Using Gatorade® to control serum sodium levels of patients with hyponatremia

Hannah Elizabeth Degen

Follow this and additional works at: https://huskiecommons.lib.niu.edu/allgraduate-thesesdissertations

Recommended Citation
Degen, Hannah Elizabeth, "Using Gatorade® to control serum sodium levels of patients with hyponatremia" (2016). Graduate Research Theses & Dissertations. 6593. https://huskiecommons.lib.niu.edu/allgraduate-thesesdissertations/6593

This Dissertation/Thesis is brought to you for free and open access by the Graduate Research & Artistry at Huskie Commons. It has been accepted for inclusion in Graduate Research Theses & Dissertations by an authorized administrator of Huskie Commons. For more information, please contact jschumacher@niu.edu.
ABSTRACT

USING GATORADE® TO CONTROL SERUM SODIUM LEVELS OF PATIENTS WITH HYPONATREMIA

Hannah E. Degen, M.S.
School of Family, Consumer and Nutrition Sciences
Northern Illinois University, 2016
Josephine Umoren, Thesis Director

**Background:** Hyponatremia is a condition in which serum sodium levels are less than 135 mmol/L. It is the most prevalent sodium disorder in hospitalized patients. Currently, the most commonly used treatment for the condition include fluid restriction, carefully monitored hypertonic IV solution and diuretic therapy. In athletes with hyponatremia, low serum sodium levels have been corrected with the administration of an isotonic beverage. Therefore, giving Gatorade® to patients with hyponatremia may be an alternative treatment method to increase serum sodium levels.

**Objective:** The purpose of the study was to examine the effect of oral Gatorade® protocol on serum sodium levels of hospitalized elderly patients with hyponatremia.

**Methods:** In this randomized control experimental study, subjects were randomly assigned to the experimental (n=15) or control group (n=15). Ten participants were on a fluid-restricted diet; 20 participants did not have a fluid restriction. In the experimental group, there were five participants on fluid restriction and ten participants not on a fluid restriction. The same composition was found in the control group. The participants were enrolled in the study for seven days. Over those seven days, the participants in the fluid restriction were given water or Gatorade® with their medicine. Participants not on a fluid restriction were given 4 oz. of water
or Gatorade® at each meal. Serum sodium levels were tested before and after the study. The foods and beverages consumed during the study were documented and total sodium consumed was calculated. The hypothesis was tested using ANOVA and paired-samples t-test.

Results: The results of this study found there was not a significant difference between serum sodium levels of patients with hyponatremia who were given Gatorade®, as compared to water, when not on a fluid-restricted diet. There was a significant difference (p < .05) between pre- and post-test serum sodium levels in non-fluid-restricted participants consuming Gatorade® and all participants on a fluid-restricted diet.

Conclusions: These results suggest that patients with hyponatremia who are not on a fluid-restricted diet may benefit from receiving Gatorade® with meals.
USING GATORADE® TO CONTROL SERUM SODIUM LEVELS OF PATIENTS WITH HYPONATREMIA

BY

HANNAH ELIZABETH DEGEN
© 2016 Hannah Elizabeth Degen

A THESIS SUBMITTED TO THE GRADUATE SCHOOL IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE MASTER OF SCIENCE

SCHOOL OF FAMILY, CONSUMER, AND NUTRITION SCIENCES

Thesis Director
Josephine Umorden
ACKNOWLEDGEMENTS

Many people have contributed to my thesis with their expertise, skills, knowledge, and time. First and foremost, I would like to thank my family without their support I would not have succeeded in this endeavor. I would also like to thank my thesis advisor, Dr. Josephine Umoren, from whom I have learned so much. It is through her that I developed a deeper understanding of the research process. To my committee members, Dr. Judith Lukaszuk and Dr. Sheila Barrett, thank you for your dedication and support to help make this happen. I would like to thank Marianjoy Rehabilitation Hospital for allowing me to complete the study at their facility. I am indebted to Mary Frost and the dietitians at Marianjoy, without whose time and support this would never have come to fruition.
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>LIST OF TABLES</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>v</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LIST OF APPENDICES</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>vi</td>
</tr>
</tbody>
</table>

## Chapter

1. INTRODUCTION

   - Background........................................................................................................... 1
   - Statement of the Problem.................................................................................... 3
   - Hypotheses ........................................................................................................... 3

2. REVIEW OF LITERATURE

   - Introduction ....................................................................................................... 5
   - Sodium ................................................................................................................. 7
   - Hyponatremia ....................................................................................................... 8
     - Hyponatremia in Athletes .............................................................................. 11
     - Osteoarthritis and Hyponatremia .............................................................. 12
     - Hyponatremia in Elderly .............................................................................. 13
     - Mortality Rates ............................................................................................... 14
     - Treatment of Hyponatremia .......................................................................... 17
     - Fluid Restriction ............................................................................................. 19
     - Sports Drinks ................................................................................................. 20
<table>
<thead>
<tr>
<th>Chapter</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conclusion</td>
<td>21</td>
</tr>
<tr>
<td>3. METHODS</td>
<td>23</td>
</tr>
<tr>
<td>Experimental Design</td>
<td>23</td>
</tr>
<tr>
<td>Participants</td>
<td>24</td>
</tr>
<tr>
<td>Data Collection</td>
<td>25</td>
</tr>
<tr>
<td>Intervention</td>
<td>26</td>
</tr>
<tr>
<td>Statistical Analysis</td>
<td>27</td>
</tr>
<tr>
<td>4. RESULTS</td>
<td>28</td>
</tr>
<tr>
<td>Characteristics of the Sample</td>
<td>28</td>
</tr>
<tr>
<td>Sodium Intake</td>
<td>28</td>
</tr>
<tr>
<td>Serum Sodium Levels</td>
<td>30</td>
</tr>
<tr>
<td>5. DISCUSSION</td>
<td>33</td>
</tr>
<tr>
<td>Conclusion</td>
<td>36</td>
</tr>
<tr>
<td>6. LIMITATIONS AND FUTURE RESEARCH</td>
<td>37</td>
</tr>
<tr>
<td>Limitations of the Current Study</td>
<td>37</td>
</tr>
<tr>
<td>Recommendations for Future Study</td>
<td>38</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>39</td>
</tr>
<tr>
<td>APPENDICES</td>
<td>44</td>
</tr>
</tbody>
</table>
LIST OF TABLES

<table>
<thead>
<tr>
<th>Table</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Experimental Design</td>
<td>24</td>
</tr>
<tr>
<td>2. Characteristics of All Subjects</td>
<td>29</td>
</tr>
<tr>
<td>3. Comorbidities</td>
<td>30</td>
</tr>
<tr>
<td>4. Sodium Intake Levels Per Day</td>
<td>30</td>
</tr>
<tr>
<td>5. Serum Sodium Levels Pre- and Post-Test</td>
<td>32</td>
</tr>
</tbody>
</table>
## LIST OF APPENDICES

<table>
<thead>
<tr>
<th>Appendix</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>A.</td>
<td>FLUID RESTRICTION AT MARIANJOY</td>
<td>44</td>
</tr>
<tr>
<td>B.</td>
<td>MARIANJOY IRB SUBMISSION FORM</td>
<td>47</td>
</tr>
<tr>
<td>C.</td>
<td>CONSENT FORM</td>
<td>51</td>
</tr>
<tr>
<td>D.</td>
<td>RECRUITMENT LETTER</td>
<td>57</td>
</tr>
<tr>
<td>E.</td>
<td>MARIANJOY IRB APPLICATION</td>
<td>59</td>
</tr>
<tr>
<td>F.</td>
<td>GATORADE® NUTRITION INFORMATION.</td>
<td>64</td>
</tr>
<tr>
<td>G.</td>
<td>FOOD AND FLUID INTAKE</td>
<td>66</td>
</tr>
</tbody>
</table>
CHAPTER 1

INTRODUCTION

Background

Disorders in water and sodium balance are a common finding among hospitalized patients. Sodium is the principal extracellular cation and hyponatremia is a disorder in which plasma sodium concentrations are less than 135 mmol/L, characterized by decreased osmolality. Normal serum sodium concentration levels range between 135-144 mmol/L.

There are multiple causes for development of hyponatremia, including fluid imbalance, kidney disorders, and impaired hypothalamus thirst center. Alterations in sodium and water balance affect the central nervous system. Hyponatremia is a potentially life-threatening disorder that can contribute to neurological problems including dizziness, lethargy, seizures, and coma. Early diagnosis and treatment can prevent complications of hyponatremia.

Studies have shown that mild hyponatremia can have long-lasting consequences. These include deficits in gait and attention, falls, decreases in bone density, and fractures. These effects are especially prevalent in the elderly. Adults with hyponatremia have been found to present with significantly lower bone mineral density and an increased prevalence of osteoporosis. There is a significant increase in length of stay for hospitalized patients with hyponatremia. There are also significantly higher morbidity and mortality rates associated with hyponatremia.
The consequences of hyponatremia can result in adverse effects in both hospitalized patients and otherwise healthy individuals.

Older adults have an increased risk of hyponatremia due to degenerate physiology, multiple co-morbidities, increased risk of dehydration, and stress from fracture and surgical interventions. They are at an increased risk for fluid and electrolyte imbalances due to their compromised renal and water-conserving ability as well as their impaired thirst mechanism, which decreases their fluid consumption.

Patients hospitalized with hyponatremia can be treated with several different mechanisms. One method of treatment is the use of diuretic therapy to reduce body fluid content by inhibiting the antidiuretic hormone (ADH), which results in increased fluid loss via the kidneys. A fluid-restricted diet is another common method used to treat hyponatremia among patients. This method is used to reduce edema and to prevent further dilution of serum sodium levels.

Exercise-associated hyponatremia is induced by excessive fluid consumption while exercising, not for medical reasons. Exercise-associated hyponatremia is most commonly found in athletes who participate in ultra-endurance events. It is a result of excessive fluid intake, increased retention of fluid, elevated sweat sodium loss, and an impaired glomular filtration rate.

The use of isotonic beverages comprised of sodium, glucose, and potassium has been shown to help athletes better maintain their serum sodium levels and prevent hyponatremia. Glucose, electrolytes, and water stores need to be replenished when exercising to prevent depletion and dehydration. When the stores are not replenished, the athlete is at increased risk for hyponatremia. Athletes who drink isotonic solutions have been shown to replenish body stores.
more quickly than athletes who drink water alone. The isotonic beverage appears to help better control their serum sodium levels and prevent hyponatremia. Therefore, it is proposed that elderly patients with hyponatremia may normalize their serum sodium levels earlier when provided an isotonic beverage.

Statement of the Problem

Evidence indicates drinking an isotonic beverage increases athletes’ serum sodium levels. However, this has not been explored in hospitalized patients with low serum sodium levels. This study investigated the effect of Gatorade® consumption on serum sodium levels among patients on both fluid-restricted and non-fluid-restricted diets.

Independent Variable

Fluid intake: Gatorade® (experimental) or plain water (control).

Dependent Variable

Serum sodium levels

Hypotheses

The following hypotheses were investigated:
1. Elderly patients with hyponatremia on a fluid-restricted diet will have significantly higher serum sodium levels when given Gatorade® compared to those patients on the standard treatment protocol.

*Independent Variable*: Fluid intake: Gatorade® or water

*Dependent Variable*: Serum sodium level

2. Elderly patients with hyponatremia not on a fluid-restricted diet will have significantly higher serum sodium levels when given Gatorade® compared to those patients on the standard treatment protocol.

*Independent Variable*: Fluid intake: Gatorade® or water

*Dependent Variable*: Serum sodium level
CHAPTER 2

REVIEW OF LITERATURE

Introduction

Hyponatremia is a medical condition in which serum sodium levels are below 135 mmol/L, whereas normal serum sodium levels range between 135-144 mmol/L. Hyponatremia is caused by various conditions including fluid imbalance, kidney disorders, and impaired hypothalamus thirst center. Without intervention, hyponatremia can lead to neurological problems. Individuals at greatest risk for hyponatremia are the elderly, individuals with kidney disorders, impaired thirst mechanisms, and fluid overload.

Other causes of hyponatremia may not be due to medical reasons; such is the case with athletes. When athletes drink an excessive amount of water they may experience fluid overload, which could lead to hyponatremia. Older adults are at an increased risk for fluid and electrolyte imbalances due to their compromised renal and water-conserving ability as well as their impaired thirst mechanism, which decreases their fluid consumption.

The consequences of hyponatremia can result in adverse effects in both hospitalized patients and otherwise healthy individuals. Hospitalized patients with hyponatremia tend to have significantly longer hospital stays than non-hyponatremic patients. There are also significantly higher mortality rates associated with hyponatremia. Hyponatremia may result in neurological problems such as cerebral edema or brain cell swelling and herniation of the brain stem leading
to permanent brain damage. Adults with hyponatremia have been found to present with significantly lower bone mineral density and an increased prevalence of osteoporosis.\textsuperscript{6} When hyponatremia is treated too rapidly, it may increase risk of osmotic demyelination and permanent neurologic deficits. Therefore, early diagnosis and treatment are crucial for correction and prevention of brain damage.

There are currently several approaches used to treat patients hospitalized with hyponatremia. One common practice is the use of fluid restriction diet prescriptions for patients with hyponatremia. Fluid restrictions are used to minimize and reduce edema and to prevent further dilution of the serum sodium levels. Another treatment is the use of diuretic therapy in those with hyponatremia so as to reduce body fluid content by inhibiting the antidiuretic hormone (ADH), which results in increased fluid loss via the kidneys.\textsuperscript{14}

A technique that has proved to be successful in the prevention of hyponatremia in healthy athletic individuals is the use of specially designed isotonic beverages. Isotonic beverages are sports drinks that contain both sodium and glucose to help replace water and electrolytes. The use of isotonic beverages comprised of sodium, glucose, and potassium have been shown to help athletes better maintain their serum sodium levels. Such beverages are consumed in accordance to the type of activity and the environmental conditions. When engaged in physical activity, the body uses electrolytes, glucose, and water stores that must be replenished to prevent depletion and dehydration. If stores are not replenished the individual is at increased risk for hyponatremia. Athletes who drink isotonic solutions replenish body stores more quickly than athletes who drink water alone.\textsuperscript{16} This helps to better control their serum sodium levels and prevent hyponatremia.
Sodium

Normal adult serum sodium levels are between 135-144 mEq/L. Sodium is the main cation in the extracellular fluid and thus is important in maintaining fluid retention in the body. It makes up about 93% of the cations in the body. A reduction in the serum sodium concentration in the extracellular fluid may be due to an increase in the water in the extracellular fluid or a decrease in the sodium content in the extracellular fluid. Sodium works to maintain plasma volume and osmolality.

When serum osmolality is low, osmosis shifts the fluid out of the extracellular fluid space into the intracellular fluid space to increase the serum osmolality. This shift in fluid results in the swelling of the cells. The brain is very susceptible to the changes in body fluid volume because it has a limited ability to expand. The brain cells will expand when there is a drop in serum sodium levels. This is due to the fact that the brain cells do not have time to adapt to the extracellular fluid hypotonicity and therefore swell, leading to neurological damage or death.

On the other hand, hypernatremia occurs when serum sodium concentration increases above 144 mmol/L due to a net fluid loss and/or an increased retention of sodium in the body. In hospitalized patients, the causes may include intravenous infusion of hypertonic saline, excessive salt ingestion, and bicarbonate administration during cardiac arrest. Patients with hypernatremia may have neurological complications or death if untreated.

Sodium concentrations in the body’s plasma are maintained by homeostasis within a narrow range. The mechanisms involved include thirst, ADH, aldosterone, and renal control of water excretion.

The kidneys regulate extracellular fluid volume and blood pressure by the renin-angiotensin-aldosterone system. When there is a decrease in blood pressure or plasma sodium
levels the kidneys activate the system. Renin is secreted by the granular cells in the juxtaglomerular apparatus. Renin hydrolyzes angiotensinogen into angiotensin I. Angiotensin I is then converted into angiotensin II. Angiotensin II acts as a vasoconstrictor which reduces the glomerular filtration rate and the filtered load of sodium. Angiotensin II also stimulates the release of aldosterone from the adrenal cortex. Aldosterone increases sodium reabsorption in the renal tubules by increasing the sodium channels and Na\(^+\)-K\(^+\) pumps. This causes an increase in water and salt reabsorption and increases blood pressure.

Sodium concentrations play a role in maintaining the electrical gradients across cell membranes. Sodium also interacts in nerve impulse transmissions and muscle excitation through the Na\(^+\)/K\(^+\)-ATPase pump. In this pump, sodium is exchanged for potassium, which causes the hydrolysis of ATP. The electrochemical potential gradient causes an impulse or nerve conduction.

When a large amount of fluid is consumed, hypo-osmolality occurs, which stimulates osmoreceptors to decrease the release of ADH from the pituitary gland. The decreased ADH secretion results in an increase in the permeability of renal tubular cells to water. The water is reabsorbed from the collecting ducts and distal tubules of the kidneys and returned to the circulation, thereby causing hyponatremia.

**Hyponatremia**

Normal serum sodium concentration is 135-144 mEq/L. Hyponatremia results when serum sodium concentration falls below 135 mmol/L. The condition occurs when there is an excess of fluid in relation to sodium stores in the body. Hyponatremia is the most common electrolyte disorder in clinical practice. Mild hyponatremia (serum sodium concentrations of
130-135 mmol/L) occurs in 15-30% of hospitalized patients. If hyponatremia is left untreated, it can cause neurological issues. Hyponatremia treated too rapidly can cause significant risk for osmotic demyelination and permanent neurologic deficits.

Hyponatremia occurs due to disruption of fluid and sodium homeostasis. This balance is usually maintained by multi-system mechanisms in the body. The serum osmolality is affected by water intake and the renal clearance of water. When the excretion of fluid by the kidney is impaired, it results in increased retention of fluid in circulation; this causes the serum sodium levels in the body to become diluted.

The kidneys are an important system in the regulation of sodium. Low sodium levels may be due to the glomerular filtration rate being low. The capillaries in the glomerulus filter water and electrolytes from the plasma. This allows the kidneys to regulate fluid and electrolyte homeostasis. In a healthy kidney, a change in fluid and electrolyte intake would cause the volume and constituents of the urine to vary. Having a low glomerular filtration rate would decrease the water excretion. The glomerular filtrate needs to be adequately delivered to the renal tube in order for the urine to be diluted.

Another important function of the kidneys is the reabsorption of sodium in the distal tubule. ADH must be present for the reabsorption of water from the renal tubule into circulation. ADH increases the permeability of water in the collecting ducts. The increase in water can decrease the osmolarity of the blood. The posterior pituitary also has to regulate ADH secretion in response to serum osmolality. A decrease in serum osmolality causes ADH secretion to stop. Impaired kidney functions can lead to failure to excrete water or inappropriate reabsorption of water, which would cause serum sodium levels to decrease.
Other causes of hyponatremia include diseases, pharmacotherapy, and pathophysiological variations. Patients taking medications including thiazide diuretics, chemotherapeutic agents, and psychotropic agents may develop hyponatremia.\textsuperscript{2} Heart failure, renal disease, thyroid disease, adrenal insufficiency, and cirrhosis are some of the diseases associated with hyponatremia.\textsuperscript{13}

Kidney failure is associated with hyponatremia. In this condition, the excretion of water by the kidney is impaired, which causes retention of water in blood circulation. The increased water dilutes serum sodium levels.\textsuperscript{13} Advanced cirrhosis can impair the kidney’s ability to eliminate solute-free water. This causes water retention and decreases the serum sodium concentration, which results in hyponatremia and hypo-osmolality.\textsuperscript{25}

Hyponatremia occurs in roughly 20\% of patients admitted with heart failure.\textsuperscript{9, 26-28} Patients with heart failure have increased hormones including renin, norepinephrine, and ADH levels. This is due to a decrease in blood pressure and cardiac output.\textsuperscript{29} The increased hormones impair the body’s ability to excrete water. Hyponatremia in heart failure patients may also be due to the diuretic therapy used to manage the disease. The diuretics cause renal sodium loss and therefore decrease the body’s sodium levels.\textsuperscript{9}

Euvolemic hyponatremia is associated with urine sodium greater than 30 mEq/L and is the result of an increase in the total body water with a small change in serum sodium. It usually occurs with nonosmotic ADH secretion (syndrome of inappropriate ADH hormone release [SIADH]). This happens when there is continued release of ADH even though there is low serum osmolality in the body. ADH controls renal clearance of water and water intake. It causes reabsorption of water and urination.\textsuperscript{20} ADH secretion stops when plasma sodium is $<135$ mEq/L; 35\% of patients with hyponatremia have SIADH.\textsuperscript{30} In most cases of SIADH, advanced age is a significant risk factor for the development of hyponatremia.
**Hyponatremia in Athletes**

Athletes may experience hyponatremia due to an excessive water intake, which results in fluid overload. The increased fluid causes dilutional hyponatremia. For shorter distances, the American College of Sports Medicine recommends a fluid intake of 0.6-1.2 l/h (20.3-40.6 oz./h). Although it can be difficult to make a recommendation because everyone has different water loss and weather conditions affect the amount of water the body needs.31

If no fluid is consumed when exercising, the plasma sodium concentration and osmolality increase depending on the loss of electrolytes and water in sweat. The plasma osmolality increases because less sodium is lost in sweat than water. The water lost in sweat can either be from the extracellular fluid or the intracellular fluid. When athletes consume water or sports drinks of up to 25 mEq Na⁺ l⁻¹ in volumes that match the rate of fluid lost in sweat, their plasma sodium and osmolality decrease at similar rates.32

Males retained significantly more fluid when given drinks with increased sodium concentration. In addition, the blood and plasma volumes increased after drinking higher sodium drinks.33 A different study found a carbohydrate and sodium drink had a significant effect on excretion of electrolytes and water in urine. The higher sodium intake decreased the urine volume and increased the urinary sodium loss.32 In addition, female participant’s beverages with sodium had a significantly higher serum sodium concentration than participants given beverages without sodium.34
Osteoarthritis and Hyponatremia

In most instances patients with hyponatremia are significantly older (mean age of 67.8), have a lower bone mineral density and an increased prevalence of osteoporosis. In the US, there are approximately 30-50 million people with osteoporosis. Osteoporosis is a disease in which there is deterioration of bone tissues and low bone mineral density. This increases the risk for fractures due to fragile bones.

A study of 1,408 female patients who underwent bone mineral density measurements found patients with hyponatremia (serum sodium less than 135 mmol/L) had a 2.86-increased odds ratio of having a fracture occur compared to patients without hyponatremia. In patients with a fracture, 8.7% of them had hyponatremia while 3.2% of patients with hyponatremia did not have a fracture.

Renneboog et al. matched 122 elderly patients (72±13) with falls to 244 control patients. The results showed the patients with hyponatremia (serum sodium between 115-132 mEq/L) experienced falls at a rate of 21% compared to 5% of patients without hyponatremia. The same authors found an increase in falls with patients who have chronic hyponatremia compared to patients without hyponatremia.

One animal study found mild hyponatremia is associated with increased risk of osteoporosis at the hip. In rats with SIADH having hyponatremia for three months significantly decreased bone mineral density by 30%. There was also a decrease in cortical bone and trabecular bone due to increased bone resorption and decreased bone formation. Hyponatremia also stimulated osteoclasogenesis and resorptive activity which causes resorptive osteoporosis.
Elderly patients with fractures have an increased risk of hyponatremia due to their degenerate physiology, increased risk of dehydration due to hospitalization, homeostatic stress from the fracture, and multiple co-morbidities.\textsuperscript{12}

\textbf{Hyponatremia in Elderly}

The elderly have an increased risk for electrolyte and fluid imbalances because of impaired renal sodium and water-conserving ability as well as decreased sensitivity to thirst. The elderly have lower glomerular filtration rates. This can cause a decrease in the delivery of filtrate to the distal tubule and decrease the water excreted.\textsuperscript{13, 24} Having a low glomerular filtration rate would decrease the water excretion. They may also be taking medications that impair the distal tubules ability to reabsorb sodium from the urine. Elderly patients may have increased levels of ADH, which would cause an increase in water reabsorption. This is because ADH secretion increases the permeability of water in the collecting ducts.\textsuperscript{24} They may have a comorbid condition (heart failure, renal disease, thyroid disease, cirrhosis, adrenal insufficiency) which is associated with the development of hyponatremia.\textsuperscript{13}

Renal and other age-related physiological changes increase the sensitivity of older adults to dehydration. Dehydration can cause impairment of physical and cognitive performance. As a person ages there is a decrease in lean body mass leading to an increase in the ratio of extracellular to intracellular fluids. This causes the total amount of water in the body to decrease by 10-15\%. The thirst mechanism in older adults may also be impaired due to hormonal changes, this would decrease fluid intake.\textsuperscript{35} If the hypothalamus thirst center does not register that a person needs fluid due to an increase in extracellular fluid osmolality or decrease in blood volume, then they will not feel thirsty.\textsuperscript{17} This will decrease the amount of fluid consumed.
Older adults have an impaired sensitivity to thirst, which can cause dehydration. Older men (ages 54-70 years) rated carbohydrate-electrolyte solutions (6% carbohydrate and 18.0 mmolL$^{-1}$ NaCl) as having a better flavor and higher overall acceptance than water. Older women (ages 54-70 years), on the other hand, rated water as having a better flavor, aftertaste, and overall acceptance than a carbohydrate-electrolyte solution. The total fluid intake of carbohydrate-electrolyte solution was significantly higher in both males and females than water. The plasma volume was at or above baseline for all subjects when consuming carbohydrate-electrolyte solution. The subjects were put on a cycle ergometer and cycled at an intensity of 65± 1% of VO$_2$ for 15 minutes followed by 15 minutes of rest, at which time subjects were allowed to drink. This was continued until the subject had completed four 15-minute bouts of cycling and four 15-minute rest periods. The subjects were given a 700 mL bottle of fluid (either water or carbohydrate-electrolyte solution) randomly assigned. The volume of fluid intake was measured after rest periods 1-3 and recovery. The subjects were not aware their fluid consumption was being measured. When exercising, the participants drank enough fluid to match their sweating rates.

In older adults, there is a decrease in renal mass caused by glomerular loss. This inhibits the kidney’s ability to retain sodium and water. The kidney’s tubular function and medullary concentration gradient are impaired, which decreases the kidney’s ability to concentrate urine and control water and electrolyte balance. This causes an increased risk for hyponatremia.

**Mortality Rates**

Low serum sodium levels in patients are associated with increased mortality rates. Patients with hyponatremia (serum sodium less than 135 mEq/l) have significantly lower
survival rates when admitted to the hospital than patients without hyponatremia. A cohort study of 3,551 patients in an ambulatory setting found there is a two-fold increase in risk of death even when adjusting for major risk factors (age, diabetes, CKD, cirrhosis, use of diuretics, and a history of cancer) when a patient has hyponatremia.\(^{10}\)

Patients admitted with hyponatremia (serum sodium less than 135 mEq/L) have a 50% increased risk of death than patients with normal serum sodium levels.\(^2\) A prospective cohort study of 98,411 patients hospitalized in Boston, Massachusetts, found patients with hyponatremia have an increased death risk during their hospital stay as well as at 1-year and 5-year follow-ups than patients without hyponatremia. At the 5-year follow-up, patients admitted with serum sodium levels of 130-140 mEq/L had an increased risk of death of 24%, patients at 125-129 mEq/L had a risk of death of 33%, and patients serum sodium if 120-124 mEq/Lv had a 29% increased risk of death.\(^2\) Another cohort study with 53,236 hospitalized patients found patients with hyponatremia had a higher percentage of co-morbidities (heart failure, chronic kidney disease, diabetes, liver disease, dementia) and were associated with more severe diseases.\(^{39}\)

Hyponatremia is associated with ascites, hepatorenal syndrome and death from liver disease. In patients on the liver transplant wait list, a decrease in the serum sodium levels is associated with an increased risk of death. Serum sodium levels between 125-140 mmol/L had the biggest effect on mortality in patients with hyponatremia. There was a 5% increase risk of death per unit decrease in the serum sodium concentrations between 125-140 mmol/L. A study examining 13,940 patients on the wait list for a liver transplant found patients with hyponatremia (serum sodium between 125-140 mmol/l) had increased morbidity and mortality during the
postoperative period. Hemodialysis patients (age 58 ± 13 years) who have a lower serum sodium level (≤138.4 MMOL/l) have a significantly poorer survival rate.

Patients admitted for musculoskeletal surgery, metastatic cancer, or cardiovascular disease have an increased risk of in-hospital mortality when admitted with hyponatremia. A study examining acute ST-elevation myocardial infarction in 978 patients found patients with acute ST-elevation myocardial infarction and hyponatremia (serum sodium less than 136 mEq/L during the first 72 hours of hospital stay) had an increased probability of death during the 31-month follow up. There was also an increased probability of heart failure during follow-up in patients admitted with hyponatremia.

Hyponatremia is also associated with prolonged length of hospital stay. A study of 2,880 patients with a mean age of 78.6 ± 6.98 found patients with hyponatremia (serum sodium ≤131 mmol/l) have a significantly longer hospital stay (19.8 ± 8.3 days) compared to patients without hyponatremia (16.8 ± 8.9 days). In a cohort study of 964,263 adults undergoing major surgery, patients with hyponatremia (serum sodium less than 135 mEq/L) who underwent an operation had a longer length of stay by a median of one day.

Lower serum sodium levels is an independent predictor for higher risk of infection-related hospitalization in patients with hemodialysis. One study with 332 patients with end-stage renal disease found hyponatremia might result in an increased susceptibility to infection and infectious disease, which contributes to mortality. There was a significant association between low serum sodium levels and an increased risk of infection-related hospitalization. The study also found there was a significant association between low serum sodium levels and mortality. Patients with preoperative hyponatremia are also at increased risk for infection and pneumonia.
Hyponatremia before liver transplant has been associated with adverse post-transplant outcomes. Liver transplant patients with low values of pre-transplant serum sodium had an increased risk of death. A study done on 318 liver transplant patients found patients with hyponatremia (serum sodium \( \leq 130 \) mEq/L) have a shorter survival time 1, 5, and 10 years after liver transplant compared to normonatremic (serum sodium greater than 130 mEq/L) patients\(^{46}\). Post-transplant patients with cirrhotic hyponatremia had an increased risk of infection, neurological, and renal disorders than normonatremic patients.\(^{47}\) Another study found that a patient with liver disease had a significant increase in risk of death for patients with serum sodium concentrations of 120-124 mEq/L.\(^{2}\)

**Treatment of Hyponatremia**

The treatment of hyponatremia depends on the underlying cause. Treatments include fluid restriction, saline solution, and diuretic therapy.\(^{14}\) The rate at which serum sodium levels are corrected is important in treating hyponatremia. If the pace is too rapid it can create a risk for osmotic demyelination syndrome and lead to permanent neurological deficits.\(^{23}\) Osmotic demyelination syndrome causes cells to shrink. Therefore, a patient’s sodium levels should be monitored carefully to ensure hyponatremia is not being corrected too quickly.

Patients with hypovolemic hyponatremia cannot have intravenous fluids because it would increase the volume overload. It also cannot be used in patients with SIADH because it will cause more retention of free water. Isotonic saline may be given if it is unclear if a patient is volume depleted or has SIADH. In elderly patients, volume status may be difficult to tell, in which case giving isotonic saline would help determine the volume. If the patient’s sodium levels improve after a small dose of saline is given, the intravenous fluids should be continued.
because the diagnosis is usually volume depletion. If the patient’s sodium levels fall, the intravenous fluids should be discontinued.\textsuperscript{13}

Patients with symptomatic hyponatremia are usually given hypertonic saline (3\% sodium chloride). This causes a rapid rise in serum sodium and resolution of neurological symptoms. To determine the infusion rate of hypertonic saline, the Androge-Madias formula may be used. For every 1L of infused solution, the change in serum sodium is \( \frac{(Na + K) \text{inf used} - \text{serumNa}}{\text{totalbodywater(l)} + 1} \). This formula does consider the body a closed system and does not take into account the urinary losses of potassium and sodium\textsuperscript{13}.

Patients may be given demeclocyline an antibiotic that inhibits AVP. It is not FDA approved for the treatment of hyponatremia. The correction rate is generally slow taking 2-3 days before an effect is seen. It is used sparingly because it has significant nephrotoxic potential in cirrhotic patients.\textsuperscript{13}

Loop diuretics can help manage the fluid volume of patients with hyponatremia. Patients with volume overload and severe hyponatremia may be given hypertonic saline and loop diuretics to help manage their fluid volume. They may also increase water excretion because it inhibits hypertonic medullary gradient needed for water reabsorption.\textsuperscript{13}

AVP receptor antagonists compete with AVP for the vasopressin type 2 receptor and block AVP to increase free water absorption. It causes a rise in serum sodium levels. Patients given AVP receptor antagonists have to be monitored for their serum sodium levels because it is difficult to predict the correction rate of serum sodium levels.\textsuperscript{13}
Fluid Restriction

Treatment of hyponatremia by fluid restriction is considered the standard of care by many physicians.\textsuperscript{48,49} Compared to no treatment, the use of a fluid restriction decreased the time of resolution of hyponatremia.\textsuperscript{50} The recommended fluid restriction is $< 1$L per day of fluid over the daily urinary volume.\textsuperscript{51} Fluid restriction is used to decrease water in the body. If the water intake is limited, then water excretion should be greater than water intake. This will cause a decrease in fluid in the body and increase serum sodium osmolality.\textsuperscript{13}

Patients on a fluid restriction need to have their fluid balance assessed. If the fluid volume given in excess of the fluid lost in the urine, it will lower the serum sodium levels. Therefore, the assessment of urine-free water losses and nonrenal free water loss is needed. The urine-free water loss can be estimated by $\text{freewater}_{\text{bss}} = \text{urine}_{\text{vol}} - \frac{\left(\text{urinesodium} + \text{potassium}\right)}{\text{plasmasodium}}$.

A randomized control trial of 64 patients found patients given a stricter fluid restriction (1,000 mL/d) after being discharged had a higher quality of life after 60 days compared to the usual-care group (given discharge instructions and education).\textsuperscript{52} This may be due to the control of serum sodium levels and not the actual fluid-restricted diet. The patients who had a conservative dietary sodium intake, 1,000 mL/d fluid restriction, and high diuretic dose had significantly better outcomes at 6 months than other groups.\textsuperscript{50} Other studies have found being on a fluid-restricted diet negatively affects a patient’s quality of life.\textsuperscript{53-54}

Studies have found successful fluid restriction can raise serum sodium levels up to 3 mEq/L.\textsuperscript{55-56} In order to be efficient, fluid restrictions require patient compliance. The
hyponatremia registry found out of 1,524 participants, 48% were treated with fluid restriction. The study found participants on a fluid restriction had a modest increase in serum sodium level with a median rate of 2.0 mEq/L/d.⁵⁵

**Sports Drinks**

During exercise the body uses electrolytes, water, and glucose stores to replenish the muscle and liver depletion. The use of these stores may lead to dehydration. Using isotonic solutions to replenish these stores can allow the body to maintain homeostasis.¹⁶

Isotonic beverages are composed of sodium, glucose, and potassium. If the amount of carbohydrates in a beverage is increased, it leads to a decrease in the delivery of fluids throughout the body. When there is a high concentration of carbohydrates in the intestine, it causes water to move out of the body and into the lumen of the intestine. This can increase the effects of dehydration because the water is leaving body stores and moving into the intestine depleting the body of more water.

One study found that males given a beverage with glucose content above 6% had a decrease in fluid delivery compared to when they were given water.⁵⁷ The same study found that increasing the sodium content of the beverage had no effect on the fluid delivery.⁵⁷

Another study of 15 men age 19-49 years (34.4±10) found having a 12% carbohydrate fluid with electrolytes had a greater fluid retention than water and water with electrolytes. An 8% carbohydrate and higher beverage emptied more slowly from the intestine and decreased the intestinal fluid uptake. A 12% carbohydrate beverage caused an increase in plasma glucose, which increased the plasma osmolality and stimulated vasopressin, insulin, and renin. The
increase in insulin would cause an increase in sodium reabsorption. These responses may have caused the increase in fluid retention for the 12% carbohydrate beverage.$^{19}$

The World Health Organization recommends a 90 mmol/l sodium and 11 mmol/l glucose for the treatment of dehydration induced by diarrhea. The solution is used to help with fluid absorption by the intestinal sodium-glucose cotransporter.$^{19}$

Studies have found isotonic beverages help to decrease the decline in serum sodium levels. One study found participants given a carbohydrate-electrolyte beverage during exercise had a decrease in the decline in serum sodium from pre- to post-exercise compared with beverages that do not contain sodium.$^{18}$ Another study found consuming a beverage that contains a moderate amount of sodium (19.9 mmol/L) at a rate equal to body mass change helped to reduce the decrease in the plasma sodium concentrations as well as preserve the plasma volume during exercise.$^{58}$

Giving athletes Gatorade® compared to water significantly increased their maximal exertion time.$^{59}$ This suggests that Gatorade® may be able to rehydrate better than water. The degree of dehydration in the athletes was less when drinking Gatorade® compared to water.

**Conclusion**

Hyponatremia is the most common electrolyte disorder among hospitalized patients. It increases patient hospitalization time and mortality rates.$^{10,11}$ Research shows that beverages with a higher sodium content have decreased the decline of serum sodium levels in athletes compared to beverages with lower sodium concentration.$^{19,57-59}$ Pursuing this further is important to determine if isotonic beverages can be used as an alternative treatment for hyponatremia in
hospitalized patients. The purpose of this study was to determine if Gatorade® increased serum sodium levels in patients with hyponatremia.
CHAPTER 3

METHODS

Experimental Design

The study was a randomized experimental control design. Participants were divided into two groups according to their diet prescription upon admission: fluid restriction or non-fluid restriction. Within each diet prescription the participants were placed in either the control group or the experimental group. The participants in the control group on a fluid restriction were given the standard protocol of water to take with their medicine, while the control group participants not on a fluid restriction were given 4 oz. of water on each meal tray (Table 1). The participants in the experimental group not on a fluid restriction were given 4 oz. of Gatorade® with each meal tray. The experimental group on a fluid-restricted diet were given Gatorade® to take with their medicine. All participants in the fluid restriction group were given either water or Gatorade® ranging from 9.3-18.6 oz. per day to take with their medicine, depending on the prescribed fluid restriction (Appendix A).
**Table 1. Experimental Design**

<table>
<thead>
<tr>
<th>Diet Prescription</th>
<th>Control Group</th>
<th>Experimental Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Fluid Restriction</td>
<td>Given 4 oz. of water with each meal</td>
<td>Given 4 oz. of Gatorade® with each meal</td>
</tr>
<tr>
<td>Fluid Restriction</td>
<td>Given prescribed amount of water to take with medicine (Ranging from 9.3-18.6 oz. per day)</td>
<td>Given prescribed amount of Gatorade® to take with medicine (Ranging from 9.3-18.6 oz. per day)</td>
</tr>
</tbody>
</table>

**Participants**

Subjects were recruited by the registered dietitians assigned to the floors on which the attending physicians assented for the study. Subjects for this study were recruited using a convenience sampling method at Marianjoy Rehabilitation Hospital (Marianjoy), a physical rehabilitation hospital. All participants in this study were diagnosed with hyponatremia (serum sodium less than 135 mmol/L). Individuals were eligible to participate if they had hyponatremia, were being treated for hyponatremia, and were between the ages of 60-85 years old. Treatment for hyponatremia in this facility included a fluid-restricted diet ranging from 1000 ml-2000 ml per day (Appendix A) or a non-fluid-restricted diet. Individuals on a renal diet were excluded from the study because their diet prescription limited their sodium intake to less than 2,400 mgs per day. In addition, individuals with cognitive disorders including dementia, Alzheimer’s disease and organic brain syndrome were excluded from the study because they could not give consent to participate in the study.
Originally all subjects with a hyponatremia diagnosis in this facility had been prescribed a fluid-restricted diet. The fluid restriction regimens ranged from 1000 ml-2000 ml per day, the standard protocol for the facility, and were prescribed by the attending physicians. However, due to the low facility census and lack of patients prescribed fluid-restricted diets, the study protocol was modified to include patients with hyponatremia not on fluid restriction diets with IRB approval (Appendix B).

Prior to enrollment in the study, the primary researcher explained the study requirements to potential participants. Participants were informed of confidentiality in participation of the study. In addition, they were informed of the risks and benefits associated with this study and were required to sign written consent (Appendix C, D) before participating in accordance with the study procedures approved by the Marianjoy Rehabilitation Hospital Institutional Review Board (IRB) (Appendix E). Subjects were also informed the study was voluntary and that their decision to participate in the study would not affect their care at Marianjoy.

**Data Collection**

Participants’ fluid intake was monitored and recorded daily by the diet technicians and the nursing staff. The fluid that the participants used to take their medicine with was documented by the nursing staff in their medical records; any leftover fluids were put on the participants’ meal tray to be measured and recorded by the researcher. The fluids consumed with meals were monitored and documented by the diet technicians as trained by the researcher. The diet technicians documented all fluids and foods ordered by the patient in Comptrition (2014), a foodservice software used to track the foods and beverages patients receive from the hospital kitchen.
The researcher measured and recorded all leftover food from the participants’ plates after each meal, to the nearest ounce, using the A&D SJ Series Digital Portion Scale. The leftover fluid from the meals and medicine was measured using a C and A Scientific PL-C 250 plastic 250 mL cylinder to the nearest milliliter.

The participants’ demographic information was obtained from their individual medical charts. This information included their age, gender, and ethnicity. In addition, the participants’ weight, fluid input and output, and the presence of pitting edema were recorded from the medical charts. Medications and presence of confounding diseases such as diabetes, liver disease, or heart disease were noted from the medical charts.

Prior to the study, subjects had their blood drawn by trained hospital phlebotomists wearing medical exam gloves and lab coats. The phlebotomist drew one serum separator tube of .7 mL whole blood. The clotted blood sample was centrifuged for 15 minutes at 3500 RPM (model 642). The blood was separated into its components of plasma, red blood cells, and white blood cells. The blood was stored in a refrigerator at 33.8-42.8°F before it was sent to Central DuPage Hospital for analysis. During transportation the blood was kept in a cooler at 33.9-42.8°F. A minimum of 0.3 mL of serum or plasma was required in order for the serum sodium test to be performed. The sodium was then measured using an indirect ion-selective electrode potentiometer (Roche, Indianapolis IN).

**Intervention**

The participants in the experimental group received G2 lemon-lime flavor obtained from PepsiCo Foodservice (55 West Monroe St, Chicago IL). The composition of the Gatorade® per ounce is 0.5 g carbohydrates (1.63g sucrose, 0.15g glucose), 18.75 mg sodium, 5.6 mg
potassium (Appendix F). Gatorade® was selected for use in this study based on results from sports nutrition research that show when there is a decrease in serum sodium levels among healthy adults, consumption of Gatorade® helps to increase the serum sodium levels.19,57-59

**Statistical Analysis**

Descriptive measures were used to describe the study population. One-way analysis of variance (ANOVA) was used for inferential statistics. Within- and between-group differences in sodium intake and serum sodium levels were analyzed using repeated-measures ANOVA. ANOVA was used to determine if there was a significant difference between the serum sodium levels of the groups. A paired-samples test was used to examine serum sodium levels pre and post-study. Statistical significance for all data analysis was accepted at the $p<0.05$ level of confidence. Data was analyzed by using the Statistical Package for Social Sciences (SPSS) for Windows (Version 21.0, 2013, SPSS, Inc., Chicago, IL).
CHAPTER 4

RESULTS

Characteristics of the Participants

Participant characteristics are shown in Table 2. A total of 32 patients consented to participate in the study; however, two of the participants did not complete the 7-day study. Therefore, 30 participants completed the study. Subjects ranged in age from 60-85 years of age, with a mean age for all participants of 75.4±6.44, and were predominantly male (60%) (Table 2).

The majority of participants had hypertension (80%) while 5 out of 30 (16.67%) participants had diabetes. Comorbidities are shown in Table 3.

Sodium Intake

The mean sodium intake from food for participants in the experimental group on a fluid restriction was 3,115.4 ± 337.39mg per day. The mean total sodium intake from both food and Gatorade® was 3,315.40 ± 327.60mg. Participants in the fluid restriction control group had a mean sodium intake from food of 3,251.60 ±769.60mg. The non-fluid-restricted experimental group consumed an average of 2,639.70 ± 678.21mg of sodium from their food for an overall mean total of 2,798.70 ± 678.21mg sodium. The non-fluid-restricted control participants consumed a mean sodium intake of 2,575.50 ± 994.91mg. The mean total sodium intake from
food and Gatorade® per day was 3,166.31±493.58mg. The average mean sodium intake from food of all participants was 2,982.83±491.06mg (Table 4). There was a statistically significant difference (p<0.05) between sodium intake levels of participants in the control and experimental groups.

Table 2. Characteristics of All Subjects

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>n (%)</th>
<th>Mean ±SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>30 (100)</td>
<td>75.40 ± 6.94</td>
</tr>
<tr>
<td>60-65</td>
<td>2 (7)</td>
<td>NA</td>
</tr>
<tr>
<td>66-70</td>
<td>4 (13)</td>
<td>NA</td>
</tr>
<tr>
<td>71-75</td>
<td>7 (23)</td>
<td>NA</td>
</tr>
<tr>
<td>76-80</td>
<td>11 (37)</td>
<td>NA</td>
</tr>
<tr>
<td>80-85</td>
<td>6 (20)</td>
<td>NA</td>
</tr>
<tr>
<td>Gender</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Male</td>
<td>18(60)</td>
<td>NA</td>
</tr>
<tr>
<td>Female</td>
<td>12(40)</td>
<td>NA</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>White</td>
<td>23(76.7)</td>
<td>16.07 (+5.21)</td>
</tr>
<tr>
<td>African American</td>
<td>6(20.0)</td>
<td>81.88 (+17.27)</td>
</tr>
<tr>
<td>Asian</td>
<td>1(3.3)</td>
<td>131.07 (+2.72)</td>
</tr>
<tr>
<td>Length of Stay (days)</td>
<td>30(100)</td>
<td>134.37 (+3.20)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>30(100)</td>
<td>2,982.83 (+491.06)</td>
</tr>
<tr>
<td>Sodium Levels (mmol/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre</td>
<td>30(100)</td>
<td></td>
</tr>
<tr>
<td>Post</td>
<td>30(100)</td>
<td></td>
</tr>
<tr>
<td>Average Daily Sodium Intake (mg)</td>
<td>30(100)</td>
<td></td>
</tr>
<tr>
<td>Edema</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Presence</td>
<td>9(30)</td>
<td></td>
</tr>
<tr>
<td>Absence</td>
<td>21(70)</td>
<td></td>
</tr>
</tbody>
</table>
Table 3. Comorbidities

<table>
<thead>
<tr>
<th>Comorbidity</th>
<th>All participants</th>
<th>Non fluid restriction</th>
<th>Non fluid restriction</th>
<th>Fluid restriction</th>
<th>Fluid restriction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>24(80)</td>
<td>8(80)</td>
<td>9(90)</td>
<td>4(80)</td>
<td>3(60)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>5(16.67)</td>
<td>2(20)</td>
<td>2(20)</td>
<td>0</td>
<td>1(20)</td>
</tr>
<tr>
<td>Chronic Heart Failure</td>
<td>2(6.67)</td>
<td>0</td>
<td>1(10)</td>
<td>0</td>
<td>1(20)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>4(13.33)</td>
<td>1(10)</td>
<td>1(10)</td>
<td>1(20)</td>
<td>1(20)</td>
</tr>
<tr>
<td>Hypothyroidism</td>
<td>3(10)</td>
<td>2(20)</td>
<td>0</td>
<td>1(20)</td>
<td>0</td>
</tr>
<tr>
<td>Cancer</td>
<td>3(10)</td>
<td>1(10)</td>
<td>1(10)</td>
<td>1(20)</td>
<td>0</td>
</tr>
<tr>
<td>COPD</td>
<td>4(13.33)</td>
<td>2(20)</td>
<td>0</td>
<td>1(20)</td>
<td>1(20)</td>
</tr>
</tbody>
</table>

Table 4. Sodium Intake Levels per Day

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Sodium Intake per Day Mean ±SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental a</td>
<td>10</td>
<td>2,798.70 ± 678.21</td>
</tr>
<tr>
<td>Control b</td>
<td>10</td>
<td>2,575.50 ± 994.91</td>
</tr>
<tr>
<td>Non-Restriction ab</td>
<td>20</td>
<td>2,687.10 ± 836.58</td>
</tr>
<tr>
<td>Experimental restriction c</td>
<td>5</td>
<td>3,115.40 ± 337.39</td>
</tr>
<tr>
<td>Control restriction d</td>
<td>5</td>
<td>3,251.60 ± 769.60</td>
</tr>
<tr>
<td>Restriction cd</td>
<td>10</td>
<td>3,283.54 ± 558.63</td>
</tr>
<tr>
<td>Total abcde</td>
<td>30</td>
<td>3,166.31±493.58</td>
</tr>
</tbody>
</table>


Serum Sodium Levels

Hypothesis 1 (Elderly patients with hyponatremia on a fluid-restricted diet will have a significantly higher serum sodium level when given Gatorade® compared to those patients on the standard treatment protocol) was not supported. The mean post-test serum sodium level increased significantly in all groups except the non-fluid-restricted control group. Nine of the ten
participants from the experimental group without a fluid restriction had an increase in serum sodium levels while the one participant’s serum levels remained unchanged. Of the participants not in the fluid restriction control group, 60% (n=6) had increased serum sodium levels while 40% (n=4) showed no difference in their serum sodium levels from pre- to post-test study. All ten of the participants on the fluid-restriction diet had an increase in their serum sodium levels in the post-test.

A paired-samples t-test was conducted to determine if there was a difference in the serum sodium levels before and after Gatorade® was used in the treatment of hyponatremia. Participants in the fluid-restricted experimental group had a mean pre-test serum sodium level of 128.00 ± 3.16mg/dl and a mean post-test serum sodium level of 132.2±1.30mg/dl (Table 5). There was a statistically significant difference (p<0.05) in serum sodium levels between the pre- and post-test study for participants in the experimental fluid-restricted diet group.

Participants in the control fluid-restricted diet group had a mean pre-test serum sodium level of 134.00 ± 3.36 mg/dl and a mean post-test serum sodium level of 134.00 ± 2.74 mg/dl (Table 5). This was a significant difference in serum sodium levels (p<0.05).

Of the total participants on the fluid-restricted diet, the difference in the serum sodium levels between the pre- and post-test study was also statistically significant p<0.05 (132.00±1.81mg/dl and 135.00±3.46mg/dl respectively).

Subjects not on a fluid-restricted diet in the experimental group had a mean pre-serum sodium level of 132.00±1.83mg/dl and a mean post-test serum sodium level of 135.80±3.19 mg/dl (Table 5), which was significantly different in serum sodium level( p<0.05).
The control group not on a fluid-restricted diet had a mean pre-test serum sodium level of 132.00±1.88 mg/dl and a mean post-serum sodium level of 134.20±3.71 mg/dl (Table 5). There was not a significant difference in serum sodium levels in this group.

Among the total participants not on a fluid-restricted diet, there was a significant difference in the serum sodium between the pre- and post-test study ($p<0.05$). The mean serum sodium levels in the pre-test for participants on a fluid restriction diet was 129.20±1.05 mg/dl, while the mean serum sodium level in the post-test was 133.10±2.22 mg/dl.

For the pre-test, serum sodium levels were significantly different between the four groups ($p<0.05$). There was a significant difference in the experimental group between the experimental fluid-restricted group and the experimental non-fluid-restricted group ($p<0.05$). There was also a significant difference between the control and the experimental fluid-restricted group ($p<0.05$). Participants in both the experimental and control groups had an increase in serum sodium levels.

**Table 5. Serum Sodium Levels Pre- and Post-Test**

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Pretest Mean ±SD</th>
<th>Posttest Mean ±SD</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental $^a$</td>
<td>10</td>
<td>132.00±1.83</td>
<td>135.80±3.19</td>
<td>0.024 $^ac$</td>
</tr>
<tr>
<td>Control $^b$</td>
<td>10</td>
<td>132.00±1.88</td>
<td>134.20±3.71</td>
<td>0.16</td>
</tr>
<tr>
<td>Experimental restriction $^c$</td>
<td>5</td>
<td>128.00±3.16</td>
<td>132.20±1.30</td>
<td>0.024 $^bc$</td>
</tr>
<tr>
<td>Control restriction $^d$</td>
<td>5</td>
<td>130.40±3.36</td>
<td>134.00±2.74</td>
<td>0.00</td>
</tr>
<tr>
<td>Total $^e$</td>
<td>30</td>
<td>131.07±2.71</td>
<td>134.37±3.20</td>
<td>0.020 $^de$</td>
</tr>
</tbody>
</table>

CHAPTER 5

DISCUSSION

The purpose of the study was to determine whether using Gatorade® to treat hyponatremia would increase serum sodium levels of subjects with a diagnosis of hyponatremia. In this randomized experimental control study, every other subject was randomly assigned to either the experimental or the control group, resulting in 10 subjects without a fluid restriction in the experimental group assigned to the Gatorade® treatment and 10 to the control group without a fluid restriction who received plain water, five subjects on a fluid restriction in the experimental group assigned to Gatorade® five subjects on a fluid-restricted diet in the control group receiving plain water. The subjects participated in the study for 7 days.

The results of the study found all groups had an increase in serum sodium levels after 7 days of observation. There was a significant difference over time between pre- and post-test mean values for both the experimental and control groups in their serum sodium levels.

Although not every participant in the study had an increase in serum sodium levels, all ten of the fluid-restricted participants had an increase in serum sodium levels. This supports the current treatment modality of using fluid-restricted diets to increase serum sodium levels. There was a significant increase pre- and post-test study in serum sodium levels in both the fluid-restricted groups (experimental and control groups). These findings support current research that
fluid-restricted diets aid in increasing serum sodium levels.\textsuperscript{55} Although some studies did not find a significant increase in serum sodium levels, those studies were of much shorter duration and lasted only for 72 hours. These shorter studies focused on the effects of medications on serum sodium levels.\textsuperscript{50} The study at hand was conducted over 7 days to adequately assess the effect of Gatorade\textregistered intake while on a fluid-restricted diet.

The difference in sodium consumed by participants may have contributed to the lack of significant differences between serum sodium levels of experimental and control groups. The participants in this study were not on a controlled sodium intake. The mean sodium intake for participants on a fluid-restricted diet in the experimental group was 3,115.40 \( \pm \) 337.39mg, while the fluid-restricted participants in the control group consumed on average 3,251.60 \( \pm \)769.60 mg of sodium per day. If participants in the control group consumed more sodium than the experimental group, their serum sodium level may have risen more. In addition, 80\% of the participants were diagnosed with hypertension and could have been on medication affecting fluid and electrolyte balance.

A fluid-restricted diet is used to treat hyponatremia because the restriction decreases the water in the body and increases the serum sodium concentration.\textsuperscript{13} Previous research examined active adults (age 22-36) given isotonic beverages to prevent a decrease in serum sodium during exercise in hot temperatures. In the current study, the majority of the participants with hyponatremia on a fluid-restricted diet had an increase in serum sodium levels, with 90\% of those in the experimental group and 60\% of the control group increasing serum sodium concentration. The results of the current study support previous study findings that reported participants given a beverage with sodium reduced the decline in serum sodium levels compared to beverages without sodium.\textsuperscript{18,58}
Participants not on a fluid-restricted diet in the experimental group had a statistically significant increase in serum sodium levels while the participants in the control group did not have a significant increase in serum sodium levels. Gatorade® helps with hyponatremia in athletes by replenishing the body’s stores of sodium that are depleted during exercise.\(^\text{16}\) Although the non-fluid-restricted control group did not have a statistically significant increase in serum sodium levels, there was not a statistically significant difference between the non-fluid-restricted groups. This implies Gatorade® will help increase serum sodium levels over a 7-day period, but it does not increase serum sodium levels significantly more than water. This contradicts previous research findings using isotonic beverages to increase serum sodium levels. This may be due to the difference in population that was studied; previous research examined active adults age 22-36 years old exercising in heat, while the current study examined elderly hospitalized patients age 60-85 years old.\(^\text{18,58}\)

While no significant difference was found between the total experimental and control populations on serum sodium levels in the current study, further studies of Gatorade® consumption designed to control the sodium intake levels of participants might reveal significant differences between the two groups. The current study demonstrated a significant difference between pre- and post-test serum sodium levels for all fluid-restricted participants and the non-fluid-restricted experimental group. These results indicate that a fluid-restricted diet may help to increase serum sodium levels and Gatorade® consumption on a non-fluid-restricted diet may be useful in increasing serum sodium levels in patients with hyponatremia. This may lead to an alternative method of treatment for patients who have hyponatremia and improve their quality of life. Patients who do not want to be on a fluid-restricted diet may find consuming Gatorade® to be a more palatable treatment option. The treatment of hyponatremia is important because it
increases a patient’s length of stay. If Gatorade® could be used to increase serum sodium levels, it may decrease the patient’s hospitalization time and save the institution money. In addition, hyponatremia is associated with increased mortality rates; if hospitals use Gatorade® to treat hyponatremia it may decrease the mortality rates of patients. Treating patients with hyponatremia with Gatorade could benefit both the hospital and the patients.

**Conclusion**

The results of this study suggest people with hyponatremia who are not on a fluid restriction may benefit from consuming Gatorade® to help increase their serum sodium levels. The current study gave participants with hyponatremia who were not on a fluid-restricted diet 4 oz of Gatorade® with each meal. Gatorade® consumption may have caused their serum sodium levels to significantly increase over a 7-day period, although the increase was not significantly different than the control group receiving water. Although more research is needed, this may be an alternative treatment option for patients with hyponatremia.

Moreover, hospitalized patients may also increase their serum sodium level by being put on a fluid-restricted diet. Both the participants in the control and experimental groups who were on a fluid-restricted diet had a significant increase in serum sodium levels. Studies have shown quality of life is negatively affected when patients are on a fluid-restricted diet, which is why giving Gatorade® to people with hyponatremia may be a reasonable alternative treatment option. Patients who do not want to be on a fluid-restricted diet may find consuming Gatorade® daily to be an easier task to achieve in order to increase their serum sodium levels. Also, hospitals may save money by decreasing the length of stay for patients who have hyponatremia.
CHAPTER 6

LIMITATIONS AND FUTURE RESEARCH

Limitations of the Current Study

Several limitations of this study should be noted. One limitation is the small sample size. The recruitment process was selective, leading to lower participation rates. Completing a study in a small hospital made it difficult to obtain a large sample size. The small sample size limited the power of the study significance. Previous studies examining increase serum sodium levels had funding from the pharmaceutical companies, which may explain the increased sample size. The current study was not funded by any company or organization.

The study was designed to examine if Gatorade® consumption increased serum sodium levels in subjects with hyponatremia. The amount of sodium participants consumed widely varied between subjects. Having a standard amount of sodium each participant consumed throughout the day may have helped regulate how much sodium was being consumed.

Another limitation to the study may be the participants quality of life. Studies have shown being on a fluid-restricted diet affects patients’ quality of life. Participants in the fluid-restricted group may have had a decrease in their quality of life.

In addition, the lemon-lime flavor of Gatorade® was not always a favorite. A few potential participants declined the study due to the Gatorade® flavor. Some participants became
tired of the lemon-lime flavor of Gatorade®. If participants were given a variety of flavors to choose from, they may have been more compliant in consuming the Gatorade®.

**Recommendations for Future Study**

Future studies would likely benefit from increased compliance and decreased attrition rates if participants were given a choice of Gatorade® flavor to consume. Some participants did not like the lemon-lime flavor. Other participants wanted more variety in their drink; they got tired of having the same flavor beverage three times a day.

Furthermore, having participants consume similar sodium levels of food may eliminate confounding variables in the analysis of the study. There was a wide range of intake from sodium in foods. This may have affected the study results.

Additionally, increased sample population would allow for greater confidence in the study findings. Having a greater sample size may show increased significant differences between the groups. A greater sample size would increase the power to detect differences in serum sodium levels between gender and ethnicity.

Another important factor to examine is the patient’s quality of life. Research shows a fluid-restricted diet can decrease a patient’s quality of life. Examining whether giving patients Gatorade® increases their quality of life compared to patients on a fluid-restricted diet is an important factor which should be considered.
REFERENCES


34. Pahnke MD, Trinity JD, Zachwieja JJ, Stefan JR, Hiller WD, Coyle EF. Serum sodium concentration changes are related to fluid balance and sweat sodium loss. Medicine & Science in Sports & Exercise. 2010; 1669-1674.


APPENDIX A
FLUID RESTRICTION AT MARIANJOY
### Amount of Fluid Provided on Patient Trays for Fluid-restricted Diets

<table>
<thead>
<tr>
<th>Fluid Restriction</th>
<th>Breakfast</th>
<th>Lunch</th>
<th>Supper</th>
<th>Daily Total from Meal Trays</th>
<th>Nursing Fluid Allowance between meals</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 ml</td>
<td>1 cup (8 oz.)</td>
<td>1 cup (8 oz.)</td>
<td>1 cup (8 oz.)</td>
<td>24 oz. (720ml)</td>
<td>9.3 oz. (280ml)/day</td>
</tr>
<tr>
<td>1200 ml</td>
<td>1.5 cup (12 oz.)</td>
<td>1 cup (8 oz.)</td>
<td>1 cup (8 oz.)</td>
<td>28 oz. (840ml)</td>
<td>12 oz. (360ml)/day</td>
</tr>
<tr>
<td>1500 ml</td>
<td>1.5 cup (12 oz.)</td>
<td>1.5 cup (12 oz.)</td>
<td>1.5 cup (12 oz.)</td>
<td>36 oz. (1080 ml)</td>
<td>14 oz. (420ml)/day</td>
</tr>
<tr>
<td>1800 ml</td>
<td>2 cup (16 oz.)</td>
<td>2 cup (16 oz.)</td>
<td>1.5 cup (12 oz.)</td>
<td>44oz (1320 ml)</td>
<td>16oz (480 ml)/day</td>
</tr>
<tr>
<td>2000 ml</td>
<td>2 cup (16 oz.)</td>
<td>2 cup (16 oz.)</td>
<td>2 cup (16 oz.)</td>
<td>48 oz. (1440 ml)</td>
<td>18.6 oz. (560ml)/day</td>
</tr>
</tbody>
</table>

### Fluid Content of Beverages Served at Marianjoy

<table>
<thead>
<tr>
<th>Item</th>
<th>Ounces (oz.)</th>
<th>milliliters (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carton of Milk</td>
<td>8 oz.</td>
<td>240 ml</td>
</tr>
<tr>
<td>Nectar thick Milk</td>
<td>8 oz.</td>
<td>240 ml</td>
</tr>
<tr>
<td>Orange Juice</td>
<td>6 oz.</td>
<td>180 ml</td>
</tr>
<tr>
<td>Cranberry Juice</td>
<td>6 oz.</td>
<td>180 ml</td>
</tr>
<tr>
<td>Apple Juice</td>
<td>6 oz.</td>
<td>180 ml</td>
</tr>
<tr>
<td>Prune Juice</td>
<td>4 oz.</td>
<td>120 ml</td>
</tr>
<tr>
<td>Lemonade</td>
<td>4 oz.</td>
<td>120 ml</td>
</tr>
<tr>
<td>Apricot Nectar</td>
<td>4 oz.</td>
<td>120 ml</td>
</tr>
<tr>
<td>V-8 Juice</td>
<td>5.5 oz.</td>
<td>165 ml</td>
</tr>
<tr>
<td>Nectar thick juices</td>
<td>4 oz.</td>
<td>120 ml</td>
</tr>
<tr>
<td>Nectar thick water</td>
<td>4 oz.</td>
<td>120 ml</td>
</tr>
<tr>
<td>Regular Health shakes</td>
<td>6 oz.</td>
<td>180 ml</td>
</tr>
<tr>
<td>Glucerna Shakes</td>
<td>8 oz.</td>
<td>240 ml</td>
</tr>
<tr>
<td>Soda: Cola/ Lemon lime</td>
<td>8 oz.</td>
<td>240 ml</td>
</tr>
<tr>
<td>Item</td>
<td>Quantity</td>
<td>Volume</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>----------</td>
<td>---------</td>
</tr>
<tr>
<td>Gingerale</td>
<td>8 oz.</td>
<td>240 ml</td>
</tr>
<tr>
<td>Jell-O</td>
<td>4 oz.</td>
<td>120 ml</td>
</tr>
<tr>
<td>Ice Cream</td>
<td>4 oz.</td>
<td>120 ml</td>
</tr>
<tr>
<td>Sherbet</td>
<td>4 oz.</td>
<td>120 ml</td>
</tr>
<tr>
<td>Sorbet</td>
<td>4 oz.</td>
<td>120 ml</td>
</tr>
<tr>
<td><strong>Green Coffee or Tea Cup</strong></td>
<td>6 oz.</td>
<td>180 ml</td>
</tr>
<tr>
<td>Iced Tea (8 oz. cup)</td>
<td>6 oz.</td>
<td>180 ml</td>
</tr>
<tr>
<td>Ensure Clear</td>
<td>6.8 oz.</td>
<td>200 ml</td>
</tr>
<tr>
<td>Green Bowl of Soup (6 oz. bowl)</td>
<td>4 oz.</td>
<td>120 ml</td>
</tr>
<tr>
<td>Fruit Smoothie</td>
<td>8 oz.</td>
<td>240 ml</td>
</tr>
</tbody>
</table>
APPENDIX B
MARIANJOY IRB REVISION SUBMISSION FORM
REVISION SUBMISSION FORM

Instructions: Revisions of a procedural nature, revisions that change the consent form, and changes in risk are sent to the IRB Board for full review and should be submitted two weeks prior to the IRB meeting. Revisions of a minor nature, e.g., minor wording changes, changes in personnel, corrections, are reviewed administratively. Revisions may be considered by the IRB chair to be non-substantive minor revisions to protocol procedures. If this is so determined, then the revisions will be reviewed by the Chairperson of the MRHC/MMG IRB. All other revisions will be reviewed by the full IRB committee at the next scheduled meeting. This form should be used to submit revisions outside of the Periodic Review. If you are requesting a Revision as part of the Periodic Review process this request can be included in the Periodic Review form.

1. Submission Date: 11/10/15
2. Principal Investigator Name: Hannah Degen
   Phone: 630-303-0886    Fax: None    E-Mail: hdegen@niu.edu
3. Submission Prepared By: Hannah Degen
   Phone: 630-303-0886    Fax: None    E-Mail: hdegen@niu.edu
4. Project Title: Using Gatorade® to Control Serum Sodium Levels of Hyponatremic Patients on a Fluid-restricted Diet

5. Investigator Brochure (IB): IB Version Date and Number:
   Does this new IB represent any changes to risks listed in the current approved consent form? □ YES  x NO
   If new risks are described in the investigator’s brochure, a new consent form must be attached. Additional comments can be written in the two columns below.

6. Revision Description:
   6.1. This revision was initiated by: PI  x  Study Sponsor □
   If by the Study Sponsor: Protocol Amendment #    dated

   6.2 Revision Type:
   Please check all applicable categories:
   x□ Change in Protocol (this includes inclusion/exclusion criteria, data collection, and recruitment)**
   □ Change in total number of subjects
   □ Change in investigator or other authorized personnel**
   x□ Change in consent/information documents **
   □ Other (for example, change in title): **
**NOTE:** Revisions that may affect the Research Informed Consent And Authorization for Uses and Disclosures of Protected Health Information for Research form.

7. **Consent Form:** Do the revisions require modification to the consent form(s)? ☒ YES ☐ NO ☐ Not Applicable
   If yes, attached a newly revised consent form(s) with the changes highlighted.
   Newly Revised Consent Form(s) Version: Date:

To aid in the review, please describe the nature of the change(s) and the rationale for change(s).

**Changes to protocol or consent form should be highlighted and attached to this submission.**

Revisions involving change in Authorized Personnel should reflect those changes in the Personnel table provided below. An explanation of the role additional personnel have in the research study should be provided in the rationale section below. Do not include a new research proposal form. If additional information or comments are needed, please attach an additional sheet.

<table>
<thead>
<tr>
<th>PRESENT SITUATION REQUESTED/RATIONALE</th>
<th>REVISION</th>
</tr>
</thead>
<tbody>
<tr>
<td>There has been an increase in the number of patients being dehydrated at Marianjoy. To help prevent this from happening fewer patients are being put on a fluid restriction. Over the last two months there has been a decrease in the number of hyponatremic patients being put on a fluid restriction. In order to obtain 30 participants for the study the participant requirements need to be changed.</td>
<td>The original study required participants to have hyponatremia and be on a fluid-restricted diet. Due to the decrease in patients on a fluid restriction the participants being recruited after the protocol revision will have hyponatremia and not be on a fluid-restricted diet. These participants will receive 4 oz. of either Gatorade® or water on every meal tray (12 oz. daily). Changing the subject requirements will allow the study to obtain 30 participants.</td>
</tr>
</tbody>
</table>

Revisions to Authorized Personnel: Complete the information below for all changes to personnel.

<table>
<thead>
<tr>
<th>Name of Changed Personnel</th>
<th>Role in Project</th>
<th>Phone Number:</th>
<th>E-mail address:</th>
<th>Nature of Personnel change: Addition or Removal</th>
<th>IRB Administrator has a copy of CITI Training Certificate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Add ☐ Yes ☐ No</td>
</tr>
<tr>
<td>Remove</td>
<td>Add</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------</td>
<td>-----</td>
<td>-----</td>
<td>----</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Investigator’s Name and Signature ___________________________ Date __________

After completing this form, it can be sent electronically to Renée Ecklund, IRB Administrator, recklund@marianjoy.org. Print and submit a hard copy of last page with signature.
APPENDIX C
CONSENT FORM
RESEARCH INFORMED CONSENT

and

AUTHORIZATION FOR USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION FOR RESEARCH

Patient Participant: ___________________ Account Number: ___________________

Date: _______________ Time: _______________

1. Title of Research Study: Using Gatorade® to control serum sodium levels of hyponatremic patients on a fluid-restricted diet
2. Sponsor: Hannah Degen
3. Marianjoy Principal Investigator: Hannah Degen
4. Co-Investigators: None
5. Introduction:
You are being asked to volunteer to be a subject in a research study. This form is designed to provide you with the information necessary for you to make an informed decision regarding participation in this study.
Marianjoy Rehabilitation Hospital & Clinics/Marianjoy Medical Group (MRHC/MMG) recognizes the valuable role that participants play in research regarding rehabilitation and disability. To that end, MRHC/MMG is committed to protecting the safety and well-being of patients within our organization who participate in any research study.
The MRHC/MMG Human Subjects Institutional Review Board (IRB00004428) oversees all research done at MRHC/MMG. The IRB stamp above indicates that this review board has approved the study described in this consent form. As a participant in a research study, it is important that you read this form completely. Please ask questions if you do not understand any information presented in this form.
6. **Purpose of Research Project:**
   - You are being asked to participate in this research study because you are a hyponatremic patient on a fluid-restricted diet.
   - The purpose of this research study is to examine if giving Gatorade® to rehabilitation patients on a fluid restriction with hyponatremia will increase their serum sodium levels compared to hyponatremic patients given water.
   - Your participation is expected to last one week.
   - Approximately 30 people will be enrolled in the study.

7. **Research Procedures:** The following information describes what will happen when you participate in this research study:
   - When you are given your medicine you will be given a premeasured amount of Gatorade® or water based on your fluid restriction. In addition, you will have your blood drawn and the sodium levels test on the first, third, and seventh day of the study. The researcher will access your medical records to obtain demographic information and comorbidities.

8. **Risks:** Participation in this study involves:
   - No foreseeable risks.

9. **Benefits:**
   - The potential benefits include:
     - Increasing serum sodium levels through Gatorade® consumption.
   - Participation in this study may aid in better understanding of:
     - Treatment of hyponatremia.

10. **Alternatives:** Participation in this study is voluntary; the alternative is to choose not to participate.

11. **Investigators Access to and Use of Protected Health Information:**
    - Protected health information (PHI) is private information about a person’s health that includes identifying information that would make it possible to figure out whose information it is. The law protects this private information, and gives you the right to decide who can see it.
    - If you choose to take part in this research study, the researchers (the investigators listed above in sections 3 and 4, and their research staff individuals carrying out the study) will access your PHI for the research described in this consent form. The researchers are required to maintain confidentiality of your entire PHI.
    - The PHI that is being collected as part of this research study is demographic information and comorbidities.
    - The researchers will get this PHI from the patient’s medical records. When reviewing medical or billing records to collect the data, the researchers might see PHI that they do not need to collect for the research study. This PHI that is unintentionally accessed might include details about mental illness or developmental disabilities, HIV/AIDS test results, drug/alcohol abuse, results from generic testing, or information about sexually transmitted diseases. Any PHI that is viewed unintentionally will not be collected or reported as part of this research study.
    - As soon as you sign this consent, you authorize the researchers’ access to and use of your PHI. This authorization to access and use your PHI will expire:
when the following event occurs: participant has completed the study.

However, you may ask the researchers (either verbally or in writing) to stop using your PHI at any time. The person to notify to do this is Hannah Degen. If you tell the researcher to stop using your PHI, your participation in the study will end and the researchers will stop collecting new PHI from or about you. However, the researchers will continue to use the PHI already collected up to the time they received your request asking them to stop.

12. Access to Protected Health Information by Authorized Representatives of MRHC/MMG or Affiliate:
   If you choose to take part in this research study, other authorized representatives of MRHC/MMG or Affiliates (in addition to the investigators/researchers as described in section 11) might see your PHI. These persons are also required to maintain confidentiality of your PHI and include the following:
   - Authorized representatives of MRHC/MMG might see your (PHI) in order to (1) fulfill orders associated with research study participation, and/or (2) address correct payment for tests and procedures ordered by the investigators.
   - Authorized representatives of MRHC/MMG Human Subjects Institutional Review Board might see your PHI in order to monitor the conduct of the research study.

13. Confidentiality:
   The protected health information collected for the study will be stored for research purposes. Your information will be stored electronically and in paper form. Your protected health information is confidential. The following physical and technical safeguards will protect it: All records connecting your name with the protected health information will be stored on a Marianjoy computer behind the Marianjoy firewall. This research study might produce results related to your medical treatment. If the research results are related to your medical treatment, then the research results will be placed in your MRHC/MMG medical record. If the results of this study are reported in medical journals or at meetings, you will not be identified.
   In addition, parts of your PHI may be copied and sent to a central location, only after all of your identifying information has been removed. This is then referred to as de-identified information. Your de-identified PHI may be passed on to other persons or groups not named here.

14. Disclosure of Protected Health Information:
   Your protected health information might be disclosed as required by law. Your protected health information might be disclosed in response to an order from a court of law. Your protected health information might also be disclosed to authorized representatives not affiliated with MRHC/MMG including:
   a. The Office for Human Research Protections (OHRP) for the purpose of ensuring the subject’s protection.
   b. The U.S. Food and Drug Administration (FDA) for the purpose of monitoring research data accuracy.
c. External sponsors of the research study for the purpose of monitoring research data accuracy and for performing data analyses.

The authorized entities above are required to maintain confidentiality of your protected health information; however, MRHC/MMG cannot guarantee the confidentiality of information disclosed after its receipt by others.

15. **Research Photographs and Videotapes:**

At the end of this consent form, you will be given the option of allowing us to take photographs and/or make videotape recordings of you. These photographs and/or videotapes may be used in medical or scientific publications and presentations. These photographs and/or videotapes will not be labeled with your personal information.

16. **Financial Information:**

There are no charges to you for any of the research procedures that you receive as described in this form. The study sponsor will pay for all procedures that are directly associated with this research study. Any procedures or drugs that are part of your routine medical care for your condition will be the responsibility of you or your insurance company.

17. **Research Related Injury:**

If a research related injury occurs, the investigators will address any harmful consequences you may have experienced from research participation. The medical staff of MRHC/MMG and any other affiliated institutions will provide immediate medical attention for any physical injury resulting from your participation in this project. If such medical attention is provided, MRHC/MMG and its affiliates neither admit liability nor waive legal defense. If you are injured as a result of the research procedures, your injury will be treated. You will be responsible for any charges related to such treatment. This hospital makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge.

18. **Subject’s Rights:**

Participation in this study is voluntary and you are free to withdraw at any time. You may withdraw from the study by providing a verbal or written and dated notice to the investigator of this study Hannah Degen at hdegen@mairainjoy.org, Wheaton, IL 60187. You are also free not to let the researchers and other groups see and share your health information. If you choose not to be in the study or not to let the researchers and other groups use your health information, there will be no penalties. In other words, you will still be able to get medical treatments without being in the study and it will not affect your eligibility for any health plan or any health plan benefits or payments for which you may be eligible. Marianjoy’s Notice of Privacy Practices specifies how you may access your protected health information, including information resulting from participation in this research study. Contact the Privacy Officer at (630) 909-8032 if you have a need to review your protected health information collected for this study. Any new findings developed during the course of this research that may affect your willingness to continue will be provided to you. Participation or withdrawal will not affect your present or future medical treatment.
We may want to contact you after you are no longer participating in this study. We may contact you by telephone regarding participation in additional research. You do not, however, have to agree to participation in this additional research. Information regarding your rights can also be obtained from the MRHC/MMG Human Subjects Institutional Review Board Administrator at telephone number (630) 909-7140.

19. **Contact Persons:** If you have questions about this study at any time you can call the Researchers at 630-303-0886 or 815-753-6351. If you have any questions about your rights associated with the use and disclosure of protected health information for this research study, you may contact MRHC/MMG Privacy Officer at (630) 909-8032.

**Consent:** I have read this form and the research study has been explained to me. I have been given the opportunity to ask questions about my participation in this study and the use and disclosure of my protected health information and my questions have been answered to my satisfaction. If I have additional questions, I have been told whom to contact. I voluntarily agree to participate in the research study described above. I authorize the collection, uses and sharing of my protected health information as described in this form. I will receive a copy of this signed consent form after I have signed it.

____________________________
**Printed Name of Subject**

**Subject’s Signature**

**Date**

____________________________
Printed Name of Person Providing Information/Obtaining Written Consent

____________________________
Signature of Person Providing Information/Obtaining Written Consent

**Date**
APPENDIX D
RECRUITMENT LETTER
Hello!

My name is Hannah Degen and I am a graduate student working on my master’s degree in Nutrition and Dietetics at Northern Illinois University. To graduate a thesis project is required and I need your help fulfilling this part of my graduation requirements. For my thesis I am interested in studying how Gatorade® can be used to help patients with hyponatremia meet their fluid needs. You have been asked to participate in this study because you are on a fluid-restricted diet because of hyponatremia.

If you decide to participate in this study, all of your fluid intake will be measured, and you will be given a premeasured amount of Gatorade® or water based on your fluid restriction when you are given your medicine. Your food intake will also be documented to obtain the amount of sodium in your diet. In addition, your blood will be drawn for the sodium levels on the first, third, and seventh day of the study. I will also use information from your medical chart to obtain the results of the sodium blood test as well as other demographic information, weight, pitting-edema, urine input and output. As a participant, you will remain on the study while you are in the hospital.

This study is voluntary and you may choose to participate or not to. You may also stop participation at any time during the study and it will not affect your treatment nor will it affect your relationship with Marianjoy. If you have any questions about the study, please contact Hannah Degen (e-mail:hdegen1@niu.edu) or Dr. Josephine Umorden, faculty advisor email jxu1@niu.edu.

Thank you very much.

Sincerely,
APPENDIX E
MAIRNJOY IRB APPLICATION
# Research Proposal Application

**Title of Proposed Research Study**

<table>
<thead>
<tr>
<th>Principal Investigator: Hannah Degen</th>
<th>Location: Marianjoy Rehabilitation Hospital</th>
<th>Phone:</th>
</tr>
</thead>
</table>

**Co-investigators:**

**Date of Submission:**
- Projected project period:

**P.I. of record and applicant institution, if consortium or subcontract:**

**Sponsoring agency:**

**Agency #, if renewal/revision:**

**Direct cost requested:**

**Indirect cost:**

**Location of program activity:** (List all sites, locations, etc., where subjects or data will be recruited.)

1. Marianjoy Rehabilitation Hospital
**Purpose of Application:**
- ☒ New
- ☐ Revision

<table>
<thead>
<tr>
<th>Type of Study:</th>
<th>Vulnerable Populations (check all that apply):</th>
</tr>
</thead>
<tbody>
<tr>
<td>☒ Prospective</td>
<td>☒ Women</td>
</tr>
<tr>
<td>☐ Retrospective</td>
<td>☐ Children</td>
</tr>
<tr>
<td>☐ Case Study</td>
<td>☒ Cognitively Impaired</td>
</tr>
<tr>
<td>☐ Single Subject Design</td>
<td>☐ Prisoners</td>
</tr>
<tr>
<td></td>
<td>☑ Comatose Patients</td>
</tr>
<tr>
<td></td>
<td>☑ Terminally Ill Patients</td>
</tr>
<tr>
<td></td>
<td>☐ Elderly Patients</td>
</tr>
<tr>
<td></td>
<td>☐ Minorities</td>
</tr>
<tr>
<td></td>
<td>☐ Students, Employees and/or normal volunteers</td>
</tr>
</tbody>
</table>

**Brief Abstract of Research Proposal:** (300 word or less non-technical summary of the research proposed including brief statement of purpose, background, limitations and description of study design, methods and procedures.)

The purpose of this study is to examine if giving Gatorade® to rehabilitation patients on a fluid restriction with hyponatremia will increase their serum sodium levels compared to hyponatremic patients given water. Hyponatremia is serum sodium levels less than 135 mmol/L. It is the most common electrolyte disorder among hospitalized patients. Patients with hyponatremia have significantly longer length of stay in the hospital and increased probability of complications during their hospital stay. The increased risk to dehydration with age places older adults at an increased risk for hyponatremia. Older adults also tend to have impaired renal and other age-related physiological changes which cause a decrease in fluid consumption.

Isotonic beverages may be able to help hyponatremic patients normalize serum sodium levels. One such isotonic beverage Gatorade®, has been used to assist athletes better control the decline in serum sodium levels. To date there is no available research to document the effect of Gatorade® intake on serum sodium levels among patients with hyponatremia.
The experimental group’s Gatorade® allowance will be monitored by the study trained nursing staff and diet technicians. Participants in the control group will be given pre-measured water from the nursing staff when they are given their medicine based on their fluid requirements. Participants in the experimental group will be given Gatorade® by the nursing staff when medicine is administered. The amount of fluid given by the nurses ranges from 280 ml-560 ml/day. The Gatorade® will be measured out and labeled for each participant by the researcher every night and stored in the prearranged refrigerator. The nursing staff will take the pre-measured fluid out of the refrigerator and give to the patient when they are given their medicine. Any leftover fluid will be put on a designated cart to be measured by the researcher using a 250 ml cylinder and record the fluid to the nearest ml on a chart. In addition the nursing staff will leave the patients trays after meals on a designated cart.

**Objectivity in Research**

I have read the Wheaton Franciscan Healthcare IRB/Research policy.  
☐ Yes  ☐ No

Do you, your spouse, or dependent children, or any professional personnel listed on your research proposal have any significant financial interest that would reasonably appear to be affected by the research or whose financial interest would reasonably appear to be affected by this research?

☐ Yes  ☒ No

*If yes, the principal investigator and/or appropriate professional personnel listed must complete a Confidential Financial Disclosure Statement to be submitted with these forms.*

**Funding**

<table>
<thead>
<tr>
<th>External funding being sought:</th>
<th>Internal funding being sought:</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Yes ☒ No</td>
<td>☒ Yes ☐ No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SPF #</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Potential Funding Source:</th>
<th>Signature/Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SVP responsible for Special Purpose Funds:</td>
</tr>
</tbody>
</table>

Do these research procedures involve (check those that apply):

☐ Radioactive materials  ☐ Drugs  ☐ Investigational drugs/devices*

Name of drug or device:

Is this an investigational drug or device?  ☐ Yes  ☐ No
IND/IDE #:
Sponsor or manufacturer:
Is this a significant risk (SR) or nonsignificant risk (NR) device?  □ SR  □ NR
Any FDA restrictions:
*Requires approved indemnifications of Wheaton Franciscan Healthcare, and/or Marianjoy Rehabilitation Hospital sponsor prior to initiation of research.

<table>
<thead>
<tr>
<th>Name of Authorized Research Team Member</th>
<th>Phone Number</th>
<th>E-mail address</th>
<th>Role in Project</th>
<th>IRB Administrator has a copy of CITI training Certificate</th>
<th>IRB Administrator Verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hannah Degen</td>
<td>xxx-xxx-xxx</td>
<td><a href="mailto:Hdegen1@niu.edu">Hdegen1@niu.edu</a></td>
<td>Primary Researcher</td>
<td>Yes  □ No</td>
<td>Name</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Date</td>
</tr>
</tbody>
</table>

IRB Administrator Verification that all CITI program or equivocal certificates of completion are on file for research team.

Principal Investigator’s Assurance

Subject to the approval of this project by the Institutional Review Board (IRB), I agree not to involve human subjects in this project until I have received the IRB’s formal written approval. I agree not to involve human subjects in this project until I have obtained the legally effective informed consent of the subjects or their legally authorized representative. No change in the proposal affecting human subjects or the text of the informed consent documentation will be made without the prior written approval of the IRB. I attest that I have read and will follow all Wheaton Franciscan Healthcare and Marianjoy Rehabilitation Hospital institutional policies related to this research, DHHS, principles of the Belmont Report, and FDA guidelines regarding the ethical use of human subjects in research.

Signature of Principal Investigator:_____________________________________

Date:________________________
**Gatorade**

GATORADE® G2 LEMON LIME - 12 fl. oz. (355 ml)

**Nutrition Facts**

<table>
<thead>
<tr>
<th>Serving Size</th>
<th>1 Bottle (355 mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amount per Serving</td>
<td>Calories 30</td>
</tr>
<tr>
<td>% Daily Value*</td>
<td>Total Fat 0g 0%</td>
</tr>
</tbody>
</table>

Not a significant source of calories from fat, saturated fat, Trans fat, cholesterol, dietary fiber, vitamin A, vitamin C, calcium and iron.  * Percent Daily Values are based on a 2,000 calorie diet.

**INGREDIENTS:** WATER, SUGAR, CITRIC ACID, NATURAL FLAVOR, SALT, SODIUM CITRATE, MONOPOTASSIUM PHOSPHATE, SUCRALOSE, ACESULFAME POTASSIUM, YELLOW 5, BLUE 1.

Case UPC 100-52000-12463-4
Package UPC 0-52000-12463-7
Packaging 4 /6 pack
Kosher Status No
USDA Competitive Foods Compliant Yes – H
Document Updated 7/14
APPENDIX G
FOOD AND FLUID INTAKE
<table>
<thead>
<tr>
<th>Participant #:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food Item</td>
<td>Amount Served</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>