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Layers

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Layers of dirt, rock and bone,
dark, damp, days of carefully peeling off one by one
with a fine-tooth comb.
Focus, hope, patience, needed to defend against
anticipation.
The agitation can become overwhelming in the
mine, I've seen it happen o're again.

When digging too deep without repose,
this awakens the earth, protecting what is trying to
be exposed.
One can put their whole being into this purpose,
scars and ache to tell.

Know well that under dirt, rock and bone there may
be gold.

Folding layers of hardship and worn nerve can hide
a soul.
Life like gold.
Just as the treasures of the earth are hidden.

Let then the miner and physician know
that below the surface there is true color
to show.
For how much more precious is a life than metal?
We must persist in uncovering the layers.

POEM COMMENTARY

The central theme of this poem was to describe the persistence required of physicians when working with patients that may be difficult to understand, and how that could connect to the process of gold mining. They (doctor and miner) both share a persistence in the act of uncovering, whether uncovering a precious metal in mining or removing individual barriers to get to know a patient (alternative: person). Structurally, the poem includes two lines of true rhyming followed by two lines of dissidence to build tension. Every new stanza begins with an early connecting rhyme to attempt to bring relief to the previous stanza's tension. This echoes the fact that the physician's process of uncovering is an ebb and flow of tension and resolve. The poem was designed to end without a resolve with a reference to the title. This was meant to prompt the reader to look inward, contemplate the theme as a whole and connect the weight of how much time and effort should be invested in people. It may be difficult to appreciate the complete meaning throughout the lines, so the next section is meant to address some of those nuances.

Lines 1–7: The poem begins with a vague reference to mining that may be unfamiliar to most people. In placer mining, many days are spent in machinery peeling back the earth, slowly descending towards the layers in which gold can be found. This mystery to which the poem is initially referring was meant to draw the readers in and promote a moment of wonder. The type of wonder is defined as, "a feeling of surprise mingled with admiration, caused by something beautiful, unexpected, unfamiliar, or inexplicable" (McKean, 2005). This wonder and curiosity can be the same way students and physicians may feel initiating a connection with a new patient. Line 4 describes how gold mining can feel like an endless process. One may find oneself asking the following questions: 'Will this be worth it? are we going to find gold? and What does it even look like?' The anticipation is unbearable, and one needs a strong sense of hope and vision to keep going. The same concept must be applied to patients. It may be easy to give up on someone and believe that there is nothing worth digging for. Sometimes all a person wants to do is give up, and the anticipation and waiting can seem overwhelming but hope helps them persist.

Lines 8–14: This stanza suggests that mining can be a dangerous process. If one is not careful with maintaining the angle of repose when excavating the earth, the walls can cave in. For clarification, the angle of repose is defined as, "the steepest angle at which a sloping surface formed of a particular loose material is stable" (McKean, 2005). When excavating the earth, the walls can cave in. Mistakes like this happen when the miner gets impatient or greedy. Just like the earth can protect its precious metals, so too patients cover themselves and hide if 'rubbed' the wrong way. The process requires great care and patience, and if done in a careful manner there may be a reward at the end.

Lines 15–18: This stanza reveals and confirms the connection between gold mining and humanity, with layers of hardship being the experiences that may need to be uncovered to find what is beneath. The gold in humanity is not meant to be a specific human trait, but rather the unique good in each individual. Also, a fascinating characteristic about gold is that every piece is highly unique in color and shape, and one does not need to be an expert to find a piece of it in an inconceivably large mess of dirt. One always knows when one sees it.

Lines 19–22: The last stanza alludes to 'true colors'. This makes an important distinction of neutrality because what is revealed may in fact not be beautiful or precious, but they are true colors nonetheless. Sometimes, even after the long hours, days, and years of trying to uncover this treasure, there may not be any gold at the end of one's pursuit. It is a sad truth, but both the miner and the physician must continue on in hope regardless. With regard to the line 'For how much more precious is a life than metal?', one must consider how vigorously we seek and sacrifice for our worldly desires and question whether we ought to give an even more significant effort in caring for our patients.

What the author hopes the readers will learn from this poem is that people and situations can be complex and difficult to work with, but one must persist in hope of finding the value in a person. Physicians, after all, are just like miners, and despite major setbacks, wall cave-ins, bankruptcy, or hardship, they will be back to continue digging with a renewed vigor and hope for treasure.

The author is currently in his fourth year of medical school. Prior to committing to a career in medicine he worked for six summer seasons, gold mining in the Alaska Range.

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Psychodermatology: The Intersection of Two Fields – A Narrative Review

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Introduction: *There is much overlap between the fields of psychiatry and dermatology and the fields are inherently intertwined. Many psychiatric conditions either have dermatologic manifestations or can exacerbate previously existing skin conditions. On the other hand, many dermatologic conditions, especially if widespread and severe or easily noticeable, may cause stress and a psychiatric response.*

Objective: *This paper will discuss the three main categories of psychodermatologic conditions: psychophysiologic disorders, primary psychiatric disorders, and secondary psychiatric disorders, which are not to be confused with pseudopsychodermatologic conditions. Certain conditions may be induced by psychiatric drug treatments. There are many psychiatric manifestations that can accompany dermatologic conditions, including alienation and substance abuse, which may go unrecognized. Many psychodermatologic conditions can have a huge impact on patients' quality of life, which should be assessed periodically if there is concern. This paper considers the current status of psychodermatology as a field today, and provides a brief overview of the categories of psychodermatologic conditions as well as management strategies based on recent relevant literature.*

Conclusions: *An appropriate approach to a psychodermatologic condition is imperative, as recognition and thorough evaluation of the psychiatric component of disease may be difficult for physicians in a busy clinic setting. In addition, many dermatologists feel unprepared to navigate the field of psychodermatology. There are several options for treatment, which will vary based on the specific type of psychocutaneous condition being managed. This article considers each angle of psychodermatology and provides an overview of approach, treatment, and management, and is informed by peer-reviewed literature.*

Keywords: *psychodermatology; neuro-immuno-cutaneous system; pseudopsychodermatologic; psychocutaneous; psychophysiologic*

INTRODUCTION

P psychodermatology is a field that has garnered increasing amounts of interest in recent years and delves into the mind–body connection. It is an intersection of psychiatry and dermatology that may be divided into several distinct categories. These include psychophysiologic disorders, primary psychiatric disorders, and secondary psychiatric disorders.¹ Psychophysiologic disorders are those that are exacerbated by stress and emotional responses from the patient, such as atopic dermatitis that is worsened by acute stress.¹ Primary psychiatric disorders are those psychiatric conditions that directly cause various dermatologic phenomena, such as trichotillomania, which results in hair loss.¹ Secondary psychiatric disorders are the direct result of deforming dermatologic conditions, which may affect how an individual is perceived by society.¹ Dermatologic disorders can also be held responsible for poor self-esteem and stress when patients are confronted with a public environment.²

These associations are given in Fig. 1. In addition, the treatment of certain psychiatric conditions can lead to various dermatologic findings, such as worsening psoriasis.²

An article in the *Indian Journal of Dermatology* suggests that 30–40% of patients with dermatologic conditions are believed to have concurrent psychiatric diagnoses.³ Due to the large amount of overlap, it is important that those specializing in psychodermatologic disease be well versed in both the psychiatric component as well as the dermatologic component. Likewise, awareness of psychocutaneous disease is imperative for both the practicing dermatologist and psychiatrist as both are likely to encounter these disease processes regularly. These conditions are best treated with a combination of pharmacologic treatment and therapy. It is necessary to consider the patient in the biopsychosocial context including the way an individual interacts with their environment starting at a molecular level, for appropriate management of the condition.

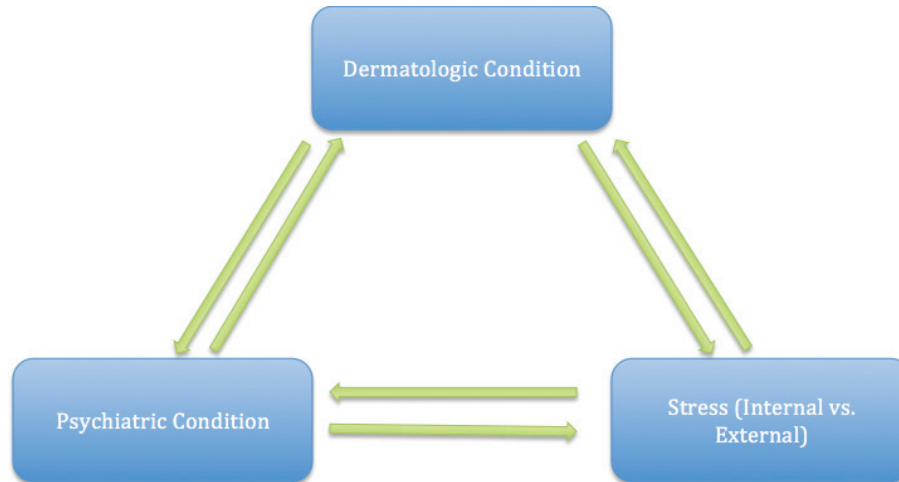


Figure 1. The association between dermatologic conditions, psychiatric conditions, and stress.

THE NEURO-IMMUNO-CUTANEOUS SYSTEM

The neuro-immuno-cutaneous system has been long described in the literature. The concept originates from the fact that the nervous system, the immune system, and skin all derive from the ectoderm during development.⁴ The interplay between these three systems is thought to be important in the development of psychocutaneous conditions. For example, research on the pathogenesis of psoriasis indicates that imbalance of substance P and vasoactive intestinal peptide, two neuropeptides, may play a role in the development of this disease.⁴ Herpes simplex is another example of a disease of neuro-immuno-cutaneous origin; herpes simplex remains dormant in neurons and leads to a cutaneous phenomenon when reactivated.⁴

ETIOLOGIES OF PSYCHODERMATOSES

Psychophysiological Disorders

Psychophysiological disorders are those that are generally worsened by an emotionally stressed state of the patient, such as atopic dermatitis, psoriasis, urticarial, and many others.^{1,5} Certain conditions may be affected by stress to a greater degree than other conditions of this category.⁴ Stressors include internal stress at a molecular level as well as external stress inflicted on the patient by the environment.² In other words, stress can be considered as any occurrence that alters homeostasis.⁶ Stressors activate hormones involved in the hypothalamic-pituitary-adrenal (HPA) axis to prepare the body to react to the altered state.⁶

The external environment that a patient experiences can play a large role in the course of psychophysiological disease.⁴ For example, patients with atopic dermatitis whose mothers underwent counseling regarding the disease had a significantly higher rate of improvement of lesions than those who did not have parental counseling.⁴

Most important, perhaps, is the subjective feeling of stress that a patient experiences in reaction to the external happenings.² Stress and the patient's individual experience of stress is known to worsen several chronic psychophysiological conditions including atopic dermatitis, herpes simplex, psoriasis, and acne vulgaris.^{1,2,7} Also, important is the way an individual is able to cope with psychological stress.⁶ Stress has been shown to impair the barrier function of the epidermis, which is likely a contributory factor to stress-related exacerbations of conditions such as atopic dermatitis and psoriasis.⁸

Primary Psychiatric Disorders

Primary psychiatric conditions relating to psychodermatology are conditions such as delusional disorder of infestation, trichotillomania, and repetitive skin picking.^{1,2} These disorders may be misleading and can initially be confused with a dermatologic condition. For example, trichotillomania may be initially perceived and treated as alopecia.¹ The DSM-5 recognizes several primary psychiatric diagnoses that are psychocutaneous conditions, including skin picking disorder (SPD) and trichotillomania.⁹

Many primary psychiatric conditions are caused by excessive or compulsive instrumentation of the skin.⁹ For example, neurotic excoriations result from difficulties of impulse control.¹⁰ An altered sensation may occur from the skin in a particular location – for example, patients may feel an itchy sensation from the scalp and may scratch or pick the scalp as a result.⁹ The scalp, along with the face, lips, and perineum, is frequently a target of instrumentation resulting from primary psychiatric conditions due to the high density of sensory neurons originating in these locations.⁹ In addition, patients with dermatitis artefacta may self-inflict injuries to assume a ‘sick’ role in order to be cared for by family, friends, and health care professionals.¹⁰

Sometimes certain physical manifestations may vary with regard to the primary psychiatric conditions between men and women.⁴ Acne excoriee is a common example, in which patients pick incessantly at their skin.⁴ Interestingly, in male patients, this may be a sign of worsening depression or anxiety, while in female patients, it may be more indicative of an immature or inadequately developed personality.⁴ A knowledge and familiarity of common presentations and associated psychiatric diagnoses is important when seeing such patients in a clinic setting for routine care.

Secondary Psychiatric Disorders

Secondary psychiatric disorders are those skin conditions that result in physical deformation, which then leads to a psychiatric reaction within the patient.² For example, extensive vitiligo may cause a patient to experience depression or anxiety about their physical appearance. Alopecia areata is another condition that may both be precipitated by and lead to great anxiety.⁵ The more severe a skin condition is, the more likely it is to be associated with a psychiatric condition.¹¹ Malignant melanoma is often associated with situational depression due to the poor prognosis of the condition.¹² This depression can in turn weaken the immune function of the body thereby worsening the prognosis.¹² It is important to screen patients with deforming or widespread skin conditions with regard to their coping mechanisms in order to determine if there is a secondary psychiatric condition which can then be treated.² By doing so, it may be possible to reverse the negative effects of depression and other psychiatric illnesses on the body’s ability to heal.¹²

PSYCHIATRIC DRUG-INDUCED CONDITIONS

Drugs used to treat common psychiatric conditions may also have an impact on the skin. Lithium, a mood-stabilizing agent commonly used in the treatment of bipolar disorder, and fluoxetine, an antidepressant, are both associated with the development of psoriasis or worsening of preexisting psoriasis.¹¹ Bupropion is a commonly used antidepressant that is thought to worsen psoriasis, and should therefore not be used to treat depression that may accompany this disease.¹¹ Conversely, drugs used to treat skin conditions, such as isotretinoin for severe acne, may be thought to induce psychiatric disturbances such as depression and suicidality.¹³ Though not considered as one of the three main categories of psychodermatology, it is still imperative that a provider remain aware of medications that a patient may be taking for a psychiatric condition given the possible dermatologic side effects.

PSEUDOPSYCHODERMATOLOGIC CONDITIONS

It is important for treating physicians to keep in mind the possibility of psychocutaneous disease as part of the differential diagnosis in any cutaneous condition. However, it is important to perform a thorough workup and investigate all other possibilities as well. A pseudopsychodermatologic condition is one that may initially appear as a psychodermatologic problem. For example, a clinician may believe that a patient is picking at the skin causing dermatitis artefacta, when in fact a dermatologic condition such as localized bullous pemphigoid or eczema is responsible for the findings.⁴ Therefore, while keeping the possibility of a psychocutaneous disease in mind is crucial, it is just as vital to investigate other disease processes as well.

PSYCHIATRIC RAMIFICATIONS

Alienation

Historically, patients with skin disease have often been shunned or ostracized by society.¹⁴ Although this may be more subtle in the modern world, the way a person appears to his or her peers plays a huge role in how that person integrates within their society. A patient’s given dermatologic condition may play a huge role in self-esteem and self-image, which can further affect socialization and the way a patient interacts with his or her peers.²

Stigmatization of dermatologic conditions such as vitiligo and psoriasis is a common phenomenon.^{11,14} A patient may bear the brunt of public disgust toward

his or her condition, which may result in social difficulties and feelings of shame experienced by the patient.¹¹ A condition like psoriasis also has a significant detrimental impact on a patient's relationships with family, friends, and romantic partners.¹¹ It may even impact patients at work, and several studies have found that patients with severe psoriasis have a significantly lower income than those with mild psoriasis.¹¹

Acne is another disease that has a significant effect on a patient's mental health.¹⁴ This skin condition can seriously damage a patient's self-esteem starting in adolescence and may continue to do so throughout the rest of the patient's life.¹⁴ Patients with acne consider the burden to be comparable in its psychosocial toll to chronic diseases such as diabetes and asthma.¹⁴ Adolescents with acne find it more difficult to fit into existing social networks and make meaningful relationships.¹⁴

The label or stigma attached to certain diseases may change the way a patient and his or her specific lifestyle are perceived by the general public. For example, a patient with rhinophyma resulting from rosacea might be perceived as an alcoholic even though this may not be accurate.¹⁴ Onlookers may make further assumptions about the patient based on the presence of a rhinophyma; this can be very frustrating for patients.¹⁴

Substance Abuse

Substance abuse may also be more prevalent in patients with severe or extensive dermatologic conditions. For example, patients with severe psoriasis have a higher rate of alcohol use and abuse.¹¹ The same result was found with smoking, even though this is known to worsen psoriasis.¹¹

Psychiatric Illness

Some of the most common psychiatric conditions that are present with psychocutaneous disorders include anxiety, depression, psychosis, and obsessive-compulsive disorder.⁷ These may be primary conditions leading to secondary dermatologic phenomenon, or they may result from a dermatologic condition or exacerbate existing skin disease. Adolescents with acne are often found to have depression and anxiety resulting from their skin condition, which may be accompanied by suicidality, especially among boys.¹⁴

Quality of Life

Patients with dermatologic disease experience markedly reduced quality of life based on surveys of patients

with rosacea, acne, seborrheic dermatitis, and other skin conditions.¹⁴ Quality of life is improved if cosmetic camouflage is employed using makeup.¹⁴ Optimism is also found to be associated with improved quality of life in psoriasis patients.¹⁵ Cutaneous body image, or CBI, is the way a person perceives his or her own skin and how he or she believes it appears to others.⁹ Patients with poor CBI generally have a worse quality of life. Since a poor CBI is also found in Body Dysmorphic Disorder (BDD),⁹ it is important to screen for this psychiatric condition so that patients can receive appropriate treatment, especially when considering that patients with BDD have a higher rate of suicide than the general population.

TREATMENT

Barriers

There are many obstacles that are present in the field of medicine that prevent patients with psychocutaneous conditions from receiving adequate care and management for their disease. A study performed to investigate deficiencies in psychodermatology in the United Kingdom showed that patients may have decreased access to psychological support.¹⁶ Patients with psychocutaneous disease may be improperly treated by dermatologists, who often do not investigate the psychiatric component of the patient's disease process due to lack of time in a busy specialty clinic.¹⁶ Psychodermatology programs may not have adequate funding to be successful.¹⁶ Treating physicians may not have enough training and feel they lack the comfort level needed to manage patients with psychodermatologic conditions.¹⁶ A recent survey showed that most dermatologists do not feel that they have adequate training in managing psychocutaneous disorders, with a mere 18% of responders admitting to a solid understanding of the actual meaning of psychodermatology.¹⁷ A widespread lack of training in psychodermatology is certainly a barrier to appropriate treatment of psychocutaneous conditions.¹⁶

Approach

First, it is important to remain aware that a psychodermatologic condition may be responsible for a patient's skin manifestations, and to keep this as part of the differential diagnosis. Approach to a psychodermatologic condition requires inspection of the physical dermatologic complaint as well as identification of factors that may be contributing to the condition including poignant social issues.

Psychophysiologic disorders require critical evaluation of a patient's internal stress as well as coping mechanisms and stress management. For patients with seemingly dermatologic complaints such as hair loss, it is useful to evaluate for primary psychiatric condition, especially if the patient is not responsive to treatment. Keeping a psychiatric diagnosis such as obsessive-compulsive disorder on the differential diagnosis is important.⁷ If a physician suspects that a patient may have a primary psychiatric diagnosis, it is important to keep in mind that the patient may deny self-inflicting any lesions.³ Physicians should continue to elicit relevant information from the patient, but should not challenge the patient's statements, as this would be destructive to the therapeutic alliance between the physician and the patient.³

Finally, it is critical to evaluate patients for a comorbid psychiatric condition and to evaluate the impact of the dermatologic disease on patients' lives. Recognition of the huge impact a skin condition such as psoriasis may have on a patient's day-to-day life is often lost on clinicians.¹¹

It is important for dermatologists to acknowledge psychological problems a patient may be having and ensure that he or she receives appropriate psychiatric treatment and follow-up, rather than assuming that any depression or anxiety may be diagnosed and managed by the patient's primary physician.

Management

The general sentiment toward managing psychodermatologic conditions among dermatologists is a feeling of unpreparedness in treating these conditions due to a lack of training.⁷ Management of a psychodermatologic condition requires a two-pronged approach; treatment of the skin condition itself must be combined with psychiatric treatment, which may include medications or psychotherapy.¹ Dermatologists should attempt to discuss stress as well as stress management techniques with patients if a psychodermatologic condition is suspected.⁷ Studies have shown that even with treatment resulting in improvement of a primary dermatologic condition, such as psoriasis, patients still score just as poorly on psychiatric evaluations as they did prior to treatment.¹¹ Therefore, even after the dermatologic condition is treated, patients still suffer from the accompanying depression or anxiety. This may stem from poor coping mechanisms developed earlier on in the disease process.¹¹ This can be improved via techniques such as

cognitive behavioral therapy which focuses on changing how a patient reacts to a certain situation or stressor.¹¹

Treatment of psychophysiologic conditions involves the treatment of the primary dermatologic disorder as well as stress management. The treating physician should attempt to garner an idea about the patient's situation and both internal and external stresses that the patient may be experiencing. Medications such as selective serotonin reuptake inhibitors (SSRIs) may be used in the treatment of these conditions.⁷

Since primary psychiatric disorders have a secondary impact on patient's skin, management of the psychological aspect is imperative.⁷ However, in order to appropriately treat these conditions, it is necessary to first diagnose them. Because of this, awareness of psychodermatologic conditions is vital so that they may be discovered and treated in the correct way.⁷ Patients should undergo a psychiatric evaluation for conditions such as BDD, delusional parasitosis, impulse control disorder, obsessive-compulsive disorder, and others.⁷ Patients with primary psychiatric disorders may deny the possibility that their dermatologic condition is secondary to a psychiatric disorder⁷; as a result, dermatologists may play an even more important role in care. It is important to start a supportive dermatologic treatment as well as psychiatric medication to develop a therapeutic alliance with the patient.⁷

Many primary psychocutaneous conditions have generally accepted guidelines for treatment. Pimozide, an antipsychotic, is the treatment of choice for delusional disorders.¹³ BDD and obsessive-compulsive disorders are treated best with SSRIs, although this medication class will likely take 2 months to show effect.¹³

Secondary psychiatric disorders require careful evaluation of the effect of chronic skin disease on patients' mental health. Particular attention should be paid to self-image and self-esteem, as well as depression and possible suicidal ideation.⁷ It is also important to discuss how a patient's condition may affect them socially.⁷ Screening for substance abuse is also a vital part of the management of these conditions.⁷

Management of anxiety associated with skin conditions should include pharmacologic treatment and psychotherapy. Cognitive behavioral therapy plays a large role in developing coping mechanisms.^{7,18} Benzodiazepines may be used but should be administered with caution due to the possibility of addiction and abuse.⁷ Non-benzodiazepines such as buspirone or

high dose SSRIs can be helpful and have no potential for addiction.^{7,13}

Biofeedback is another viable therapy option in the treatment of many psychocutaneous diseases.⁴ Hypnosis has also been described as being helpful in the diagnosis and management of several psychodermatologic conditions. For example, if a diagnosis of dermatitis artefacta, a condition in which patients induce lesions on their own skin by scratching or picking, is suspected, hypnosis may be useful in providing information that could be diagnostic.⁴

The Dermatology Life Quality Index (DLQI) scale should be used in dermatologist offices in order to screen for a skin condition's negative impact on daily life.¹⁹ This 10-item scale screens for a reduction in quality of life secondary to dermatologic disease and attempts to ascertain this by asking patients to rank how much their skin creates problems for them in various aspects of work and social life.¹⁹ Patients scoring highly on the scale will need further psychosocial support and referral to a mental health provider as well as understanding and support from their dermatologist.¹⁸ A multidisciplinary approach is best for these patients so that dermatologists (if not psychodermatologists), psychiatrists, psychologists, and nurses can work together to manage a patient's condition in a holistic manner.¹⁸

Since approximately 40% of patients are noncompliant with the treatment plan, it is important to engage patients to be proactive about their health and well-being.¹⁸ Strong rapport is extremely important in cases of psychodermatology.¹⁸ In order to develop the appropriate therapeutic alliance with the patient, the dermatologist must first recognize the psychiatric aspect of a patient's skin disease. Awareness of the field of psychodermatology and screening for psychiatric conditions are imperative in successful treatment of this large population of patients.

CONCLUSIONS

Psychodermatology is a field that has been recognized for many years, although practical application may be somewhat lacking. There is a fairly widespread deficit in knowledge regarding psychocutaneous conditions. As practicing dermatologists, a familiarity with these conditions as well as related psychiatric complications is imperative for treatment of the given condition and for maintaining the patient's well-being, which is the goal of any physician.

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Comparative Efficacy of Pharmacological and Nonpharmacological Interventions in Managing Primary and Secondary Outcomes of Fibromyalgia Syndrome

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Objective: The aim of this literature review is to individually compare the efficacy of pharmacological and nonpharmacological treatments in managing primary and secondary outcomes of fibromyalgia syndrome (FMS). The primary and secondary outcomes under evaluation include pain, fatigue, sleep management, depressed mood, and health-related quality of life. When evaluating for primary and secondary outcomes of FMS, a nonpharmacological approach has greater efficacy in managing a larger scope of fibromyalgia symptoms.

Methods: Research analysis was performed through searching online databases and journals by using specific words and phrases that were relevant to the topic of choice. Journal article searches were filtered by publications no earlier than 2006 to help ensure relevancy and accuracy of data. An evidence table was further created to better organize and evaluate the articles found.

Results: Analysis of seven trials with a total of 2,795 patients and four active interventions (duloxetine, pregabalin, aerobic exercise, and cognitive behavioral therapy) were included. Nonpharmacological intervention trials (exercise and cognitive behavioral therapy) were small but did show promising effects for improving pain and quality of life. In larger trials, the pharmacological treatment had an advantage over placebo when pain and quality of life were assessed. Efficacy toward secondary outcomes of sleep and depression were either statistically nonsignificant or of questionable clinical relevance regardless of numerical significance for all trials except pregabalin. The nonpharmacological trials were unable to assess a broader range of fibromyalgia symptoms such as sleep difficulties and depression.

Conclusions: Nonpharmacological interventions did not show clinical significance in managing a broader range of fibromyalgia symptoms. A larger study sample size is needed to compare the efficacy of pharmacological and nonpharmacological interventions in primary and secondary outcomes of fibromyalgia.

Keywords: fibromyalgia; treatment; exercise; pharmacological; cognitive behavioral therapy; duloxetine; pregabalin

Fibromyalgia syndrome (FMS) is characterized by chronic widespread musculoskeletal pain and is one of the most common disorders seen by rheumatologists.¹ According to the Centers for Disease Control and Prevention (CDC), the prevalence of fibromyalgia is around 2% and is seen more often in women than in men (3.4% vs. 0.5%).¹ The precise pathophysiology of FMS is unclear but is hypothesized to be largely due to central or peripheral hyperexcitability at the spinal or brainstem level.² Although the etiology of fibromyalgia is unknown, the treatment is mainly focused on identifying and controlling the primary and secondary outcomes of FMS.¹ The most common symptoms aside from widespread

pain include sleep disturbances, fatigue, depressed mood, and impaired daily functioning.² Being a chronic disorder, FMS impairs physical and emotional health, which impacts the overall quality of the patient's life. Pain with various overlapping symptoms becomes a complex and dynamic phenomenon that makes fibromyalgia a challenging disorder to treat. There is no definitive cure for fibromyalgia, which is why a multidisciplinary approach involving medical, self-management, and alternative interventions is suggested as treatment.^{1,2}

The aim of this literature review is to individually compare the efficacy of the first-line pharmacological and nonpharmacological treatments in FMS patients

when evaluating for pain, fatigue, sleep management, depressed mood, and health-related quality of life (HRQOL). Fibromyalgia symptoms affect every aspect of quality of life and have a significant impact on the ability of the patient to work. The underlying chronic pain experienced by patients is likely to contribute to a sedentary lifestyle which leads to poor physical conditions in affected individuals.³ Exercise has been suggested as an important part of FMS treatment when it is individually tailored to the patients' scope of physical abilities. Even with a variety of treatment options available, a stronger recommendation is given to pharmacological rather than nonpharmacological therapies by clinicians.⁴ The primary objective of this review is not limited to assessing the efficacy of treatment options on the main outcome of FMS pain, but to address which treatment options have a broader effect on other domains of fibromyalgia as well. This can potentially help clinicians in selecting a treatment plan tailored to the heterogeneity of symptoms of each individual with fibromyalgia.

Systemic reviews and previous meta-analyses evaluated a wide variety of pharmacological and non-pharmacological treatment options for health care professionals and patients with FMS. The American Pain Society strongly recommends pharmacological interventions including serotonin-norepinephrine reuptake inhibitors (SNRIs), gamma-aminobutyric acid (GABA) analogs, as well as nonpharmacological treatments such as aerobic exercise and cognitive behavioral therapy (CBT).⁵ The following treatment options that fit this study's inclusion criterion will be assessed for their efficacy in the treatment of primary and secondary outcomes of FMS, including pain, sleep, depression, and HRQOL.

ANTIDEPRESSANTS – SNRIS (DULOXETINE)

Duloxetine is a SNRI that has been approved by the US Food and Drug Administration (FDA) for the treatment of major depressive disorder (MDD), and the management of peripheral neuropathic pain. Previous studies support the efficacy of duloxetine in the reduction of pain in FMS patients, with adverse effects of nausea, dry mouth, constipation, and somnolence.⁶

ANTICONVULSANTS: CALCIUM CHANNEL BLOCKERS (PREGABALIN)

Pregabalin is a structural GABA analog but acts by inhibiting high-voltage activated calcium channels.

This results in a decreased release of many excitatory neurotransmitters including glutamate, norepinephrine, and substance P at the nerve terminals, which is assumed to be the basis of the drug's analgesic effects. Pregabalin produces common side effects of dose-related sedation and dizziness.⁷

AEROBIC EXERCISE

Exercise is one of the main nonpharmacological treatments clinically recommended for the management of FMS symptoms. More specifically, aerobic exercise along with the addition of flexibility and strength training programs have been shown to produce positive health benefits when targeting widespread joint pain, stiffness, muscle fatigue, and overall physical function.^{8,9}

COGNITIVE BEHAVIORAL THERAPY

CBT is a psychotherapeutic option used to treat FMS patients by targeting the cognitive and behavioral factors behind the premise of chronic pain. Through the use of relaxation training and stress reduction, CBT leads to modification of pain behavior, dysfunctional thoughts, and health-seeking behavior.^{10,11}

METHODOLOGY

Databases Used

The scientific literature used in this review contained a variety of studies that included randomized control trials (RCT), retrospective and prospective cohort studies, cross-sectional studies, as well as literary reviews. A literature search was conducted through the use of various databases and online journals including but not limited to the following: *Pubmed Central*, *Google Scholar*, *Medscape*, and *the American Journal of Medicine*. Specific journals pertaining to the chosen topic such as *Rheumatology*, *PAIN*[®], and *The Clinical Journal of Pain* were further assessed for relevant studies. Journal article searches were filtered to publications no earlier than 2006 to help ensure the relevancy and accuracy of data.

Search Strategy

The search strategy used for the purpose of this review included FDA-approved, first-line pharmacological treatments and nonpharmacological treatments for patients with fibromyalgia. To narrow the search for the most relevant articles, the title and abstract sections were analyzed accordingly.

Search Terms

First, a broad search was conducted using the following keywords: *fibromyalgia treatment, pharmacological, and nonpharmacological treatment*. A focused search was then conducted to narrow down to the most relevant articles. Search terms used are indicated as follows: *aerobic exercise, antidepressants, calcium channel blockers, and cognitive behavioral therapy*. Based on these terms, the retrieved literature was analyzed for relevancy to the hypothesis and statistical significance.

Eligibility Criteria

Articles and RCTs published in English and no earlier than 2006 that fulfilled the following inclusion criteria were obtained and analyzed: patients of any age diagnosed with fibromyalgia based on the criteria for classification by the American College of Rheumatology were included for analysis. Studies that used treatment options approved by the FDA for FMS management were included. Treatment options reviewed were: antidepressants, GABA analogs, aerobic exercise, and CBT. Studies that assessed primary and a minimum of one secondary outcome were included. Primary outcomes analyzed in FMS patients posttreatment were pain, whereas sleep, depressed mood, and quality of life were specified as secondary outcomes. Studies without randomization and control interventions were excluded.

Data Grading and Organization

RCT and literature review included in this paper were organized in an evidence table (Appendix A). Articles were sorted by publication design, study design, sample size, study population, and exposure. Each study was then ranked according to the Level of Evidence criteria, with level 1 being of highest value. Systematic reviews with RCT were considered level 1. Systematic reviews with cohort studies or prospective cohort studies were considered level 2. Observational studies with controls were considered level 3, while observational studies without control were considered level 4.

RESULTS

Characteristics of Included Trials

Seven trials with a total of 2,579 patients that met the inclusion criteria were included in the literature review and analysis. The articles were published no earlier than 2006, and the trial duration ranged from 6 to 12 months. Two trials evaluated duloxetine (850 patients); two trials, pregabalin (1,498 patients); two trials, Aerobic Exercise

(106 patients); and one trial, CBT (125 patients). The pharmacological trials had a placebo control, while the nonpharmacological trials had a nonintervention or minimally active control, such as attention placebo (AP). The majority of the patients were women of Caucasian descent, with an average age ranging from 47 to 55 years. Table 1 was generated to summarize the comparative data of all trials included in this review and analysis.

Pain and Impairment

Table 1 shows the effect on pain in seven trials after treatment with either active pharmacological or nonpharmacological interventions and placebo. Pain and impairment were assessed by either the Brief Pain Inventory (BPI) average pain score or the Fibromyalgia Impact Questionnaire pain score (FIQ) in each trial. The BPI is a short form that assesses average pain during the past 24 h on a scale from 0 to 10 (no pain to very severe pain).¹² The FIQ is a 20-item patient-administered survey that measures the patient's physical functioning, well-being, and outcomes over the past week. Primary and secondary outcomes of pain, fatigue, stiffness, difficulty working, and other symptoms of FMS are assessed. Total scores range from 0 to 80, where a higher score indicates a more negative impact of the intervention.¹³

Although the Chappell et al.¹⁴ trial showed numerical improvement in duloxetine-treated patients in the primary measures of mean change in the BPI average pain score (duloxetine -1.62 , placebo -1.13 , $p = 0.053$), the differences between the two groups were not considered statistically significant. Treatment with duloxetine showed no significant difference in the BPI average pain severity response rate, defined as $>50\%$ reduction from baseline to end point (duloxetine 29.1%, placebo 25.1%, $p = 0.455$). Average pain severity scores in BPI based on $>30\%$ reduction from baseline also showed no significant difference between duloxetine (38.0%, $p = 0.355$) and placebo (32.9%). Secondary measures in the FIQ pain score compared to the placebo-treated patients did show statistically significant improvement (mean change duloxetine -1.69 , placebo -1.06 , $p = 0.03$).¹⁴

Analysis of the Russell et al.¹⁵ trials showed that patients treated with duloxetine 120 mg/day improved significantly more on primary outcomes in the BPI average pain severity at 3 months (duloxetine -2.31 , placebo -1.39 , $p < 0.001$) and at 6 months (duloxetine -2.26 , placebo -1.43 , $p = 0.003$). Response rates for the BPI average pain severity at $>50\%$ reduction from

Appendix A: Evidence Table

| First Author | Date of publication | Study Design | Evidence Rating | Sample Size | Study Population | Exposure | Results |
|--------------|---------------------|---|-----------------|-------------|--|--|--|
| Arnold, L.M | 2008 | Randomized, Double Blinded controlled trial | 1 | 750 | >18 y/o patients who met ACR fibromyalgia criteria with VAS pain score > 40mm | Pregabalin 300/450/600 mg twice daily | Mean changes in pain score, improvement on PGIC and sleep patterns with pregabalin compared to placebo along with common side effects of dizziness and drowsiness |
| Bernardy, K. | 2010 | Systemic review with Meta-analysis | 2 | 1482 | Female fibromyalgia patients age range 16-54 years | CBT | Reduction in depressed mood and self efficacy pain at follow up. Limited reduction in pain, fatigue, sleep disturbances and HRQOL |
| Castel, A | 2012 | Randomized control trial | 1 | 93 | 18-65 y/o patients who met ACR fibromyalgia criteria | CBT, CBT with hypnosis, Standard drug therapy | patients receiving CBT or CBT with hypnosis showed greater improvements than patients who received standard drug therapy |
| Chappell, A. | 2008 | Randomized, Double Blinded controlled trial | 1 | 330 | >18 y/o patients who met ACR fibromyalgia criteria with or without MDD | Duloxetine 60/120 mg once daily | Significant improvement in FIQ pain score, BPI lease pain score, BDI-1, and SF-36. No significant difference in BPI pain scores, Nausea and headache most common adverse effect |
| Hauser, W. | 2010 | Systemic review with Meta-analysis | 2 | 2494 | 13-59 y/o patients | AE: cycling walking, aquatic jogging, games, dance, boxing | Post treatment: Positive effects on reducing pain, fatigue, depressed mood. No effect on sleep. Follow up: No positive affection on pain, fatigue or sleep. Continuing AE necessary to maintain positive effects upon follow ups |
| Mease, P. | 2008 | Randomized, Double Blinded controlled trial | 1 | 748 | >18 y/o patients who met ACR fibromyalgia criteria | Pregabalin 300/450/600 mg twice daily | Significant improvement in mean pain scores, FIQ total scores, sleep assessment and global improvement scale. Dizziness and somnolence most common adverse effects |
| Russell, J. | 2008 | Randomized, Double Blinded controlled trial | 1 | 520 | >18 y/o patients who met ACR fibromyalgia criteria with average pain severity >4 | Duloxetine 20/60/120 mg once daily | Improvement in BPI pain scores at 3 and 6 month treatment intervals. No positive effects on sleep quality or depression scale. Nausea and headache most common adverse effect |
| Sanudo, B. | 2010 | Randomized, Double Blinded controlled trial | 1 | 64 | Women who met ACR fibromyalgia criteria | Aerobic Exercise twice weekly | 14-15% improvement in FIQ pain scores from baseline and decrease in BDI pain scores |
| Sanudo, B. | 2018 | Randomized, Double Blinded controlled trial | 1 | 42 | Women age 18-65 y/o patients who met ACR fibromyalgia criteria | Aerobic, strength, flexibility exercises | Improvement in FIQ pain scores and health related quality of life (SF-36) scores. |
| Thieme, K. | 2006 | Randomized, Double Blinded controlled trial | 1 | 125 | >18 y/o patients who met ACR fibromyalgia criteria | CBT weekly 2 hour sessions | Significant reduction in pain intensity, improvement in cognitive functioning, physical functioning, and coping mechanism |

ACR: American College of Rheumatology, **AE:** Aerobic Exercise, **BPI:** Brief Pain Inventory, **BDI:** Beck Depression Inventory, **BDI-1:** Beck Depression Inventory, **CBT:** Cognitive Behavioral Therapy, **FIQ:** Fibromyalgia Impact Questionnaire, **HRQOL:** Health-Related Quality of Life, **MDD:** Major Depressive Disorder, **PGIC:** Patients' Global Impression of Change, **SF-36:** Short Form Health Survey 36, **VAS:** Visual Analogue Scale



Table 1. Summary of average pain, sleep, depression and health-related quality of life scores from all seven included trials.^{5,14-19}

| Study | Year | Subject | Mean Age | Sample Size | Treatment | Duration | Outcomes | Adverse Effects |
|--|------|-------------------------------------|----------|-------------|--|-----------|--|---|
| PHARMACOLOGICAL INTERVENTIONS | | | | | | | | |
| Chappell | 2008 | Female (93.3%) Caucasian (90.9%) | 50 | 330 | Duloxetine 60/120 mg once daily | 6 months | Pain (BPI): -1.22, Placebo -0.73 P=0.046 Pain (FIQ): -1.69, Placebo -1.03 P=0.009 Sleep: N/A Depressed mood (BDI): -3.42, Placebo -1.45, P=0.017 HRQOL (SF-36): 3.37 (Mental), Placebo: 0.79 P=0.026 | Nausea, headache, dry mouth, diarrhea, constipation, arthralgia, somnolence |
| Russell | 2008 | Female (94.8%) Caucasian (84.2%) | 51 | 520 | Duloxetine 20/60/120 mg once daily | 6 months | Pain (BPI): -2.26, Placebo: -1.43 P<0.003 Pain (FIQ): N/A Sleep: N/A Depression (HAMMD): -5.2/-6.9/-7.2, Placcbo: -4.8 P=0.022 HRQOL (SF-36): 2.56/3.68/4.41 (Mental) Placebo: 1.75 | Nausea, dry mouth, constipation somnolence |
| Arnold | 2008 | Female (94.5%) Caucasian (91.0%) | 50 | 750 | Pregabalin 300/450/600 mg twice daily | 14w | Pain (BPI): -1.75/-2.03/-2.05; Placcbo:-1.04 P<0.001 Pain (FIQ): -10.70, -12.98, -13.08; Placcbo: -7.74 P<0.005 Sleep Quality: -1.90/-2.28/-2.51; Placebo:-1.16 P<0.005 Depression (HADS): -0.39/-0.85/-0.81 Placcbo: -0.53 P<0.7 HRQOL: N/A | Dizziness, somnolence |
| Mease | 2008 | Female (94%) Caucasian (90%) | 49 | 748 | Pregabalin 300/450/600 mg twice daily | 13w | Pain (BPI): -1.84/-1.87/-2.06; Placebo: -1.40 P<0.05 Pain (FIQ): -16.15/-15.71/-14.88; Placebo:-13.66 P<0.6 Sleep Quality: -2.19/-2.29/-2.53; Placebo: -1.32 P<0.0001 Depression (HADS): N/A HRQOL: N/A | Dizziness, somnolence |
| NON-PHARMACOLOGICAL INTERVENTIONS | | | | | | | | |
| Sañudo | 2010 | Female (100%) | 55 | 64 | Aerobic Exercise twice weekly | 6 months | Pain (BPI): N/A Pain (FIQ):-8.8 P<0.02 Sleep: N/A Depression (BDI): -8.5 P<0.001 HRQOL (SF-36): 8.9 P<0.01 | |
| Sañudo | 2011 | Female (100%) | 50 | 42 | Aerobic, strength, flexibility exercises | 6 months | Pain (BPI): N/A Pain (FIQ):-8.2 Control: 2.9 P=0.027 Sleep: N/A Depression (BDI): -6.2; Control: 3.6 P=0.556 HRQOL (SF-36): 7.9; Control: -1.4 P=0.043 | |
| Thieme | 2006 | Female (100%) | 47 | 125 | CBT weekly 2 hour sessions | 12 months | Pain (BPI): N/A Pain (FIQ):-0.93 Control: 1.01 P<0.001 Sleep: N/A Depression (HADS): N/A HRQOL: N/A | |

BPI: Brief Pain Inventory, **BDI:** Beck Depression Inventory, **CBT:** Cognitive Behavioral Therapy, **FIQ:** Fibromyalgia Impact Questionnaire, **HADS:** Hospital Anxiety and Depression Scale, **HAMD:** Hamilton Depression Rating Scale, **HRQOL:** Health-Related Quality of Life, **N/A:** Not Applicable, **SF-36:** Short Form Health Survey 36

baseline to 6 months end point were significantly greater for duloxetine 20/60 mg/day (36.4%, $p = 0.025$), 60 mg/day (32.6%; $p = 0.045$), and 120 mg/day (35.9%; $p = 0.009$), compared to placebo (21.6%). Analysis showed that response rates defined as >30% reduction from baseline to 6 months' end point were significantly greater for duloxetine 20/60 mg/day (51.9%; $p = 0.045$) but not for 60 mg/day (47.2%, $p = 0.118$) or 120 mg/day (49.3%; $p = 0.054$) compared with placebo (37.4%). Secondary measures in FIQ scores showed that duloxetine 60 and 120 mg/day demonstrated significantly greater improvements compared with placebo-treated patients.¹⁵

Trials by Arnold et al.¹⁶ demonstrated significant mean changes in pain scores at end point in all three pregabalin monotherapy patient groups compared to placebo-treated patients (300 mg/day -1.71 , 450 mg/day -2.03 , 600 mg/day -2.05 , placebo -1.04 , $p < 0.001$). Response rates for the average pain severity at >30% and >50% reduction from baseline were significantly greater in all treatment groups when compared to placebo treatment groups. Response rates defined at >30% reduction from baseline for 300 mg/day was 42% ($p = 0.0172$), 50% in the 450 mg/day ($p = 0.0002$), and 48% in the 600 mg/day pregabalin ($p = 0.0006$), compared to 30% in placebo treatment group. Whereas, response rates defined as >50% reduction from baseline for 300 mg/day was 24% ($p = 0.0372$), 27% in the 450 mg/day ($p = 0.0038$), and 30% in the 600 mg/day pregabalin ($p = 0.001$), compared to 15% in the placebo treatment group. Patients reported improvements in total FIQ scores for 450 and 600 mg/day doses when compared with the placebo treatment groups.¹⁶

Pregabalin trials by Mease et al.⁵ showed statistically significant improvements in mean pain in all three treatment groups from baseline compared with patients receiving placebo treatment (300 mg/day -1.84 , 450 mg/day -1.87 , 600 mg/day -2.06 , placebo -1.04 , $p < 0.005$). The 600 mg/day treatment group showed the most improvement compared to 350 mg/day, 450 mg/day, and placebo treatment group. Response rates defined at >30% reduction from baseline for 300 mg/day was 40%, 43% in the 450 mg/day, and 44% in the 600 mg/day pregabalin, compared to 35% in the placebo treatment group. Although the response rates were higher in all three treatment groups compared to the placebo treatment group, the differences were not statistically significant for any pregabalin dosage. FIQ pain scores for all three pregabalin treatment groups

were numerically but not statistically greater than the placebo treatment group.⁵

Two randomized controlled trials by Sañudo et al.^{17,18} showed significant improvements in health status in patients assigned to the exercise group over the control group. Significant improvements were seen in the FIQ pain score after the 24-week intervention period (RCT 2010: -8.8 , $p < 0.02$, RCT 2011: -8.2 $p < 0.027$).^{17,18} Trials including CBT as a primary intervention by Thieme et al. also showed a significant reduction in pain intensity and impairment which was assessed by the FIQ score reports (-0.93 , $p < 0.001$).¹⁹

Sleep

Table 1 summarizes the effect on sleep in seven trials after treatment with either active pharmacological or nonpharmacological interventions and placebo. Sleep quality and outcomes were assessed by the mean sleep quality or Medical Outcomes Study (MOS)-Sleep scale. The MOS-Sleep scale is a 12-item form that assesses the quality of sleep including parameters such as sleep disturbance, snoring, awakening with a headache, and somnolence. Scores range from 0 to 100 with higher scores indicating higher impairment in quality of sleep with treatment intervention.²⁰

Effect on sleep quality did not have a positive outcome in the Chappell et al.¹⁴ or Russell et al.¹⁵ trials with duloxetine. Sleep disturbance and somnolence were the reported adverse events that occurred in >5% of duloxetine-treated patients.^{14,15} Pregabalin trials by Arnold et al.¹⁶ and Mease et al.⁵ were both associated with significant improvements in sleep quality and outcomes in all three dosage groups. (Arnold et al.; $1.90/-2.28/-2.51$; Placebo: -1.16 $p < 0.005$, Mease et al.; $-2.19/-2.29/-2.53$; placebo: -1.32 $p < 0.001$).^{5,16} Secondary outcomes of sleep with nonpharmacological treatments were unknown in trials by Sañudo et al. and Thieme et al.¹⁷⁻¹⁹

Depressed Mood

Table 1 summarizes the effect on depressed mood in seven trials after treatment with either active pharmacological or nonpharmacological interventions and placebo. Depressed mood and outcomes were assessed by the Hamilton Depression Rating Scale (HAM-D), Beck Depression Inventory-II total score (BDI-II), or Hospital Anxiety and Depression Scale (HADS). The HAM-D is a 17-item observational rating that measures the severity of depression and improvement during the treatment intervention period. The multiple item questionnaire

scores range from 0 to 52, indicating no depression to severely depressed.²¹ The BDI is a 21-item questionnaire designed to measure the severity of depression during the course of the treatment. The total score ranges from 0 to 63 with a higher score indicating severe depressive symptoms.²² The HADS is a 14-item questionnaire that measures the levels of anxiety and depression the patient is experiencing during the course of the treatment.²¹

The Chappell et al.¹⁴ and Russell et al.¹⁵ trials showed that duloxetine-treated patients improved numerically more than placebo-treated patients on the BDI-II total score (Chappell et al.; duloxetine -3.42 , placebo -1.45 , $p = 0.017$) and on the HAMD scale (Russell et al.; duloxetine 20 mg -5.2 , 60 mg -6.9 , 120 mg -7.2 , placebo: -4.8 $p = 0.022$). Analysis of secondary outcomes of depression assessed by the HADS scale in pregabalin trials by Arnold et al.¹⁶ and Mease et al.⁵ did not show significant improvements compared to placebo.^{5,16} No significant improvements in the BDI scores for depression were reported by Sañudo et al. in either trial.^{17,18} No depression scale was used by Thieme et al. for their CBT trials.¹⁹

Health-Related Quality of life

Table 1 summarizes the effect on HRQOL in seven trials after treatment with either active pharmacological or nonpharmacological interventions and placebo. HRQOL was assessed by the Short Form Health Survey (SF-36), a 36-item self-administered questionnaire that measures the physical functioning, social functioning, and emotional and mental health of the patient through the treatment course. Scores range from 0 to 100, where higher scores indicate a better HRQOL experienced by the patient.²³

In trials by Chappell et al.¹⁴ and Russell et al.,¹⁵ duloxetine-treated patients improved significantly more compared with placebo-treated patients in the SF-36 mental component summary score (Chappell et al.; duloxetine 6.63, placebo 1.19, $p = 0.005$). The Russell et al.¹⁵ trial with duloxetine-treated patients at the 3-month phase showed increased improvement in the SF-36 mental component score but did not achieve statistical significance compared to placebo. Significant improvement and statistical significance were demonstrated at the 6-month treatment phase in all duloxetine treatment groups compared to the placebo group (duloxetine 20 mg 2.56, 60 mg 3.68, 120 mg 4.41, placebo 1.75, $p = 0.05$).¹⁵ Pregabalin trials by Arnold et al.¹⁶ and Mease et

al.⁵ showed improvement in SF-36 scores compared with the placebo group.^{5,16} Exercise intervention trials by Sañudo et al. showed significant improvements in SF-36 scores in most domains such as physical function, and general and mental health.^{17,18} Improvement in quality of life was not assessed in CBT intervention trials by Thieme et al.¹⁹

DISCUSSION

Over the past 20 years, fibromyalgia has been one of the leading causes of visits to rheumatologists and has been estimated to affect 5 million US adults, with its prevalence still on the rise.¹ The long-term course of fibromyalgia characterized by severe impairment and chronic pain makes it difficult to draw a definitive conclusion for the most appropriate first-line therapy in managing this disease. Current research shows a wide array of pharmacological and nonpharmacological interventions that can be effective in reducing primary symptoms such as chronic pain. Chronic pain is likely to cause physical and psychological impairment leading to an impact on the quality of life. Additional psychological symptoms are often present including sleep abnormalities, cognitive impairment, anxiety, and depression.⁴

The aim of this literature review was not limited to analyzing the effects of treatment on the primary symptom of pain but also to compare the broader effects of the recommended interventions on secondary domains of fibromyalgia. The high variability in measuring treatment outcomes in each trial for reporting results was a barrier for conducting this literature review and analysis. In order to accept the hypothesis that a nonpharmacological treatment plan has greater efficacy in managing a larger scope of fibromyalgia symptoms, evidence in the literature needed to show statistically significant improvement in a broader range of FMS symptoms for treatments such as aerobic exercise and CBT over the control treatment group.

The first pharmacological trial reviewed for this analysis was a 6-month, double-blind, placebo-controlled, randomized clinical trial of duloxetine by Chappell et al.¹⁴ published in the *International Journal of General Medicine*. Duloxetine-treated patients had significantly greater improvement in the FIQ pain scores compared to placebo-treated patients. However, no statistically significant differences were seen between treatment and placebo groups for primary measures of pain using the BPI average pain score.¹⁴ In Chappell's trial, the overall change in BPI pain scores from baseline to end point

were not consistent with those reported in other clinical trials evaluating duloxetine as a treatment option for fibromyalgia.

Analysis of the randomized, double-blind control trial by Russell et al.¹⁵ with duloxetine 60 mg/day and 120 mg/day showed greater efficacy in reducing pain severity after 3 and 6 months of treatment compared to placebo. Analysis showed that patients treated with 120 mg/day improved significantly on primary outcomes in the BPI average pain severity at 3 and 6 months. The 20 mg dose did not significantly improve the pain severity score compared to placebo and was included in the trial to determine the minimum effective dose for the treatment of fibromyalgia. The trial also showed significant improvement in the total FIQ scores and SF-36 mental component summary at 3 and 6 months in both duloxetine groups compared to placebo. In both duloxetine trials, the most common adverse effects within the first 3 months of treatment were headache, dry mouth, and nausea. Less common adverse effects reported were somnolence and sleep-related issues.¹⁵

As of 2007, pregabalin was the first drug to be approved by the FDA and the European registry for the treatment of fibromyalgia.⁷ In the 14-week, randomized, double-blinded control trial by Arnold et al.¹⁶ with 300–600 mg/day pregabalin therapy, statistically significant improvements in pain scores were demonstrated in all treatment groups. In all three treatment groups of pregabalin, more patients had >30% and >50% decrease in pain rating over the treatment course compared to patients in the placebo group. Pregabalin treatment groups also showed improvements in the secondary outcomes of fibromyalgia including sleep quality.¹⁶ Surveys found that poor sleep is one of the key symptoms of fibromyalgia and that sleep problems have been cited as an aggravating factor by 79% of FMS patients.²⁴ Compared to the placebo group, patients in all three pregabalin groups showed significant improvement in sleep outcomes as measured by the MOS index and the sleep quality diary. These results provided important evidence that pregabalin has statistically significant effects on primary outcomes of pain as well as secondary sleep problems in patients with fibromyalgia. Other secondary outcomes such as anxiety and depression did not statistically improve when assessed with the HADS scores in all pregabalin groups. Treatment groups with 450 mg/day and 600 mg/day did show significant improvements in the Vitality score on the SF-36. However, a lack of significant improvement in all parameters of the SF-36 scores

indicates that a 14-week treatment plan might not be sufficient time to evaluate significant changes in HRQOL.¹⁶

The 13-week RCT by Mease et al.⁵ showed similar results with pregabalin treatment dosages of 300, 450, and 600 mg/day. All three pregabalin treatment groups showed statistically significant improvement in pain scores compared to the placebo group at the end of the treatment trials. However, the FIQ total score was not significantly improved in any of the three treatment groups compared to placebo. Along with improvements in pain scores in all three treatment groups, patients also showed significant improvements in sleep quality assessed by the daily sleep diary and MOS-Sleep scale. These statistically significant data show that pregabalin may be beneficial for FMS patients with both pain and sleep problems. The most common adverse effects of dizziness and somnolence were dose-dependent in both treatment trials.^{5,16} The high incidence of dizziness and somnolence may indicate that patients with fibromyalgia might be more sensitive to Central Nervous System (CNS)-related adverse effects. Overall, pregabalin was generally well tolerated with a favorable benefit to risk ratio.⁵

The two presented trials by Sañudo et al.^{17,18} showed positive effects of aerobic exercise in patients with fibromyalgia, but the study sample was relatively small, making the results not fully comparable for analysis. The 6-month trial with aerobic exercise showed an improvement in HRQOL, FIQ scores, BDI depression scale, and SF-36 scores. The improvement in FIQ scores showed 14–15% magnitude of improvement, a clinically relevant improvement seen in patients with FMS. Improvement in average BDI scores indicated that aerobic exercise can potentially improve depressive symptoms in patients with FMS.^{17,18}

Another nonpharmacological trial included the analysis of the efficacy of CBT in treating psychological pain in patients with FMS. This CBT trial conducted by Thieme et al. (2006) reported significant improvements in physical functioning, pain, and emotion distress at 6- and 12-month posttreatment compared with the AP group which showed significant deterioration. The most significant changes with CBT were seen in pain and cognitive variables. The results indicate that CBT treatment successfully targeted the coping strategies of patients and reduced affective distress.¹⁹

LIMITATIONS AND FUTURE DIRECTION

The results presented were limited due to the small number of trials analyzed in this review. Other limitations arise

from the exclusion criteria of selecting FMS patients with no other psychiatric or medical comorbidities, resulting in the exclusion of more severely affected FMS patients. The results cannot be generalized toward patients with unstable psychiatric or medical disorders or secondary fibromyalgia pain. Fibromyalgia is a chronic condition, but the trials discussed in this review were of acute duration ranging from 6 to 12 months. Therefore, the results discussed cannot be generalized to a longer duration of treatment for a patient with fibromyalgia.^{5,14-19} The pharmacological trials did not include an active medication as a comparison since the study was intended to evaluate the efficacy of monotherapy in the treatment of FMS outcomes.^{5,14-16} The nonpharmacological trials with aerobic exercise were also limited by sample size, which may have resulted in a type II error.^{17,18} Along with the small sample size, these trials were also limited by the range of outcomes assessed after treatment.¹⁷⁻¹⁹

For results to be clinically comparable, the impact of nonpharmacological treatments on secondary key factors such as sleep patterns, depression, and anxiety should also be assessed in future studies. Future trials should assess the long-term efficacy of the presented pharmacological and nonpharmacological treatment plans because FMS is a chronic condition that will likely require treatment for longer than 6–12 months. Future research should analyze a larger number of trials that directly compare pharmacological treatments with nonpharmacological interventions which have been shown to be efficacious in the treatment of FMS symptoms. Larger studies are needed to duplicate the results of trials with a small sample size.

CONCLUSION

The purpose of this review was to individually compare the efficacy of pharmacological and nonpharmacological interventions in the treatment of primary and secondary outcomes of FMS. In these seven trials with a total of 2,795 patients with FMS, the nonpharmacological trials were very small, but aerobic exercise and CBT showed promising effects in reducing pain and improving the quality of life.¹⁷⁻¹⁹ In larger trials, the pharmacological treatment had an advantage over placebo when pain and quality of life were assessed. Efficacy toward secondary outcomes of sleep and depression were either not statistically significant or of questionable clinical relevance, regardless of numerical significance for all trials except pregabalin.^{5,14-16} The nonpharmacological trials were

unable to assess a broader range of FMS symptoms such as sleep difficulties and depression compared to the pharmacological treatment trials, therefore rejecting the proposed hypothesis. Evidence toward effective first-line treatment for fibromyalgia is limited. No single monotherapy is completely effective in treating the wide array of primary and secondary symptoms in patients with fibromyalgia. This suggests that a multidisciplinary treatment plan that targets different outcomes of fibromyalgia may be the best strategy in clinical practice.

CONFLICT OF INTEREST AND FUNDING

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Systematic Review of the Role of Dietary Fiber in Weight Loss

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Hypothesis: A diet rich in fiber will help overweight and obese patients lose weight, as well as improve their metabolic profile.

Methods: A search of PubMed and Google Scholar was conducted for articles relating to fiber intake and weight loss/management from 2010 to August 2017. Studies were included if fiber was measured, tracked, or manipulated throughout the trial, and changes in weight, whether positive or negative, were observed. The participants in the studies also had to be overweight or obese, and have or be at risk for metabolic syndrome.

Results: A total of 10 studies were included. The high fiber diets led to weight loss in all of the studies, even up to a 3.3 kg (95% CI -2.4 to -4.2) loss in an 8-week study. In addition to weight loss, there were also advantageous changes in other parameters, including body mass index, total body fat, truncal fat, waist circumference, cholesterol, insulin sensitivity, and glucose levels.

Conclusions: Diets that are high in fiber are favorable in aiding in weight loss for overweight and obese patients. High fiber diets are easy to comply with and also aid in patient satiety. Constructing a diet containing high amounts of fiber should be considered when weight loss is desired in patients.

Keywords: dietary fiber; body weight; BMI; weight loss; metabolic syndrome

INTRODUCTION

In recent years, the health industry has gained increasing popularity as our society has become more consumed with the idea of living a healthier lifestyle. Since health consciousness has been on the rise, lifestyle modifications, including long-term diets, fad diets, and physical activity of all kinds, have been making their way to the forefront of many peoples' lives. Lifestyle modifications are becoming increasingly important for weight loss as the development of obesity has been on the rise. The rise in obesity can be attributed to many factors, including a combination of genetic and behavioral causes, which allows for multiple approaches to intervention.¹ Currently, over one-third of the US population is obese, where obesity is defined by a body mass index (BMI) ≥ 30.0 kg/m².² Being obese not only harbors limitations to daily activities but also places obese individuals at an increased risk for developing numerous, sometimes fatal, health issues. Obesity is associated with a high morbidity, which includes cardiovascular disease, hypertension, osteoarthritis, sleep apnea, and stroke, to name a few.³ In addition, metabolic syndrome is a relatively common comorbidity in patients that are overweight and obese. As of 2015, it was estimated that close to 35% of the US adult population had metabolic

syndrome. The diagnosis of metabolic syndrome is based on a combination of factors including large waist circumference, high blood pressure, low high density lipoprotein (HDL), high triglyceride, and high blood glucose levels.⁴ These factors combined in an unfavorable combination can further put people at risk for the more serious comorbidities mentioned previously. With that being said, obesity and the development or progression of metabolic syndrome can be prevented by modifications to dietary patterns and physical activity levels, which is where the incline in a health conscious society can play a role.

A modification in dietary patterns may be the first step in weight loss for individuals who are currently or on the brink of being classified as obese. There have been many trials that have evaluated the effects of various macronutrient content in diets on weight loss. Among them, the intake of fiber has been shown to be related to weight loss in several studies in a wide range of patient profiles.² Dietary fiber is not only beneficial for normal bowel health and cholesterol levels but also a valuable substance in maintaining satiety and aiding in weight loss.⁵ Fiber has also been shown to help decrease postprandial hyperglycemia and delays the absorption of nutrients leading to prolonged feelings of satiety,⁶

65 both factors being extremely beneficial for managing
weight and metabolic profiles. Those benefits alone
make fiber a substance worth investigating. A typical
70 diet is recommended to contain 25 g of dietary fiber a
day for females and 38 g a day for males under the age
of 50.³ While this is a recommended value, it is estimated
that less than half of the US population actually meets
this criterion,⁷ and thus, many people are missing the
opportunity for weight loss and positive changes to
75 their metabolic profiles. This review has been formatted
to show that a diet that simply meets or exceeds the rec-
ommended daily amounts of fiber can aid in the weight
loss of patients who are currently overweight or obese,
and also to show that there are favorable changes in
metabolic profiles.

80 METHODS

In order to find relevant articles, searches of the
electronic databases PubMed and Google Scholar
were conducted in August 2017. These searches
were limited to cohort studies, randomized con-
85 trolled trials (RCTs), and cross-over studies that have
occurred since 2010. Key search terms included 'high
fiber', 'fiber intake', 'weight loss', 'dietary fiber', 'meta-
bolic syndrome', and 'obesity'. Inclusion criteria for
this review included study population with patients
who were considered overweight or obese accord-
90 ing to their BMI, patients at risk for metabolic syn-
drome (meeting some but not all criteria mentioned
in the Introduction section) or previously diagnosed
with metabolic syndrome, and patients whose fiber
intake was being monitored or manipulated in some
95 form. The inclusion criteria used for overweight and
obese (25.0–29.9 kg/m² and ≥30.0 kg/m², respec-
tively) were adopted from the Centers for Disease
Control and Prevention. Another inclusion criterion
was that there was an increase in the fiber intake in
100 the experimental group of each study, whether an
increase from their baseline intake or to reach the rec-
ommended daily value, either being equally valid as
an inclusion criteria for this review. If there was no
intervention, such as the addition of a fiber supple-
105 ment or food product, the study was included when
the participants were required to track their daily fiber
intake. Exclusion criteria were if participants had any
other serious underlying health issue including car-
diovascular problems, stroke, epilepsy, and so on.
110 Studies were also excluded if the results focused
solely on biochemical results, such as Hemoglobin

A1c (HbA1c) and insulin levels, without touching on
physical parameters like weight loss, body fat, or
waist circumference.

115 The studies used in this review were compiled and
summarized in an evidence table found in the appendix.
Each of the study trials contained various data regarding
the final results for the participants. Changes in weight
loss, total body fat, truncal fat, and waist circumference
120 were of highest importance for this review. The data were
analyzed and determined to be significant if there was a
corresponding *p*-value of less than 0.05 for the given
measurement. As the study participants across all of the
trials varied in their starting body measurements, the
125 *p*-value was of specific importance for noting an overall
change in relation to fiber intake rather than just number
of pounds/kilograms. An evaluation of the 95% confi-
dence interval (CI), if provided, was also important for
ensuring that the value ranges were narrow enough to
130 show the mean was significant and the results could be
repeated if another round of the study was conducted. A
single study contained data centered on regression coef-
ficients. For this review, if the regression coefficient was
related to fiber intake and body/metabolic measure-
135 ments, a negative value would be preferred to show that
an increase in fiber caused a decrease in the studied
value. In addition, various metabolic profile changes
were also examined for each study, including total cho-
lesterol, low density lipoprotein (LDL), insulin sensitivity,
140 and HbA1c. These were also determined significant by
looking at the *p*-value as well as the 95% CI.

145 RESULTS

A total of 10 studies were included in this review: seven
randomized control trials and three cohort studies.
Of the articles used, all contained study populations
that were considered to be overweight or obese at the
beginning of the study period. Two of the studies
150 included only participants who had already been diag-
nosed with metabolic syndrome or type 2 diabetes. The
remainder consisted of participants who were consid-
ered to be at risk (values near the diagnosis criteria
mentioned in the introduction and/or meeting some,
but not all criteria) for the diagnosis of metabolic syn-
155 drome and/or type 2 diabetes in the future. Seven of the
10 studies relied on the report of the participants' daily
fiber intake via questionnaires and logs, while the
remaining three studies had direct intervention via soy
biscuits, fiber granules, or fiber powder; therefore, the
amount of fiber did not need to be reported by the

participants. All 10 of the studies looked at how fiber intake related to weight loss over varying time periods, ranging from 8 weeks to 6.5 years. Of the 10 studies, two of them focused on specific type of fiber such as from cereals or fruits and vegetables. In addition to weight loss, more than half of the studies analyzed different variables such as truncal fat, BMI, body fat percentage, insulin sensitivity, cholesterol, and waist circumference.

In order to determine whether the presence of fiber in the body has any effect on the digestive system, feelings of satiety, and ultimately weight loss, a study conducted by Solah et al observed how supplemental fiber played a role in frequency of eating and weight loss over a 12-week period.⁸ A total of 118 overweight adults were enrolled in a three-arm, parallel, blind, randomized control trial consisting of a control group consuming 5 g of rice flour daily, a study group consuming a 4.5-g fiber tablet, and a study group consuming 5 g of fiber granules a day. The difference found at the end of the study was that compared to the controls, the study group consuming 5 g of fiber granules daily had the greatest decrease in weight ($-1.4 \text{ kg} \pm 0.10$, $p < 0.01$), waist circumference ($-2.50 \text{ cm} \pm 0.60$, $p = 0.03$), and BMI (-0.5 ± 0.10 , $p < 0.01$), in addition to a decrease in eating occasions per day (-1.4 ± 1.20 , $p < 0.01$). The control group and the fiber tablet group showed modest decreases in the said measurements although less significant than the fiber granules.

Similarly, 159 overweight Australian participants were enrolled in a 52-week study examining the supplementation of fiber for weight loss. At the end of 52 weeks, 127 participants remained, among which were members of three different study groups: a control group consuming 5 g of rice flour three times a day, an experimental group consuming 5 g of a non-starch polysaccharide (PGX) three times a day, and an experimental group consuming 5 g of psyllium fiber (PSY) three times a day. After 6 months, both the PGX and PSY groups had lost weight (PGX [-2.7% , $p = 0.001$] and PSY [-2.6% , $p = 0.002$]), while the control groups remained at baseline values. Body fat measured by a dual-energy x-ray absorptiometry (DEXA) machine showed a significant decrease at 12 months between the controls and the experimental groups (12 months in the PSY [$p = 0.038$] and PGX [$p = 0.012$] groups). There was also a decrease in waist circumference ($p < 0.01$) and body fat percentage (12 months in the PGX [$p = 0.008$] and PSY [$p = 0.018$] groups), as well as an increase in lean body mass at both 6- and 12-month follow-up (Fig. 1). Total energy

intake at 6 months decreased significantly in both the PGX (-15.3% , $p = 0.002$) and the PSY (-14.4% , $p = 0.002$) groups compared to controls. Physical activity among the participants remained the same throughout the entire study period.

Guerin-Deremaux et al also examined how supplementing dietary fiber in the form of a mixture contributed to weight loss in 120 overweight men, as well as body fat percentages and daily energy intake.⁹ A total of seven participants dropped out of the trial for reasons unrelated to the study. Seventeen grams of fiber was consumed in 250 mL of juice two times throughout the day by the experimental group for 12 weeks, while the control group received a placebo mixture in 250 mL juice two times daily. The experimental fiber group resulted in an average reduction in body weight of 1.5 kg ($p < 0.001$), BMI of 0.5 kg/m² ($p < 0.001$) and body fat percentage of 0.3% ($p < 0.001$). The experimental group also reported a lower daily energy intake (3,079 kJ/day, $p < 0.001$) as early as 3 days into the study (Fig. 2). On a scale of 1–6, 1 being hungry and 6 being full, the control group had an average self-reported value of 3.8 (range 3.0–4.1) compared to the test groups' average self-reported value of 4.3 (range 4.0–4.6).

In a specific study conducted by Tucker et al, the effects of dietary fiber intake against weight and fat gain were examined.¹⁰ Over the course of 20 months, 252 women with a baseline BMI of 24 ± 3.3 were instructed to measure and weigh out everything that they consumed, both liquids and solids, in a 7-day food diary. The final assessment of the participants revealed that for every 1 g of fiber increase per 1,000 kcal in the diet, there was a subsequent 0.20 kg decrease in total body weight. In addition, for every 1 g of fiber increase per 1,000 kcal in the diet, there was a 0.19% decrease in total body fat.¹⁰ Overall, the increase in dietary fiber consumed by individuals over an extended period of time was beneficial in reducing the risk of gaining weight and fat.

Three additional studies sought to determine how the amount of dietary fiber affected body composition. Ma et al examined 240 adults with a BMI between 30 and 40 that had been diagnosed with metabolic syndrome.¹¹ The study consisted of comparing two different diet plans: a diet focused solely on increasing fiber intake ($\geq 30 \text{ g/day}$) and a diet that followed the American Heart Association (AHA) dietary guidelines involving focus on all the macronutrient (carbohydrates, proteins, fats) with the goal of also consuming about 30 g of fiber a day. Both the high fiber and the AHA diet resulted in a

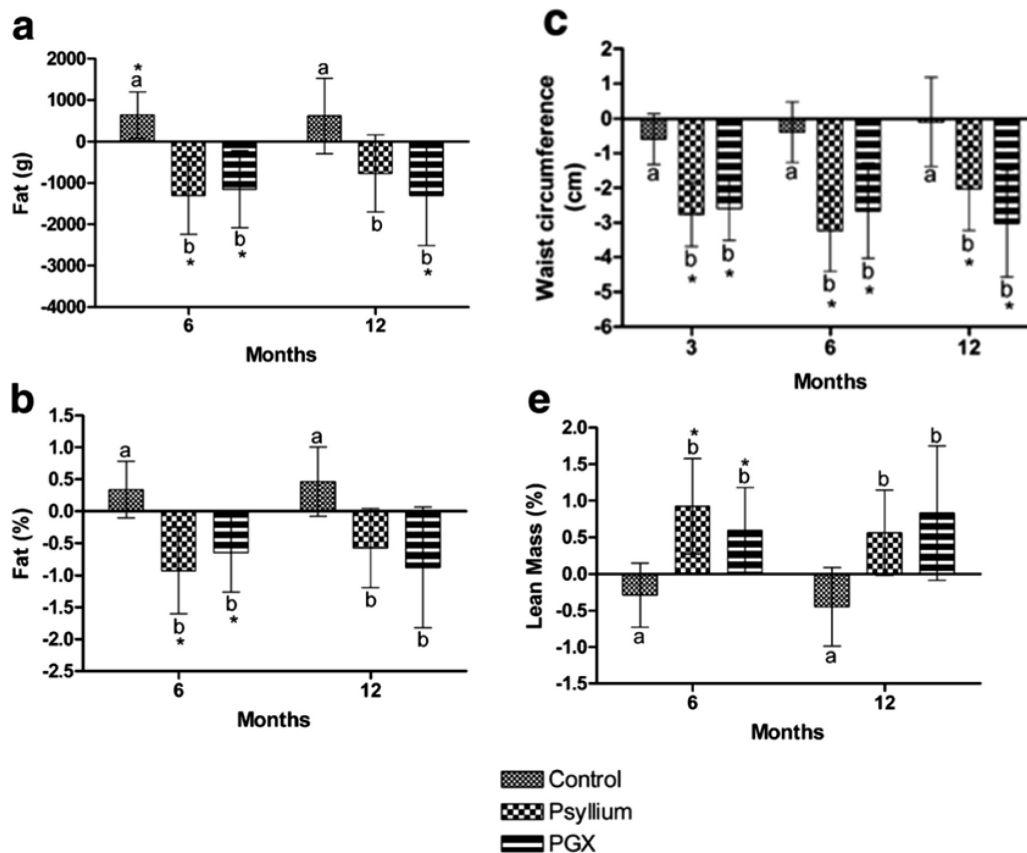


Figure 1. Graphical representation of the changes in measurements from baseline in participants taken at 3, 6 and 12 months. The standard error bars are a 95% confidence interval from the mean represented by the end point of the bar. (From Pal et al¹⁸).

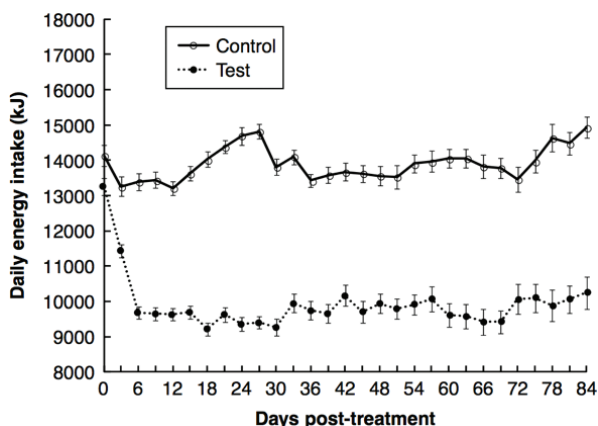


Figure 2. Difference in daily energy intake (kJ) between the control and test group in Guerin-Deremaux et al's 12-week fiber supplement study. The values are expressed as means with the bar representing the standard error of each mean ($p < 0.001$). (From Guerin-Deremaux et al⁹).

decrease in weight, -4.6 pounds [95% CI -6.4 to -2.9] and -6.0 pounds [95% CI -7.7 to -4.3], respectively.¹¹ There was also a decrease in systolic and diastolic blood pressures, -3.5 mmHg and -2.5 mmHg, from baseline at 12-month follow-up, as well as a decrease in fasting insulin [-2.2 μ U/mL (95% CI -4.0 to -0.6)], HDL [-0.8 mg/dL (95% CI -2.0 to 0.3)], LDL [-1.1 mg/dL (95% CI -5.4 to 3.3)], total cholesterol [-4.0 mg/dL (95% CI -9.0 to 1.00)], and triglycerides [-7.6 mg/dL (95% CI -16.8 to 1.1)] in the high fiber group. Participants in the high fiber group also reported that ease in transitioning to a new diet as only one variable (fiber) was to be manipulated in comparison to the AHA diet where focus was placed on multiple nutrients. Similarly, Fujii et al compared the benefits of dietary fiber on weight loss and metabolic profiles using two different diets: Japanese diet and Western diet.¹² The Japanese diet consisted of a lower intake of fiber (15 g/day) than the

recommended Western diet (25–38 g/day). At the end of the one month study, the regression coefficients for BMI, waist circumference, fasting plasma glucose, HbA1c, and triglycerides were all negative [−0.18 ($p < 0.001$), −0.56 ($p < 0.001$), −0.049 ($p = 0.007$), −0.24 ($p = 0.009$), −0.013 ($p = 0.009$), respectively]. Abdominal obesity and hypertension were also found to be negatively associated with fiber intake.

An additional study with women having a BMI ≥ 27 compared the effects of a diet high in protein versus high in fiber over an 8-week study period.¹³ Results showed that consuming a diet high in fiber (≥ 40 g/day) from sources such as breads, cereals, fruits, vegetables, nuts and legumes had a beneficial effect on decreasing not only total weight [−3.3 kg (95% CI −2.4 to −4.2)] but also BMI [−1.2 kg/m² (95% CI −0.9 to −1.5)], fat mass [−2.5 kg (95% CI −3.5 to −1.6)], truncal fat [−1.8 kg (95% CI −2.5 to −1.3)], waist circumference [−4.7 cm (95% CI −3.6 to −5.8)], fasting plasma glucose [−2.6 mmol/L (95% CI −4.9 to −0.4)], total cholesterol [−0.46 mmol/L (95% CI −0.66 to −0.27)], LDL [−0.31 mmol/L (95% CI −0.47 to −0.15)], and triglycerides [−0.18 mmol/L (95% CI −0.29 to −0.08)]. There was also an increase in HOMA2 insulin resistance by 10.6% [95% CI −1.5% to 21.2%].¹³ Similar to Ma et al's study, participants in the high fiber group reported less overall hunger throughout the day as well as less preoccupation with food.

The effects of specific types of fiber, including soy, cereal, fruits, and vegetables, found significant results in two trials. In a study of 39 overweight and obese college students, the effects of consuming a soy fiber biscuit as breakfast for 12 weeks were compared to the consumption of a control biscuit.¹⁴ The nutrients between the two biscuits were equal except for the control containing only 3.2 g of fiber in comparison to 27.5 g of fiber in the soy biscuit. At the end of 12 weeks, the soy fiber group had close to double a change in body weight, BMI, and waist circumference in comparison to the control group with a −1.39 kg ($p = 0.001$) in body weight, −0.51 kg/m² ($p = 0.002$) in BMI, and −1.75 cm ($p = 0.003$) in waist circumference. The soy fiber group showed additional favorable outcomes by reducing body fat percentage (−0.66%, $p = 0.026$), truncal fat mass (−0.64 kg, $p = 0.006$), total cholesterol (−0.58 mmol/L, $p < 0.001$), LDL (−0.41 mmol/L, $p = 0.020$), fasting glucose (−0.95 mmol/L, $p < 0.001$), and HbA1c (−0.01%, $p < 0.001$). Compared to the study participants in the previous two trials with varying amounts of fiber intake, the participants consuming the soy fiber biscuits for

breakfast report less hunger and preoccupation with thoughts of food throughout the day.

Du et al also wanted to explore the effects of various types of fiber on weight loss, specifically insoluble cereal fiber versus soluble fruit and vegetable fiber.¹⁵ The study was a part of the Diet, Obesity, and Genes (DiOGenes) project in Europe, spanned 6.5 years, and originally included 1,46,543 participants. The participant count dropped to 89,432 by the end of the study. Dietary information collected via questionnaires and meta-analyses showed that although the fiber intake was still below the recommended daily values (25 g/d for females, 38 g/d for males), those that consumed more insoluble cereal fiber had a greater increase in weight loss than those who consumed most of their fiber in the form of fruits and vegetables. For every 10 g of cereal fiber a day increase, there was a −77 g a year loss in weight [95% CI −127 to −26] and −0.10 cm a year loss in waist circumference [95% CI −0.18 to −0.02]. Fruit and vegetable fiber consumption showed similar changes in waist circumference but only a −2 g a year loss in weight for every 10 g of fruit and vegetable fiber increase per day.

Taking the beneficial health effects of fiber one step further, the examination of a diet high in both fiber and protein as a method of weight loss was conducted.¹⁶ The study consisted of 89 women between the ages of 18 and 65 who were classified as overweight or obese. The participants were divided into control group and high-protein high-fiber (HPHF) group that were matched in kcals but further instructed to consume at least 35 g of fiber daily.¹⁶ In comparison to the control group, the experimental HPHF participants lost more weight, total fat, and truncal fat on average (Table 1). There was also a greater change in BMI [−0.4 kg/m² (95% CI −0.7 to −0.2,

Table 1. Results from 8 week study conducted by Te Morenga et al. examining the effects of a high fiber diet (≥ 40 g/day) on weight loss and other various physical and biochemical measurements.

| Variable Measured | Change (CI 95%) |
|---------------------------------|----------------------|
| Body Weight (kg) | −3.3 (−2.4, −4.2) |
| BMI (kg/m ²) | −1.2 (−0.9, −1.5) |
| Fat Mass (kg) | −2.5 (−3.5, −1.6) |
| Truncal Fat (kg) | −1.8 (−2.5, −1.3) |
| Waist Circumference (cm) | −4.7 (−3.6, −5.8) |
| Fasting Plasma Glucose (mmol/L) | −2.6 (−4.9, −0.4) |
| Total cholesterol (mmol/L) | −0.46 (−0.66, −0.27) |
| LDL (mmol/L) | −0.31 (−0.47, −0.15) |
| Triglycerides (mmol/L) | −0.18 (−0.29, −0.08) |

$p < 0.0001$), total cholesterol [-0.34 mmol/L (95% CI -0.55 to -0.14 , $p = 0.001$)], LDL [-0.18 mmol/L (95% CI -0.35 to -0.02 , $p = 0.027$)], and insulin resistance among the HPHF group compared to the control diet. The overall change in body weight between the controls and HPHF group was -1.2 kg (95% CI -1.8 to -0.6 , $p < 0.0001$). Total fat and truncal fat also decreased by -1.0 kg (95% CI -1.8 to -0.2 , $p = 0.014$) and -0.7 kg (95% CI -1.3 to -0.1 , $p = 0.034$), respectively.

DISCUSSION

This review provides support for the original hypothesis that increasing the amounts of fiber in your diet on a daily basis can aid in weight loss as well as provide additional health benefits. Solah et al found that over a 12-week period, the daily intake of 5 g of fiber granules can assist in weight loss.⁸ In addition to weight loss, the study revealed a marked decrease in BMI, waist circumference, and frequency of eating. These results provide evidence for the idea that fiber alone can play an extremely important role in helping individuals lose weight. By reducing the frequency of eating, an individual can create a calorie deficit, where they are using more calories than they are consuming, which is essential for the initial steps of weight loss. If a weight loss of an appreciable amount can occur, these already obese patients can decrease their chances of developing metabolic syndrome or other harmful comorbidities. The results of this study also showed that fiber in the form of granules creates a greater weight loss than in soft gels, which makes the incorporation of fiber into various meals throughout the day more practical.

Mixing fiber into a water drink three times a day and measuring the health benefits is what Pal et al set out to do. PSY is most widely used as a bulk forming laxative, as it can help both constipation and diarrhea. It has also been shown to work at lowering blood sugar and cholesterol.¹⁷ In order to highlight some clarity on the additional benefits PSY can have on body composition, Pal et al created a 52-week double-blind study.¹⁸ The PSY showed its greatest benefits at about 6 months where body weight, fat, fat percentage, and waist circumference were all decreased the most from baseline. Toward the 12-month mark, psyllium did not show any favorable outcomes. This suggests that psyllium as a weight loss tool may be valuable to get started, but will not hold beneficial in long-term weight loss or weight loss management. In addition, the psyllium created a feeling of fullness that was almost detrimental rather than

helpful. The participants were so full from the excess fiber that they were consuming fewer calories and substance overall, thus decreasing important macronutrient intake. Although a calorie deficit is essential for weight loss, missing out on key macronutrients is not advantageous to overall health. As psyllium does have additional health benefits aside from weight loss, it would be worth studying whether a lower dose throughout the day would provide superior and more long-term results.

Guerin-Deremaux et al conducted a double-blind, placebo study where participants (overweight, Chinese men) in the experimental group had 17 g of dietary fiber mixed into fruit juice to be consumed twice daily.⁹ The experimental group showed weight loss, reduction in body fat, decreased BMI, and decreased energy intake in comparison to the control group at the end of the 12-week study period. The control group's measurements remained relatively constant throughout the study period. This alone suggests that incorporating a large amount of fiber, in this case 34 g a day, into the diet can aid in weight loss. Those results are of increasing significance because the recommended daily value for men is 38 g/day, where the fiber supplementation alone in this study almost reaches this value. By simply consuming the fiber supplemented fruit juice and consuming one day's worth of food, these participants were not only reaching but far exceeding the recommended daily intake of dietary fiber. The other extremely significant finding of this study was the great decrease in daily energy intake between the control and experimental groups. A great decrease in energy intake will again cause a calorie deficit that may be the greatest contributor to weight loss in the participants. The data presented in this study provide an incentive for incorporating dietary fiber into a daily regime and show that it can be as simple as mixing it into a beverage. With that being said, to further validate the results of this study, it would be beneficial to conduct a study similar in design but include individuals of different race and gender. Expanding the study population diversity would allow the results to potentially be applied to a greater population and give the study more strength.

Furthermore, naturally occurring sources of fiber rather than supplements have shown an even greater positive impact on preventing weight gain and aiding in and sustaining weight loss. To examine how fiber intake, both soluble and insoluble, achieves this, Tucker et al

tracked the diets of overweight women for 20 months.¹⁰ In order to examine the effects of fiber alone, the confounding variables, such as physical activity, fat intake, and age, were considered and the results were still extremely conclusive. 'Analysis revealed that women who decreased their fiber intake over the nearly two-year study were at much greater risk of weight gain compared with their counterparts. The converse was also true; women who increased their fiber intake over time actually increased their likelihood of losing weight'.¹⁰ Simply put, without adequate daily dietary fiber, weight gain will occur. These results are promising for the potentially large impact fiber can have on preventing weight gain and progression or development of other more serious diseases. But whether or not they can be applied to other, less homogenous groups of individuals are a considerable limitation. Of the study participants, all were women, mostly all were Caucasian, and more than half were considered well-educated. Further investigation as to whether these conclusions apply to men as well as various ethnicities and social stratifications would be necessary. With the limitations aside, it is still important to place an emphasis on increasing fiber-rich foods, such as whole-grains, cereals, fruits, and vegetables, in the diets of people looking for long-term weight management as there were not any adverse effects of doing so. The results from this study can be further applied and investigated in how fiber can not only help with halting weight gain but also supplement significant weight loss.

Different from the purely observational studies as discussed above, Ma et al assessed whether interventional guidance on macronutrient intake played a significant role in weight loss in obese patients with metabolic syndrome,¹¹ specifically whether the multi-component AHA dietary recommendations provide greater health benefits compared to a single-component high fiber diet. The AHA diet focuses on consuming fruits and vegetables, whole grain, high-fiber foods (≥ 30 g/d), fish twice a week, lean animal and vegetable proteins, and reducing sugary beverages, sugar intake, sodium intake. Also important are moderate to no alcohol intake; obtaining 50–55% of calories from carbohydrate, 15–20% calories from protein and 30–35% calories from fat; limiting intake of saturated fat to <7% of energy, trans-fat to <1% of energy and cholesterol to <300 mg/day.¹⁹ At 12 months, both of the study groups had shown weight loss, with the AHA diet slightly higher. Although the AHA diet did provide more weight loss, it also had a

higher dropout rate over the course of the study (12.6%). This dropout rate is likely due to the multiple dietary guidelines that must be followed in the AHA diet regime. Having several strict guidelines to meet along with restrictions in a diet is bound to lead to a decreased compliance or even drop out of the study. It is clearly more advantageous for the individual's success to alter a single aspect of a diet, fiber in this case, rather than every macronutrient in the diet. In addition, the minimal weight loss difference between the two groups is another incentive to start with a single basic change and later add focus on other nutritional aspects if more weight loss is desired.

The comparison of two different diets can be helpful when expanded further than one population. In the case of Fujii et al, the comparison of fiber intake in a Japanese diet versus a Western diet yielded valuable results.¹² The Japanese participants were receiving most of their fiber in the forms of rice, followed by vegetables and legumes. The amount of fiber in the diet showed a negative regression coefficient with the various measurements performed, indicating that any increase in the amount of fiber was related to any subsequent decrease in the said measurement. The main measurements were a decrease in BMI, abdominal obesity, and several different metabolic panels. Of added importance, HbA1c, cholesterol, and triglyceride levels all decreased as well as fasting plasma glucose. For the participants in this study already being diagnosed with type 2 diabetes, reducing these values is of pronounced significance in order to lessen the risk of developing comorbidities such as cardiovascular disease and metabolic syndrome. An additional key finding via the food intake questionnaires was that the typical Japanese participant was only consuming about 15 g of fiber a day. This amount is comparable to the actual amount of Western diet people of the United States are consuming,⁷ but the difference is in the countries' recommended daily intake values. Japanese guidelines recommend >19 g a day for males and >17 g a day for females in comparison to the >38 g a day for males and >25 g a day for females in the United States.¹² Therefore, in this study population where 15 g of fiber a day may initially seem low, it is important to look at the ethnic context. Japan has a lower recommended daily intake, and these participants are just about reaching it, while the United States has a much higher recommended value that is close to double the amount that is actually consumed by the patients. As the participants in this study were

570 consuming similar sources of fiber (rice and vegetables)
present in both the Japanese and Western diets, the
575 results can more easily be applied to a broader popula-
tion thus strengthening the credibility of the study. In
other words, if Western diet increased their daily intake
of fiber to meet a recommended value similar to that in
Japan (~15 g/day), they would be consuming more fiber
580 than their baseline value even if they are not reaching
the higher recommended daily value (25–38 g/day) set
out by the US Department of Health. A major limitation
to this study was the lack of outline comparing the other
585 components of the diet. The diets were just simply
referred to as Japanese diet and Western diet, where
fiber was the only nutrient specified. Other nutrients
that are consumed in a normal diet, fats and proteins for
example, could be influencing the weight loss and met-
abolic panels but are not factored into the data or even
mentioned in detail.

590 Similarly, focusing on increased fiber intake, in the
8-week study on women with a BMI ≥ 27 , increasing
daily fiber enhanced weight loss results. Women were
instructed to aim for a fiber intake of 40 g a day through
the consumption of 'high-fiber breads, cereals, fruits,
595 vegetables, nuts and legumes'.¹³ The resulting weight
loss was notable in these women at the end of 8 weeks.
The women also noted having less hunger and preoccu-
pation with food, which helps not only to decrease the
daily caloric intake leading to weight loss but also to
ease the patients' mindset. Moreover, the high fiber diet
had a significant impact on the patient's metabolic pro-
file, notably insulin levels and sensitivity to insulin. The
600 increased HOMA2 value represents an increase in insulin
sensitivity and pancreas beta cell function.¹³ In these
patients with a BMI in the overweight range, it is increas-
ingly important to make sure that their bodies are pro-
cessing and utilizing sugars properly to decrease the risk
of developing metabolic syndrome, so the positive out-
come of increased beta cell function is noteworthy. The
605 results here can be applied as they help reduce body
weight and waist circumference as well as increase insu-
lin sensitivity, which are two of the major diagnostic fac-
tors for metabolic syndrome.⁴ While Te Morenga et al
provided valid conclusions about how increasing your
610 fiber intake can aid in weight loss, it would be advanta-
geous to extend this study design for a longer period of
time.¹³ Eight weeks is only a short period of time, and
when patients have a lot of weight to lose, they will lose
more in the first few months of lifestyle change.²⁰ It is
615 also important to determine whether 40 g a day of fiber

is sustainable over a longer time period and in a consis-
tent pattern.

620 Different from the previous studies, Hu et al deter-
mined that a specific type of fiber, soy fiber, provides
more health benefits than whole-grain fiber.¹⁴ Including
a soy fiber biscuit (27.5 g of fiber) in your breakfast daily
625 for 12 weeks can lead to a decreased waist circumfer-
ence, weight, BMI, body fat percentage, truncal fat, total
cholesterol, LDL, blood glucose, and HbA1c levels, all
while leaving you with less thoughts of food throughout
the day and feeling full. An additional extremely impor-
630 tant conclusion from this study was that it may only take
one large serving of fiber throughout the day to reap
the benefits. That fact alone may make a high fiber diet
easier to follow and result in more compliance. A poten-
tial downfall to this trial is the population of participants.
635 The study was relatively small including 39 patients.
In addition, college students are much more likely to
take advantage of a program that provides free food,
soy biscuits in this case, so the dropout rate was
extremely low. It would be of value to see if these results
640 would hold true if this study design were applied to a
more heterogeneous population where a free meal was
not an incentive. Needless to say, implementing soy
fiber in your diet regime has enormous health benefits
for anyone looking to lose weight and decrease risk of
developing harmful diseases.

645 A look further into specific types of fiber revealed that
the source of fiber consumed may actually be very
important. Du et al initially noted that 'fiber is not a
homogenous entity,' implying that although you may
consume large amounts of total fiber from different
650 sources, such as cereals, fruits, and vegetables, the
body's physiologic process to digest and utilize each
variant is different thus resulting in different health and
metabolic outcomes.¹⁵ The nearly 70 g a year difference
in weight loss between the cereal and fruits and vegeta-
655 ble fiber groups creates a strong case for a greater
emphasis on increasing cereal fibers first and foremost.
Even though 70 g of fiber doesn't account for an
extremely great decrease in weight a year, it can be a
great starting point for individuals who are in desperate
660 need of weight loss in order to salvage their health.
Although this study did provide a comparison of the
weight loss and metabolic benefits of various fibers, it is
important to consider the disparity in fiber content per
food item, for example, comparing the fiber content of
665 strawberries, corn, and barley. These products provide 3,
3.6, and 6.0 g of fiber per one cup, respectively.³

Therefore, in order to reach the same amount of total fiber intake, it would require almost double the serving of these specific fruits and vegetables to equal a single serving of the barley. With increased quantity there come changes in overall caloric intake, as well as other macronutrients that may all contribute a less favorable weight loss profile in comparison to the cereal fibers.

Another significant finding from the Du et al study centered on the total fiber intake amount. This study found that the average fiber intake was close to 23 g a day over a 6.5-year period, rising from the average baseline of 15 g a day. As mentioned previously, the recommended daily intake is 25 g a day for females and 38 g a day for males.³ The participants in this study were still not reaching the daily recommended values, but they were still managing to achieve weight loss and a decrease in waist circumference. These findings suggest that although the amount of fiber intake may be important, increasing intake from the usual baseline alone can be therapeutic.

As it has already been established that fiber plays an important role in weight loss, it can be of added interest to determine how fiber in combination with other substances could also assist in healthy changes. Specifically, protein alone can also be beneficial for weight loss and in combination with fiber. Protein alone can cause an increased postprandial thermogenesis and resting metabolism aiding in weight loss,²¹ as well as increase and sustain satiety after meals. In a clinical study where a high fiber diet was combined with a high protein diet for 10 weeks, there was a modest decrease in weight and total body fat¹⁶ with a more significant finding related to the decrease in total cholesterol, LDL, and insulin resistance. The resulting decrease in all the measured values creates a strong incentive for constructing a diet high in protein and fiber in order to lose weight. While many patients with metabolic syndrome are overweight with an increased waist circumference, the more detrimental aspects of their diagnosis is the harmful metabolic profiles they possess. The high cholesterol and LDL levels place them at an increased risk for heart disease, heart attacks, and stroke.²² The insulin resistance increases the chances of developing type 2 diabetes mellitus and problems with glucose metabolism. By increasing fiber intake to ≥ 35 g a day, with a high level of protein as well, patients can make a positive impact on their metabolic profiles to decrease chances of developing metabolic syndrome or lessen chances of adverse events occurring in already diagnosed cases.

In conclusion, dietary fiber has been shown to provide numerous health benefits for all patients alike. Fiber can be of added value to overweight and obese individuals who are on the verge of the harmful diagnosis of metabolic syndrome by tipping their metabolic profiles to the healthy side of the scale. In addition, as there are not many known harmful effects of following a high-fiber diet, the benefits most definitely outweigh the risks of such diet. Included in this review were studies that took place in various parts of the world, ranging from Japan and Australia to the United States. The wide range of participants and cuisine consumed by each provide solid evidence that fiber can be universally beneficial in weight loss. By simply consuming a fiber rich biscuit, adding fiber powder to your morning juice, or increasing fruit and vegetable intake, one can increase one's chances of living a healthier, lighter, disease-free life.

Conflict of interest and funding

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Appendix Table. Summary of studies used in systematic review and outcomes of respective studies.

| Evidence Table | | | | | | |
|-----------------|---------------------|-----------------------------------|--------------------|--|--|--|
| First author | Date of publication | Study design | Number of patients | Study population and length | Therapy or exposure | Outcome/result |
| Du | March 2010 | Prospective Cohort | 89,432 | European participants who were free of cancer, cardiovascular disease, and diabetes at baseline; 6.5 years | Daily dietary fiber amounts over a 6.5-year time period | Total fiber intake was inversely related to weight and weight circumference change, where a diet with the main fiber source as cereal resulted in a greater change in both variables in comparison to the main fiber source coming from fruits and vegetables. |
| Fujii | December 2013 | Prospective Cohort | 4,399 | Japanese patients | Daily dietary fiber intake assessed via self-administered questionnaire | BMI, fasting plasma glucose, HbA1c, triglycerides, and C-reactive protein were all negatively associated with dietary fiber intake. Dietary fiber was also associated with a decrease in abdominal obesity and other metabolic syndrome components. |
| Guerin-Deremaux | May 2011 | Randomized controlled trial (RCT) | 120 | Overweight men (aged between 20 and 35 years); 12 weeks | 17 g of dietary fiber in juice 2x daily | Consuming 17 g of fiber two times daily results in weight loss greater than the control group who did not consume extra fiber. Body fat percentage and BMI also decreases, as well as total energy intake. |
| Hu | May 2013 | RCT | 39 | Overweight and obese college adults (aged between 19 and 39 years); 12 weeks | Soy Fiber biscuit (100 g) | Intake of soy fiber had favorable effects on body weight, BMI, and LDL cholesterol in the study group. |
| Ma | February 2015 | RCT | 240 | Adults with metabolic syndrome; 4.5 years | AHA diet or high fiber diet | Both the AHA dietary group and the high fiber diet group lost weight after a year of following the diet plan. Recommendations for further testing was given. |
| Morenga | September 2010 | RCT | 89 | Overweight and obese women (aged between 18 and 65 years); 10 weeks | High protein and fiber diet | Participants in the study group of high protein and fiber diet lost more body weight, truncal fat, and total fat than the standard diet study group. |
| Morenga | April 2011 | RCT | 83 | Women with a BMI greater than 27; 8 weeks | High protein or high fiber diet | Participants in both the high protein and the high fiber groups lost weight in the 10 week study period, but there was a greater loss seen in the high protein diet group. |
| Pal | November 2016 | RCT | 159 | Australian subjects with a BMI between 25 and 47; 1 year | 5 g of rice flour, 5 g of psyllium fiber (PSY), or 5 g of PolyGlycopleX® (PGX) | Both the PSY and the PGX groups had a significant decrease in weight loss and body fat at both 6 and 12 month measurements compared to the controls consuming rice flour. |
| Solah | February 2017 | RCT | 118 | Overweight adults; 12 weeks | Fiber granule or soft gel supplementation | In the fiber granule group, there was a reduction in waist circumference, body weight, BMI, and number of eating occasions that was significant from the start of the study. |
| Tucker | January 2009 | Prospective Cohort | 252 | Women located in Salt Lake City region; 20 months | 7 day food log | At the end of the 20 month period, it was found that for every 1 g decrease in total fiber intake there was a 0.45 pound increase in weight. |

Advance Directive Status in the Greater Than 65-Year-Old Emergency Department Population

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Objective: To assess the status of Advance Directives of elderly patients who present to the Emergency Department including their knowledge of the topic, what documents are in place, and how they were produced.

Advance directives are an important aspect of medical care for the elderly given the uncertainty of health and longevity. In their absence, family and physicians are often left with questions regarding what patient's wishes would entail if they become incapacitated. Individuals >65 years presenting to the ED were surveyed during the months of June-September 2015 by study investigators regarding their knowledge and utilization of advance directives. 168 patient surveys were completed with a mean age of 77.2 (SD ±7.45 years; range 65-97). Of those, 91% were either "very familiar" or "somewhat familiar" with Advance Directives with 76.1% having some form of documented advance directives in place. Of those who felt family were aware of their wishes, 84.9% had assigned a Medical Durable Power of Attorney. Only a small minority had developed advance directives with their physician's assistance (6.8%). The majority of patients stated that they had prepared their end of life documents with a Lawyer (72%). Only 35.8% of patients sampled had even mentioned the topic or their specific wishes with their primary care or ED physician. Overall rates of formalized advance directives would appear to be highly utilized in this patient population with little variation based upon respondents' self-assessment of physical health. A surprising finding was how minor of a role physicians appear to play in the development of ADs. This provides an opportunity to enhance the physician-patient relationship and improve patient education regarding end of care discussions. Physicians should take initiative and begin having these conversations, in order to ensure that patients are making educated decisions and that proper documentation is occurring.

Keywords: advanced directive (AD); living will; do not resuscitate (DNR); Medical durable power of attorney (MDPOA); emergency department; emergency room; elderly

INTRODUCTION

End of life decisions are a difficult topic for many patients to think about, but they are becoming increasingly more important as modern medicine advances. These decisions are expressed to physicians via Advance Directive (AD) documents. Without these documents, treatment decisions for incapacitated patients are left to family members and the health care team. This could potentially result in certain types of medical care being performed against the patient's wishes. To combat lack of knowledge on the topic of ADs, a federal law called the Patient Self Determination Act was passed in 1991. This law states that health care institutions are required to provide patients with information about end of life decisions, document their decisions properly, and not discriminate against patients for whether they have ADs in place (1). Despite this law being passed, rates of ADs in both primary care practice and the Emergency Department (ED) are exceedingly low (2,3). In addition, the amount of research that has been done on this topic, specifically in the

Emergency Department (ED), is very limited (5,6). In this study, we sought to establish the rates in which three types of ADs were previously established by patients over 65 years of age who presented to the ED: Medical Durable Power of Attorney, Living Will, and Do Not Resuscitate orders. We believe that finding correlations between certain patient characteristics and the presence of these documents could help uncover reasoning behind why rates are so low. Previous studies over a decade old have also shown that very few primary care physicians are directly involved in establishing advance directives with their older patients (5,6). One study specifically found that only 5% of their surveyed population had discussed the topic of ADs with their doctor (6). Research has also shown that patients would like their physician to be the one to initiate the conversation (7,8). We wanted to determine if these discoveries have resulted in any changes in the conversation between physician and patient or the utilization of ADs in those >65 years of age.

METHODS

Design and Setting

A cross-sectional survey was performed of a convenience sample of patients over the age of 65 that presented to the ED at Sparrow Hospital, a large community based academic hospital which sees over 100,000 ED patients per year. Patients were sampled during the months of July, August, and September of 2015. The population included patients over the age of 65 who could answer questions. Patients who were unresponsive, incompetent or were suffering from immediate, life threatening terminal illnesses were not included in the sample. Patients were surveyed during a convenience sample performed by a medical student and a resident researcher during respective morning and afternoon shifts. A total of 168 patients met inclusion criteria for this study. The Institutional Review Board of Sparrow Hospital approved study.

Survey

The surveys were either given directly to the patient, their family (if they were knowledgeable of the patient's wishes and wished to participate), or read to them by the participating researcher. All participants were informed that the survey was optional and it would not affect their plan of care. Verbal and written consent was received prior to beginning the questionnaire, and the survey was provided in English. The presence of advance directives that were included in the study questions were Medical Durable Power of Attorney, defined as written documentation of an individual they appointed to make medical treatment decisions and related personal care decisions when they can no longer make the decisions for themselves, Living Will, defined as a written document informing doctors, family members and others what type of medical care they wish to receive should they become terminally ill or permanently unconscious, and Do Not Resuscitate (DNR) Order, defined as a written document that states wishes to not be resuscitated should they go into cardiac or respiratory arrest. Additional questions in the survey included: age, gender, ethnicity, number of hospital admissions in past year, insurance type, primary care physician, frequency of visits to primary care doctor, understanding of ADs (very familiar, somewhat, not at all), how well family members know the patient's wishes (very knowledgeable, somewhat, very limited), presence of a Medical Durable Power of Attorney, presence of Living Will, presence of Do Not Resuscitate Order, if ADs were

discussed with their Primary Care Physician (PCP), how ADs were produced (with a lawyer, on their own with a premade form, on their own written in a free text, or established with their PCP), why ADs are not present, and if they would like additional information on ADs.

RESULTS

Demographics of the population sampled are shown below, with the majority of patients being Caucasian and Female (Figure 1). The mean age of the population was 77.2 with a range of 65-97 years, and 56% of the population being female. Ethnicity was predominantly Caucasian, followed by African American, Hispanic, and "other".

Familiarity with Advance Directives

The overwhelming majority of patients sampled were at least somewhat familiar with ADs, with 91% being either "very familiar" (51%) or "somewhat familiar" (40%). Only 9% were "unfamiliar". Of note, a large number of patients did not know what the words "Advance Directives" themselves meant, but once words like "Medical Power of Attorney" or "DNR" were mentioned, they quickly expressed familiarity of "Advance Directives". These patient's answers were recorded after the explanation. Of the patients that answered either "very familiar" or "somewhat familiar", 76.1% of these had some form of documented AD in place (Durable Power of Medical Attorney, Living Willing and/or DNR status).

Familial Awareness of Wishes

Only about 64% of patients felt that their family was very familiar with their wishes for end of life care. Of those who felt family were aware of their wishes, 84.9% had assigned a Medical Durable Power of Attorney.

| | | |
|-----------------------|------------------|-----|
| Sex | Male | 42% |
| | Female | 58% |
| Ethnicity of Patients | Caucasian | 92% |
| | African American | 3% |
| | Hispanic | 3% |
| | Indian | 1% |
| | Native American | 1% |

Figure 1. Ethnicity and Sex of All Patients Surveyed.

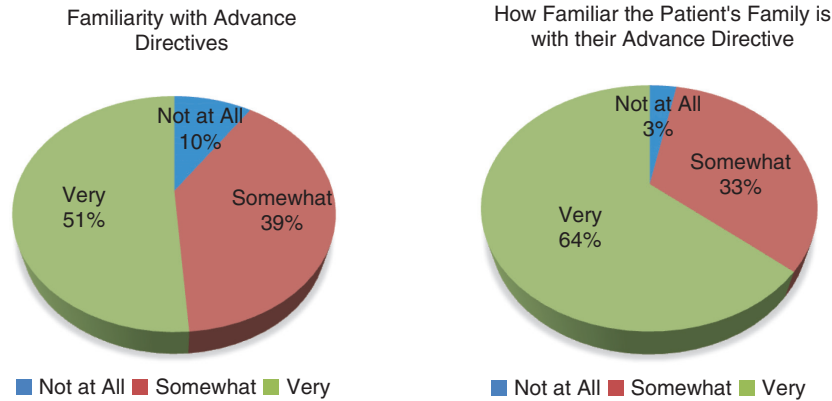


Figure 2. Patient familiarity with ADs and family familiarity with the patients AD.

Overall Advance Directive Status

In our population, 74.4% of patients had a documented Durable Power of Attorney, 55.8% of patients had a documented living will, and 39.5% had documented DNR orders. Overall, 77% had at least one of these options in place. Of the patient’s that didn’t have any, the most common reason given was “I don’t want to think about dying”, followed by “I will worry about that when I am older”, and “I don’t know enough about it”.

Impact of Health on Advance Directives

Those who considered themselves to be in “excellent, very good, or good” health were equally as likely to have some form of advance directives as those who considered themselves to have “fair or poor” health (74.1% vs 80.40%; p=0.89). Similarly, the number of previous hospitalizations within the past 12 months (those with ≥3 or <3) did not result in differences in rates of ADs (75.8% vs 77.8%; p=0.99).

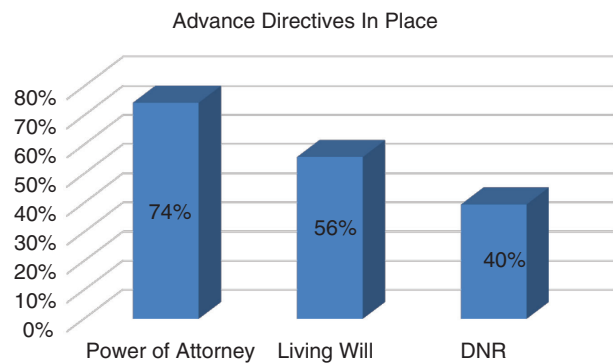


Figure 3. Advance Directive Status in Overall ED Population.

Preparation of Advance Directives

The majority of patients stated that they had prepared their End of Life documents with a Lawyer (72%), whereas only 22% had made them with a physician, 5% on their own, and 1% other (Figure 1).

Physician Involvement in End of Life Decisions

Most surprisingly, regardless of knowledge or status of ADs, only 35.8% of patients sampled had discussed the topic or their specific wishes with their primary care or ED physician.

DISCUSSION

Overall, our study showed that a large number of patients in our convenience sample at this single institution were aware of ADs in order to express their wishes about end of life decisions. Our sample had a higher utilization of advance directives than that found by

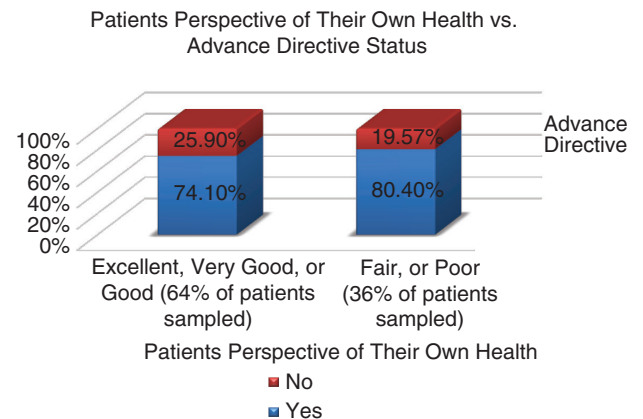


Figure 4. Patients Perspective of Their Own Health vs. Advance Directive Status.

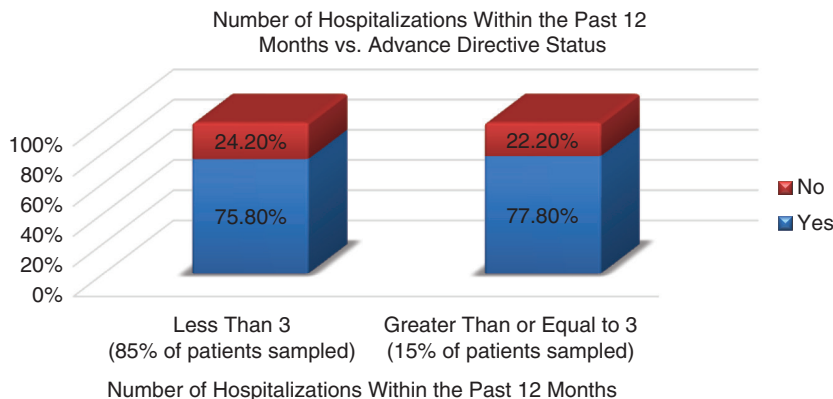


Figure 5. Number of Hospitalizations Within the Past 12 Months vs. Advance Directive Status.

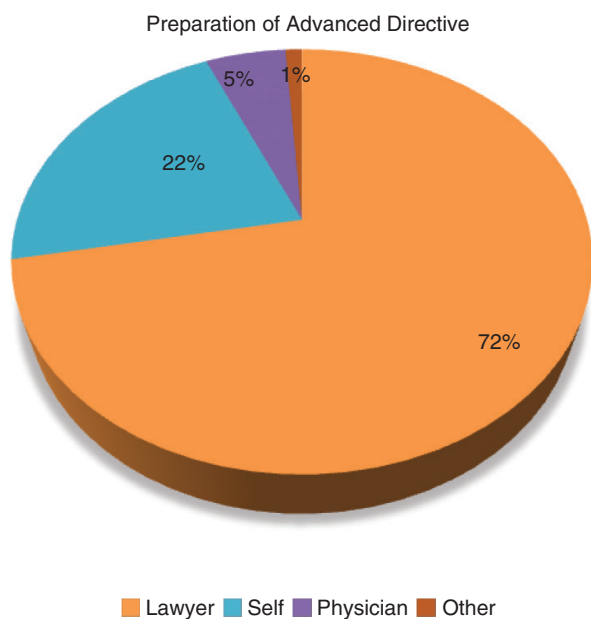


Figure 6. Preparation of Advance Directive.

O’Sullivan et al in a review of 6 studies from 1996-2012 that found in patients >65 years old rates of AD completion varied between 21% and 46% (2). This is substantially less than the 77% of ED patients in our population who had at least one AD in place, suggesting that more people are beginning to utilize these documents. Also, contrary to previous studies, this study found that patients with poor physical health and more hospitalizations were no more likely to have ADs in place than their healthier peers (2,3).

A surprising finding of our study was how minor of a role physicians appear to play in the development of ADs. In 1991 Emanuel et. al. determined only 5% of their survey population had discussed the topic of ADs

with their physician (6). Today, our data shows that this number has increased to 35.8%. Although progress has been made, we still have a long way to go. A very important aspect in helping to build the physician-patient relationship should be a conversation about end of life wishes. Studies have shown that patients prefer physicians to initiate the conversation, but physicians cite not wanting to make the patient feel uncomfortable and thus wait for them to raise the topic (7). Regardless of the reasons, these important conversations are occurring much less frequently than they should. This brings up a great opportunity for physicians to take initiative and begin having these conversations, in order to ensure that patients are making educated decisions and that proper documentation is occurring.

Limitations

This study represents a convenience sample with the accompanied possible bias that not all patients over 65 years of age presenting to the ED were included. Further, because the survey was not offered in other languages, and the majority of survey responders were Caucasian, it may not have been representative of the true ethnic diversity of the ED. Individuals may have been inaccurate in their answers, wanting to appear that they were more aware of ADs than they truly were as no proof of this AD documentation was required.

Conclusion

Our study has uncovered some promising Advancements in the utilization of ADs. Far more patients are becoming familiar with these documents

and putting them in place to ease the burden on their families. However, a surprising number of patients have not created ADs with their physician, nor have they involved their physician in the decision, or even informed them that such documents are in place. This exposes some new potential areas for patient and physician education. Patients should be encouraged to let all providers know about these wishes, and physicians should be asking these questions to get the conversation started.

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Pilot Study: Increasing Knowledge and Collaboration Primarily among Christian Faith Leaders and Health Providers for PTSD Survivors

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Background: *The risk of exposure to trauma is part of the human condition, and given the mortality and morbidity associated with post-traumatic stress disorder (PTSD) properly supporting trauma survivors represents an important public health issue.*

Objectives: *The aim of our study is to assess a collaborative training model for faith leaders and health providers designed to help enhance their knowledge of PTSD and their confidence to collaborate together to support trauma survivors. The hypothesis was that our training model would increase participant knowledge of PTSD and increase confidence with interdisciplinary collaborations.*

Methods: *The study used experimental and interventional methods to develop and assess the training model. The curriculum for our training model is based on a learner-centered model of collaborative learning as described by the curriculum design for the interdisciplinary study. The study sample was drawn exclusively from conference participants. The total number of participants who completed all of the pre- and post-conference assessments was 16, of whom 7 were faith leaders and 5 health providers. All registered conference attendees aged 18 years or older were eligible to participate in the study. The instruments were designed by the research team, who administered pre- and post-conference instruments. The instruments examined subjective and objective knowledge of PTSD, as well as comfort in identifying and managing PTSD symptoms.*

Results: *The quantitative results of our study suggest the training model is effective for faith leaders and health providers to increase their knowledge and enhance their self confidence in participating in interdisciplinary collaborations between each other to support trauma survivors.*

Conclusions: *Future follow-up research is needed to determine the degree to which the participants actually applied their increased knowledge of PTSD and ability to collaborate with faith and or health providers.*

Keywords: *post-traumatic stress disorder (PTSD); religion; spirituality; clergy; collaborative care; training model*

INTRODUCTION

In the United States, an estimated 70% of adults have experienced a traumatic event at least once in their lives and up to 20% of these individuals develop post-traumatic stress disorder (PTSD).¹ An estimated 5% of adult Americans – more than 13 million people – have PTSD at any given time.¹ Approximately 8% of all adults – 1 of 13 people – will develop PTSD during their lifetime.¹ PTSD is associated with high mortality (i.e., suicide) and morbidity (i.e., major depression and substance use).¹

Therefore, properly supporting trauma survivors with PTSD represents an important public health issue. In addition to PTSD some trauma survivors may experience a spiritual crisis (e.g., feel anger at and/or abandoned by God).² Given the possible need to seek resolution of a spiritual crisis and their accessibility, faith leaders are commonly the first resource to which trauma survivors go for support.³ Faith leaders are therefore in a crucial position to offer spiritual guidance to trauma survivors and direct them to mental health services.⁴ (This paper

understands faith leaders as lay or formally trained and/or ordained people who are appointed by their religious community with the task of advancing its particular beliefs and comprehensive doctrines.) Given the complicated spiritual and biopsychosocial issues that may arise after a traumatic experience, there is a clear need for interdisciplinary collaboration between faith leaders and health providers to support trauma survivors.⁵⁻⁹ However, collaboration between those groups can be limited by conflicting world views, divergent interventional approaches, and a long-standing distrust between these faith and medical disciplines; such obstacles must be overcome to promote effective collaborative care.^{10,11}

There is a dearth of literature on concrete collaborations between faith leaders and health providers that improve assessment and treatment of the traumatized. To our knowledge there is no literature describing specific strategies or interventions to resolve barriers to collaboration between those two groups. To address those gaps we developed, implemented, and tested an educational program designed to foster interdisciplinary collaborations between faith leaders and health providers.

To that end, we developed a conference entitled 'Healing from a Broken Place: Supporting Trauma Survivors through Collaboration of Ministry and Mental Health Providers' (HFBP). Our study was done in the conference. The goal of the conference was to create a space where faith leaders, health providers, and the broader public could learn about how to collaborate to support survivors of trauma. Our collaborative training model is based on a curriculum¹² teaching about the clinical aspects of psychological trauma and how religious and spiritual themes and faith communities can help support those influenced by traumatic experiences. Our primary objectives were to describe any increase in participant knowledge in identifying and managing PTSD symptoms and depict confidence level in supporting trauma survivors through interdisciplinary collaborations between faith leaders and health providers. Our hypothesis was that the HFBP conference would increase knowledge of PTSD and confidence to engage interdisciplinary collaborations to support trauma survivors.

BACKGROUND

Grame asserts that collaborative care is more efficacious than usual care, as detailed in a 2012 Cochrane Summary that reviewed 79 randomized controlled trials and 24,308 patients across the world.¹³ Literature shows that

collaboration with faith leaders is important for health providers to better assist trauma survivors.^{3,14,15} Research has demonstrated a relationship between religion/spirituality and improved health outcomes, such as in post-traumatic healing,¹⁵ lower levels of distress,¹⁵ finding meaning and will to live,¹¹ quality of life,¹¹ less hospital time,^{11,15} and reduced cost of care.^{11,15} Some specific spiritual or religious interventions shown to reduce PTSD symptoms include but are not limited to writing about traumatic events from a religious perspective,¹⁶ prayer,¹⁷ and meditation.¹⁸ With the exception of collaborations between faith leaders and health providers aimed at improving assessment and treatment of the traumatized, interdisciplinary collaborations between faith leaders and health providers with the aim of improving mental health outcomes for an individual, family, or group^{19,20} have been well documented in literature and have traditionally involved various forms of consultation and referral.^{10,14,21-23} There is research supporting that a 'bidirectional' collaboration model (i.e., team members contribute to reaching the common clearly defined objective) between faith leaders and health providers is effective.²² Advocates of a bidirectional approach argue that it offers a greater possibility for shared respect and dialog between all parties involved.^{14,22} Collaboration between faith leaders and medical providers should therefore include consideration of attitudes held among both groups towards collaborating together.²²

Faith leaders are generally open to collaboration with various members of the medical community, especially 'when shared values are recognized and appreciated'.¹⁴ Faith leaders are more likely to collaborate with nurses than with psychologists or psychiatrists,²⁴ because faith leaders may feel undervalued by health providers, psychologists, and psychiatrists in particular.²³ In addition, they perceive that sometimes psychological and or medical interventions can be in conflict with spiritual interventions.²³ The literature also indicates that health providers may be less willing to collaborate than their faith leader counterparts. Some health providers believe that faith leaders are too dogmatic to collaborate with,²² spiritual interventions compete with psychological or medical interventions,²² and sometimes have a fear that patients will not accept their limitations after religious or spiritual professional consultation.^{19,25}

In addition to attitudes, it is important to consider what faith leaders and health providers actually *know* about the psychiatric, religious, and spiritual

aspects of trauma.²⁶ Few studies have examined the level of trauma knowledge demonstrated by faith leaders and health providers, which limits their generalizability.²³ These few studies suggest that faith leaders have views about the causes and treatments of mental illness consistent with most health providers (i.e., there exists some biological and social components to mental illness).²³ However, research suggests that faith leaders lack 'concrete knowledge about psychopathology';²² knowledge of 'access to mental health resources';²² and 'experience in dealing with severe mental illness'.²² Moreover, health providers lack adequate exposure to matters of spirituality and health in their practical training,^{19,25,26} resulting in a general lack of awareness of how spirituality influences the course of mental illness.²² Such knowledge gaps illustrate the need for better education on the multidimensional nature of trauma among faith leaders and health providers.

METHODS

This pilot study used both experimental (pre- and post-tests) and interventional methods via a conference focused on faith leaders and health providers. We designed a conference to help address the dearth of literature concerning the efficacy of collaborations between faith leaders and health providers by targeting faith leaders from all walks of religious life, health providers, and trauma survivors. The intervention was attendance at the conference, which provided opportunities for faith leaders and health providers to hear from trauma experts and survivors and to discuss ideas to improve assessment and collaborative management of psychological trauma. The conference format provided an appropriate setting to offer practical approaches to collaborate and increase PTSD knowledge.

Curriculum Design

Our curriculum draws from a culturally responsive, bidirectional, and learner-centered model of collaborative learning as described by the curriculum design for the interdisciplinary study (CDIS)¹² (see Table 3). The conference featured speakers who were both faith leaders and health providers, and panel discussants composed of trauma survivors focused on assessment and treatment approaches from faith and health disciplines.

Recruitment of Participants

The study sample was recruited from attendees at the 1-day HFBP conference, held on October 13, 2011, in

Dewitt, Michigan, at the St. Francis Retreat Center. The Michigan Victim Alliance and Eli Lilly's Sustaining Pastoral Education Grant financially cosponsored this inaugural HFBP conference. The conference targeted faith leaders from all Christian denominations (but welcomed faith leaders from any religious tradition), trauma survivors, and health providers, as well as the general public. The primary methods of recruitment were word of mouth and email using various listservs for faith leaders and health providers in the area. The cost of admission to the HFBP conference was \$50 for nonstudents and \$10 for students. Sixty-six individuals

Table 1. Participant information (N = 16).

| | Number | Percent |
|---|--------|---------|
| Gender | | |
| Male | 6 | 37.5 |
| Female | 10 | 62.5 |
| Age | | |
| 18–30 | 1 | 6.3 |
| 31–45 | 2 | 12.5 |
| 46–60 | 6 | 37.5 |
| 61 or above | 7 | 43.8 |
| Education | | |
| Some college or professional degree | 4 | 25.0 |
| Master's degree | 9 | 56.3 |
| Doctorate degree | 3 | 18.8 |
| Annual household income | | |
| <\$25,000 | 1 | 6.3 |
| \$25,000–\$50,999 | 4 | 25.0 |
| \$51,000–\$75,999 | 5 | 31.3 |
| \$76,000–\$100,000 | 4 | 25.0 |
| >\$100,000 | 1 | 6.3 |
| Prefer not to answer | 1 | 6.3 |
| Religion/spirituality | | |
| Catholicism | 4 | 25.0 |
| Non-Catholic Christian | 8 | 50.0 |
| Buddhism | 1 | 6.3 |
| Other (no religion, agnostic, atheist) | 3 | 18.8 |
| Occupation | | |
| Faith/religious/spiritual leader | 7 | 43.8 |
| Health provider | 5 | 31.3 |
| Other | 4 | 25.0 |
| Exposure to PTSD | | |
| Caregiver of someone with PTSD | 1 | 6.3 |
| Treat people with PTSD | 6 | 37.5 |
| Diagnosed with PTSD | 2 | 12.5 |
| I have not been significantly exposed to PTSD | 5 | 31.3 |
| Prefer not to answer | 1 | 6.3 |
| Other | 1 | 6.3 |

Table 2. Pre-/post-conference attitude difference.

| Q | Pretest | | Posttest | | N | 95% CI | t | df |
|-----------|-------------|-------------|-------------|-------------|-----------|------------------------|--------------|-----------|
| | M | SD | M | SD | | | | |
| 1 | 5.79 | 2.19 | 8.29 | 1.14 | 14 | 1.2355, 3.7645 | 6.01 | 13 |
| 2 | 4.71 | 2.61 | 7.79 | 1.58 | 14 | 1.0619, 4.0810 | 5.69 | 13 |
| 3 | 5.64 | 2.17 | 8.21 | 1.12 | 14 | 1.3185, 3.8243 | 6.62 | 13 |
| 4 | 4.71 | 2.46 | 7.29 | 1.77 | 14 | 1.1494, 3.9935 | 6.62 | 13 |
| 5 | 4.50 | 2.25 | 7.32 | 1.71 | 14 | 1.5254, 4.1175 | 4.84 | 13 |
| 6a | 7.38 | 2.36 | 8.08 | 1.12 | 13 | -0.7859, 2.0716 | 1.39* | 12 |
| 6b | 7.31 | 1.97 | 8.23 | 1.42 | 13 | -0.2699, 2.1161 | 1.95* | 12 |
| 6c | 8.08 | 1.66 | 8.92 | 0.86 | 13 | -0.1548, 1.8471 | 2.51 | 12 |
| 6d | 8.75 | 1.89 | 9.00 | 0.82 | 4 | -2.7621, 3.2621 | 0.40* | 3 |
| 7 | 4.71 | 1.90 | 7.93 | 1.44 | 14 | 2.1181, 4.3105 | 7.62 | 13 |
| 8 | 4.57 | 1.65 | 7.36 | 1.28 | 14 | 1.8326, 3.7389 | 7.61 | 13 |
| 9 | 7.92 | 2.29 | 8.77 | 1.17 | 13 | -0.5376, 2.2299 | 1.34* | 12 |

p ≤ 0.05; *Represents correct answer.

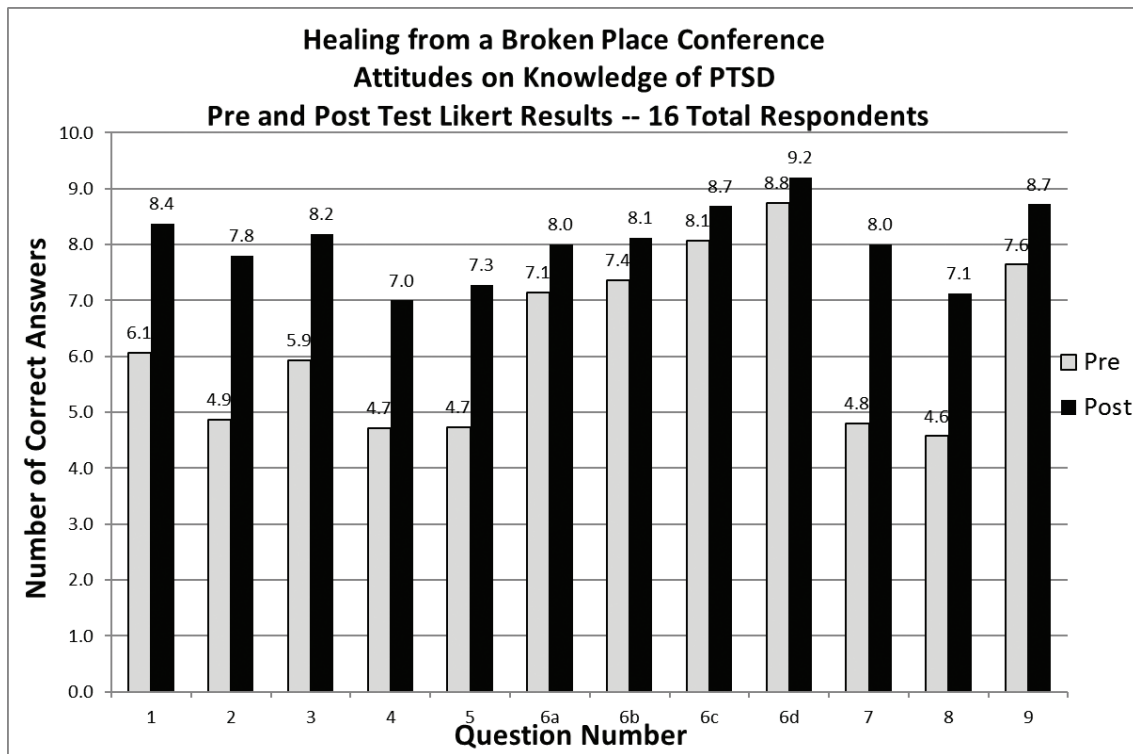


Figure 1. Subjective knowledge of trauma/PTSD and self-confidence in participating in interdisciplinary collaboration.

attended the event. Conference attendees were eligible for continuing pastoral educational credits through the American Association of Pastoral Counselors. Members of the research team informed conference attendees of the voluntary study onsite during conference check-in. All registered conference attendees

aged 18 years or older were eligible to participate in the study.

Study Instruments

The research team designed the pre- and posttest instruments. We solicited information in three

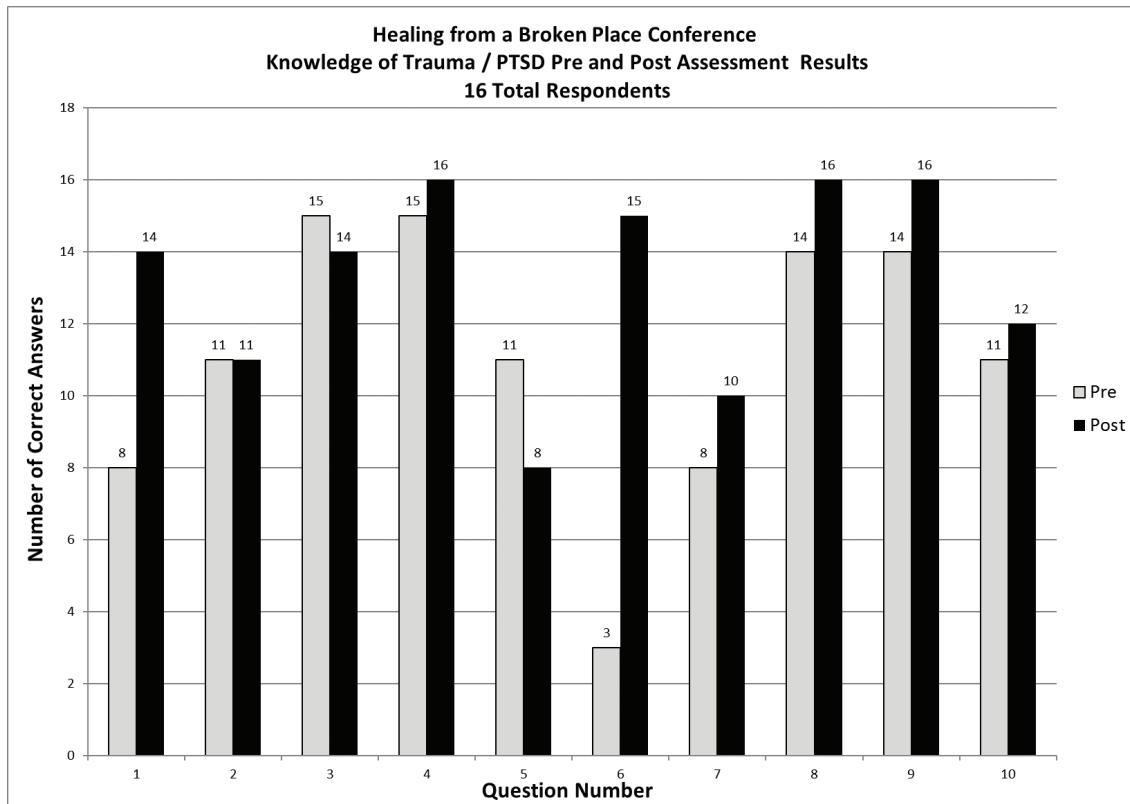


Figure 2. Objective knowledge of trauma/PTSD.

sections: (1) demographic information (see Table 1); (2) *subjective* knowledge of trauma and PTSD and confidence with participating in interdisciplinary collaboration between faith and health providers (using nine questions in Likert-type scale format) (see Figure 3); and (3) *objective* knowledge on trauma and PTSD (using nine multiple choice questions with five foils) (see Figure 4). *Subjective* knowledge of trauma and PTSD was measured by self-reported comfort in identifying and managing PTSD symptoms. Self-confidence with participating in interdisciplinary collaboration was measured by self-reported comfort with locating community or religious support networks and working with faith or health providers.

Data Collection

We assessed PTSD knowledge and attitudes to measure the degree to which participants assimilated content offered during the HFBP conference. We also measured confidence in merging religion or spirituality and medical science in the assessment and treatment of trauma survivors. Last, we measured the degree of comfort in

collaborating with faith leaders and/or health providers. The preconference instrument was administered at registration, and the post-conference instrument was administered just as the conference concluded, at the conference site. In addition, members of the research team observed group discussions and breakout sessions to assess, in more depth, the most pressing concerns of attendees and emerging ideas on how to address these concerns. (However, that qualitative data was not included in this article.) The research team requested that one person from each breakout group note the content of the round table discussions and nonverbal expressions, in order to develop a holistic understanding of the interactions.²⁷ The participants were consented and given identifiers according to protocol approved by the Michigan State University Institutional Review Board.

RESULTS

Quantitative Findings

Of the 66 conference attendees, 16 individuals (24.2%) completed both the pre- and post-conference instruments; they represent the study sample. As shown in

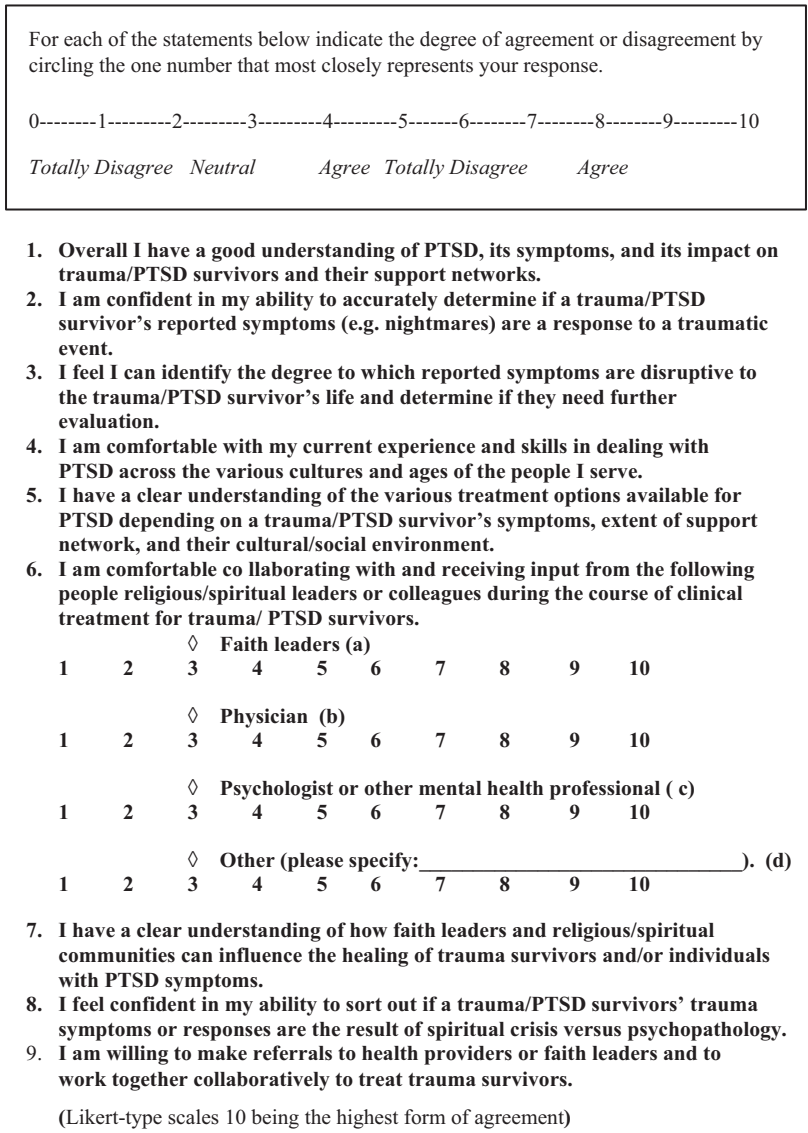


Figure 3. Subjective knowledge about trauma/PTSD and comfort participating in interdisciplinary collaborations between faith and health professionals.

Table 1, there were 10 females and 6 males; most (13) were over the age of 46 years, and 7 were over the age of 61 years. All participants had completed high school, and 12 had a master's or doctorate degree. Most participants were Christian (14). There was a mix of occupations between health providers (5) and faith, religious, or spiritual leaders (7) – in addition to these two occupation choices participants were provided the following three options: veteran or active military, student, and other. The remaining respondents (4) indicated 'other'. Most participants (9) had some direct contact with PTSD.

Two indicated they were diagnosed with PTSD, six of the study participants *treated* individuals with PTSD, and one served as *caregiver* to someone with PTSD. Five participants indicated they had not been significantly exposed to PTSD.

Analysis of the pre- and post-conference instruments revealed difference in PTSD attitudes resulting from conference attendance. We used a paired two-sample *t*-test to test for difference between pre- and post-attendance (see Table 2 and Fig. 4, for the corresponding questions). There was a significant difference for Question 6a in the

Table 3. Curriculum design and phases.

| Phases | Introductory | Thematic | Integrative kernel |
|---------|---|--|--|
| Purpose | Provide basic and introductory knowledge of PTSD: <ul style="list-style-type: none"> o History o DSM criteria o Epidemiology o Neurobiology o Neuroanatomy | Discuss common and important congregational and clinical difficulties that faith and health professionals may encounter (i.e., sexual abuse by clergy) as well as the wider base of knowledge, skills, attitudes, behaviors required to support survivors of extreme trauma. Explore support of trauma survivors in various relational settings: <ul style="list-style-type: none"> o Clergy to health provider o Health provider to clergy o Health provider to patient o Clergy to parishioner o Clergy to congregation | Reinforce the key concepts of traumatology, as well as the historical context of PTSD. |
| Format | Interactive Power Point presentation by PTSD expert: Frank Ochberg, MD | Live testimonies of those dealing with PTSD from the group Michigan Victim Alliance, followed by panel discussants of trauma survivors, faith, and medical and mental health professionals. | Seven subject-specific breakout groups: <ol style="list-style-type: none"> (1) Pastoral care and compassion fatigue (2) Spousal support for traumatized loved ones (3) Caring for child abuse survivors (4) Religious themes in therapy (5) Using humor in ministerial and medical roles (6) Exploring interfaith approaches to healing (7) Trauma and healing in the urban context |

pretest ($M = 7.38$, $SD = 2.36$) and post-conference ($M = 8.08$, $SD = 1.12$) responses; $t(12) = 1.39$, $p = 0.05$. There was a significant difference for Question 6b in pre-conference ($M = 7.31$, $SD = 1.97$) and post-conference ($M = 8.23$, $SD = 1.42$) responses; $t(12) = 1.95$, $p = 0.05$. There was a significant difference for Question 6d in pretest ($M = 8.75$, $SD = 1.89$) and post-conference ($M = 9.00$, $SD = 0.82$) responses; $t(3) = 0.40$, $p = 0.05$. There was a significant difference for Question 9 in preconference ($M = 7.92$, $SD = 2.29$) and post-conference ($M = 8.77$, $SD = 1.17$) responses; $t(12) = 1.34$, $p = 0.05$.

As shown in Fig. 1, participants' self-confidence for engaging in interdisciplinary collaborations between faith leaders and/or health providers increased (see Fig. 4, for the corresponding questions). Participants reported that they were more willing to make referrals to health providers or faith leaders and to engage in interdisciplinary collaborations to treat trauma survivors. All answers to questions assessing self-confidence

in participating in interdisciplinary collaborations increased.

Participants reported an improvement in their *subjective* knowledge of trauma and PTSD and their self-confidence with participating in interdisciplinary collaboration (see Fig. 4, for the corresponding questions). Participants improved their *subjective* knowledge as suggested by indicating that they feel better equipped to understand the symptoms and risk factors of PTSD and provide care for trauma survivors. All questions assessing *subjective* knowledge showed improvements: 1 (pretest 6.1 and posttest 8.4), 2 (pretest 4.9 and posttest 7.8), 3 (pretest 5.9 and posttest 8.2), 4 (pretest 4.7 and posttest 7.0), 5 (pretest 4.7 and posttest 7.3), 7 (pretest 4.8 and posttest 8.0), and 8 (pretest 4.6 and posttest 7.1).

Objective knowledge of PTSD symptoms also increased (see Fig. 2 and Fig. 4 for the corresponding questions). Awareness that PTSD symptoms must be present for at least 1 month for a possible diagnosis showed a sizable

1. **1. For a diagnosis of PTSD to be made, symptoms associated with it must be present for at least:**
 - a. one week
 - b. two weeks
 - *c. one month**
 - d. two months
 2. **2. Survivor guilt refers to:**
 - a. the concentration and insomnia symptoms of PTSD
 - *b. a condition outside of the PTSD diagnosis, often seen in combat veterans**
 - c. guilt for killing the enemy in war
 - d. numbing and avoidance after trauma
 3. **3. Whenever a diagnosis of PTSD has been made caregivers, family, friends, and others should pay special attention to indications of:**
 - a. substance abuse
 - b. additional anxiety disorder
 - c. depression
 - *d. all of the above**
 3. **4. PTSD includes:**
 - a. feeling numb
 - b. being overly anxious
 - c. having unwanted memories of trauma
 - *d. all of the above**
 5. **5. All of the following are signs of hyper-arousal found in PTSD, except:**
 - *a. hallucinations and delusions**
 - b. frequently on the lookout for threats
 - c. difficulty concentrating
 - d. trouble falling asleep
 4. **6. When exposed to similar traumatic events:**
 - *a. PTSD appears twice as frequently among women**
 - b. PTSD appears twice as frequently among men
 - c. PTSD appears equally in men and women
 - d. PTSD appears 5% more often in women
 7. **7. People with mental conditions, including PTSD, are most likely to first seek help from:**
 - a. specialists in psychiatry and psychology
 - *b. general practitioners or clergy**
 - c. teachers
 - d. none of the above
 7. **7. Which represents the most important first step in the treatment of PTSD?**
 - a. medication
 - b. hospitalization
 - *c. establishing a sense of safety and separation from the trauma**
 - d. brain imaging
 8. **8. Which of the following represents one of the most useful treatments of PTSD?**
 - a. hypnosis
 - b. focusing on childhood relationship to parents
 - c. electroconvulsive therapy
 - *d. reinterpreting a traumatic event by adjusting one's thoughts, attitudes, and belief systems**
 9. **9. Identify the true statement:**
 - a. only people having experienced a traumatic event will develop PTSD
 - b. all people having experienced and or witnessed a traumatic event will develop PTSD
 - *c. having experienced and or witnessed a traumatic event does not guarantee that a person will have PTSD**
 - d. all are false
- *represents correct answer

Figure 4. Objective knowledge of trauma/PTSD (administered pre- and posttest).

improvement. Awareness that PTSD appears twice as frequently in women when compared to men when they are exposed to similar trauma showed a larger increase. Interestingly, the five participants who reported that

they had not been significantly exposed to PTSD all answered this gender-based question (Question 6) incorrectly in the preconference instrument; however, *all five of them answered it correctly* on the post-conference

instrument. For the participants with little exposure to PTSD, similar increases appeared for two additional questions (Questions 1 and 10). For each of those questions, only one participant with little exposure to PTSD answered correctly in the preconference instrument; however, *all* of them answered those two questions correctly in the post-conference instrument.

DISCUSSION AND APPLICATIONS TO PRACTICE

To our knowledge this is the first study that incorporates interventional and experimental methods to measure the potential of an interdisciplinary training model to enhance the formation and efficacy of collaborations between faith leaders and health providers in the assessment and treatment of trauma survivors. Our intent was to assess and improve knowledge and attitudes. The results support our hypothesis that the HFBP conference format and curriculum offers a pragmatic collaborative care training model for faith leaders and health providers to increase comfort level for interdisciplinary collaborations between those two groups and increase their knowledge of trauma that can precipitate PTSD.

Participants showed an increase in knowledge about PTSD. There was an increase in *subjective* level of knowledge. Participants indicated that they gained confidence in understanding religious and spiritual aspects of trauma. On the whole, participants in our sample had a fairly high preconference level of knowledge of PTSD and confidence in developing interdisciplinary collaborations between faith leaders and health providers. Participants reported that they were willing to make referrals to health providers or faith leaders and were willing to collaborate to treat trauma survivors. This data suggests that participants increased their confidence in developing interdisciplinary collaborations between faith leaders and health providers. Those participants with a lower exposure to trauma and interdisciplinary collaborations between faith and medicine demonstrated larger pre- and posttest gains. Therefore, individuals with low knowledge of PTSD and low comfort with interdisciplinary collaborations could experience even higher differences as a result of attending a similar conference in the future.

LIMITATIONS

There are several limitations in this study, and we highlight three important considerations. First, the study was limited by selection bias. The small numbers of participants were already inclined to consider collaborations and PTSD, given the focus of the conference they decided

to attend absent knowledge of the study. The absence of control groups representative of both faith leaders and health providers should be considered in evaluating replicability. The size and nature of our sample restricted our ability to utilize statistical modeling to evaluate specific outcomes by holding constant potential confounding characteristics. In addition, the small number of participants included in this study limits any overall conclusions that can be drawn from the effectiveness of the educational interventions involved in this study. Second, we are not clear to what degree the participants *applied* their improvement in attitude and increase in knowledge about PTSD and whether application translated into more effective care, for faith leaders and health providers. Third, we do not know if participants actually increased collaborations between faith leaders and health providers when supporting trauma survivors. Addressing these limitations would require a specific post-conference follow-up, as well as longitudinal assessments of larger, more representative samples to measure efficacy in practice. As stated, the potential for selection bias exists because only attendees of this conference were included in the sample; thus it may be biased toward those with an interest in faith and medicine collaborations.

CONCLUSION AND FUTURE DIRECTIONS

Notwithstanding these limitations, this study offers insights for educators, researchers, faith leaders, and health providers who are interested in studying and/or participating in collaborative medicine, specifically between faith leaders and mental health professionals, to better support trauma survivors. Participants increased their perceived and actual knowledge about PTSD, reported that they were more willing to make referrals to health providers or faith leaders, and were more comfortable in collaborating with each other to treat trauma survivors.

Insights from the HFBP conference could better facilitate health education interventions for psychological trauma, while advancing supplementary and complementary collaborations between faith leaders and health providers. Future investigators should consider using larger, representative numbers in similar educational interventions. A study with a larger sample size, and consequently greater power to measure differences across the sample, would enable researchers to investigate statistically significant outcomes for participants. A key consideration for future efforts is to identify and recruit a larger sample of religious and health providers with little or no prior knowledge of

PTSD and minimal exposure to collaborations between religious and health communities. Lastly, future longitudinal follow-up research is needed to determine to what degree the participants *applied* their improvement in knowledge about PTSD and increased in willingness to collaborate with faith leaders and/or health providers to support trauma survivors.

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