

**Research Proposal: The Effects of a Vegetarian Diet on Juvenile Idiopathic Arthritis**

Jessica Christensen

Submitted in partial fulfillment  
of the requirements for the degree of  
Master of Science in Dietetics  
Mount Mary University

Janine M. Bamberger, MS, RDN, CD  
Assistant Professor, Department of Dietetics

Linda Gleason, MS, RD, CD  
Instructor, Department of Dietetics

December 11, 2022

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### **Abstract**

Research has shown that a plant-based or vegetarian diet can affect the disease activity of those with Rheumatoid Arthritis, but there is limited research on the use of this diet in children with Juvenile Idiopathic Arthritis. There is also evidence that suggests a vegetarian diet can positively influence quality of life. The purpose of this proposal is to establish if a vegetarian diet has any effect on the disease activity including symptoms, laboratory values, and quality of life. It is hypothesized that consuming a vegetarian diet for one year will improve disease activity and quality of life compared to those following an omnivorous diet. This non-randomized control study will have 32 subjects ranging in ages from eight to 16 in the vegetarian intervention group and 16 in the omnivorous control group. Data will be collected at baseline, three months, six months, nine months, and 12 months via questionnaires and laboratory blood draws. Statistically significant improvements are anticipated in various laboratory values, symptoms, and quality of life markers ( $p < 0.05$ ). Findings from this study will aid in evaluating effective dietary interventions for this population.

*Keywords:* vegetarian, children, Juvenile Idiopathic Arthritis, quality of life, dietary intervention.

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# THE EFFECTS OF A VEGETARIAN DIET ON JUVENILE IDIOPATHIC ARTHRITIS

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## **Chapter 1: Introduction to the Study**

### **Background**

Juvenile Idiopathic Arthritis (JIA), formally known as Juvenile Rheumatoid Arthritis, is an autoimmune disease that causes joint swelling and inflammation in joints in children. JIA's epidemiology is not fully understood and disease progression differs among patients and individuals. The name change occurred because it is not a juvenile version of Rheumatoid Arthritis, but a group of different subtypes of arthritis. A vegetarian diet may influence the disease course and symptoms of those with rheumatoid arthritis (RA).

### **Problem Statement**

Most research is focused on adults with RA and their disease activity as it relates to their diet, medication, or other influential factors. Specifically, the majority of research focuses on a vegetarian diet and adults with RA. There is not a large body of literature on the physical effects of a vegetarian diet on children diagnosed with a form of JIA.

### **Purpose of the Study**

The purpose of this study is to determine if a vegetarian diet will mitigate symptoms, improve quality of life, and reduce the overall disease activity of children diagnosed with JIA. This study will help with determining if diet intervention is useful to help treat those with chronic illnesses. In the following section, a literature review of JIA, vegetarian diet, quality of life, research methodology, results, and discussion will be included.

**Research Question**

The research question is as follows:

Q: Does a vegetarian diet influence symptoms and disease progression of children diagnosed with JIA?

Research Sub-Question 1:

H<sub>01</sub>: A vegetarian diet pattern is not associated with a lower occurrence of JIA-related symptoms and a slower disease progression by biochemical values.

H<sub>a1</sub>: A vegetarian diet pattern is associated with a lower occurrence of JIA-related symptoms and a slower disease progression by biochemical values.

Research Sub-Question 2:

H<sub>02</sub>: A vegetarian diet is not related to better quality of life outcomes.

H<sub>a2</sub>: A vegetarian diet is related to better quality of life outcomes.

Research Sub-Question 3:

H<sub>03</sub>: A vegetarian diet pattern is associated with a lower occurrence of JIA-related symptoms and a slower disease progression by self reported symptoms.

H<sub>a3</sub>: A vegetarian diet pattern is associated with a lower occurrence of JIA-related symptoms and a slower disease progression by self reported symptoms.

**Nature of the Study**

For this non-randomized controlled trial, there will be two groups: a treatment (vegetarian diet) group, and a control group (normal/omnivorous diet). The setting will be at Camp MASH in central Wisconsin. The study population is subjects 8 to 17 year olds diagnosed with a form of

JIA. They will be surveyed multiple times throughout the study to assess symptoms, and quality of life. Significance will be tested using a T-test.

### **List of Definitions**

Definitions of terms used in this study are listed according to reference.

*Idiopathic*: a disease or condition where the origin is unknown

*Pathophysiology*: abnormalities that contribute to or characteristics of a disease

*Uveitis*: inflammation of the iris in the eye

*Erythrocyte sedimentation rate*- a test using red blood cells to determine inflammation in the body

*Osteopenia*: mild weakening of bones

*Flavonoids*: chemicals that may help protect cells from oxidative damage. These are found in fruits and vegetables that may also provide health benefits (Medical Dictionary of Health terms: J-P 2011)

*Microflora*: the bacteria that inhabit the digestive tract, specifically the intestines. (NCI Dictionary of Cancer terms)

*Selenium*: a mineral

*Solanine*: is a glycoalkaloid that can be found in some parts of potatoes, sprouts, and tubers which may cause poisoning if ingested (Dalvi, 1983)

*Metabolite*: any substance produced during a metabolic reaction

*Oligoarthritis*: arthritis affecting one to four joints

*Glucocorticoids*: also known as corticosteroids, or steroids used to treat diseases that may cause inflammation

*Tryptophan catabolites*: byproducts of catabolism from tryptophan, an amino acid (Aust A-C, Benesova E et al., 2021)

*Microbiome*: where various microorganisms such as bacteria and viruses live (NCI Dictionary of Cancer terms)

### **Assumptions**

For this study, participants will answer survey questions honestly regarding their symptoms and food intake. Another assumption is that subjects are already aware of current allergies and reactions to food.

### **Limitations**

Potential limitations include the following: 1) food intake 2) adherence to a vegetarian diet as well as 3) symptom frequency and intensity. Another limitation may be the sample size. Even though many children have a form of JIA, it still is a small percentage of the total population. Two to 20 out of 100,000 children have JIA (Angeles-Han et al., 2013). This limitation also includes the consideration of attrition.

### **Delimitations**

For this study, both medicated and non-medicated participants are included. Those with similar autoimmune diseases such as Lupus, will not be chosen to participate. Those who are also on other specialty diets such as gluten free, will not be included.

**Significance**

Results from this study can bridge the gap in current research by exploring the effects of a vegetarian diet on the disease activity in youths with JIA. This study can also provide a baseline for future studies regarding JIA including those that might include alternate forms of treatment. Additionally, study findings can help healthcare professionals guide young patients into healthier living habits to help cope and treat their illness.

**Summary**

JIA is a disease with unknown origin and it can develop and display different symptoms in those with it. More research of treatment for children with JIA can help them develop and grow into physically high functioning adults. With results from this study, researchers and healthcare professionals can seek answers and treatments for their patients.

## **Chapter 2: Review of Literature**

This section will define as well as discuss the diagnosis, treatment, and pathophysiology of JIA. An introduction to the effects of diet on JIA as well as a definition of a vegetarian diet and how it relates to JIA management will also be discussed.

### **Literature Research Strategy**

For this literature review, article searches were conducted through Pubmed, Pubmed Central, Primo at Mount Mary University's Haggerty Library, and Google Scholar. Keywords and combination of keywords included "Juvenile Idiopathic Arthritis", "Rheumatoid Arthritis", "Vegetarianism", "Microbiome", "JIA medication and treatment", "Quality of life", "JIA pathophysiology", "JIA symptoms", and "Diet and JIA".

### **Background**

Juvenile Idiopathic Arthritis is the most common arthritis in children; it affects approximately 16-150 out of 100,000 children in the United States. Girls are three times more likely to have JIA than boys (Angeles-Han et al., 2013; Calder et al., 2009; Cattalini et al., 2019). This autoimmune condition causes inflammation in the joints, leading to long-term disability, damage, and pain (Alwarith et al., 2019; Weiss & Ilowite, 2007). The epidemiology of JIA is not fully known. Moreover, it is similar to rheumatoid arthritis (RA) and includes seven different subtypes which lead to variability in outcomes, disease progression, and joints affected (Alwarith et al., 2019). Genes and environmental factors such as infections, smoking, and lack of breastfeeding are the leading theories of why JIA occurs (Alwarith et al., 2019; Ellis et al., 2010). Other factors such as sex, age, hormones, socioeconomic factors, joint trauma, viral infection, race, as well as dietary habits may also contribute to the onset of this illness (Calder et

al., 2009; Weiss & Ilowite, 2007). More research is needed to determine risk associations as well as true causation. Currently, environmental and genetic factors are the two leading causes of JIA development.

The immune system largely impacts the pathophysiology of RA and JIA. The synovial membrane of joints thickens and swells with fluid due to damage which further causes an accumulation of other inflammatory cells. The joints are damaged by constant swelling, which is triggered by an immune response by T-cells that fail to regulate the immune response in joints (Calder et al., 2009). Symptoms include stiffness and joint pain. Some of the JIA subtypes can cause growth problems, uveitis, fever, rash, and swollen lymph nodes (Mayo Clinic Staff, n.d.).

Determination of diagnoses and assessment of disease activity varies with each case due to its heterogeneous nature. Common diagnostic tests include: 1) blood tests to identify biomarkers such as white blood cell count, platelet counts, immunoglobulin tests, and acute phase reactants; 2) imaging such as MRI's and ultrasounds, and 3) full physical examinations which include multiple types of joint counts, pain measures, and functional ability (Consolaro et al., 2009; Giancane et al., 2016). Evaluation of disease activity pre- and post-diagnosis is crucial to determining the effectiveness of pharmaceutical and non-pharmaceutical interventions. No singular test can fully determine the diagnosis and scale of disease activity (Consolaro et al., 2009). The American College of Rheumatology created a set of six measures to define disease state in JIA. These six measures include physician assessment of disease activity, parent/patient global assessment of well-being, active joint count, restricted joint count, functional assessment, and a laboratory measure of inflammation (Giannini et al., 1997). In 2009, the Juvenile Arthritis Disease Activity Score (JADAS) was developed using four measures. These four measures include physician global assessment of disease activity measures, parent/patient global

assessment of child well-being, joint count with active disease, and the erythrocyte sedimentation rate (ESR) or C-reactive protein (Trincianti et al., 2021). Recently, following an evaluation of nearly 5,000 rheumatoid factor-negative polyarthritis and oligoarthritis patients, Trincianti et al (2021) redefined criteria of disease activity with updated cutoffs of statistical values for determining inactive, minimal, moderate, and high JIA disease. Systemic JIA specific JADAS was also developed (Trincianti et al., 2021).

A multidirectional approach to treatment has aided in better life quality for those with arthritis. Common treatments include nonsteroidal anti-inflammatory drugs (NSAIDs), intra-articular corticosteroid injections (AIC), disease-modifying antirheumatic drugs (DMARDs), biologic agents/DMARDs, and tumor necrosis factor (TNF) inhibitors (Giancane et al., 2016; Weiss & Ilowite, 2007). These medications help JIA to improve and preserve the function of joints, promote normal growth and overall development, control pain, and inflammation, and promote better well-being. (Weiss & Ilowite, 2007). Medications may cause side effects or symptoms that may (undermine their benefits) and combat the benefits they promote.

NSAIDs promote control of pain and inflammation with few gastrointestinal side effects. Some side effects of this medication are skin rashes, headaches, and difficulty concentrating. Corticosteroid treatments increase the risk of osteopenia and osteoporosis, weight gain, and elevated blood sugar, as well as increase the risk of infection and skin changes at the injection site (Weiss & Ilowite, 2007). DMARDs are classified into non-biologic and biologic agents. Non-biologic agents, including medications like Methotrexate can cause side effects such as hepatotoxicity, interstitial pneumonitis, myelosuppression, increased cancer risk, oral mucosal ulcerations, teratogenicity, pulmonary disease, and pregnancy and conception complications (John Hopkins Arthritis Center, n.d.; Weiss & Ilowite, 2007). Biologic DMARDs include TNF

inhibitors that increase the risk of pneumonia, urinary tract infections, and bacterial, viral, and skin infections. Cancer risk and malignancies have also been seen in patients taking TNF inhibitors (John Hopkins Arthritis Center, n.d.; Weiss & Ilowite, 2007). Many medications fall under these types of treatments that include specific side effects and methods of action.

Non-pharmaceutical treatments are also important remedies for JIA. Physical activity, physical and occupational therapy, and participation in sporting or group activities are highly encouraged to promote physical wellness, social and psychosocial development, and improve quality of life (Giancane et al., 2016; Takken, 2003; Weiss & Ilowite, 2007). Along with these listed non-pharmaceutical treatments, recent studies also indicate that dietary intervention may influence the onset and diet progression of JIA. Dietary interventions for JIA, including a vegetarian dietary pattern, in particular, were included in this literature review.

### **Diet and RA Pathophysiology**

Dietary factors may be linked to the development of RA. One study conducted by Hu et al. (2015) found that women who consumed diets low in red meat with moderate amounts of alcohol had a lower risk for developing RA. Increased intake of red meat, meat products, and total protein intake was found to be a risk factor for the development of RA (Pattison et al., 2004).

In another study, He et al. (2016) found that women who consumed more sugar-sweetened beverages had a higher risk of developing RA, specifically seropositive RA. In the third study by Hu et al (2017), there were no specific foods other than moderate alcohol consumption and red meat that were associated with RA exacerbation. This study revealed association between increased legume intake and RA diagnosis.

He et al. (2016) also found that low intakes of beans, poultry, dairy, mushrooms, and citrus were found in patients with RA, and high intakes of citrus, mushrooms, and dairy may be protective against development.

No studies were found suggesting that dietary habits in infancy or childhood are associated with JIA risk. A Swedish study, however, did find an association between breastfeeding for less than four months and the early introduction of formula with increased JIA risk. The authors theorize that this phenomenon is related to the early introduction of enzymes and anti-inflammatory agents found in breast milk, which is crucial in immune system development (Kindgren et al., 2017).

These studies suggest that there is conflicting research regarding if there is an association between diet and the onset of RA with specific food consumption. More research is needed to conclusively make an association with the development of JIA since it has been explored very little. Some research suggests that early intervention of a biodiverse microbiome may influence disease onset.

### **Influence of Diet on RA**

Over the last 30 years, an increasing number of studies have indicated that diet may have an influence on RA symptoms and disease progression. In 2017, Tedeschi et al. found that 24% of the subjects reported that at least one food had a positive impact on RA symptoms by decreasing occurrence of symptoms. Also, 10% of subjects had a negative impact from at least one food on their symptoms. Foods like spinach and blueberries were found to be more helpful than foods with high sugar content, which worsened symptoms (Tedeschi et al., 2017). A study by Bustamante et al. (2020) was influenced by several studies investigating diet and its effect on RA. The authors reviewed studies relating all food groups, a variety of spices, herbs, and

beverages, to their inflammatory promoting properties. Recommendations from the review include high fiber intake and daily probiotics that promote a healthy gut microbiome and subsequently positively affect immunity. Other suggestions that positively affect the inflammatory state include reduced intake of red meat and increased intake of foods rich in antioxidants, phytochemicals, and flavonoids found in fruits and vegetables. These studies suggest that diet affects JIA/RA in ways that are positive and negative. Consumption of a diet rich in fruits, vegetables, and whole grains is suggested to help with inflammation starting at a microbiological level; these influence how a child or adult feels day to day with stiffness in joints, mobility, and overall quality of life.

### *Grains*

Grains are a staple in many cuisines all over the world. They are filling and rich in fiber, minerals, and vitamins. The dietary fiber in wheat and other whole grains in this review is described in relation to its effect on the microbiome. Fiber is fermented by the microflora which results in the production of short-chain fatty acids. These short-chain fatty acids protect colonocytes that prevent gut permeability which reduces inflammation and other inflammatory biomarkers (Alwairth et al., 2019; Khanna et al., 2017); however, there is conflicting research on this topic. Whole grains also provide minerals and vitamins that may influence inflammation. Antioxidants, vitamin E, and selenium are just a few nutrients that may act as anti-inflammatory agents. (Khanna et al., 2017). A study by Vanegas et al. (2017) showed that consumption of whole-grain foods reduces inflammation; however, this may be a result of weight loss. More studies are needed to determine a direct association with whole grains, fiber, inflammation, and inflammatory biomarkers. More studies, however, focus on the fiber intake from consuming fruits and vegetables.

*Fruits and Vegetables*

Fiber is also found in fruits and vegetables. Along with fiber, vegetables and fruits also contain sugar that assists in the fermentation process which, as previously discussed, reduces inflammation. Fruits and vegetables have anti-inflammatory components such as antioxidants, phytochemicals, vitamins, and minerals (Bustamante et al., 2020). Review studies that included vegetable intake influence the development of RA. A high intake of fruits and vegetables did reduce the risk of RA development; however, no changes in risk occurred with general, less than 2.9 servings/day, of fruit and vegetable consumption. More research is needed due to the low number of studies (Boeing et al., 2012). Additionally, phytochemicals in fruits and vegetables have been shown to reduce symptoms in RA as well as other diseases with chronic inflammation due to its ability to reduce oxidation in. A review found that continual high intakes of fruits have been associated with slowing progression of RA and prevention of disease onset (Khanna et al., 2017).

Interestingly, not all fruits and vegetables have been shown to have beneficial effects. Studies have found that nightshade vegetables such as eggplant, potatoes, and tomatoes may have the opposite effect (Bustamante et al., 2020). These types of vegetables contain solanine, which may increase gut permeability causing inflammation in the intestines (Bustamante et al., 2020). However, these vegetables also have high amounts of antioxidants which are also associated with anti-inflammation (Khanna et al., 2017). Little research has been conducted associating nightshade vegetables with RA or JIA directly. Since there are so many benefits to nightshade vegetables, eliminating this specific group of vegetables has not been recommended or encouraged. Elimination of any one food group has not been recommended, however, some specific foods may be pro-inflammatory and therefore be excluded from eating plans.

### *Meat*

Consumption of meat, specifically red meat, has been associated with inflammation. The main concern for red meat consumption is saturated and trans-fat that red meat contains. Processed meat, saturated fat, and trans-fat have been shown to be pro-inflammatory (Bustamante et al., 2020). Meat contains choline which is a precursor for trimethylamine-N-oxide (TMAO), a pro-inflammatory metabolite (Koeth et al., 2013). Vegetarians produce less TMAO (Koeth et al., 2013). Some studies have shown a positive association between all meat, red meat, processed meat, protein intake, and RA symptoms. These foods have been associated with pro-inflammatory biomarkers such as C-Reactive Protein (CRP), interleukin-6, and homocysteine (Alwarith et al., 2019). Weight has been associated with meat and inflammation. Higher body weight in individuals and dietary intake of meat have been shown to exacerbate RA symptoms. Fish intake, however, has been associated with more anti-inflammatory activity, mostly due to its polyunsaturated fat content (Khanna et al., 2017). More research is needed to determine if all meat or red meat specifically influences RA symptoms, or if weight and body or dietary fat have a significant influence on this association. Likewise, with meat consumption, dairy may also contribute to the worsening or onset of symptoms.

### *Dairy*

Full-fat dairy products, like meat, have also been shown to have pro-inflammatory properties, as it contains saturated fat, trans fat, and choline (Bustamante et al., 2020). Dairy consumption may also trigger the onset of RA or JIA flares. One theory of why arthritis occurs relates to digestive tract issues or the immune system. In one study after a four-week vegan, low-fat diet, dairy was reintroduced and RA symptoms returned (McDougall et al., 2002). The return of these symptoms may be due to large proteins in dairy causing inflammation in the gut thus

increasing gut permeability (McDougall et al., 2002; Alwarith et al., 2019). Gut permeability also causes bacteria and foreign proteins from foods into the bloodstream, causing antibodies to be released or produced. Higher concentrations of these antibodies are seen in those with RA. (McDougall et al., 2002). Another theory of why dairy may be inflammatory is the concept of molecular mimicry. RA and JIA are autoimmune diseases. The immune system recognizes its own tissues as foreign and mounts an inflammatory response against them. Bovine albumin has a similar structure to human collagen; thus, it is theorized that in cases of autoimmune conditions, consumption of dairy causes an immune response to the bovine albumin, by recognizing it as foreign (McDougall et al., 2002). These studied adults with RA and not children with JIA. More research is needed to determine a stronger association between dairy consumption and the effects of JIA.

### **Nutrition Concerns in JIA**

Malnutrition or nutritional impairment from JIA have been found to induce growth complications, anemia, osteoporosis, and other ailments (Cleary et al, 2004). This population is at risk for malnutrition likely due to chronic inflammation. Chronic inflammation increases the production of cytokines and tumor necrosis factor which in turn increases protein breakdown and metabolic rate (John Hopkins Arthritis Center, n.d.). JIA patients also have decreased lean muscle mass and increased fat mass (Weiss & Ilowite, 2007). A project conducted in Liverpool, United Kingdom studied the effects of nutrition impairment and JIA diagnosis. This research study found that those with a lower body mass index had a higher risk of a JIA diagnosis with five or more joints being impaired. This study also suggests that JIA, especially the subtype oligoarthritis, may be a risk factor for nutrition impairment, not just low energy intake (Cleary et al., 2004).

For a Brazilian project, Caetano et al. (2009) researched the dietary intake of children and adolescents with JIA. They assessed energy and nutrient intake from 24-hour recall data in seventy subjects. Of those with active JIA, 8.3% were considered malnourished and 16.7% were considered obese. They also found high intakes of energy (12.5%), protein (75%), and lipids (31.3%) among subjects. More than 50% of subjects had low intakes of vitamin B2, C, A, zinc, manganese, calcium, and phosphorus. Subjects ate lower than recommended servings of milk products, fruits, and vegetables but had a meal pattern high in oils, fats, and sugars. Statistical analysis showed no association between age, sex, dietary intake, and use of medication for managing RA. Their results were similar to those of other studies related to this topic.

As important as it is to monitor and assess malnutrition in those with JIA, it is also important to assess for overweight and obesity. Individuals with JIA are also at risk for being overweight or obese (Więch et al., 2018). Some studies have shown that children with JIA have different body compositions from those without JIA (Schenck et al., 2015; Więch et al., 2018). A German study conducted from 2003 to 2012 determined that there was a 5.9% decrease in overweight and obese children with JIA (Schenck et al., 2015). One suspected reason for this decline is that the use of glucocorticoids decreased between the same years and the increased use of biologic therapy increased. In this study, the authors did not find a significant difference between obesity and overweight rates in those with JIA compared to the general population; however, the rate of obesity and being overweight has decreased over time (from 14.2% in 2003 to 8.3% in 2012s). They also found an association between JADAS-10, disease activity, and being overweight that is also reflected in other studies. Obesity and overweight may contribute to low-grade inflammation, however, more research is needed (Schenck et al., 2015). Pelajo did not find an association between the 18% of their overweight JIA subjects and disease activity (Pelajo

et al., 2012). They did however determine that disease activity in adults with obesity is associated. BMI may also increase the risk of RA development. Studies have shown that excess body weight has been associated with a decreased chance of remission and more severe outcomes in terms of disease activity in RA, compared to those at a normal BMI (Alwarith et al., 2019). More research is needed regarding obesity and overweight in patients with JIA and how it affects their disease activity. This discrepancy in data may be due to the subtypes of JIA being studied as well as non-pharmaceuticals and biopharmaceuticals being used. These studies also did not consider nutrition in terms of intake or current nutritional status.

### **Vegetarian Diet**

Vegetarianism has been practiced throughout history in various cultures and religions. Within the last few centuries, the health benefits, concerns about animal welfare, and the environmental impact of vegetarianism have been recognized and prompted the adoption of this lifestyle and diet (Hargreaves et al., 2021; “Position of the American Dietetic Association and Dietitians of Canada,” 2003). There are many variations on the vegetarian diet including flexitarian, consuming non-red meat up to once per week, pescatarian, eating no meat except fish and seafood, lacto-ovo vegetarian, which is defined as excluding all meat but including milk and/or eggs, and lastly, veganism, which excludes all animal products. The position of vegetarianism by the American Dietetic Association and Dietitians of Canada states that when properly planned, a vegetarian diet provides adequate nutrition and promising benefits (2003) A vegetarian diet provides adequate nutrition and is promising for the treatment of diseases, such as rheumatoid arthritis. In addition, a plant-forward diet has been shown to be negatively associated with biomarkers of inflammation in those with RA. Conversely, a diet that includes a higher intake of processed meats and high fat has been found to have a positive association with

inflammatory biomarkers (Alwarith et al., 2019). These findings suggest that children with JIA can reduce inflammation and RA symptoms as well as meet their nutritional needs by following a vegetarian meal pattern.

Vegetarianism has benefits that can help the general population as well as those with JIA. Vegetarianism has been linked to lower risks of cancer, obesity, and Type II Diabetes (Kiely, 2021). Children who were raised on a vegetarian diet were also more likely to be taller and have a healthier body weight (Kiely, 2021). A diet rich in vegetables, fiber, and fruit and low in meat and other animal products has been shown to be associated with lower BMI, inflammation, and disease activity (Alwarith et al., 2019). Alwarith et al. (2019) state in their review that veganism, specifically with high intakes of fruit and vegetables and low animal products, has been shown to reduce risks of autoimmune diseases such as hyperthyroidism, hypothyroidism, and multiple sclerosis. Interestingly, not many studies have concluded that diet influences other skeletal muscular diseases, such as lupus (Alunno et al., 2021). Although more research is needed regarding diet and disease activity, consuming more fruits, vegetables, and fiber and reducing intake of processed meat and sweets decreases the risk of other conditions such as cardiovascular disease and obesity. The more restrictive the vegetarian diet, the more at risk a child is for malnutrition (Kiely, 2021) Incorporating nutrient-dense foods such as legumes, beans, peas, and lentils as well as a variety of fruits, vegetables, and whole grains can reduce risk of malnutrition.

Nutrition concerns of those with JIA were previously mentioned. With any diet that eliminates certain foods, there are some nutritional risks. Some nutrients that may be at risk for low consumption in a vegetarian diet are vitamin B12, vitamin D, calcium, protein, and DHA. Other micronutrients at risk are iron, iodine from iodized salt, and zinc (Kiely, 2021; Schürmann et al., 2017). Those with JIA may be at risk for deficiency of these nutrients as well. As

mentioned previously, a well-planned vegetarian diet has been shown to promote health, however, professional help and support may be one key to optimizing nutrient intake on a vegetarian diet, especially for those who are at nutritional risk.

### **Diet and Microbiome**

The gut microbiome is largely influenced by diet and research is finding that the gut microbiome influences disease development and progression. A positive association exists between microbiota health and inflammatory diseases. As previously discussed, gut permeability has a direct influence on inflammation in the gut and may influence the pathophysiology of RA. The diversity of bacteria in the microbiome, as well as the lack of fiber, has been associated with RA risk (Alwarith et al., 2019). Fiber intake has been shown to be linked to lower inflammation in the gut. Disease pathophysiology may start at birth and breastfeeding. In the study by Kindgren et al. (2017) previously discussed, researchers found that breastfeeding may be linked to the prevention of JIA due to the microbiome and its impact on the immune system. Studies investigating whether breastfeeding influences the risk of JIA are still in development (Weiss & Ilowite, 2007). The gut microbiome, specifically the lack of biodiversity, has been linked to the development of autoimmune disease (Kindgren et al., 2017). Kjeldsen-Kragh (1999) suspects that the microbiome, particularly the presence of a high concentration of *P. mirabilis*, has been linked to the pathophysiology of RA. This bacteria is known to cause urinary tract infections; however, antigen activity of HLA-DR4 against this bacteria increases the risk of RA. Kjeldsen-Kragh et al. (1995) also conducted a study researching the effects of diet and *P. mirabilis* antigen activity. This study suggests that a vegetarian diet reduced antigen activity and decreased RA disease activity in participants.

Research suggests that there are differences in the composition of the microbiome of vegetarians, vegans, and omnivores. A raw-vegan diet rich in *Lactobacillus* was found to alter the microflora of patients with RA resulting in reduced disease activity. When the diet supports a higher percentage of *L. bacillus*...in the gut then disease severity is reduced.(Peltonen et al., 1994; Scher et al., 2013).

*Prevotella copri* has been shown to be found in the gut microbiome of many untreated and newly diagnosed patients with RA (Bustamante et al., 2020, Scher et al., 2013). In a study by Scher et al., healthy patients had low concentrations of *P. copri*. Those with RA with lower disease activity have *P. copri* concentrations that are similar to those of healthy patients. One theory is due to the relationship between C-reactive protein and this bacteria. C-reactive protein may have an influence on bacteria by binding with the bacteria and causing an inflammatory response, specifically with RA. C-reactive protein is shown to be higher in newly diagnosed RA patients, but not in other diseases such as Lupus which suggests that flaring RA patients may have unique inflammation response due to their gut microbiome.

*Lactobacillus* bacteria have been shown to be anti-inflammatory and antioxidative. *Lactobacillus* releases tryptophan catabolites that help decrease gut permeability and provide homeostasis in the intestinal tract (Bustamante et al., 2020). The consumption of yogurt, a food item rich in *Lactobacillus*, has been shown to have anti-inflammatory effects (Bustamante et al., 2020).

These studies suggest that early implementation of microbiome-positive habits, such as breastfeeding, may reduce the risk of the development of RA and decrease disease activity. The microbiome is mutable, ever-adapting on its influence on body systems and disease. Research on the microbiome and its influence on the pathophysiology of RA and disease activity is growing

as well. Current research suggests that the presence of certain bacteria may inhibit or improve RA symptoms and disease activity.

### **Quality of Life**

Quality of life is a subjective indication of how one feels about their current state of well-being (Hargreaves et al., 2021). Many factors can influence how one feels about themselves and their life situation. Quality of life can be divided into four domains: physical, social, environmental, and psychological. The physical domain consists of general physical health including disease, symptoms, or energy (Hargreaves et al., 2021). Over the last few years, mental health awareness has increased. It is important to consider the effects of disease on the quality of life of children with chronic illnesses.

In individuals with a chronic disease quality of life is impacted by symptoms of the condition whether the symptoms are active or inactive. In turn, each of the four domains of quality of life can negatively or positively influence food choices, especially the physical domain. In one study, across three geographical areas including Eastern and Western Europe and Latin America, children diagnosed with JIA were found to have a lower health-related quality of life than those of healthy children. Determinants of quality of life for this study included physical function, body pain or discomfort, self-esteem, relationship with family, and general health (Gutierrez-Suarez et al., 2006). This study by Gutierrez-Suarez et al. did however include that the participants of this study were not considering the socio-economic status or other demographic information. The study may not be fully representative of the JIA population. They did however determine that pain and disability were the most influential determinants of quality of life.

### **Diet and Quality of Life**

A vegetarian diet may help aid RA and JIA symptoms largely affecting the physical domain of quality of life (Weiss et al., 2014). Some studies have shown that joint pain and inflammation may decrease with dietary interventions. In one review, authors concluded that diets that include all animal products, including dairy and red meat, can exacerbate symptoms. Conversely, a diet rich in fiber, fruits, and vegetables helped reduce symptoms (Alwarith et al., 2019). A study investigated the impact of a vegetarian diet following a seven to ten-day subtotal fast on patients with RA. On this fast, subjects consumed herbal teas, vegetable broth, potatoes, garlic, and juices from only vegetables and not fruit. Compared to the omnivore group, all symptoms and disease activity decreased, including tenderness, stiff joints, and morning stiffness over the next year. Several explanations were suggested as to why the vegetarian diet decreased disease activity. The first potential reason is a psychiatric or placebo effect. The responders were participants who overall believed in non-conventional medical treatment. However, the researchers discussed that it may be difficult to explain the placebo effect on those who responded to treatment after a year on the vegetarian diet. They theorize that placebo in addition to psychological treatment can help patients cope with their RA and reduce disease activity. A second explanation is that a decreased energy intake may have lowered immune system function. RA and JIA are commonly treated with immunosuppressants, thus it questions whether the improvement was related to medication or the lower energy intake of the vegetarian diet. Third, an alteration in fat intake may alter the subject's blood lipid profile, thus directing a change in an inflammatory response. Lastly, a change in gut microflora and the presence of *Proteus mirabilis* increased inflammation. The increased presence of the antigen for this bacteria was inversely related to disease activity.

A study of a low-fat vegan diet on RA disease activity showed that stiffness, joint tenderness, ability to function, and severity of morning stiffness decreased. Results also showed that subjects with the most severe symptoms at baseline improved the most. This study also discusses the diet and its influence on gut permeability and overall gut microbiome health. Indications include that diet, specifically plant-based diet, has positive effects, possibly through multiple modes of action on symptoms in patients with RA and therefore improved quality of life in the physical domain (Hargreaves et al., 2021).

There is a consideration of quality of life in the social domain when adopting a vegetarian diet (Hargreaves et al., 2021). Patients with JIA are at risk of perceiving a low quality of life due to a lack of social support, how they view their identity, and how they appear in society to feel “normal” (McDonagh et al., 2016). One study found that older children and adolescents with JIA found that to maintain a positive social identity, they minimize the appearance of symptoms and use disclosure of disease onset and self-management (McDonagh et al., 2016). Social support and acceptance can come from parents, friends, classmates, and other adults such as teachers (Hargreaves et al., 2021; Mańczak et al., 2016). A vegetarian diet has been described as being a part of one’s social identity and may bring about a sense of belonging to this subculture (Hargreaves et al., 2021). However, those who participate in a vegetarian lifestyle may be subjected to discrimination or pressure to eat meat from friends, family, or society (Hargreaves et al., 2021). In the future, research could investigate the social effects of JIA diagnosis and the adoption of a vegetarian diet or lifestyle.

In the environmental domain, quality of life can be influenced by the living environment such as safe and clean spaces and recreational areas (Hargreaves et al., 2021). This domain also considers socioeconomic status as well as access to care (Seid et al., 2014). One study found an

association between socioeconomic status and perceived JIA disease activity (Verstappen et al., 2015). In this study, JADAS-10 was used to determine disease activity in juvenile patients. The findings of this study revealed that disease activity rated similarly throughout all socioeconomic statuses, however there were perceived differences of pain, disease activity, and functional ability for participants and their families in lower socioeconomic statuses (Verstappen et al., 2015). This study also found that patients in lower socio-economic statuses reported that their diagnosis has caused emotional difficulties that influenced their schoolwork and social activities. They reported issues with behavior, less family time as well as tension in the family (Verstappen et al., 2015). This study determined socioeconomic status based on the location of the families, rather than actual family income. The environmental domain of those with JIA may be influenced by socioeconomic status and can impact treatment options due to access and affordability of healthcare. Cost and access to vegetarian foods can be a concern. However, depending on where one lives, a vegetarian diet may be more convenient and cost-effective than an omnivorous diet (Hargreaves et al., 2021). Like the social domain, the association between the environmental quality of life domain, JIA, and the vegetarian diet has been the focus of few research studies. Lastly, the psychological domain includes self-esteem, feelings about oneself, body image, and overall mental health (Hargreaves et al., 2021; Fair et al., 2019). Studies have found that depression and anxiety symptoms occur more frequently in children with JIA than in healthy children. Depression and anxiety directly impact the quality of life, especially when the disease is more active (Fair et al., 2019). There may also be an association between disease activity in JIA and depression and anxiety on a physiological level. One study discovered the association between specific neurotransmitters indicated likely elevated activity of enzymes in dopamine and serotonin pathways (Fair et al., 2019; Korte-Bouws et al., 2019). A vegetarian diet

may moderate symptoms of JIA, thus potentially influencing the psychological domain.

Vegetarianism itself may also positively affect mental health and psychological quality of life.

Practicing vegetarianism may allow one to feel better about their behaviors and way of thinking.

Vegetarianism may also allow one to feel a sense of belonging, which will also positively affect the psychological well-being and quality of life (Hargreaves et al., 2019).

JIA diagnosis and its activity in patients impact quality of life in all (4) domains. Several studies have also shown that practicing a vegetarian diet may positively influence these domains. More research is needed to strengthen associations between patients with JIA who practice a vegetarian diet may have improved areas of quality of life.

### **Residential Summer Camp**

Approximately 14 million children attend a summer camp each year (American Camp Association, n.d). Summer camps across the country are created to serve multiple populations and missions while providing a range of activity and education programs. There is promising research that suggests camps, particularly group-based for those with chronic illnesses, offer outcomes such as better coping, empowerment, social support, and normalization (Nicholas et al., 2009). These camps offer programs such as arts and crafts, physical activity in the form of games and activities, and educational programming that promote conversation and reflection of their medical conditions (Nicholas et al., 2009). Depending on the nature and purpose of camps, some also offer nutrition education and programming. Research has suggested that residential camps as short as one week can increase the development of some positive behaviors that are sustained after camp (Ventura & Garst, 2013). Camp MASH (Make Arthritis Stop Hurting) is a week-long camp for those with JIA and similar autoimmune diseases. It is an overnight camp that hosts both boy and girl campers ranging from eight to 17 years old. All meals and snacks are

provided to campers during their stay. It would be opportune to provide a healthful, vegetarian diet to campers under encouragement and supervision of the researchers.

### **Summary**

A vegetarian diet rich in whole grains, vegetables, fiber, and plant-based proteins may positively influence symptoms and disease activity of those with Rheumatoid Arthritis. Dietary intervention may also positively affect quality of life. A vegetarian dietary intervention should be studied to determine if there is any effect on symptoms, disease activity, and quality of life with children diagnosed with Juvenile Idiopathic Arthritis. This proposed study will use various methodology from authors mentioned during this literature review to determine associations with diet and JIA activity.

### Chapter 3: Research Methodology

#### Introduction

This chapter will include the study design and methodology of this project on how a vegetarian diet affects children diagnosed with Juvenile Idiopathic Arthritis. More research is needed to determine the effect of diet on disease activity and progression of children diagnosed with JIA. In this section research protocol, description of subjects, data collection, data analysis, threats to validity, as well as ethical procedures will be discussed.

#### Research Design

##### Research Question:

The research question is as follows:

Q: Does a vegetarian diet influence symptoms and disease progression of children diagnosed with JIA?

Research Sub-Question 1:

H<sub>01</sub>: A vegetarian diet pattern is not associated with a lower occurrence of JIA-related symptoms and a slower disease progression by biochemical values.

H<sub>a1</sub>: A vegetarian diet pattern is associated with a lower occurrence of JIA-related symptoms and a slower disease progression by biochemical values.

Research Sub-Question 2:

H<sub>02</sub>: A vegetarian diet is not related to better quality of life outcomes.

H<sub>a2</sub>: A vegetarian diet is related to better quality of life outcomes.

Research Sub-Question 3:

H<sub>03</sub>: A vegetarian diet pattern is associated with a lower occurrence of JIA-related symptoms and a slower disease progression by self-reported symptoms.

H<sub>a3</sub>: A vegetarian diet pattern is associated with a lower occurrence of JIA-related symptoms and a slower disease progression by self-reported symptoms.

### **Study Design**

As discussed above, the disease activity of JIA may be influenced by other factors such as diet. For further research and development of treatment for these children, it is important to research methods of managing symptoms. For this study, the study design is a non-randomized controlled trial, specifically a parallel study. For this study, there will be two groups, a treatment (vegetarian diet) group, and a control group (normal/omnivorous diet). The results of the intervention will then be compared (Parab, 2010).

The setting will be on location at Camp MASH as well as off the camp property. Subjects on the vegetarian diet will eat a vegetarian diet provided by the facility. Camp is on a Sunday in August through the following Friday. During this time, they will consume a vegetarian diet and participate in one, hour-long nutrition activity learning about the benefits of a vegetarian diet as well as ways to follow this diet. Before leaving camp, they will be provided information such as vegetarian-friendly foods as well as other information for parent(s)/guardian(s). The nutrition activity and information material are located in the appendix. Both groups will then follow their prospective diets for one year.

**Table 1***Research Questions and Variables*

Research Question	Independent Variable	Dependent Variable
Will biochemical data be affected by a vegetarian diet?	Vegetarian Diet	Erythrocyte sedimentation rate, c-reactive protein, sodium, potassium, chloride, glucose, creatinine, albumin, protein (total), calcium, and bilirubin (total), and count of blood cells (white blood cell, red blood cell, hemoglobin, hematocrit, mean corpuscular hemoglobin concentration, mean corpuscular volume, auto neutrophil, lymphocyte, monocyte, eosinophil, and basophil, antigen activity of HLA-DR4, and Immunoglobulin IgG, IgA, and IgM
Will the quality of life be affected by a vegetarian diet? (Questions in Appendix)	Vegetarian Diet	Quality of life outcome
Will symptoms of JIA be affected by a vegetarian diet? (Questions in Appendix)	Vegetarian Diet	Symptom Severity

### **Population**

A convenience sample, based on the number of individuals attending camp, will be used. The sample used in this study are children who have been diagnosed by a physician with any form of JIA. Participants in this study will be the age included in this study is 8-17 years old.

### **Recruitment**

For the recruitment of subjects, researchers will acquire access to those registered for Camp MASH (Make Arthritis Stop Hurting) for the upcoming year. With this data, we will email and call parents to inquire about their interest in having their child participate in this study. On average, 100 campers are registered for camp. The goal of this study is to reach 50 participants: 25 for the vegetarian group, 25 for the omnivorous group. Groups will be determined by the willingness to participate. As parents or guardians sign up for the study, they will choose which group the child will fall into. This decision will 1) allow parents and subjects to plan accordingly to a vegetarian diet and 2) perhaps allow better adherence to diet if subjects choose their diet. Camp MASH is only offered to those who have been diagnosed with JIA or a similar disease. Exclusion criteria include those who have not been diagnosed with JIA specifically, for example Lupus. Those who are also on other specialty diets such as gluten free, will be excluded For the purpose of this study, both individuals on and off medication will be included.

### **Data Collection Process**

For data Collection, a private Google Form will be used for questionnaire data. This survey will be sent out at baseline, 1 month, 3 months, 6 months, 9 months, and 12 months post dietary intervention for those in the vegetarian group and those in the control group. Questions

will include topics such as quality of life, medication status, and questions on arthritis symptoms. The initial questionnaire at baseline will include questions on economic status and general biochemical questions such as age, diagnosis of disease, etc. A full list of questions is included in Appendix D. Questions regarding Personal information of subjects will be collected and saved in a locked filing cabinet.

In addition to data collection, there will also be an analysis of bloodwork. Protocols for this will be followed under consideration and policies in place by the IRB and other legal entities upon approval (IRB, n.d.). Following the pediatric procedures for blooddrawing provided by the IRB will be followed. Procedures and guidelines will be provided (See Appendix A). Bloodwork will be collected at baseline, 3 month, 6 month, 12 month post dietary intervention. With permission from the Medical College of Wisconsin IRB, human subject research can occur at various locations in Wisconsin including the Versiti Blood Center of Wisconsin, Children's Hospital of Wisconsin, and the Froedert Health System which includes its health clinics and hospitals. Upon consenting to participate in the study, researchers will help subjects determine a lab closest to their home address that is approved by the IRB (Medical College of Wisconsin, n.d.). The blood samples will reflect laboratory levels of erythrocyte sedimentation rate, c-reactive protein, count of blood cells, antigen activity of HLA-DR4, and Immunoglobulin IgG, IgA, and IgM. These tests will allow researchers to determine levels of inflammation, disease activity, and monitor diet effectiveness.

Weight and height will be taken at baseline and at the 12-month mark. At baseline, subjects will be weighed and height will be measured using a medical grade portable scale and measuring tape, respectively. Subjects will be allowed to provide a visit summary from their healthcare provider from a recent medical visit for height and weight.

### **Instrumentation**

Within the questionnaire, a visual analog scale will be used to aid in determining the quality of life and severity of symptoms. Quality of life will be assessed using the Paediatric Rheumatology Quality of life Scale (PRQL) as it relates to physical health and psychosocial health. This assessment has been shown to be reliable and valid during evaluation. In one study, the reliability was studied and scored. The test-retest reliability was found to have coefficients of 0.91 for the total score, 0.85 for the physical subscale, and 0.92 for the psychosocial subscale (Carle et al., 2011). These questions will be used to determine how the subject rates their quality of life. Validity was processed to find that face, content, discriminative, and construct validity have been established during evaluation. However, the psychosocial subscale did not strongly support validity. For blood work collection, we will utilize a clinical laboratory to draw samples and produce results for our coordinators. The severity of symptoms will be evaluated using a visual analog scale to assess symptoms including the degree of RA-related pain, functional ability, morning stiffness, duration of morning stiffness, and swelling (Mcdougall et al., 2004). JADAS-10 will be used to determine disease activity (Backstrom et al., 2016). The list of questions regarding these topics will be in the appendix.

### **Data Analysis Plan**

For statistical analysis, the summary will be shown in Table 2. Research Questions and Statistical Analysis. Independent and dependent variables described in Table 1 will be analyzed and statistical significance between the two variables will be used on both groups of subjects. Questionnaires will be included in Appendix E.

**Table 2***Research Questions and Statistical Analysis*

Research Question	Potential Responses	Test of significance	Reason for test	Level of Measurement
Q1: Will biochemical data be affected by a vegetarian diet?	Various biochemical markers.	<i>t</i> -test	Nominal data and testing significance with two different classification groups.	Interval
Q2: Will the quality of life be affected by a vegetarian diet? (Questions in Appendix)	From 0 (never) to 3 (all the time)	<i>t</i> -test	Ordinal data and testing significance with two different classification groups.	Ordinal
Q3: Will symptoms of JIA be affected by a vegetarian diet? (Questions in Appendix)	From 0 (never) to 3 (all the time)	<i>t</i> -test	Ordinal data and testing significance with two different classification groups.	Ordinal

**Threats to Validity**

Some threats to validity include attrition from the study. Multiple reasons such as pressure from peers and family members may cause attrition. Other factors may include being unable to afford foods that are appropriate for a vegetarian diet, parent(s)/guardian(s)' decision to drop out of the study, and risk of nutritional deficiencies based on survey data. Not completing the questionnaire, not understanding the questions, or answering dishonestly also threaten the validity of this study. Social influence from family and peers may also alter the food intake of subjects. External influence may affect adherence to the diet thus influencing validity.

**Ethical Procedures**

For the safety of the subject's data and subject information will be kept private under collaborators' supervision using password coded forms, encrypted emails, and documents. For security Google Sheets only shared with collaborators and locked to those not approved to view documents and research data. Printed personal information will be locked in a secured filing system. Google sheets will also be used to track subject data including survey results and bloodwork results (Hoces de la Guardia & Sturdy, 2019).

Consent and assent forms will also be emailed to the parent(s)/guardian(s)' of subjects. These must be completed before beginning the study. Examples of the consent and assent forms are located in Appendix B and C. IRB approval will be obtained before the study and guidance will be followed before, during, and after the study. IRB approval form is located in Appendix A.

**Summary**

In conclusion, this study will compare the effects of a vegetarian diet on the disease activity of 8 to 17 year old children diagnosed with Juvenile Idiopathic Arthritis. The treatment group will practice a vegetarian diet while the control group will be omnivorous. Camp MASH has an average attendance of 100 campers. The goal is to have 50 campers participate in the study, 25 vegetarian and 25 omnivorous. Chapter 4 will include the predictive outcomes of the study. Following chapter 4, chapter 5 will include a discussion of anticipated results of the study as well as limitations, strengths, and recommendations for future studies.

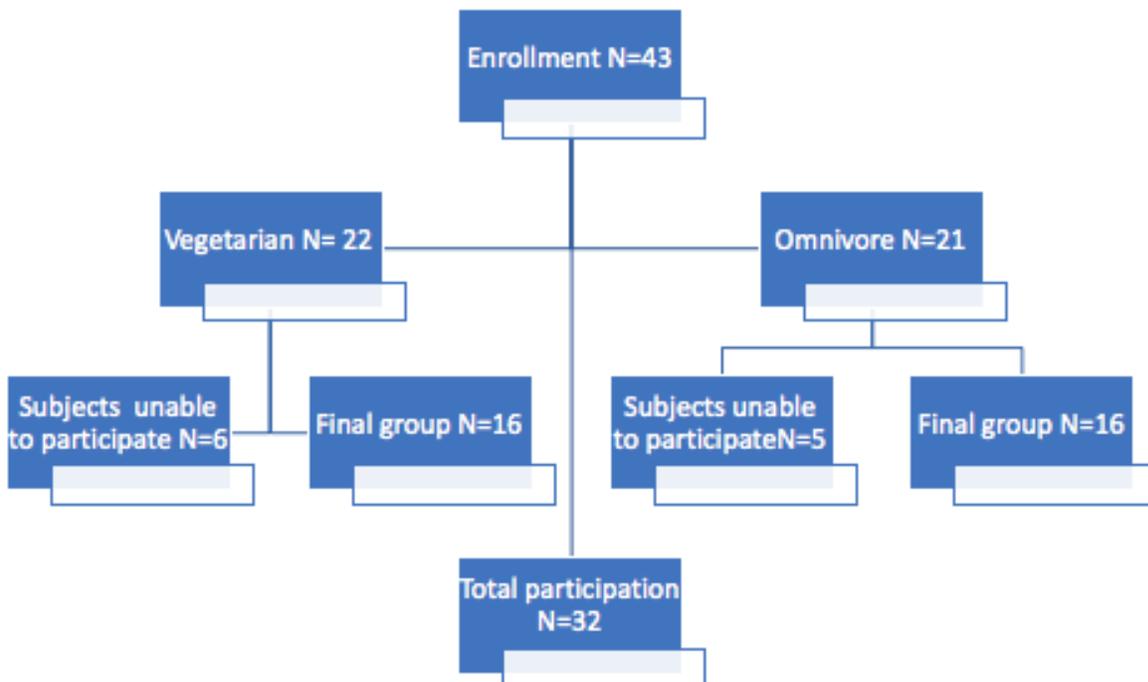
## Chapter 4: Anticipated Results

### Characteristics of Study Population

An estimated 43 subjects will consent to participate in the study after registering for Camp MASH. An estimated 22 subjects will volunteer for the vegetarian group and 21 for the omnivore group. Those who complete all of the surveys and blood draws in the time allotted, will be used in the final statistical analysis. After loss due to attrition, a total of 32 subjects are expected to complete the study, 16 in the vegetarian group and 16 in the omnivore group. A breakdown of the participants will be shown in Figure 1.

**Figure 1.**

*Illustration of participants in study.*



**Laboratory, Quality of Life, and Symptom Outcomes**

Laboratory values will be collected at baseline and continue every three months until one year later. Surveys will be completed at the same time intervals. The Juvenile Arthritis Disease Activity Score (JADAS) will be calculated by researchers with assistance from pediatric rheumatology physicians. At 12 months, data will be compared with the vegetarian group and the omnivore group using simple *t*-test. For Table 3a, 4a, and 5a, only significant values will be included and in bold. For all three tables, p-value <0.05 will be considered statistically significant. Average monthly values and p-value will be shown on Table 3b, 4b, and 5b will be included in Appendix under Tables.

Table 3a.

	Vegetarian N=16		Omnivore N=16		P-Value
	Baseline	12 month	Baseline	12 month	
Erythrocyte sedimentation rate	29.5	6.8	27.0	22.1	<b>0.0000105</b>
C-reactive protein mg/dL	7.9	3.6	7.7	7.1	<b>0.0031601</b>
Blood Urea Nitrogen (mg/dL)	19.5	11.2	18.4	18.6	<b>0.0003356</b>
WBC 10e3/uL	10.9	7.5	11.6	12.2	<b>0.0000604</b>
RBC 10e6/uL	4.5	4.6	4.6	4.6	0.4892604
Hemoglobin g/dL	14.3	14.0	13.6	14.1	<b>0.0286131</b>
Hematocrit %	40.6	40.0	39.9	41.8	0.4982775
MCH pg	29.2	28.9	30.1	29.0	0.4300007
MCHC g/dL	33.6	33.6	33.8	33.4	<b>0.0999369</b>
MCV fl	88.2	87.0	85.6	86.6	0.3732769
RDW %	13.4	13.2	13.7	13.4	0.1449352
Platelet Count 10e3/uL	339.8	321.8	342.2	331.7	0.2145699
MPV fl	15.1	13.7	13.5	12.4	0.4743464
Auto Neutrophil %	60.8	59.8	65.1	62.2	0.1310752
Auto Lymphocyte %	28.7	30.4	29.4	27.8	0.2391310
Auto Monocyte %	4.9	8.5	5.2	5.4	<b>0.0001490</b>
Auto Eosinophil %	1.9	5.0	2.3	2.0	<b>6.12099E-11</b>
Auto Basophil %	0.1	0.1	0.0	0.0	0.1665851
Antigen activity of HLA-DR	3.1	1.6	3.2	3.0	<b>0.0000001</b>
Immunoglobulin IgG (g/L)	12.5	12.5	12.4	11.3	0.3021165
Immunoglobulin IgA (g/L)	208.1	168.8	11.6	10.3	<b>1.55982E-09</b>
Immunoglobulin IgM (g/L)	273.0	259.4	264.5	254.6	0.4699069

**Table 4a.***Quality of Life Values*

	Vegetarian N=16		Omnivore N=16		P-Value
	Baseline	12 month	Baseline	12 month	
<b>Physical Health Scale</b>					
Been limited in taking care of him/herself, that is, eating, dressing, or washing him/herself?	3.33	1.10	2.79	3.00	<b>0.00000429</b>
Been limited in walking one block or climbing one flight of stairs?	2.67	1.05	3.04	3.13	<b>0.00001060</b>
Been limited in doing activities that take a lot of energy, such as running, playing soccer, or dancing?	3.14	0.95	2.96	2.88	<b>0.00012189</b>
Been limited in doing schoolwork or activities with friends?	3.33	0.76	2.71	3.00	<b>0.00000095</b>
Had bodily discomfort?	2.86	0.86	2.96	2.94	<b>0.00000214</b>
<b>Psychosocial Health Scale</b>					
Felt sad or blue?	3.29	0.81	3.33	3.38	<b>0.00000087</b>
Felt anxious or acted nervous?	3.00	1.10	2.88	3.00	<b>0.00000126</b>
Had troubles getting along with other children?	2.95	0.71	2.92	2.75	<b>0.00000062</b>
Had difficulty concentrating or paying attention?	3.19	1.00	3.38	2.88	<b>0.00000008</b>
Felt dissatisfied about his/her looks or abilities?	2.95	0.76	2.79	3.13	<b>0.00000004</b>

**Table 5a.***JADAS and Symptom Results*

	Vegetarian N=16		Omnivore N=16		P-Value
	Baseline	12 month	Baseline	12 month	
<b>JADAS Questions</b>					
JADAS Overall Score	11.55	5.24	10.33	11.00	<b>0.00002858</b>
Considering all the ways in which the illness affects your child at this time.	7.05	2.48	7.63	6.69	<b>0.00000003</b>
How much pain do you think your child had because of their illness in the past week?	7.43	2.29	7.33	7.50	<b>0.00000003</b>
Considering the whole sign and symptoms of disease at the time of present visit.	7.19	3.05	7.29	7.19	<b>0.00000179</b>
How many swollen joints does your child have today?	21.76	1.95	18.13	17.06	<b>0.0000000017</b>
What is the duration of morning stiffness in joints?	2.40	0.52	2.44	2.63	<b>0.000000014</b>

## **Chapter 5: Discussion**

Current research suggests no specific dietary interventions for children diagnosed with JIA. Research conducted by Kjeldsen-Kragh, J. et al. (1999), McDougall et al. (2004), and Bustamante et al. (2020) found that following a plant-based or vegetarian diet is positively associated with decreased Rheumatoid Arthritis symptoms. In this chapter, interpretation of the anticipated results will be compared with actual results from the studies listed above. This chapter will discuss the strengths and limitations of this proposed study and it will provide future suggestions for future studies.

### **Interpretation of Results**

This one-year long study will evaluate the effects of a vegetarian diet on children diagnosed with JIA. Quality of life and disease activity will be compared to the same values as those who continue with an omnivorous diet. The anticipated results indicate that the null hypothesis is to be rejected and the alternate hypothesis to be accepted. Anticipated results include statistically significant improvements in disease activity including symptoms and laboratory values as well as perception of quality of life compared to those following an omnivorous diet. At baseline, weight and height was collected, at the 12 month mark, weight for all subjects increased, however no significance was found to determine if weight and other factors such as blood values, quality of life, and symptoms were related.

### **Comparison of a Study Design and Population**

This study included similarities and differences in the methodology and population characteristics when compared with other research involving RA and vegetarian diet intervention. This study focused on juveniles between ages of 8-17 years; the majority of

participants (81.2%) were female and the average age of participants was 13 years old. In the randomized placebo-controlled, single-blinded study by Kjeldsen-Kragh, J. et al (1999), researchers tested a total of 54 adults with RA. 27 of the subjects were in the dietary intervention group and the remaining 26 were in the control group. In this study, the intervention group started the first 7-10 days on a fasting diet. The fasting diet consisted mostly of teas, garlic, vegetable broth, and concentrated vegetable juice. In this study, instead of a fast, campers ate a vegetarian diet during their week at camp. This allowed campers to experience vegetarianism with other campers and consume plant-based foods first hand. For the next three and a half months, the intervention group was on a gluten-free and vegan diet. After the three and a half months, participants followed a lacto-ovo vegetarian diet including gluten for the remaining 10 months. Similar to the structure of this study, Kjeldsen-Kragh, J et al., performed a clinical examination at one, four, seven, 10, and 13 months during the study as well as dietary recalls during intervals.

In the McDougall et al. (2004) study, the population also consisted of adults with RA, mostly female (92%) and made a point to exclude those with other chronic conditions such as heart disease, cancer, and high blood pressure. The intervention was shorter than this study as well as Kjeldsen-Kragh, J et al. (1999). In the McDougall study, the intervention lasted four weeks on adults with RA. The intervention group underwent a low-fat, vegan diet. Similar to this study, McDougall et al. had an educational component during the intervention. Unlike this study, McDougall et al. provided a weekly menu and encouraged subjects to eat “ad libitum” in addition to the menu. The authors of this study stated that due to the educational component of their study as well as providing a menu and encouraging “ad libitum”, the attrition rate was low (22 out of 24 staying in the study). This study, however, did not have a control group. Results of

both studies despite methodology differences, did indicate dietary intervention being significant in RA symptoms and clinical measurements.

For methodology comparison, Bustamante et al. (2020), focused on designing a diet that had a high compliance rate. This study was omnivorous, however the focus was on subjects' eating habits, beliefs on food, accessibility to food, diet schedule, instruction from researchers, and diet strategy to develop a diet. 34 subjects with RA followed a 14 day, Mediterranean diet influenced, low gluten, omnivorous diet. Different amounts of subjects were included in the different stages of diet design. Statistical tests were not conducted to determine adherence as the sample size was too small.

For participation, this study was similar in terms of number of subjects, sex, and attrition to the study compared to other studies, however age and diagnoses of participants differed. Methodology to increase compliance to study as well as effectiveness of dietary intervention mirrored similar studies that had strengths in study design. This study aimed to provide education and resources to subjects to decrease attrition as well as increase effectiveness of a vegetarian intervention (See Appendix F).

### **Comparison of a Vegetarian Diet and RA symptoms**

The anticipated results of this study share similar findings from Kjeldsen-Kragh, J. et al. (1999) and McDougall et al. (2004) regarding a vegetarian dietary intervention and RA symptoms. The results of Kjeldsen-Kragh, J. et al. found that 12 out of the 27 vegetarians were responsive to the diet and the remaining had little to no response clinically. In the control or omnivore group, two out of the 26 had clinical improvements. Similar to the anticipated results of this study, the erythrocyte sedimentation rate (ESR) ( $p < 0.002$ ), c-reactive protein ( $p < 0.005$ ),

white blood cell count ( $p < 0.006$ ), and platelet count ( $p < 0.001$ ) all improved after the 13 month intervention. In addition to laboratory values changing, symptoms including pain ( $p < 0.02$ ), duration of morning stiffness ( $p < 0.0001$ ), tender joints ( $p < 0.0001$ ), and swollen joints ( $p < .02$ ) decreased or improved after intervention. Kjeldsen-Kragh points out several potential explanations that some responded to a vegetarian diet. The first suggestion being that those who responded tend to find that traditional medicine isn't effective in treating RA, thus psychobiology plays a role in influencing results. This effect may be related to placebo effect, however one year after the study, the responders still had clinical effects present in symptoms. The other theory being that decreased energy, protein, vitamin, and mineral intake can lower immune response, which is the most effective treatment in RA.

In the McDougall et al. (2004) study, energy intake and rheumatoid factor was measured in addition to other laboratory values. Results of this study indicate that energy intake decreased ( $p < 0.001$ ). Other laboratory values such as c-reactive protein ( $p < 0.05$ ) and rheumatoid factor ( $p < .004$ ) decreased after dietary intervention. This study found that ESR, using the Westergren method similar to this study, did not alter significantly after intervention ( $p > 0.05$ ). Similar to this study and the study by Kjeldsen-Kragh, pain ( $p < 0.004$ ), ability to function ( $p < 0.001$ ), tender joints ( $p < 0.01$ ), swollen joints ( $p < .02$ ), and morning stiffness ( $p < 0.04$ ) decreased or improved after intervention. Unlike these studies, the duration of morning stiffness did not improve or change ( $p > 0.05$ ).

Similar to Kjeldson-Kragh and McDougall, anticipated findings of this study mirrored statistically significant improvements in clinical laboratory values as well as symptoms after dietary interventions.

### **Comparison of a Vegetarian Diet on Microbiome and RA**

The anticipated results of this study suggests that the antibody for *Proteus mirabilis* was lower in the vegetarian group compared to the omnivore group. This result is similar to those of the diet responders in the Kjeldsen Kragh study as well. They theorize that RA symptoms influenced by changes in the microbiome can occur in several ways. The first theory being that diet changes the fecal flora, thus altering what bacterial substances the mucosa of the intestines absorb which then can influence inflammatory processes in the joints. The second theory is that there can be a relation to RA and the bowel, thus a change in bowel function related to a change in bacteria concentration changes disease activity of RA. The last theory being that there can be an unknown connection that hasn't been truly found yet connecting RA and alterations in the microbiome.

### **Comparison of a Vegetarian Diet on Quality of Life**

Increased anticipated perception of quality of life could be due to a decrease in disease activity. In studies by Mańczak, M., Rutkowska-Sak, L., & Raciborski, F. (2016) and Carle, A. C., Dewitt, E. M., & Seid, M. (2011) quality of life and disease activity are related. Both of these studies mainly took into account disease activity altered via medication, however the concept is similar. Children with less stress regarding pain, limitation to activities, perceived judgements from their peers are likely to have better quality of life outcomes.

**Strengths, Limitations, and Suggestions**

This study has many strengths. The first strength in the study being that subjects were able to choose their diet, thus perhaps increasing compliance with the vegetarian diet. The second strength in the study being that education classes during camp, as well as resource material to guide subjects to make picking vegetarian options easier as well as allowing more flexibility. The third strength of the study being that many children who attend camp have likely gone to this camp before, thus they may have some peer comradery when following this diet for the year's time. I have been a volunteer and dietitian at this camp for many years and likely to build rapport with subjects as well as parents/guardians.

The first limitation of this study is the small population size. The second limitation being that there were different ways the study could have been more comprehensive. For example, having subjects fill out food diaries, more blood tests such as lipid profiles, more nutrient analysis, etc. Providing weekly or monthly menus provided to families could have also made the study stronger. These limitations, however, are suggestions for future researchers who have a larger team, more funds, and larger sample groups. Many of these limitations were also considered during planning. With more questionnaires, food diaries, and blood draws, though there is a risk for higher attrition.

Other suggestions include broadening recruitment to reach out to pediatric rheumatology clinics as well as adding more follow up with both groups one year post study to test for any long term effects of a vegetarian diet.

## **Conclusion**

This review has touched on how diet may influence disease development, disease progression, and disease severity independent of genetic and other environmental factors, for patients with Rheumatoid Arthritis and Juvenile Idiopathic Arthritis. A few theories indicate how diet affects disease development and activity (Calder et al., 2009; Weiss & Ilowite, 2007). Phytochemicals in plant foods, inflammatory proteins and fats in animal products, and the effect of the diversity of the microbiome may be the mode of action for the positive outcomes associated with a vegetarian diet. Vegetarianism has been shown to have positive effects on pathophysiology, disease management and activity, and quality of life. There are concerns about malnutrition or inadequate nutrient intake for those following a vegetarian lifestyle to a plant-forward (plant-based) eating pattern can positively affect many domains of quality of life. Studies used in this review reflect data based on RA in adults. In the JIA population, research on diet in relation to pathophysiology, disease activity, and overall quality of life is limited. The purpose of this research is to address the need to fill in the gaps regarding Juvenile Idiopathic Arthritis and non-pharmaceutical interventions, such as how a vegetarian diet relates to clinical and quality of life outcomes.

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**Appendix A: IRB Form**

**Mount Mary University  
Institutional Review Board (IRB)  
for the Protection of Human Subjects**

Application for IRB Review

**DATA COLLECTION CANNOT BEGIN  
UNTIL THE IRB HAS APPROVED THIS PROJECT**

**Directions:**

- Faculty and student researchers, as well as student research advisors, should **read all relevant information on the University IRB page in My Mount Mary before initiating an application.** This includes full knowledge of the US Department of Health and Human Services Code of Federal Regulations Title 45 (Public Welfare), Part 46 (Protection of Human Subjects). <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.
- All applicants must verify completion of Human Subjects Training. See <http://www.citiprogram.org>.
- The IRB application must be filed and approved by the IRB prior to any Mount Mary University faculty, staff, or student (undergraduate or graduate), initiating a research project/study.
- If there is a cooperating institution, attach a copy of their IRB approval.
- In the case of a student research project, the student may complete the IRB application but the student's research advisor must sign and submit the application to the IRB for approval. It is the responsibility of the faculty research advisor to ensure that student applications and all attachments (e.g., informed consent forms and survey instruments) are in their final edited form. Even though a student research project may qualify as exempt from full IRB review, the research advisor may request the student to complete and submit a full IRB application.
- Complete this application using your word processing program (e.g. Word), then send it on or print it out and obtain signatures from all investigators and advisors. (Handwritten applications will not be accepted.) For your benefit, save the completed application on your computer in case it needs to be revised and resubmitted.
- This is a professional document; please check spelling, grammar and punctuation.
- Submit an electronic copy, via email, of the completed application with required signatures and attachments, in a single pdf, to Tammy Scheidegger, IRB Chair, [scheidet@mtmary.edu](mailto:scheidet@mtmary.edu). You will receive an email verifying receipt of the application.
- Allow a minimum of 30 working days to process your application. Make sure this timeframe is accounted for when considering initiation of data collection and due dates for student projects. Please be aware that if, upon completion of the application, you find that no exemptions apply to your research, your application will need to go through a full IRB Committee review which can take as many as 60 days to be completed.
- For class projects you must submit IRB applications to the IRB Chair by October 31st of the fall semester and March 31st for the spring semester. For summer classes, please consult with the IRB Chair.
- Upon receipt of the IRB letter of approval, data collection may begin.

**I. Required Documentation - No action will be taken without these attachments.**

Are the following attached to the IRB application?

- Informed Consent Document  Yes Informed Consent Documents should include an explanation of procedures, risk, safeguards, freedom to withdraw, confidentiality, offer to answer inquiries, third party referral for concerns, signature and date. See Appendix A and use the **MMU Informed Consent Template to avoid delays in the process.**
  
- Survey/Interview Instrument(s)  Yes If a survey is being administered in any written format (e.g., Google Forms, Survey Monkey, Qualtrics), a copy of that survey must accompany this application. If a survey/interview is being conducted verbally, a copy of the introductory protocol/comments and survey questions being asked must be attached to this application. If survey/interview includes focus group questions, a complete list of the question must be attached. For research using a published/purchased instrument, a photocopy of the instrument will suffice.
  
- Verification of Human Subjects Training  Yes Copy of transcript, certificate or other evidence that ALL members of the research team have completed the required training.
  
- Copy of cooperating institution's IRB approval.  Yes Not required if there is no cooperating institution.

**II. Investigator(s):**

Name:  Phone:

Affiliation with Mount Mary University (e.g. faculty, student, etc.):   
 Email:

Signature:  Date:

Name:  Phone:

Affiliation with Mount Mary University:   
 Email:

Signature:  Date:

**If student, list Research Advisor and complete the application. Research Advisor must provide requested information and verify.**

Research Advisor's Name:  Department:   
 Email:  Phone:

Research Advisor: Have you completed Human Subject's Training?  Yes  No

**Research advisor's signature indicates responsibility for student compliance with all IRB requirements.**

Signature:  Date:   
 Research Advisor

**Individuals who participate in research play an important and active role in the advancement of knowledge. In recognition of their important contributions to research, humans will be referred to as "participants" rather than "subjects."**

**III. Project Description – Required by all applicants**

**Instructions:** Briefly describe the proposed project including the sample and methodology (e.g. human subjects, data collection, data analysis and instruments).

1) Objectives (purpose of project):

The purpose of this study is to determine if a vegetarian diet will mitigate symptoms, improve quality of life, and reduce the overall disease activity of children diagnosed with JIA.

2) Relevance to practice/body of knowledge:

A lack of evidence exists in current literature that explores if a vegetarian diet has any positive or negative effects on the symptoms of children diagnosed with Juvenile Idiopathic Arthritis (JIA). This study will also assess if a vegetarian diet can increase quality of life of those with JIA. Results from this study will assist in potential future dietary recommendations for this population.

3) Describe the research design (e.g. subject/participant selection and assignment, design, intervention, data analysis):

Population- Children diagnosed with JIA from the ages of 8-17. Recruitment will begin at registration for Camp Make Arthritis Stop Hurting (MASH).  
Design and intervention-  
During registration, subjects will fill out consent form and choose which group, vegetarian or omnivore, to participate in. During the week long, over night, camp vegetarian subjects will participate in nutrition activities to learn what to eat healthfully in a vegetarian diet, it's benefits, and ask questions. Parents will also be given educational material to facilitate a healthful vegetarian diet. A survey completed by parents or older subjects will be completed at baseline, three months, six months, nine months, and 12 months. Blood draws will also be taken at the coordinating times. Protocols for this will be followed under consideration and policies in place by the IRB and other legal entities. Following the pediatric procedures for blooddrawing provided by the IRB will be followed. With permission from the Medical College of Wisconsin IRB, human subject research can occur at various locations in Wisconsin including the Versell Blood Center of Wisconsin, Children's Hospital of Wisconsin, and the Froedert Health System which includes its health clinics and hospitals.  
Data analysis will consist of using google sheets and T-test calculation to determine p-value.

4) What measurement/data collection tools are being used?  
Google Forms will facilitate the survey that includes questions regarding quality of life and symptom questions. JADAS (Juvenile Arthritis Disease Activity Score) will be used to determine disease activity. Paediatric Rheumatology Quality of life Scale (PRQL) to determine a score for perception of quality of life.

**IV. Additional Project Information – Required by all applicants**

1) What human subjects training has the researcher completed (e.g. course work, online certification)?

2) What process is used for obtaining informed consent? See Appendix A for consent content requirements and use the template, available on the MMU IRB webpage, when constructing your informed consent form. A written letter requiring signature to participate in the program.

- 3) Does the research include special populations?
- Minors under 18 years of age?  Yes  No
  - Persons legally incompetent?  Yes  No
  - Prisoners?  Yes  No
  - Pregnant women, if affected by research?  Yes  No
  - Persons institutionalized?  Yes  No
  - Persons mentally incapacitated?  Yes  No

*If **YES**, describe additional precautions included in the research procedures.*

- 4) Does the research involve any of the following procedures?
- False or misleading information to subjects?  Yes  No
  - Withholds information such that their informed consent might be questioned?  Yes  No
  - Uses procedures designed to modify the thinking, attitudes, feelings, or other aspects of the behavior of the subjects?  Yes  No

*If **YES**, describe the rationale for using procedures, how the human subjects will be protected and what debriefing procedures are used.*

5) Does the research involve measurement in any of the following areas?

- Sexual behaviors?  Yes  No
- Drug use?  Yes  No
- Illegal conduct?  Yes  No
- Use of alcohol?  Yes  No

***If YES, describe additional precautions included in the research procedures.***

6) Are any portions of the research being conducted online?

- Survey posted on a website?  Yes  No
- URL for survey includes information that could identify participants?  Yes  No
- Invitation to participate sent by email?  Yes  No
- Items use drop-down box?  Yes  No  
If yes, assure that items allow choice of “no response”
- Will you be recording virtual interviews?  Yes  No  
 Audio only  Video only  Audio & Video  
 If video recording is being used, assure anonymity by only recording audio unless the research necessitates visual recording.

***If YES, to any of the above items, describe additional procedures.***

The survey will be sent by using Google Forms by invitation only by researcher. The notification for the survey will be notified by email to parents of subjects. No personal information will be included on surveys.

7) Describe the methods used to ensure confidentiality of data obtained.

For the safety of the subject's data and subject information will be kept private under collaborators' supervision using password coded forms and documents. Coding will take place using Google 's R style guide using Google Sheets only shared with collaborators and locked to those not approved to view documents and research data. Google sheets will also be used to track subject data including survey results and bloodwork results

**Risks and Benefits**

1) Describe risks to the subjects and the precautions that will be taken to minimize them. (Risk includes any potential or actual physical risk of discomfort, harassment, invasion of privacy, risk of physical activity, risk to dignity and self-respect, and psychological, emotional or behavioral risk.)

Participants in the vegetarian group will be asked to follow a ovo-lacto vegetarian diet for one complete year. This time line assures that a diet long term will serve with potential useful data. The diet itself should be minimal risk to subjects. Blood draws have risks associate, but minimal. Blood drawing will comply with IRB expectations and regulations.

2) Describe the benefits to subjects and/or society. (These will be balanced against risk.)

The vegetarian subjects may experience lower disease activity and less swelling and pain in joints and may experience higher quality of life. This survey may also help create dietary recommendations to children recently diagnosed with JIA or those who have a flare/increased disease activity reach remission or lower disease activity.

**V. Is the proposed project “research” as defined by Institutional Review Board requirements? - Required by all applicants**

Per 45 CFR 46.102: “Research is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes.”

Per HHS.gov and the Office for Human Subjects Research (<https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-activities-deemed-not-be-research-public-health-surveillance/index.html#:~:text=For%20purposes%20of%20the%202018,by%20a%20public%20health%20authority>), the following activities are deemed **not** to be research:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

A human subject is defined as a living individual about whom an investigator obtains either 1) data through intervention or interaction with the individual; or 2) identifiable private information. In social science research, human subjects may be referred to as research subjects or research participants.

Does the research involve human subjects/participants or official records about human subjects/participants?  
 Yes  No

*If “no”, STOP here, and submit application.*

If the results will be available in the library, presented at a professional conference (includes any presentation to group(s) outside of the classroom), or published, please check the Yes box:  
 Yes  No

*If “yes”, proceed to SECTION VI.*

*If “no”, STOP here, and submit application.*

**VI. Exemptions - Required by all applicants**

Are you requesting exemption from IRB review in one of the federally approved categories?  
 Yes  No

*If yes, please reference OHRP website <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html> and continue with application.*

- 1) Does the research meet the criteria for exempt category 1 (education)? [45 CFR 46.104(d)(1)]? Is the research conducted in established or commonly accepted educational settings (e.g. schools, Universities, or other sites where educational activities regularly occur)?

Yes  No

## **Appendix B: Consent Form**

**Title of study:** The Effects of a Vegetarian diet on Juvenile Idiopathic Arthritis:

**Invitation to participate and purpose of study:** You are invited to participate in a study that will evaluate the effects a vegetarian diet has on disease activity of children diagnosed with Juvenile Idiopathic Arthritis (JIA). This study may also help researchers determine other treatment options for similar diseases such as lupus, adult rheumatoid arthritis, or other autoimmune/rheumatic diseases. This study will be at no financial cost to you.

**Study Length:** The expected length of time the participant will participate in the study will be a full year after the first day of Camp Make Arthritis Stop Hurting (MASH). The first day of camp is Sunday, August 6, 2023 and the last day of the study is Tuesday, August 6, 2024

**Required Procedures:** Google surveys will be sent to you via email a week before camp and 3 months, 6 months, 9 months, and 12 months after camp. For data Collection, Google Forms will be used for questionnaire data. Bloodwork is also required for this study and the intervals will be the same as the questionnaire. For the blood draw, the researchers will coordinate with you on the location and time of the blood draw. For ease, we will help coordinate with already scheduled blood draws at the discretion of your physician. We will be looking at different values including: erythrocyte sedimentation rate, c-reactive protein, and count of blood cells, antigen activity of HLA-DR4, and immunoglobulin IgG, IgA, and IgM. Weight and height will be taken at baseline and the 12 month mark. We will weigh and take your child's height at check-in for camp. For the 12 month mark, you will be asked to provide us with documentation from a recent visit with a physician that includes a height and weight.

**Risks and Discomforts:** Foreseeable risks or discomforts may come from the questions from our surveys, the blood draws, as well as adhering to a new diet. A new diet can be a lifestyle change that takes some getting used to. Risks include no change or an increase in disease activity or a lower quality of life.

**Benefits:** Benefits of participating will help researchers and healthcare professionals understand potential treatments for children with JIA. As a subject, your child may experience a decrease in symptoms from JIA or a quality of life increase.

**Alternates, Noncoercive Disclaimer and Right to Withdraw:** You can always withdraw or

reject participating in this study. Participation is voluntary and your child and family may exit the study at any time without penalty.

**Compensation and Medical Treatment in Event of Injury:** A statement as to whether there will be any compensation or reimbursement for expenses such as travel, as well as medical treatment available in case of injury.

**Contact Person for Questions:** If you have any questions about the research, your/your child's rights regarding this study, and who the participant should contact in the event of a research-related injury, please contact Jessica Christensen at 262-498-1740 or [jchri@mtmary.edu](mailto:jchri@mtmary.edu)

**Confidentiality:** Your child's medical information and other personal information will be and remain confidential to only the researchers in this project.

**Consent:** By signing below, you are indicating that you have read and agreed to this consent form. You also agree that you and your child agreed to voluntarily participate in this study and have been given the opportunity to ask questions. As stated above, you may withdraw from the study without penalty.

Signature of Participant \_\_\_\_\_ Date: \_\_\_\_\_

Signature of Parent/Guardian: \_\_\_\_\_ Date: \_\_\_\_\_

### **Additional Components**

*There are unforeseeable or unknown risks to the participant. Per IRB, blood draws are a minimal*

*risk and the researchers will be following policies and procedures under the IRB for pediatric*

*research. Participation in this study may be terminated under certain circumstances. You will be*

*notified about new findings from the study that could affect your willingness to continue participation.*

**Appendix C: Assent Form**

**Name of study:** The Effects of a Vegetarian diet on Juvenile Idiopathic Arthritis:

**Invitation to study:** You are invited to be in a study that will help us know if a vegetarian diet helps with symptoms of your Arthritis. This study costs no money to be in.

**Study Length:** The time you'll be in the study will be a full year after the first day of Camp Make Arthritis Stop Hurting (MASH). The first day of camp is Sunday, August 6, 2023 and the last day of the study is Tuesday, August 6, 2024

**What will you do during the study?** You, with the help of your parent(s) will fill out Google surveys. You will get a survey in an email one week before camp and three months, six months, nine months, and 12 months after camp. You will also need to do blood draws. For the blood draw, the researchers will coordinate with you on where to go and time of the blood draw. For ease, we will help schedule blood draws with your doctor. We will be looking at different labs to see if your blood is showing improvements. Weight and height will be taken before camp and the 12-month mark. We will weigh and take your height at check-in for camp. For the 12-month mark, you will be asked to give us notes from a recent visit with a doctor that includes a height and weight.

**Risks and Discomforts:** There may be risks or discomforts from the questions from our surveys, the blood draws, as well as being on a new diet. A new diet can be hard and takes some getting used to. Risks include no change or an increase in symptoms or a lower quality of life.

**Benefits:** Benefits of being in the study will help us and doctors to understand potential treatments for children with JIA. You may have less symptoms from JIA or better quality of life.

**Right to Withdraw:** You can always leave or reject participating in this study. Participation is voluntary and you and your family may exit the study at any time without penalty.

**Compensation and Medical Treatment in Case of Injury:** Medical treatment is available in case of injury.

**Contact Person for Questions:** If you have any questions about the study, your rights with this study, and who you should contact in the event of a research-related injury, please call Jessica Christensen at 262-498-1740 or email [jchri@mtmary.edu](mailto:jchri@mtmary.edu)

**Confidentiality:** Your medical information and personal information will be private to only the researchers in this project.

**Consent:** If you sign this sheet, you are letting us know that you have read and are okay to be in the study. You also agree that you are volunteering to be in this study and have been able to ask questions. You may leave the study without penalty.

Signature of Participant \_\_\_\_\_ Date: \_\_\_\_\_

Signature of Parent/Guardian: \_\_\_\_\_ Date: \_\_\_\_\_

**Additional Components**

*There are unforeseeable or unknown risks to the participant. Per IRB, blood draws are a minimal risk and the researchers will be following policies and procedures under the IRB for pediatric research. Participation in this study may be terminated under certain circumstances. You will be notified about new findings from the study that could affect your willingness to continue participation.*

**Appendix D: IRB Guidelines for Blood Draws and Versiti Blood Center of Wisconsin's Privacy Policy**

IRB policy and guidelines regarding blood draws with certain constraints in children under the age of 18:

- a. For children older than 2 years of age, one research phlebotomy only for children under 6 years of age, with a limit of 3 attempts; remainder of planned blood draws should be coordinated to occur at the time of clinical care draws; use of local anesthetic left to judgment of phlebotomist.
- b. For children older than **6 years of age but less than 12 years of age**, 2 research phlebotomies at least 28 days apart, with a limit of 3 attempts at each procedure; remainder of planned blood draws should be coordinated to occur at the time of clinical care draws; use of local anesthetic left to judgment of phlebotomist.
- c. For children **older than 12 years of age**, 3 research phlebotomies at least 28 days apart between each procedure, with a limit of 3 attempts at each procedure; remainder of planned blood draws should be coordinated to occur at the time of clinical care draws; use of local anesthetic left to judgment of phlebotomist.
- d. Maximum allowable volumes (Clinical & Research combined): 2.5% of total blood volume, with 7.0 Hgb minimum; refer to blood volume allowable draw by weight below
- e. Keep in mind that regardless of allowable volumes, phlebotomy on children under 2 years of age is not considered minimal risk and must be reviewed by a full committee.

## Privacy Policy

Last modified: March 12, 2021

### 1. Introduction

This Privacy Policy describes how Versiti collects and uses Personal Data about you through the use of our website and mobile application and through email, text, and other electronic communications between you and Versiti.

Versiti respects your privacy, and we are committed to protecting it through our compliance with this policy ("**Privacy Policy**"). The terms "**Versiti**," or "**we**," "**our**," or "**us**," used throughout this Privacy Policy refer to and include Versiti, Inc., Versiti Blood Research Institute Foundation, Inc., Versiti Illinois, Inc., Versiti Indiana, Inc., Versiti Michigan, Inc., and Versiti Wisconsin, Inc.

This Privacy Policy describes the types of information we may collect from you or that you may provide when you visit the website Versiti.org and the Versiti Donor mobile application (collective, the "Site"), and our practices for collecting, using, maintaining, protecting, and disclosing that information. This Privacy Policy does not apply to information collected by us offline or through other means and does not apply to information collected by any third party, including through any application or content that may link to or be accessible from or on the Site.

If you are using the Site on behalf of your employer, company, or organization (the "**Organization**"), you represent and warrant that you have the authority to accept this Privacy Policy on behalf of the Organization. If you (and your Organization, if applicable) do not agree to our Privacy Policy, please do not use the Site. The term "you," "your," etc. refers to both you as an individual user and your Organization (if applicable).

Please read this Privacy Policy carefully to understand our policies and practices regarding your information and how we will treat it. If you do not agree with our policies and practices, your choice is not to use our Site. By accessing or using our Site, you agree to this Privacy Policy. This Privacy Policy may change from time to time (see Changes to Our Privacy Policy). Your continued use of our Site after we make changes is deemed to be acceptance of those changes, so please check this Privacy Policy periodically for updates.

## 2. Protected Health Information

This Privacy Policy applies to information collected through the Site. Please review our separate Notice of Privacy Practices that describes our privacy practices regarding your protected health information.

Some information Versiti collects constitutes protected health information ("PHI") under the U.S. Health Insurance Portability and Accountability Act ("HIPAA"). Versiti provides you with a Notice of Privacy Practices describing how we collect, use, maintain, protect, and disclose your PHI.

## 3. Children Under the Age of 13

Our Site is not intended for children under the age of 13 and children under the age of 13 are not permitted to use our Site. We will remove any information about a child under the age of 13 if we become aware of it.

Our Site is not intended for children under 13 years of age. No one under age 13 may provide any information to us or through the Site. We do not knowingly collect Personal Data from children under 13. If you are under 13, do not use or provide any information on our Site or on or through any of its features, including your name, address, telephone number, email address, or any screen name or user name you may use. If we learn we have collected or received Personal Data from a child under 13 without verification of parental consent, we will delete that information. If you believe we might have any information from a child under 13, please contact us [privacyofficer@versiti.org](mailto:privacyofficer@versiti.org) or call us at (414) 937-6418.

## 4. Information We Collect About You and How We Collect It

We collect different types of information about you, including information that may directly identify you, information that is about you but individually does not personally identify you, and information that we combine with our other users. This includes information that we collect directly from you or through automated collection technologies.

### Generally

We collect several types of information from and about users of our Site (collectively, "**Personal Data**"), specifically information:

- by which you may be personally identified, such as name, home address, billing address, e-mail address, telephone numbers, bank account, credit, or debit card information (for processing donation payments only), date of birth, gender, your medical history, health information, and other information you chose to submit to us; and
- about your Internet connection, the equipment you use to access and use our Site, and usage details, such as traffic data, logs, referring/exit pages, date and time of your visit to or

use of our Site, error information, clickstream data, and other communication data and the resources that you access and use on or through our Site.

**We collect this information:**

- directly from you when you provide it to us;
- automatically as you navigate through the Site. Information collected automatically may include usage details, IP addresses, and information collected through cookies and other tracking technologies; and
- From third parties, for example, our business partners.

**Information You Provide Us**

The information we collect on or through our Site is:

- information that you provide by filling in forms on Site. This includes information provided at the time of registering with us or requesting our services. We may also ask you for information when you report a problem with our Site;
- records and copies of your correspondence (including email addresses), if you contact us; and
- details of transactions you carry out through our Site.

**Information We Collect Through Automatic Data Collection Technologies**

As you navigate through and interact with our Site, we may use automatic data collection technologies to collect certain information about your equipment, browsing actions, and patterns, specifically:

- details of your visits to our Site, such as traffic data, location, logs, referring/exit pages, date and time of your visit to our Site, error information, clickstream data, and other communication data and the resources that you access and use on our Site; and
- information about your computer, mobile device, and Internet connection, specifically your IP address, operating system, browser type, and mobile application version information.

Our mobile applications collect real-time information about the location of your device. If you do not want us to collect this information do not download the mobile app or delete it from your device. You can also choose whether or not to allow our mobile app to collect and use real-time information about your device's location through the device's privacy settings. If you block the use of location information, some parts of our mobile application may then be inaccessible or not function properly.

The information we collect automatically may include Personal Data or we may maintain it or associate it with Personal Data we collect in other ways or receive from third parties. It helps us to improve our Site and to deliver a better and more personalized service by enabling us to:

- estimate our audience size and usage patterns;
- improve our business operations and services offering;
- store information about your preferences, allowing us to customize our Site according to your individual interests; and
- recognize you when you return to our Site.

The technologies we use for this automatic data collection may include:

- **Cookies (or browser cookies).** We and our service providers may use cookies, web beacons, and other technologies to receive and store certain types of information whenever you interact with our Site through your computer or mobile device. A “cookie” is a small piece of data sent from a website and stored on the user’s computer by the user’s web browser while the user is browsing. On your computer, you may refuse to accept browser cookies by activating the appropriate setting on your browser, and you may have similar capabilities on your mobile device in the preferences for your operating system or browser. However, if you select this setting you may be unable to access certain parts of our Site. Unless you have adjusted your browser or operating system setting so that it will refuse cookies, our system will issue cookies when you use or direct your browser to our Site.
- **Google Analytics.** We use Google Analytics, a web analytics service provided by Google, Inc. (“Google”) to collect certain information relating to your use of the Site. Google Analytics uses cookies to help the Site analyze how users use the site. You can find out more about how Google uses data when you visit our Site by visiting “How Google uses data when you use our partners’ sites or apps,” (located at <https://www.google.com/policies/privacy/partners/>). For more information regarding Google Analytics please visit Google’s website, and pages that describe Google Analytics, such as <https://www.google.com/analytics/learn/privacy.html>.

## 5. How We Use Your Information

We use your Personal Data for various purposes described below, including to:

- provide our Site to you;
- provide you with information you request from us;
- enforce our rights arising from contracts;
- notify you about changes; and
- to provide you with information about your donor account.

We use information that we collect about you or that you provide to us, including any Personal Data:

- to present our Site and its contents to you;

- to provide you with information, products, or services that you request from us or that may be of interest to you;
- to process, fulfill, support, and administer donations and other program or service related transactions (including processing credit card and debit card transactions) that you request and we agreed to provide;
- to register and service your Versiti account;
- to contact you in response to a request;
- to administer quizzes, surveys, sweepstakes, promotions, and contests;
- to fulfill any other purpose for which you provide it;
- to carry out our obligations and enforce our rights arising from any contracts entered into between you and us;
- to notify you about changes to our Site, or any related products or services we offer or provide through the Site;
- in any other way we may describe when you provide the information; and
- for any other purpose with your consent.

We may also use your information to contact you about goods and services that may be of interest to you, including through newsletters. If you wish to opt-out of receiving such communications, you may do so at any time by clicking unsubscribe at the bottom of these communications or by visiting your Account Preferences page. For more information, see Choices About How We Use and Disclose Your Information.

As set forth above, Versiti provides a Notice of Privacy Practices describing our use of PHI. Versiti will use PHI only as described in the Notice of Privacy Practices.

#### **6. Disclosure of Your Information**

We do not share, sell, or otherwise disclose your Personal Data for purposes other than those outlined in this Privacy Policy. We may disclose your Personal Data to a few third parties, including:

- our affiliates and third party service providers that we use to support our business;
- to a company we merge, acquire, or that buys us, or in the event of change in structure of our company of any form;
- to comply with our legal obligations;
- to enforce our rights; and
- with your consent.

We do not share, sell, or otherwise disclose your Personal Data for purposes other than those outlined in this Privacy Policy. However, we may disclose de-identified, aggregated information about our users without restriction.

We may disclose Personal Data that we collect or you provide as described in this Privacy Policy:

- to affiliates, contractors, service providers, and other third parties we use to support our business and our Site (e.g., data storage, data processing, marketing, IT support, etc.) including to process and administer donation transactions (our payment processor's privacy policy may be found at <https://www.blackbaud.com/company/privacy-policy/north-america>);
- to a buyer or other successor in the event of a merger, divestiture, restructuring, reorganization, dissolution, or other sale or transfer of some or all of our assets, whether as a going concern or as part of bankruptcy, liquidation, or similar proceeding, in which Personal Data held by Versiti about our Site users are among the assets transferred;
- to fulfill the purpose for which you provide it;
- for any other purpose disclosed by us when you provide the information; and,
- with your consent.

We may also disclose your Personal Data:

- to comply with any court order, law, or legal process, including to respond to any government or regulatory request;
- to enforce or apply our Terms of Use and other agreements; and,
- if we believe disclosure is necessary or appropriate to protect the rights, property, or safety of Versiti, our donors, customers, supporters, partners, or others. This includes exchanging information with other companies and organizations for the purposes of fraud protection and credit risk reduction.

As set forth above, Versiti provides a Notice of Privacy Practices describing our disclosure of PHI. Versiti will disclose PHI only as described in the Notice of Privacy Practices.

## 7. Choices About How We Use and Disclose Your Information

We offer you choices on how you can opt out of our use of tracking technology and disclosure of your Personal Data for our advertising to you.

We strive to provide you with choices regarding the Personal Data you provide to us. We have created mechanisms to provide you with control over your Personal Data:

- **Tracking Technologies and Advertising.** You can set your browser or operating to refuse all or some cookies, or to alert you when cookies are being sent. If you disable or refuse cookies, please note that some parts of our Site may then be inaccessible or not function properly.
- **Location Information.** You can choose whether or not to allow our mobile application to collect and use real-time information about your device's location through the device's privacy settings. If you block the use of location information, some parts of the mobile application may then be inaccessible or not function properly.

- **Promotional Emails from Versiti.** If you do not wish to have your email address used by Versiti to promote our own products and services, you can opt-out at any time by clicking the unsubscribe link at the bottom of any email or other marketing communications you receive from us. This opt out does not apply to information provided to Versiti as a result of your use of our services.
- **Text Messages from Versiti.** If you do not wish to receive informational text messages from Versiti, you can opt-out at any time by texting the word STOP in response to any text message you receive. We may confirm your opt out by text message.

#### **8. Your Rights and Choices Regarding Your Information and Accessing and Correcting Your Information**

You may review and change your personal information by contacting us or by visiting your donor account page.

Please Contact Us if you have any questions or concerns about our collection or use of your Personal Data. You can access and modify certain Personal Data we have about you through our your donor account page on our Site or you can contact us email or otherwise as indicated in our Contact Information below. Please notify us of any changes or errors in any Personal Data we have about you to ensure that it is complete, accurate, and as current as possible or to delete your Versiti accounts. We may not be able to delete certain Personal Data if we believe it would violate any law or legal requirement or cause the information to be incorrect. You have certain rights under HIPAA with respect to your PHI. Please review our Notice of Privacy Practices for more information.

#### **9. Do Not Track Signals**

We currently do not use automated data collection technologies to track you across websites. We currently do not honor do-not-track signals that may be sent by some browsers.

Some web browsers permit you to broadcast a signal to websites and online services indicating a preference that they “do not track” your online activities. At this time, we do not honor such signals, but we currently do not use automated data collection technologies to collect information about your online activities over time and across third party websites or other online services (behavioral tracking).

#### **10. Data Security**

Information transmitted over the Internet is not completely secure, but we do our best to protect your Personal Data. You can help protect your Personal Data and other information by keeping your login credentials to your donor account confidential.

We have implemented data security measures designed to secure your Personal Data from accidental loss and from unauthorized access, use, alteration, and disclosure. We use encryption technology for information sent and received by us.

The safety and security of your information also depends on you. Where you have chosen a password in connection with the use of our Site, you are responsible for keeping this password confidential. You should not share your password with anyone.

Unfortunately, the transmission of information via the Internet is not completely secure. Although we do our best to protect your Personal Data, we cannot guarantee the security of your Personal Data transmitted to our Site. Any transmission of Personal Data is at your own risk. We are not responsible for circumvention of any privacy settings or security measures contained on the Site, or in your operating system.

#### **11. Changes to Our Privacy Policy**

We will post any changes to our Privacy Policy on our Site. If we make material changes to our Privacy Policy, we may notify you of such changes through your contact information and invite you to review (and accept, if necessary) the changes.

We may change this Privacy Policy at any time. It is our policy to post any changes we make to our Privacy Policy on this page with a notice that the Privacy Policy has been updated on the Site's home page. If we make material changes to how we treat our users' Personal Data, we will notify you by email to the email address we have on file for you and/or through a notice on the Site's home page. The date this Privacy Policy was last revised is identified at the top of the page. You are responsible for ensuring we have an up-to-date active and deliverable email address for you, and for periodically visiting our Site and reviewing this Privacy Policy to check for any changes.

#### **12. Contact Information**

You may contact us through the contact information below.

If you have any questions, concerns, complaints, or suggestions regarding our Privacy Policy or otherwise need to contact us, you may contact us at the contact information below or through the Customer Service page on our Site.

#### **How to Contact Us:**

Versiti, Inc.  
638 North 18th Street

Milwaukee, Wisconsin 53233

Attention: Privacy Officer

Telephone: (414) 937-6418

Email: [privacyofficer@versiti.org](mailto:privacyofficer@versiti.org)

**Appendix E: Questionnaire at Time Intervals**

## Questionnaire

Questions are, with permission, from the Biomedical Center: Pediatric Rheumatology Quality of Life Scale  
<https://ped-rheum.biomedcentral.com/articles/10.1186/1546-0096-11-43/tables/2>

1. Considering the past 3 months, how often has your child been limited in taking care of him/herself, that is, eating, dressing, or washing him/herself?

*Mark only one oval.*

1	2	3	4
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

2. Considering the past 3 months, how often has your child had troubles getting along with other children?

*Mark only one oval.*

1	2	3	4
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3. Considering the past 3 months, how often has your child had difficulty concentrating or paying attention?

*Mark only one oval.*

1	2	3	4
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4. Considering the past 3 months, how often has your child felt dissatisfied about his/her looks or abilities?

Mark only one oval.

	1	2	3	4
<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; border-radius: 50%; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; border-radius: 50%; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; border-radius: 50%; width: 20px; height: 20px; margin: 0 auto;"></div> <div style="border: 1px solid black; border-radius: 50%; width: 20px; height: 20px; margin: 0 auto;"></div> </div>				

5. Considering all the ways in which the illness affects your child at this time, please indicate how your child is doing by filling in a circle

	VERY WELL		VERY POORLY	
		<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="display: flex; gap: 5px;"> <span>0</span><span>0.5</span><span>1</span><span>1.5</span><span>2</span><span>2.5</span><span>3</span><span>3.5</span><span>4</span><span>4.5</span><span>5</span><span>5.5</span><span>6</span><span>6.5</span><span>7</span><span>7.5</span><span>8</span><span>8.5</span><span>9</span><span>9.5</span><span>10</span> </div> </div>		

---

6. How much pain do you think your child had because of their illness in the past week? Please fill in the circle to indicate how severe your child's pain has been

	VERY WELL		VERY POORLY	
		<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="display: flex; gap: 5px;"> <span>0</span><span>0.5</span><span>1</span><span>1.5</span><span>2</span><span>2.5</span><span>3</span><span>3.5</span><span>4</span><span>4.5</span><span>5</span><span>5.5</span><span>6</span><span>6.5</span><span>7</span><span>7.5</span><span>8</span><span>8.5</span><span>9</span><span>9.5</span><span>10</span> </div> </div>		

---

7. Considering the whole sign and symptoms of disease at the time of present visit, please indicate what your rheumatologist would say the overall level of disease activity.

	NO ACTIVITY		MAXIMUM ACTIVITY
		<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="display: flex; gap: 5px;"> <span>0</span><span>0.5</span><span>1</span><span>1.5</span><span>2</span><span>2.5</span><span>3</span><span>3.5</span><span>4</span><span>4.5</span><span>5</span><span>5.5</span><span>6</span><span>6.5</span><span>7</span><span>7.5</span><span>8</span><span>8.5</span><span>9</span><span>9.5</span><span>10</span> </div> </div>	

---

8. Considering the past 3 months, how often has your child felt anxious or acted nervous?

*Mark only one oval.*

1	2	3	4	5
<input type="radio"/>				

9. Considering the past 3 months, how often has your child felt sad or blue?

*Mark only one oval.*

1	2	3	4
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

10. Considering the past 3 months, how often has your child had bodily discomfort?

*Mark only one oval.*

1	2	3	4
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

11. Considering the past 3 months, how often has your child been limited in doing schoolwork or activities with friends?

*Mark only one oval.*

1	2	3	4
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

12. Considering the past 3 months, how often has your child been limited in doing activities that take a lot of energy, such as running, playing soccer, or dancing?

*Mark only one oval.*

1	2	3	4
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

13. Considering the past 3 months, how often has your child been limited in walking one block or climbing one flight of stairs?

*Mark only one oval.*

1	2	3	4
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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Google Forms

## Appendix F: Education Material for Parent/Guardians and Subjects

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Guidelines for the introduction of solid foods are the same for vegetarian and non-vegetarian infants. Breastfed infants 6 months and older should get iron from foods, such as iron-fortified infant cereal.

After an infant starts eating solids, protein-rich vegetarian foods can include pureéd tofu, cottage cheese, yogurt or soy yogurt, and pureéd and strained legumes (such as beans, split peas, chickpeas, and lentils).

### What About Vegetarian Toddlers?

Toddlers are already a challenge when it comes to eating. As they come off of breast milk or formula, pay extra attention to offering iron-rich foods, including iron-fortified cereals.

Toddlers are typically picky about which foods they'll eat. Vegetarian toddlers also may feel full before they get enough of the calories and nutrients they need. That's because the amount of vegetables served might be too bulky for their tiny stomachs. Use snack time to boost nutrition by offering healthy food between meals.

Talk to the doctor to see if your toddler needs a vitamin or mineral supplement.

### Older Vegetarian Kids and Teens

Preteens and teens often voice their independence through the foods they choose to eat. One strong statement is the decision to stop eating meat.

If it's done right, a meat-free diet can be a good choice for teens, especially considering that vegetarians often eat more of the foods that most teens don't get enough of — fruits and vegetables.

A vegetarian diet that includes dairy products and eggs (lacto-ovo) is the best choice for growing teens. A more strict vegetarian diet can meet your teen's nutritional needs, but will need more attention and planning. If you're concerned that your child is not getting enough important nutrients such as iron, calcium, and vitamins D and B12, talk to your doctor, who may recommend a vitamin and mineral supplement.

The good news for young vegetarians — and their parents — is that many schools have vegetarian fare, including salad bars and other healthy vegetarian choices. Check your school's upcoming lunch menus to see if your child will have a vegetarian choice. If not, you can pack lunch.

If your child would rather make their own school lunch or buys lunch, keep in mind that their idea of a healthy vegetarian meal may be much different from yours (e.g., French fries and a soda). Talk to your child about the importance of eating right, especially when following a vegetarian diet.

Also be wary if your child has self-imposed a very restrictive diet. A teen with an eating disorder may drastically reduce calories or cut out all fat or carbohydrates and call it "vegetarian" because it's considered acceptable and healthy.

Even if preteens or teens approach vegetarian diets in a healthy way, it's still important for them to understand which nutrients might be missing. To support your child's choice and focus on what they should be eating, consider having the whole family eat a vegetarian meal at least one night a week.

### A Healthy Lifestyle

A vegetarian diet can be a healthy choice for all kids, as long as it's planned well.

The basics of a vegetarian diet are the same as for any healthy diet — provide a variety of foods including plenty of fruits and vegetables, whole grains, legumes (like beans, soy, and lentils), nuts, and seeds. Be careful when it comes to processed foods, which tend to be low in nutrients and high in fat, calories, and salt.

If you aren't sure your child is getting all needed nutrients or if you have any questions about vegetarian diets, check in with your family doctor, pediatrician, or a registered dietitian.

**Reviewed by:** Mary L. Gavin, MD

Date reviewed: January 2021

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When you don't pick it off the vine yourself, how do you know produce is fresh? From green beans to cantaloupe, all fruits and vegetables give hints about their ripeness and freshness:

- Choose vegetables that look fresh and colorful. Most should be crisp and firm. Don't buy vegetables if they're limp or showing signs of decay.
- When choosing fruits, avoid bruised pieces, but remember that a perfect exterior doesn't necessarily mean the best quality.
- Careful storage means that fresh produce will last longer. Some vegetables will keep in the refrigerator for a couple of days. Others, including cabbage and root vegetables like carrots, will keep even longer. Store potatoes and onions in a cool, dark place for maximum freshness. Plan to use delicate fruits and vegetables first, and hardier ones later in the week.

#### **Frozen and Canned Fruits and Veggies**

Fresh produce is delicious, but frozen and canned fruits and vegetables are convenient. Frozen and canned fruits and veggies last longer and are as nutritious as fresh. Choose products without sauces or added sugar. With canned fruits, look for ones that are packed in juice, not syrup.

And just as you wouldn't buy fruit that's bruised, don't buy a package of frozen vegetables if the bag is ripped or the box is soggy or torn. With canned products, watch out for any can that has a large dent, looks swollen, or leaks.

#### **Make Room for a Treat**

As you focus on a healthy lifestyle for your family, you might be tempted to ban snacks and treats. But completely cutting out sweets and favorite snacks can backfire. If kids feel deprived, they might overeat off-limits foods when they're not home.

Instead of taking a hard line or completely giving in, find a balance. Try not to talk about "bad foods," and let your kids choose an occasional treat at the grocery store or at home. A child who likes chips and dip, for instance, could choose a lower-fat bag of chips and a jar of salsa at the store. When you get home, put out small bowls of chips and salsa and it's snack time!

**Reviewed by:** Mary L. Gavin, MD

Date reviewed: August 2020

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## Healthy Eating

Whether you have a toddler or a teen, here are five of the best strategies to improve nutrition and encourage smart eating habits:

1. Have regular family meals.
2. Serve a variety of healthy foods and snacks.
3. Be a role model by eating healthy yourself.
4. Avoid battles over food.
5. Involve kids in the process.

Sure, eating well can be hard — family schedules are hectic and grab-and-go convenience food is readily available. But our tips can help make all five strategies part of your busy household.

### Family Meals

Family meals are a comforting ritual for both parents and kids. Children like the predictability of family meals and parents get a chance to catch up with their kids. Kids who take part in regular family meals are also:

- more likely to eat fruits, vegetables, and grains
- less likely to snack on unhealthy foods
- less likely to smoke, use marijuana, or drink alcohol

Also, family meals are a chance for parents to introduce kids to new foods and to be role models for healthy eating.

Teens may turn up their noses at the prospect of a family meal — not surprising because they're busy and want to be more independent. Yet studies find that teens still want their parents' advice and counsel, so use mealtime as a chance to reconnect.

You might also try these tips:

- Let kids invite a friend to dinner.
- Involve your child in meal planning and preparation.
- Keep mealtime calm and friendly — no lectures or arguing.

What counts as a family meal? Whenever you and your family eat together — whether it's takeout food or a home-cooked meal with all the trimmings. Strive for nutritious food and a time when everyone can be there. This may mean eating dinner a little later to accommodate a teen who's at sports practice. It also can mean setting aside time on the weekends when it may be more convenient to gather as a group, such as for Sunday brunch.

### Stock Up on Healthy Foods

Kids, especially younger ones, will eat mostly what's available at home. That's why it's important to control the supply lines — the foods that you serve for meals and have on hand for snacks.

Follow these basic guidelines:

- **Work fruits and vegetables into the daily routine**, aiming for the goal of at least five servings a day. Be sure you serve fruit or vegetables at every meal.
- **Make it easy for kids to choose healthy snacks** by keeping fruits and vegetables on hand and ready to eat. Other good snacks include low-fat yogurt, peanut butter and celery, or whole-grain crackers and cheese.
- **Serve lean meats and other good sources of protein**, such as fish, eggs, beans, and nuts.



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## Being a Vegetarian

For much of the world, vegetarian diets are largely a matter of economics. Meat can cost a lot more than beans or rice, so meat is a special-occasion dish (if it's eaten at all).

In countries like the United States where meat is not as expensive, people often eat vegetarian diets for reasons other than cost. These can include:

- parental preferences
- religious or other beliefs
- health issues
- concern over animal rights or the environment

No matter the reason, if you eat a vegetarian diet, be sure to get the nutrition you need by including plenty of fruits and vegetables, whole grains, legumes (like beans, soy, and lentils), nuts, and seeds. Be careful when it comes to processed foods, which tend to be low in nutrients and high in fat, calories, and salt.

### What Are the Types of Vegetarian and Semi-Vegetarian Diets?

People can eat different kinds of vegetarian diets:

- A **vegetarian** eats no meat at all, including poultry or fish.
- A **lacto-ovo vegetarian** eats dairy products and eggs.
- A **lacto vegetarian** eats dairy products but not eggs.
- An **ovo vegetarian** eats eggs but not dairy products.
- A **vegan** (pronounced: VEE-gun) does not eat eggs, dairy, or other animal products like honey and gelatin.

Many people try to eat the amount of meat in their diets. Some people who don't eat red meat but may eat poultry or fish consider themselves semi-vegetarians, sometimes called flexitarians. People who follow a vegetarian diet but eat fish and seafood are called pescatarians.

### Are Vegetarian Diets OK for Teens?

The Academy of Nutrition and Dietetics endorses vegetarian eating, saying that "appropriately planned vegetarian diets, including total vegetarian or vegan diets, are healthful, nutritionally adequate, and may provide health benefits in the prevention and treatment of certain diseases."

So what does this mean for you? Being a vegetarian is a good choice if you can plan a well-balanced diet. Simply dropping some foods from your diet isn't the way to go if you're interested in maintaining good health, a high energy level, and strong muscles and bones.

Vegetarians must include these key nutrients into a vegetarian diet:

- iron
- calcium
- protein
- vitamin D
- vitamin B12

If meat, fish, dairy products, and/or eggs are not going to be part of your diet, you'll need to know how to get enough of these nutrients. The stricter the diet, the harder it will be to get enough of these from the foods you eat.

Talk to your doctor or a registered dietitian to see if you need to take daily vitamin and mineral supplements.

#### Iron

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Vegetarians can get enough iron in the plant-based foods they eat. Sea vegetables like nori, wakame, and dulse are very high in iron. Less exotic but still good options are iron-fortified breakfast cereals, legumes (chickpeas, lentils, and baked beans), soybeans and tofu, dried fruit (raisins and figs), pumpkin seeds, broccoli, and blackstrap molasses. Eating these foods along with foods high in vitamin C (citrus fruits and juices, tomatoes, and broccoli) will help your body absorb iron better.

Girls need more iron because some is lost during menstruation. Some girls who are vegetarians may not get enough iron from their diet and may need a daily supplement. Check with your doctor about your own iron needs.

#### **Calcium**

Milk and yogurt are good sources of calcium if you're eating dairy products. Tofu, calcium-fortified milk alternatives, calcium-fortified orange juice, green leafy vegetables, and dried figs are also excellent ways to get calcium. Remember: You're building strong bones during the teen years to last for the rest of your life.

Because women are more likely to have osteoporosis (weak bones), it's particularly important for girls to make sure they get enough calcium. If you don't get enough in your diet, your doctor may recommend taking a calcium supplement.

#### **Vitamin D**

Vitamin D helps get calcium into the bones. Your body makes vitamin D when your skin is exposed to sunlight. Cow's milk is top on the list for food sources of this vitamin. Vegans can try vitamin D-fortified milk alternatives and fortified breakfast cereals.

Your doctor may recommend a daily vitamin D supplement.

#### **Protein**

Vegetarians can get all the protein they need by eating a variety of plant foods throughout the day. Choose nuts and nut butters, tofu and other soy products, beans, lentils, seeds, grains, cereals, and vegetables to get all the protein your body needs. Lacto-ovo vegetarians also get protein from eggs and dairy products.

If you don't think you're getting enough protein in your diet, talk to your doctor or a registered dietitian.

#### **Vitamin B12**

B12 is an essential vitamin found in animal products, including eggs and dairy. Fortified milk alternatives, fortified breakfast cereals, and nutritional yeast also have this important vitamin. It's hard for vegans to get enough vitamin B12 so you may need a B12 supplement.

#### **Fat, Calories, and Fiber**

Besides vitamins and minerals, vegetarians need to keep an eye on calories and fat. Vegetarian diets tend to be high in fiber and low in fat and calories. That may be good for people who need to lose weight or lower their cholesterol, but it can be a problem for kids and teens who are still growing. High-fiber diets tend to be more filling, so some vegetarians may feel full before they've eaten enough calories to keep a healthy weight.

Some vegetarians may not get enough healthy omega-3 fatty acids. Omega-3 fats are good for heart health and are found in fish and eggs. Plant sources of omega-3 fatty acids include some vegetable oils (such as soybean, canola, and flaxseed), chia seeds, ground flax seeds, and walnuts.

#### **Getting Some Guidance**

Let your doctor know if you eat a vegetarian diet or are planning to. Your doctor can talk to you about healthy vegetarian diets or recommend a registered dietitian to help you plan a vegetarian diet that's right for you.

**Reviewed by:** Mary L. Gavin, MD

Date reviewed: January 2021

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## Smart Snacking

Teens are busy, and often skip meals. Even if you eat three meals a day, you may still feel hungry between meals. Either way, it can be tempting to grab something fast, like cookies, chips, and candy. Instead, get a nutrition boost with healthy snacks. Choose fruits, veggies, whole grains, dairy, and protein foods to get the most out of your snacks.

Eating a healthy snack can help you stay focused, give you energy, and keep hunger in check.

### Smart Snacking Strategies

When you want a snack, choose fruits and vegetables, whole grains that have 3 grams of fiber or more, and protein-rich foods, such as peanut butter or low-fat yogurt or cheese. Avoid snacks that are high in sugar, salt, and fat.

Here are some ways to make healthy snacking part of your everyday routine:

- **Keep healthy snacks in your refrigerator or pantry.** This will make it easier to make the healthy choice when it comes to snacking.
- **Make sweets, chips, and other treats the exception rather than the rule.** An occasional treat is fine, but choose healthy snacks most of the time.
- **Have a schedule for meals and snacks.** When you graze throughout the day you may not notice when you are hungry or full and eat extra calories. When you skip meals, you are more likely to make poor food choices and overeat when you do eat.
- **Practice mindful eating.** Eat all snacks and meals at the table. Don't watch TV, play video games, or be on your phone when you are eating.
- **Read the nutrition facts label when buying packaged snacks.** Look for snacks that are low in added sugar and high in nutrients, like fiber, protein, and calcium. Check the serving size, especially when eating typical snack foods, like chips. What looks like a small package may be 2 or more servings — which means double or even triple the amounts of fat, calories, and sugar shown on the label.
- **Bring healthy snacks with you.** Make it a habit to stash some fruit, nuts, whole-grain crackers, or baby carrots in your backpack or workout bag so you have a healthy snack when you need it.

### What Are Some Healthy Snacks?

Here are a few healthy snacking ideas:

- **Smoothies:** Blend fresh or frozen fruit or veggies, like kale or spinach, with yogurt, milk, or a dairy-free milk option. Add a tablespoon of peanut butter or almond butter for extra protein.
- **Whole-grain pita, veggies, and hummus:** Toast a pita, then cut it into triangles. Serve with cut-up veggies and your favorite hummus.
- **Homemade trail mix:** Combine 1 cup whole-grain toasted oat cereal with ¼ cup chopped walnuts and ¼ cup dried cranberries for a healthy trail mix.
- **Air-popped or lite popcorn:** Spice up your popcorn by sprinkling it with parmesan cheese or other seasonings, like chili powder or lemon pepper.
- **Banana "ice cream":** Peel several ripe bananas, break them into 1-inch pieces, and freeze them in a sealed plastic bag. Just before serving, whirl the pieces in the blender with a small amount of water or milk. Add berries for a different flavor or top with fruit or nuts.

**Reviewed by:** Mary L. Gavin, MD  
Date reviewed: January 2021

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Appendix E: *Lesson Plan*

## Vegetarian Basics

Young people will understand the different types of vegetarian diets and the nutrients that are important to be aware of when following a vegetarian diet.

**Ages**

9-14 Years Old

**Duration**

30 Minutes

**What You Need**

- [Vegetarian Diets Online Learning Activity](#)  
(<https://healthpoweredkids.org/smartboard/vegetarian/story.html>)
- Pictures of foods to fit different vegetarian diets
- Poster-board
- Markers and/or crayons
- Glue

**Resources**

Healthy Families Newsletter  
[English \(pdf\)](#)  
([https://healthpoweredkids.org/wp-content/uploads/2015/08/Vegetarian-Basics-Health-Families-Handout-Print\\_521.pdf](https://healthpoweredkids.org/wp-content/uploads/2015/08/Vegetarian-Basics-Health-Families-Handout-Print_521.pdf))

[Spanish \(pdf\) \(/spanish/43-Spa\\_Vegetarian-Basics-Health-Families-Handout-Print\\_521.pdf\)](#)

To find out how this health safety lesson fits Physical Education and Health Education standards [click here \(https://healthpoweredkids.org/health-standards\)](https://healthpoweredkids.org/health-standards).

## Lesson Overview

This lesson helps young people understand healthful ways to follow vegetarian diets by researching the different types and how to get enough nutrients while following each one.

## Introduction

Ask the youth:

- *Has anyone has heard of vegetarian diets?*
- *Do you know of anyone or do you follow a vegetarian diet?*
- *What do you think it means to be a vegetarian?*

Explain that a vegetarian diet is one way of meeting an individual's nutritional needs. A person may follow a vegetarian diet for cultural, ethical, environmental or health reasons.

## Activity: All About Vegetarian Diets

Introduce young people to the different kinds of vegetarian diets in the [Vegetarian Online Learning Activity \(https://healthpoweredkids.org/smartboard/vegetarian/story.html\)](https://healthpoweredkids.org/smartboard/vegetarian/story.html). Young people may explore the lesson independently on computers or mobile devices, or it can be projected on the classroom's SMART or Promethean Board.

Review the 4 types of vegetarian diets listed in the presentation.

1. **Strict Vegetarian or Vegan:** This diet includes only plant-based foods. It doesn't include any kind of animal food sources, such as meat, fish, eggs and dairy products.
2. **Lacto-vegetarian:** This diet includes all plant-based foods and dairy products. It doesn't include fish or eggs.

3. Lacto-ovo Vegetarian: This diet includes all plant-based foods, dairy products and eggs. It doesn't include meat and fish.

4. Flexitarian: This diet includes mostly plant-based foods and occasionally includes eggs, fish, dairy products and meats.

Conclude that there are many different types of vegetarian eating styles. One is not necessarily better than the other and all can fit into a healthy lifestyle. Explain that if a person chooses not to eat a certain type of food or food group, he or she may not get the right amount of some nutrients. Some of these nutrients include calories, protein, and calcium, Vitamin D, Iron, Zinc and Vitamin B12.

### **Activity: Vegetarian Nutrition Research**

Have the young people research one type of vegetarian diet and create a poster board and the nutrients that may be missing from that diet. Have them include what food sources may be included instead that would provide the nutrients they need. Each poster should include the following:

- The name of the type of vegetarian diet
- Nutrients that may be missing or hard to get from this diet
- Pictures of allowed food sources to meet those nutrient needs.

Invite each young person or group to present their project to the class.

### **Conclusion**

Remind young people that it is possible to be healthy while following a vegetarian diet if you know about healthful sources of protein, calcium, and Vitamins D and B12. Young people considering vegetarian diets should refer to [MyPlate's Information for Vegetarians \(https://www.choosemyplate.gov/ten-tips-healthy-eating-for-vegetarians\)](https://www.choosemyplate.gov/ten-tips-healthy-eating-for-vegetarians) to get more information.

### **Continuing the Conversation**

Hand out the [Healthy Families Newsletter in English \(https://healthpoweredkids.org/wp-content/uploads/2015/08/Vegetarian-Basics-Health-Families-Handout-Print\\_521.pdf\)](https://healthpoweredkids.org/wp-content/uploads/2015/08/Vegetarian-Basics-Health-Families-Handout-Print_521.pdf) or [Spanish \(/spanish/43-Spa\\_Vegetarian-Basics-Health-Families-Handout-Print\\_521.pdf\)](/spanish/43-Spa_Vegetarian-Basics-Health-Families-Handout-Print_521.pdf), with information about vegetarian diets so that families can continue discussing balanced nutrition at home.

### **Additional Instructor Resources**

[Vegetarian Lifestyles from Academy of Nutrition and Dietetics](http://www.eatright.org/resources/food/nutrition)

(<http://www.eatright.org/resources/food/nutrition>)

[Vegetarian Nutrition \(http://vegetariannutrition.net/\)](http://vegetariannutrition.net/)

[Tips for Vegetarians from ChooseMyPlate.gov \(https://www.choosemyplate.gov/ten-tips-healthy-eating-for-vegetarians\)](https://www.choosemyplate.gov/ten-tips-healthy-eating-for-vegetarians)

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 (<https://www.pinterest.com/allinahealth/health-powered-kids/>)

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## Tables

**Table 1***Research Questions and Variables*

Research Question	Independent Variable	Dependent Variable
Will biochemical data from blood work be affected by a vegetarian diet?	Vegetarian Diet	laboratory levels of erythrocyte sedimentation rate, c-reactive protein, and count of blood cells (white blood cell, red blood cell, hemoglobin, hematocrit, mean corpuscular hemoglobin concentration, mean corpuscular volume, auto neutrophil, lymphocyte, monocyte, eosinophil, and basophil, antigen activity of HLA-DR4, and immunoglobulin IgG, IgA, and IgM
Will the quality of life be affected by a vegetarian diet? (Questions in Appendix)	Vegetarian Diet	Quality of life outcome
Will symptoms of JIA be affected by a vegetarian diet? (Questions in Appendix)	Vegetarian Diet	Symptom Severity

**Table 2***Research Questions and Statistical Analysis*

Research Question	Level of Measurement	Potential Responses	Test of significance	Reason for test
Will biochemical data from blood work be affected by a vegetarian diet?	Interval	Various biochemical markers.	<i>t</i> -test	Reason for this test is that it is nominal data and testing significance with two different classification groups.
Will the quality of life be affected by a vegetarian diet? (Questions in Appendix)	Ordinal	From 0 (never) to 3 (all the time)	<i>t</i> -test	Reason for this test is that it is ordinal data and testing significance with two different classification groups.
Will symptoms of JIA be affected by a vegetarian diet? (Questions in Appendix)	Ordinal	From 0 (never) to 3 (all the time)	<i>t</i> -test	Reason for this test is that it is ordinal data and testing significance with two different classification groups.

Table 3a.

*Laboratory Values*

	Vegetarian N=16		Omnivore N=16		P-Value
	Baseline	12 month	Baseline	12 month	
Erythrocyte sedimentation rate (mm/hr)	29.5	6.8	27.0	22.1	<b>0.0000105</b>
C-reactive protein mg/dL	7.9	3.6	7.7	7.1	<b>0.0031601</b>
Blood Urea Nitrogen (mg/dL)	19.5	11.2	18.4	18.6	<b>0.0003356</b>
WBC 10e3/uL	10.9	7.5	11.6	12.2	<b>0.0000604</b>
Hemoglobin g/DL	14.3	14.0	13.6	14.1	<b>0.0286131</b>
MCHC g/dL	33.6	33.6	33.8	33.4	<b>0.0999369</b>
Auto Monocyte %	4.9	8.5	5.2	5.4	<b>0.0001490</b>
Auto Eosinophil %	1.9	5.0	2.3	2.0	<b>6.12E-11</b>
Antigen activity of HLA-DR4 (log2)	3.1	1.6	3.2	3.0	<b>0.0000001</b>
immunoglobulin IgA (g/L)	208.1	168.8	11.6	10.3	<b>00000155981</b>

Table 4a.

*Quality of Life Values*

	Vegetarian N=16		Omnivore N=16		P-Value
	Baseline	12 month	Baseline	12 month	
<b>Physical Health Scale</b>					
Been limited in taking care of him/herself, that is, eating, dressing, or washing him/herself?	3.33	1.10	2.79	3.00	<b>0.00000429</b>
Been limited in walking one block or climbing one flight of stairs?	2.67	1.05	3.04	3.13	<b>0.00001060</b>
Been limited in doing activities that take a lot of energy, such as running, playing soccer, or dancing?	3.14	0.95	2.96	2.88	<b>0.00012189</b>
Been limited in doing schoolwork or activities with friends?	3.33	0.76	2.71	3.00	<b>0.00000095</b>
Had bodily discomfort?	2.86	0.86	2.96	2.94	<b>0.00000214</b>
<b>Psychosocial Health Scale</b>					
Felt sad or blue?	3.29	0.81	3.33	3.38	<b>0.00000087</b>
Felt anxious or acted nervous?	3.00	1.10	2.88	3.00	<b>0.00000126</b>
Had troubles getting along with other children?	2.95	0.71	2.92	2.75	<b>0.00000062</b>
Had difficulty concentrating or paying attention?	3.19	1.00	3.38	2.88	<b>0.00000008</b>
Felt dissatisfied about his/her looks or abilities?	2.95	0.76	2.79	3.13	<b>0.00000004</b>

Table 5a.

*JADAS and Symptom Results*

	Vegetarian N=16		Omnivore N=16		P-Value
	Baseline	12 month	Baseline	12 month	
<b>JADAS Questions</b>					
JADAS Overall Score	11.55	5.24	10.33	11.00	<b>0.00002858</b>
Considering all the ways in which the illness affects your child at this time.	7.05	2.48	7.63	6.69	<b>0.00000003</b>
How much pain do you think your child had because of their illness in the past week?	7.43	2.29	7.33	7.50	<b>0.00000003</b>
Considering the whole sign and symptoms of disease at the time of present visit.	7.19	3.05	7.29	7.19	<b>0.00000179</b>
How many swollen joints does your child have today?	21.76	1.95	18.13	17.06	<b>0.0000000017</b>
What is the duration of morning stiffness in joints?	2.40	0.52	2.44	2.63	<b>0.000000014</b>

Table 3b.

	Vegetarian N=16					Omnivore N=16					P-Value
	Baseline	3 Month	6 month	9 month	12 month	Baseline	3 Month	6 month	9 month	12 month	
Erythrocyte sedimentation rate (mm/l)	29.5	28.9	18.1	15.1	6.8	27.0	25.8	25.7	19.8	22.1	<b>0.0000105</b>
C-reactive protein mg/dL	7.9	6.6	2.6	3.0	3.6	7.7	6.9	6.1	7.2	7.1	<b>0.0031601</b>
Blood Urea Nitrogen (mg/dL)	19.5	16.6	12.1	11.6	11.2	18.4	18.8	18.1	17.4	18.6	<b>0.0003356</b>
WBC 10e3/uL	10.9	10.2	7.7	7.0	7.5	11.6	11.6	11.4	11.7	12.2	<b>0.0000604</b>
RBC 10e6/uL	4.5	4.4	4.3	4.6	4.6	4.6	4.4	4.5	4.7	4.6	0.4892604
Hemoglobin g/DL	14.3	14.2	13.4	14.2	14.0	13.6	14.1	14.3	13.7	14.1	<b>0.0286131</b>
Hematocrit %	40.6	42.4	40.6	41.5	40.0	39.9	42.4	40.7	40.0	41.8	0.4982775
MCH pg	29.2	28.9	28.8	28.1	28.9	30.1	29.2	28.6	29.3	29.0	0.4300007
MCHC g/dL	33.6	33.3	34.0	33.9	33.6	33.8	33.8	34.1	34.3	33.4	<b>0.0999369</b>
MCV fl	88.2	87.4	88.0	85.4	87.0	85.6	87.1	84.4	87.2	86.6	0.3732769
RDW %	13.4	13.2	14.0	13.7	13.2	13.7	13.6	13.7	13.7	13.4	0.1449352
Platelet Count 10e3/uL	339.8	365.0	338.7	332.3	321.8	342.2	346.2	341.8	347.8	331.7	0.2145699
MPV fl	15.1	13.2	14.5	15.2	13.7	13.5	16.1	12.9	16.5	12.4	0.4743464
Auto Neutrophil %	60.8	60.2	59.4	55.0	59.8	65.1	59.3	64.6	62.0	62.2	0.1310752
Auto Lymphocyte %	28.7	29.2	27.6	29.0	30.4	29.4	28.7	28.6	28.1	27.8	0.2391310
Auto Monocyte %	4.9	5.4	8.6	7.7	8.5	5.2	4.5	5.4	4.9	5.4	<b>0.0001490</b>
Auto Eosinophil %	1.9	2.2	3.2	3.3	5.0	2.3	1.8	1.8	1.8	2.0	<b>6.121E-11</b>
Auto Basophil %	0.1	0.1	0.1	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.1665851
Antigen activity of HLA-DR4 (log2)	3.1	2.3	2.5	2.4	1.6	3.2	3.1	2.9	2.8	3.0	<b>0.0000001</b>
Immunoglobulin IgG (g/L)	12.5	12.8	12.9	12.3	12.5	12.4	12.8	12.3	11.9	11.3	0.3021165
Immunoglobulin IgA (g/L)	208.1	187.8	183.3	190.5	168.8	11.6	10.7	10.8	10.5	10.3	<b>1.56E-09</b>
Immunoglobulin IgM (g/L)	273.0	264.4	282.1	270.5	259.4	264.5	259.7	300.4	280.9	254.6	0.4699069

**Table 4b.***Quality of Life Values*

	Vegetarian N=16					Omnivore N=16					P-Value
	Baseline	3 Month	6 month	9 month	12 month	Baseline	3 Month	6 month	9 month	12 month	
<b>Physical Health Scale</b>											
Been limited in taking care of him/herself, that is, eating, dressing, or washing him/herself?	3.33	1.43	1.14	0.95	1.10	2.79	3.00	2.96	2.75	3.00	<b>0.00000429</b>
Been limited in walking one block or climbing one flight of stairs?	2.67	2.05	1.14	0.86	1.05	3.04	2.79	3.08	3.04	3.13	<b>0.00001060</b>
Been limited in doing activities that take a lot of energy, such as running, playing soccer, or dancing?	3.14	1.95	0.86	1.24	0.95	2.96	2.96	2.79	3.08	2.88	<b>0.00012189</b>
Been limited in doing schoolwork or activities with friends?	3.33	1.19	1.10	1.19	0.76	2.71	3.04	2.96	3.04	3.00	<b>0.00000095</b>
Had bodily discomfort?	2.86	1.62	0.86	1.14	0.86	2.96	3.00	3.08	3.00	2.94	<b>0.00000214</b>
<b>Psychosocial Health Scale</b>											
Felt sad or blue?	3.29	1.95	0.95	0.81	0.81	3.33	3.04	3.00	2.75	3.38	<b>0.00000087</b>
Felt anxious or acted nervous?	3.00	2.19	1.00	0.76	1.10	2.88	2.96	3.13	3.00	3.00	<b>0.00000126</b>
Had troubles getting along with other children?	2.95	1.00	0.81	0.90	0.71	2.92	2.79	3.00	3.04	2.75	<b>0.00000062</b>
Had difficulty concentrating or paying attention?	3.19	1.57	1.00	1.05	1.00	3.38	3.25	3.08	3.00	2.88	<b>0.00000008</b>
Felt dissatisfied about his/her looks or abilities?	2.95	1.38	0.95	0.95	0.76	2.79	3.29	2.88	3.00	3.13	<b>0.00000004</b>

**Table 5b.***JADAS and Symptom Results*

	Vegetarian N=16					Omnivore N=16					P-Value
	Baseline	3 Month	6 month	9 month	12 month	Baseline	3 Month	6 month	9 month	12 month	
<b>JADAS Questions</b>											
JADAS Overall Score	11.55	6.86	5.76	5.10	5.24	10.33	10.71	10.38	10.42	11.00	<b>0.00002858</b>
Considering all the ways in which the illness affects your child at this time.	7.05	5.24	2.19	2.48	2.48	7.63	8.00	7.42	7.79	6.69	<b>0.00000003</b>
How much pain do you think your child had because of their illness in the past week?	7.43	4.81	2.52	2.57	2.29	7.33	7.33	7.75	8.33	7.50	<b>0.00000003</b>
Considering the whole sign and symptoms of disease at the time of present visit.	7.19	4.76	2.33	2.52	3.05	7.29	7.42	8.29	7.92	7.19	<b>0.00000179</b>
How many swollen joints does your child have today?	21.76	8.76	1.71	2.43	1.95	18.13	20.71	21.38	19.54	17.06	<b>0.0000000017</b>
What is the duration of morning stiffness in joints?	2.40	1.24	0.50	0.60	0.52	2.44	2.27	2.38	2.29	2.63	<b>0.000000014</b>

**Figures**

**Figure 1.**

*Illustration of participants in study.*

