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Recommendation of Intermittent Fasting in the Treatment of Chronic Musculoskeletal Pain: Evaluating Healthcare Provider Behavior and Patient Fasting Behavior.

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Recommendation of Intermittent Fasting in the Treatment of Chronic Musculoskeletal Pain: Evaluating Healthcare Provider Prescribing Behavior and Patient Fasting Behavior

by

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Dedication

This project is dedicated to my friends and family who have supported me throughout this journey. It has taken longer than planned but thank you for being patient with me. Thankful to my mom and dad- for always giving me that push when I needed it the most. I miss you Mom, and I wish you were here for this day. Dad, thank you for always giving me words of encouragement. Taylor and Shelby- I love you girls more than you will know, and I pray I have been the best role model I can be for you. ♥

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Abstract

Background: Chronic musculoskeletal pain was a significant problem in this primary care clinic. A total of 75% of the primary care providers (PCPs) agreed to consider an alternative treatment for chronic pain and Intermittent fasting (IF) was introduced as an option.

Purpose: Quality improvement project to introduce IF as an adjunct to traditional pain management for chronic musculoskeletal pain, evaluate PCPs' application, and patient response to provider recommendation of IF.

Methods: A virtual continuing education (CE) program on IF was presented to PCPs in family medicine to establish baseline competency. For two months, 29 patients were recommended IF who presented with chronic low back pain (N=13), chronic neck pain (N=7), and osteoarthritis (N=9). Retrospective chart reviews verified that PCPs recommended and documented the use of IF. Within two weeks, telephone calls collected patients' pre- and post-intervention continuous fasting hours and pain perception in response to IF.

Results: Chart reviews showed 62.5 % of PCPs recommended IF. A paired *t*-test was conducted to compare pre-(M = 7.78, SD = 0.74) and post-intervention (M = 11, SD = 1.51) continuous fasting hours, and a significant positive difference was calculated from these fasting hours; t (28) = 10.8, p = < .001. There was a 36% increase in continuous fasting hours post-intervention, but the Fisher's Exact test (p = .05) did not indicate a significant association between change in continuous fasting hours and pain improvement.

Conclusion: Although a change in fasting hours did not lead to pain improvement, the recommendations by PCPs and patients' willingness to trial IF were positive outcomes.

Keywords: *chronic musculoskeletal pain, fasting, intermittent fasting, inflammation*

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Recommendation of Intermittent Fasting in the Treatment of Chronic Musculoskeletal Pain: Evaluating Healthcare Provider Prescribing Behavior and Patient Fasting Behavior

Problem Statement

The International Association for the Study of Pain defines chronic pain as lasting longer than three months (Dydyk et al., 2022). Pain is a prevalent condition in primary care and contributes to a significant financial burden on society (Dydyk et al., 2022). Chronic pain has been linked with increased morbidity and mortality in chronic illnesses such as depression and anxiety, higher divorce rates, suicide, substance abuse, perceived poor health, and reduced quality of life (Cohen et al., 2021). Nociceptive pain is the most common form of chronic pain, so understanding its mechanisms is essential to guide holistic and appropriate treatment (Stanos et al., 2016).

Background/Significance

According to the World Health Organization (WHO), 20-30% of the world's population has some form of chronic musculoskeletal pain (El-Tallawy et al., 2021). Of those with chronic pain, 70%-80% have an underlying chronic musculoskeletal disorder (Flynn, 2020). Pain is ranked third among the top twelve causes of disability in the United States and is one of the main contributors to disability worldwide (Flynn, 2020; El-Tallawy et al., 2021). The Institute of Medicine released a report in 2010 that estimated that chronic pain in the United States is associated with costs of $560 to $635 billion per year (Stanos et al., 2016; Cohen et al., 2021; Mills et al., 2016). This estimate exceeds the cost for cancer, diabetes, and cardiovascular disease

combined (Stanos et al., 2016). Higher prevalence rates have been found in individuals living in rural areas, those from lower socioeconomic groups, women, and military veterans (Cohen et al., 2021). According to the Centers for Disease Control and Prevention (CDC, 2015), one in four adults is diagnosed with arthritis in Kentucky, and pain is ranked fifth in the top ten causes of disability in Kentucky (Kentucky Comeback, n.d.).

Literature Review

Problem

The DNP (Doctor of Nursing Practice) student (henceforth the project manager) conducted an extensive literature review to investigate the anti-inflammatory effects of Intermittent Fasting (IF) and the significant role played in treating chronic musculoskeletal pain. The most common form of chronic pain is nociceptive pain, which originates in nociceptor neurons from peripheral nerves within tissues such as joints, muscles, and bones. Noxious stimuli such as extreme heat (thermal), intense mechanical pressure (stretch/strain), or a chemical stimulus (pH change) cause these nociceptor receptors to be sensitized and immune cells to be activated (Baral et al., 2019). Lymphocytes, monocytes, and mast cells trigger an inflammatory cascade, releasing chemical substances that act through nociceptor receptors and lead to pain sensitization (Caron et al., 2022; Pinho-Ribeiro et al., 2017).

These chemical substances include cytokines, histamine, bradykinin, lipid mediators, and growth factors that have a pro-inflammatory effect on nociceptor neurons. A cytokine known as interleukin -1β (IL-1β) is a potent thermal and mechanical hyperalgesia substance and, when released, involves driving pain sensitivity in many forms of arthritis. Interleukin-6 (IL-6) is released in response to hyperalgesia to mechanical and thermal stimuli and is an essential

mediator of pain response. Interleukin-7 (IL-7) drives inflammation in many autoimmune and inflammatory diseases. These levels increase with mechanical stimuli (Baral et al., 2019).

Interleukin-10 (IL-10) is a unique anti-inflammatory cytokine with anti-nociceptive properties. This cytokine directly affects nociceptor neurons and inhibits the pro-inflammatory effects of IL-6, IL-1β, and tumor necrosis factor (TNF). IL-10 maintains the balance of the immune response when there is an injury or illness, and mast cells release TNF to create inflammation for protection to trigger the inflammatory process. When excess TNF cannot be inactivated, inflammatory conditions develop (Baral et al., 2019; Pinho-Ribeiro et al., 2017).

Arachidonic acid is released during inflammation at tissue damage sites and metabolizes to lipid mediators such as prostaglandins and leukotrienes, subsequently increasing pain sensitivity. Pain sensitization of peripheral nerve receptors induces cyclooxygenase 2 (COX2) expression in neurons, causing an accumulation of potent boosters known as prostanoids (Baral et al., 2019; Pinho-Ribeiro et al., 2017).

The neuroimmune system is bidirectional and regulates nociceptive pain. Inflammatory mediators are released by immune cells that act on peripheral nociceptors and Central Nervous System (CNS) neurons to sensitize pain. Peripheral nociceptors release neuropeptides from peripheral nerve terminals, potentially affecting innate and adaptive immune cells (Ji et al., 2018; Pinho-Ribeiro et al., 2017). Several innate and adaptive immune cells are in the CNS's dorsal root ganglia (DRG) cell bodies. Nociceptor terminals activate action potentials, which are transduced to the spinal cord's dorsal horn, and neurotransmitters relay signals to second-order postsynaptic neurons. A signal is then relayed to the brain and perceived as pain (Koop et al., 2021; Baral et al., 2019; Pinho-Ribeiro et al., 2017).

Peripheral sensitization is continuous nociceptive pain that increases inflammatory mediators' release from tissue injury. Peripheral nerve nociceptors develop increased sensitivity to thermal and mechanical stimuli by sensitizing them or lowering neuronal activation thresholds to increase action potential firing rates (Baral et al., 2019; Ji et al., 2018; Stanos et al., 2016). Neuroinflammation develops if the immune system fails to maintain balance from the continuous nociceptive pain. Central sensitization is driven by neuroinflammation in the peripheral nervous system (PNS) and CNS. Nociceptors either become hypersensitive to stimuli, nonharmful stimuli cause over-responsiveness, or pain is produced without stimuli (Baral et al., 2019; Ji et al., 2018; Dragan et al., 2020). The persistent pro-inflammatory state of chronic musculoskeletal pain causes continuous changes in neuronal structure and sensitization, altering how pain is perceived (Dragan et al., 2020).

Intervention

Intermittent Fasting (IF) is defined as meal schedules that cycle between voluntary fasting and eating over a given period, including multiple forms of timed eating patterns. (Armutcu, 2019). The categories of IF include alternate-day fasting (ADF), time-restricted feeding (TRF), and whole-day fasts. TRF will be used in this intervention. This strategy consists of 12-18 hours of fasting (which includes sleeping hours) and the remaining hours available for eating (Visioli et al., 2022). During the fasting period, an individual may consume up to 2.5 liters of any calorie-free liquid (Wilhelmi de Toledo et al., 2013).

There must be at least 12 hours of fasting in TRF for beneficial effects such as lowering blood glucose and insulin levels, improving insulin sensitivity, increasing ketone body production, mobilization of fatty acids, and decreasing markers of oxidative stress and

inflammation (Caron et al., 2022). Liver glycogen is the most predominant source of plasma glucose after an overnight fast. A continued period of fasting will reduce glycogen stores, and at that point, new formations of glucose come mostly from muscles. The liver takes up these amino acids and fatty acids from the muscles. They continue accumulating in the liver, and once the storage is sufficient, they are broken when the byproduct is released into the plasma as ketone bodies (Attina et al., 2021). The body utilizes ketone fatty acids as the major energy source. This major energy switch is known as intermittent metabolic switching and has been shown to have anti-inflammatory effects. The switching between glucose and ketones can occur intermittently, depending on energy needs and diet. In the fasting state, the body relies on ketones, and when carbohydrates are consumed, insulin is released, and the body switches to glucose as an energy source (Nain et al., 2020).

Justification

IF can be recommended as an alternative intervention or used with conventional medicine to improve overall pain management (Caron et al., 2022). IF may contribute to treating chronic conditions such as degenerative and inflammatory diseases (Armutcu, 2019). In osteoarthritis, IF has been shown to protect against cartilage degradation by enhancing insulin sensitivity. (Caron et al., 2022). Inflammatory pain is secondary to damaged tissues, and these damaged tissues trigger an inflammatory cascade that releases cytokines such as IL-1β, IL-6, TNF-α, and prostaglandins from immune cells. These mediators then sensitize the nociceptor neurons on peripheral nerve endings, producing signals to the brain and perceived as pain (Caron et al., 2022; Baral et al., 2019). Several studies have investigated IF regimens on immune system functioning and shown a decrease in the number of circulating lymphocytes and monocytes and a reduction in pro-inflammatory cytokines such as TNF-α, IL-6, and IL-1β (Caron et al., 2022).

Xie et al. (2022) performed an RCT comparing the effects of early and mid-day TRF with a control group and reported a reduction in plasma levels of inflammatory markers TNF-α and IL-8 in the early TRF group. Kökten et al. (2021) reviewed observational studies and RCTs, providing an overview of strategies to reduce calories, health outcomes, and knowledge about inflammatory diseases. Armutcu (2019) also reported studies showing that fasting reduced the inflammatory marker IL-6. The Comprehensive Assessment of Long-Term Effects of Reducing Intake of Energy (CALERIE) was three RCT pilot studies examining short and midterm calorie restriction effects and lowered blood pressure, LDL-cholesterol, and triglycerides. It increased HDL- cholesterol levels. Lipid mediators such as prostaglandins and leukotrienes are pain sensitizers that significantly signal pain (Baral et al., 2019). These results display the impact that lipids can have on the inflammatory process (Kökten et al., 2021). These findings set the groundwork that fasting may be a favorable treatment for approaching chronic pain syndromes (Michalsen & Lin, 2013).

Needs Assessment

Chronic musculoskeletal pain was a significant problem identified in this primary care setting. The project manager requested a data analysis report in the Epic medical record system for the average number of chronic pain patients presented to the clinic each month. Epic is the electronic medical record (EMR) system within the clinic, and the data analyst assigned to the clinic reported that an average of 657 patients were treated for chronic pain each month by all providers combined. This query included patients with a diagnosis of chronic neck pain, chronic low back pain, and osteoarthritis.

Four nurse practitioners and fourteen family physicians/residents practiced in the project site clinic. Each provider was emailed a survey to determine prescribing behavior when treating chronic musculoskeletal pain. Responses were received from 75% of the PCPs, and they reported treating 6 to 100 patients with chronic musculoskeletal pain within the previous two months. All PCPs responded with "yes" when asked if they would consider recommending a non-pharmacologic treatment to their patients when treating chronic musculoskeletal pain. PCPs have often assumed the role of managing the treatment plan for patients with chronic pain but have reported minimal confidence in their prescribing abilities. Many felt they have had insufficient education and training in chronic pain to implement into their clinical practice (Stanos et al., 2016). The role of managing chronic pain was often assumed, but the fear of liability was increased if a prescription opioid was warranted. Fears included sanctions from state medical boards, scrutiny from the Drug Enforcement Agency, or being labeled a "high prescriber" by insurance or pharmacies (American Medical Association Pain Task Force, 2020). Family medicine was an appropriate area of practice for this DNP project to be implemented because there was an established core of chronic pain patients without additional cost or staff.

Conceptual Framework/Model

The Model for Improvement provided a framework to develop, test, and implement changes to lead to improvement (Institute for Health Improvement, 2022). The Plan, Do, Study, Act (PDSA) cycle was the improvement model that guided this project. It was a continual problem-solving model with four stages evaluated on a smaller scale (Institute for Health Improvement, 2022). In the first stage, the plan was created to increase PCP prescribing behavior and to increase patient fasting behavior by increasing continuous fasting hours. The second stage was the "do" stage, or the implementation stage. A CE program was presented on the use of IF in

chronic pain treatment during the weekly grand rounds meeting with the PCPs and discussed how to implement the recommendation. The project manager also met with ancillary staff to provide an overview of the project and their responsibilities. The PCPs provided the IF intervention to appropriate patients and furnished them with educational material. The third stage is "study," where the project manager collected data with retrospective chart reviews to validate the recommendation of IF by documentation in the patient chart. A follow-up telephone call was placed to patients to collect reported continuous fasting hours and pain perception. The last stage, "act," evaluated PCP prescribing and patient fasting behavior outcomes and determined what practice changes were needed for future improvement cycles (Appendix A).

Purpose/Specific Aims/SMART Goals

The purpose of this DNP quality improvement project was to introduce IF as an adjunct to traditional pain management in those with chronic musculoskeletal pain and to evaluate PCPs' application of this modality and patient response to provider recommendation of IF. Specific aims were to 1) evaluate PCPs' application of IF as an adjuvant musculoskeletal pain therapy and 2) evaluate the patient's perceived improvement of musculoskeletal pain using IF as an adjuvant therapy two weeks following the patient's agreement to trial IF. The first objective for applying IF was that by the end of the 2-month project, 50% of the PCPs had recommended IF to their chronic pain patients, as evidenced by EMR charting. The second objective for evaluating the patient's perceived improvement of musculoskeletal pain was to observe a 10% increase in continuous fasting hours and a positive improvement in their perception of pain.

Methods

Design

The program manager used the Institute of Health Improvement's quality improvement (QI) model (Plan, Do, Study, Act) to evaluate the value of IF as a non-pharmacological pain management modality for those with musculoskeletal pain (Institute for Health Improvement, 2022). The use of a QI model was appropriate for this project because it allowed for the collection and analysis of data to enable project changes based on observations and measurements and led to improved patient outcomes.

Setting

The project manager implemented this quality improvement project within a family medicine clinic in a blended academic and community environment. The clinic had 25 examination rooms with a computer station utilizing an EMR system. A full spectrum of on-site services included well-care visits for children and adults, X-rays, lab work, spirometry, EKG, and minor surgical procedures. The patient population ranged from birth to older adults. Insurance plans, including Passport/Kentucky Medicaid, Medicare, and Commercial Plans, were accepted. Clinic hours were Monday through Thursday from 8:00 am to 5:00 pm and Friday from 9:00 am to 5:00 pm. The clinic was a teaching facility designed to educate and train future providers.

Sample

The target population included physicians, residents, and nurse practitioners who currently practiced in the family medicine clinic. Patients were included in the project if they were established within the clinic and met any of the following criteria: (1) low back pain ≥ 3 months; (2) neck pain ≥ 3 months; or (3) osteoarthritis. The project manager excluded those with

(1) a Type 1 or Type 2 Diabetes diagnosis, (2) a history of an eating disorder, (3) pregnant, or (4) less than 18 years old.

Context

Chronic pain can be designated as nociceptive, nociplastic, or neuropathic. There are some similarities that exist among these types of pain (Cohen et al., 2021). Inflammation can contribute to pain in each, but it is a significant cause of nociceptive pain in which the immune system will trigger inflammation to provide protection. When this occurs, substances known as inflammatory mediators are released. These mediators can also carry harmful results that may lead to chronic inflammatory states, including chronic pain.

Stakeholders

Stakeholders with varying degrees of influence existed for this project. They included ancillary staff, primary care providers (PCPs), administration/clinical operations managers, and patients. The educational intervention focused on the PCPs, composed of physicians/residents and nurse practitioners. PCPs were crucial because they evaluated patient treatment plans and prescribed recommended therapies for pain. The administration and clinical operations managers were foundational when the project was implemented and managed. The patients were the consumers of the intervention and the most critical group of stakeholders.

Facilitators/Barriers

The facilitators of this project were the PCPs and the ancillary staff within the family medicine clinic. Ancillary staff triaged patients to identify those who presented with chronic pain initially. The PCPs identified and considered IF recommendation to patients for whom it was beneficial, and a non-pharmacologic treatment approach was appropriate. If the patient met the

inclusion criteria, but the PCP did not recommend IF, the PCP provided the rationale for exclusion. A significant barrier during the implementation of this DNP project was that the PCPs and involved patients perceived the intervention as a substitution for the patient's current treatment plan and were not familiar with IF. To mitigate this barrier, the project manager provided the PCPs with evidence-based literature and a continuing education program that demonstrated that IF had been utilized in chronic pain treatment and shown to have had effective results. The project manager understood PCPs had reservations and hesitancy since they were not accustomed to this treatment but were available to address their concerns or questions.

There was a delay in the time from the presentation of the CE program until the project's initial implementation. The CE program date was assigned by the University of Louisville Medical School and was determined by the scheduled dates for grand rounds. This was an inherent barrier to the implementation of this DNP project. To mitigate this barrier, the project manager emailed the PowerPoint presentation to all PCPs who attended the CE program so they could review the material as necessary before the project's implementation. The project manager provided patients with educational material written at a standard sixth-grade level to explain IF and why their PCP recommended this treatment.

Procedure

Following U of L Biomedical Institutional Review Board approval, the project manager presented a one-time virtual PowerPoint continuing education (CE) program on Microsoft Teams to the family medicine providers (Appendix B). This CE program focused on utilizing IF for chronic musculoskeletal pain. The PCPs had access to the CE presentation for review, and the project manager was available if needed. One week before implementation, the

project manager met with ancillary staff and provided an overview of the project and a description of their responsibilities. Data collection forms (Appendix C), patient education forms (Appendix D), a laminated project implementation flowsheet (Appendix E), and preamble consents (Appendix H) were placed in each nurse station for ancillary staff to have readily available for appropriate patients.

Once implementation began, the certified medical assistant (CMA) or nurse brought the patient to the exam room to obtain vitals and the reason for their visit. The assistant initiated a data collection form if the patient reported their chief complaint as musculoskeletal pain or pain medication refill. The patient medical record number from the Epic EMR system and the date of visit were entered on the form and left in the room for the visit. This alerted the PCP to consider recommending IF in their treatment plan. If the PCP decided that the patient met the inclusion criteria and it was appropriate for their treatment plan, the patient was provided with a copy of the preamble consent. The patient was asked to review the consent and given time to read the form entirely and ask any questions. The PCP explained the consent to the patient, which included the purpose, procedures, risks, benefits, and alternatives to participation. The approximate time for the PCP to explain the consent varied with each patient, depending on any concerns or questions. Adequate time was provided during the visit, but if needed, the project manager was available for questions or concerns that patients had either by telephone or while they were present in the clinic. Once the patient was presented and reviewed the consent, they were asked the following questions to assess their understanding, "Do you know what pain management strategy is being offered in the study?" and "Do you know how and when you will let the project manager know if you have been fasting and if your pain has improved?" The PCP documented on the data collection form that the patient agreed to a follow-up telephone call from

the project manager in approximately two weeks to inquire about fasting and pain. The PCP documented the following in the patient chart: "This patient meets the inclusion criteria to recommend IF, and a preamble consent has been provided to them. They have accepted the educational material and agree to be contacted by the project manager for a follow-up telephone call." By accepting the educational material, they agreed to participate and to receive a follow-up telephone call from the project manager. The original patient education presented to the providers during the CE presentation was revised to a seventh-grade literacy level. The PCP marked “yes” on the data collection form that IF was recommended and “yes” that the patient agreed to be contacted by a follow-up telephone call from the project manager. If the PCP did not recommend IF, then “no” was marked on the data collection form, nothing was provided to the patient, and the PCP indicated why they did not recommend IF on the data collection form. The data collection forms were returned to the medical assistant or nurse, given back to the project manager daily, and locked in a drawer in the office, and only the project manager had a key. The date of the visit and medical record number were included in the data set. The medical record number was replaced with a study identification number to preserve patient confidentiality. The study identification number was utilized on the retrospective chart review form, and chart reviews were done once weekly (Appendix F). The chart review verified that the PCP recommended IF to the patient and provided documentation in the patient's record. After data collection, the study identification number was marked through to de-identify the patient. The preamble consent was obtained because it was not usual practice in this clinic for patients to be contacted by telephone after office visits to acquire health information. The project manager conducted follow-up telephone calls to patients who agreed to trial IF within two weeks after the PCP recommendation. In phase one of this project, the telephone call obtained the following: (1)

the hours of fasting before the PCP recommendation of IF and after the recommendation; and (2) the perception of pain measured by a report of improvement or no improvement. The data set did not include the telephone number to contact the patient. The project manager recognized that patients reported inconsistent pre- and post-intervention fasting hours and required more clarity because they primarily reported their sleeping hours. It was determined that data needed to be more consistent and reflective of pre- and post-intervention total continuous fasting hours achieved in a 24-hour period, and a subsequent 2-month implementation period was planned. A brief email was sent to all PCPs and staff one to two weeks before the initial start date for phase two to review the project implementation process. The implementation process was repeated, but the follow-up telephone call to patients included: “Your provider recommended that you fast for several hours through the day. Considering that you are fasting during the hours you are asleep, you count these hours as fasting. Before your provider recommended IF, how many hours in a row during the day in a 24-hour period did you go without consuming food? How many hours in a row during the day in a 24-hour period did you go without consuming food after their recommendation?” The project manager also included the following to collect the patient's perception of pain: “Has your pain improved or not improved since your provider recommended IF?” A codebook was developed to record data on an Excel spreadsheet (Appendix G). At the project's conclusion, the patients' responses were deleted on all electronic devices.

No funding or grants was used for this quality improvement project. The education program provided to PCPs was virtual. The meeting with ancillary staff was presented during a routine staff meeting, so there was no additional cost for the intervention site. Printed education materials provided to PCPs, ancillary staff, and patients cost approximately $230. The project manager provided lunch and dessert for those who attended the staff meeting.

Ethical Considerations/Permissions

Approval from the University Institutional Review Board (IRB) was obtained before starting this quality improvement project. A meeting was scheduled on Thursday, February 24, 2022, with the clinic director, operations manager, several attending physicians, clinic manager, and several ancillary staff members and introduced the concept of this project. An email correspondence occurred on Monday, February 7, 2022, with the clinic director, who discussed approval of this project being implemented at the University of Louisville Health (ULH) Cardinal Station clinic. The ULH operations manager signed a written agreement and Interdisciplinary Research Oversight Committee Leadership Approval form on September 19, 2022. The project manager signed the CE program planning and disclosure of financial relationships for continuing education on December 15, 2022, and emailed it to the program coordinator for continuing medical education and professional development for family and geriatric medicine, who completed the educational planning documentation for CE credit.

The project manager conducted the retrospective chart reviews and was the only individual with access to data. Chart reviews took place on an encrypted, password-protected facility computer. The data collected was stored on a password-encrypted and password-protected project computer. A study identification number preserved patient confidentiality. The original data collection and chart review forms were locked in a drawer in the office, and only the project manager had a key. At the completion of this DNP project, all forms are secured for at least five years before being destroyed. The University of Louisville Health Insurance Portability and Accountability Act (HIPAA) policies and procedures and the International Review Board regulations were followed.

Measures

Process measure:

- For this quality improvement project, the project manager conducted a one-time virtual PowerPoint CE presentation on the use of IF in treating chronic musculoskeletal pain and established baseline competency for prescribing IF.
- The CE PowerPoint slides were emailed to all participants before the presentation.
- This CE program was designated for a maximum of 0.75 AMA PRA Category 1 Credit(s) by the University of Louisville School of Medicine. The participants checked in on their computer or phone browser before the presentation and entered their log-in information. An activation code was provided at that time that was joined at the start of the CE program session. The CE credit was sent electronically to their CE transcript at the program's completion.
- The University of Louisville School of Medicine is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.
- This process was measured by the following: (1) the percentage of providers in the clinic that attended and completed the CE program, which was 100%; and (2) a post-presentation evaluation conducted by the University of Louisville School of Medicine, which is still pending.

Prescriber behavior:

- To evaluate PCPs' application of IF as an adjuvant musculoskeletal pain therapy, the following measures occurred: (1) a baseline poll was taken before the CE program was presented to identify PCPs that had previously recommended IF for chronic pain; (2) retrospective chart reviews to verify documentation of IF recommendation.

Patient fasting behavior:

- The patient's perceived improvement of musculoskeletal pain using IF as an adjuvant therapy two weeks following the patient's agreement to a trial of IF, the following measures occurred: : (1) a telephone call two weeks after the IF recommendation by PCP obtained the number of continuous hours fasting before and after implementation of IF, as well as their perception of how IF affected their pain measured by reporting of improvement or no improvement.

Data Analysis

Data analysis was conducted using IBM SPSS 27 Statistical Software. The virtual PowerPoint CE program on IF's use in treating chronic musculoskeletal pain was presented to the PCPs, served as the process measure, and established baseline competency for prescribing IF. The number of PCPs that had recommended IF before the CE program was collected. The number of PCPs that had recommended and documented the use of IF in charts during the 2-month project was collected during retrospective chart reviews. The project manager conducted a follow-up telephone call to patients who agreed to trial IF within two weeks after the PCP recommendation. The continuous fasting hours pre- and post-intervention were collected and documented on retrospective chart review forms. Phase one of this project was concluded as a formative pilot and a subsequent 2-month implementation period was conducted. A brief email

was sent to all PCPs and staff one to two weeks before the initial start date for phase two to review the project implementation process.

The mean and standard deviation for pre- and post-intervention continuous fasting hours were calculated, and a paired t-test was conducted to determine a statistical significance between the means. A change in the continuous fasting hours (total post-intervention hours minus total pre-intervention hours) with the mean of these changes was computed. “As shown in Table 1 (see Appendix I)”. The sample size was small (N=29), and variables were grouped into the following categories on a two-by-two contingency table: (1) pain improvement /no pain improvement; and (2) >3 hours fasting/< 3 hours fasting. Each observation from the sample was designated to one of four cells on the contingency table: (1) >3 hours fasting/no pain improvement; (2) > 3 hours fasting/pain improvement; (3) <3 hours fasting/no pain improvement; or (4) <3 hours fasting/pain improvement. The number of observations in each cell was totaled, and a Fisher's Exact test was computed to determine if there was a statistically significant association between fasting hours and pain response. “As shown in Table 2 (see Appendix J)”.

Results

The first aim of this project was to evaluate PCPs’ application of IF as an adjuvant to musculoskeletal pain therapy. The baseline for the number of PCPs that had recommended IF was zero. Retrospective chart reviews conducted during phase one revealed 100% compliance (n=16) with the recommendation and documentation of IF. In phase two, the percentage of PCPs that recommended and documented IF in the chart was calculated by the number of PCPs who recommended and documented IF (n=10) divided by the total number of PCPs at the project site (n=16) and then multiplied by 100 to equal 62.5%. The first objective was that 50% of PCPs

would recommend IF to chronic musculoskeletal pain patients by the end of the 2-month intervention period, as evidenced by electronic medical charting. These findings are indicative that the first aim and first objective were met. The second aim of this project was to evaluate the patient's perceived improvement of musculoskeletal pain using IF as an adjuvant therapy two weeks following their agreement to trial IF. The second objective of this project was a 10% increase in continuous fasting hours and a positive improvement in patient perception of pain. The percentage increase in post-intervention continuous fasting hours was 36%.

There were 33 patients identified to be eligible for IF recommendation. Those charts were reviewed, and 29 patients were recommended IF with recorded documentation. Two patients were not recommended for "other reasons," and two were not recommended due to "not medically indicated." Of the 29 patients that were recommended IF, the chief complaints were chronic low back pain (N=13), chronic neck pain (N=7), and osteoarthritis (N=9). The mean pre- and post-intervention continuous fasting hours were 7.78 (SD = 0.74) and 11 (SD = 1.51), respectively. The mean change in reported continuous fasting hours was 3.29 (SD= 1.64), and a paired *t*-test computed $t\ (28) = 10.8$, $p < .001$. The Fisher's Exact test ($p = .05$) determined the association between pain response and fasting hours. The project manager contacted patients for their pre- and post-intervention continuous fasting hours and pain response. Therefore, the second aim of this project was met. Password-encrypted and password-protected computers were used for chart reviews and data collection, a study identification number was assigned, and original data collection and chart review forms were locked in a drawer in the project office. These measures ensured that patient confidentiality was preserved.

The project manager was present at the clinic site and was available throughout the implementation period for any questions or concerns presented by PCPs, staff, or patients. A

barrier often recognized was that the standard schedules implemented in this clinic seldom allocated enough time for PCPs to discuss patient involvement in this project. This was mitigated by reassurance that the project manager was available when needed. There were a few patients who were apprehensive about agreeing to trial the IF intervention because they misunderstood that this intervention was an adjunct to their current pain treatment regimen, not a replacement. Time was taken to address the patients' concerns, and they were provided with accurate information, alleviating their apprehension.

Discussion

Summary

This DNP project focused specifically on patients with chronic pain, particularly those with musculoskeletal disorders, in a family medicine clinic. Inflammation is significant in chronic pain; reducing inflammation can effectively manage pain. One aim of the project was to assess the application of IF by PCPs in managing chronic pain. To evaluate this, this project conducted a retrospective chart review and found that significant recommendations were made by PCPs who attended the CE program on the use of IF as an adjunct in pain management therapy. An additional project aim was to evaluate the relationship between increased fasting hours and a positive perception of pain. These findings showed that the recommendation of IF resulted in increased patients' fasting hours but not an association with a positive response to pain improvement.

Interpretation

As previously discussed, 20-30% of the world's population has some form of chronic musculoskeletal pain (El-Tallawy et al.,2021). The PCPs acknowledged this to be a problem in

the clinic and agreed to consider recommending a non-pharmacologic treatment modality such as IF. There were objectives set for this DNP project, and the first was that 50% of PCPs would recommend IF as an adjunct therapy for chronic musculoskeletal pain. This objective was met by showing that 62.5% of PCPs recommended and documented IF. There were more recommendations in phase one (N=16) than in phase two (N=10), which can be attributed to the longer time interval between the CE program and phase two than when initially presented in phase one.

A paired sample t-test was conducted to compare the means between pre-and post-intervention continuous fasting hours. The results indicated a significant difference between pre-intervention (M =7.78, SD = 0.74) and post-intervention continuous fasting hours (M = 11, SD = 1.51); [t (28) = 10.8, p = < .0001]. The results of the Fisher's Exact test (p = .05) did not indicate a significant association between pain response and fasting hour. The second objective of this DNP project was to evaluate the patient's pain perception to observe a 10% increase in continuous fasting hours and positive improvement. There was an observation of a 36% increase in continuous fasting hours but not a positive improvement in pain. The PCPs and patients had initial misconceptions and concerns about using IF, but these were addressed through education provided by the CE program and patient education.

Limitations

This project was performed in one Family Medicine clinic with a small sample size of PCPs, staff, and patients, as well as demographics, compared to other clinics. The findings and conclusions drawn from this project were specific to the clinic, which limited the generalizability of the results to other clinics. To minimize this limitation, future projects would include multiple

clinic sites with similar patient populations. Internal validity was addressed in several ways for this DNP project: (1) a standard protocol was developed for data collection and providing the intervention, and it was to be strictly followed by all PCPs and staff to maintain consistency; (2) pre- and post-intervention measures were collected, which allowed for comparison between groups at different time periods for reported continuous fasting hours; and (3) appropriate statistical tests such as the paired *t*-test and the Fisher Exact test were used to determine the observed results.

Conclusions

Chronic pain management was a significant problem identified in this Family Medicine clinic. This DNP project connected PCPs with IF as a non-pharmacologic intervention for chronic pain treatment. An initial retrospective chart review indicated 100% compliance with recommending IF to patients, and a subsequent chart review revealed that PCPs continued to recommend, which showed an adoption and continued application to practice. The patients gained the necessary knowledge to make informed choices about their pain management strategies and were provided with education regarding the benefits of adjunct therapy. A positive outcome from this project was supported by the observed increase in the change of continuous fasting hours after IF was recommended. The effects of IF on chronic pain were extensively researched for this project. Although there was not an association determined between pain response and fasting hours, the results of this project could still contribute to the knowledge surrounding this subject and be influential in incorporating IF as a complementary therapy for various other health benefits. Implications for future studies exist, which could lead to more effective interventions for pain management through expanding knowledge regarding pain etiologies. Exploring factors that could influence pain response, such as co-morbid medical

conditions, could assist in developing more effective interventions. This project could continue to be sustained safely and evidence-based in the Family Medicine clinic. Training programs for healthcare professionals can be offered to expand knowledge further and partner with nutritionists to enhance fasting regimens. This clinic could also collaborate with studies to investigate the benefits and risks of IF. This would establish their credibility in recommending this adjunct therapy. Additional implications for this study include a larger sample size of patients and multiple clinic sites to involve more PCPs. The PDSA cycle can be repeated to allow for adjustments within the project. Overall, this DNP project has the potential to contribute to the mindset around chronic pain management in a Family Medicine clinic.

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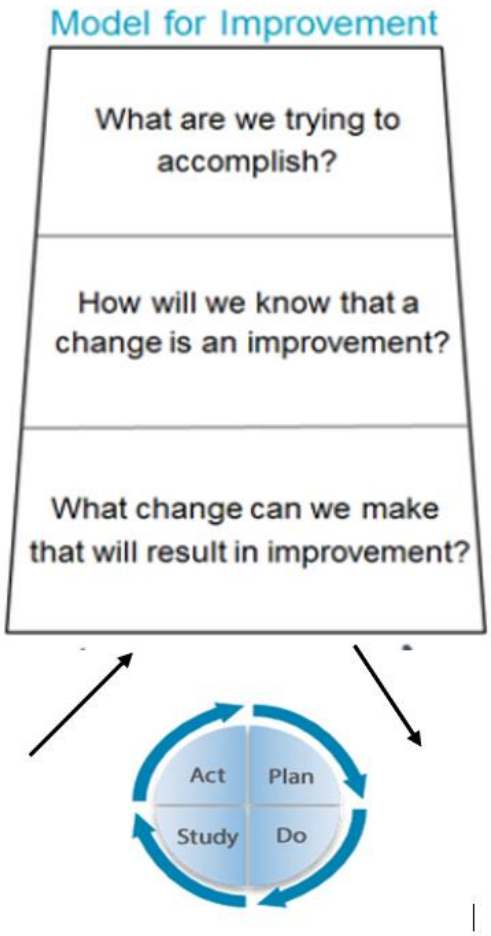
Appendix A

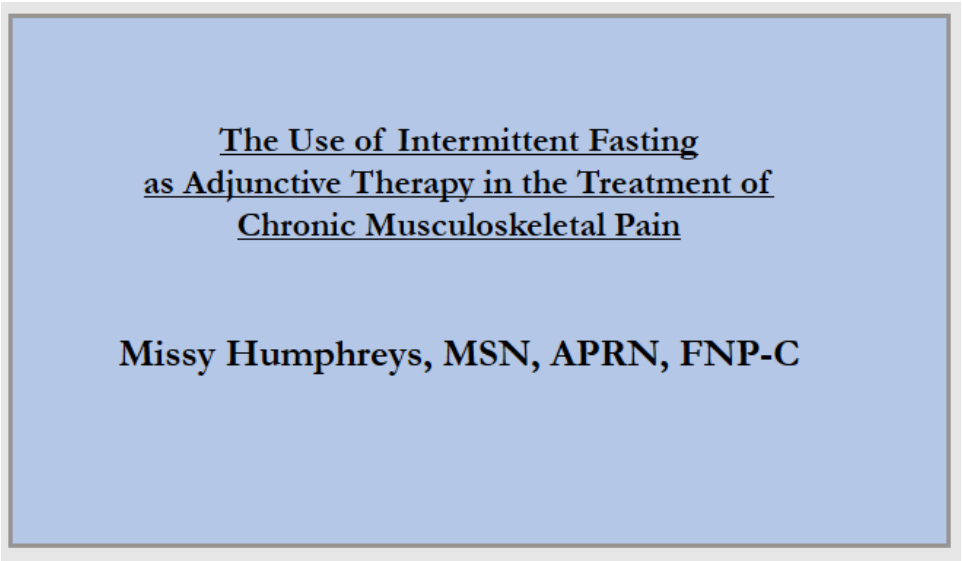
IHI Model for Improvement

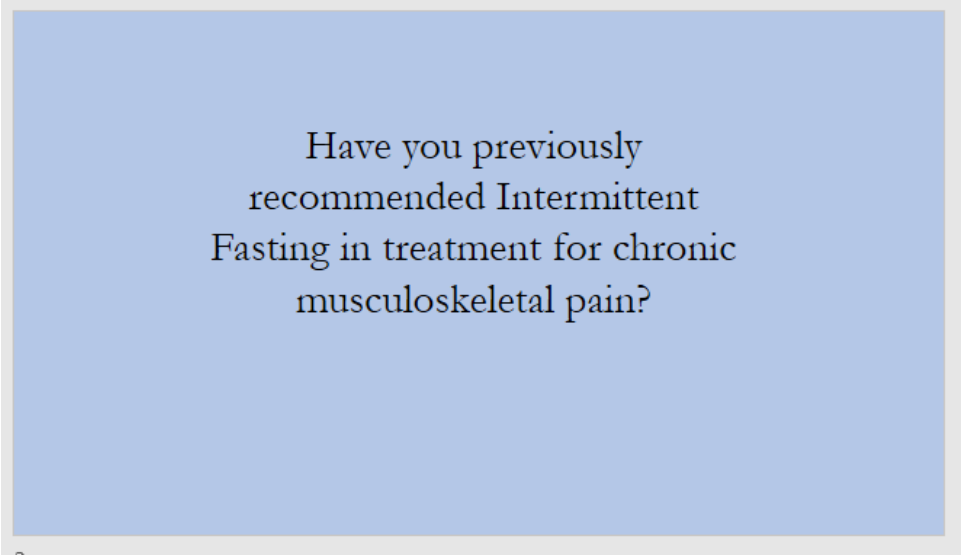


From "Science of Improvement: How to Improve," 2022, Institute for Healthcare Improvement. http://www.ihi.org/resources/pages/howtoimprove/scienceofimprovementhowtoimprove.aspx

Appendix B

PowerPoint CE Program Slides





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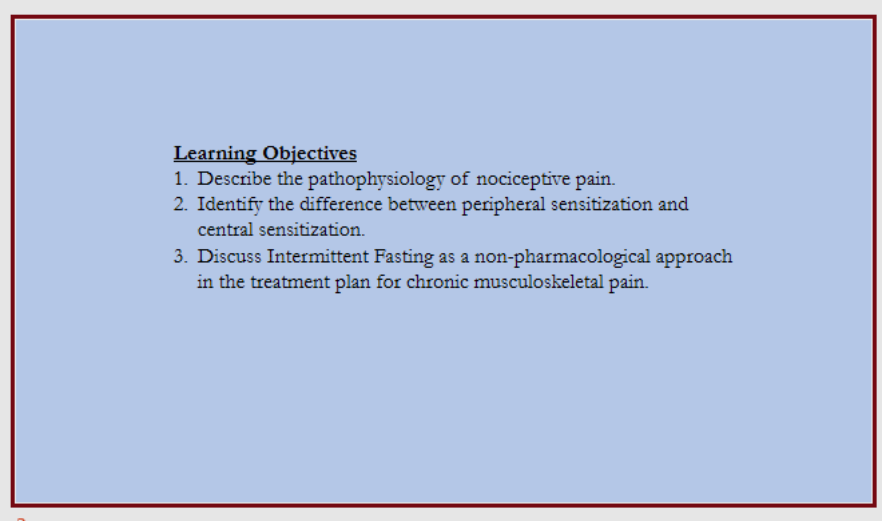
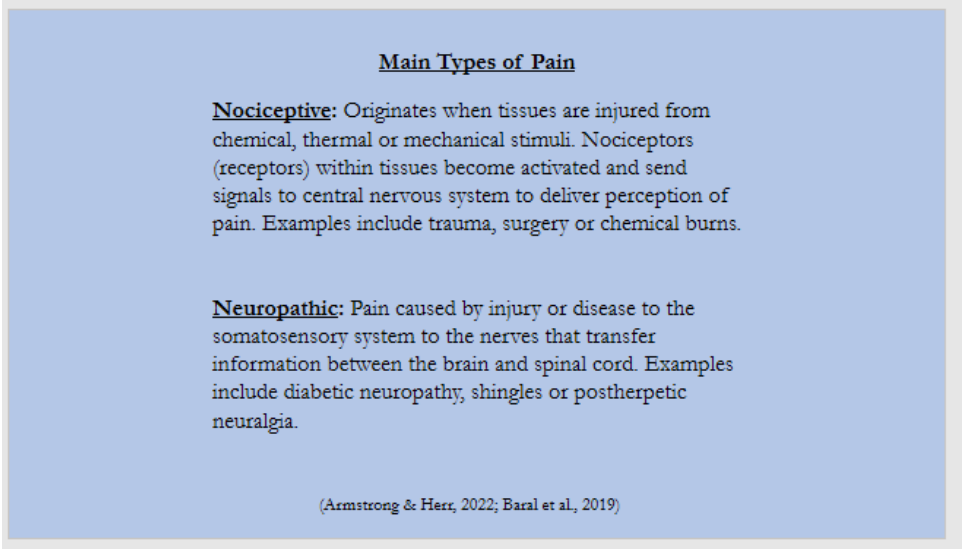
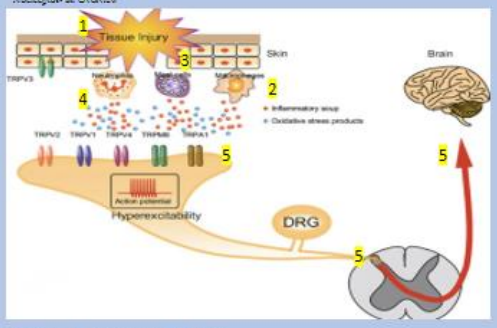




Appendix B (cont.)

Nociceptive Pain

- Nociceptors activate pain at site of tissue injury (1)
- Receptors in peripheral nerves become sensitive and trigger immune cells (2)
- Lipid mediators released at tissue injury (3)
- Neuropeptides released at peripheral nerve terminals and detect inflammatory mediators (4)
- Nociceptor terminals activate action potentials that are transduced to the dorsal horn of the spinal cord, neurotransmitters relay signal to second order postsynaptic neurons, relay signal the brain, and perceived as pain (5)



(Koop et al., 2021; Baral et al., 2019)
Note. From *Diseases of the Nervous System,* by H. Sontheimer, 2021, (https://doi.org/10.1016/C2019-0-03228-0)

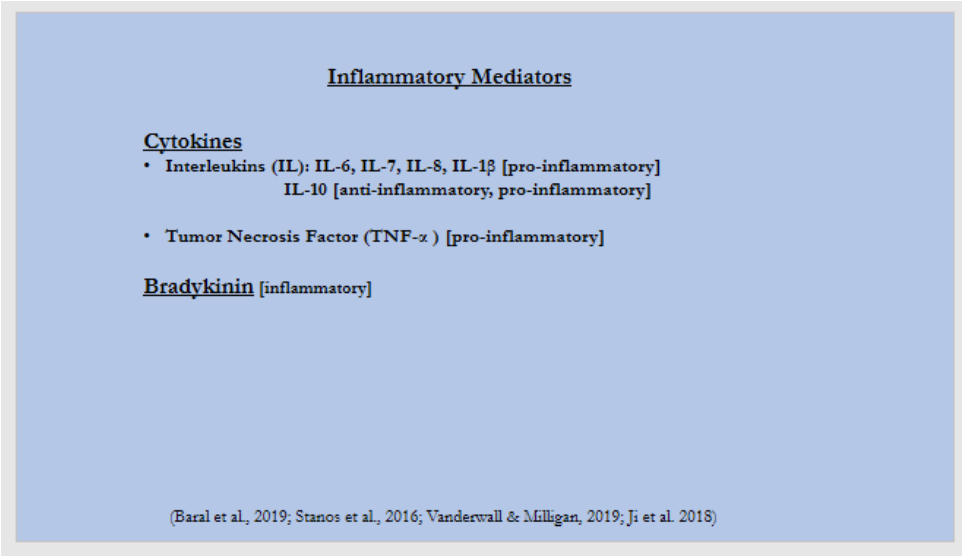
Peripheral tissues injured by noxious stimuli:

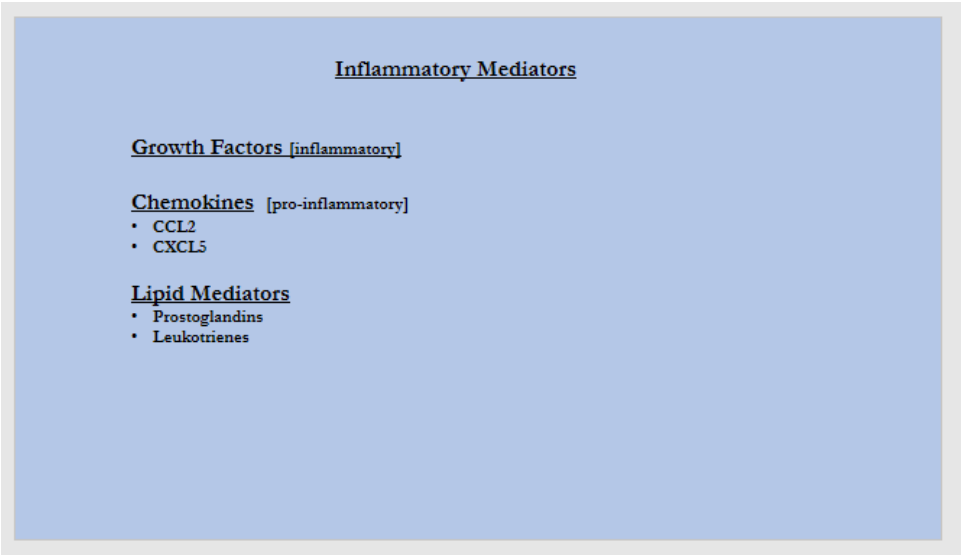
- **Skin**
- **Muscle**
- **Joint**
- **Bone**

Immune cells that activate and release mediators to regulate nociceptor activity on peripheral nerve terminal:

- **Mast Cells**
- **Macrophages**
- **Neutrophils**
- **T-cells**

Appendix B (cont.)





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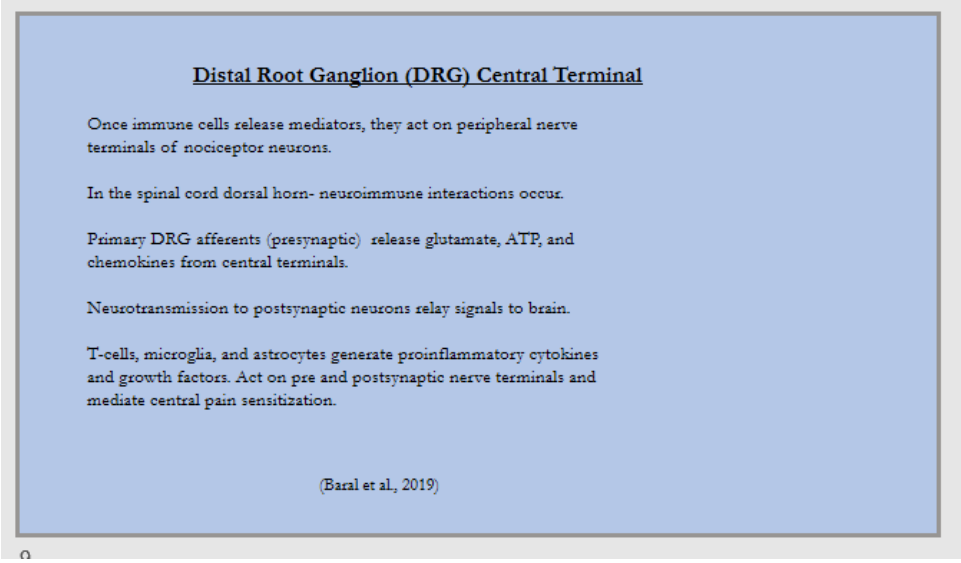

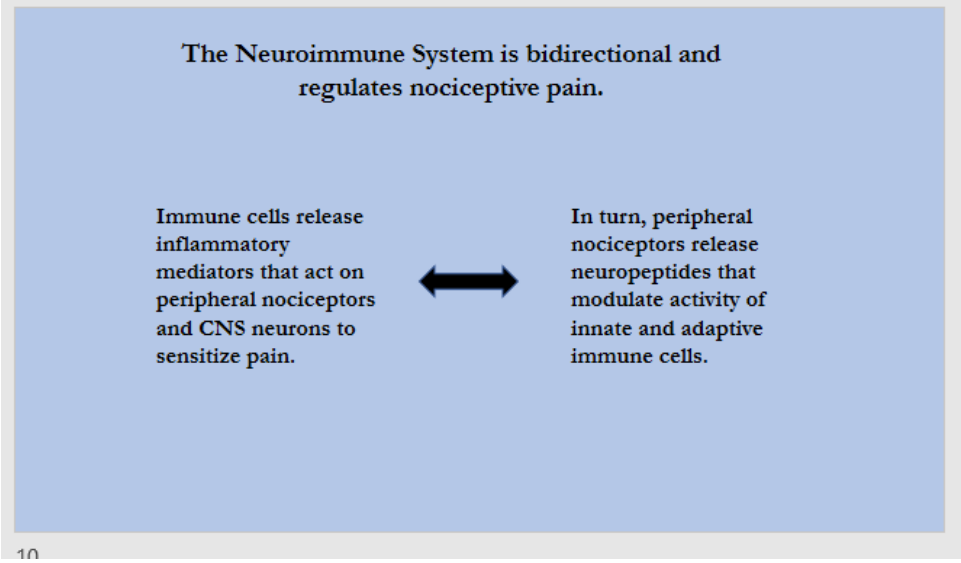

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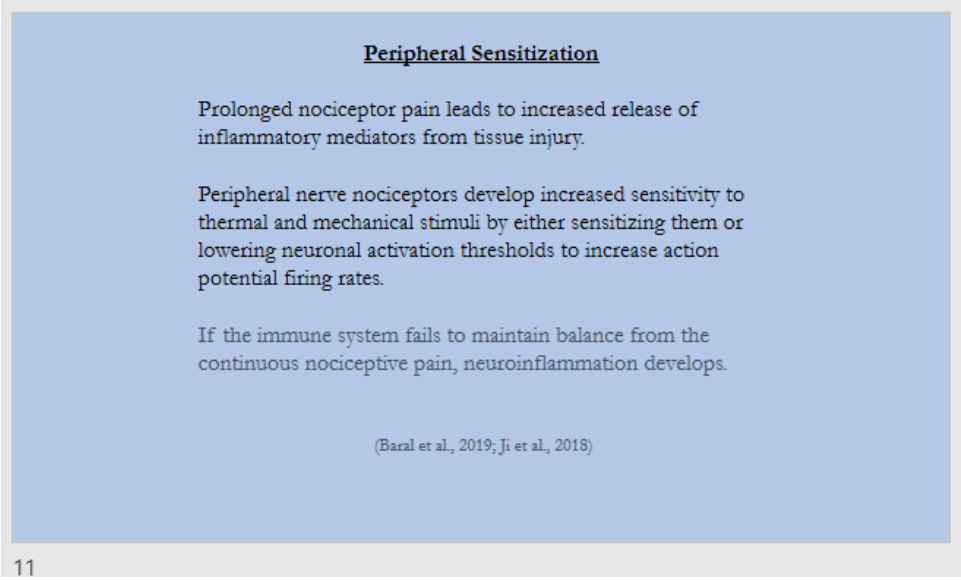
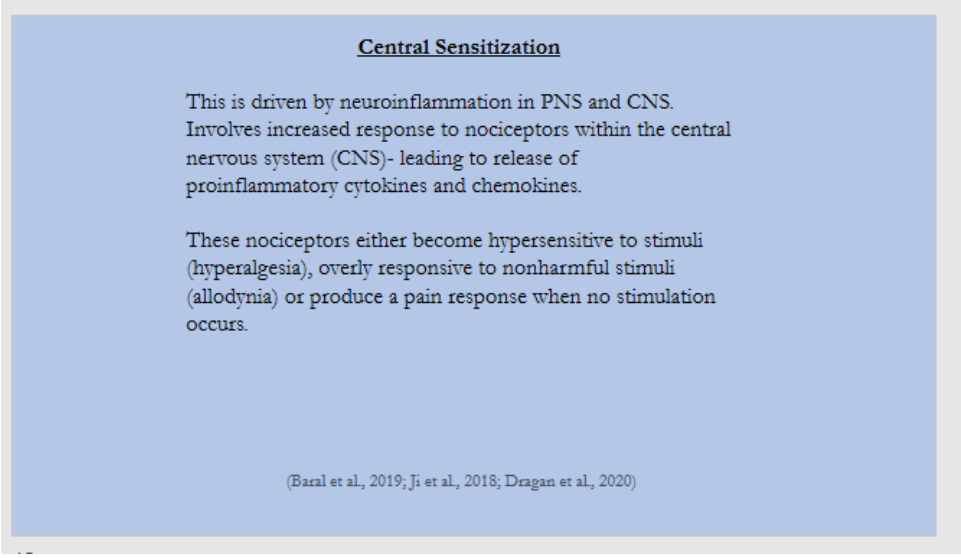




Appendix B (cont.)

What is Intermittent Fasting (IF)?

IF is defined as intermittent restriction in energy intake.

Categories

Alternate- Day Fasting	Time-Restricted Feeding	Whole-Day Fasts
Fast one day/ ab libitum the next day	Practice same routine- Certain amount of hours fasting/remaining hours eating	One to two days of complete fasting per week/ ab libitum on other days

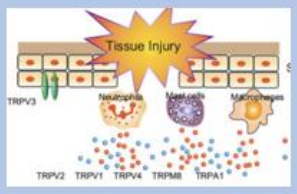
(Vissoli et al., 2022)

13

Physiologic benefits of IF with evidence to mechanisms underlying chronic pain

Decrease blood glucose levels/reduce insulin levels/improve insulin sensitivity

- Glucose-to-ketone switch - "Metabolic Switching"
- Decreases adipose tissue which contributes to cartilage degradation in OA



Baral et al., 2019; Caron et al., 2022

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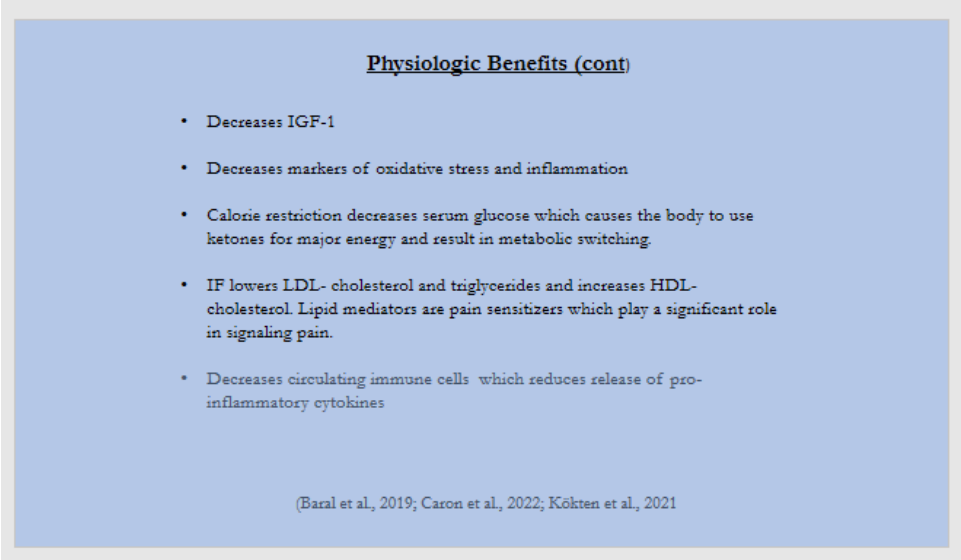

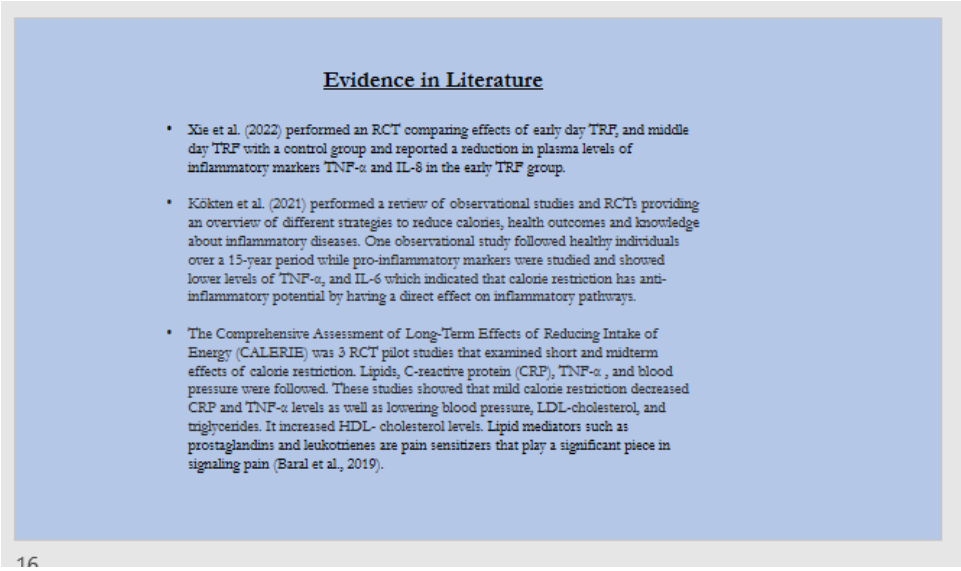

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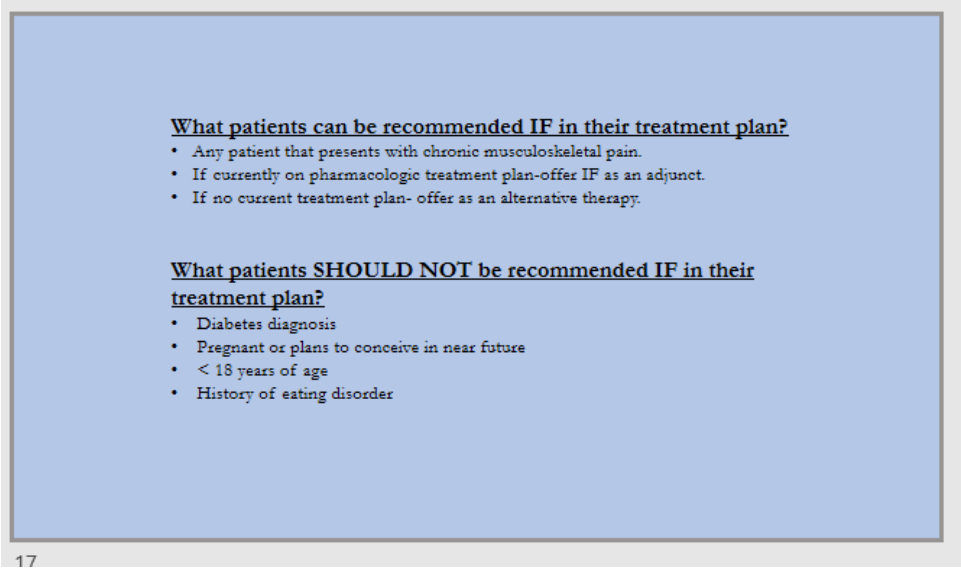


Appendix B (cont.)

Managing

CHRONIC MUSCULOSKELETAL PAIN

With

INTERMITTENT FASTING

Your PCP has recommended a non-pharmacologic option known as Intermittent Fasting to help treat your chronic pain.

What is Intermittent Fasting?

This concept is defined as periods of eating at regular times with periods of voluntary abstinence from food and liquid intake (Armutcu, 2019). You are probably wondering why your PCP would suggest that you go without food to help with your pain!

They are working with you to help manage chronic pain that you are dealing with each and every day. Chronic pain is defined as both an ongoing and recurrent pain that lasts beyond three to six months and affects the individual's well-being (Mallick-Searle, 2021). When your pain becomes chronic, the objective shifts from eliminating the pain to controlling the pain. This form of pain is included in conditions known as chronic inflammatory diseases.

Believe it or not, your immune system and nervous system play a role in how your body responds to pain. Here is how it works:

Nerves within Joints/muscles/bones receive some type of painful stimulant message	⇨	Message is sent to nerve endings connected to spinal cord which then sends message to brain and perceived as pain.
	⇨	As process continues, inflammation develops and immune system releases chemicals that produces more inflammation- which leads to more and more pain.

During fasting periods, your body uses ketones as the major energy sources. This major energy switch is known as intermittent metabolic switching and has shown to have anti-inflammatory effects (Nain et al., 2020). Fasting has shown to reduce the number of circulating chemicals that are released by the immune system that cause inflammation (Caron et al., 2022).

Here is how you follow the fasting regimen:

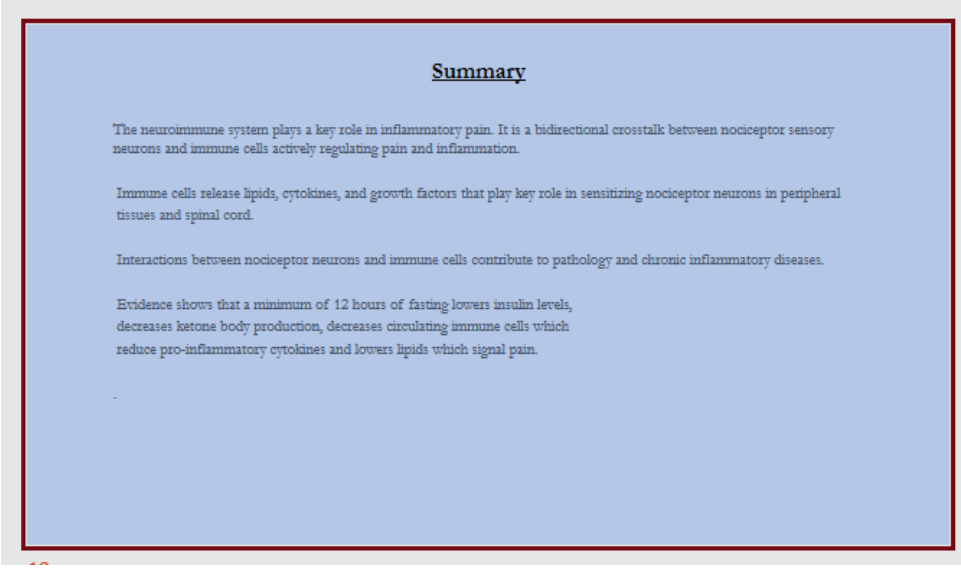
Your body will need at least 12 hours of fasting to receive the anti-inflammatory effects needed to help reduce inflammation. You can easily get these 12 hours because the time you are sleeping counts! For example, you can extend your fast for a few hours before or after your sleeping time. **During this time, no food is allowed to be eaten (no exceptions). But you can have up to 2.5 liters of any non-calorie liquid.**

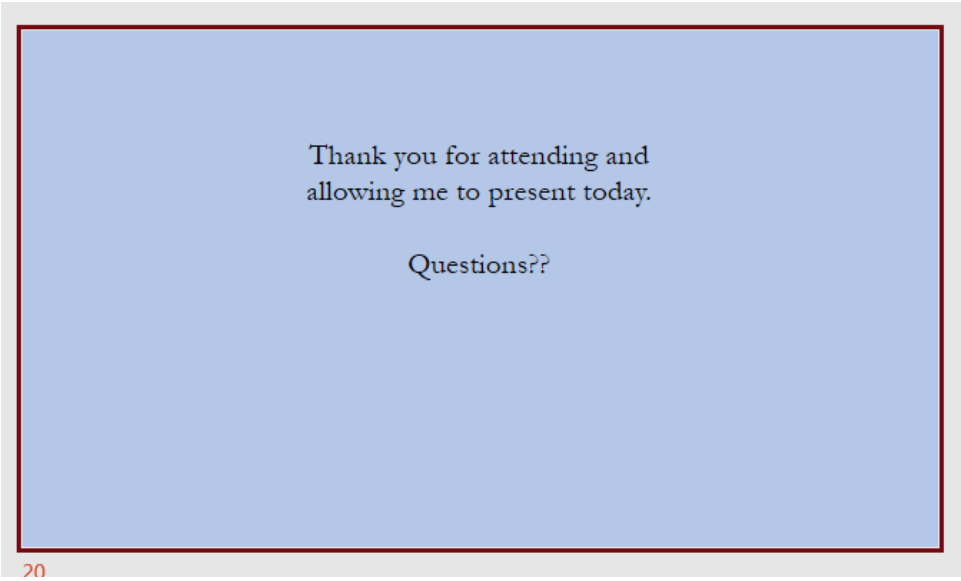
Please refrain from engaging in Intermittent Fasting if you have a history of Diabetes, history of an eating disorder, are pregnant or think you might be pregnant or less than 18 years of age.

References: Will be printed on back of form

(Slide 18 enlarged)

Appendix B (cont.)





Appendix B (cont.)

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Kökten, T., Hansmannel, F., Ndiaye, N.C., Heba, A.C., Quilliot, D., Dreumont, N., Arnone, D., & Peyrin-Biroulet, L. (2021). Calorie restriction as a new treatment of inflammatory diseases. *Advances in Nutrition, 12*(4), 1558-1570.

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Appendix C

Data Collection Form

Patient medical record number: _____

Date of Visit: _____

Chief Complaint (Inclusion criteria):

___ chronic low back pain _____ chronic neck pain

_____ osteoarthritis _____ other

Exclusion criteria

__ Diabetes _____ History/current eating disorder

__ Pregnant _____ Age < 18 years old

Was IF recommended?

_____ yes

_____ no

Does the patient agree to a follow-up telephone call in approximately 2 weeks from the project leader to inquire about fasting and pain?

_____ yes

_____ no

If not recommended, why?

_____ not medically indicated.

_____ other

Appendix D

Patient Education

Treating

CHRONIC MUSCULOSKELETAL PAIN

With

INTERMITTENT FASTING

Your provider has suggested Intermittent Fasting to help treat your chronic pain.

What is Intermittent Fasting?

It is when you have a certain number of hours that you eat each day and then other times that you do not eat. You are probably wondering why they would tell you to go without food to help your pain.

They are working with you to help treat the chronic pain that you have every day. Chronic pain is pain that can last longer than three to six months. When your pain becomes chronic, it gets harder to get rid of the pain.

Believe it or not, your immune and nervous systems control how your body deals with pain. Here is how it works:

- Nerves in joints and muscles, and bones get a pain message.
- That message gets sent to nerve endings connected to the spinal cord and sends that message to the brain, and then you have pain.
- If this keeps going, inflammation builds up, and the immune system lets chemicals out that leads to more and more pain.

Fasting brings down the number of chemicals that get let out in the body by the immune system that cause inflammation.

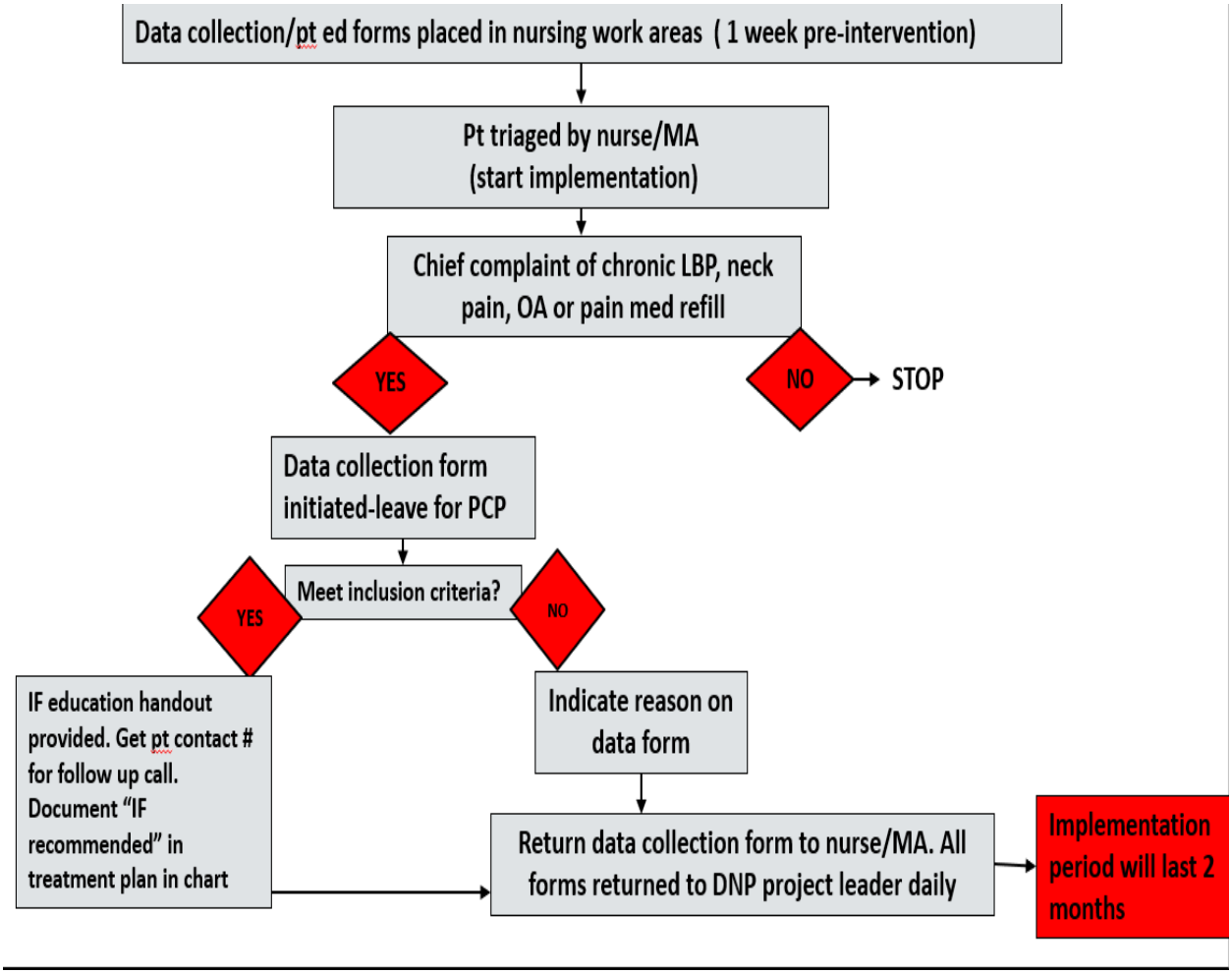
Here is how to do the fast:

Your body will need at least 12 hours of fasting. You can easily get these 12 hours because the time you are sleeping counts! For example, you can spread your fast for a few hours before or after you sleep. **During this time, no food is allowed to be eaten. But you can have up to 2.5 liters of any non-calorie liquid.**

Please do not do Intermittent Fasting if you have a history of Diabetes, or any eating disorder, are pregnant, or think you might be pregnant or less than 18 years old.

Appendix E

Project Implementation Flowsheet



Appendix F

Retrospective Chart Review

Study Identification Number: _____

Was IF recommended?

_____ yes

_____ no

If not recommended, why?

_____ not medically indicated.

_____ other

Number of fasting hours prior intervention/recommendation_____

Number of fasting hours after intervention/recommendation _____

Response in pain level _____ improved

_____ not improved

Appendix G

Codebook for Data Analysis

Data Collection Form

Study identification number: _____

Retrospective Chart Review

Was IF recommended and documented in the chart?

(0) No

(1) Yes

If not recommended, what were the exclusion criteria?

(1) not medically indicated

(2) other

Number of fasting hours prior recommendation_____

Number of fasting hours after recommendation _____

Response in pain level

(1) Improved

(2) Not Improved

Appendix H

Preamble Consent

Recommendation of Intermittent Fasting in the Treatment of Chronic Musculoskeletal Pain: Evaluating Healthcare Provider Prescribing Behavior and Patient Fasting Behavior

Dear Participant,

You are being invited to participate in an evaluation using fasting as a pain management strategy in addition to your current treatment plan. The study is conducted by Dr. Frances Hardin- Fanning, Dr. Candace Harrington and Missy Humphreys, Nurse Practitioner at Family Medicine Cardinal Station and DNP student, of the University of Louisville School of Nursing.

Taking part in this evaluation is voluntary. You are eligible to participate if you have chronic neck pain, chronic back pain, or osteoarthritis. The possible risks for participating in this study include headache, fatigue, lightheadedness, irritability, sleep disturbance, dehydration, increased hunger, mood changes secondary to a modified diet regimen, and negativity from others not participating in the study. By accepting educational material and agreeing to receive a telephone call you agree to speak with Missy Humphreys 2-4 weeks after your office visit. You may choose not to take part at all.

Your participation in the project will involve receiving educational material during your office visit explaining intermittent fasting and how it can reduce pain. The telephone call from Missy will take approximately 10 minutes. The information you provide will include the number of hours you fasted and if there has been any reduction in pain over the past 2-4 weeks. Your information will be stored on a locked and encrypted computer. The information learned may be helpful to others.

Individuals from the University of Louisville School of Nursing, the Institutional Review Board (IRB), the Human Subjects Protection Program Office (HSPPO), and other regulatory agencies may inspect these records. In all other respects, however, the data will be held in confidence to the extent permitted by law period should the data be published comma your identity will not be disclosed.

If you have any questions, concerns, or complaints about the quality improvement project, please contact Dr. Frances Hardin-Fanning (502) 852- 3949 or Missy Humphreys (502) 588-8720.

If you have any questions about your rights as a participant, you may call the Human Subjects Protection Program office at (502)852-5188. You can discuss any questions about your rights in private, with a member of the Institutional Review Board (IRB). The IRB is an independent committee made up of people from the university community, staff of the institutions, as well as people from the community not connected with these institutions. The IRB has reviewed this project.

If you have concerns or complaints about the quality improvement project or project staff and you do not wish to give your name, you may call 1-877-852-1167. This is a 24-hour hotline answered by people who do not work at the University of Louisville.

Sincerely,

Signature of PI/DNP Student
Version date: 4/25/2023

Appendix I

Table 1.

Summary of Continuous Fasting Hours

	Pre-Intervention	Post-Intervention	Change in Hours
	M =7.76 *SD* =0.74	*M*= 11 SD =1.51	*M* = 3.29 *SD* = 1.64
			t = 10.8 * df = 28
Study ID			
1	7	10	3
2	8	11	3
3	8	10	2
4	8.5	12	3.5
5	9	9	0
6	7	9	2
7	8	12	4
8	7	12	5
9	7.5	12	4.5
10	8	11	3
13	8	8	0
14	8	11	3
17	7	7	0
18	7	12	5
19	7.5	10	2.5
20	9	12	3
21	6	12	6
22	8	10	2
23	8	12	4
24	7	13	6

	Pre-Intervention	Post-Intervention	Change in Hours
	M =7.76 SD =0.74	*M*= 11 *SD* =1.51	*M* = 3.29 *SD* = 1.64
			t = 10.8* *df* = 28
Study ID			
25	8	12	4
26	8	12	4
27	9	12	3
28	7	10	5
29	8	12	4
30	9	13	4
31	8	9	1
32	7	12	5
33	8	12	4

*p = < .001

Appendix J

Table 2

Fasting Hours and Pain Response

	No Pain Improvement	Pain Improvement	Total
Greater Than 3 Hours Fasting	13	2	15
Less Than 3 Hours Fasting	7	7	14
Total	20	9	29

P = .05