treatment protocols in the future. The development of a work rule engine to be integrated into the EHR and used by health care providers at time of diagnosis of cancer-related fatigue would provide ease and convenience for providers while also ensuring the symptom is adequately addressed. Combined, these interventions might lead to improvement in current practice, changes in system-wide policy and procedure, and improved quality of life of patients who are profoundly impacted by cancer-related fatigue.

Clinical Question

The clinical question guiding this project was the following: In patients experiencing cancer-related fatigue while undergoing cancer treatment, does referring patients to physical therapy compared to current practice improve cancer-related fatigue and quality of life of patients within a 4-month time period?

Review of Literature

Search Strategy

Several databases were used to conduct a review of current literature to address the clinical question for this project including the following: Cochrane Library, CINAHL, PubMed, and MedlinePlus. The Google Scholar search engine was used initially to find preliminary data for development of the project idea related to cancer-related fatigue and interventions currently used to treat this symptom. The search terms used were quite broad and consisted of “cancer-related fatigue” and “treatment.” Additional search terms included “quality of life” and

“prevalence.” Full text articles were downloaded, reviewed, and appraised, ultimately leading to the development of the clinical question that guided the project.

For a more thorough review, a search was performed using several databases, starting with the Cochrane Library database. The initial search term was “cancer fatigue” which yielded 9,622 results. Thus, there was a need to condense these findings to be more specific to the planned project. The search terms of “cancer-related fatigue,” “treatment,” and “adult” yielded more relevant results. A filter also was applied to limit the search to articles published between 2010 and 2020 to ensure the most recent data were being reviewed. In doing so the number of articles found decreased to 288. The results remained relevant but continued to be quite broad. A final search was conducted using the search terms of “cancer-related fatigue,” “treatment,” and “exercise” which yielded 195 results. Studies conducted with cancer survivors, or a pediatric population were omitted as the focus of the project was adults currently undergoing cancer treatment.

The next database explored was CINAHL. Search terms used included “cancer-related fatigue,” “treatment” “exercise,” and “physical therapy.” A filter was again applied to limit articles to those published within the most recent 10 years. The results yielded between 145 and 268 articles. Adding the search term “adult” or “active treatment” or “chemotherapy” did not significantly decrease the number of search results, but instead added irrelevant articles. Therefore, the articles included in the search with discussion of pediatric patients, cancer survivors, as well as studies conducted with patients who were in an in-patient setting were excluded. Further, articles written in a language other than English and duplicate studies were excluded.

A similar search using PubMed and Medline plus was then completed. The search terms used in the Cochrane Library and CINAHL database searches were also used for these new searches. No new articles were located. In the PubMed and Medline Plus databases searches, filters were applied to only include articles published within the past 5 years. Again, no additional relevant literature was found.

Finally, reference pages from articles retrieved during the database searches were used to find additional pertinent literature. This proved to be highly beneficial in finding primary sources to utilize for the project. Many of the articles found during the literature search were reports of meta-analyses. These meta-analyses were helpful in identifying a significant number of studies having been conducted to support the need for the proposed project.

Appraisal Model

The Johns Hopkins Nursing Evidence-Based Practice model was used to appraise articles selected for the literature review. The purpose of this appraisal was to ensure the most current, rigorous, and relevant data were used in the development and implementation of the proposed DNP project. The Johns Hopkins Nursing Evidence-Based Practice appraisal allowed evaluation of data in a few key areas to ensure this purpose was met. These areas included: evaluating whether the topic addressed the clinical question ensuring relevance, assessing the level of evidence to ensure the highest level possible was utilized, and evaluating study findings to ensure the data reported was rigorous and accurate and supported the proposed project. The model provides guidelines for appraisal of studies of various design which allows for a thorough appraisal of the different types of studies found during a literature review.

Synthesis of Literature

Evidence from the literature supported the need for and purpose of the proposed DNP project. Several studies were found that highlighted the prevalence of cancer-related fatigue as well as the impact on quality of life of patients with a diagnosis of cancer. These studies showed cancer-related fatigue is one of the most commonly reported symptoms experienced by patients diagnosed with cancer within a time frame spanning from the time of diagnosis to survivorship (Al Maqbali, et al., 2020; Charalambous & Kouta, 2016; Cheng & Lee, 2011; Gerber, 2017; Pearson, et al., 2015; Smith et al., 2019; Wang et al., 2014). Studies also supported cancer-related fatigue is exacerbated by cancer treatments such as chemotherapy and radiation (Al Maqbali et. al., 2020; Charalambous & Kouta, 2016; Gerber, 2017; Long et al., 2016). Evidence supported the assumption that many aspects of patient quality of life were negatively impacted by cancer-related fatigue including mood, relationships with others, and ability to work (Charalambous & Kouta, 2016; Cheng & Lee, 2011; Roila et al., 2018; Thong et al., 2020; Wang et al., 2014). Despite these findings while patients frequently report having cancer-related fatigue, there is a deficit in the implementation of interventions for this symptom by health care providers (Pearson et al., 2015; Smith et al., 2019; Thong et al., 2020). Partly due to the lack of intervention for cancer-related fatigue from health care providers, evidence supports that cancer-related fatigue remains severely undertreated and thus diminishes patient quality of life (Charalambous & Kouta, 2016; Pearson et al., 2015; Smith et al., 2019; Thong et al., 2020).

Despite cancer-related fatigue being a common and debilitating symptom and there being guidelines for treatment recommendations in place, there remains no gold standard of care for the treatment of cancer-related fatigue (Al Maqbali et al., 2020; Bower, 2014; Pearson et al., 2015; Wang et al., 2014). The guidelines suggest differing modalities ranging from

pharmacological interventions such as antidepressants, non-pharmacological interventions such as exercise, psychosocial interventions such as behavioral and mental health therapies, as well as complementary and alternative medicine (CAM) such as herbal remedies and acupuncture (Gerber, 2017). Selection of a modality, however, is left to the discretion of the prescribing health care provider.

A common recommendation for the treatment of cancer-related fatigue is physical exercise (Baguley et al., 2017; Bower, 2014; Hilfiker et al., 2018; Ma et al., 2020; Mitchell et al., 2014; Mustian et al., 2017; Paramanandam & Dunn, 2015; Roila et al., Thong et al., 2020; Vulpen et al., 2016; Weert et al., 2010; Wu et al., 2019). Weert et al. (2010) conducted a randomized controlled trial with patients who complained of cancer-related fatigue comparing physical training with combined cognitive-behavioral therapy, cognitive-behavioral therapy only, and no intervention. The findings of this study revealed those in the physical training combined with cognitive-behavioral therapy, and those in the physical therapy alone arms showed improvement in fatigue levels compared to those who received no intervention. The findings also suggested while those in the physical therapy in combination with cognitive-behavioral therapy arm of the trial showed improvement in fatigue levels, there were no significant differences found between this arm and the physical training only arm. This suggests cognitive-behavioral therapy provided little to no additional benefit (Weert et al., 2010). Results from several other studies suggest physical activity may be more beneficial for the treatment of cancer-related fatigue compared to other interventions such as CAM, pharmacological interventions, and/or behavioral health interventions (Baguley et al., 2017; Bower, 2014; Hilfiker et al., 2018; Mitchell et al., 2014; Ma et al., 2020). Mustian et al., 2017; Paramanandam & Dunn, 2015; Roila et al., 2019; Thong et al., 2020; Vulpen et al., 2016).

Conceptual Framework

Kotter's change theory served as the conceptual framework for the planning and implementation of this project. Kotter's theory was chosen because the end goal of the project was to introduce a system-wide change or update in policy and procedure related to health care provider assessment and treatment of cancer-related fatigue. This goal stemmed from the identification of a lack of appropriate policy and procedure for the treatment of cancer-related fatigue at the current practice site of the investigator. The implementation of a new policy and procedure can be a challenging endeavor. Change, no matter how minute, can often be difficult and requires thorough planning. If the study reveals positive outcomes, this writer will then propose the development of a policy and procedure that can be utilized system wide. With the help of subject experts, this author further plans to develop a "work rule engine flowsheet" to be utilized within the electronic health system as part of the new policy and procedure guidelines. Integrating the "work rule engine flowsheet" would prompt the provider to address cancer-related fatigue at time of diagnosis thus ensuring the provider will fully address this debilitating symptom in a timely and efficient manner. The "work rule engine" would prompt the provider to simply click the desired intervention such as referral to physical therapy which would then lead to a referral order and scheduling prompt. This process will require a change in current practices for many providers. Thus, this writer believes Kotter's change theory provides the best and most thorough framework for the proposed project.

The Kotter change theory was developed by John P. Kotter and was first published in the Harvard Business Chronicle in 1995, which ultimately led to the publication of Kotter's book "Leading Change," in 1996 (as cited in Applebaum et. al., 2012). The theory consists of eight steps all of which lead to the end goal of implementation of a change in current policy,

procedure, or process (McCaffrey, 2012). These steps include: Developing a sense of urgency, forming a coalition with key players, creating a vision for the change, communicating this vision, removing obstacles, creating short-term goals, building on the change, and finally anchoring the change within the organizational culture. Kotter's theory was best suited for the purpose of this project as it provided guidance for the initial development of the idea, recruiting a team for implementation of the idea, communicating the idea, addressing barriers to implementation of the change, and finally solidifying the idea into current practice by updating policy and procedure.

Applicability of Framework to Project

The first step in Kotter's theory is to create a sense of urgency. According to McCaffrey (2012), in order for change to be accepted, one must understand why the change is important. Evidence from a review of current literature supports that cancer-related fatigue is a prevalent concern and is exacerbated by cancer treatment (Al Maqbali et al, 2020; Gerber, 2016; Long et al., 2016; Thong et al., 2020). Health care providers do not adequately address this debilitating symptom which is often rated as moderate to severe by many patients diagnosed with cancer (Wang et al., 2014) having a profoundly negative impact on patients' quality of life (Charalambous & Kouta, 2016; Roila et al., 2018). The need for additional study and a change in system-wide policy and procedure guiding the assessment and treatment of cancer-related fatigue is supported in the literature. Presenting evidence such as this and additional information specific to the healthcare system for which the project was targeted to all stakeholders and system administrators should create a sense of urgency for change as it shows health care providers may not be providing appropriate advice to patients (Smith et al., 2019) or adequately treating a symptom that profoundly impacts patient health and quality of life.

The second step in Kotter's change theory is to form a coalition or a team in support of the change (McCaffrey, 2012). This step is crucial for the success of the change. As proposed for the project, the support of the current attending oncologist at the site selected for initial testing and implementation, other advanced practice providers within the oncology setting, and the department of physical therapy was going to be sought for implementation of a policy change related to the assessment and treatment of cancer-related fatigue. This would be achieved through communication of the evidence to support the change and involvement of all departments affected by the change in planning and implementing the project. As the proposed policy and procedure change involves a multidisciplinary approach, it would be imperative to have each department on board. Once the efficacy of the proposed change was determined, additional support from the administration team of the larger healthcare system to implement the change at a system- wide level would be sought.

The third step in Kotter's change theory is to create a vision for the change (Applebaum et al. 2012). This step involves clearly defining the proposed change and how change will be accomplished. If there is any confusion about who is involved in the change, what the exact change will be, why the change is necessary, where the change will take place, as well as when the change will occur, the project will not be successful. During this step, these attributes are clearly defined, and a roadmap is laid out. An important aspect of this step which may be unique to nursing and healthcare compared to other business models is the need to show that evidence indeed supports the change. For this project, the evidence derived from the literature supported that exercise and physical activity have been found to be highly effective for the management of cancer-related fatigue (Al Maqbali et al., 2020; Baguley et. al., 2017; Hilfiker et. al., 2018; Mustian et. al., 2017; Paramanadam & Dunn, 2015; Roila et. al., 2019; Van Vulpen et. al., 2016;

Weert et. al., 2010; Wu et. al., 2019). Thus, a treatment protocol was developed for integration into the EHR system for use by health care providers. The protocol will be integrated into the EHR in the form of a work rule engine to make use of the protocol easier for the providers who will use it. The plan provides patients with a referral to physical therapy as a treatment modality. The expected benefits to patients in terms of symptom reduction and improvement in quality of life would be presented to all involved in the project along with a timeline for implementation of the protocol into the EHR. Development of the policy and procedure for system-wide implementation would follow.

The fourth step in Kotter's change theory is communication of the vision (McCaffrey, 2012). In order to accomplish this step, several meetings with the medical oncology team, the advanced practitioners, physical therapy, support staff, as well as clinic leadership will be held. The purpose of these meetings will be to communicate the vision which was created and outlined for the project during the third step of the change process. Data to support the need for change and the process for change will be presented as well as the anticipated patient outcomes resulting from the change. A draft of the proposed policy and procedures to be implemented system-wide would be made available.

The fifth step in Kotter's change theory is to remove barriers or obstacles which may hinder the proposed change (McCaffrey, 2012). It is important the proposed change is made as easy as possible in order to be a success. If the process is smooth and streamlined, people are more likely to be compliant with the change. One barrier to the change proposed for this project is the fact that providers are very busy and adding extra things for them to do during the day would likely not be received well. To mitigate this concern, a "work rule engine" was developed to simplify the process. The work rule engine is a computer algorithm for the proposed treatment

protocol that would allow the provider to simply click on a treatment or intervention to be ordered for a particular patient, for example, referral to physical therapy from within the current EHR, once the diagnosis of cancer-related fatigue is selected. This would then prompt a prescription for a referral to physical therapy to be printed for the patient as well as prompt scheduling to arrange the appointment. These steps would allow the clinician an efficient means of providing a treatment plan using minimal computer clicks while they are already in the patient's EHR, thus ensuring the intervention is accomplished seamlessly and efficiently. Training for health care providers would be arranged to ensure a smooth transition to the use of the new protocol and system. Multiple live sessions will be made available as well as written instructions to make it as easy as possible for providers to learn the new system. The use of an information technology specialist familiar with the EHR to integrate the work rule engine into the system will assist with this part of the project.

Step number six of the Kotter change theory is to create short-term goals for the change project (McCaffrey, 2012). Changes can often be a momentous undertaking and can be very overwhelming when looking at the whole picture. The development of short-term goals can help this task seem a little less daunting and provide some guidance as to where to start and what to work on next. This step also is important to continue the momentum of the project. Setting short-term goals allows recognition of the hard work being done while it is taking place (Applebaum, 2012). A few short-term goals developed for the implementation of the project were as follows. The first goal would be the incorporation and implementation of a standardized fatigue assessment within the EHR. Once this is accomplished, the second goal would be the final development and integration of the work rule engine into the EHR. The third goal would be to complete training of health care providers in the use of the electronic protocol. The fourth goal

would be to achieve an acceptable level of compliance by health care providers with actual referral of patients to physical therapy. A fifth goal would be to evaluate the effects of the increase in referrals to physical therapy on fatigue and quality of life and sharing this with the implementation team. If outcomes are favorable, the final goal would be to update the system-wide policy and procedure related to the assessment and treatment of cancer-related fatigue.

The seventh step in Kotter's change theory is to build on the change (McCaffrey, 2012). This step allows for review and assessment of the change to identify what is going well and what areas need improvement. This step may also help identify obstacles and other opportunities for the project. Meetings with those involved in the project before implementation, at the midpoint, and at the end of the proposed project to evaluate all steps in the implementation process and outcomes of the change in current practice would be held. Doing so would allow the project team to address any concerns and barriers and to consider implementing a similar project to address other cancer related treatment issues.

The final step in Kotter's change theory is to anchor the change in the organizational culture (McCaffrey, 2012). This step involves finalizing the change so it can be implemented throughout the system. Once the change has reached this step it is adopted as policy and implemented system wide. It will then be a permanent fixture in the culture of the healthcare system. If the evidence obtained through this project were to show improvement in patient outcomes the following would need to take place in order to reach the goal of anchoring the change in the organizational culture. First, education and training would need to be developed and implemented for health care providers who will be using the new protocol system-wide. A draft of the policy and procedure change would be written and made available to all stakeholders for review prior to sending for approval by the administration team of the selected healthcare

system. Once approval is received and the new policy and procedure are fully adopted and functioning all goals for the project will have been met.

In summary, Kotter's change theory is an eight-step model that served as an excellent framework for the outlined project. This model provides a roadmap which can be utilized from the inception of an idea for change to the final implementation of a change in policy and procedure. In that the proposed project involved such a change, the use of Kotter's theory as the framework for the project was appropriate.

Implementation/Evaluation

For the initial phase of the project, a study to collect additional evidence was conducted at sites from within the selected healthcare system for which the change outlined for the project was proposed. A description of the study will be presented first. An outline of the remaining steps of the project will then follow.

Methodology

A pre- and post- intervention survey design was used to gather the additional evidence needed to answer the clinical question of whether physical therapy reduces cancer-related fatigue and leads to improvement in quality of life for patients. IRB approval was obtained for the project and permission to use the selected study instruments was received prior to recruitment of participants for the initial exploratory study. Participants were then recruited by the investigator from several outpatient oncology clinics within the same healthcare system in Atlanta, Georgia. A copy of the recruitment script can be found in appendix A. Recruitment flyers were also placed throughout select clinics in the waiting areas and exam rooms (appendix B). Each clinic was visited by the investigator to recruit study participants and obtain their informed consent.

Individuals identified as potential participants located at clinics other than the one in which the investigator is employed were called and project details discussed. Those who agreed to participate in the project were then asked to sign an informed consent form (appendix C) which was completed on their next clinic visit.

Participants

The proposed sample size for the initial phase of the project was 30 to 50 participants. Inclusion criteria were being age 18 or older, having a diagnosis of cancer of any type and having a diagnosis of cancer-related fatigue. Participants also had to be fluent in the English language, both spoken and written. It was important for participants to speak and write the English language as the consent as well as all instruments used for data collection were written in English. Participants were required to have adequate transportation to and from physical therapy and oncology clinic appointments. Finally, participants could be actively undergoing cancer treatments including chemotherapy, immunotherapy, targeted therapy, radiation therapy, or any combination thereof. Individuals who were in cancer surveillance and had completed their cancer treatments also were eligible for the study. No exclusion criteria were outlined.

A total of 9 participants were recruited from multiple outpatient oncology clinics and enrolled in the project. Recruiting from multiple oncology clinics aided in obtaining participants who were diagnosed with various cancer types and supported that the sample represented the true cancer population. Due to unanticipated barriers and time constraints, a sample consisting of three participants who completed all steps of the initial data collection and intervention phases of the project was obtained. One of the originally enrolled participants experienced progression of their cancer and was transitioned to hospice care, subsequently passing away prior to completion of data collection. The remaining five initially enrolled participants were unable to complete the

project due to their insurance not covering physical therapy or due to being unable to afford the co-payment required for physical therapy services. Demographic information related to project participants is provided in the Results section of this paper.

Setting

Participants were recruited from outpatient oncology clinics affiliated with a large health care system located in Atlanta, Georgia. Data collection took place in a private room at the oncology clinic from which each participant was recruited. For the physical therapy or intervention component of the project, participants were referred to outpatient physical therapy centers affiliated with the same health care system as the outpatient oncology clinics. As there are several locations throughout the state, participants had the ability to select a physical therapy center convenient to them. The participants also were given exercises to perform at home by the physical therapists for days they did not have scheduled physical therapy appointments. Having access to multiple outpatient physical therapy clinics and allowing participants to use the location most convenient for them helped ensure participant compliance with their physical therapy treatment plan.

Data Collection

Once informed consent was obtained, participants were asked to complete a fatigue assessment, quality of life scale, and demographic questionnaire prior to being referred for a 4 to 6 week regimen of physical therapy. The fatigue assessment and quality of life scale were repeated after participants completed the prescribed physical therapy regimen. Completion of the assessments and surveys took no more than 10-15 minutes. To make the process of completing the study instruments easier participants completed the data collection instruments via pen and

paper. The post intervention surveys were often completed by the participant at a time when they were already scheduled to come to the oncology clinic for treatment or follow-up. This helped minimize any inconvenience for participants.

Data Collection Instruments

EORTC QLQ FA-12

To measure cancer-related fatigue, the EORTC QLQ FA-12 was used (Appendix D). This instrument is used to assess for the presence of fatigue and to determine the severity of fatigue a participant is experiencing. The instrument encompasses other aspects of fatigue beyond the physical, extending into the emotional and cognitive aspects of fatigue by asking questions such as “do you have trouble thinking” and “do you feel discouraged.” Permission to use the instrument for the project was obtained from the appropriate source prior to the start of the project.

A study by Kecke et al, (2017) in which the 3-question version of the fatigue assessment and the 12-question version of the survey was compared and favored the use of the 12-question survey as it encompasses a more holistic approach to the assessment of fatigue. A Cronbach’s alpha of 0.92 for this instrument was noted in the study. The 12-question survey was used for this project. Participants were asked to respond to each question on the assessment on a scale of one to four with “1” representing “not at all,” “2” representing “a little,” “3” representing “quite a bit,” and “4” representing “very much.” Scores on each item are summed to reach a total score on the instrument with higher scores indicating a higher level of fatigue. The highest possible score is 48 with the lowest possible score being 12.

The Flanagan Quality of Life Scale

To measure quality of life, the Flanagan Quality of Life Scale (Appendix E) was used. The purpose of this instrument was to help determine to what extent, and in what ways, cancer-related fatigue impacted the participants' quality of life. Burckhardt and Anderson (2003) reported the Cronbach's alpha for the instrument has consistently been between 0.82 and 0.92. The survey has been found to be a valid instrument with results remaining consistent regardless of culture, age, or gender (Burckhardt & Anderson, 2003).

The Flanagan Quality of Life Scale consists of 16 questions which cover a wide breadth of quality-of-life aspects including an individual's relationships with others, their work, and their leisure activities. Participants are asked to answer each question on a scale between one and seven with "1" representing "terrible," "2" representing "unhappy," "3" representing "mostly dissatisfied," "4" representing "mixed," "5" representing "mostly satisfied," "6" representing "pleased," and 7 representing "delighted." Scores on each item are summed to reach a total score with higher scores indicating a better quality of life. The highest possible score on this instrument is 112, while the lowest possible score is 16.

Demographic Questionnaire

A brief demographic questionnaire was completed by each participant (Appendix F). The questionnaire consisted of six questions which gathered information regarding the participant's cancer diagnosis, cancer stage, gender, age, and current treatment regimen.

Intervention

Upon participant completion of pre-intervention data collection, an order was placed in the EHR by the investigator for participant referral to outpatient physical therapy. Within two business days of the order being placed, participants were contacted to schedule the physical

therapy appointment. Notice of the plan of care was forwarded from the physical therapists to the prescribing provider as the document required a co-signature, thus alerting the provider when treatment had begun. Participants completed up to 6 weeks of physical therapy. The exact length and number of days of therapy was individualized based on each participant's specific situation and needs. During this time, physical therapists informed the investigator of any participant absences or non-compliance with therapy.

Data Analysis

When all data had been collected, they were reviewed, cleaned, entered into the Statistical Package for the Social Sciences (SPSS) version 26, and analyzed to determine if referral to physical therapy was an effective treatment intervention for cancer-related fatigue and if it affected quality of life. Assistance with data analysis was obtained from the chair of the committee for the DNP project, Dr. Lisa Cranwell-Bruce as well as the co-chair, Professor Laura DeMars. Assistance was also obtained from the GSU statistician Dr. Melissa Osbourne. Due to the small sample size obtained, it was determined that no inferential statistics would be relevant. Thus, pre-intervention and post-intervention scores were examined for each of the three participants to determine any trends in the findings. A discussion of the pre-intervention survey results compared to the post-intervention survey results follows.

Results

The first participant to complete the study was a 54-year-old gentleman with a diagnosis of stage IV non-small cell lung cancer (NSCLC). He completed 6 weeks of physical therapy. His pre-intervention fatigue score was 25. His post-intervention fatigue score dropped to 22. This reveals his fatigue level improved by 3 points. His pre-intervention quality-of-life score was 93.

His post-intervention quality-of-life score dropped to 88. This suggests that despite his fatigue score improving, his quality-of-life score decreased by 5 points. The participant reported the reason for the decrease in quality-of-life from pre-intervention to post-intervention was due to the need for frequent thoracentesis which ultimately led to a PleurX drain being placed.

The second participant to complete the study was a 77-year-old female with a diagnosis of stage IV non-small cell lung cancer (NSCLC) who completed 6 weeks of physical therapy. Her pre-intervention fatigue score was 30. Her post-intervention score totaled 19 points which reveals an 11-point improvement in fatigue score. Her pre-intervention quality-of-life score was 70. Her post-intervention quality of life score was 89. This revealed a 19-point improvement in the participant's quality-of-life score. For this participant both the fatigue and quality of life scores improved. While no inferential statistics were able to support this as statistically significant, it is promising.

The final participant who completed the project was a 54-year-old female with stage IV colorectal cancer who completed 4 weeks of physical therapy. Her pre-intervention fatigue score was 34. Her post-intervention fatigue score decreased to 27. This was a 7-point improvement in the fatigue score. Her pre-intervention quality-of-life score was 57. Her post-intervention quality-of-life score was 73. This shows a 16-point increase in the quality-of-life score. Improvement in both the fatigue and quality-of-life scores was achieved in this participant.

An overview of the results from the three participants revealed all showed improvements in their fatigues scores after completing up to 6 weeks of outpatient physical therapy. Two of the three participants also showed improvement in their quality-of-life scores. While there could be no accurate correlations made given the small sample size, the results are promising. Of the three participants, the second participant to complete the project showed the most improvement in both

fatigue and quality-of-life post intervention. Figure 1 shows the comparison of the pre-intervention fatigue survey scores and the post-intervention fatigue survey scores by participant. Figure 2 shows the comparison between pre-intervention quality-of-life scores and post-intervention quality-of-life scores among the 3 participants who completed the project.

Discussion

While the results of the initial phase of the project could not be used to generate any inferences about the effects of patient completion of a physical therapy regimen on cancer-related fatigue or quality of life of patients experiencing fatigue, it did bring to light some barriers to the utilization of physical therapy as a treatment approach for cancer-related fatigue. Four of the participants of this project were unable to complete the physical therapy aspect due to their inability to afford the co-payments or because their health insurance did not cover physical therapy services. In addition, recruitment for the project was greatly hindered by the emergence of the COVID-19 pandemic which led to fear of undue exposure to the virus if the individual were to participate in outpatient physical therapy sessions. Some patients also did not want to have to travel as far as would be required for the physical therapy appointments. For some patients it seemed counter-intuitive to exercise when their fatigue levels were so great despite being informed of the research which supports exercise as a highly effective treatment option. A discussion with physical therapists also brought to light the fact that it is often difficult to motivate patients to be active and participate in exercises such as physical therapy when they were not very active prior to their cancer diagnosis. In order for physical therapy to be beneficial, the patient must be willing to put the time and effort into the treatment plan. Although barriers may exist to the use of physical therapy as a treatment method for cancer-related fatigue, alternatives to overcome several of these barriers are available.

Practice Implications

Although the sample recruited in the initial phase of the project was too small to conduct any meaningful statistical analysis or make any concrete conclusions regarding the effectiveness of the treatment of physical therapy on cancer-related fatigue and quality of life in the project group, other aspects of the project continued to be developed. For example, a flow sheet was designed outlining the development or modification of a work rule engine (Appendix G) within the EHR for use by health care providers when cancer-related fatigue was entered as a diagnosis. This was done with the help of Professor Laura DeMars, co-chair for this project. In essence, this flow sheet can be used to set up an algorithm within the EHR for use when the diagnosis of cancer-related fatigue is entered into the HER. Following this entry, the provider would be prompted to select an intervention to address the symptom. In the case of cancer-related fatigue, a few options would be pre-populated to select from. These would include: “Ambulatory Referral to Outpatient Physical Therapy, Internal,” “Ambulatory Referral to Outpatient Physical Therapy, External,” “Patient declines intervention at this time,” and “Other.” The difference in internal and external referral is to provide patients the option of using a physical therapy center that may be more convenient to them. Also, patients do have the right to decline intervention. As there are other options for treating cancer-related fatigue, the provider would then have the option to choose an alternative treatment modality such as cognitive behavioral therapy or medications. Once the health care provider signed the order, it would either be electronically submitted, or a hard copy of the order would be printed for the patient. This would automatically be documented within the EHR.

Additional testing of the effects of referral to physical therapy of patients with cancer-related fatigue will be completed to provide a more appropriate sample size and the ability to

obtain meaningful statistical analysis of the data. Results of the project will be presented to the leadership and administrative team of the selected healthcare system and if they support referral to physical therapy as an effective treatment for cancer-related fatigue, a proposal will be made to move forward with the implementation of the remaining steps of the project in the hope that the change in protocol will be adopted into the standards of care and treatment of patients with cancer-related fatigue. Kotter's change theory will be used to guide implementation of this change in current practice.

Fear of Exposure to Infectious Diseases

The COVID-19 pandemic has impacted many aspects of life including healthcare. Despite lockdowns and restrictions imposed due to the pandemic, patients diagnosed with cancer continue to need their treatments in order to survive. These treatments often lead to patients being immunocompromised which places them at an increased risk of not only contracting the infection but also of death from COVID-19. The COVID-19 pandemic has forced health care providers to become creative in how they provide their services. One way the healthcare system was recently successful in this area was the use of telehealth and telemedicine services. The COVID-19 pandemic allowed for temporary laws via emergency executive orders that made it possible for providers to complete telehealth visits with patients and required insurance companies to cover these services (Lewis, 2021). More research also has recently been conducted to evaluate the effectiveness of using telehealth services including those offered within the physical therapy discipline. Sarfo et al. (2018) conducted a systematic review of the literature evaluating the effectiveness of tele-rehabilitation after stroke. The authors concluded that the literature supports the use of tele-rehabilitation for stroke patients (Sarfo et al., 2018). Azma et al. (2017) conducted a randomized controlled clinical trial comparing the efficacy of

tele-rehabilitation with that of office-based physical therapy. Results of this study revealed there was no significant difference between the two modalities. While studies evaluating the efficacy of physical therapy via telehealth services for the treatment of cancer-related fatigue were not found, studies such as those mentioned above would support that physical therapy sessions offered via telehealth systems could be a promising alternative to in person physical therapy treatments.

Patients diagnosed with cancer who are undergoing chemotherapy will often have worsened fatigue symptoms and, due to their treatment, can have compromised immune systems. For this reason, even prior to the pandemic, this patient population was at increased risk for developing life threatening infections. These infections can arise from bacteria and viruses that normally would be handled by a healthy immune system or cause only mild symptoms. With the advancement of telehealth services, offering at home treatment options to patients with cancer-related fatigue may prove to be just as beneficial as on-site treatments while decreasing the need for undue exposure to infectious diseases for patients with cancer.

According to the United States Census Bureau, one in five Americans live in rural areas (census.gov, 2017). Those living in rural communities often experience health disparities which are exacerbated by lack of access to health care services (Hirko et al., 2020). People living in these communities often must travel long distances to access healthcare services including physical therapy. This barrier to care could also be closed by providing telehealth services, such as physical therapy, to rural communities.

Financial Barriers

The cost of having cancer can become quite burdensome even for those who have access to health insurance. It is important to note the health issues a person has, such as heart disease or

diabetes, do not go away simply because they develop cancer; neither do the costs associated with those health issues. When one factors in the cost of co-payments for office visits, labs and imaging services, cancer drugs and supportive medicines such as anti-emetics, travel costs, and so on, it is easy to see how the financial burden associated with cancer can become overwhelming. Adding the cost for a service such as physical therapy to this list of expenses could be quite difficult for many individuals. Some patients' insurance policies do not cover physical therapy services, and some require co-payments at the time of each visit. Many insurance companies require a medical necessity for physical therapy which requires the patient to go once weekly to the physical therapy clinic. Many patients who were approached to participate in this project simply stated they would be unable to afford these services, and several who did enroll in the project were unable to complete it due to the financial barriers.

Many of the larger healthcare systems providing oncology services have cancer support programs which are often free for patients. There could be opportunity to have some form of physical therapy session or sessions provided for the patient in a collaborative manner with the physical therapy team through this type of program. If this could be accomplished, the possibility exists for patients to learn some basic exercises to perform at home to help improve fatigue levels and ultimately their quality of life.

For individuals who are 65 years of age and older who participate in Medicare, a program called Silver Sneakers™ is available to some to help meet their physical activity needs, depending on the Medicare plan they are enrolled in. The services provided through the program include free membership to local gyms as well as access to all classes and other services offered by each facility including yoga and other exercise classes (silversneakers.com, n.d). The website associated with the Silver Sneakers™ program also includes access to online fitness classes as

well as nutritional advice at no additional cost (silversneakers.com, n.d). This service would be a viable alternative for patients who have financial difficulties and those who simply want to become more active. This program would be beneficial for those who live in rural areas where physical therapy clinics are too far for them to easily access as it utilizes local community resources and has online options as well.

Other options for those who face financial barriers to participation in physical therapy or are not eligible for the Silver Sneakers™ program would be to collaborate with local organizations such as the YMCA or local area fitness instructors who may be able to provide physical activity services for no or reduced cost. Patients who encounter financial barriers to physical therapy should be encouraged to reach out to their health insurance carriers to see what health and wellness incentive programs may be offered as part of their insurance coverage. Some insurance companies offer services similar to the Silver Sneakers™ program such as reduced cost of gym memberships. Regardless of what options are available to patients with cancer-related fatigue, health care providers should encourage patients to explore all avenues for enhancing their ability to engage in physical activity as a treatment for their fatigue.

Work Rule Engine

Once a more robust study can be conducted for the project, improvement in the work rule engine will be critical to the successful integration of the project treatment protocol into practice. The work rule engine will ensure the provider can quickly diagnose and easily make a referral to physical therapy for patients with cancer-related fatigue while simultaneously capturing necessary information for billing and coding purposes. This work rule engine will need to be integrated into the current EHR system by an information technology specialist. Once this has been completed the workflow for ordering treatment for cancer-related fatigue will become

seamless. The healthcare provider will be able to enter a diagnosis of cancer-related fatigue into the EHR as they would enter any other diagnosis. The EHR system will then have a “pop-up” which prompts the provider to choose from a pre-populated selection of orders. This list would include the following options: “Ambulatory Referral to Outpatient Physical Therapy, Internal,” “Ambulatory Referral to Outpatient Physical Therapy, External,” “Patient Declines at this time,” and “Other.” Each order for physical therapy will be pre-populated with instructions such as “evaluate and treat” and all other necessary information for an order such as diagnosis code and provider information. The order options allow the provider to select the most appropriate treatment for the patient. For those patients who live relatively near the healthcare facilities, the “internal” referral may be best for the patient. If the facility has several locations to choose from, a drop-down menu can be created as part of the work rule engine to allow the selection of the most appropriate location. However, some patients may have physical therapy centers closer to their homes that they would prefer to use that are not part of the referring healthcare organization.

The patient would have the right to refuse a referral to physical therapy which would lead the provider to select “patient declines.” This option would include space for the provider to indicate the reason the patient declines. The provider would also have the option to choose “other” which will prompt them to type in an alternative intervention for the treatment of fatigue. Once the provider signs the referral request, an electronic order will be sent to the appropriate facility for internal referrals or a hard copy order for physical therapy will be printed and provided to the patient to present to the physical therapy clinic of their choice.

The importance of the work rule engine outlined in this project is two-fold. Firstly, it will prompt the health care provider to actually select an intervention for a patient’s cancer-related

fatigue thus ensuring the symptom is adequately addressed. As mentioned earlier, cancer-related fatigue is frequently reported by patients diagnosed with cancer, and most clinics screen for cancer-related fatigue; however, it is often left untreated (Pearson et al., 2015; Smith et al., 2019; Thong et al., 2020). The work rule engine will help mitigate this phenomenon by prompting the provider to address the symptom in real time. Secondly, it is important the ordering of an intervention for cancer-related fatigue be as easy as possible for providers to implement. The work rule engine will allow providers to diagnosis, provide intervention, and document these actions through an easy to use, efficient, integrated system.

Conclusion

Cancer-related fatigue is one of the most commonly reported symptoms experienced by patients with a diagnosis of cancer. This symptom is often exacerbated by the treatments patients undergo for their cancer. Cancer-related fatigue has a significant negative affect on quality-of-life. Studies have shown that despite patients reporting fatigue and most oncology clinics screening for fatigue, this symptom often remains untreated. This may be due to the lack of a gold standard of care and protocols for the treatment of cancer-related fatigue.

Many studies have shown exercise to be beneficial in reducing cancer-related fatigue (Baguley et al., 2017; Bower, 2014; Hilfiker et al., 2018; Mitchell et al., 2014; Ma et al., 2020). Mustian et al., 2017; Paramanandam & Dunn, 2015; Roila et al., 2019; Thong et al., 2020; Vulpen et al., 2016). Therefore, referring patients to physical therapy could prove to be an effective treatment for cancer-related fatigue. This practice could be implemented into a standard of care protocol to be utilized by providers within outpatient oncology clinics. Although the sample obtained for the study completed for this project was too small to make any statistically significant inferences all three participants who were able to complete the data collection and

intervention portions of the project did show improvement in their fatigue levels. Two of the three also showed improvement in their quality-of-life scores. Additional testing of the effects of referral to physical therapy of patients with cancer-related fatigue will need to be completed to provide a more appropriate sample size and the ability to obtain meaningful statistical analysis of the data. Repeating the exploratory portion of the project with a larger sample size would provide additional evidence to support or refute the efficacy of physical therapy as a treatment modality for cancer-related fatigue and whether this intervention decreases the level of cancer-related fatigue and/or increases patients' quality of life. This will be important when presenting the vision for the project to others, including leadership and administration, and for supporting a change in system wide policy and procedure for the assessment and treatment of cancer-related fatigue.

There were many barriers to participant recruitment and completion of data collection for this project including the emergence of and ongoing concerns surrounding the COVID-19 pandemic. Also, financial barriers for participants were encountered which were originally not anticipated. These factors are important for healthcare providers to consider when prescribing treatment for cancer-related fatigue. A more robust pilot project would be beneficial to conduct to gather further support for the creation of a treatment protocol in which a referral to physical therapy is made to address cancer-related fatigue. A work rule engine could then be integrated into EHR systems to improve the system workflow process and ensure this symptom is appropriately addressed. This could lead to the development of a standardized treatment protocol for the treatment of cancer-related fatigue system-wide thus improving a significant symptom experienced by patients diagnosed with cancer as well as improving their quality of life.

Figure 1

Fatigue Scores

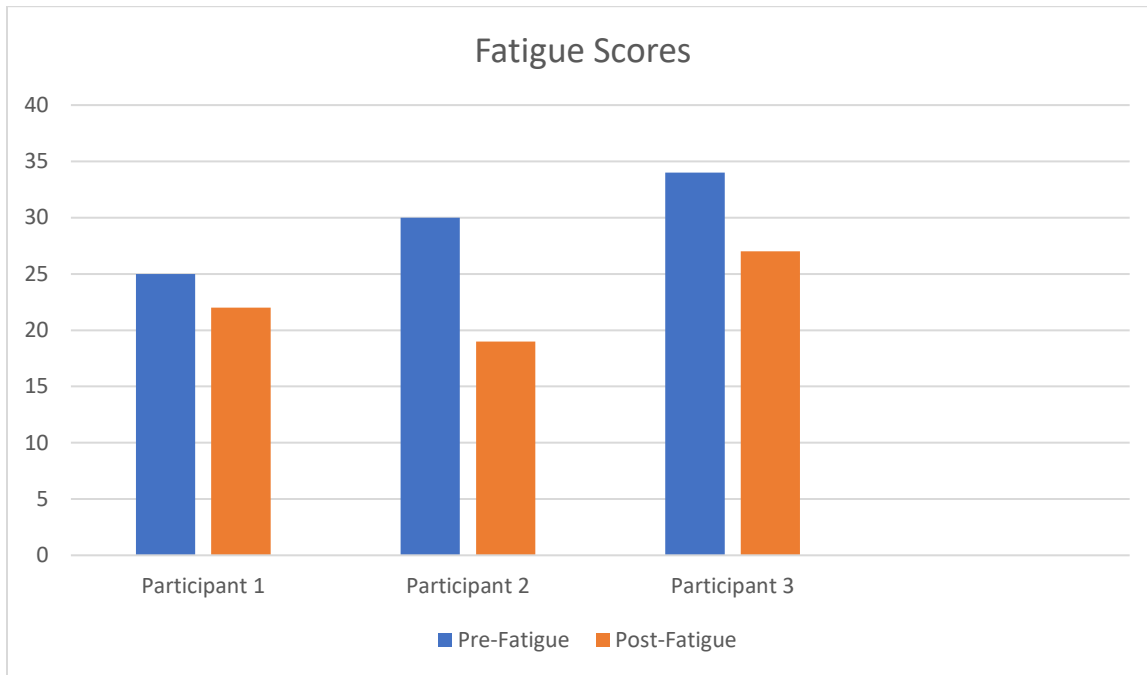
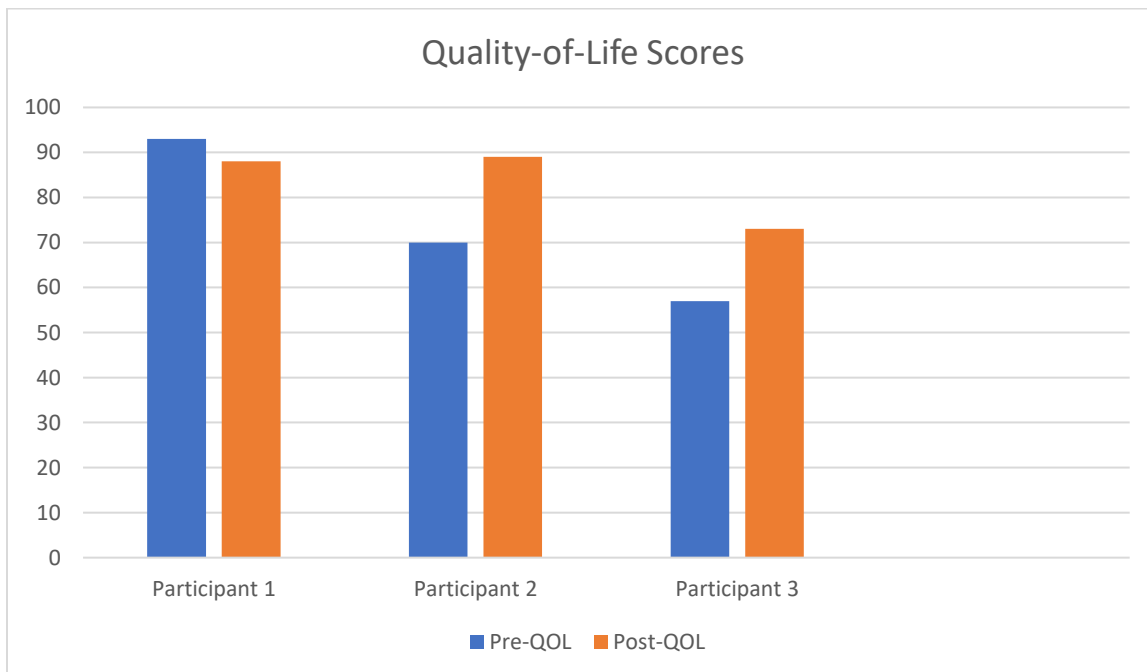


Figure 2

Quality of Life Scores



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Appendix A

Participant Recruitment Script

Hello, my name is Codi Rhear. I am a doctoral student at Georgia State University working to obtain my doctorate in nursing practice (DNP). I am conducting a study regarding cancer-related fatigue, and I would like to invite you to participate. I am reaching out as I believe you may be eligible to participate in this study.

This study consists of patients who have cancer-related fatigue being referred to outpatient physical therapy as a treatment. Prior to going to physical therapy each participant will be asked to complete a survey regarding their level of fatigue as well as a survey regarding quality of life. These surveys will take approximately 10-15 minutes to complete. You will be asked to complete these same surveys after completion of physical therapy. Physical therapy treatment will be individualized to the participants needs per the physical therapist which typically last from 6-8 weeks.

Please be aware that, if you are eligible for this study, your participation in this study is completely voluntary. There will be no consequences to you whether you chose to participate or not participate in this study. If you chose not to participate in this study your regular medical care will not be affected by this choice.

If you have any further questions or would like to participate in this study, I can be reached at crhear1@student.gsu.edu or by calling 404-425-1777.

Appendix B

Participant Recruitment Flyer



The flyer features a light blue and green background with abstract curved shapes. On the left, there is a large image of a yellow stethoscope with a red heart icon. To its right is a grid of six smaller images: a person in a hospital bed, a doctor examining a patient, hands being held together, a woman in a hospital gown, a person in a hospital bed, and a woman in a white hoodie.

Cancer Fatigue Study

Who May Qualify?

Patients who have been diagnosed with Cancer AND Have fatigue due to Cancer.

If you have cancer, are experiencing fatigue, and are interested in participating in this project OR would like to find out more information on a project that could improve your cancer related fatigue, please let your Oncology team know.

You can also contact Codi Rhear, NP directly for additional information or to see if you qualify.

Codi Rhear, NP
Email: Codi.Rhear@Piedmont.org
Phone: 715.892.4369

Appendix C

Informed Consent

Title: Cancer-related fatigue: Referral of patients to physical therapy as a collaborative treatment approach.

Principal Investigator: Dr. Lisa Cranwell-Bruce

Co-Investigator: Laura DeMars

Student Principal Investigator: Codi Rhear

Introduction and Key Information

You are being asked to take part in a research study. It is up to you to choose if you would like to be in the study.

The goal of this study is to figure out if sending patients with fatigue from cancer to physical therapy will make fatigue and quality of life better.

Your role in the study will last around 6 to 8 weeks depending on the physical therapy plan.

You will be asked to do the following: Fill out a form that asks about your fatigue and to fill out another form that asks about your quality of life. These forms will be filled out at the start of the study and then again at the end of the study. You will also be asked to go to physical therapy visits and do anything at home given to you by the physical therapist.

Being in this study will not expose you to any more risks than you would have in a typical day. There are possible risks related to physical therapy which include but are not limited to your fatigue not getting better, worsening of conditions you already have, higher heart rate or blood pressure during physical activity, falls which could lead to broken bones.

This study is meant to benefit you by making fatigue from cancer and quality of life better. This is not promised to happen. We hope to gain ideas about how physical therapy can help patients with cancer fatigue.

The participant is responsible for any cost including co-pays that may come with the physical therapy treatment. This study has no funding to help pay for such costs.

If you do not have to take part in this study, the alternative is to take part in physical therapy for your cancer fatigue without taking part in the study.

Purpose

The goal of this study is to figure out if sending patients with fatigue from cancer to physical therapy will make fatigue and quality of life better.

You are being asked to take part in this research study because you have cancer and have also have cancer fatigue. A total of 30 – 50 people will be asked to take part in this study.

Procedures

If you decide to take part, you will be asked to do the following:

1. Fill out a form about your fatigue.
 - a. This will be filled out before the start of physical therapy.
 - b. You will also be asked to fill out this same form when you are done physical therapy as well.
 - c. This form will take 5 to 10 minutes to fill out.
 - d. This form can be filled out at an office visit.
2. Fill out a quality-of-life form.
 - a. This will be filled out before the start of physical therapy.
 - b. You will be asked to fill out this same form once you are done with physical therapy as well.
 - c. This form will take 5-10 minutes to fill out.
 - d. This form can be filled out at an office visit.
3. You will be given an order to physical therapy. You will be asked to go to all physical therapy visits and do any at home therapy prescribed to you by the physical therapist.
 - a. Physical therapy plan will be made and guided by the physical therapist.
 - b. You may pick any Piedmont Healthcare physical therapy location that is close to you.
 - c. Physical therapy plan can last from 6 to 8 weeks.
 - d. If you do not show up for physical therapy visits, you may be removed from the study.
4. Medical record collection
 - a. By being part of this study, you are giving permission for the research team to collect the following records from your medical records.
 - i. Date of Birth
 - ii. Medical Record Number
 - iii. Cancer diagnosis and staging
 - iv. Cancer treatment
 - v. Physical therapy notes

Future Research

Researchers will remove information that may identify you and may use your data for future research. If we do this, we will not ask for any additional consent from you.

Risks

In this study, you will not have any more risks than you would in a normal day of life. There are potential risks related to physical therapy which include but are not limited to your fatigue not getting better, worsening of conditions you already have, higher heart rate or blood pressure during physical activity, falls which could lead to broken bones.

No injury is expected from this study, but if you believe you have been harmed, contact the research team as soon as possible. Georgia State University and the research team have not set aside funds to compensate for any injury.

Benefits

This study is designed to benefit you by improving cancer-related fatigue and quality of life. However, this is not promised to happen. Overall, we hope to gain information about the benefits of physical therapy for patients with cancer fatigue.

Alternatives

You do not have to take part in this study to receive treatment for your cancer-related fatigue. You may take part in physical therapy without being in this study. You may also talk with your doctor about other treatments that may be available.

Costs:

The participant and/or his/her insurance will be billed for the cost of physical therapy sessions as they would normally be billed.

Voluntary Participation and Withdrawal

You do not have to be in this study. If you choose to be in the study and change your mind, you have the right to drop out at any time. You may skip questions or stop being in the study at any time.

You may refuse to take part in the study or stop at any time. This will not cause you to lose any benefits to which you are otherwise entitled.

Confidentiality

We will keep your records private to the extent allowed by law. The following people and entities will have access to the information you provide:

- Dr. Lisa Cranwell-Bruch, Laura DeMars, and Codi Rhear
- GSU Institutional Review Board
- Office for Human Research Protection (OHRP)

We will use your initials rather than your name on study records. The information you provide will be stored on a laptop computer that is protected with Norton 360 security software and is also password protected.

When we present or publish the results of this study, we will not use your name or other information that may identify you.

We will keep your personal information private. Your privacy will be kept to the extent allowed by law.

The health information you give us will be used in this research study. We will remove all information that can identify you. We will share it with other people for this research study. If you decide you want to be in this study it means that you agree to let us use and share your personal health information for the reasons we have listed in this consent form.

While we are doing this research, the research team may use only the personal health information that you have given us: name, date of birth, medical record number. The people and places that will be able to look at your personal health information are Codi Rhear, Lisa Cranwell-Bruce, and Laura DeMars. They will look at it so they can work on this research study. We may also share your health information with the Georgia State University Institutional Review Board (IRB). Your personal health information may be shared by the people or places we have listed, but it will be shared in a way that does not fall under the protection of federal regulations that apply to the privacy of health information. This research may be shown to other researchers. This research may be published, but we will take steps to make sure that you cannot be identified.

If you sign this consent form you are letting us use your personal health information until the end of the study. You have the right to say that you do not want us to use your personal health information after we have collected it. If you decide you don't want us to use your information anymore you must write a letter asking us not to use your information. You will need to send the letter to the investigator who received your completed questionnaires. This will be the only person who will be able to know which information is yours. We want to let you know that because the questionnaires do not have your name or address on them, we might not know which questionnaire is yours. If you don't want us to use your information anymore, we will stop using it, but any information that we have already used in the study will not be removed.

You may not be able to look at or get a copy of your health information that you gave us while we are doing the research; however you will be able to look at or get a copy at the end of the study.

Contact Information

Contact Codi Rhear at 715-892-4369 or via email at crhear1@student.gsu.edu or Dr. Lisa Cranwell-Bruce at 404-413-1189 or via email at lcranwellbruce@gsu.edu.

- If you have questions about the study or your part in it
- If you have questions, concerns, or complaints about the study.

The IRB at Georgia State University reviews all research that involves human participants. You can contact the IRB if you would like to speak to someone who is not involved directly with the study. You can contact the IRB for questions, concerns, problems, information, input, or questions about your rights as a research participant. Contact the IRB at 404-413-3500 or irb@gsu.edu.

Consent

We will give you a copy of this consent form to keep.

If you are willing to volunteer for this research, please sign below.

Printed Name of Participant

Signature of Participant

Date

Principal Investigator or Researcher Obtaining Consent

Date

Appendix D

EORTC QLQ- FA12 Fatigue Survey

**EORTC OLO-FA12**

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you.

During the past week:	Not at all	A little	Quite a bit	Very much
1. Have you lacked energy?	1	2	3	4
2. Have you felt exhausted?	1	2	3	4
3. Have you felt slowed down?	1	2	3	4
4. Did you feel sleepy during the day?	1	2	3	4
5. Did you have trouble getting things started?	1	2	3	4
6. Did you feel discouraged?	1	2	3	4
7. Did you feel helpless?	1	2	3	4
8. Did you feel frustrated?	1	2	3	4
9. Did you have trouble thinking clearly?	1	2	3	4
10. Did you feel confused?	1	2	3	4
11. Did tiredness interfere with your daily activities?	1	2	3	4
12. Did you feel that your tiredness is (was) not understood by the people who are close to you ?	1	2	3	4

----- Forwarded message -----

From: <no-reply@eortc.be>

Date: Tue, Feb 9, 2021 at 3:18 AM

Subject: Your request for an EORTC-questionnaire Request ID : 73505

To: <clrhear@gmail.com>

Dear Codi Rhear,

Thank you for registering on the EORTC Quality of Life Group website.

Your registration to obtain permission to use our tools has been approved. During the registration process you agreed to our terms and conditions regarding the academic use of our questionnaires. You can review the terms and conditions [here](#).

Please find below the links to the requested tools:

[Fatigue Module \(FA12\) - English](#)

Scoring Manuals:

[FA12 Scoring Manual](#)

EORTC

<http://www.eortc.org>

<http://qol.eortc.org>

NOTE:

This email was automatically generated. Since this email is an automatic notification, we are unable to receive replies. Please do not respond to this email address.

Appendix E

Flanagan Quality of Life Scale

QUALITY OF LIFE SCALE (QOLS)

Please read each item and circle the number that best describes how satisfied you are at this time. Please answer each item even if you do not currently participate in an activity or have a relationship. You can be satisfied or dissatisfied with not doing the activity or having the relationship.

	Delighted	Pleased	Mostly Satisfied	Mixed	Mostly Dissatisfied	Unhappy	Terrible
1. Material comforts home, food, conveniences, financial security	7	6	5	4	3	2	1
2. Health – being physically fit and vigorous	7	6	5	4	3	2	1
3. Relationships with parents, siblings & other relatives – communicating, visiting, helping	7	6	5	4	3	2	1
4. Having and rearing children	7	6	5	4	3	2	1
5. Close relationships with spouse or significant other	7	6	5	4	3	2	1
6. Close friends	7	6	5	4	3	2	1
7. Helping and encouraging others, volunteering, giving advice	7	6	5	4	3	2	1
8. Participating in organizations and public affairs	7	6	5	4	3	2	1
9. Learning – attending school, improving understanding, getting additional knowledge	7	6	5	4	3	2	1
10. Understanding yourself – knowing your assets and limitations – knowing what life is about	7	6	5	4	3	2	1
11. Work – job or in home	7	6	5	4	3	2	1
12. Expressing yourself creatively	7	6	5	4	3	2	1
13. Socializing – meeting other people, doing things, parties, etc.	7	6	5	4	3	2	1
14. Reading, listening to music, or observing entertainment	7	6	5	4	3	2	1
15. Participating in active recreation	7	6	5	4	3	2	1
16. Independence, doing for yourself	7	6	5	4	3	2	1



SPECIAL TERMS

These User License Agreement Special Terms ("Special Terms") are issued between Mapi Research Trust ("MRT") and Codi Rhear ("User").

These Special Terms are in addition to any and all previous Special Terms under the User License Agreement General Terms.

These Special Terms include the terms and conditions of the User License Agreement General Terms, which are hereby incorporated by this reference as though the same was set forth in its entirety and shall be effective as of the Special Terms Effective Date set forth herein.

All capitalized terms which are not defined herein shall have the same meanings as set forth in the User License Agreement General Terms.

These Special Terms, including all attachments and the User License Agreement General Terms contain the entire understanding of the Parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. If the terms and conditions of these Special Terms or any attachment conflict with the terms and conditions of the User License Agreement General Terms, the terms and conditions of the User License Agreement General Terms will control, unless these Special Terms specifically acknowledge the conflict and expressly states that the conflicting term or provision found in these Special Terms control for these Special Terms only. These Special Terms may be modified only by written agreement signed by the Parties.

1. User information

User name	Codi Rhear
Category of User	Student
User address	P.O. Box 724453 Atlanta 31139 Georgia United States of America
User VAT number	
User email	cirhear@gmail.com
User phone	
Billing Address	P.O. Box 724453 Atlanta 31139 Georgia United States of America

2. General information

Effective Date	Date of acceptance of these Special Terms by the User
Expiration Date ("Term")	Upon completion of the Stated Purpose
Name of User's contact in charge of the request	Codi Rhear

3. Identification of the COA

Name of the COA	QOLS - Quality of Life Scale
Author	Burckhardt CS
Copyright Holder	Mapi Research Trust
Copyright notice	QOLS © Mapi Research Trust, 2016. All Rights Reserved
Bibliographic reference	<p>Burckhardt CS and Anderson KL. the Quality of Life Scale (QOLS): Reliability, Validity and Utilisation. Health and Quality of Life Outcomes. 2003 Oct;1:60 (Full text article)</p> <p>Burckhardt CS, Anderson KL, Archenholtz B, Hagg O. The Flanagan Quality of Life Scale: Evidence of Construct Validity. Health Qual Life Outcomes. 2003 Oct 23;1(1):59(Full text article)</p> <p>Burckhardt CS et al. Quality of life of adults with chronic illness: a psychometric study. Res Nurs Health 1989;12:347-354 (PubMed Abstract)</p>
Modules/versions needed	QOLS

4. Context of use of the COA

The User undertakes to use the COA solely in the context of the Stated Purpose as defined hereafter.

4.1 Stated Purpose

Other project

Title	DNP project
Disease or condition	Cancer-related fatigue
Planned Term*	Start: 2/2021; End: 12/2021
Description (including format or media)	Patients diagnosed with cancer-related fatigue will be asked to complete a fatigue survey and a quality of life survey prior to being referred to physical therapy. Upon completion of physical therapy, they will be asked to complete these same surveys again to assess for changes in fatigue level and quality of life.

4.2 Country and languages

MRT grants the License to use the COA on the following countries and in the languages indicated in the table below:



Version/Module	Language	For use in the following country
QOLS	English	the USA

The User understands that the countries indicated above are provided for information purposes. The User may use the COA in other countries than the ones indicated above.

5. Specific requirements for the COA

- In case the User wants to use an e-Version of the COA, the User shall send the Screenshots of the original version of the COA to MRT or ICON LS for review and approval. The Screenshots review may incur additional fees.
- The Copyright Holder of the COA has granted ICON LS exclusive rights to translate the COA in the context of commercial studies or any project funded by for-profit entities. ICON LS is the only organization authorized to perform linguistic validation/translation work on the COA.
- In case the User wants to use an e-Version of the COA, ICON LS shall update (if needed) and populate the COA translations into the User's or IT Company's system and the User shall send the Screenshots of the translations of the COA to ICON LS for approval. The update (if needed), population of translations and the Screenshots review may incur additional fees.

By accepting these Special Terms, the User acknowledges and confirms that it has read and approves the User Agreement General Terms.

Appendix F

Demographic Questionnaire

Demographic Questionnaire

- 1. Age _____
- 2. Gender _____
- 3. Cancer Type _____
- 4. Cancer Stage _____
- 5. Date of Diagnosis _____
- 6. Current Cancer Treatment _____

Appendix G

Work Rule Engine

