

The Popular Calorie Counter App, MyFitnessPal, Used to Improve Dietary Sodium

Intake: A Four-Week Randomized Parallel Trial

by

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## ABSTRACT

Nutrition instruction has become more accessible; it is no longer relegated to the doctor's office, dietitian briefing, outpatient clinic, or hospital. Now it is available in people's hands, pockets, and purses via their smartphone. Since nutrition instruction has become more accessible, health professionals and members of the general public are increasingly interested in using smartphone apps to assist with health-related dietary changes. With more and more of the population required to follow certain dietary recommendations and/or monitor specific nutrient intake, commercially available apps may be a useful and cost-effective resource for the public. The purpose of this four-week intervention was to determine if the popular calorie counter app, MyFitnessPal, can be used to reduce sodium intake to  $\leq 2,300$  mg/day compared to the traditional paper-and-pencil method. This four-week randomized parallel trial enrolled 30 generally healthy adults who were 18 to 80 years of age. Participants were randomly assigned to the MyFitnessPal ("APP") group or to the paper ("PAP") group and required to meet three times with the researcher for screening, baseline (start), and completion of the study. There was a significant difference in the mean urinary sodium change between the APP group and the PAP group from the start of the intervention to the completion ( $-24.0 \pm 32.6$  and  $8.5 \pm 41.9$  mmol/g creatinine respectively,  $p = 0.027$ ). Other positive trends that resulted from the intervention included a decline in dietary sodium in both groups and a higher adherence in the APP group compared to the PAP group regarding recording method. The MyFitnessPal app proved to be a useful tool in reducing and/or monitoring sodium intake. Thus, this trial reinforces the potential of this app to be used for monitoring other nutrients, but further research needs to be conducted.

## DEDICATION

I dedicate this work to my loving mother, Annette Dunkelman, who never stopped believing in me. She instilled in me the stamina to always work hard, the independence to speak my mind, and the motivation to achieve my goals. Thank you, mom.

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# CHAPTER 1

## INTRODUCTION

According to the Pew Research Center's Internet and American Life Project, as of May 2013, approximately 56% of Americans own a smartphone (Smith, 2013). Of those that own smartphones, about half have downloaded an app to their mobile device (Purcell, 2011). There are a plethora of health and wellness apps available, with an estimated 40,000 to 60,000 that cover a variety of interests such as diet, calorie counters, fitness, lifestyle management, and chronic health conditions (Silow-Carroll & Smith, 2013). With this newfound technology, smartphone apps have the potential to improve the overall diet quality and health of the general public. A few popular calorie counters that are available to be downloaded for free include MyFitnessPal, LoseIt, Fooducate, etc. The primary function of these apps is to monitor caloric intake. However, what if these commercially available calorie counters, such as MyFitnessPal, had the potential to monitor individual and/or therapeutic diets (Dietary Approached to Stop Hypertension (DASH), diabetic diet, renal diet, low cholesterol diet, low fat diet, etc.)?

Since smartphone apps are a fairly new field, there is limited research relating to diet-related apps. Also, there are only a handful of apps that have the potential to be used to monitor specific dietary behaviors. However, they have not been evaluated to determine their accuracy and efficacy for performing the needed dietary change. In a society where more and more individuals are asked to adhere to certain dietary recommendation, it is important that they have a tool to support these changes. The impact of these apps could be a phenomenal benefit to the overall dietary health of the general public and to the healthcare system. If these tools were available to the general public, patients could

educate themselves on proper nutrition and possibly reduce hospital stays and benefit from improved healthcare costs (Silow-Carroll & Smith, 2013). It would reinforce the importance of registered dietitians and nutrition specialists in the healthcare setting. This research niche has the potential of changing the outlook of the healthcare setting and the health of the public.

Of the research that is available, there are studies that support the use of apps to monitor dietary intake. Furthermore, they conclude that participants who used apps to assess their diet reported satisfaction with the mobile device and were willing to continue using the device after the completion of the study (Lieffers & Hanning, 2012). A few examples of areas where apps are being researched include dietary recording, weight management (loss, gain, or maintenance), diabetes, and fitness. An example study includes a proposed six-week, two-arm, parallel, randomized trial currently in progress that assesses the use of the SaltSwitch app to lower-salt food choices for individuals diagnosed with cardiovascular disease (Eyles, 2014). Its intended goal is to determine the effectiveness of the SaltSwitch app for those with CVD or who live with a family member with CVD. SaltSwitch was designed to scan food labels and, if the product is high in sodium, to provide alternative products lower in sodium (Eyles, 2014). This trial has not yet been completed, but report provides the protocol for this intervention.

Sodium, a required nutrient for the body, has become an increasing health concern in the United States due to its potential link with hypertension. For the past half century, research has supported the reduction of sodium intake in lowering blood pressure (Alderman & Cohen, 2012). According to the data found in the NHANES 2007-2008, the mean sodium intake for adults  $\geq 20$  years of age in the United States (U.S.) was about

3,400 mg/day (Cogswell et al., 2012). These values are significantly higher than the recommendations provided by the American Heart Association (AHA), the Dietary Guidelines for Americans (DGA) 2010, and the Institute of Medicine (IOM). There is controversy over current sodium recommendation, since studies have both supported and refuted these recommendations. However, it is apparent that sodium intake in the American diet is high. Most sodium found in foods is in the form of sodium chloride (NaCl), also referred to as salt. Dietary sodium alone is not completely at fault. It is usually when sodium is combined with other elements or compounds that it may pose a threat.

As Americans snack on their favorite chips or feast on a hamburger from one of the nearby fast food restaurants, they are not realizing the potential impact that it can have on their health. To clarify, fast food and/or processed food occasionally is not the problem; it is when these items are consumed on a routine basis. In the United States diet, greater than 75% of sodium is found in restaurant and packaged food items (Cogswell et al., 2012). It has been postulated that lowering sodium intake is key to the prevention and treatment of high blood pressure. According to the third National Health and Nutrition Examination Survey, one in four individuals in the U.S. have high blood pressure (Kannel, 1996). High blood pressure is a major risk factor of cardiovascular events.

Of the studies conducted on blood pressure, several focus on the effect of sodium levels on blood pressure and urinary sodium excretion. Two of the studies have a higher subject pool of 169 and 117 participants, whereas the third study had 20 (He, Markandu, & MacGregor, 2005). Participants in all three studies either had a high systolic and/or diastolic blood pressure with no previous treatment for raised blood pressure. Prior to the

start of the study, participants were placed on a salt-restricted diet for a period ranging from two to four weeks (MacGregor, Markandu, Sagnella, Singer, & Cappuccio, 1989). Then, they entered into a randomized, double-blind study, varying between four to twelve weeks in duration, where they were either assigned to the slow sodium tablet group or placebo tablet group. Adhering to sodium intakes of 2000 – 4800 mg/day, the results of all three studies were unanimous in finding that those assigned to the group consuming less sodium/salt displayed a more significant reduction in blood pressure than those who consumed more (He et al., 2009).

What if there is a way to use these commercially available calorie counter apps (MyFitnessPal, LoseIt, Fooducate, etc.) to monitor a specific nutrient or dietary modification in hopes of preventing or minimizing health complications? The purpose of this four-week randomized parallel trial was to examine the effect of using the MyFitnessPal app or paper method of recording to reduce dietary sodium intake to  $\leq 2,300$  mg/day in adults between the ages of 18 to 80 years with normal or high blood pressure. Urinary sodium, blood pressure, dietary sodium intake, and adherence to the recording method were outcome measures of this study and used to determine whether the intervention was a success. Ultimately, the goal was to determine whether the MyFitnessPal app was a valuable tool for implementing a single dietary modification. If proven effective, the app can be used in future research to modify other changes to diet behavior. To date, there is no published study that focuses on lowering sodium intake via a commercially available calorie counter app. All research was conducted at the ASU downtown campus in the Nutrition and Health Promotion research lab located in the Arizona Biomedical Collaboration Building.

### *Hypotheses.*

- Diet instruction, using either the journal method or the smartphone app, will not impact urinary sodium excretion in healthy adults.
- Diet instruction, using either the journal method or the smartphone app, will not affect blood pressure in healthy adults.
- Diet instruction, using either the journal method or the smartphone app, will not influence dietary sodium intake in healthy adults.
- Adherence to diet instruction will reflect an inverse correlation with the outcome measures. Thus, an increase in adherence to the diet instruction will result in a decline in the outcome measures.

### *Definition of Terms*

- Elevated blood pressure: a systolic blood pressure of greater than or equal to 120 mm Hg and/or a diastolic blood pressure greater than or equal to 80 mm Hg, or the subject was informed by their healthcare professional that he or she has high blood pressure
- App: a program or software that is designed for a specific purpose, usually compatible with mobile phones, tablets and computer desktops (Purcell, 2011).
- Excess alcohol consumption: greater than two to three servings daily for women and men respectively.
- Urinary sodium excretion: measured via two consecutive first morning voids and reported as sodium/creatinine ratio and reference.

### *Limitations*

- Subjects may not adhere to the prescribed changes in dietary behavior.

- Diet records are prone to participant recording error and researcher data entry error.
- The MyFitnessPal app may not have the exact food product that the participant consumed. Thus, a nutritionally similar product, but not exact, is selected.
- Two consecutive first morning urine collections may not reflect the amount of urinary sodium excreted with a 24-hour urine collection.
- To determine diet quality, subjects were provided a REAPS survey reference.

### *Delimitations*

Participants involved in the study were required to have either an iPhone, iPad or Android; be between 18 and 80 years old; and have normal or raised blood pressure or were informed by their healthcare professional that he or she has high blood pressure. Also, those included in the study were nonsmokers, individuals not diagnosed with a chronic disease (heart disease, renal disease, liver disease, stroke, or diabetes), and individuals not pregnant or recently pregnant or lactating for the past six months. Those excluded include individuals with inconsistent prescription drug use for the past three months or excess alcohol consumption. The study began in early August and concluded the end of December 2014.

## CHAPTER 2

### REVIEW OF LITERATURE

Smartphones, a popular mobile device, have become increasingly prevalent among consumers. Apps are housed on smartphones and are downloaded for a variety of functions. One such function relates to health. Sodium intake has increased over recent decades in the United States (U.S.) concomitant with the introduction of processed foods and the increased popularity of restaurants. Studies have shown that high sodium intake is linked to high blood pressure, a risk factor for numerous chronic diseases. What if there were a way to marry an app and reduced sodium intake into an effective tool? Thus, the purpose of this four-week randomized, parallel trial was to examine the effect of using the MyFitnessPal app or journal instruction to reduce dietary sodium intake to  $\leq 2,300$  mg/day and to reduce blood pressure, urinary sodium excretion, and dietary sodium intake in generally healthy adults between the ages of 18-80 with normal or high blood pressure. Areas of interest that need to be explored further to support this study include smartphone apps, sodium consumption, and high blood pressure.

#### *Smartphone Apps*

*Mobile Devices/Smartphones.* The first phone call via a mobile device was made on April 3, 1973, using the prototype of what would become the Motorola DynaTAC 8000x (Brenner, 2013). The device permitted 30 minutes of talking time and weighed a total of two pounds. Over time, mobile phone technology evolved by creating smaller mobile devices, promoting longer battery life, and transmitting calls at a faster speed. As of January 2007, Steve Jobs, Chief Executive of Apple, released the first smartphone (Brenner, 2013). Thus, the very first smartphone was none other than the iPhone. A

smartphone was similar to a miniaturized computer, which fit conveniently in one's purse, pocket, or palm. It provided a plethora of features, including calling, texting, emailing, accessing the web, listening to music, playing games all at the touch of the finger. This revolutionary device also housed apps.

*Electronic Predecessors to the Smartphone App.* Before the use of smartphone apps to help improve dietary and health behaviors, two other mobile options existed. The more limited option was using the existing features of mobile phones, which included text messaging as a motivational tool and cameras as a tool for collecting health-related data throughout the day. The second option was the personal digital assistant (PDA), the true electronic predecessor to the smartphone. This device acted as an information manager and offered a web browser, audio capabilities and mobile phone. At the time, it was hypothesized, similar to the smartphone, that this would be a better method for recording daily food consumption.

The use of a mobile device was implemented in a six month randomized clinical trial for weight loss, where participants were either assigned to the paper record group or the PDA group. The study consisted of 192 overweight/obese participants (mean BMI 34.1 kg.m<sup>2</sup>) (Acharya, Okan, Sereika, Styn, & Burke, 2011). Overall, the purpose of the study was to explain and compare dietary changes via the use of paper record versus PDA. For those assigned to the paper record group, it required participants to document the number of calories and fat (in grams) in all the products consumed throughout the day. They were also supplied with a reference booklet used to find nutrition information when food labels were unavailable. In contrast, the PDA group was given Palm Tungsten E2 PDAs with dietary self-monitoring software (Dietmate Pro) (Acharya et al., 2011). At the



start of the study, participants had relatively the same calorie intake, percent of fat from calories, and number of servings of the food groups being examined in the study. After six months, both the PDA and paper record group displayed a noteworthy reduction in weight, percent calories from fat and saturated fat, and caloric intake (Acharya et al., 2011).

However, the PDA group showed a greater decline in consumption of refined grains and increased consumption of fruits and vegetables (Acharya et al., 2011). Even though the PDA proved to be effective in this intervention, it did have its limitations. Limitations with the PDA included longer learning time to understand the device and, depending on the age (elderly) and literacy rate (lower literacy), the PDA may be difficult to use. A limitation to the study in general was related to the homogeneity of the sample population (Acharya et al., 2011). Most of the participants in the study were white, educated females who were employed full-time. The strengths of this study included improved weight loss and self-monitoring adherence with the PDA and high retention of participants after six months (Acharya et al., 2011). Thus, several aspects of diet quality improved in the PDA group compared to the paper record group.

A second study that shows the advantage of using PDAs included a 2-arm, 12-month randomized study consisting of 70 adults with a BMI  $> 25$  and  $\leq 40$  kg/m<sup>2</sup> (Spring, 2013). The goal of the study was to evaluate whether the use of PDAs and telephone coaching in conjunction with the standard-of-care obesity treatment was more beneficial than the standard-of-care obesity treatment alone. Participants were assigned either to the standard-of-care group treatment alone (standard group) or to the standard and connective mobile technology system (+ mobile group). The study consisted of two phases—the intervention (weight loss) phase (months 1-6) and the weight loss maintenance phase

(months 7-12) (Spring, 2013). For two weeks prior to the start of the study, participants were loaned a PDA to input food intake, weight, and physical activity daily. Those assigned to the standard group returned their PDA at the start of the six-month intervention phase. During the intervention phase, both groups attended MOVE! sessions twice a week (Spring, 2013). The sessions were led by dietitians, psychologists, or physicians and emphasized the importance of nutrition, physical activity, and behavior change. Both groups were encouraged to self-monitor their daily food intake. However, the + mobile group had the PDA which was an added incentive to record daily food consumption (Spring, 2013). The + mobile group was expected to record their energy intake everyday for the first two weeks and once per week until the completion of the intervention in six months. During the weight loss maintenance phase, the + mobile group was asked to record and transmit food intake biweekly from the seventh month through the ninth month and only needed to record food consumption for one week per month from the tenth month through the twelfth month (Spring, 2013). The primary limitation of this study was not being able to determine whether it was the PDA that was beneficial or the coaching that was involved in + mobile group. The results of this study concluded that those provided with the PDA, the + mobile group, exhibited a mean weight loss of 3.9 kg compared to the standard group (Spring, 2013). Thus, by implementing the PDA and telephone coaching, short-term weight loss was achieved.

*History of Apps.* Apps originated with the introduction of the Apple iPhone in early 2007 (Purcell, 2011). Apple, being the creator of apps, spurred the movement of other smartphone platforms to take part in the app trend. As more smartphone providers accepted this new movement, apps became increasingly popular among smartphone users.

Smartphones and apps encompass a fairly new technology market that has only been around for the past seven years. The number of apps being downloaded is increasing, but it is limited to a select demographic. This demographic includes young adults of higher education and income living in urban and suburban areas. (Fox & Duggan, 2012). Top apps that continue to dominate the market are games, music, social networking, maps and navigation, weather, and news (Fox & Duggan, 2012).

*Health apps.* Of the 56% who own smartphones, 19% have at least one health app downloaded to his or her phone (Fox & Duggan, 2012). Those apps of interest to smartphone owners are exercise/fitness, diet/calorie counter, and weight. According to the Health Tracking Survey of 2012, the top health indicators tracked in order of rank include: 60% track weight, diet, or exercise regimen; 33% track health indicators such as blood pressure, headaches, sleep patterns, etc.; and 12% track health indicators for those that they love (Fox & Duggan, 2013). The Pew Research Center's Internet and American Life Project and the California Healthcare Foundation sponsored this survey. A sample size of 3,014 adults living throughout the United States was surveyed via telephone interviews (Fox & Duggan, 2013). This survey concluded that those with chronic illness are more willing to track his or her health condition. In a society where chronic illness is more common than not, it is pertinent to monitor one's health either through tracking via an app or by hand. Research shows that about 49% monitor their health in their head, 34% monitor their health using a journal, and 21% monitor their health using technology/apps (Fox & Duggan, 2013). It is evident by the statistics provided that this target population is willing to monitor their health and what better way than to encourage than through an app. It also has been proven that self-monitoring is key to improving health complications,

especially those who want to control blood pressure, blood sugar, and weight (Fox & Duggan, 2013). Because apps are fairly new to the technology field, limited research has been conducted on the effectiveness of these apps in implementing a desired intervention or behavior change. Currently, research on health apps focus on weight loss.

*Apps Used for Weight Loss.* With the growing rate of obesity in our nation, researchers have been determined to find a method that may prove effective in this target population group. It has been demonstrated in numerous studies that self-monitoring one's diet leads to improved health outcomes, especially when it comes to weight loss. The main methods of monitoring dietary behaviors include 24-hour recalls, food frequency questionnaires, and food records. However, these methods are prone to inaccuracy, such as underreporting, lack of consistency in recording, and overall burden of logging food intake (Wharton, Johnston, Cunningham, & Sterner, 2014). To improve accuracy and reduce the burden of food logging, technology has stepped in to provide its assistance. With the age of smartphones in its prime, health apps allow for easy and rapid logging of dietary intake and instantaneous feedback on nutrient intake at each meal.

A total of three studies concentrated on the importance of smartphones and smartphone apps in recording dietary intake. Each was different in its sample size, study design, participants, and limitations. An eight-week randomized controlled trial, in the field of apps, focused on weight loss. The objective of the study was to compare the commercially available "Lose It!" app to traditional methods of dietary recording and counseling using the paper-and-pencil method and the memo feature provided on smartphones (Wharton et al., 2014). Participants were healthy, weight stable adults between the ages of 18 to 65 years. With a total of 57 participants, each was randomly

assigned to either the app group (AP), the memo group (ME), or the paper group (PA) (Wharton et al., 2014). The “Lose It!” app was downloaded to those assigned to the app group, in which participants were trained to record their daily food intake via the app. This group did not receive any dietary advice other than what was provided via the “Lose It!” app. The second group used the memo function on their smartphone to record their dietary intake for the day. The last group simply recorded their daily food intake using the paper-and-pencil method (Wharton et al., 2014). Both the ME and PA group did receive one-on-one nutrition counseling, in which they were provided with a personalized diet plan prior to the start of the study in combination with email reminders during the study. The results of the study reflect a greater consistency in daily food recording with both the AP and ME group compared to the PA group (Wharton et al., 2014). Participants in all three group lost weight, but one group did not out perform the others. Limitations include the possibility that, because the app group had the ability to track exercise, they consumed more calories, thus lost less weight. Also, due to the social benefits of the “Lose It!” app, where app users had the ability to interface with others, may have had an impact over time on the amount of weight lost. This study further reinforces that smartphone apps may in fact be beneficial in monitoring dietary behavior changes.

Another randomized controlled trial that implemented the use of a smartphone app for weight management consisted of 128 overweight volunteers with a BMI of  $\geq 27 \text{ kg/m}^2$  and between the 18 to 65 years (Carter, Burley, Nykjaer, & Cader, 2013). The purpose of the study was to determine the acceptability and feasibility of using a smartphone app compared to a website and paper diary in a self-monitoring weight management intervention (Carter et al., 2013). This trial lasted for a total of six months, in which

participants were randomly assigned to either the smartphone app, website, or paper diary group. The app developed specifically for this trial was My Meal Mate (MMM). Prior to being implemented, the MMM app was tested against other commercially available systems in appearance and functionality, such as the MyFitnessPal app (Carter et al., 2013). The features of the MMM app include goal setting, self-monitoring of diet and exercise, and feedback through weekly text messages. Those participants assigned to the website group used an already existing website that was developed by Weight Loss Resources (Carter et al., 2013). This company also supplied the paper diaries. The primary outcomes measured in this trial were feasibility and acceptability of adherence to the intervention. Secondary outcome measures included anthropometric measurements. Limitations of this study include the homogeneity of the sample population, the MMM app developed for this study often encountered bugs that caused the app to close, and twenty participants stated that they used another intervention during the trial in addition to the one randomly assigned to them (Carter et al., 2013). The results from this six month trial were that those provided the app had a higher adherence rate (92 days) compared to the website group (35 days) and the diary group (29 days) (Carter et al., 2013). In all three groups, weight loss did occur depending on the assigned group. The smartphone group had the greatest mean weight loss of 4.6 kg. Second to the app group was the diary group with a mean weight loss of 2.9 kg, followed by the website group with a mean weight loss of 1.3 kg (Carter et al., 2013). Similar to the trial discussed above, this study shows the significance of using smartphone applications in weight loss management.

The third was a crossover study, in which participants completed three different 7-day food records, using a computer, smartphone, and paper-based method. The

participants were healthy or overweight women (BMI 21 to 30 kg/m<sup>2</sup>) between the ages of 18 to 30 years (Hutchesson, Rollo, Callister, & Collins, 2014). The goal of this study was to evaluate the accuracy and acceptability of three different methods of recording dietary intake (Hutchesson et al., 2014). Both the computer and smartphone method utilized an online weight management program. By contrast, the paper method required the participants to record food intake on a food record sheet that included the time, type, and amount of food and beverages consumed. Additionally, the paper method required participants to record the calorie content in each food and beverage item using a calorie counter book. A total of 22 women were recruited for the study, but only 18 finished the study (Hutchesson et al., 2014). A potential limitation to this study is its relatively small sample size and homogeneity of the participants recruited for the study. Of the 18 total participants, 50% preferred the computer method (n = 9), 44.4% preferred the smartphone method (n = 8), and 6% preferred the paper method (n = 1) (Hutchesson et al., 2014). The main reasons that participants favored the computer and smartphone methods were due to ease of use and access. In reference to the paper method, participants found it time consuming, difficult to complete, and embarrassing to carry a calorie counter around.

*Apps Used for other Health and Diet Behavior changes.* Weight loss has been the primary focus of app research. However, research is in its infancy stage when it comes to researching the use of apps for other health interventions. The research that is available focuses on health interventions, such as monitoring physical activity, self-managing diabetes, and educating patients with Coronary Artery Disease (CAD).

The SMART MOVE was an eight-week parallel, randomized controlled trial with a total of 90 participants. Participants recruited were greater than 16 years of age who

owned an Android. The aim of this study was to examine the factors that encourage or prevent the use of smartphones in promoting physical activity in primary care (Glynn et al., 2013). Prior to the start of the study, the smartphone app, Accupedo-Pro Pedometer, was downloaded to eligible recruits' smartphones, but not made visible to the user. For a week, participants used this app to establish baseline data on his or her normal physical activity. After a week, participants were randomly assigned either to the intervention group or to the control group. The intervention group received the Accupedo-Pro Pedometer app (step count made visible), information on the benefits of physical activity, instructions to increase physical activity to a goal of 10,000 steps per day, and encouragement to use the app in completing this goal (Glynn et al., 2013). Similarly, the control group was provided with the app but the step count remained invisible, information regarding the benefits of exercise, and instructions to increase physical activity with a goal of an additional 30 minutes of walking per day (equivalent to 10,000 steps). Even though the goal of 10,000 steps was not met, there was an improvement in mean daily steps in both the control and intervention group of 4,365 steps at week one to 5,138 steps at week eight (Glynn et al., 2013). The primary limitation to this study is the absence of other similar studies using apps for physical activity to determine if in fact they are useful (Casey et al., 2014). Thus, physical activity did improve in both groups, even though not to the intended goal, but it still shows that apps can be a beneficial tool for exercise.

Two chronic diseases, Coronary Artery Disease (CAD) and diabetes, are being embraced by the world of apps. A recent study, as of 2014, was conducted for the primary purpose to develop an educational app for patients with CAD and to assess users



satisfaction. The app Strong Heart was created for those CAD patients who were recently discharged from the hospital who needed information on how to manage this illness. The Strong Heart smartphone app consists of six main learning sections, which cover general information about CAD, risk factors, daily life management, drug management, dietary management, and exercise management (Cho, Sim, & Hwang, 2014). Additional features provided via the app include statistics regarding the incidence of CAD, real patient cases, check personal risk of CAD, precaution tips/prevention of risk factors associated with CAD, and self-tests regarding lifestyle improvements (Cho et al., 2014). A total of thirty CAD outpatients between the ages of 31 to 67 years of age observed the design of the app and were asked to complete a questionnaire upon viewing it. A major limitation of this study is it did not measure the learning content, but rather the design content. Overall, the participants showed a high satisfaction with the visual design of the Strong Heart app (Cho et al., 2014). However, further research needs to focus on the actual use of the app by CAD patients. With that being said, the app Strong Heart can currently be downloaded from the iPhone App Store and the Android Play Store.

Diabetes is another health concern where apps may prove beneficial in the everyday self-management. In an area where limited information is available, a recent three-month pilot study in 2012 was conducted on 12 adolescent children between the ages of 13 to 19 years with type 1 diabetes (Frøisland, Arsand, & Skårderud, 2012) The aim of this study was to examine the use of two different mobile phone applications in managing diabetes in adolescents (Frøisland et al., 2012). Two applications were provided to the participants. The first app was a picture-based diabetes diary to record physical activity and the camera feature on the phone was used to take pictures of food consumed,

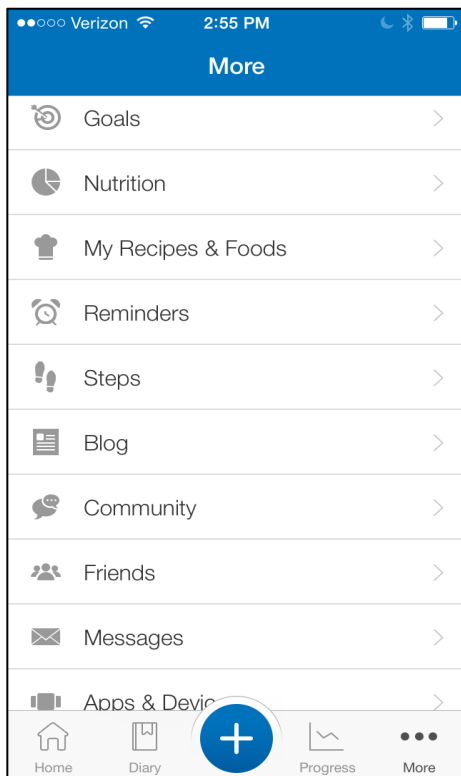
which in turn communicated with Bluetooth technology to determine blood glucose values. The objective of this application was to visually instruct the participant on the connection between food consumed and the resulting blood sugar levels. The second application was a short message system (SMS) where the participants could communicate with their providers and receive educational messages (Frøisland et al., 2012). Potential limitations to this study include a biased sample of participants who were more comfortable with technology, the short intervention phase reduced the potential for providing statistical significance, and technological problems arose (Frøisland et al., 2012). The results of this study found that participants enjoyed the picture-based diary. The picture-based diary application was an engaging educational tool to the user in which insulin dosage, physical activity, and pre-and post-prandial glucose measurements were all presented in a visually appealing way (Frøisland et al., 2012). Thus, implementing both the picture-based diary and SMS application with adolescents was effective in allowing them to better understand their diabetes treatment.

*MyFitnessPal.* The MyFitnessPal app functions as a calorie counter with the intended purpose of helping people lose weight. It is free to consumers and is easily accessed via smartphones, tablets, and the Internet. MyFitnessPal confirms that studies support the recording of daily food intake and tracking physical activity as important components to lose weight (“Lose weight with MyFitnessPal.com — for free,” 2005). Additionally, they realize that recording daily food intake and physical activity can be a tedious feat if not using the right tool. Thus, the goal of their program is to make meal logging as simple for the consumer as possible. Because the easier the logging method is

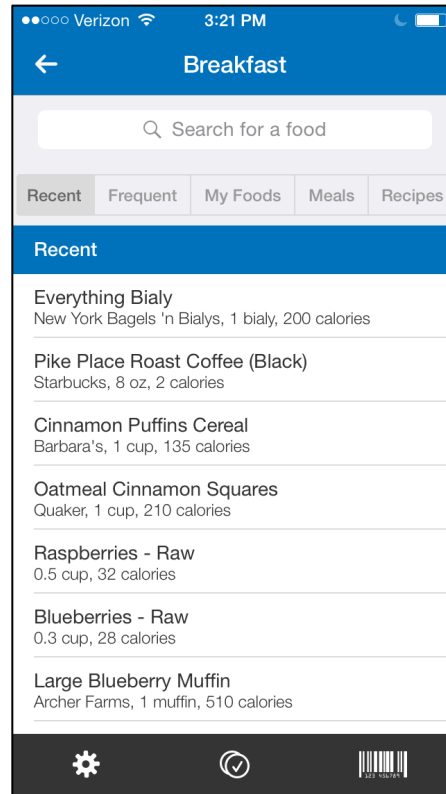
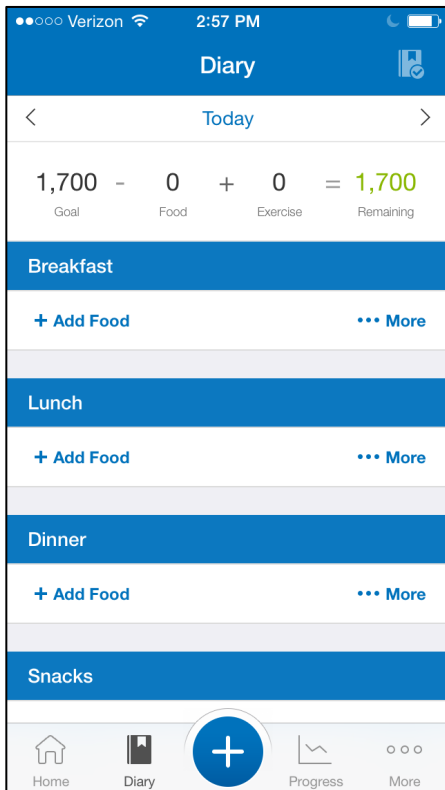
the more likely the user will continue to use the MyFitnessPal app (“Lose weight with MyFitnessPal.com — for free,” 2005).

The app provides a variety of features to the user. It has a searchable food database of over one million food items. It has the ability to create recipes for those who cook. It has a scanner to scan the barcode of food products to learn more about the product. It has the ability to interact with other members using the MyFitnessPal app. It also allows the user to track their weight loss progress and nutrition intake. The app is not limited to just these features it has a number of other functions not listed. Ideally, the MyFitnessPal app is used as a weight loss tool. However, due to number of features that it offers, it has the potential to monitor and improve dietary habits.

*Images of Features of the MyFitnessPal App.* The following images are just a few of the features that the MyFitnessPal app has to offer.



	Total	Goal	Left
<b>Total Fat (g)</b>	0	47	47
Saturated Fat (g)	0	19	19
Polyunsaturated Fat (g)	0	0	0
Monounsaturated (g)	0	0	0
Trans Fat (g)	0	0	0
<b>Cholesterol (mg)</b>	0	300	300
<b>Sodium (mg)</b>	0	2300	2300
<b>Potassium (mg)</b>	0	3500	3500
<b>Total Carbohydrates (g)</b>	0	234	234
Dietary Fiber (g)	0	25	25
Sugars (g)	0	64	64
<b>Protein (g)</b>	0	85	85
<b>Vitamin A</b>	0%	100%	100%
<b>Vitamin C</b>	0%	100%	100%
<b>Calcium</b>	0%	100%	100%
<b>Iron</b>	0%	100%	100%



Because apps are fairly new to the mobile technology field and were developed only seven years ago with the smartphone, there is minimal research in this area. Each study discussed is unique in nature and involved different participants, interventions, study designs, results, and limitations. Examining the research literature relating to weight loss, physical activity, and other dietary behaviors just further reaffirms that apps are effective in stimulating the desired behavior change. However, further research and app prototyping are needed to increase and support the field of health apps.

### *Sodium Consumption.*

*Current and Past Sodium Intake.* According to the Dietary Guidelines for Americans 2010, the mean sodium intake of Americans ages two and older is 3,400 mg/day (US Department of Health and Human Services [DHHS], 2010). However, due to the addition of salt during cooking and at the table and the underestimate of food

consumption, the projection of actual sodium consumption is closer to 3,800 mg/day (Jacobson, Havas, & McCarter, 2013). Americans consumed an estimated 1,200 mg/day more of sodium in 2007—2008 compared to the early 1970s (Jacobson et al., 2013). In the typical American diet, sodium is often consumed in the form of salt. Salt, as a food ingredient, has countless functions, including curing meats, baking, enhancing flavors, masking odors, and preserving moisture (US DHHS, 2010). The main contributors to excess sodium intake are processed/convenient foods and restaurant foods (US DHHS, 2010). During a span of approximately 20 years, from the start of the National Health and Nutrition Examination Survey (NHANES) I (1971—1974) to the end of the NHANES III (1988-1994), mean sodium intake increased among all age groups (Briefel & Johnson, 2004). However, it seems that the trend in mean sodium intake leveled off between NHANES III and NHANES 1999—2000 (Briefel & Johnson, 2004). Even though the trend seemed to remain relatively constant during this time period, sodium intake among all age groups and genders is high compared to the dietary recommendations for sodium. Analyzing sodium trends among the population is fairly difficult, due to the erratic changes in the manufacturers' food products, the lack of a universal food composition database, and the complication of calculating the total amount of sodium in food items (Briefel & Johnson, 2004).

*Dietary Guidelines for Sodium.* There are several dietary guidelines provided for sodium intake. However, it is a continual battle for the general public to meet these guidelines due to the surplus of sodium in the food supply. It does not help that a majority of food items found at the grocery store are highly processed and have excess amounts of sodium. Also, it does not help that restaurants provide enticing food options, often in a

large portion size, that contain high sodium amounts. Of the many guidelines and organizations that tout reduced sodium intake, the most popular include the Healthy People 2020, Dietary Guidelines for Americans 2010, American Heart Association (AHA), and the Institute of Medicine (IOM) (Levings, Cogswell, & Gunn, 2014). A commonality present among Healthy People 2020, Dietary Guidelines for Americans 2010, and the American Heart Association is a sodium intake of 2,300 mg/day or less for those two years of age or older (Levings et al., 2014). However, a 1,500 mg/day requirement is advised for those age 51 and older, African Americans, or those with diabetes, high blood pressure, and chronic kidney disease (Levings et al., 2014). To provide a better visual of what 2,300 mg/day of sodium is in serving size, it is about one teaspoon of salt (DeSimone, Beauchamp, Drewnowski, & Johnson, 2013).

In contrast, the newly published draft of the Dietary Guidelines for Americans 2015 does not necessarily reinforce the 2,300 mg/day of sodium for the entire population. It does support the reduction of sodium to no more than 2,400 mg/day for those adults that have high blood pressure. The 2,400 mg/day was implemented, since it is the average urinary sodium excreted by those involved in the DASH sodium trial (Rodgers, 2015). Even if the goal of no more than 2,400 mg/day is not met, just by lowering sodium intake by 1,000 mg/day is beneficial in lowering blood pressure (Rodgers, 2015). Overall, adults with high blood pressure should follow the DASH diet in combination with lowering sodium intake (Rodgers, 2015). In contrast, there is no recommendation provided for children regarding sodium. The only comment made in the document is as sodium intake decreases in children so does blood pressure for those between the ages of birth and 18 years (Rodgers, 2015).

The IOM references an adequate intake (AI) for sodium of 1,500 mg/day for ages 9 to 50 years (US DHHS, 2010). Children (ages 1 to 3 years: 1,000 mg/day; ages 4 to 8 years: 1,200 mg/day) and older adults (ages 51 to 70 years: 1,300 mg/day; 71 years and older: 1,200 mg/day) have lower established AIs for sodium (US DHHS, 2010). The AI for sodium was created based on energy requirements. At 2,300 mg/day, the tolerable upper intake level (UL) for sodium was set to prevent excess consumption and adverse effects. This level was determined based on the concern of sodium and its link with high blood pressure and several research trials, including the Dietary Approaches to Stop Hypertension (DASH)-Sodium Trial (US DHHS, 2010). The DASH-Sodium Trial reinforced that when sodium intake was reduced to 2,300 mg/day or below blood pressure also declined (US DHHS, 2010). The main contributors to excess sodium consumption and its link to high blood pressure are processed foods and restaurants.

*Nationwide Efforts to Improve Product Nutrition labeling and Restaurant Menu Labeling.* As of 1990, the United States Congress enacted the Nutrition Labeling and Education Act (NLEA). By May 1994, new labels that limit health claims, use standardized portion sizes, and emphasize nutrients associated with chronic illnesses were introduced to the public (Kristal, Levy, Patterson, Li, & White, 1998). Nutrition labels on food products prior to 1994 were often confusing to understand and capricious in their health claims. Two population-based surveys were conducted both before and after the implementation of the new nutrition labels. This study compares both the before and after responses to these surveys to determine whether there was an increase in those using nutrition labels, whether there were changes in the nutritional information most often used, and whether consumers report fewer barriers with this new nutrition label (Kristal et

al., 1998). The first survey was administered between August 1992 and August 1993 (prior to the new nutrition labels) and the second survey was administered between September 1995 and September 1996 (after the implementation of the new nutrition labels) (Kristal et al., 1998). About 1,001 participants completed the first survey and 1,450 completed the second survey (Kristal et al., 1998). Participants were obtained from the Washington State Cancer Risk Behavior Survey. Positive outcomes from this study include usual label use increased in both men (11%) and women (9%) from 1993 to 1996 and fewer people found the labels to be confusing and burdensome (Kristal et al., 1998). However, more than 70% of the participants still thought that the nutrition labels could be easier to understand and more user friendly (Kristal et al., 1998). Additional measures could be implemented such as further label modification to make them easier to understand and educational programs on reading nutrition labels.

In March 2010, Congress passed the Patient Protection and Affordable Care Act (ACA) (Stein, 2011). The main purpose of Section 4205 of the ACA is to address the overweight and obesity epidemic in the U.S. (Koh & Sebelius, 2010). Section 4205 mandates that restaurants and food vendors with 20 or more locations must provide and display calorie information on menus and menu boards (Stein, 2011). Additional nutrition information must be provided, including fat, saturated fat, carbohydrates, protein, fiber, and sodium (Stein, 2011). The regulatory agency enforcing this mandate is the U.S. Food and Drug Administration (FDA). The FDA had one year to determine the rules and standards needed to implement this mandate. By March 23, 2011, its proposal was due and restaurant owners had six months to become compliant with this Act (Stein, 2011). This



Act is still in its infancy and will require more time to determine if awareness of caloric content of menu items will change the consumers eating behavior.

*Processed and Restaurant foods.* As consumers travel down the aisles of grocery stores in search for food items, it is shocking to see the number of highly processed food items that line the shelves. It is even more startling to see the amount of sodium provided in one serving size. Has sodium been slowly creeping into our food supply or has it always been a concern that the population was unaware of until lately? The following studies were conducted during the time the period in which ACA was being passed. Thus, caloric content and additional nutrition information relating to restaurant menu items may not have been readily available to the consumer. The question is would it make a difference. Would having the calories available and additional nutrients, have influenced consumers' eating habits for the better?

Of interest are two studies that examine the sodium content in both processed and restaurant foods. The first study published in 2012 determined the top ten food categories contributing to high sodium intake. In this study, data was obtained from 7,227 participants ages two years and older enrolled in the *What We Eat in America* (WWEIA), 2007—2008 NHANES (Centers for Disease Control and Prevention [CDC], 2012). Participants were required to complete two 24-hour dietary recalls that served as a basis for assigning each food to a specific food code in the U.S. Department of Agriculture (USDA) Food and Nutrition Database for Dietary Studies (FNDDS) (CDC, 2012). The 7,000 foods coded were further allocated to one of the 100 food categories determined by customer use and foods consumed in the diet (CDC, 2012). Results from this study displayed that the average sodium intake among this group of participants was about 3,266

mg/day (CDC, 2012). After detailed analysis, the top ten food categories contributing to excess sodium consumption, by rank, are breads and rolls, cold cuts/cured meats, pizza, poultry, soups, sandwiches, cheese, pasta mixed dishes, meat mixed dishes, and savory snacks (CDC, 2012). Possible limitations of this study include the exclusion of institutionalized populations, not all participants completed two 24-hour dietary recalls, the method of categorizing food contributing to sodium is variable, the 24-hour dietary recalls are prone to self-reporting errors and food coding, and the FNDDS database may not have the correct food product needed (CDC, 2012). According to the results of this study, these top ten food categories comprised approximately 44% of the sodium consumed in ages two years and older living in the U.S. Most of the sodium consumed was from foods purchased at grocery stores compared to the 25% of sodium consumed from restaurants (CDC, 2012). However, restaurants tend to have more sodium per calorie compared to products purchased from the grocery store. Larger food portion is an additional factor to account for higher sodium content at restaurants.

The second study, published about a year later in 2013, focuses on whether changes have been made in sodium content between 2005 and 2011 of 402 commonly eaten processed foods and 78 restaurant foods (Jacobson et al., 2013). The processed foods being assessed were commonly found at three supermarkets in Washington, DC, and a Walmart in Elverston, Pennsylvania. The restaurant foods being evaluated were from large chain restaurants, which included Arby's, Chick-fil-A, Domino's Pizza, Jack in the Box, KFC, McDonald's, Panera Bread, Pizza Hut, Subway, and Wendy's (Jacobson et al., 2013). Sodium content in identical foods was evaluated via a survey in 2005, 2008, and 2011 (Jacobson et al., 2013). Food items were limited to those that were marketed all

three years in which the survey was conducted. The results in this study reflect a food processing and restaurant industry in which minimal efforts have occurred in regards to changes in sodium content over this time period (Jacobson et al., 2013). Of the processed food items being analyzed, sodium content in some of the processed foods did decline by at least 30% between 2005 and 2011, while a greater number of foods increased in sodium content by at least 30% (Jacobson et al., 2013). There was a mean sodium decline of 1% between 2005 and 2008 and a decline of 2.5% between 2008 and 2011 in processed foods (Jacobson et al., 2013). In contrast, restaurant foods increased in mean sodium levels by 1.6% between 2005 and 2008 and increased by 1% between 2008 and 2011 (Jacobson et al., 2013). Thus, the mean total increase for sodium was 2.6% for restaurant foods and the mean sodium decrease of 3.5% for processed foods (Jacobson et al., 2013). The strengths of this study include food items were chosen without prior knowledge of product reformulation and foods selected were representative of the top five sources of sodium consumption in the United States (Jacobson et al., 2013). In contrast, a limitation of the study is that it only surveys a small portion of the food products and restaurant items available to consumers. Additional limitations involve short duration in which products and restaurants were surveyed, not all food brands and categories were included, only chain restaurants were included, and low-sodium products were not analyzed (Jacobson et al., 2013).

Two additional studies, described below, concentrate on fast-food and chain restaurants and their contribution to sodium consumption prior to the passage of the ACA. Approximately 82% of American adults eat out at least once per week (Wu & Sturm, 2013). Restaurants are a key staple in the American diet. However, they are also a key

contributor to excess sodium consumption, larger portion size, and higher caloric intake (Wu & Sturm, 2013). It is ambiguous as to the true nutritional content of a restaurant meal due to the introduction of new menu items, the reformulation of existing items, and no comprehensive assessment provided by the food industry. The first study addresses four main points, which in brief include the current availability of nutritional data of standard menu items at major U.S. chain restaurants, the energy and nutrient content of these standard food items, comparison of these restaurant food items to existing state/local labeling laws, and the number of menu items that meet the government-issued nutrition requirements (Wu & Sturm, 2013). Study sample was recruited from the *2009 Restaurants and Institutions* magazine's list of the top 400 chain restaurants according to sales in 2008 (Wu & Sturm, 2013). Out of the 400 chain restaurants, only 245 were eligible and classified as providing complete nutrition information (Wu & Sturm, 2013). Complete nutrition information is defined as providing energy content for a majority of the standard menu items. This information was obtained either via restaurant websites or upon email request. Upon evaluation of the 245 restaurants, it was determined that appetizers had the highest amount of energy, fat, saturated fat, and sodium (Wu & Sturm, 2013). Salads with dressing had nutrient values similar to that of main entrees. When caloric content of main entrees were compared to one-third of the U.S. Department of Agriculture's estimated daily energy needs, a majority of the entrees fell below this benchmark. Additionally, less than 3% of the main entrees were within the limits for sodium, fat, and saturated fat (Wu & Sturm, 2013). Since data was collected prior to the ACA, a limitation of this study is that the web-based or self-reported nutrition content of menu items are not subject to a standardized rhetoric and may be variable in accuracy (Wu & Sturm, 2013). Even though

this study analyzed the menu content of a plethora of large chain restaurants, it did not represent all types of restaurants available to the consumer. This study acts as a baseline for future studies, especially those after the implementation of the ACA, to determine if changes have been made by both the food industry and consumers eating habits.

The purpose of the second study is to examine the change in sodium content of menu items in the U.S. over a period of 14 years (Rudelt, French, & Harnack, 2014). This study focused on analyzing sodium at eight leading fast-food restaurants, which were selected based on number of locations and annual sales (Rudelt et al, 2014). Menu items were analyzed for sodium content using the University of Minnesota Coordinating Center (NCC) Food and Nutrition Database. Trends in sodium consumption were evaluated a total of seven times every two years due to software updates (Rudelt et al, 2014). Nutrition information for food and beverages on the restaurants' breakfast, lunch, and dinner menu were obtained via either company website or publications made by the company. This information was used to update NCC Food and Nutrition Database. Results of this 14-year study found that the number of non-beverage menu items of the eight fast food restaurants increased from 450 to 695 menu options (Rudelt et al, 2014). Between 1997 and 2010, mean sodium content of menu items increased by  $23\pm 4\%$  at the eight fast food restaurants (Rudelt et al, 2014). Mean sodium levels of entrée items increased by  $17\pm 2\%$  and condiments increased as well by  $26\pm 1\%$ , whereas side dishes decreased by  $6\pm 6\%$  (Rudelt et al, 2014). Limitations to this study include difficulty in analyzing bundled meal options (value meals, kids meals, etc.) and difficulty in finding the comparable serving size in the food database. The difficulty in finding a comparable serving size may result in underestimating the amount of sodium in menu item (Rudelt et al, 2014). It can be

concluded that, over a period of 14 years, there was not a significant reduction in sodium content for menu items across these eight leading fast food restaurants (Rudelt et al, 2014).

Two studies focusing on analyzing the nutritional content of menu items provided at chain restaurants in the U.S. were conducted after the enactment of the ACA. Data was collected for both of these studies between 2010 and 2011 (Wu & Sturm, 2014). The purpose of the first study was to track the changes being made in both calories and sodium content of main entrees of U.S. chain restaurants (Wu & Sturm, 2014). Changes in menu items were tracked during the time period of spring 2010 to spring 2011 when the ACA implemented a mandate in which restaurants with 20 or more outlets must follow certain menu labeling requirements (Wu & Sturm, 2014). The sample population of this study includes a larger data set of 213 restaurant brands that comprise a total of 155,021 U.S. based food outlets and about a quarter of all U.S. restaurants in 2010 based on the InfoUSA retail database (Wu & Sturm, 2014). In contrast, the second study focused on a smaller niche of 21 chain restaurants in the Philadelphia region. The intended goal was to assess the nutritional value of meals provided at full-service national restaurant chains after the passing of the ACA (Auchincloss et al., 2014). Both studies involved similar data collection methods by obtaining the nutritional information via restaurant websites, email requests, or printed menus. For the first study, baseline data was collected between February and May 2010 and follow-up data collection was between April and May 2011 (Wu & Sturm, 2014). The second study also had a similar time period as the first study's follow-up data collection. The second study's data collection started a month earlier in March 2011 and ended May 2011 (Auchincloss et al., 2014). Limitations of both studies

include that website nutrition information may not accurately reflect the actual menu items being offered and food preparation may affect the accuracy of the reported nutritional content of the menu items. Both studies in their results show that minimal changes have been made in sodium content of menu items. The first study showed only a 70 mg decrease in main entrees for sodium and the authors speculated it could be due to chance (Auchincloss et al., 2014). In contrast, the second study analyzing 21 food outlets in Philadelphia found that sodium exceeded the current recommendations of 2,300 mg/day for a single meal at one of these restaurants (Wu & Sturm, 2014). Even though these two studies occurred after the implementation of the ACA, the Act is still in its infancy and substantial changes in nutrition content of menu offerings will be minute at first. A colossal industry such as food will require time to determine if this Act is influential and whether bringing awareness to consumers via providing nutritional information will change their eating habits. It is not necessarily the case that the foods at these restaurants are unhealthy, as it could be that the portion sizes are too large.

*Portion Size Influences Sodium Intake.* If portion sizes increase, it is only logical that caloric intake, sodium, fat, etc. will increase as well. The menu options being selected at restaurant establishments may be nutritionally adequate if the correct serving size is provided. It does not help when local fast-food restaurants advertise sandwiches and meals options that are well over 1,000 calories and are larger than one serving size. However, the trend present at many fast-food restaurants is the supersizing phenomenon (Nielsen & Popkin, 2003). One study suggested that the larger the food package the more food served from it (Ello-Martin, Ledikwe, & Rolls, 2005). Additionally, the size of the food package not only affected the portion size being served, but also the amount that one consumes.

Several studies conducted by Rolls et al. jointly explain the current concern with portion sizes. In these studies, the investigators focused on the manipulation of portion sizes and energy density of the following food items; macaroni and cheese, submarine-type sandwiches, potato chips. (Ello-Martin et al., 2005). The results from each of these studies were unanimous—participants will increase intake with increased portion sizes. An additional study measured current portion sizes and compared them to both past portion sizes and the U.S. Department of Agriculture (USDA) and the U.S. Food and Drug Administration (FDA) standards (Young & Nestle, 2002). This study sampled a variety of food products available for immediate consumption from popular fast-food joints, take-out eateries, and family-style restaurants. Foods were sampled from the top food categories in national surveys as primary contributors to increased energy consumption and marketed as single portions. Overall, the study concluded that portion sizes from these restaurants have increased drastically from 1970 to 2000 and well exceeded the portion size standards provided by USDA and FDA (Young & Nestle, 2002). Thus, this study further proves that portion sizes of menu options may also be a contributing factor to excess sodium consumption.

*Sodium-Potassium Ratio.* Sodium is found naturally occurring in foods. However, the culprit for increased sodium in the diet is in the form of salt, or sodium chloride, added to processed/convenience foods and restaurant menu items. Potassium is a nutrient found in fruits and vegetables, such as bananas, apricots, potatoes, sweet potatoes and spinach, as well as in low-fat and fat-free yogurt (Levings & Gunn, 2014). Sodium is a required on nutrition labels, but potassium is not. According to the Academy of Nutrition and Dietetics, 90% of Americans consume sodium in excess, whereas a majority consumes



inadequate potassium (Levings & Gunn, 2014). For those ages 14 and older, the Institute of Medicine established the adequate intake for potassium at 4,700 mg/day (Levings & Gunn, 2014). Current intake of potassium is well below this parameter with an estimated range of 2,400 to 3,200 mg/day, depending on gender and age (Drewnowski et al., 2012).

A study combined three cycles of NHANES analyses (2003-2004, 2005-2006, 2007-2008) to determine typical sodium and potassium intake based on socio-demographic and health characteristics in comparison to the current recommendations of the IOM, AHA, and U.S Department of Health and Human Services (USDA) (Cogswell et al., 2012). An additional purpose was to observe whether typical sodium and potassium intake has changed from 1988-1994 (Cogswell et al., 2012). Recommendations from the IOM, AHA, and USDA all tout reduced sodium intake and increased intake of potassium-rich foods to minimize the risk of high blood pressure and cardiovascular disease (CVD) (Cogswell et al., 2012). A complex, multistage survey of non-institutionalized U.S. population, the NHANES survey was conducted by the National Center for Health Statistics (NCHS), CDC. Data of about 10,000 participants were released in two-year cycles from counties throughout the U.S (Cogswell et al., 2012). Two 24-hour recalls were used to evaluate the participants' usual sodium and potassium intake. Results displayed that the median usual sodium intake for U.S. adults age 20 years and older was about 3,371 mg/day and the median usual potassium intake was 2,631 mg/day in 2003-2008 (Cogswell et al., 2012). Additionally, 99.4% of U.S. adults exceed the AHA recommendation of 1,500 mg or less and 90.7% exceed that of the IOM tolerable upper intake level of 2,300 mg or less (Cogswell et al., 2012). In contrast, only about 2% of U.S. adults and about 5% of men 20 years and greater met or exceeded the potassium

recommendation of  $\geq 4,700$  mg/day (Cogswell et al., 2012). A main strength of this study is a large sample size that is representative of U.S. population. A limitation was the 24-hour recalls had an underestimation in energy intake by 11% and this may have resulted in an underestimation of the actual intake of sodium (Cogswell et al., 2012). The nutrient database used to analyze sodium and potassium intake may vary from the actual intake of these nutrients. A further limitation is that sodium from table salt, antacids, and supplements were not included in daily sodium intake. The conclusion obtained from this study is that adults in 2003-2008 exceeded the sodium recommendations of the IOM, AHA, and USDA and few met the recommended potassium intake (Cogswell et al., 2012). Thus, sodium consumption is excessive and potassium consumption is inadequate.

Sodium and potassium are two electrolytes with an inverse relationship. Often, when potassium intake is higher, sodium intake is lower and vice versa. It has been suggested in emerging research that the sodium to potassium ratio has a greater influence on high blood pressure and CVD risk than the individual electrolytes alone (Levings & Gunn, 2014). However, there are limited studies that evaluate the association between the sodium-to-potassium ratio and blood pressure. Two studies that follow focus on the relationship of both sodium and potassium together.

The goal of the first study is to evaluate the simultaneous compliance of sodium and potassium with the recommended guidelines using data from 2003-2008 NHANES (Drewnowski et al., 2012). The 2010 Dietary Guidelines for Americans stress the importance of reducing sodium intake to  $< 2,300$  mg/day or  $< 1,500$  mg/day for those in specific populations and the concurrent increase in potassium intake of  $\geq 4,700$  mg/day (Drewnowski et al., 2012). Data such as sodium, potassium, and energy intake was

obtained from a sample size of 12,038 adults age 20 years and older who had completed two non-consecutive 24-hour dietary recalls (Drewnowski et al., 2012). Based on the results, it seemed near impossible to reduce sodium intake while also increasing potassium intake. Only 0.12% of the participants involved in the study reduced their sodium intake to < 2,300 mg/day while simultaneously increasing potassium intake (Drewnowski et al., 2012). Furthermore, 0.015% reduced their sodium intake to < 1,500 mg/day while jointly meeting the potassium intake recommendation (Drewnowski et al., 2012). A limitation to this study was that the participants' nutritional intake was based on two 24-hour dietary recalls, which is not representative of their habitual intake. Additionally, nutritional intake is self-reported and thus prone to underreporting or over-reporting. Another limitation is that table salt and supplements are not included in these sodium values. Thus, it may be an underestimate of the actual sodium intake (Drewnowski et al., 2012). Overall, this article concludes that only a select few have been able to meeting the sodium and potassium recommendations.

The purpose of the second study was to examine the relationship between sodium and potassium intake and blood pressure and hypertension. The NHANES 2005-2010 was used to obtain data from 10,563 participants ages 20 years and older who were not taking blood pressure medication or on low sodium diets (Zhang et al., 2013). An average of the three blood pressure reading was reported, after five minutes of rest and following the protocol provided by the AHA. Hypertension status was based on the average blood pressure reading received during examination and self-reported history of hypertension (Zhang et al., 2013). Dietary sodium and potassium data was obtained via two 24-hour dietary recalls. After the data was analyzed, the average usual intake of sodium was 3,569

mg/day and potassium was 2,745 mg/day with a ratio of 1.41 (Zhang et al., 2013). These three measures were notably associated with the systolic blood pressure. In this study, the sodium-to potassium ratio increased by 0.5 units when the systolic blood pressure increased by 1.05 mmHg (Zhang et al., 2013). The average ratio for sodium-to-potassium for adults ages 20 years and older is 1.41 (Levings & Gunn, 2014). This ratio increased when sodium intake is high and potassium intake is low. Thus, limitations include 24-hour recalls were used to determine usual sodium and potassium intake, 24-hour recalls may reflect an underestimate or overestimate of actual sodium intake, and blood pressure may not have been measured accurately (Zhang et al., 2013). According to this article, there is strong evidence showing that high sodium and low potassium intake is linked to hypertension.

*High Sodium Intake Linked to High Blood Pressure.* For three decades, it has been publicized that eating less salt will lower blood pressure (Taubes, 1998). Numerous research studies have supported the notion that high sodium intake is associated with high blood pressure (He & MacGregor, 2009). Two studies, one dating from the early 2000s and the other from the late 1980s, show a benefit of reducing sodium consumption in lowering blood pressure.

A three-month, double-blind randomized crossover study was conducted in the late 1980s involving 20 participants with hypertension (MacGregor, Markandu, Sagnella, Singer, & Cappuccio, 1989). Participants involved in the study were a mean age of 57 and were not taking any anti-hypertensive medication. Prior to the start of the study, participants reduced their salt intake to 50 mmol/day (1,150 mg/day) for a month (MacGregor et al., 1989). They were then randomly assigned to one of the three groups

that received varying levels of sodium via slow sodium tablets. Thus, participants were either assigned to receive 50 mmol/day (1,150 mg/day), 100 mmol/day (2,300 mg/day), or 200 mmol/day (4,600 mg/day) (MacGregor et al., 1989). The average fall in blood pressure between those receiving 200 mmol/day to those receiving 50 mmol/day was 16 mmHg for systolic and 9 mmHg for diastolic (MacGregor et al., 1989). A major limitation of this study was the participants' compliance with a salt restrictive diet (MacGregor et al., 1989). This study concluded that reducing salt intake does progressively lower blood pressure.

A six-week randomized, double-blind crossover trial with the intended purpose of reducing salt intake and lowering blood pressure in three ethnic groups (white, blacks, and Asians) with untreated hypertension (He et al., 2009). There were a total of 169 participants between the ages of 30 and 75 years, with either a sitting diastolic blood pressure of 90 to 105 mmHg or a sitting systolic blood pressure of 140 to 170 mmHg (He et al., 2009). Participants were placed on a reduced-salt diet for two weeks before being randomly assigned to the placebo or slow sodium tablet group. From the slow-sodium group receiving about 9.7 g of salt per day (3,800 mg/day of sodium) to the placebo group receiving about 6.5 g of salt per day (2,600 mg/day of sodium), there was a significant decline in blood pressure from  $146\pm 13/91\pm 8$  mmHg to  $141\pm 12/88\pm 9$  mmHg ( $p < 0.001$ ) (He et al., 2009). Similar to the prior study, a key limitation is the participants' compliance with the salt-restrictive diet. This study concludes that reduced salt/sodium intake does result in a decline in blood pressure.

### *High Blood Pressure.*

*Definition, Prevalence and Factors that Increase Blood Pressure.* High blood pressure, also referred to as hypertension (HTN), is defined as a systolic blood pressure of 140 mm Hg or greater or a diastolic blood pressure of greater than or equal to 90 mm Hg (Carretero & Oparil, 2000). There are two main categories of hypertension, primary hypertension and secondary hypertension. Primary hypertension can also be referred to as idiopathic or essential hypertension. Primary hypertension is when the cause is unknown and secondary causes such as renal failure, pheochromocytoma, aldosteronism, etc. are not present (Carretero & Oparil, 2000). Primary hypertension accounts for 95% of the cases (Carretero & Oparil, 2000). According to the World Health Organization (WHO), high blood pressure is the third leading killer in the world and is the cause of one in eight deaths worldwide (Kottke, Stroebel, & Hoffman, 2003). There are a number of factors that increase blood pressure, such as family history, advancing age, cigarette smoking, sedentary lifestyle, stress, obesity, insulin resistance, high alcohol intake, high salt intake, low potassium intake and low calcium intake (Carretero & Oparil, 2000).

*Pathology of High Blood Pressure and its Relation to Sodium.* Various systems, hormones, and mechanisms are involved in the pathophysiology of primary hypertension (high blood pressure). Primary hypertension arises from a complex interaction between genetics and environmental influences (Huether, McCance, Brashers, & Rote, 2008). It is through these influences that one or multiple of the following occur—insulin resistance, inflammation, or dysfunction of the sympathetic nervous system (SNS), renin-angiotensin aldosterone (RAA) system, and natriuretic hormones. Insulin resistance results in a decline in the endothelial release of nitric oxide and other vasodilators (Huether et al., 2013). The

endothelium is a thin inner layer that lines blood vessels. If vasodilators are not being released, it not only results in vasoconstriction of the blood vessels, but it also affects the kidneys resulting in retention of salt and water (Huether et al., 2013). Thus, it causes overactivity of the SNS and the RAA system. These events lead to increased peripheral resistance and increased blood volume ultimately leading to sustained hypertension (Huether et al., 2013). Inflammation due to endothelial blood vessel injury or damage can cause a decrease in the production of vasodilators and an increase production of vasoconstrictors (Huether et al., 2013). The events that follow are similar to insulin resistance—the SNS and RAA system become involved and result in the retention of salt and water by the kidney. Both of these occurrences bring about increased peripheral resistance and increased blood volume eventually leading to sustained high blood pressure (Huether et al., 2013).

Sodium is a key player as a component of extracellular fluid and guaranteeing adequate arterial pressure, blood volume, and organ perfusion (Stolarz-Skrzypek, Bednarski, Czarnecka, Kawecka-Jaszcz, & Staessen, 2013). One hypothesis suggests that certain renal channels and transporters predispose the body to the retention of extracellular sodium, which may negatively affect blood pressure (Stolarz-Skrzypek et al., 2013). Additionally, research has identified that salt can be stored in subcutaneous interstitial compartments by binding to proteoglycans and glycosaminoglycans without resulting in water retention (Stolarz-Skrzypek et al., 2013). As a result, hypotheses can be made as to the influence of dietary salt intake and its effect on blood pressure, but it is inconclusive as to the exact mechanism of how it occurs.

*Untreated High Blood Pressure Leads to Chronic Conditions.* As blood pressure increases, the incidence of a myocardial infarction, heart failure, and stroke also increases. The CDC recently analyzed the percentage of adults' ages 18 and older with hypertension that was controlled (Yoon, Gillespie, George, Wall, & CDC, 2012). Two survey cycles of the NHANES (2005-2006 and 2007-2008) were analyzed to obtain the data. There were a total of 10,043 participants involved. Of those participants, 3,567 had hypertension (Yoon et al., 2012). Hypertension, in this study, was defined as one of the following—an average systolic blood pressure of 140 mm Hg or greater, or an average diastolic blood pressure of 90 mm Hg or greater, or self-reported use of blood pressure medication (Yoon et al., 2012). Blood pressure control was classified as an average systolic blood pressure of less than 140 mm Hg and an average diastolic blood pressure of less than 90 mm Hg (Yoon et al., 2012). Results concluded that the prevalence of hypertension has remained relatively constant from 1999-2000 (28.7%) to 2007-2008 (29.5%) (Yoon et al., 2012). Furthermore, the prevalence of those with controlled hypertension, including those taking blood pressure lowering medication, has improved during the ten-year period from 1999 to 2008 (Yoon et al., 2012). Subgroup populations between the age of 18 to 39 years had the lowest prevalence of controlled blood pressure compared to those age 40 and older (Yoon et al., 2012). However, it was interesting that younger individuals currently taking blood pressure lowering medication had the highest control levels of 84.1% among the three age groups surveyed (Yoon et al., 2012).

A prospective study published in *the New England Journal of Medicine* in 2001 examined the potential risk of cardiovascular disease in both men and women with high blood pressure (hypertension) (Vasan et al., 2001). Participants from the Framingham



Heart Study were recruited for this trial. There were a total of 6,859 participants that met the eligibility requirement for this investigation (Vasan et al., 2001). At baseline screening, medical history, laboratory measurements, two blood pressure readings, and an electrocardiography were conducted (Vasan et al., 2001). Participants were classified into three blood pressure categories, which included optimal, normal, or high. Optimal was defined as a systolic blood pressure of less than 120 mm Hg and a diastolic blood pressure of less than 80 mm Hg (Vasan et al., 2001). Normal was classified as a systolic between 120 and 129 mm Hg or a diastolic between 80 to 84 mm Hg (Vasan et al., 2001). High was defined as a systolic blood pressure of 130 to 139 mm Hg or a diastolic of 85 to 89 mm Hg (Vasan et al., 2001). Cardiovascular events were evaluated based on the participant medical history, physical examination, hospitalization records, and communication with the participant physician every four-years (Vasan et al., 2001). Additionally, three expert investigators reviewed participants' medical records and other pertinent documents. The primary outcome of interest was the timing of certain cardiovascular events during the 12-year follow-up of the study. Cardiovascular events included any of the following: death due to cardiovascular disease, recognized myocardial infarction, congestive heart failure, or stroke (Vasan et al., 2001). The results of the baseline screening reflected that a quarter had high-normal blood pressure, a third had normal, and the rest had optimal blood pressure (Vasan et al., 2001). After the data was analyzed, those participants with higher baseline blood pressure displayed a stepwise increase in cardiovascular events. For those with high-normal blood pressure between the ages of 35 to 64 years, the 10-year cumulative incidence of experiencing a cardiovascular event was four percent for women and eight percent for men (Vasan et al., 2001). Of those

subjects between the age range of 65 to 90 years, the 10-year cumulative incident of experiencing a cardiovascular risk was 18 percent for women and 25 percent for men (Vasan et al., 2001). A limitation of this study was that blood pressure values were measured on a single occasion, which may underestimate the relationship between high-normal blood pressure and cardiovascular disease (Vasan et al., 2001). Thus, it can be concluded from this prospective study that participants with high-normal blood pressure were at a higher risk of cardiovascular events compared to those with optimal blood pressure (Vasan et al., 2001).

*Diets with Protective Effects.* Considerable research has validated that certain diets, such as the Dietary Approaches to Stop Hypertension (DASH) diet, the Mediterranean diet, and the vegetarian diet, improve blood pressure measures. All three of these diets are encouraged by the Dietary Guidelines for Americans 2010 and have protective effects on health. The DASH diet provides specific portion sizes and number of servings, whereas the Mediterranean and vegetarian diet do not have defined measurements. The DASH diet emphasizes a well-balanced diet that includes fruits, vegetables, whole grains, low-fat dairy products, poultry, seafood, and nuts. It also highlights the importance of eating a diet lower in sodium, red meats, processed foods, sweets, and sugar-containing beverages (US DHHS, 2010). In contrast, the Mediterranean diet incorporates fruits, vegetables, grains (often whole grains), nuts, and small amounts of full-fat dairy products (US DHHS, 2010). A key staple of the Mediterranean diet is olive oil. The vegetarian diet, depending on the type, varies but in general it includes vegetables, fruits, whole grains, nuts, and low-fat dairy (US DHHS, 2010). Both research and the Dietary Guidelines for Americans, 2010 support the DASH, Mediterranean, and

vegetarian diets in improving blood pressure outcomes in those with or without high blood pressure.

An 11-week feeding study analyzed three different dietary patterns, one being the DASH diet, to determine their effect on blood pressure. A total of 459 subjects, age 22 and older who were not currently taking antihypertensive medication, were involved in the randomized controlled trial (Appel et al., 1997). For subjects to participate, they had to have an average systolic blood pressure of < 160 mm Hg and a diastolic blood pressure between 80 and 95 mm Hg (Appel et al., 1997). For the first three weeks, subjects adhered to the control diet, which included a diet low in vegetables, fruits, dairy products, and a fat content that corresponded with the average diet in the United States (Appel et al., 1997). Participants were then randomized either to the control diet, the fruits-and-vegetables diet, or the combination diet (DASH diet) for the next eight-weeks. The fruits-and-vegetables diet included higher intakes of potassium and magnesium at levels closer to the 75<sup>th</sup> percentile of U.S. consumption and a higher intake of fiber (Appel et al., 1997). The combination diet was rich in vegetables, fruits, low-fat dairy products and had reduced amounts of cholesterol, total fat, and saturated fat (Appel et al., 1997). Regarding adherence, the percentage of participants that completed the intervention period for the control diet, fruits-and-vegetables diet and the combination diet was 95.5%, 97.4%, and 98.7% (Appel et al., 1997). Blood pressure fell in both the combination diet and fruits-and-vegetables diet, but the combination diet had a more significant decline in blood pressure. The combination diet had a decline of 5.5 mm Hg more for systolic blood pressure and 3.0 mm Hg more for diastolic blood pressure than did the control diet (Appel et al., 1997). Similarly the fruits-and-vegetables diet also displayed a decline in blood

pressure compared to the control diet, with a decline of 2.8 mm Hg for systolic blood pressure and a decline of 1.1 mm Hg for the diastolic blood pressure (Appel et al., 1997). A primary limitation of this study is participants' adherence rate. Even though the adherence rate was high, not all meals were consumed on-site. Subjects did have to adhere over the weekends and holidays (Appel et al., 1997). Adherence was based on what the participant said, which is not an accurate measurement. In general, this study confirms the importance of a combination diet, also termed the DASH diet, for lowering blood pressure.

The second study tested two diets, the control diet and the DASH diet, in conjunction with three different levels of sodium consumption and its effect on blood pressure. The control diet represents the typical American diet. The three levels of sodium consumption include 150 mmol/day (3.5g/day), 100 mmol/day (2.3 g/day), and 50 mmol/day (1.5g/day) (Sacks et al., 2001). Total, there were 412 participants 22 years and older with an average systolic blood pressure between 120 and 159 mm Hg and an average diastolic blood pressure between 80 and 95 mm Hg based on three screening visits (Sacks et al., 2001). This study was a randomized control trial with a crossover study design, in which the intervention lasts for 30 days. Thus, participants were randomly assigned to either the control diet or DASH diet. Once assigned to a diet, they were randomly allocated to one of the three sodium levels and then switched after 30 consecutive days (Sacks et al., 2001). Compared to the control diet, the DASH diet displayed lower systolic blood pressure at each of the three sodium levels. It also showed a decline in diastolic blood pressure at sodium levels of 3.5g and 2.3g/day (Sacks et al., 2001). In the control diet, reducing sodium from 3.5g to 2.3 g/day resulted in a drop in the systolic blood

pressure of 2.1 mm Hg (Sacks et al., 2001). The DASH diet resulted in a decline in systolic blood pressure of 1.3 mm Hg when sodium intake was reduced from 3.5g to 2.3g/day (Sacks et al., 2001). When sodium was reduced even further from 2.3g to 1.5g/day, the control diet showed a decline in systolic blood pressure of 4.6 mm Hg and the DASH diet showed a decline of 1.7 mm Hg (Sacks et al., 2001). A key limitation of this study is the intervention only lasted for 30 days. Future studies may benefit from a longer intervention period. This study reaffirms the importance of eating a DASH diet in combination with reducing sodium to 2.3 g/day or less to improve blood pressure.

The traditional Mediterranean diet originated in Crete, Greece and Southern Italy where olives were grown (Estruch & Salas-Salvadó, 2013). A traditional Mediterranean diet included a high consumption of cereals, legumes, vegetables, and fruit; a fairly high intake of fat mainly in the form of olive oil; a moderate to high consumption of fish; a moderate to low intake of poultry and dairy products; a moderate intake of alcohol primarily in the form of red wine; and a low consumption of meats, especially red meats (Estruch & Salas-Salvadó, 2013). An essential component of the diet is olive oil. Studies, such as the PREDIMED trial and the Lyon Heart Study, exhibit the beneficial effects of a Mediterranean diet in the prevention and reduction of CVD (Estruch & Salas-Salvadó, 2013). However, the interest lies on whether the Mediterranean diet can improve blood pressure measures.

This study described is a four-year follow-up of the PREDIMED primary prevention trial, which originally focused on the relationship between adhering to a Mediterranean diet and reducing the risk of CVD (Toledo et al., 2013). The object of this study was to evaluate the long-term effect of adhering to a traditional Mediterranean diet

on blood pressure. There were a total of 7,158 men (55 to 80 years) and women (60 to 80 years) who were of high risk for CVD involved in the study (Toledo et al., 2013). The participants were randomly assigned either to receive a control diet (low-fat diet), a Mediterranean diet supplemented with extra virgin olive oil (EVOO), or a Mediterranean diet supplemented with nuts (almonds, walnuts, hazelnuts) (Toledo et al., 2013). Counseling via Dietitians was provided at baseline and then quarterly thereafter, either one-on-one or in-group settings. The group provided with the Mediterranean diet supplemented with EVOO received a liter per week for themselves and family. The other group supplemented with nuts received 30 grams per day (Toledo et al., 2013). Blood pressure was measured at baseline and once every year for four years. The measurement was obtained by calculating an average of the second and third blood measure readings. Based on the results, there was a decline in systolic and diastolic blood pressure in the three groups (Toledo et al., 2013). The mean difference of systolic blood pressure between the group provided the Mediterranean diet supplemented with nuts compared to the control was 0.72 mm Hg and the mean difference in diastolic blood pressure was 0.65 mm Hg (Toledo et al., 2013). In contrast, the mean difference in systolic blood pressure for the group provided the Mediterranean diet supplemented with EVOO compared to the control was 0.39 mm Hg and the mean difference in diastolic blood pressure was 1.53 mm Hg (Toledo et al., 2013). A limitation of this study was the primary end-point of the PREDIMED trial was not to observe changes in blood pressure (Toledo et al., 2013). This was its secondary end-point. Additionally, there was a subset of participants during follow-up where blood pressure information was not available. Overall, this study

reinforced the importance that there are other diets besides the DASH diet that provide beneficial effects on blood pressure.

Another alternative besides the DASH diet and Mediterranean diet in possibly lowering or controlling blood pressure is the vegetarian diet. There are a variety of vegetarian eating patterns, which include vegans who do not eat any animal products, lacto-ovo vegetarians who eat eggs and milk products, and those vegetarians who eat small amounts of seafood, poultry, and meat. Two studies that follow support the link between a vegetarian diet and a decline in blood pressure.

Two studies similar in nature are 14-week randomized crossover trials in which omnivore subjects are introduced to a lacto-ovo vegetarian diet (Rouse, Beilin, Armstrong, & Vandongen, 1983). The first two weeks participants followed an omnivorous diet. After the two weeks, they were either randomly assigned to the control group or to one of the two experimental groups. The control group adhered to an omnivorous diet for the remaining 12-weeks. The other two experimental groups followed a lacto-ovo vegetarian diet for either the first six weeks or the second six weeks of the trial period (Rouse et al., 1983). The main difference between these two studies is that the first involves normotensive subjects and the second involves mildly untreated hypertensive subjects. There were a total of 59 participants between the ages of 25 and 63 years with normotensive blood pressure who were involved in the first study (Rouse et al., 1983). The second study had a total of 58 subjects between the ages of 30 and 64 with mild untreated hypertension (Margetts et al., 1985). To be eligible for the second study, subjects could not have two consecutive systolic blood pressure readings that exceeded 180 mm Hg or two consecutive readings that exceeded 110 mm Hg for diastolic blood

pressure (Margetts et al., 1985). In the first study, participants were required to eat two meals from the hospital cafeteria from the vegetarian or omnivorous menu. In contrast, those participants in the second study were not supplied meals from the facility, but rather had to adhere to the dietary protocol on their own (Margetts et al., 1985). Those assigned to eat a lacto-ovo vegetarian diet avoided meat products and continued to consume eggs, dairy products, and sodium as close to their usual intake (Rouse et al., 1983). Blood pressure was read during the initial two weeks of the omnivorous diet and then five weeks of each experimental intervention in the first study. In contrast, the second study had blood pressure measured every two weeks of the 14-week study. During the time that the participants were on the vegetarian diet in the first study, mean systolic and diastolic blood pressure declined. Those receiving the intervention the first six-weeks showed a decline of  $7.9 \pm 8.9$  mm Hg in systolic blood pressure and a decline of  $2.7 \pm 6.0$  in diastolic blood pressure compared to the control group (Rouse et al., 1983). The group that received the intervention for the second eight-weeks exhibited a decrease in mean systolic blood pressure of  $5.6 \pm 8.7$  mm Hg and a decrease in mean diastolic blood pressure of  $2.6 \pm 6.8$  mm Hg (Rouse et al., 1983). When the group consuming a vegetarian diet for the first six-weeks resumed a omnivorous diet for the last six-weeks, the mean systolic blood pressure increased by  $8.8 \pm 7.6$  mm Hg and the mean diastolic blood pressure increased to  $4.3 \pm 6.6$  mm Hg (Rouse et al., 1983). The results of the second study showed decline in systolic blood pressure only in those consuming a vegetarian diet for both the first six-weeks and second six-weeks of the intervention (Margetts et al., 1985). During both six-weeks of the vegetarian diet, there was a decline of 3.5 mm Hg in systolic blood pressure (Margetts et al., 1985). In the first study of normotensive subjects, a limitation is that subjects were



recruited from 1,000 staff members of a hospital who were dedicated to the study (Rouse et al., 1983). Thus, this explains the low drop out and high compliance rate. An additional limitation is that the study was unable to be conducted on a blind basis, therefore bias may have occurred due to the ability of the participants to determine the hypothesis being tested (Rouse et al., 1983). In contrast, a limitation of the second study has to do with compliance to the vegetarian diet. Participants did not have most of their meals provided to them, as did the study that involved the normotensive participants, therefore adherence to the diet may have been more difficult. It can be concluded from both of these studies that there is strong evidence to support a lowering effect in blood pressure for those consuming a lacto-ovo vegetarian diet in normotensive and mildly untreated hypertensive participants.

*Other Lifestyle Modifications Besides Dietary Approaches.* Besides dietary changes, lifestyle modifications to reduce blood pressure include weight reduction, physical activity, decrease in dietary sodium intake, and moderate alcohol intake. The first study was phase one of two trials that examined the effect of certain non-pharmacologic interventions on lowering diastolic blood pressure. There were two main objects of phase one of the Trials of Hypertension Prevention (TOHP), which involved testing particular nutritional and behavioral interventions and their short-term effect on blood pressure and to determine whether a long-term trial using these non-pharmacologic interventions was plausible (Satterfield et al., 1991). It was three-year U.S. national, multicenter, randomized trial funded by the National Heart, Lung, and Blood Institute (NHLBI). A total of 2,182 women and men between the ages of 30 to 54 with slightly elevated diastolic blood pressure (80 to 89 mm Hg) were enrolled in the trial (Satterfield et al.,

1991). The three lifestyle changes, of interest in this trial, were weight loss, sodium reduction, and stress management. Participants were randomly assigned to one of the three lifestyle changes groups. Group counseling sessions occurred on a weekly basis the first two to three months and less frequently in the next 18 months. Data was obtained at the following time periods: 3-month, 6-month, 12-month, and 18-month. Data collection included blood pressure, weight, pulse rate, medical history, Psychological General Well-Being scale, physical activity questionnaires, demographics, and urine specimens (Satterfield et al., 1991). Weight reduction was measured via participants' weight loss, skinfolds and girth measurements. In the sodium reduction group, sodium was measured through food frequency questionnaires, 24-hour recalls, and five 24-hour urine collections (Satterfield et al., 1991). The stress management group was analyzed using the Psychological General Well-being Scale, Lazarus' Hassles Scale, and cardiovascular reactivity to mental stressors (Satterfield et al., 1991). All groups completed food frequency questionnaires, 24-hour recalls, and 24-hour urine collections. The adherence rate for group intervention meetings were 88% or greater for weight reduction, 70% or greater for sodium reduction, and 86% or greater for stress management (*Results of the TOHP-1*, 1992). There was a decline in mean sodium excretion in the sodium reduction group of 55-60 mmol/24-hours at 6, 12, and 18 months (*Results of the TOHP-1*, 1992). Blood pressure results for the sodium reduction group compared to the control group was a decline of 0.9 mm Hg in diastolic blood pressure and 1.7 mm Hg for systolic blood pressure (*Results of the TOHP-1*, 1992). In the weight reduction group, weight loss was the highest at 6 months at 5.7 kg (12.5 lbs.) compared to the control group. Weight loss declined slightly to 3.9 kg (8.6 lbs.) at 18 months compared to the control group (*Results*

of the TOHP-1, 1992). Blood pressure dropped by 2.3 mm Hg for diastolic blood pressure and 2.9 mm Hg for systolic blood pressure (*Results of the TOHP-1, 1992*). In contrast, the stress management group did not show any significant difference in stress levels compared to the control during the trial period and did not show any significant changes in blood pressure. Limitations involved in this phase of the trial include under/over reporting in both food frequency questionnaire and 24-hour diet recalls, compliance to intervention, and equipment and staff errors when obtaining measurements. Of the non-pharmacologic lifestyle changes being tested, both weight reduction and sodium reduction were effective in reducing blood pressure. However, weight reduction was the most effective strategy tested.

Thus, the second phase of the TOHP focused on incorporating the two lifestyle changes that were effective in phase I, weight reduction and sodium reduction. The goal of phase II was to examine the following interventions—weight reduction alone, sodium reduction alone, and a combination of the two and its effect on both systolic and diastolic blood pressure. Similar to the first phase, it is a three-year multicenter, U.S. National, randomized study funded by the NHLBI. There were a total of 2,382 women and men with a diastolic blood pressure of 83 to 89 mm Hg and a systolic blood pressure below 140 mm Hg (Herbert et al., 1995). Participants also had a percent ideal body weight of 110 to 165% (Herbert et al., 1995). They were randomly assigned to one of the three intervention groups or the control group (no active intervention). Group counseling sessions were provided on a weekly basis for the first 2 ½ to three months and twice month or monthly sessions for an additional three to four months (Herbert et al., 1995). Sessions became less frequent, mandating an attendance of three to four sessions annually. The sodium

requirement was a mean group value of 1,800 mg or less per day and the target weight loss goal was a group mean of 10 lbs. (Lasser et al., 1995). The proposed deadline for both the sodium and weight loss targets to be met was at the ends of the first six months. These goals were to be maintained over the course of the next three to four years (Lasser et al., 1995). Every six months, weight and blood pressure measurements were obtained. Physical activity was assessed via a questionnaire and 24-hour recalls were used to assess dietary intake (Stevens et al., 2001). The dietary intervention focused on reducing calorie intake via excess calories such as sugar, fat, and alcohol. The goal for physical activity was 30 to 45 minutes per day for four to five times per week (Stevens et al., 2001). In the weight reduction group, there was a mean weight loss of 4.4 kg at six months, 2.0 kg at 18 months, and 0.2 kg at 36 months compared to the control group (Stevens et al., 2001). Regarding diastolic blood pressure of this group compared to the control, the mean differences were a decline of 2.7 mm Hg at six months, 1.3 mm Hg at 18 months, and 0.9 at 36 months (Stevens et al., 2001). The mean difference in systolic blood pressure between the weight reduction and control group was a decline of 3.7 mm Hg at six months, 1.8 mm Hg at 18 months, and 1.3 mm Hg at 36 months (Stevens et al., 2001). The sodium reduction group also experienced a decline in both systolic and diastolic blood pressure compared to the control. There was a decline of  $2.9\pm 0.5$  at six months,  $2.0\pm 0.5$  at 18 months, and  $1.2\pm 0.5$  at 36 months for systolic blood pressure (Kumanyika et al., 2005). Regarding diastolic blood pressure, there was a mean change decline of  $1.6\pm 0.4$  at six months,  $1.2\pm 0.4$  at 18 months, and  $0.7\pm 0.4$  at 36 months (Kumanyika et al., 2005). The main limitation of phase II of this trial was that there may not be a simple dose response relationship between intervention attendance and weight loss. There may have been other

factors that encouraged weight loss other than the attendance to intervention meetings (Stevens et al., 2001). In summary, both weight reduction and sodium reduction alone are effective interventions in lowering blood pressure. It is inconclusive whether the combination of the two is successful.

Additional studies have been conducted on the effect of aerobic and resistance training on lowering blood pressure in those with hypertension. It has been concluded that moderately intense aerobic exercise has proven beneficial in the prevention and treatment of high blood pressure (Collier et al., 2008). Additional studies are focusing on whether resistance exercise alone or in conjunction with aerobic exercise will be advantageous in lowering blood pressure in those who are hypertensive. One study stated that aerobic exercise and resistance exercise had a similar decline in blood pressure, but resistance exercise resulted in an increase in arterial stiffness whereas aerobic exercise resulted in a decrease (Collier et al., 2008). Arterial stiffness can best be defined as the elasticity of the arteries. If the arteries are stiffer, the heart has to bump harder to allow the flow of blood to the rest of the body. However, the article also states that during resistance exercise there is increased arterial stiffness, but to compensate for this stiffness there is a greater increase in vasodilatory capacity (Collier et al., 2008). Another article stated that resistance exercise resulted only in a small decrease in both resting systolic and diastolic blood pressure (Kelley & Kelley, 2000). Future studies need to further analyze the effect of resistance exercise on blood pressure. It seems fairly conclusive that aerobic exercise is in fact useful for lowering blood pressure in those with and without hypertension.

Another lifestyle modification that is advised for those with hypertension is to limit or moderate alcohol consumption. Both cross-sectional and epidemiological studies

with large numbers of subjects have repeatedly confirmed that alcohol consumption is one of the most critical modifiable risk factor (Xin et al., 2001). In contrast, several clinical trials with small participant numbers have been conducted regarding alcohol intake and blood pressure. These studies have been inconclusive in their findings (Xin et al., 2001). Thus, there is an inconsistency in research on this topic. Certain studies state that moderating or reducing alcohol consumption in heavy drinkers is beneficial, while others are uncertain. Additional research needs to be conducted in this area to conclude that alcohol moderation is an effective lifestyle change for those with hypertension.

## CHAPTER 3

### METHODS

*Participants.* Generally healthy participants, age 18 to 80 years, with either normal blood pressure (< 120/80 mm Hg), elevated blood pressure (systolic blood pressure of  $\geq$  120 mm Hg and/or diastolic blood pressure of  $\geq$  80 mm Hg), or were informed by a healthcare professional that he or she has high blood pressure. Subjects were recruited from Arizona State University (ASU) and the surrounding community for this four-week sodium intervention. Participants were required to own an iPhone, iPad, or Android, were nonsmokers, were free of chronic disease (heart disease, renal disease, liver disease, stroke, or diabetes), and were not pregnant or recently pregnant or lactating for the past six months. Individuals were also excluded if they had inconsistent prescription drug use for the past three months, were currently taking diuretic medication, and/or consumed excess alcohol daily (> 2-3 servings/day for women and men respectively). All participants provided written consent to record their daily sodium intake either via the MyFitnessPal app or paper-based journal for the duration of the trial. The ASU Institutional Review Board (IRB) approved the study in July 2014 (Appendix A).

*Recruitment.* Recruitment of subjects was via college department Listservs provided by Arizona State University, verbal announcements, electronic messages, and posted flyers. During recruitment, subjects interested in the study were emailed a brief questionnaire regarding medical and diet history (Appendix B). The completion of this questionnaire determined whether he or she was eligible to participate in the study. Subjects that met the requirements were scheduled for the screening visit (visit 1).

*Study Design.* This study consisted of a four-week randomized, parallel trial with a total of 30 participants, which were stratified according to age, sex, blood pressure, and body mass index (BMI). The 30 participants were randomized via simple randomization to either the MyFitnessPal app group (“APP”) (n = 15) or the paper group (“PAP”) (n = 15). Both groups were informed to reduce their dietary sodium intake to  $\leq 2,300$  mg/day either using the app or paper method of recording (independent variable). Outcome measures, such as urinary sodium excretion, blood pressure, and dietary sodium intake, were analyzed to determine if an effect occurred (dependent variables). The study required a total of three visits to the Nutrition and Health Promotion Research lab located on ASU downtown campus. The three visits included screening, baseline, and completion.

*Screening (Visit 1).* The screening visit occurred prior to the start of the study. All thirty participants signed the consent form (Appendix C) and completed a health history questionnaire and a Rapid Eating and Activity Assessment for Patients (REAPS). The health history questionnaire addressed questions that included diet, weight, medical conditions, medication, physical activity, etc. (Appendix D). The REAPS questionnaire was a short one page, validated questionnaire that assessed diet quality (Appendix E). Anthropometric measurements for blood pressure, body weight, body fat, BMI, height, and waist circumference were obtained. Prior to blood pressure reading, participants were advised to relax for about 10 minutes and empty their bladder fully. Blood pressure was measured three times using a calibrated blood pressure cuff from Omron Healthcare (Bannockburn, Illinois; model HEM-907XL). The last two readings were averaged and recorded. Body weight, body fat, and BMI were obtained using the Tanita (TBF-300A Body Composition Analyzer). Height was measured using a freestanding height rod.



Waist circumference was measured around the umbilicus using a research grade tape measure. Participants were instructed to complete a three-day diet record (Appendix F) and to collect two consecutive first morning urine voids and store them in the refrigerator (Appendix G).

*Baseline (Visit 2).* The baseline visit marked the start of the four-week study. Participants returned both their three-day diet record and two urine specimens. Those randomly assigned to the APP group downloaded the free MyFitnessPal app on their iPhone, iPad, or Android. The app was programmed to monitor six nutrients, which included sodium, potassium, cholesterol, calcium, fat, and calories. These nutrients could only be programmed via the MyFitnessPal website. The participant would log into MyFitnessPal using the username and password that he or she created. Under the food tab, setting was selected to allow for these six nutrients to be monitored by the researcher. Additionally via the participant's mobile device under the more tab of the app, the settings option was selected to activate the sharing feature. By activating the sharing feature, the researcher was able to view the participant's food diary and daily totals for the six selected nutrients. The MyFitnessPal app was already programmed with a sodium level of 2,300 mg/day, thus no further programming was required. Both verbal and written instructions on using the app were provided to the APP group, which focused on food entry and sodium monitoring (Appendix H1). In contrast, participants randomly assigned to the PAP group were provided with a journal to record their daily food and sodium intake. Educational material provided in the journal included a MyPlate diagram, tips to reducing sodium intake, a list of foods high in sodium, a diagram of a nutrition label, and foods high in potassium (Appendix H2). This educational material was provided both verbally

and written to those participants assigned to the PAP group. Verbal instruction was brief only lasting a maximum of 10 minutes. All participants were supplied with the materials to complete a second urine collection that followed the same procedure as the first.

Anthropometrics were obtained similar to the screening visit, except that height was excluded. The two urine specimens for each participant were sent to Sonora Quest to be measured for sodium.

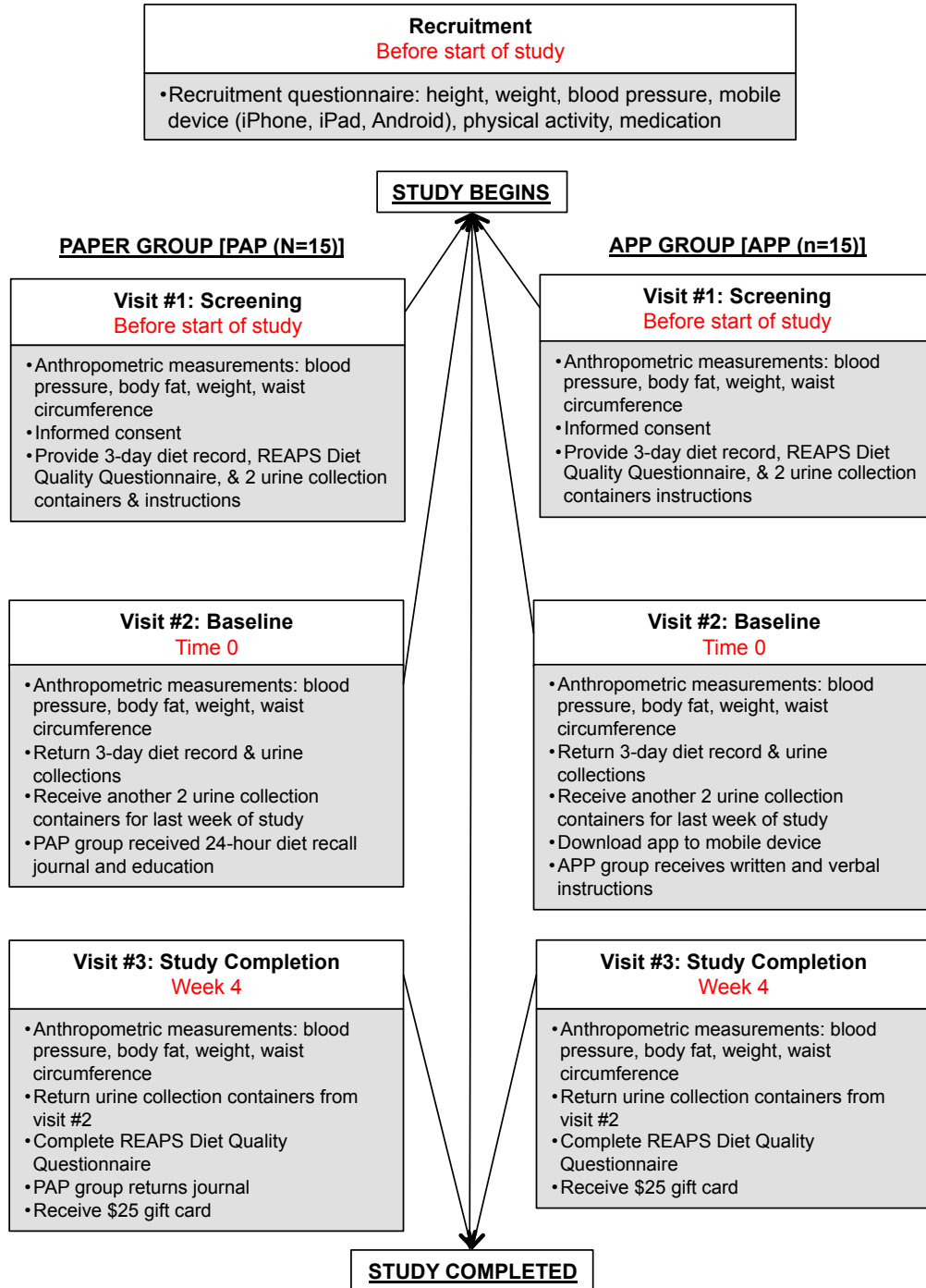
*Completion (Visit 3).* The last visit denoted the completion of the study.

Participants returned their two urine specimens and those in the PAP group returned their journal. A gift card was provided to those who successfully completed the four-week intervention. A REAPS and exit questionnaire was completed. The exit questionnaire addressed the relative ease of reducing sodium intake and the method used to record sodium intake (Appendix I). The same anthropometrics were obtained as the baseline visit and the two urine specimens for each participant were sent to Sonora Quest Laboratory. Sonora Quest provided results for normalized sodium in the urine expressed as mmol/gram (g) of creatinine. Dietary intake was evaluated based on whether the food record was complete. A complete food record was the consumption of  $\geq 800$  kcalories over a 24-hour period.<sup>11</sup> The food records submitted by the PAP group were analyzed using Food Processor SQL nutrition and Fitness Software by ESHA Research, Inc. (version 10.11.0, Salem, OR). Dietary data was inputted by personnel trained on the Food Processor Software. If the exact food or beverage code was unable to be determined from the dietary record, a default list of  $> 450$  food and beverage codes were used to identify the item. Since three dietary days were recorded prior to the start of the study to determine the average sodium, potassium, and calorie intake at baseline, the last three complete days

( $\geq 800$  kcalories/day) were used to determine the average end value for the same three nutrients for both groups. The APP group did not need further analyzing by Food Processor, since MyFitnessPal provides daily totals of select nutrients.

*Statistical Analysis.* Data was interpreted by the Statistical Package for Social Sciences (SPSS 22 for Windows, 2010, Chicago, Illinois) and reported as mean  $\pm$  standard deviation (SD). The Shapiro Wilks test was used to assess whether the data was normally distributed. If normality assumption was not met ( $p > 0.05$ ), data was log transformed. An independent t-test was used to determine the mean difference between the two groups. If the data was unable to be log transformed, the Mann-Whitney nonparametric test was conducted. Furthermore, a correlation was implemented to examine the relationship between variables. A univariate analysis was conducted controlling for the significant variable to determine if it influenced the outcome measures of interest. Statistical significance was set at  $p < 0.05$ .

**METHODOLOGY TIMELINE: 4-Week Randomized Parallel Trial**  
 Participants stratified by age, gender, BMI, and blood pressure



## CHAPTER 4

### JOURNAL ARTICLE/RESULTS

#### **The Popular Calorie Counter App, MyFitnessPal, Used to Improve Dietary Sodium Intake: A Four-Week Randomized Parallel Trial**

##### **ABSTRACT**

**Background:** Nutrition instruction has become more accessible; it is no longer relegated to the doctor's office, dietitian briefing, outpatient clinic, or hospital. Now it is available in people's hands, pockets, and purses via their smartphone. Since nutrition instruction has become more accessible, health professionals and members of the general public are increasingly interested in using smartphone apps to assist with health-related changes. With more and more of the population required to follow certain dietary recommendations and/or monitor specific nutrient intake, commercially available apps may be a useful and cost-effective resource for the public.

**Objective:** The purpose of this four-week intervention was to determine if the popular app, MyFitnessPal, can be used to reduce sodium intake to  $\leq 2,300$  mg/day compared to the traditional paper method of recording.

**Design:** This four-week randomized parallel trial enrolled 30 generally healthy adults who were 18 to 80 years of age. Participants were randomly assigned to the MyFitnessPal ("APP") group or the paper ("PAP") group and required to meet three times with the researcher for screening, baseline (start), and completion of the study.

**Results:** There was a significant mean difference in urinary sodium excretion between the APP group and the PAP group from the start of the intervention to the completion

( $-24.0 \pm 32.6$  and  $8.5 \pm 41.9$  mmol/g creatinine respectively,  $p = 0.027$ ). Other positive trends that resulted from the intervention included a decline in dietary sodium in both groups and a higher adherence in the APP group compared to the PAP group regarding recording method.

**Conclusions:** The MyFitnessPal app proved to be a useful tool in reducing and/or monitoring sodium intake. Thus, this trial reinforces the potential of this app to be used for monitoring other nutrients, but further research needs to be conducted.

## INTRODUCTION

As of May 2013, approximately 56% of Americans own a smartphone.<sup>1</sup> Of those who own smartphones, about half have downloaded apps on their mobile device.<sup>2</sup> Currently, there are an estimated 40,000 to 60,000 health and wellness apps available to the general public.<sup>3</sup> These apps encompass a variety of interests, including diet, fitness, calorie counters, lifestyle management (diabetes, blood pressure, etc.), and monitoring chronic diseases and illnesses.<sup>3</sup> With this newfound technology, smartphone apps have the potential to improve eating habits and overall diet quality. Some popular calorie counters that can be downloaded for free include MyFitnessPal, Fooducate, Loseit, and Sparkpeople. The intended purpose of these apps is to monitor caloric intake. However, what if these apps provided additional functions besides calorie counting? What if they had the potential to monitor individual nutrients and/or therapeutic diets (Dietary Approaches to Stop Hypertension (DASH) diet, diabetic diet, renal diet, low fat and/or cholesterol diet, low sodium diet, etc.)?

Sodium has been a nutrient of interest due to its potential link with hypertension. For at least a half century, research has supported the reduction of sodium intake in

lowering blood pressure.<sup>4</sup> However, there is controversy in the healthcare community as to the proper sodium recommendation for the general public.<sup>4</sup> Studies have both supported and refuted current sodium recommendations. Nevertheless, it is evident that the average sodium intake of the American diet is too high. The major contributors to this increase in dietary sodium are processed/convenience foods and restaurant foods.<sup>5</sup> On average, the mean sodium intake for ages two years and older, according to the 2010 Dietary Guidelines for Americans is 3,400 mg/day.<sup>6</sup> However, due to the addition of salt during cooking and at the table and the underestimate of food consumption, actual sodium consumption is closer to 3,800 mg/day.<sup>7</sup> This well exceeds the current recommendations provided by the American Heart Association (AHA), the Institute of Medicine (IOM), and the 2010 Dietary Guidelines for Americans (DGA). Both the AHA and DGA 2010 follow similar recommendations: reduce sodium intake to < 2,300 mg/day.<sup>6</sup> Adults who are 51 years and older, African Americans, and those with hypertension, diabetes, or chronic kidney disease should reduce their sodium to 1,500 mg/day.<sup>6</sup> The IOM recommends an adequate intake (AI) of 1,500 mg/day for ages nine to 50 years, 1,300 mg/day for ages 51 to 70 years, and 1,200 mg/day for those 71 years and older.<sup>6</sup>

Worldwide, hypertension is the leading cause of mortality and disability. Thus, the American Medical Association's primary focus is to treat or minimize hypertension to prevent cardiovascular conditions.<sup>8</sup> Some healthcare professionals speculate that a long-term reduction in sodium intake for those with uncontrolled hypertension of 400 mg/day at the national level will eliminate 1.5 million cases of uncontrolled hypertension and save about \$2.3 billion annually in healthcare costs.<sup>9,10</sup> It has further been concluded that reducing sodium intake to the proposed sodium recommendation of 2,300 mg/day will

reduce hypertension cases by 11 million and save an estimated \$18 billion in medical expenses.<sup>9,10</sup> Thus, the use of commercially available apps to regulate sodium intake may be a valuable resource for improving both communication between healthcare professionals and their clients and the overall health of the general public.

In a society where more and more individuals are asked to adhere to certain dietary recommendations, it is important that tools are available such as apps to support these changes. When used as a client-counseling tool, apps can assist healthcare professionals in educating their client on specific dietary modifications and holding clients accountable for their food choices. Additionally, health apps have the potential to revolutionize the healthcare system by improving health outcomes, reducing health disparities, and controlling medical costs.<sup>3</sup> To date, there is limited research in the use of health apps to support these dietary changes. Thus, the goal of this study was to focus on a single dietary modification, such as reducing sodium intake to  $\leq 2,300$  mg/day, to determine if the MyFitnessPal app is a valuable resource tracking and reinforcing this change when compared to the traditional paper method of recording. Researchers hypothesize that reducing sodium intake, using either the app or paper method, will not impact urinary sodium excretion, blood pressure, and dietary sodium intake. Furthermore, it was hypothesized that an increase in adherence to the dietary modification of reducing sodium intake will result in a decline in these outcome measures (urinary sodium excretion, blood pressure, and dietary sodium intake).



## **METHODS**

### **Participants/Recruitment**

The participants consisted of generally healthy adults, age 18 to 80 years, with either normal blood pressure (< 120/80 mm Hg), elevated blood pressure (systolic blood pressure of  $\geq$  120 mm Hg and/or diastolic blood pressure of  $\geq$  80 mm Hg), or some who had been informed by healthcare professional that he or she has high blood pressure. Participants were required to own an iPhone, iPad, or Android device, were free of chronic disease (heart disease, renal disease, liver disease, stroke, or diabetes), were nonsmokers, and were not pregnant or recently pregnant or lactating for the past six months. Exclusion criteria included inconsistent prescription drug use for the past three months, diuretic medication use, and consumption of excess alcohol (> 2-3 servings/day for women and men respectively). All participants provided written consent to record their daily sodium intake either via the MyFitnessPal app or paper-based journal for the duration of the trial. The ASU Institutional Review Board approved the study as of July 2014.

Subjects were recruited from Arizona State University (ASU) and the surrounding community via college department Listservs, verbal announcements, electronic messages, and posted flyers for this four-week sodium intervention. During recruitment, subjects interested in the study were emailed a brief questionnaire regarding medical and diet history. The completion of this questionnaire determined whether he or she was eligible to participate in the study. Subjects that met the requirements were scheduled for the screening visit (visit 1).

## **Study Design**

This study was a four-week randomized parallel trial that was conducted from August 2014 to December 2014. Participants were stratified according to age, sex, blood pressure, and body mass index (BMI). A total of 30 participants were randomized via simple randomization into either the MyFitnessPal app group (APP) (n = 15) or the paper group (PAP) (n = 15). Both groups were informed to reduce their dietary sodium intake to  $\leq 2,300$  mg/day of sodium. Outcome measures assessed were urinary sodium excretion, blood pressure, dietary sodium intake, and adherence to the assigned method of recording. Participants were required to attend three visits (screening, baseline, and completion) at the Nutrition and Health Promotion Research lab at the ASU downtown campus.

## **Screening**

The screening visit occurred prior to the start of the study. All thirty participants signed the consent form and completed a health history questionnaire and a Rapid Eating and Activity Assessment for Patients (REAPS). The health history questionnaire addressed questions including diet, weight, medical conditions, medication, physical activity, etc. The REAPS questionnaire was a short one page, validated questionnaire that assesses diet quality.<sup>11-13</sup> Anthropometric measurements for blood pressure, body weight, body fat, BMI, height, and waist circumference were obtained. Prior to blood pressure reading, participants were advised to relax for about 10 minutes and empty their bladder fully. Blood pressure was measured three times using a calibrated blood pressure cuff from Omron Healthcare (Bannockburn, Illinois; model HEM-907XL). The last two readings were averaged and recorded. Body weight, body fat, and BMI were obtained using the Tanita (TBF-300A Body Composition Analyzer). Height was measured using a

freestanding height rod. Waist circumference was measured around the umbilicus using a research grade tape measure. Participants were instructed to complete a three-day diet record and to collect two consecutive first morning urine voids.

### **Baseline**

The baseline visit marked the start of the study. Participants were required to return both their three-day diet record and two urine specimens. Those randomly assigned to the APP group downloaded the free MyFitnessPal app on their iPhone, iPad, or Android. The app was programmed to monitor six nutrients, which included sodium, potassium, cholesterol, calcium, fat, and calories. These nutrients could only be programmed via the MyFitnessPal website. The participant would log into MyFitnessPal using the username and password that he or she created. Under the food tab, setting was selected to allow for these six nutrients to be monitored by the researcher. Additionally via the participant's mobile device under the more tab of the app, the settings option was selected to activate the sharing feature. By activating the sharing feature, the researcher was able to view the participant's food diary and daily totals for the six selected nutrients. The MyFitnessPal app was already programmed with a sodium level of 2,300 mg/day, thus no further programming was required. Both verbal and written instructions on using the app were provided to the APP group, which focused on food entry and sodium monitoring (Appendix H1). In contrast, participants randomly assigned to the PAP group were provided with a journal to record their daily food and sodium intake. Educational material provided in the journal included a MyPlate diagram, tips to reducing sodium intake, a list of foods high in sodium, a diagram of a nutrition label, and foods high in potassium (Appendix H2). This educational material was provided both verbally and

written to those participants assigned to the PAP group. Verbal instruction was brief only lasting a maximum of 10 minutes. All participants were supplied with the materials to complete a second urine collection that followed the same procedure as the first.

Anthropometrics were obtained similar to the screening visit except for height was excluded. The two urine specimens for each participant were sent to Sonora Quest to be measured for sodium.

### **Completion**

The last visit denoted the completion of the study. Participants returned their two urine specimens and those in the PAP group returned their journal. A gift card was provided to those who successfully completed the four-week intervention. A REAPS and exit questionnaire was completed. The exit questionnaire addressed the relative ease of reducing sodium intake and the method used to record sodium intake (app or journal). The same anthropometrics were obtained as the baseline visit and the two urine specimens for each participant were sent to Sonora Quest Laboratory. Sonora Quest provided a report of urine sodium normalized expressed as mmol/gram (g) of creatinine. Dietary intake was evaluated based on whether the food record was complete. A complete food record was the consumption of  $\geq 800$  kcalories over a 24-hour period.<sup>11</sup> The food records submitted by the PAP group were analyzed using Food Processor SQL nutrition and Fitness Software by ESHA Research, Inc. (version 10.11.0, Salem, OR). Dietary data was inputted by personnel trained on the Food Processor Software. If the exact food or beverage code was unable to be determined from the dietary record, a default list of > 450 food and beverage codes were used to identify the item. Since three dietary days were recorded prior to the start of the study to determine the average sodium, potassium, and

calorie intake at baseline, the last three complete days ( $\geq 800$  kcalories/day) were used to determine the average end value for the same three nutrients for both groups. The APP group did not need further analyzing by Food Processor, since MyFitnessPal provides daily totals of select nutrients.

### **Statistical Analysis**

Data was interpreted by the Statistical Package for Social Sciences (SPSS 22 for Windows, 2010, Chicago, Illinois) and reported as mean  $\pm$  standard deviation (SD). The Shapiro Wilks test was used to determine if the data was normally distributed. Data was log transformed if normality assumption was not met. An independent t-test was used to analyze the mean difference between the two groups. If data was not normally distributed or unable to be log transformed, a Mann-Whitney nonparametric test was conducted. Furthermore, a correlation was implemented to examine the relationship between variables. A univariate analysis was conducted controlling for the significant variable to determine if it influenced the outcome measures of interest. Statistical significance was set at  $p < 0.05$ .

### **RESULTS**

A total of 33 participants were enrolled in this four-week randomized trial. Three participants withdrew prior to being randomized to a group, stating personal issues, medical conditions, and/or time constraints. Thus, a total of 30 participants completed the four-week intervention. Baseline characteristics were measured and included age, anthropometrics (body weight, body mass index, body fat, waist circumference), urinary sodium, blood pressure, and dietary intake of select nutrients (sodium, potassium, calories). At baseline, age was statistically significant ( $p = 0.001$ ). A Spearman correlation

was conducted between variables that were statistically significant and age to determine if age affects the variable. Baseline (pre), completion (post), and change (post – pre) data for both the APP and PAP groups are provided as mean±SD in Table 1.

The outcome variables of interest in this study included urinary sodium excretion, blood pressure, dietary intake of selected nutrients (sodium, potassium, and calories), and adherence. There was no significant mean difference in the change data for systolic blood pressure, diastolic blood pressure, or dietary intake of selected nutrients between the APP and PAP groups. However, the primary outcome measure, the change in urinary sodium, was statistically significant ( $p = 0.027$ ). The mean difference for the APP group for urinary sodium was  $-24.0 \pm 32.6$  mmol/g creatinine compared to the PAP group of  $8.5 \pm 41.9$  mmol/g creatinine. A Spearman correlation was performed between age and the change in urinary sodium ( $r = 0.244$ ). Additionally, a univariate analysis was also conducted for change urinary sodium, while controlling for age. There was a significant mean difference in age between the APP and PAP group ( $p = 0.013$ ). Urinary sodium was measured using two consecutive first morning urine samples at the beginning and end of the four-week intervention. Recent research published that first morning spot urine samples had a sodium/creatinine ratio that strongly correlated with 24-hour urine sodium excretion ( $r = 0.728$ ).<sup>15</sup> Furthermore, there was a trend regarding adherence that seemed to favor the app. Adherence was measured as a percentile according to the number of days each participant recorded a complete food record ( $\geq 800$  kcalories/24-hour period) out of the total number of days of the trial (28 days). Adherence was  $92.1 \pm 16.2\%$  for the APP group and  $82.1 \pm 25.1\%$  for the PAP group ( $p = 0.083$ ).

Diet quality was assessed via the REAPS questionnaire. There were a total of thirteen questions, each scored out of three points. Thus, the questionnaire had a total of 39 points, in which a score of 39 reflects good diet quality. Questions focused on skipping breakfast, eating out, fruits, vegetables, dairy products, processed foods, fried foods, snack foods, sweets, and sugar-sweetened beverages. There was no significant difference in the questionnaire responses at the end of the intervention compared to the beginning between the two groups ( $p = 0.116$ ) (Table 1).

The exit questionnaire provided at the end of the study consisted of seven questions that concentrated on the method of recording dietary sodium intake and the behavior of reducing sodium intake. Each of the questions were scored one to five, one being strongly disagree to five being strongly agree. The questions were individually analyzed according to mean $\pm$ SD and significance between the APP and PAP group in Table 2. Two out of seven of the questions provided on the exit questionnaire were statistically significant between the two groups ( $p = 0.001$ ) (Table 2). The first question focused on whether the method of recording daily food intake was too time consuming to be practical. The APP group disagreed with this statement according to the mean value of  $2.2\pm 1.1$ . In contrast, the PAP group agreed with this statement with a mean value of  $3.7\pm 1.1$ . The second question asked the participant whether he or she enjoyed the method of monitoring his or her diet. The APP group agreed that they enjoyed the method of recording diet with a mean value of  $4.1\pm 1.0$ , whereas the PAP group vacillated between disagree and no opinion with a mean value of  $2.5\pm 1.2$ .

## DISCUSSION

This study concluded that there was a significant mean difference in urinary sodium between the APP and PAP group from the start to the end of the intervention ( $p = 0.027$ ). The average urinary sodium for the APP group at baseline was  $126.0 \pm 55.4$  mmol/g creatinine, and at completion it was  $102.0 \pm 57.2$  mmol/g creatinine. Thus, the mean difference in urinary sodium between baseline and completion was  $-24.0 \pm 32.6$  mmol/g creatinine. In contrast, urinary sodium increased in the PAP group from baseline to completion by  $8.5 \pm 41.9$ . At baseline, urinary sodium was  $85.4 \pm 26.0$  mmol/g creatinine and at completion it increased to  $93.9 \pm 44.2$  mmol/g creatinine. Even though significance was not present, both groups had a decline in dietary sodium intake at the end of the intervention compared to baseline. At baseline, the APP group had a sodium intake of  $2666.2 \pm 935.9$  mg/day and by the end of the study sodium intake was  $1912.0 \pm 761.1$  mg/day. Similarly, the PAP group also showed a decline in sodium intake from  $3326.9 \pm 2406.6$  mg/day at the beginning to  $2192.5 \pm 666.0$  mg/day at the end.

Adherence in the APP group was  $92.1 \pm 16.2\%$  compare to the PAP group, which was  $82.1 \pm 25.1\%$ . There was a trend in adherence that favored the app, but it was not statistically significant. As reflected in the exit questionnaire, the app group overall enjoyed their method of recording and did not find it too time consuming to input their daily intake. In contrast, the PAP group had the opposite viewpoint about their mode of recording and level of enjoyment with the journal. They felt that it was time consuming to record their daily intake and was not enjoyable.

The current randomized parallel trial was underpowered at 50% with a power of 0.8. Thus, a total sample size of 60 participants would support this power, in which 30



participants were assigned to each group. Another limitation is that two consecutive first morning urine collections at baseline and completion may not accurately reflect 24-hour urine collections. Lastly, diet records are prone to participant recording error and researcher data entry error.

This four-week sodium intervention provided valuable insight into the use of the MyFitnessPal app as a tool for monitoring a single dietary nutrient compared to the traditional paper-and-pencil method of recording. Positive trends in urinary sodium, dietary sodium intake, and adherence present in the APP group reinforce that the MyFitnessPal app is a successful tool in monitoring sodium. Further research needs to be conducted on whether these commercially available apps can monitor other nutrient(s) and/or therapeutic diets. Smartphone apps such as MyFitnessPal have the potential to improve dietary recording and monitoring. They also have the potential to be an educational tool and means of communication between healthcare professionals and their clients. If more focus is placed on monitoring and reducing certain nutrient(s), the general public can learn step-by-step about the foods they are eating. Small steps in dietary modifications lead to lasting changes in overall dietary behaviors. Thus, the MyFitnessPal app and similar apps have the potential to change society's outlook on eating healthy.

**Table 1.** Pre, Post, and Change Values for Four-Week Sodium Intervention Based on Recording Method<sup>a</sup>

	MyFitnessPal App Recording (n=15)			Paper Recording (n=15)			Change <sup>e</sup> P-value <sup>d</sup>
	Pre	Post	Change <sup>b</sup>	Pre	Post	Change	
	Mean±SD <sup>c</sup>			Mean±SD			
Weight (lb)	155.1±38.5	154.2±37.9	-0.9±2.1	159.6±28.0	160.3±28.8	0.7±3.7	0.784
BMI <sup>c</sup> (kg/m <sup>2</sup> )	25.3±4.9	25.7±5.9	0.4±2.2	25.5±3.5	25.6±3.6	0.1±0.6	0.055
Body fat <sup>f</sup> (Percent)	27.8±7.5	27.7±8.1	-0.1±1.3	31.7±8.9	31.9±8.9	0.2±1.3	0.593
Waist circumference (cm)	80.5±16.0	80.1±15.3	-0.4±2.0	80.9±11.3	80.2±11.4	-0.7±2.4	0.774
Urinary sodium <sup>g</sup> (mmol/g creatinine)	126.0±55.4	102.0±57.2	-24.0±32.6	85.4±26.0	93.9±44.2	8.5±41.9	0.027
Systolic Blood Pressure (mm Hg)	115.1±11.5	112.8±11.4	-2.3±6.4	118.2±16.3	118.0±14.6	-0.2±6.5	0.387
Diastolic Blood Pressure (mm Hg)	70.7±9.9	72.5±9.1	1.8±6.3	74.1±9.9	78.3±10.7	4.2±6.8	0.325
Dietary sodium (mg/day)	2666.2±935.9	1912.0±761.1	754.2±1080.7	3326.9±2406.6	2192.5±666.0	-1134.5±2388.7	0.552
Dietary potassium <sup>h,i</sup> (mg/day)	1880.2±1612.3	1440.7±718.6	-550.3±1213.2	1354.6±804.6	995.8±456.1	-358.8±641.2	0.142
Calories (kcal/day)	1817.2±448.0	1609.6±427.4	-207.7±406.0	1845.4±1214.5	1453.1±356.6	-392.3±1118.2	0.424
REAPS Questionnaire <sup>i</sup>	32.1±2.5	30.3±3.5	-1.8±2.9	30.5±4.1	30.7±3.6	0.3±4.0	0.116

<sup>a</sup>Thirty participants were enrolled in the four-week parallel trial. Age did differ by group at baseline, but did not correlate with the change in urinary sodium.

<sup>b</sup>Change = Post – Pre

<sup>c</sup>SD = standard deviation

<sup>d</sup>Denotes significance for normally distributed and log transformed data using an independent t-test with a p < 0.05.

<sup>e</sup>BMI was not obtained for one participant (n = 29; 15 for the APP group and 14 for the PAP group), since participant was wearing compression stockings.

<sup>f</sup>Body fat percent was not measured for two participants (n = 28; 15 for the APP group and 13 for the PAP group), due to equipment and special garment (compression stockings).

<sup>g</sup>Urinary sodium data was unable to be calculated for one participant (n = 29; APP group n = 15, PAP group n = 14), since urinary sodium analyte was below the measurement of <20 mmol/L.

<sup>h</sup>Data was not able to be normalized; thus a Mann-Whitney nonparametric test was used with p < 0.05.

<sup>i</sup>Dietary potassium was not obtained by two participants (n = 28; APP group n = 15; PAP group n = 13).

<sup>j</sup>Diet quality was assessed via the Rapid Eating and Activity Assessment for Patients (REAPS). Reaps was scored out of 39 points, in which a score of 39 represents a good diet quality score.

**Table 2.** Pre, Post, and Change Values for the REAPS Questionnaire based on Recording Method<sup>a</sup>

Questions <sup>b</sup>	MyFitnessPal App Recording (n=15)			Paper-Based Recording (n=15)			Change p-value <sup>e</sup>
	Pre	Post	Change <sup>c</sup>	Pre	Post	Change <sup>c</sup>	
<b>In an average week, how often do you:</b>	<b>Mean±SD<sup>d</sup></b>			<b>Mean±SD</b>			
1. Skip breakfast?	2.7±0.6	2.7±0.5	0.1±0.3	2.6±0.6	2.4±0.8	-0.2±0.9	0.305
2. Eat 4 or more meals from sit-down or take out restaurants?	2.2±1.0	2.2±0.9	0.0±1.0	2.7±0.6	2.4±0.7	-0.3±0.8	0.385
3. Eat less than 2 servings of whole grain products or high fiber starches a day?	2.3±0.9	2.4±0.7	0.1±0.8	2.3±0.7	2.3±0.6	0.0±0.8	0.927
4. Eat less than 2 servings of fruit a day?	2.2±0.9	2.0±0.7	-0.2±0.9	1.9±0.7	2.0±0.9	0.1±0.8	0.375
5. Eat less than 2 servings of vegetables a day?	2.5±0.7	2.5±0.7	0.1±0.7	2.2±0.8	2.0±0.8	-0.2±0.7	0.293
6. Eat or drink less than 2 servings of milk, yogurt, or cheese a day?	2.2±0.8	1.8±0.7	-0.4±0.6	1.9±0.9	1.7±0.6	-0.2±1.3	0.563
7. Eat more than 8 ounces of meat, chicken, turkey, or fish per day?	2.2±0.9	2.0±0.9	-0.2±0.7	2.1±0.8	2.3±0.9	0.2±1.0	0.159
8. Use regular processed meats instead of low fat processed meats?	2.8±0.4	2.5±0.6	-0.3±0.6	2.8±0.4	2.7±0.5	-0.1±0.6	0.340
9. Eat fried foods, such as fried chicken, fried fish, french fries, fried plantains, tostones or fried yuca?	2.2±0.4	2.5±0.5	0.3±0.5	2.5±0.7	2.6±0.5	0.1±0.6	0.392
10. Eat regular potato chips, nacho chips, corn chips, crackers, regular popcorn, nuts instead of pretzels, low-fat chips or low-fat crackers, air-popped popcorn?	2.6±0.6	2.1±0.9	-0.5±1.0	2.2±0.8	2.4±0.7	0.2±0.8	0.017
11. Add butter, margarine or oil to bread, potatoes, rice or vegetables at the table.	2.7±0.7	2.3±0.8	-0.3±0.6	2.3±0.8	2.6±0.6	0.3±0.8	0.036
12. Eat sweets like cake, cookies, pastries, donuts, muffins, chocolate and candies more than 2 times per day.	2.6±0.6	2.5±0.7	-0.1±0.7	2.3±0.7	2.5±0.6	0.3±0.8	0.208
13. Drink 16 ounces or more of non-diet soda, fruit drink/punch or Kool-Aid a day?	3.0±0.0	2.7±0.6	-0.3±0.6	2.7±0.6	2.9±0.4	0.1±0.4	0.027

<sup>a</sup>All thirty subjects completed a REAPS questionnaire at the start and end of the study

<sup>b</sup>Questions were scored out of 3 points. The following states the point system: 1 = usually/often, 2 = sometimes, 3 = Rarely/Never.

<sup>c</sup>Change = Post – Pre

<sup>d</sup>SD = standard deviation

<sup>e</sup> Denotes significant difference between recording methods for the listed characteristics using Mann-Whitney test with p<0.05.

**Table 3.** Exit Questionnaire based on Recording Method<sup>a</sup>

Questions	MyFitnessPal App Recording (n=15)	Paper-Based Recording (n=15)	p-value <sup>c</sup>
	Mean±SD <sup>b</sup>	Mean±SD	
1. Recording my daily food intake was helpful in keeping me on track toward my sodium goal.	4.5 ± 0.7	3.9 ± 1.1	0.097
2. The method I used for recording my daily food intake was too time consuming to be practical.	2.2 ± 1.1	3.7 ± 1.1	0.001
3. I was more aware of my eating habits because I was recording my food intake.	4.5 ± 0.8	4.3 ± 1.0	0.548
4. I enjoyed my method of monitoring my diet.	4.1 ± 1.0	2.5 ± 1.2	0.001
5. I am more confident in my ability to identify sodium in my diet after participating in this study.	4.4 ± 0.8	4.6 ± 0.5	0.752
6. I will continue to record my food intake after the study is over.	3.7 ± 1.4	3.4 ± 1.4	0.491
7. It was difficult to achieve my sodium goal.	2.3 ± 1.5	2.7 ± 1.5	0.412

<sup>a</sup>All thirty subjects completed the exit survey at the end of the study. Each question was scored 1 to 5, 1 being strongly disagree to 5 strongly agree

<sup>b</sup>SD=standard deviation

<sup>c</sup>Denotes significant difference between recording methods for the listed characteristics using Mann-Whitney test with p<0.05.

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## CHAPTER 5

### SUMMARY/CONCLUSION

This study confirmed that the popular calorie counter app, MyFitnessPal, is an effective tool in monitoring sodium intake. The goal of this study was to determine which method of recording, the MyFitnessPal app or paper-and-pencil method, was most effective in reducing sodium intake to  $\leq 2,300$  mg/day. Outcome variables measured in this four-week randomized parallel trial included urinary sodium, blood pressure, dietary intake of select nutrients (sodium, potassium, and calories), and adherence. The results of this study supported that the primary variable urinary sodium was statistically significant ( $p = 0.027$ ). Additionally, there was a trend in adherence that seemed to favor the app and both the MyFitnessPal app and paper groups did reduce their sodium intake. These findings further reinforce the potential of the MyFitnessPal app to assist, not just with calorie counting, but also monitoring single dietary modifications. Future research should focus on whether commercially available apps, either the MyFitnessPal or others, have the ability to monitor another nutrient and/or nutrients and perhaps even a specific therapeutic diet (DASH, diabetic diet, renal diet, etc.).



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APPENDIX A  
IRB APPROVAL

APPROVAL: EXPEDITED REVIEW

Carol Johnston  
 SNHP - Nutrition  
 602/827-2265  
 CAROL.JOHNSTON@asu.edu

Dear Carol Johnston:

On 7/8/2014 the ASU IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	Adapting an iPhone app for diet instruction
Investigator:	Carol Johnston
IRB ID:	STUDY00001280
Category of review:	(3) Noninvasive biological specimens, (4) Noninvasive procedures, (7)(b) Social science methods, (7)(a) Behavioral research
Funding:	None
Grant Title:	None
Grant ID:	None
Documents Reviewed:	<ul style="list-style-type: none"> <li>• Consent, Category: Consent Form;</li> <li>• Protocol, Category: IRB Protocol;</li> <li>• Diet recall (for journal), Category: Measures (Survey questions/Interview questions /interview guides/focus group questions);</li> <li>• Diet quality questionnaire, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions);</li> <li>• Diet record, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions);</li> <li>• Educational materials (myplate), Category: Other (to reflect anything not captured above);</li> <li>• Educational material (diet instruction), Category: Other (to reflect anything not captured above);</li> <li>• App instructions, Category: Other (to reflect anything not captured above);</li> </ul>
	<ul style="list-style-type: none"> <li>anything not captured above);</li> <li>• recruitment materials, Category: Recruitment Materials;</li> <li>• Screener survey, Category: Screening forms;</li> <li>• Health history questionnaire, Category: Screening forms;</li> <li>• Urine collection instructions, Category: Technical materials/diagrams;</li> </ul>

The IRB approved the protocol from 7/8/2014 to 7/7/2015 inclusive. Three weeks before 7/7/2015 you are to submit a completed "FORM: Continuing Review (HRP-212)" and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 7/7/2015 approval of this protocol expires on that date. When consent is appropriate, you must use final, watermarked versions available under the "Documents" tab in ERA-IRB.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator

APPENDIX B  
RECRUITMENT QUESTIONNAIRE

Exit this survey

\* 1. Please provide your email address.

2. Is your systolic blood pressure ≥ 130mm Hg (the first value) and/or your diastolic blood pressure ≥ 80 mm Hg (the second value)? Or, have you ever been told by a healthcare professional that you have high blood pressure?

- Yes
- No

If you know your blood pressure, please write it below.

\* 3. Are you 18 to 80 years of age?

- Yes
- No

\* 4. What is your weight in pounds?

\* 5. What is your height in inches? (5 feet = 60 inches)

\* 6. Do you own any of the mobile devices listed below?

- iPhone
- iPad
- Android

7. How comfortable are you using your mobile device?

- Not comfortable at all
- Moderately comfortable
- Extremely comfortable

\* 8. Are you willing to record food intake daily for 4 weeks on your iPhone or Android? (The app will be provided at no cost.)

- Yes
- No

9. Are you willing to record food intake daily for 4 weeks using a written journal?

- Yes
- No

\* 10. Have you lost or gained more than 5 pounds in the past 3 months due to a change in your diet ?

- Yes
- No

\* 11. For women only: Are you currently pregnant, breast-feeding, or planning to get pregnant?

- Yes
- No

\* 12. Do you train athletically to compete?

- Yes
- No

\* 13. Are you willing and able to travel to the ASU Downtown Campus (5th Street and Van Buren) to meet with the research investigators on three separate mornings?

- Yes

No

\* 14. Are you willing to collect 3-hour urine samples (3-6 pm) on four days during the study?

- Yes
- No

15. If you take prescription medication(s), how long have you been on the medication(s)?

- less than one week
- less than a month
- 1 month
- 2 month
- 3 months or longer

16. Have you ever been diagnosed with any of the following conditions: heart disease or other heart problems, stroke, kidney disease, liver disease, or a mental illness?

- Yes
- No

Done

APPENDIX C  
INFORMED CONSENT

## ASU NUTRITION: Smartphone App and Diet Instruction

### **INTRODUCTION**

The purposes of this form are (1) to provide you with information that may affect your decision as to whether or not to participate in this research study, and (2) to record your consent if you choose to be involved in this study.

### **RESEARCHERS**

Dr. Carol Johnston, ASU nutrition professor, and Michelle Ipijan, graduate student, have requested your participation in a research study.

### **STUDY PURPOSE**

The purpose of this research study is to evaluate the usefulness of a smartphone app as a tool to help individuals follow low-sodium diet instructions.

### **DESCRIPTION OF RESEARCH STUDY**

Qualifying participants will have either high blood pressure or normal blood pressure and are willing to use either their iPhones/Androids or a written journal daily to record food intake for four weeks. The intention of the study is to instruct participants on diet strategies to reduce sodium intake and improve potassium intake. Participants will be randomly assigned to one of two study groups: one group will use a smartphone app (at no cost) and the other group will keep a written journal. You will be asked to record all food and beverage intake daily – either via the app or via a written journal. Initially you will come to the test site to complete a brief health history questionnaire to demonstrate the absence of medical conditions or situations that may impact the study and a diet quality form. At this visit you will be trained to complete 3-day diet recalls and a urine collection. The urine collection entails collecting the first morning void on 4 days during the study. You will receive urine collection kits at no cost. You will also receive diet instruction from a trained nutrition expert. Your blood pressure, weight, and height will be measured, and we will measure your waist circumference. At the first visit, you will be scheduled for study visits 2 and 3. All visits should take 20-30 minutes and will be at the ABC1 building on the ASU Downtown Campus. You will receive weekly emails from the researchers so any questions can be answered. There is a short exit survey we will ask you to complete at the end of the trial.

If you begin taking new medications during the study, you are to notify the study investigators. About 30 people will participate in this study.

### **RISKS**

There are no foreseeable risks associated with this study. Individuals may become bored or frustrated with the daily protocol of food entry on the iPhone/Android or in a written journal. Urine collections will be inconvenient and require careful handling of urine including repeated hand washing.

### **BENEFITS**

This study will provide information regarding the usefulness of a smartphone app for improving diet. You may learn more about your diet if you participate in this study.

### **NEW INFORMATION**

If the researchers find new information during the study that would reasonably change your decision about participating, then they will provide this information to you.

### **CONFIDENTIALITY**

All information obtained in this study is strictly confidential unless law requires the disclosure. The results of this research study may be used in reports, presentations, and publications, but your name or identity will not be revealed. In order to maintain confidentiality of your records, Dr. Johnston will use subject codes on all data collected, maintain a master list separate and secure from all data collected, and limit access to all confidential information to the study investigators.

### **WITHDRAWAL PRIVILEGE**

You may withdraw from the study at any time for any reason without penalty or prejudice toward you. Your decision to withdraw would not affect you in any manner.

### **COSTS AND PAYMENTS**

You will receive a gift card to Target if you participate in this study. At visit 3, you will receive the \$25 gift card.

### **COMPENSATION FOR ILLNESS AND INJURY**

If you agree to participate in the study, then your consent does not waive any of your legal rights. However, in the event of harm, injury, or illness arising from this study, neither Arizona State University nor the researchers are able to give you any money, insurance coverage, free medical care, or any compensation for such injury. Major injury is not likely but if necessary, a call to 911 will be placed.

### **VOLUNTARY CONSENT**

Any questions you have concerning the research study or your participation in the study, before or after your consent, can be answered by Dr. Carol Johnston (602-827-2265).

If you have 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 Chair of the Human Subjects Institutional Review Board, through the ASU Office of Research Integrity and Assurance, at 480-965 6788.

This form explains the nature, demands, benefits and any risk of the project. By signing this form you agree knowingly to assume any risks involved. Remember, your participation is voluntary. You may choose not to participate or to withdraw your consent and discontinue participation at any time without penalty or loss of benefit. In signing this consent form, you are not waiving any legal claims, rights, or remedies. A copy of this consent form will be given to you.

Your signature below indicates that you consent to participate in the above study.

\_\_\_\_\_  
Subject's Signature

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Date

\_\_\_\_\_  
Contact phone number

\_\_\_\_\_  
Email (print clearly)

### **INVESTIGATOR'S STATEMENT**

"I certify that I have explained to the above individual the nature and purpose, the potential benefits, and possible risks associated with participation in this research study, have answered any questions that have been raised, and have witnessed the above signature. These elements of Informed Consent conform to the Assurance given by Arizona State University to the Office for Human Research Protections to protect the rights of human subjects. I have provided the subject/participant a copy of this signed consent document."

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Date

APPENDIX D  
HEALTH HISTORY QUESTIONNAIRE

**HEALTH / HISTORY QUESTIONNAIRE**

ID# \_\_\_\_\_

1. Gender: M F Age: \_\_\_\_\_ To be completed →  
by study personnel Weight \_\_\_\_\_ Height \_\_\_\_\_ Waist \_\_\_\_\_  
BP #1 \_\_\_\_\_ BP #2 \_\_\_\_\_ BP #3 \_\_\_\_\_

2. Has a doctor told you that you have high blood pressure or hypertension? Yes No

3. Have you lost or gained more than 5 lbs in the last 3 months? Yes No

If yes, how many pounds lost or gained? \_\_\_\_\_ How long ago? \_\_\_\_\_

4. Do you follow a special diet? (weight gain/loss, vegetarian, low-fat, etc.) Yes No  
If yes, please explain: \_\_\_\_\_

5. Are you willing to record food consumed on a daily basis for 4 weeks either on your iPhone or using a written journal? Yes No

6. Education (please circle one) High school Some college College graduate

7. Ethnicity: (please circle one) Hispanic or Latino Not Hispanic or Latino

8. Race: (please circle) American Indian/Alaska Native African-American White  
Native Hawaiian/Other Pacific Islander Asian Other

9. Do you smoke? No, never \_\_\_\_\_ Yes \_\_\_\_\_ # Cigarettes per day = \_\_\_\_\_  
I used to, but I quit \_\_\_\_\_ months/years (circle) ago

9. Do you take any medications regularly? Yes No

If yes, list type and frequency:

Medication	Dosage	Frequency
_____	_____	_____
_____	_____	_____

10. Do you currently take supplements (vitamins, minerals, herbs, etc.)? Yes No

If yes, list type and frequency:

Supplement	Dosage	Frequency
_____	_____	_____
_____	_____	_____

PLEASE TURN OVER

11. How much alcohol do you drink? (average drinks per day) \_\_\_\_\_

12. Are you OK collecting a 3-hour urine (from 3-6 pm) on 4 occasions during the study? Yes No

13. Please ANSWER (YES) if **you have ever** been diagnosed with any of the following diseases or symptoms:

	YES		YES
Coronary Heart Disease		Any Heart Problems	
High Blood Pressure		Cancer	
Stroke		Lung Disease	
Diabetes		Liver Disease	
Emotional Disorders		Kidney Disease	

Are there any unresolved medical conditions that we should know about?  
\_\_\_\_\_  
\_\_\_\_\_

14. How would you rate your lifestyle? (please check)  
Not active \_\_\_\_\_ Active \_\_\_\_\_  
Somewhat active \_\_\_\_\_ Very Active \_\_\_\_\_

15. Please circle **the number of times** you did the following kinds of exercises **for more than 15 minutes** last week.

**Mild exercise** (minimal effort):

Easy walking, golf, gardening, bowling, yoga, fishing, horseshoes, archery, etc.

Times per week: 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14+

**Moderate exercise** (not exhausting):

Fast walking, easy bicycling, tennis, easy swimming, badminton, dancing, volleyball, baseball, etc.

Times per week: 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14+

**Strenuous exercise activities** (heart beats rapidly):

Running, jogging, hockey, football, soccer, squash, basketball, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling, etc.

Times per week: 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14+

16. Do you have any food allergies? Yes No

If yes, please explain:  
\_\_\_\_\_



APPENDIX E  
REAPS SURVEY

**REAPS (Rapid Eating Assessment for Participants - Shortened Version)**  
 CJSegal-Isaacson, EdD RD, Judy-Wylie-Rosett, EdD RD, Kim Gans, PhD, MPH

In an average week, how often do you:	Usually/ Often	Sometimes	Rarely/ Never	Does not apply to me	
1. Skip breakfast?	O	O	O		
2. Eat <u>4 or more</u> meals from sit-down or take out restaurants?	O	O	O		
3. Eat <u>less than 2 servings</u> of whole grain products or high fiber starches a day? <b>Serving</b> = 1 slice of 100% whole grain bread; 1 cup whole grain cereal like Shredded Wheat, Wheaties, Grape Nuts, high fiber cereals, oatmeal, 3-4 whole grain crackers, ½ cup brown rice or whole wheat pasta, boiled or baked potatoes, yuca, yams or plantain.	O	O	O		
4. Eat <u>less than 2 servings</u> of fruit a day? <b>Serving</b> = ½ cup or 1 med. fruit or ¼ cup 100% fruit juice.	O	O	O		
5. Eat <u>less than 2 servings</u> of vegetables a day? <b>Serving</b> = ½ cup vegetables, or 1 cup leafy raw vegetables.	O	O	O		
6. Eat or drink <u>less than 2 servings</u> of milk, yogurt, or cheese a day? <b>Serving</b> = 1 cup milk or yogurt; 1½ - 2 ounces cheese.	O	O	O		
7. Eat <u>more than 8 ounces</u> (see sizes below) of meat, chicken, turkey or fish <u>per day</u> ? <b>Note:</b> 3 ounces of meat or chicken is the size of a deck of cards or ONE of the following: 1 regular hamburger, 1 chicken breast or leg (thigh and drumstick), or 1 pork chop.	O	O	O	Rarely eat meat, chicken, turkey or fish  O	
8. Use <u>regular processed meats</u> (like bologna, salami, corned beef, hotdogs, sausage or bacon) instead of low fat processed meats (like roast beef, turkey, lean ham; low-fat cold cuts/hotdogs)?	O	O	O	Rarely eat processed meats  O	
9. Eat <u>fried foods</u> such as fried chicken, fried fish, French fries, fried plantains, tostones or fried yuca?	O	O	O		
10. Eat <u>regular potato chips, nacho chips, corn chips, crackers, regular popcorn, nuts</u> instead of pretzels, low-fat chips or low-fat crackers, air-popped popcorn?	O	O	O	Rarely eat these snack foods  O	
11. <u>Add butter, margarine or oil</u> to bread, potatoes, rice or vegetables at the table?	O	O	O		
12. Eat <u>sweets</u> like cake, cookies, pastries, donuts, muffins, chocolate and candies more than 2 times per day.	O	O	O		
13. <u>Drink 16 ounces or more</u> of non-diet soda, fruit drink/punch or Kool-Aid a day? <b>Note:</b> 1 can of soda = 12 ounces	O	O	O		
	<b>YES</b>			<b>NO</b>	
14. You or a member of your family usually shops and cooks rather than eating sit-down or take-out restaurant food?	O			O	
15. Usually feel well enough to shop or cook.	O			O	
16. How willing are you to make changes in your eating habits in order to be healthier?	1 Very willing	2	3	4	5 Not at all willing

APPENDIX F  
3-DAY DIET RECORD



APPENDIX G  
URINE COLLECTION INSTRUCTIONS

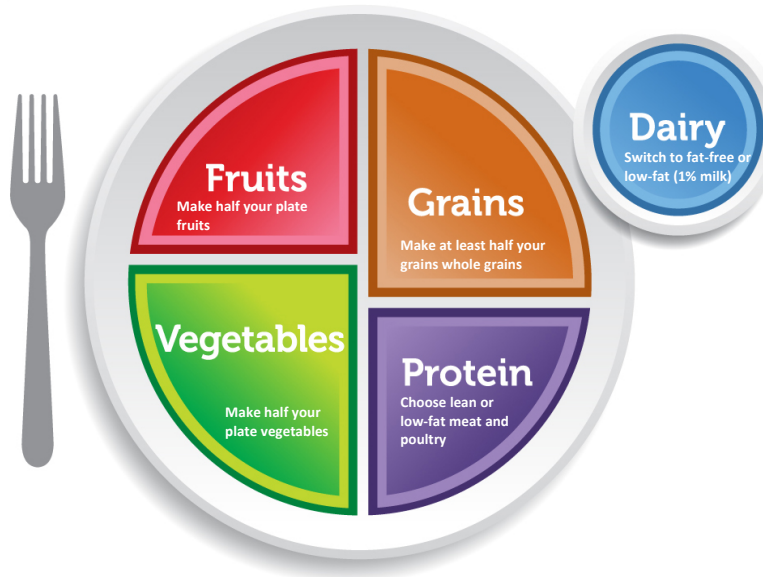
## URINE COLLECTION



### **Instructions:**



- Make sure to collect urine **two days in a row**
  - Collect **first morning void**
- \*\*After urine is collected store in the refrigerator\***

APPENDIX H1  
APP GROUP MATERIALS








#### MyFitnessPal App Instructions

##### Adding Food Items to Diary




1. When on the home screen – select diary icon . It will bring you to a screen with breakfast, lunch, and dinner. Select the meal you want to add the food item to by tapping add food icon . Continue to follow steps 2-6.


OR

You can also add food by selecting the + icon . It will then prompt you to select one of the five options: status, water, food, exercise, or weight. Select the food icon . Once the food icon is chosen, it will prompt you to select a meal you want to add the food item to. Continue to follow steps 2-6.

2. Once the meal is selected, either type the food item into the search option or use the scanner function to locate the item (scanner icon  displayed on the bottom right of the screen)
3. After searching for the food item, select the food that you want to add to the journal.
4. The next screen will prompt you to select serving size and number of servings. Once that is complete, select the check mark icon  (upper right corner of the screen) to add the food item.
5. The food item will appear under the meal selected on main screen of the food diary.
6. Once you have completed the food diary for the day, scroll to the bottom of the screen and select the icon complete entry .

##### Viewing Daily Sodium Value

1. Return to the home screen by selecting the home icon . Once on the home screen, select the diary icon .
2. Scroll to the bottom of the screen and select the nutrition icon .

3. Once the nutrition icon is selected, it will bring you to a screen that shows a pie chart displaying the calorie breakdown for carbohydrates, fat, and protein.
4. In the upper right hand corner of the screen, there is an icon that resembles a list . Once this icon is selected, it will bring you to a screen that shows you a list of nutrients.
5. Look for sodium from the list. It should be after total fat and cholesterol. When looking at sodium, there are three columns labeled total, goal, and left. Total is referring to the total amount of sodium that you have consumed. Goal is the recommended amount of sodium that you want to consume per day. Left refers to how much sodium you have leftover for the day.



APPENDIX H2  
PAPER GROUP MATERIALS

### Where's the Sodium?

Only a small amount of sodium occurs naturally in foods. Most sodium is added during processing. The table below gives examples of sodium in some foods. (Table provided by National Heart, Lung, and Blood Institute)

FOOD GROUPS	SODIUM (mg)
<b>Grains and Grain Products</b>	
Cooked cereal, rice, pasta, unsalted (1/2 cup)	0-5
Ready-to-eat cereal (1 cup)	0-360
Bread (1 slice)	110-175
<b>Vegetables</b>	
Fresh or frozen, cooked without salt (1/2 cup)	1-70
Canned or frozen with sauce (1/2 cup)	140-460
Tomato juice, canned (3/4 cup)	820
<b>Fruit</b>	
Fresh, frozen, canned (1/2 cup)	0-5
<b>Low-fat or fat-free dairy products</b>	
Milk (1 cup)	107
Yogurt (1 cup)	175
Natural cheese (1 1/2 oz.)	110-450
Process cheeses (2 oz.)	600
<b>Nuts, seeds, and Legumes</b>	
Peanuts, salted (1/3 cup)	120
Peanuts, unsalted (1/3 cup)	0-5
Beans, cooked from dried or frozen, without salt (1/2 cup)	0-5
Beans, canned (1/2 cup)	400
<b>Lean meats, fish and poultry</b>	
Lean meat, fish, poultry (3 oz.)	30-90
Tuna caned, water pack, no salt added (3 oz.)	35-45
Tuna canned, water pack (3 oz.)	230-530
Ham, lean, roasted (3 oz.)	1,020

### Tips to Reduce Salt and Sodium

(Tips provided by National Heart, Lung, and Blood Institute)

- ✓ Choose low- or reduced-sodium, or no-salt-added versions of foods and condiments when available.
- ✓ Choose fresh, frozen, or canned (low-sodium or no-salt added) vegetables.
- ✓ Use fresh poultry, fish, and lean meat, rather than canned, smoked or processed types.
- ✓ Choose ready-to-eat breakfast cereals that are lower in sodium.
- ✓ Limit cured foods (such as bacon and ham); food packed in brine (such as pickles, pickled vegetables, olives and sauerkraut); and condiments (such as mustard, horseradish, ketchup, and barbecue sauce). Limit even lower sodium versions of soy sauce and teriyaki sauce. Treat these condiments sparingly as you do table salt.
- ✓ Cook rice, pasta, and hot cereals without salt. Cut back on instant or flavored rice, pasta, and cereal mixes, which usually have added salts.
- ✓ Choose "convenience" foods that are lower in sodium. Cut back on frozen dinners, mixed dishes such as pizza, packaged mixes, canned soups or broths, and salad dressings – these often have a lot of sodium.
- ✓ Rinse canned foods, such as tuna and canned beans, to remove some of the sodium.
- ✓ Use spices instead of salt. In cooking and at the table, flavor foods with herbs, spices, lemon, lime, vinegar, or salt-free seasoning blends. Start by cutting salt in half.

### Compare Nutrition Facts Labels on Foods

Information provided by National Heart, Lung, and Blood Institute

Read the Nutrition Facts labels on foods to compare the amount of sodium in products. Look for the sodium content in milligrams and the Percent Daily Value. Aim for foods that are less than 5 percent of the Daily Value of sodium. Foods with 20 percent or more Daily Value of sodium are considered high.

Compare the food labels of these two versions of Heinz ketchup. The regular Heinz ketchup (right) has 8 times as much sodium as the no salt Heinz ketchup (left).

Heinz No Salt Tomato Ketchup

Nutrition Facts	
Serving Size 1 Tbsp (17g)	
Servings Per Container about 25	
Amount Per Serving	
Calories 25	Calories from Fat 0
% Daily Value *	
Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat 0g	0%
Cholesterol 0mg	0%
Sodium 5mg	1%
Potassium 170mg	4%
Total Carbohydrate net	2%
Dietary Fiber 0g	0%
Sugars 4g	
Protein 0g	
Vitamin A 0%	Vitamin C 0%
Calcium 0%	Iron 0%

Heinz Ketchup

Nutrition Facts	
Serving Size 1 Tbsp (17g)	
Servings Per Container about 760	
Amount Per Serving	
Calories 20	Calories from Fat 0
% Daily Value *	
Total Fat 0g	0%
Saturated Fat 0g	0%
Trans Fat 0g	0%
Cholesterol 0mg	0%
Sodium 180mg	4%
Total Carbohydrate net	2%
Dietary Fiber 0g	0%
Sugars 4g	
Protein 0g	
Vitamin A 4%	Vitamin C 0%
Calcium 0%	Iron 0%

**Label Language:** Look for the following label information on cans, boxes, bottles, bags, and other packaging:

- ✓ **Sodium free or salt free:** less than 5 mg per serving
- ✓ **Very low sodium:** 35 mg or less of sodium per serving
- ✓ **Low sodium:** 140 mg or less of sodium per serving
- ✓ **Reduced or less sodium:** at least 25% less of sodium than the regular version
- ✓ **Light in sodium:** 50% less sodium than the regular version
- ✓ **Unsalted or no salt added:** no salt added to the product during processing (this is not a sodium-free food)

**Where is the Potassium:** Potassium comes from a variety of food sources. Examples are provided in the lists below by National Heart, Lung, and Blood Institute.

#### Top 5 VEGETABLES High in Potassium

1. Potato (1 medium)
2. Sweet Potato (1 medium)
3. Spinach, cooked (1/2 cup)
4. Zucchini, cooked (1/2 cup)
5. Tomato, fresh (1/2 cup)

#### Top 5 FRUITS High in Potassium

1. Banana (1 medium)
2. Apricots (1/4 cup)
3. Orange (1 medium)
4. Cantaloupe chunks (1/2 cup)
5. Apple (1 medium)

#### Top 5 NUTS AND LEGUMES High in Potassium

1. Soybeans, cooked (1/2 cup)
2. Lentils, cooked (1/2 cup)
3. Kidney beans and split peas, cooked (1/2 cup)
4. Almonds, roasted (1/3 cup)
5. Walnuts, roasted (1/3 cup)

#### Top LOW-FAT/FAT-FREE MILK PRODUCTS High in Potassium

1. Milk (1 cup)
2. Yogurt (1 cup)

#### Top LEAN MEETS, FISH, AND POULTRY High in Potassium

1. Cod, Halibut, Rockfish, Trout and Tuna (3 oz.)
2. Pork tenderloin (3 oz.)
3. Beef tenderloin, Chicken, Turkey (3 oz.)

APPENDIX I  
EXIT SURVEY

Subject # \_\_\_\_\_

EXIT SURVEY: Please answer the following questions regarding your participation in the research study on successful weight loss strategies. Mark an 'x' on the line that best fits your opinion.

1. Recording my daily food intake was helpful in keeping me on track toward my sodium goal.

strongly disagree      disagree      no opinion      agree      strongly agree

2. The method I used for recording my daily food intake was too time consuming to be practical.

strongly disagree      disagree      no opinion      agree      strongly agree

3. I was more aware of my eating habits because I was recording my food intake.

strongly disagree      disagree      no opinion      agree      strongly agree

4. I enjoyed my method of monitoring my diet.

strongly disagree      disagree      no opinion      agree      strongly agree

5. I am more confident in my ability to identify sodium in my diet after participating in this study.

strongly disagree      disagree      no opinion      agree      strongly agree

6. I will continue to record my food intake after the study is over.

strongly disagree      disagree      no opinion      agree      strongly agree

7. It was difficult to achieve my sodium goal.

strongly disagree      disagree      no opinion      agree      strongly agree