

A Day in the Life of the Study Visit

BY MEGAN BISHOP AND ASHLING SMITH, CLINICAL RESEARCH COORDINATORS



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BECOME A HERO!

Behind the launch of every new medication and treatment that becomes available to prolong or improve our lives are people like you who gave the gift of their time to participate in a clinical trial. Clinical trials are an essential step in proving the efficacy and safety of any medicine or treatment approved for widespread use in the United States. Arthritis and Rheumatism Associates is pleased to be part of the never-ending search for better therapies through The Center for Rheumatology and Bone Research (CRBR). We began participating in clinical trials in 1982 and have since helped evaluate new drugs for a wide range of rheumatological conditions.

Your ARA physician may invite you to participate in a clinical trial to potentially give you access to a drug that he or she thinks may benefit you. Naturally, many questions might run through your mind:

- *Is the drug being tested safe?*
- *Will it make me feel better?*
- *Could it have side effects or make me feel worse?*
- *How does a clinical trial work?*
- *Do I qualify to participate in a clinical trial?*

If you meet the predetermined criteria and wish to learn more, you will be seen in a treatment room just like any other in the practice except it will be located in the CRBR. You will be greeted by a clinical research coordinator who will welcome you to our study department. The coordinator will explain exactly how the study is being

continued on inside back page

Vaccinations in Rheumatic Disease

BY JEFFREY A. POTTER, MD, FACP

Patients with rheumatic disease experience an increased risk of infection, due to both their underlying disease processes and the immunosuppressive medications needed to treat their illnesses. There are several vaccinations that can help to reduce the risk of infection in patients with autoimmune diseases. This article focuses on the benefits of vaccinations for patients with rheumatic disease generally, rather than focusing on the specific characteristics of individual vaccines, which will be discussed separately.

Vaccinations for conditions such as herpes zoster, influenza, and pneumonia are widely available and recommended for patients with rheumatic diseases such as lupus, rheumatoid arthritis, psoriatic arthritis, inflammatory muscle disease (dermato-



If you have one rheumatologic condition – does that mean you will have another?

BY GRACE AHN, MD, FACP, FACR

The short answer to this question is “not always, but possibly.” For example, a 79-year-old female comes into the clinic complaining of knee pain, and she has a previous diagnosis of rheumatoid arthritis. Her rheumatoid arthritis has affected her hands and feet mostly, and she hasn’t had knee pain before. There is a possibility that her knee pain is still related to rheumatoid arthritis, but further evaluation reveals degenerative osteoarthritis in her knees. Osteoarthritis is a degenerative joint disease. As people age, with wear and tear, they can develop this type of arthritis. It is common to see osteoarthritis in a 79-year-old even though she never had similar symptoms before. If we look closer, we may even see osteoarthritis bony changes in her hands.

Another example is a 62-year-old male with acute toe and finger swelling. He is a heavy drinker, has had kidney problems before, and has been told by his primary care physician that he may have gout. Evaluation reveals that he not only has gout, but he also has evidence of rheumatoid arthritis. X-rays show changes for both gout and rheumatoid arthritis. This particular patient may have had gout for a long time and ignored his symptoms, and later developed

rheumatoid arthritis, which got progressively worse. Osteoarthritis and gout can often coexist with other inflammatory rheumatologic conditions.

The majority of people diagnosed with an inflammatory rheumatologic condition, such as rheumatoid arthritis or systemic lupus erythematosus only have that particular disease and its manifestations. However, certain rheumatologic diseases can coexist and cause atypical symptoms. These are inflammatory diseases and not the degenerative arthritis conditions mentioned previously. We call these cases overlap syndrome. As many as 25% of connective tissue disease patients can present with an overlap syndrome, with features of lupus, systemic sclerosis, polymyositis, dermatomyositis, rheumatoid arthritis, or Sjögren’s syndrome. The overlap can develop at the time of the initial diagnosis, or later in the course of the disease.

For example, a 44-year-old patient with longstanding lupus with skin and joint disease may start developing dryness in her eyes and mouth that progressively worsens. With further evaluation by her rheumatologist, she is diagnosed with secondary Sjögren’s syndrome. Another example is a 60-year-old with rheu-

matoid arthritis who develops gradual muscle weakness and later has a diagnosis of polymyositis. There are instances where some patients carry a diagnosis of undifferentiated connective tissue disease, in which a person can have features of different diseases but does not meet diagnostic criteria for one particular disease. Some of these patients later develop more specific symptoms and define themselves into a particular, more specific disease category.

Sometimes, rheumatologic and non-rheumatologic autoimmune diseases coexist. A 32-year-old female who has Hashimoto’s thyroiditis later develops joint symptoms suggestive of new rheumatoid arthritis. In this case, a thyroid autoimmune disease happened with rheumatologic autoimmune disease. We also see patients with psoriasis develop psoriatic arthritis, or patients with inflammatory bowel disease, such as ulcerative colitis or Crohn’s disease, develop inflammatory arthritis.

Rheumatologists frequently monitor for various manifestations of diseases that they are treating, and it is important to follow their recommendations. If you develop unusual or new types of symptoms that you have not had before, it is important to discuss them with your doctor.

Dermatomyositis and Polymyositis

BY SHARI B. DIAMOND, MD, FACP, FACR



Dermatomyositis and Polymyositis are multisystem autoimmune disorders. They primarily affect the muscles but also can cause skin rashes, lung inflammation and arthritis pain.

SYMPTOMS

Muscle weakness is the most common symptom of both diseases. The muscles most typically involved are the deltoids in the shoulders/upper arms and the hip flexors. Weakness of the neck flexors is also common. Distal muscle weakness of the arms and legs tends to be mild, if present at all. The muscle weakness usually develops slowly and gradually worsens over a period of several months. Patients often notice increasing difficulty when climbing stairs, getting up from a chair, carrying heavy groceries or lifting. Sometimes, muscle and/or joint pain and swelling are present as well. However, muscle weakness, rather than pain, is typically the primary problem. As these disorders progress, patients may start to notice muscle atrophy. Internal organ muscles, such as the muscles of the esophagus and heart, may be affected.

In addition to muscular symptoms, Dermatomyositis (not Polymyositis) is associated with several characteristic rashes. Gottron's papules are reddish/purple scaly patches on the knuckles of the fingers. Heliotrope eruption refers to a reddish/purple rash on the eyelids. Other typical rashes include sun-sensitive rashes on the neck and face as well as a scaly rash on the scalp that resembles psoriasis.

DIAGNOSTICS

When the blood is tested, Dermatomyositis and Polymyositis usually result in abnormal lab findings, including elevated levels of muscle enzymes, inflammatory markers and autoantibodies. If Myositis is then suspected, an MRI and electromyography will show characteristic abnormalities of inflamed muscles. A muscle biopsy is the gold standard for confirming the diagnosis.

TREATMENTS

Dermatomyositis and Polymyositis typically are treated with glucocorticoids (steroid medication such as prednisone) with glucocorticoid-sparing, immunomodulating medications. These diseases and the medications used to treat them require close, careful monitoring due to concerns about significant potential side effects. At Arthritis and Rheumatism Associates, we have many years of experience in treating these complex diseases and managing appropriate medications. We understand the different monitoring requirements for the diseases' effects and the medication toxicities.



myositis, polymyositis), and inflammatory blood vessel disorders, or vasculitis. Rheumatic diseases, in and of themselves, carry up to a two-fold increase in the risk of infections as compared to the general population. Patients living with these illnesses also have an increased risk of hospitalization and death due to infection. If the disease is poorly controlled, the patient is at even greater risk. The recent development of newer, targeted "biologic" therapies has allowed rheumatologists to better control disease activity, resulting in fewer infections overall. And while these newer, targeted therapies have reduced the need to use profound immunosuppressive drugs even the new biologic drugs carry some risk of infection.

Vaccinations for common infections such as influenza, herpes zoster and pneumonia can help to lessen the impact of infections and reduce the overall burden of treatment on both patients and health care systems. Determining an appropriate vaccination depends upon not only the individual patient being cared for, but also the specific medications being used to treat that patient's rheumatic disease. Certain vaccinations cannot be given during drug therapy, as they may cause an overwhelming infection in a patient whose immune system is being intentionally suppressed by drug therapy. Timing of vaccinations to precede the start of therapy is critical in this patient population. Also, in certain circumstances, medications used for treatment of rheumatic disorders can impact the effectiveness of a vaccine, limiting its utility. Another commonly used medication, methotrexate, can interfere with development of the necessary antibodies that help to prevent infection following vaccination. A less commonly used but very effective medication for rheumatic disease, rituximab, is designed to limit antibody production and will significantly decrease the effectiveness of vaccines administered to patients

Consulting with your rheumatologist and being aware of your status for common vaccines including zoster, pneumococcal and influenza will help your doctor make informed decisions about which vaccines are appropriate for you and the timing of administration. Given the continuing development of immunosuppressive therapies for rheumatic diseases, our knowledge of the perfect combinations of vaccinations in individual patients remains incomplete. In general, vaccinations help prevent infection in patients with autoimmune disorders and should be routinely provided whenever possible. While vaccinations are commonly available through your primary care provider or local pharmacy, safe and timely administration should be discussed with your rheumatologist.

RHEUMINATION:

Back Pain – Is It Mechanical Or A Sign Of AS?

BY DAVID BORENSTEIN MD, MACP, MACR

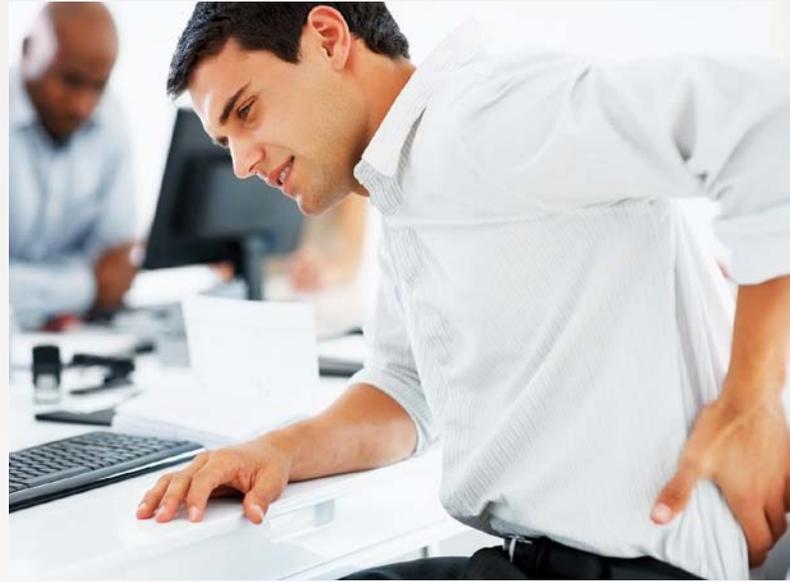
Back pain is a symptom associated with more than 60 different illnesses. It is second only to the common cold, which is the most common affliction of mankind. More than 80% of the world's population has an episode of back pain during their lives.

Trying to organize the different types of back pain into categories can be quite difficult. A commonly used system tries to separate back pain caused by mechanical disorders from those associated with systemic inflammation, like ankylosing spondylitis (AS), for example.

Mechanical disorders are associated with overuse or with the aging process. Examples of mechanical disorders include muscle sprains, herniation of spinal intervertebral discs, osteoarthritis of the lumbar spine facet joints, and lumbar spinal stenosis. These disorders can affect individuals who are young, in mid-life, or elderly. In general, these mechanical disorders are made worse with activity, and are made better with rest. Specific positions tend to make the symptoms of mechanical back pain better or worse. For example, individuals with spinal stenosis prefer to take positions that decrease pressure on spinal nerves, like sitting or walking in the grocery store leaning on a shopping cart. Many mechanical problems will improve gradually over time. Non-pharmacological (physical therapy) and pharmacologic therapies (nonsteroidal anti-inflammatory drugs) are effective in relieving symptoms of mechanical back pain.

Ankylosing Spondylitis, an inflammatory spine disorder, has symptoms and signs that are different from those associated with mechanical low back pain. Complaints associated with AS include: (1) prolonged morning stiffness of the spine lasting for hours, (2) increasing spine stiffness associated with sitting for even short periods of time, (3) back pain that improves with exercise, (4) severe eye inflammation (iritis), (5) fatigue, (6) mild weight loss, and (7) low-grade fever. AS also starts in individuals younger than 45 years of age.

The usual ankylosing spondylitis patient has a moderate degree of intermittent aching pain localized to the low back to start. The muscles on the side of the spine can contribute to pain because of spasms. The low back becomes more difficult to move. Breathing may be affected when moving one's ribs becomes painful. In a majority of patients, the initial symptoms are low back



pain and stiffness. Another common location for inflammation is the Achilles tendon and plantar fascia on the bottom of the foot. The diagnosis of AS is based upon the characteristic findings in the history, physical examination, radiographic abnormalities, and laboratory test results.

While other specialties of medicine are capable of making diagnoses of mechanical low back pain, rheumatologists have the knowledge and expertise to differentiate inflammatory back pain patients from those with the more common mechanical disorders. Identifying AS patients early in the course of their illness is very important. A wide variety of drug therapies are available for the treatment of AS that are capable of slowing the progression of the disease.

The rheumatologists at ARA are expert at the diagnosis and treatment of mechanical and inflammatory back disease. They have expertise in non-drug (including physical) therapy, and drug therapy, including the tumor necrosis factor inhibitors that are effective treatment for AS.

What is Reactive Arthritis?

BY NICOLE THOMAS, MD, FACR

Mr. Arthur Itis is a previously healthy 30-year-old gentleman. In early August, he had a bout of food poisoning from the bacteria Salmonella. Three weeks later he noticed his right heel was painful and swollen, and he had low back pain and stiffness upon arising in the morning. Later that week, his right knee and ankle and several of his fingers and toes became painful and swollen. What could this be?

Mr. Arthur Itis has reactive arthritis. Reactive arthritis occurs when an infection, such as Salmonella, alters a person's immune system, leading to autoimmune disease. The immune system is comprised of blood cells

and tissues within our bodies that usually serve to fight off bacteria and viruses. Autoimmune disease occurs when a person's immune system has become dysfunctional and attacks healthy body parts. In reactive arthritis, the altered immune system incorrectly attacks healthy joints and tendons (the fibrous connection between the muscle and bone) leading to pain and swelling.

Reactive arthritis is not to be confused with septic arthritis, which is when a bacterium has infected a person's joints. That is to say that Mr. Arthur Itis doesn't have Salmonella in his joints causing the pain and swelling, but, rather, the Salmonella infection from

weeks ago triggered his immune system to mistakenly attack his joints.

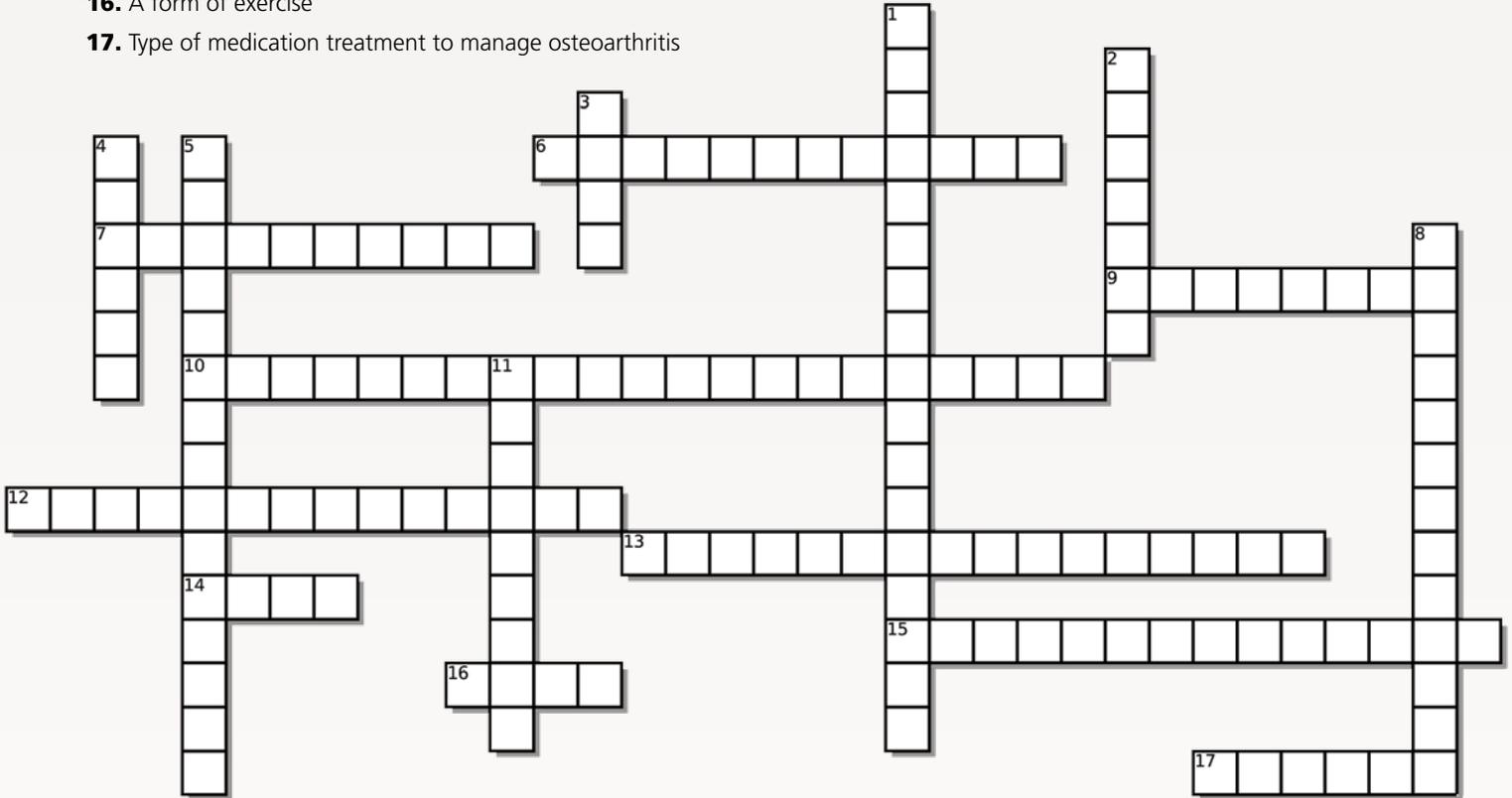
Different types of infections can trigger a reactive arthritis but the most common infections are genitourinary infections (Chlamydia) or bowel infections (Campylobacter, Salmonella, Shigella and Yersinia). Joint pain and swelling typically occur 1-4 weeks after the infection.

Reactive arthritis occurs most commonly in people between ages 20 and 50. People who carry a gene called HLA B 27 are more likely to get reactive arthritis, but reactive arthritis can happen in those

FUN RHEUM:

Across

6. Helps to reduce the risks of infections in patients with autoimmune diseases
7. Type of arthritis that commonly affects hands and feet mostly
9. Provides massive benefits to our bodies and treating medical conditions
10. An inflammatory spine disorder
12. The most common symptom of dermatomyositis and polymyositis
13. Division of ARA practice
14. Can coexist with other rheumatological conditions
15. A degenerative form of arthritis
16. A form of exercise
17. Type of medication treatment to manage osteoarthritis



Down

1. First line treatment for reactive arthritis
2. The number of minutes for exercise
3. Pain in this area is associated with over 60 conditions
4. Individuals that administer infusion medications
5. Physicians who are experts at differentiating musculoskeletal conditions
8. An autoimmune disorder that can cause skin rashes
11. Patients with rheumatic diseases have an increased risk of death if they acquire this

without the gene as well.

The most common sites affected by reactive arthritis are the heels, toes, fingers, low back, knees and ankles. A rash on the palms and soles or genitals, painful urination, or eye inflammation also can occur in some cases.

Anti-inflammatory medications such as Naproxen or Ibuprofen are considered first-line medications. Most people with reactive arthritis have little to no disease activity after 6-12 months, but 15 to 20 percent may experience persistent arthritis. Steroid medications and immunosuppressant medications may be required in these cases.

DID YOU KNOW?

ARA's infusion department is now called **Arise Infusion Therapy Services**.

arise infusion
THERAPY SERVICES

RHEUMYTHOLOGY:

The Role of Biologic Medications in Auto-Immune Conditions

BY ASHLEY BEALL, MD, FACR

Autoimmune diseases affect millions of Americans and can lead to significant interruptions in daily life as a consequence of pain and discomfort. For some patients, they can even lead to long-term disability. Medications to treat autoimmune diseases, called disease-modifying antirheumatic drugs, or "DMARDs," have been available for decades. In the 1990s a new class of medications called "biologics" was developed, ushering in a new era of better treatment options for patients whose autoimmune conditions could not be controlled by DMARDs. Though not all patients with autoimmune syndromes need them, biologic drugs can be extraordinarily effective when used in addition to, or as a substitute for, DMARDs. Since the first drugs in this class were developed, millions of patients have benefited from them and many more biologics are currently in development. All of these powerful medications have the potential for side effects, and it is important for patients to weigh and discuss the risks and benefits of using them with their physician.

The core treatment goals for patients with an autoimmune disease are to achieve the lowest possible level of disease activity, minimize joint and organ damage, and enhance physical function and quality of life. As the use of biologics has increased, rheumatology infusion nurses have become vital for safe administration and care. Nurses undergo specialized training in how to safely deliver intravenous biologics in the infusion suite and in how to teach patients about proper administration of subcutaneous biologics at home. Nurses also educate patients about their disease process and support patients in their journey to live sustainably with an autoimmune disease.

A Patient's Experience

BY ALYSON PRINCE, RN, B.S.N

A patient with rheumatoid arthritis described her experience with pain to the nurses in the clinic: "Everything you do, the way you used to do it, you never thought about it. Now, when you are doing it with rheumatoid arthritis, it hurts. When you stand on your feet, it hurts. I used to be able to do cartwheels." Nurses administering biologics have the unique opportunity to become personally acquainted with and supportive of each patient's clinical journey toward wellness. Nurses can provide holistic advice on exercise and dietary choices to maintain joint



function and achieve and/or maintain a healthy weight so that patients receiving biologic drug therapy can derive maximum benefit from their medical care.

"Biologic therapy gave me my life back!" Nurses and physicians hear this bold proclamation at least once a day as improvements in symptoms lead to dramatically improved morale and a positive outlook. Nurses and doctors witness patients taking biologic drugs regain an increased sense of hope about life and living with an autoimmune disease.

Educating patients about the side effects of biologic therapy is an integral part of the treatment plan. Physicians and nurses are on the front line to both counsel and educate patients about management of their disease process. Patients receiving biologic therapy know that the healthcare team is invested in ensuring their overall safety. They have their blood drawn routinely to check for decreased disease activity as well as to ensure there are no side effects that compromise the health of other organ systems. Patients in the infusion suite have the opportunity to engage their nurse and fellow infusion patients in discussions to become educated and share information and coping strategies. Patients are empowered by this collective knowledge and are more likely to advocate for the best treatment plan possible.

It is important for patients to ask themselves the following questions: "What does healthy look like to me?" "What does 'feeling good' mean to me?" "How am I going to reach my health goals?" With those questions answered honestly, patients can work with their rheumatologists to create the ideal treatment plan. Biologic therapies are one of the many treatment options available for autoimmune disease, but they are special in their specific targeted mechanism. Sustained health is the number one treatment goal and biologics are leading the way in making this goal a reality.

Practice News

NEW CLINICAL PROFESSORS

- Dr. Evan Siegel, Dr. Guada Respicio and Dr. Daniel El-Bogdadi are now Clinical Assistant Professors of Medicine at Georgetown University School of Medicine. Each of these physicians has Georgetown medical students participating in clinical time at our Shady Grove location.

NEW BUSINESS CENTER MANAGER

► As we wish Ceclia Pettit a happy retirement, ARA welcomes our new manager, Haimanot Worku. Ms. Worku has been working in the business center at ARA for 10 years.

MEDICAL HONOREE FOR LUPUS WALK

- Congratulations to Dr. Jeffrey Potter, who has been named medical honoree for the Lupus Foundation's walk. Please join ARA's team, Purple Potters, by registering online - dclupuswalk17.kintera.org



Baked Tilapia Recipe with Pecan Rosemary Topping

From the kitchen of Cookin Canuck. www.cookincanuck.com

Prep Time: 15 min. | Cook Time: 18 min. | Total Time: 35 min.

Serves 4

INGREDIENTS

1/3 cup chopped raw pecans

1/3 cup panko breadcrumbs

2 tsp chopped fresh rosemary

1/2 tsp (packed) brown sugar

1/8 tsp salt

1 pinch cayenne pepper

1 1/2 tsp olive oil

1 egg white

4 (4 oz. each) tilapia fillets



INSTRUCTIONS

1. Preheat oven to 350 degrees F.
2. In a small baking dish, stir together pecans, breadcrumbs, brown sugar, salt and cayenne pepper. Add the olive oil and toss to coat the pecan mixture.
3. Bake until the pecan mixture is light golden brown, 7 to 8 minutes.
4. Increase the heat to 400 degrees F. Coat a large glass baking dish with cooking spray.
5. In a shallow dish, whisk the egg white. Working with one fillet of tilapia at a time, dip the fish in the egg white and then the pecan mixture, lightly coating each side. Place the fillets in the prepared baking dish.
6. Press the remaining pecan mixture into the top of the tilapia fillets.
7. Bake until the tilapia is just cooked through, about 10 minutes. Serve.

NUTRITIONAL INFORMATION:

Serving Size 1 baked tilapia fillet | Calories 206.5

Total Fat 10.1g | Saturated Fat 1.3g | Cholesterol 55mg

Sodium 155.4mg | Total Carbohydrates 5.3g | Fiber 1.1g

Sugars 1.2g | Protein 24.8g | WW (Old Points) 5

WW (Points+) 5

continued from front cover...

A Day in the Life of the Study Visit

BY MEGAN BISHOP AND ASHLING SMITH, CLINICAL RESEARCH COORDINATORS

performed and what to expect during your study visits. Along with a physician, the study coordinator will answer any questions you may have. You will be given an Informed Consent document to read that explains your duties as a study participant and advises you of all of the potential benefits and side effects of the medications you might be given. The study coordinator and an ARA physician will help you decide whether or not to participate. If you elect to participate, the study coordinator will ask you to sign the Informed Consent

If you enroll in the study, you may be asked periodically to complete some clinical questionnaires to assess how you feel and determine how you are progressing on the investigational medicine. One difference you may notice immediately is how meticulously the research team takes notes, records measurements and explains what is happening. You likely will be relieved to learn that your regular ARA

physician is an important part of the research team and remains involved in your care. You also may be happy to learn that in most cases the study covers the costs of the medication, your office visits and lab work.

Should you decide to participate, you will not just be helping yourself. You will be contributing to the development of therapies that have the potential to help many others in the future. A study is a wonderful opportunity to get involved, for your own health and for the progress of medicine. Currently, we are enrolling clinical research trials for patients with osteoarthritis of the knee and hip, rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis and undifferentiated spondyloarthropathies, and Sjögren's syndrome. Please contact The Center for Rheumatology and Bone Research at (301) 942-6610 to determine whether you may be eligible to participate in one of our clinical trials. Be a hero!

RHEUMORS

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RHEUMORS

PRACTICE NEWSLETTER

Spring 2017

A publication brought to you by:
Arthritis & Rheumatism Associates, P.C.

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Getting the Most Out of Your Exercise Program

BY MATTHEW MORICI, PT, DPT

We have all learned about the massive benefits that exercise can have on our bodies and our health. Few other forms of treatment have been better researched or proven more effective in improving such a wide variety of different conditions than exercise. The list of conditions includes heart disease, diabetes, cancer, circulation issues, back pain, neck pain, shoulder and other types of musculoskeletal pain, pulmonary disorders and so on.

Physical Therapists are often asked by their patients for tips on how they can become more active and safely participate in exercise. Because people are all different and have unique physical challenges and circumstances, there is no one right answer. There can be a lot of factors at play when one wishes to become more physically active. However, there is almost always a way to safely increase one's physical activity. A key concept to follow is "Graded Exposure" a method of trying a novel movement or activity in a controlled and comfortable way for a short duration and then progressively increasing one's activity incrementally. This technique allows the individual to adopt a healthier lifestyle without causing any unnecessary stress and possibly injury to the body.

Graded Exposure has been a proven method of increasing activity tolerance in patients with chronic pain but it can be applied by anyone trying to increase their physical fitness. One should always first obtain medical clearance from a physician before undertaking any new exercise regimen. Once you are cleared to exercise, the next step is to select a mode of exercise of your choice such



as walking, cycling, yoga, swimming or almost any activity you want. A good way to gauge your level of exertion is through the Rating of Perceived Exertion scale. On this scale, a rating of 1 would be your body at rest and 10 would be so intense you feel that you might pass out. One's exertion level should stay in the range of 4 to 5 out of 10, indicating a moderate intensity of exercise. Remember: this scale is going to be different for everyone and your rating of 4 might not be the same as somebody else's.

The key to exposing yourself to a new activity is to do so in a comfortable manner and to do so in short intervals. A good amount of time to exercise in the beginning is about 10-15 minutes. The intensity of exercise should be enough to get your heart rate above resting. A good indicator of the right heart rate is that your breathing should allow you to talk out loud but not sing out loud. The ultimate goal for exercise is to do so in a pain free and comfortable manner while also placing stress on the boundaries of your tolerance. After performing your initial workout, assess your overall feeling of comfort. If you are noticing any negative responses, you probably exerted yourself more than you were able to tolerate. Next time, do a little less and then gradually increase incrementally by no more than 5 minutes at a time. This might be difficult for you initially but just remember to progress slowly. Exercise should be invigorating and enjoyable, not painful or scary. So have fun with it and if you have any questions at all, do not hesitate to ask your physician to refer you to a skilled Physical Therapist to help you create an exercise plan tailored to your needs.