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Ice Cream Substitute for Patients with End Stage Renal Disease

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ICE CREAM SUBSTITUTE FOR PATIENTS WITH END STAGE RENAL DISEASE

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38 Pages

Background

Quality of life for patients with end stage renal disease is less than similar-aged, general population counterparts. A large part of the decrease in quality of life is change of diet and nutritional restrictions, oral nutrition supplements are a way to combat this decrease in quality of life.

Methods

An ice cream substitute product was developed for patients with end stage renal disease and that are on dialysis. The product consisted of rice milk, egg whites, evaporated coconut milk, sugar, and vanilla bean paste. There were two flavors: cinnamon and lemon. These flavors were both tested subjectively and objectively. Sensory taste testing was with peritoneal dialysis patients using a Likert scale ballot with a comment section. Texture analysis was completed using a CT3 Brookfield texture analyzer. The results from the sensory taste testing (taste, texture, overall acceptability) and the texture analysis were analyzed using paired *t*-tests. Nutritional analysis for the product was calculated.

Results & Discussion

The sensory taste test of taste, texture, and overall acceptability between the two flavors were not significantly different. Similarly, the objective results were also not statistically significant. The nutritional analysis of this product compared to the Food and Drug

Administration’s ruling for a product to be a “good” source of protein determined that this product is technically a good source of protein.

Conclusion

Future studies using this product base could benefit from trying to add extra protein. The current recipe was within the restrictive renal diet and could be beneficial for dialysis clinics or ESRD patients to make at home for additional options for nutrition supplementation.

KEYWORDS: ice cream, food substitute, chronic kidney disease, end stage renal disease, nutrition, peritoneal dialysis

ICE CREAM SUBSTITUTE FOR PATIENTS WITH END STAGE RENAL DISEASE

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A.I.

CONTENTS

CHAPTER I: ICE CREAM SUBSTITUTE FOR PATIENTS WITH END STAGE RENAL DISEASE

Introduction

An important aspect of medical care is that a patient has a better quality of life and maintain aspects of a healthy and normal lifestyle to increase their quality of life. For end stage renal disease (ESRD) patients, maintaining quality of life is difficult due to the dietary restrictions and issues that come with these restrictions. The typical diet for ESRD patients restricts phosphorus, potassium, and sodium, though these patients also have an increased need for calories and protein. This restrictive diet restricts foods that are typically part of a healthy diet like fruits, vegetables, and whole grains (National Kidney Foundation Kidney Disease Outcomes Quality Initiative [NKF KDOQI], 2000). Yasmeen, Jamshaid, Khan, Salman, and Ullah (2015) studied the pattern of food choices and frequency before and during treatment of chronic illnesses, concluding that patients with chronic kidney disease (CKD), and furthermore ESRD, on a renal diet are expected to lose normalcy. These patients are most likely to decrease consumption of total amount of food and energy (calories), decrease in well-rounded meals, and number of snacks, which could increase calories and protein (Yasmeen et al., 2015). This decrease in snacks, sweets, and total food amount could cause a lack of normalcy as well as other nutritive issues. Sirich (2015) noted that high protein and higher fiber diets are the optimal renal diets for patients on dialysis, with the diet also being low in phosphorus, potassium, salt, and liquid. The quality of life, including mental and physical health, for patients with ESRD may be worse than the general population due to the complications, restrictions, and process of treatment of ESRD (Feroze et al., 2011; Zazzeroni, Pasquinelli, Nanni, Cremonini, & Rubbi, 2017)

As malnutrition is common in patients with renal disease, it is important to recognize research that has pushed for more exploration in supplementation for patients in dialysis (Jeloka, Dharmatti, Jamdade, & Pandit, 2013; Mah et al., 2017; Poole & Hamad, 2008). Malnutrition is persistent for a multitude of reasons for ESRD patients. A reason malnutrition is common for ESRD patients is inadequate food intake, which can be caused by altered taste sensation, difficulties buying and making meals for themselves, as well as potential chewing and swallowing difficulties. In these cases, nutrition support or supplementation is necessary to increase calorie and protein intake (NKF KDOQI, 2000).

Supplementation has been studied as a source to decrease malnutrition, linking the increase in calories and protein with better life quality and a decrease in mortality (Jeloka et al., 2013; Kalantar-Zadeh et al., 2011b; Mah et al., 2017). However, it has been observed that nutrition supplements may not always be accessible, but also not used when able to access due to dislike of taste or texture. If there were more supplement choices available for purchase, it would be more opportunities to match more ESRD patients' taste preferences. As Jeloka et al. (2013) observed that many patients will decrease supplement intake to less than 50% of the recommended amount due to taste and texture. Dahal and Kafle (2015) also observed how patients had reported disliking the taste of the oral nutrition supplement. The path towards better quality of life and subsequent calories for patients with kidney disease could begin with more types of supplements that are suitable for their needs and acceptable while on a renal diet. For this study, the focus was ice cream, as there is minimal availability of an ice cream-like product where the nutrients are acceptable for supporting a better quality of life while on a renal diet due to the phosphorus in dairy product being too high to consume while on a renal diet (Kung, 2010).

As well as ice cream being a viable choice for new supplements as they tend to be easier to swallow and report better taste scores in taste testing (Wright, Marks, & McDougall, 2008).

The purpose of this study was to test altered ice cream suitable for patients on renal diets. The study tested the sensory elements of taste, texture and overall acceptability with ESRD patients in an outpatient setting. Additionally, the objective measures of gumminess, resilience, and hardness were tested. The goal of this study was to continue efforts to pursue products made for more complex medical diets, such as the renal disease diet. This study sought to determine if alterations could be made to traditional ice cream to make it appropriate and beneficial for a patient on a renal diet. The following research questions guided this study:

1. Will a substitute ice cream be acceptable for taste, texture and overall acceptability by an ESRD population?
2. How do the substitute ice cream variations compare in objective variables of gumminess, resilience, and hardness?
3. How do the substitute ice cream variations compare nutritionally?

Methods

Participants

The product was tested in a Central Illinois renal care facility for both hemodialysis and peritoneal dialysis. However, the product was only tested with patients from the peritoneal dialysis side of the facility. All participants were over the age of 18 years old, both males and females participated in testing. Out of the 37 patients available for testing, a total of 35 patients agreed to participate by signing the informed consent (Appendix D) about the research, taste-testing the product and completing the ballot. Participants were at the facility for their monthly check-ins, as the facility had approved research with the peritoneal dialysis patients. Participants were explained the process and any questions about the survey were answered. None of the participants were trained taste-testers. Participants were given both of the flavors, first cinnamon then lemon. Participants were not told what the flavors were until after completing the ballot. Participants were given two different plastic spoons to not leave any competing flavor on the spoon. All of this process was approved by the Illinois State University Institutional Review Board.

Product Development Procedure

The products were made in a temperature regulated kitchen, with regulated refrigerators and freezers. The recipe base was the same in the two flavors: cinnamon and lemon. To start the production process, all ingredients were measured using a standard food scale. For one flavor base, 300 grams (g) of Rice Dream's Rice Drink Original was added to a large glass bowl. To act as a stabilizer for the ice cream, three grams of Bob's Red Mill gaur gum were measured and added to the same bowl. Then, 180 g of AllWhites 100% Liquid Egg Whites and 100 g of Nature's Charm evaporated coconut milk were added to the bowl. After the egg whites, 20 g of sugar and five grams of Taylor and Colledge vanilla bean paste were added in to the mixture in the bowl. Then flavoring was added in. For the lemon flavor, the recipe base was made plus three grams lemon extract. For the cinnamon flavor, 1.5 g of cinnamon was added to the recipe base mixture.

A Cuisinart 2-Quart Ice Cream Maker was set-up, including the frozen insulated bowl. Once the mixture for a flavor was combined in the glass bowl, using a whisk, it was poured into the insulated bowl and then the machine was turned on. This ice cream maker churned and froze the mixture for 25 minutes, when finished the product was of ice-cream consistency. Then, the machine was turned off and the ice cream was removed from the machine's bowl and portioned into two-ounce sampling cups using a #36 size scoop. Temperature was regulated and noted while making the product to ensure that temperature did not vary each time it was made for testing. The final product was stored in a temperature-controlled freezer for 12 hours to ensure the product was fully frozen before testing. The product was made four separate times for taste testing, and this process was followed each time to ensure the same taste, texture, and temperature during serving for each batch. Each batch made a total of 2 1/3 cups or 460 g of final product. However, due to the nature of the ice cream machine, only 2 cups of product were able to be utilized for testing as 1/3 cup of product developed ice recrystallization, making the product less desirable.

Sensory Testing

A ballot was developed to scale the likeness of the ice cream product. The ballot can be observed in Table A-1, which represents what was used for both flavors. Each product was assigned a randomized three-digit code to ensure that no hints were given about the flavor or contents of the product to the participants. The cinnamon flavor was coded as 786 and the lemon flavor was coded as 452. The ballot given was printed to be double-sided, thus one flavor on each side. A 9-point Likert scale surveyed flavor, texture, and overall acceptability of the ice cream. The scale started with 1 which indicated "*like extremely*" to 9 which indicated "*dislike extremely*." The three categories chosen to judge the product were selected to limit difficulties with untrained taste testers. There was also a comment section on each side for participants to write any comments about the product in general, or about a specific flavor. Participants were instructed on how the ballot was structured. The ice-cream like product was then given to the participant one flavor at a time, cinnamon first then lemon. The product was kept in an insulated cooler with several ice-packs to ensure the product stayed at or below 32 degrees Fahrenheit, which was monitored using a refrigerator temperature gauge. There is no control ice cream due to regular ice cream not being a part of the restrictive renal diet.

Objective Testing

Texture analysis was completed utilizing a Brookfield CT3 texture analyzer. Data report was gathered through TexturePro CT V1.4 Build 17 program from Brookfield Engineering Labs. A TA10 probe, 12.7-millimeter cylinder, was used to measure gumminess, resilience, and hardness. Thirty samples of both flavors were analyzed. The temperature of the products was kept at 32 degrees Fahrenheit throughout analyzing process by keeping the product samples in an insulated cooler with ice-packs. Temperature was monitored through a room temperature gauge as well as probe thermometers, which were inserted into the product 30 seconds before using that sample.

Nutrient Analysis

Nutrient analysis for the base product without flavoring was completed using USDA software. Nutrient data was collected from the product's nutrition fact label, as well as the USDA Branded Food Products Database and Davita Kidney Care Food Analyzer, to analyze ½ cup of the ice cream substitute product. The vanilla flavoring and lemon extract flavoring potentially added nutrients unknown due to Food and Drug Administration's Code of Federal Regulation Title 21, Volume 2, Section 101.9 ruling that certain flavorings do not need a nutrition fact label if nutrients are under 1 gram per serving. Thus, the vanilla flavoring and lemon extract nutrients are not counted into the final product nutrient analysis, instead a base product nutrient analysis and cinnamon flavor nutrient analysis was completed. Also, as part of this regulation, companies are not required to test nor disclose the phosphorus amount in a product.

Statistical Analysis

The responses from the ballot were analyzed using IBM SPSS 23 software. Data collected from the 35 taste testers' responses from the ballots were entered into the software for subjective testing. In SPSS, paired *t*-tests were completed to compare the two flavors in taste, texture, and overall acceptability. For objective testing, 30 samples from each of the flavors were analyzed and those results were inputted into SPSS software to observe mean, standard deviation, and paired *t*-test results. Data were considered significant when $p \leq 0.05$.

Results

Sensory Test Results

Two separate flavors of the same "ice cream" product were developed for taste testing. A total of 35 participants tasted both of the products and scaled the products from 1 *like extremely* to 9 *dislike extremely*. It was asked of the untrained participants, who were peritoneal dialysis patients at a Central Illinois dialysis clinic, to judge both flavors individually on taste, texture, and overall acceptability. This sensory testing was completed to determine if the base product was liked, which flavor was liked better, and compare how the participants in taste, texture, and overall acceptability. Results may be observed in Table B-1.

Taste. The mean of the cinnamon flavor's taste was 3.26 (Standard deviation [SD] = 2.01). Similarly, the mean of the lemon flavor's taste was 3.54 (SD = 2.11). Using a paired *t*-test, the comparison between both flavors' taste results equaled a *t*-value of -.952 (p = .348).

Texture. The mean of the cinnamon flavor texture was 3.11 (SD = 1.64). The mean of the lemon flavor texture was 3.00 (SD = 1.73). The comparison between both flavors' texture results equaled a *t*-value of .408 (p = .686).

Overall Acceptability. The mean of the cinnamon flavor overall acceptability was 3.40 (SD = 2.00). The mean of the lemon flavor overall acceptability was 3.51 (SD = 2.06). The comparison between both flavors' overall acceptability results equaled a *t*-value of -.437 (p = .665). These sensory results are not statistically significant.

Written Comments. The comment section on the ballot was not required to be completed by the participants. Of the 35 participants, 14 chose to comment on either a specific flavor or on the product in general. Some of these comments described the flavor; a sample of these comments are as follows: "snot-like," "cinnamon flavor could use nutmeg," "Cinnamon flavor tastes close to chocolate ice cream," "needs to be sweeter" as well as "too sweet." Other comments were about the acceptability or the potential for this being an available product. These comments include participants noting they "would eat it every day," "not crazy about it but good," and "reminds them of ice cream their mother made."

Objective Results

Objective results were collected through texture analysis, using a Brookfield CT3 Texture Analyzer. Both the cinnamon and lemon flavor were tested 30 times each to ensure accuracy. Results may be observed in Table B-2.

Gumminess. Gumminess measures the amount of force needed from a human mouth to prepare the food for swallowing (Texture Profile Analysis, 2019). The mean of the gumminess results for the cinnamon flavor was 49.15 g (SD = 61.44). Similarly, the mean of the gumminess for the lemon flavor was 44.27 g (SD = 40.73). The comparison between both the cinnamon and lemon flavors' gumminess values resulted in a *t*-value of .419 (p = .678).

Resilience. Resilience of a product determines how much the product rises after being bit down upon, and is observed as a number between 0 and 1 (Texture Profile Analysis, 2019). The mean of the resilience values for the cinnamon flavor was .050 (SD = .046). The mean of the resilience values for the lemon flavor was .058 (SD = .026). The comparison between both the cinnamon and lemon flavors' resilience equaled a *t*-value of -.745 (p = .462).

Hardness. Hardness is a measure of the force a human mouth would require to compact the product (Texture Profile Analysis, 2019). The mean of the hardness for the cinnamon flavor was 89.88 g (SD = 94.51). Whereas, the mean of the hardness for the lemon flavor was 76.07 g (SD = 48.21). The comparison between both the cinnamon and lemon flavors' hardness resulted in a *t*-value of .683 (p = .500). The objective results are not statistically significant.

Nutritional Analysis

Due to the regulation 21 C.F.R. 101.9(j)(4), which states that if nutrients are less than one gram of that nutrient per serving the product can declare that there is zero of that nutrient, the vanilla and lemon flavoring were not able to be included in the nutritional analysis. Even with such regulations, the two flavor variations are similar in nutritional analysis. Referring to Table C-1, nutrient analysis for total product made per batch and per ½ cup serving was completed. For a ½ cup serving, the base product contains 106 kilocalories (kcal), 5 g of protein, 14.5 g of carbohydrates, 2.45 g of fat, 102.5 milligrams (mg) of potassium, 11.4 mg of phosphorus, and 134.8 mg of sodium. Observed in Table C-2, the cinnamon flavor per batch had an additional 3.71 kcal, 0.06 g of protein, 1.21 g of carbohydrates, 0.02 g of fat, 6.47 mg of potassium, 0.96 mg of phosphorus, 0.15 mg of sodium.

Discussion

Subjective Results

Sensory Results. As observed in Table B-1, the paired *t*-test revealed that in comparison of the two flavors in taste, texture, and overall acceptability there were no statistically significant differences. Both flavors' means express a likeness of the products within the Likert scale. This is an indication that both flavors are likeable and acceptable for the participants. In comparison of the flavors' texture results, there was also no statistically significant differences, which was the goal as they are the same base product just different flavors, thus the texture should be similar between the two flavors. As well as the means of the textures of both the flavors were also in and around the "*like moderately*" range. Similarly, with overall acceptability, the mean of both the flavors were overall liked and in the "*like*" range on the Likert scale.

Written Comments. Many comments about the products were written in the comment section, with 14 of the 35 participants writing their thoughts on the product. As with any taste tests, some participants did not like the product at all. One participant described the texture as "snot-like." On the other side of the spectrum, one participant was curious if it would be available for purchase. Verbally, multiple participants mentioned they "missed regular ice cream" and were happy to enjoy the taste test of this product. For potential changes in the products, one participant recommended adding nutmeg to the cinnamon flavor; there were both comments about the product not being sweet enough and being too sweet. However, most participants were overall indifferent with verbal and written comments indicating that they could tell it was not regular ice cream, but they would eat it if available.

Objective Results

Following subjective results, the texture analysis results were also not significantly different. This is further representation of the idea that the two flavors are similar in all senses besides taste. These tests were chosen as they can be applied to ice cream, a semisolid food. Gumminess can develop in ice cream after being scooped, which tends to increase the stickiness and decrease the attractiveness of the exterior of the product, a unique characteristic of semi-solid foods. Gumminess is also affected by the amount and type of stabilizer and emulsifiers in the ice cream product's balance of ingredients (Goff & Hartel, 2013; Texture Profile Analysis, 2019). Resilience, which is represented by a number between 0 and 1, describes how well a product recovers after being pressed down upon. This "bite" and then recovery demonstrates how much the product expands again before a second "bite." With higher resilience, closer to one, gumminess increases in ice cream. Lower resilience is more common in higher fat ice creams and ice creams higher in stabilizers and emulsifiers amounts. There was guar gum and coconut fat from evaporated coconut milk, which also had guar gum in the product, thus a lower resilience level (Casarotto, Wolfang, & Lundgren, 2015; Texture Profile Analysis, 2019). Hardness is the force needed to fully bite the food with the average human's molar force (Texture Profile Analysis, 2019). Hardness is often affected by crystallization, which is affected by the amount of protein and fat in the ice cream (Goff & Hartel, 2013). As there were no statistically significant differences when comparing the two flavors in gumminess, resilience, and hardness, it can be determined that the two flavors were the same base product, and thus should have similar mouthfeel and texture during sensory testing. As shown in subjective testing, the texture was not statistically significantly different between the two flavors, it demonstrated that the participants were scoring the flavors seriously and understood how to use the ballot during sensory testing.

Nutritional Analysis

Supplement Comparison. There are multiple protein supplements on the market to assist patients on dialysis. Common supplements on the market include Nepro with Carb Steady and LiquiCel. For one serving of Nepro with Carb Steady, which is eight fluid ounces, there is 425 kcals, 19.1 g of protein, 37.9 g of carbohydrates, 22.7 g of fat, 250 mg of potassium, 170 mg of phosphorus, and 250 mg of sodium (Abbott Nutrition, 2017). When comparing a serving (1/2 cup) of the base ice cream substitute to a serving of Nepro, there are differences. One serving of Nepro has 319 more calories and 14.1 more grams of protein. One serving of Nepro also has 23.4 g more of carbohydrates, 20.25 g more of fat, 147.5 mg more of potassium, 158.6 mg more of phosphorus, and 115.2 mg more of sodium. One serving of the ice cream substitute is lower in potassium, phosphorus, sodium, and carbohydrates and fat compared to one Nepro serving. For one serving of LiquiCel, which is one fluid ounce, there is 90 kcals, 16 g of protein, 9 g of carbohydrate, 0 g of fat, 10 mg of potassium, 10 mg of phosphorus, and 30 mg of sodium (Global Health Productions, 2018). When comparing LiquiCel to the ice cream substitute serving, the ice cream substitute has 16 more calories, 11 g less of protein, 5.5 more grams of carbohydrates, 2.45 more grams of fat, 92.5 mg more of potassium, 1.4 mg more of phosphorus, and 104.8 mg more of sodium. The ice cream substitute has some more calories that LiquiCel, though is lower in protein per serving. However, besides sodium and potassium, the other nutrients are not many grams or milligrams higher when comparing the ice cream substitute to LiquiCel.

Recommendation Comparison. Though renal recommendations may change slightly per person depending on the type of dialysis that a person is receiving and per clinic recommendations, there are general target recommendations. Energy recommendations are 30 to 35 kcal per kilogram of dry bodyweight and protein recommendations are 1.2 g/kg per day for hemodialysis patients and 1.3 g/kg per day for peritoneal dialysis patients (NKF KDOQI, 2000). The general recommendation for phosphorus is up to 1000 mg per day (NKF, 2003). The recommendation for potassium is no more than 2 to 4 grams per day, however this level may be changed depending on serum potassium level to avoid hypokalemia and hyperkalemia. For sodium, two to three grams per day for hemodialysis and two to four grams per day for peritoneal dialysis patients (Beto, Rameriz, & Bansal, 2014). Both flavors of the product are within the recommendations for patients on dialysis with ESRD. Using the Food and Drug Administration regulation of what amount of protein is needed per serving for foods to be considered a "good source" of protein, one ½ cup serving of ice cream would need to contain five grams to nine grams of protein to be considered a good source (Devaraj, 2015). The ice cream substitute does have five grams of protein per ½ cup serving. One serving of the ice cream substitute would contribute to 1.14% of the allotted daily phosphorus amount. Based on the most restricted recommendation of potassium, one serving of this product would be 5% of the 2-gram potassium recommendation. The product would be 6.7% of the 2-gram daily sodium serving.

The only product of concern with unreported phosphorus due to Code of Federal Regulation Title 21 is evaporated coconut milk. Though it is a different product, just coconut meat for 100 gram of product is 113 mg of phosphorus. In evaporated coconut milk, it is coconut cream mixed with water, it is unknown how diluted the product is. However, if there is not enough water to dilute the coconut nutrients per 100 gram of product then there could be an additional 28 mg of phosphorus per serving of ice cream substitute. Though it is more likely that the evaporated coconut milk is diluted with enough water to decrease any further phosphorus contribution.

Limitations

One limitation of the study was that the taste testers were untrained. Though the process was explained and any questions about the process during the tasting were answered, this could cause some inconsistency throughout the testing. Untrained participants could have affected the results by either not understanding the scale or scoring the flavors by comparing them to each other instead of as individual flavors. However, the participants of this study were chosen as they were of the population this product was created for.

Another limitation of this study emerged during nutritional analysis. Flavor components do not legally have to give out nutrient information, thus companies may not have any declaration of nutrients available to provide for a product. This regulation [21 C.F.R. 101.9(j)(4)] states that flavor extracts do not need to provide a nutrition label because of the “insignificant amount of nutrient or food components” (Food Labeling, 2018). Labeling also becomes an issue when it comes to phosphorus. Phosphorus has been advocated to be on nutrition labels, and was at a time a part of a bill, however, it is still not currently required for companies to declare amount of dietary phosphorus in a food product (Borgi, 2019).

Strengths

This study was able to have ESRD patients as participants of the sensory testing, which is the population that this product was made for. This was an important step in this study, as ESRD and dialysis patients are known to have altered taste and potential chewing and swallowing problems which could increase difficulty of enjoying and consuming a nutrition supplement

(NKF KDOQI, 2000). Thus, using the population this product is aimed for, though a small sample size, is a start to ensure that the texture and taste are more likely to be enjoyed and safely consumed.

Another strength of this study was that the ice cream product was well balanced in its mix which likely led to the liked texture and flavors. As many of the ingredients were not typical of an ice cream mixture, together they created a similar texture and taste of cinnamon and lemon ice creams. While creating the product, all ingredients needed to fit in renal diet restrictions, as well create a similar structure of regular ice cream's crystallization, stabilization, and flavoring.

This recipe could be recreated at patients' homes if they had access to an ice cream machine. If this product is made elsewhere by patients, they should follow to instructions in the methods section as well as use the same brand of ingredients in this study. Though the study was performed in gram amounts, the typical US measurements are as follows: 1 ¼ cup of rice milk, one teaspoon of guar gum, ¾ cup of egg whites, seven tablespoons of evaporated coconut milk, two tablespoons of granulated sugar, one tablespoon of vanilla bean paste, two teaspoons of lemon extract for the lemon flavor and ½ teaspoon of cinnamon for the cinnamon flavor. Patients could use this recipe at home to substitute regular ice cream during family gathering to feel less left out, without going against diet recommendations, as well as a way to increase calorie and protein intake.

Conclusion

This study's purpose was to develop a product that could be a suitable ice cream substitute for ESRD patients. From the sensory results, the product currently is likeable. These flavors and ingredients used in the ice cream substitute are appropriate for the current renal diet recommendations.

Future Studies

During production of this product, it was attempted to increase the protein amount in the substitute ice cream through multiple trials which included protein powders, increase of egg whites, and powdered egg white. Though these versions of the product could have been a part of this study, the integrity and quality of the product was lost with the additional protein. If research about an ice cream renal substitute were to continue, it is suggested to focus on increasing protein while keeping a similar texture and taste to a product made during this study. In addition to increasing proteins, a different ice cream machine may change the consistency of the final product. A different form of mixing and freezing simultaneously may affect the potential amount of egg whites or other protein source, which could lead to an increase in protein and calories.

Overall, this product, especially the flavors and base products, could continue to be used for research on an ice cream substitute for ESRD patients. The recipe for this product, as is, could be released to dialysis clinics to be utilized by their patients- whether making it at the clinic or giving out the recipe for patients to be able to make at home and consume in appropriate serving sizes to help increase calories and protein.

CHAPTER II: EXTENDED LITERATURE REVIEW

End Stage Renal Disease

The prevalence of End Stage Renal Disease (ESRD) in the United States, of 2016, was more than 720,000 cases. Of these cases, 63.1% of the ESRD patients in America were on hemodialysis, whereas 7.0% of the over 720,000 cases were utilizing peritoneal dialysis (USRDS, 2018).

Chronic Kidney Disease is comprised of levels, which progresses from stage 1 to stage 5. As the stages progress, the kidney loses its ability to properly function, the kidneys become further damaged due to build-up of excess waste, such as urea. This damage and loss of function can be measured by the glomerular filtration rate. ESRD is classified as the glomerular filtration rate decreasing below 15 mL/min/1.73m^2. Kidney disease can often go undetected until the later stages (NIDDK, 2016). Patients who are at the ESRD state are recommended to begin dialysis to filter and remove the waste that the kidneys can no longer filter (Escott-Stump, 2012). According to the NIDDK (2016), as of 2016, at least 468,000 Americans utilize dialysis. There are two common forms of dialysis: peritoneal dialysis and hemodialysis. Peritoneal dialysis acts as a filter and removes through osmosis by using a hyperosmolar solution. Hemodialysis filters and removes by removing blood from the body and passing it through a filter and then the "clean" blood is returned. Peritoneal dialysis tends to waste more protein than hemodialysis. Yet, peritoneal dialysis has looser regulations for nutrients such as potassium and sodium. However, with either form of dialysis, the patient still must follow the strict renal diet (Escott-Stump, 2012; Beto, Rameriz, & Bansal, 2014).

Patients with ESRD face nutrition-related risk factors, such as protein-energy wasting, for co-morbidities and death (Kalantar-Zadeh et al., 2011a). Energy recommendations are 30 to 35 kcal per kilogram of dry bodyweight and protein recommendations are 1.2 g/kg per day for hemodialysis patients and 1.3 g/kg per day for peritoneal dialysis patients (NKF KDOQI, 2000). The general recommendation for phosphorus is up to 1000 mg per day (NKF, 2003). The recommendation for potassium is no more than 2 to 4 grams per day, however this level may be changed depending on serum potassium level to avoid hypokalemia and hyperkalemia. For sodium, two to three grams per day are recommended for hemodialysis and two to four grams per day for peritoneal dialysis patients. Fluid restrictions for hemodialysis is recommended to be around 1000 milliliters per day and peritoneal dialysis patients may have more loose restrictions with fluid due to a more individualized status with more frequent dialysis. However, fluid intake and excretion needs to be monitored to ensure that neither fluid overload (thus increasing wet weight and stress on cardiovascular system) nor a too small of intake of fluid is taking place (Beto et al., 2014; Zoccali et al., 2017).

Medical Nutrition Therapy

There is currently literature available that indicates potential liberalization of the renal diet, by observing how much of nutrients from different products is absorbed and what can be done to alter a certain nutrient amount in a food, as such a review of these potential liberalizations can be observed in Biruete and others' research (2017). Research may be more difficult to collect for ESRD disease patients and nutrition focused studies. This is due to multiple potential barriers from both the researcher and patient side, such as patients with ESRD are higher risk for comorbidities which could become difficult controlling for when collecting results, also ESRD care is already a heavy burden and can be high stress on the patient, further care or extra steps for a study may be too much to add to an already heavy medical care (Decker & Kendrick, 2014). Though there is support for liberalization in the renal diet and such liberalizations would be taught through thorough nutrition counseling and education, the current national recommendations support the more stringent renal diet (Sabatino et al., 2018). Though counseling and intervention through behavioral change is beneficial as one begins to follow a renal diet, the complexity of the diet requires the ability to sustain change, which can be difficult for ESRD patients (Campbell, Palmer, & Johnson, 2017).

Yasmeen, Jamshaid, Khan, Salman, and Ullah (2015) studied the pattern of certain foods before and after diagnosis and treatment of chronic illnesses. Chronic illnesses that involved kidney health typically dropped their consumption of amount of food total, especially snacks and sweets (Yasmeen et al., 2015). Malnutrition, which is rampantly common, is associated with increased mortality when a patient has renal disease (Jeloka et al., 2013; Mah et al., 2017; Poole & Hamad, 2008). The possible causes of malnutrition for patients with renal disease are vast. Some of these causes include “increased catabolism, low-grade inflammation, oxidative stress, and the presence of other co-morbidities” (Mah et al., 2017, p.3). Other causes could be due to the diet regulations patients are instructed to follow after being diagnosed with kidney disease; patients may stop eating certain foods completely that were once a part of their daily consumption (“How to Increase Calories,” 2016). Chronic Kidney Disease (CKD) patients, especially if they are at ESRD, have one of the most restrictive diets. These restrictions may lead to lack of adherence to the diet, which could lead to further complications (Kalantar-Zadeh, 2015). With these complications and comorbidities, ESRD patients are likely to have a decrease in quality of life when compared to the general population of a similar age (Zazzeroni et al., 2017).

Prasad-Reddy, Issacs, and Kantorovich (2017) reviewed the approaches to dietary supplementations and teachings in the renal diet, focusing on vitamin D, iron deficiencies and hypertension. Though focusing on pharmacology, the conclusion was that there were many controversies between guidelines, and for best results, supplementation should be given on an individual basis (Prasad-Reddy et al., 2017). The individual basis is important as the renal diet is different from the typical healthy American diet for good reasons. Dairy is recommended to be restricted while following a renal diet because of the risk of excessive phosphorus and calcium, which causes calcifications in soft tissue (Kung, 2010).

Protein

Sirich (2015) discussed the optimal amounts and needs for high protein and higher fiber diets for renal patients. A high protein intake (1.2 – 1.4 grams per kilogram of body weight) is the current protein recommendation for patients during ESRD while on dialysis. This higher protein intake can become a problem while a patient is on the renal diet due to many protein sources being naturally higher in phosphorus and potassium, both of which are limited for ESRD patients on dialysis (Kalantar-Zadeh, 2015). Proteins, especially animal-based proteins, end its breakdown with some acidic compounds like hydrogen chloride, sulfuric acid, and phosphoric acids. These acids are then to be filtered out and excreted from the body as waste, this process being done by the kidneys. However, in a body with low-functioning to non-functioning kidneys, this acidic waste will build up leading to metabolic acidosis (Koeppen, 2009). Yet, when a patient is on dialysis, their body is in a catabolic state, in addition to protein loss through dialysis and inflammation from ESRD as well as other comorbidities, such as cardiovascular disease and diabetes. Thus, this higher protein intake is necessary to maintain a positive nitrogen balance (Zha & Qian, 2017).

Phosphorus

Kamper and Standgaard (2017) discuss how egg whites are a suitable protein source for patients with kidney disease as in past research shows egg white protein does not affect the kidney's glomerular filtration rate (GFR). Egg whites have been used in renal focused research before. Taylor et al. (2011) used egg whites while researching phosphorus control for hemodialysis patients. Taylor's study confirmed nutritional information about the potassium and phosphorus of the AllWhites liquid egg whites brand. A whole, large egg contains 86 milligrams of phosphorus, while just the egg white of one large egg contains five milligrams of phosphorus (Noori et al., 2010).

Chang and Anderson (2017) discuss an additional importance of regulating phosphorus intake at a lower level after being diagnosed with kidney disease. If a patient were to intake a high or regular amount of phosphorus, it would cause the parts of the kidney that are still functioning to work at a higher rate, leaving more phosphorus in the blood to bind with calcium. The relationship between calcium and phosphorus could cause issues with bone health if serum phosphorus levels were kept consistently higher than the recommended amount (Chang & Anderson, 2017).

Some of the main sources of dietary organic phosphorus are common protein sources, such as meats, dairy products, legumes, and nuts. A dietary source of inorganic phosphorus is found in food additives. The difference between organic and inorganic phosphorus is the bioavailability for humans. Around 30% to 60% of organic phosphorus is able to be absorbed, while at least 90% of inorganic phosphorus is able to be absorbed. The average American diet contains foods whose ingredients include inorganic phosphorus additives, adding a potential 1000 milligrams of phosphorus per day (Noori et al., 2010). It is also not currently required for companies to included phosphorus on a product's nutrition label, though adding phosphorus to labels has been advocated for when the Food and Drug Administration has brought up change in the nutrition label requirements. There is however, other industries and large companies that advocate to keep nutrition label requirements minimal, meaning phosphorus is left off the label (Borgi, 2019).

Medications for ESRD patients can also interfere with micronutrient absorption. For example, oral phosphate binders are taken at meal time to reduce phosphorus absorption but these binders are often made from calcium, which leads to a higher absorption of calcium (Beto et al., 2014; Biruete, Jeong, Barnes, & Wilund, 2017). Phosphate binder use can also lead to an increased risk for becoming constipated. A recommended way to reduce constipation risk while on phosphate binders is to increase fiber intake. However, fiber is commonly found in food products such as whole grains, fruits, and vegetables which can have higher potassium and phosphorus contents (Beto et al., 2014).

Potassium

Potassium is of concern for an ESRD patient because of the potential for hyperkalemia, which is high blood potassium that could lead to cardiac arrythmia. However, hyperkalemia can also be caused by medications, such as diuretics, certain antibiotics, and antihypertensives. As sodium is another restriction on the renal diet, salt substitutes that are made with potassium are advised to be avoided by ESRD patients (Beto et al., 2014). As stated earlier, some whole foods, like whole grains, fruits, and vegetables, typically deemed part of a well-rounded and healthy diet need to be portioned and limited. Foods are determined as high in potassium if the food contains more than 200 milligrams of potassium per serving (NKF Potassium, n.d.) Some of these foods are able to be leached of potassium through soaking or double cooking, particularly potatoes, carrots, winter squash varieties and beets. For example, Bethke and Jansky (2008) observed that when soaking and boiling potatoes it reduced the original potassium amount by 50%.

Supplementation

Malnutrition is a detrimental problem when a patient is required to follow a renal diet (Jeloka et al., 2013; Mah et al., 2017; Poole & Hamad, 2008). A reason malnutrition is common for ESRD patients is inadequate food intake, which can be caused by altered taste sensation, difficulties buying and making meals for themselves, as well as potential chewing and swallowing difficulties (NKF KDOQI, 2000). The age, culture or religion of the patient may guide food choices and options. As such, older dialysis patients may be eating less due to a non-renal diet related reason, including increase of gastrointestinal issues when compared to age-similar non-dialysis counterpart, as well as potential decrease in food-related social activities (Johansson, 2015). In these cases, nutrition support or supplementation is necessary to increase calorie and protein intake (NKF KDOQI, 2000).

Supplementation during dialysis treatment has been observed to have a faster increase of nutrition improvement and weight gain, as well as improvement in indicators that correlate with better quality of life (Jeloka et al., 2013; Mah et al., 2017). Supplements or small meals are provided more commonly in dialysis clinics not in America. Studies reviewed that clinics that begin to provide intradialytic oral nutritional supplements tend to observe improvement in a patient’s adherence to the renal diet and increase motivation to arrive for appointments (Kalantar-Zadeh et al., 2011a). Studies designate that supplemental nutrition support is highly combatant against protein energy wasting and weight loss, both of which are predictors of mortality (Kalantar-Zadeh et al., 2011b). Oral supplementation, especially when intake of supplementation began before diagnosis of malnutrition, combats the catabolic state of dialysis (Sabatino et al., 2018). Sezer, Bal, Tutal, Uyar, and Acar (2014) observed that renal specific oral supplementation, meaning the products were lower in potassium and phosphorus than nonrenal specific oral supplements, did significantly improve malnutrition and inflammation which was noted with nutrition parameters such as anthropometrics like body mass index, fat-free mass, and muscle mass, serum albumin and transferrin.

A goal for nutrition supplements is to provide an additional 7–10 kcal/kilogram per day of energy and 0.3–0.4 g/kilogram per day of protein if the serving size of the supplement is consumed two to three times per day. This goal for supplements is to ensure the product will actually improve the patients' energy and protein intake (Kalantar-Zadeh et al., 2011a). The Food and Drug Administration has regulations for what qualifies as a good source of protein and what foods are high protein sources. Using these recommendations on ice cream, one ½ cup serving of ice cream would need to contain five grams to nine grams of protein (Devaraj, 2015). Regulated nutrients that are a part of a renal diet must also be considered when developing or choosing an oral supplement. For example, nonfat milk powder could be an oral supplement as it does contain seven grams of protein per 20 gram serving. One 20 gram serving of nonfat milk powder declares approximately 360 milligrams of potassium and 200 milligrams of phosphorous. Although egg whites from two large eggs does contain similar amount of protein, with about eight grams of protein, the amount of potassium and phosphorus is much less with only 108 milligrams of potassium and 26 mg/0.9 millimole of phosphorous (Johansson, 2015).

However, some patients cannot use the currently available supplements due to the products being too expensive, having a poor taste, or the levels of certain nutrients in supplements may exceed needs for a patient on a renal diet if the supplement was not produced with patients on a renal diet as the target population (Mah et al., 2017). Many supplements are sold in a drink form or in a powder form but are to be made into a drink. Ice cream is also a possible form of supplementation. Ice cream is sometimes preferable for patients as it could be more palatable and easier to swallow than a drink (Wright, Marks, & McDougall, 2008). However, ice cream is not suitable for a person adhering to a renal diet. Dairy products, including ice cream, are too high in potassium and phosphorus for people with ESRD to consume regularly (Escott-Stump, 2012). A supplement that is more palatable is important as Jeloka et al. (2013) observed that many patients will decrease supplement intake to less than 50 percent of the recommended amount due to taste and texture. Dahal and Kafle (2015) also observed how effective supplements were for patients with kidney disease, but many of the participants reported disliking the taste or smell of the supplementation given.

Ice Cream Product

Ice cream or frozen dessert production and research is swayed by the wants of the buyers. Production of ice cream must be a perfected and balanced process including a fat, milk (or nonfat based liquid), sweeteners, emulsifiers and stabilizers, and flavoring. Stabilizers and emulsifiers are used to induce smoothness, reduce large crystallization, reduce fat separation of ice cream, support uniformity of the product once mixed and flavorings' suspension throughout the product. Guar gum as well as other gums such as locust bean or xanthan are options for this ingredient in ice cream (Bahramparvar & Mazaheri Tehrani, 2011; Goff & Hartel, 2013).

Fats are a necessary ingredient for mouthfeel, texture, and support for the structure that forms during the mixing and freezing processes. Nondairy fats are possible to use in ice cream; however, it may not be as smooth of a mouthfeel, as well as it may contribute to a greasy film and mouthfeel. Also, nondairy fats, which are potentially unsaturated fats, may need to be blended with multiple nondairy or unsaturated fats for the most similar results to how dairy fats crystalize. Fat replacements have some more research for substitute ice cream ingredients due to past consumer demand for lower-fat food products. Different types of gums, used for emulsification and stabilization, can also act in the same roles fat is in the production of the product as they can contribute to stability but also initial structure while controlling ice crystal growth (Goff & Hartel, 2013). Rolon, Coupland, Roberts, Bakke, and Hayes (2017) observed the fat content and maltodextrin content effects on several objective variables including fat particle size, fat destabilization, hardness, and melting rate and sensory testing which included freshness of the vanilla ice cream. Lower fat content with a higher maltodextrin content was an acceptable alteration to traditional ice cream ratios with both physical properties and sensory tests (Rolon et al., 2017).

The “milk” ingredient in ice cream is to have a protein present, which enhances emulsifications and whipping capabilities. Whipping is important for air incorporation to be able to create air bubbles in the ice cream and generate a smooth mouthfeel. Condensed milks are an acceptable substitute for this ingredient; however, unsweetened will contribute smaller, more controlled crystals when freezing the ice cream compared to sweetened condensed milk. Thus, sweetener and flavor should be added separately as individual ingredients instead of being a part of another ingredient, like a combined sweetened condensed milk (Goff & Hartel, 2013). Using milk alternatives to create a substitute ice cream is possible but phosphorus and calcium additives which would be contraindicative of being acceptable for a renal diet (Kung, 2010). It is noted that if egg yolks, a potential protein source, are used in a product, it must be combined carefully otherwise it will cause a foamy end product (Goff & Hartel, 2013).

For an altered product to have a similar mouthfeel like ice cream, E., Pei, and Schmidt (2010) concluded that air is the most important factor for the mouthfeel of ice cream. It was further explained that air, air cell size, and frequency is the most important factor in the mouthfeel of ice cream due to the impact on foam stabilization. Kwak, Meullenet, and Lee (2016) observed the acceptability and coordinating properties of commercial vanilla ice creams. The mouthcoating and flavor aspects were the most noted aspects for the best acceptability. The most disliked aspects of sensory tests were bitter and metallic tastes and flavors (Kwak et al., 2016). Thus, the addition of sweeteners and flavoring to the ice cream base is needed. Lack of sweeteners not only makes the product less sweet but causes the product to have a flat taste. Without sweetener, flavorings and the flavor from fat would be construed as blander or flatter than if there was sweetener added to the ingredient mix. Flavoring options are vast, with the most common flavors being vanilla, chocolate, and fruit flavored ice creams. Other flavors including spices or inspiration from other desserts and foods are becoming more common in America and are already popular in other countries. For example, green tea, Thai red curry, and guava flavored ice creams are starting to be purchased in America (Goff & Hartel, 2013).

Creating the correct balance of these ingredients is necessary for desirable sensory results. There are multiple issues that could cause the balance to go awry, one being an incorrect balance of ingredients. However, there are also issues with the ingredients themselves being stale or rancid which affects the overall flavor palate. Some other issues that could cause an unbalance in the ice cream are too much lactose that causes a sandy texture in ice cream and increased shrinking from too little protein containing ingredients. These issues would case a product to test poorly in sensory testing, and potentially have a worse texture profile analysis than if the product was balanced (Goff & Hartel, 2013).

Gumminess can develop in ice cream after being scooped. Gumminess tends to increase the stickiness and decrease the attractiveness of the exterior of the product, a unique characteristic of semi-solid foods. The stickiness negatively effects the mouthfeel and texture of the product. Guar gum in frozen products can lead to an increase in gumminess (Goff & Hartel, 2013; Texture Profile Analysis, 2019). Resilience, which is represented by a number between 0 and 1, describes how well a product recovers after being pressed down upon. With higher resilience, closer to one, gumminess increases in ice cream, meaning a decrease in high quality mouthfeel. Lower resilience is more common in higher fat ice creams, leading to the creamy and not sticky mouthfeel most common in high quality ice creams (Casarotto et al., 2015; Texture Profile Analysis, 2019). Hardness is the force needed to fully bite the food with the average human's molar force (Texture Profile Analysis, 2019). Hardness can be affected by sugar content, stabilizer type and amount, as well as amount of fats. However, stabilizers are necessary as they help produce a smoother product due to controlling ice recrystallization and slowing melting of ice cream once in above freezing temperatures. Heavy chewing should not be needed for most flavors of ice cream, the exceptions being those flavors that have pieces of candy or nuts in the mix (Goff & Hartel, 2013).

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APPENDIX A: BALLOT FOR SENSORY TESTING

Table A-1. Example of a Product Ballot for Sensory Taste Testing

Product 786

	Like Extremely	Like Very Much	Like Moderately	Like Slightly	Neither Like Nor Dislike	Dislike Slightly	Dislike Moderately	Dislike Very Much	Dislike Extremely
Taste- Sweetness, Flavor	1	2	3	4	5	6	7	8	9
Texture- Creaminess, Smoothness	1	2	3	4	5	6	7	8	9
Overall Acceptability	1	2	3	4	5	6	7	8	9

Comments:

APPENDIX B: SUBJECTIVE AND OBJECTIVE RESULTS

Table B-1. Results of Subjective Sensory Taste Testing for the Cinnamon and Lemon Ice Cream

Variable	Mean n=35	SD
Taste		
Cinnamon	3.26	2.01
Lemon	3.54	2.11
Texture		
Cinnamon	3.11	1.64
Lemon	3.00	1.73
Overall Acceptability		
Cinnamon	3.40	2.00
Lemon	3.51	2.06

Table B-2. Results of Objective Texture Analysis Testing for the Cinnamon and Lemon Ice Cream

Variable	Mean n=30	SD
Gumminess		
Cinnamon	49.15 g	61.44
Lemon	44.27 g	40.73
Resilience		
Cinnamon	.050	.046
Lemon	.058	.026
Hardness		
Cinnamon	89.88 g	94.51
Lemon	76.07 g	48.21

APPENDIX C: NUTRIENT ANALYSIS

Table C-1. Nutritional Analysis of the Base Ice Cream Substitute Product

Ingredient	Amount	Calories	Protein	Carbohydrates	Fat	Potassium	Phosphorus	Sodium
Rice Milk	300 g	150 kcal	1.26 g	28.74 g	3.12 g	37.5 mg	18.75 mg	126 mg
Guar Gum	3 g	12 kcal	0 g	2.7 g	0 g	0 mg	----	0 mg
Egg Whites	180 g	97.2 kcal	19.57 g	0 g	0 g	293 mg	26.9	313 mg
Evaporated Coconut Milk	100 g	86.7 kcal	0 g	6.67 g	6.67 g	79 mg	----	100 mg
Granulated Sugar	20 g	77.4 kcal	0 g	20 g	0 g	.4 mg	0 mg	.2 mg
Total		423.3 kcal	20.8 g	58.1 g	9.8 g	409.9 mg	45.65 mg	539.2 mg
Per ½ Cup		106 kcal	5 g	14.5 g	2.45 g	102.5 mg	11.4 mg	134.8 mg

Table C-2. Nutritional Analysis of the Cinnamon Flavor Ice Cream Substitute Product

Product	Calories	Protein	Carbohy-drates	Fat	Potassium	Phosphorus	Sodium
Cinnamon Flavor Per ½ Cup	106.75 kcal	5.22 g	14.83 g	2.46 g	104.09 mg	11.65 mg	134.84 mg

APPENDIX D: INFORMED CONSENT

Informed Consent

Before agreeing to participate in this study, please fully read this form. If you are willing to be a part of the study, after reading the form, please sign your name and date the lines at the bottom of this form. If you do not want to be a part of this study, simply return the form without signing, there is not pressure to participate.

This research study is being conducted by Abby Iocca at Illinois State University to determine acceptability of a protein supplement.

You must be 18 years old or older to participate in this study.

Please do not participate if you have any common food allergies. The ingredients are commonly found at grocery stores and the making of the product was completed in a professional kitchen, cross-contamination was avoided but still possible, do not participate if you have a food allergy.

Procedure

Please taste the product and score each characteristic according to your opinion. Please do not write your name or any other identifier on the scoring form. If you need assistance writing or marking on the card, an assistant can help you. The tasting and scoring of the product should only take 10 minutes of your time.

Risks and Benefits

The risks associated with this research are no greater than those encountered in everyday life. You cannot participate if you have a food allergy. You may refuse to participate in the study, without any penalty.

There are no direct benefits besides helping further research for protein supplementation. This product will not treat or act as a medication for your medical condition(s). You are able to withdraw from participating at any time during the procedure, without any penalty.

Confidentiality

All information provided will remain confidential and will only be reported as group data with no identifying information.

Questions about the Research

For questions about this research, Abby Iocca can be contacted at (217)416-4483 or aliocca@ilstu.edu or Julie Schumacher at (309) 242-3706 or jmraede@ilstu.edu.

If you have any questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact the Research Ethics & Compliance Office at Illinois State University at (309) 438-5527 or via email at rec@ilstu.edu.