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# The Effects of 8 oz of Fresh vs. Commercial Orange Juice on Blood Pressure in Normotensive Males Aged 18-59

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The Effects of 8 oz of Fresh vs. Commercial Orange Juice on Blood Pressure in

Normotensive Males Aged 18-59

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## Abstract

**Background**: Oranges have been known to possess numerous health benefits for humans as they are rich in vitamin C, A, and potassium. Citrus fruits contain a substance known as "citrus sinensis juice" which boosts immune function and aids in wound healing. Sinensis juice can also reduce blood pressure, inflammation, and risk of cardiovascular disease.

**Objective:** To determine the effects of drinking eight ounces of fresh vs. commercial orange juice on blood pressure in healthy normotensive males ages 18-59 years.

Design: Randomized, single-blinded, crossover study.

**Participants:** Healthy males aged 18-59 years, willing to keep the same lifestyle, refrain from taking medications or antioxidant supplements to control blood pressure, or drinking any type of orange juice for 30 days of participation during study.

**Results:** No significant change in blood pressure was observed in both intervention groups. Statistics: Repeated measures ANOVA, linear mixed model (degradation), SPSS software (version 25).

**Conclusion:** No significant change was observed in four weeks of consumption of 8 fluid ounces fresh or commercial orange juice.

## Introduction

High blood pressure is a common health condition. Blood pressure is a normal function for all human beings and reflects the mechanics of blood acting against a vessel when it is pumped by the heart. When blood pressure exceeds normal limits, the risk for heart disease and stroke increase drastically due to excess strain on the vessels. According to the Centers for Disease Control and Prevention, about 75 million people have hypertension in the United States.<sup>1</sup> Unfortunately, only 54% of these people have their blood pressure under control.<sup>1</sup> The normal blood pressure reading is less than or equal to 120/80 mm Hg (Systolic/Diastolic).<sup>1</sup> When blood pressure readings elevate to 120/80-139/89 mm Hg, that is classified as prehypertension.<sup>1</sup> Readings at 140/90 or greater are classified as hypertensive or abnormal.<sup>1</sup>

The prevalence of hypertension is high because it is heavily influenced by lifestyle. Lack of exercise reduces circulation efficiency as well as heart health. Diets high in sodium and overconsumption of processed foods can increase blood pressure.<sup>2</sup> Excess weight can place additional strain on the heart as well as on the vessels.<sup>3</sup> Family history of hypertension may also play a role in development of hypertension. As persons age, vessels will naturally degrade in elasticity. In terms of ethnicity, African-Americans tend to develop high blood pressure more frequently than other ethnicities. Alcohol, smoking, and stress are also blood pressure increasing factors.

There are many methods for decreasing blood pressure. Thiazide diuretics, calcium channel blockers, and angiotensin-converting enzyme inhibitors are common drugs for patients who have high blood pressure. However, some remedies involve lifestyle to decrease blood pressure. William (2013) stated that walking and exercising are best methods for reducing high

3

blood pressure.<sup>4</sup> Doing so will strengthen cardiac muscles, which will lead to a more efficient heart contraction.<sup>4</sup> As a result, blood pressure will be reduced.

Two and a half hours of moderate or 75 minutes of vigorous exercise a week can help treat high blood pressure.<sup>4</sup> The "reduced sodium diet" is another popular treatment option because sodium increases the amount of fluid in the bloodstream due to the natural osmolality effect of sodium attracting water.<sup>2</sup> Yang observed that another method for reducing blood pressure is eating potassium rich foods.<sup>2</sup> Potassium is a mineral that helps rid the body of sodium.<sup>2</sup> For overweight hypertensive patients, weight loss is another recommendation for blood pressure reduction.<sup>4</sup> Losing 5% of body mass can significantly lower blood pressure.<sup>4</sup> In terms of natural supplements, aged garlic extract and fish oil have components within them that can help with reducing blood pressure.<sup>5,6</sup>

Aside from a sodium-restricted diet, consuming oranges has been shown to possibly aid in blood pressure reduction. Citrus sinensis, also known as "sweet orange," is rich in vitamin A, C, and potassium and can be eaten or juiced.<sup>7</sup> Flavonoids in oranges have been shown to reduce risk of cardiovascular disease.<sup>7</sup>

Other citrus fruits have been shown to provide benefits for treating high blood pressure. Kato (2014) noted that lemon ingestion and exercise, such as walking, can help in reducing blood pressure.<sup>8</sup> Another citrus fruit that has the potential of reducing blood pressure is grapefruit. A study by Dow (2016) involved a six-week consumption of grapefruit to determine if changes in weight lipids, and blood pressure occured.<sup>9</sup> Results showed no significant change, but further research should be done.<sup>9</sup>

A study conducted by Asgary (2013) looked at the effects of fresh orange juice and commercial orange juice on blood pressure. This was a single-blind randomized crossover study

4

that involved 22 healthy male subjects ages 18-59 years.<sup>10</sup> The duration of the study was ten weeks with the first four weeks of commercial orange juice being consumed daily, a two week washout period, and finally the last four weeks with daily fresh orange juice consumption.<sup>10</sup> The amount of fresh and commercial orange juice consumed daily was 16.9 fluid ounces (500 milliliter) two times a day for a total of 33.8 fluid ounces (1 liter), for breakfast and dinner.<sup>10</sup> Blood pressure was recorded before the study, during, and after the duration of the study.<sup>10</sup> Results showed that commercial orange juice had a significant impact on reducing both systolic and diastolic blood pressure.<sup>10</sup> Fresh orange juice, on the other hand, did not have a significant impact on blood pressure.<sup>10</sup>

High blood pressure is a common health condition. The purpose of our graduate student research study was to determine if drinking a smaller amount of orange juice (8 fluid ounces) daily can have a positive impact on decreasing blood pressure in healthy normotensive males between the ages of 18 - 59 years. We replicated the methodology from the Asgary study using a lower volume of orange juice. For this study, our source of citrus sinensis juice came from Valencia and Navel oranges. Besides the use of fresh oranges to determine changes in blood pressure, we also used commercial orange juice to compare the effects of both.

## Methods

## **Participants**

This research study consisted of 18 healthy males, but only 17 completed the study in its entirety (n=17). Participants' ages ranged from 21 to 44 years of age. Subjects were randomized into two groups (A and B) using a random name selector through a website app. Group A consisted of ten subjects with the mean age of  $28.6 \pm 6.8$  years and started with commercial orange juice intervention. Group B consisted of seven subjects with the mean age of  $26.3 \pm 2.8$ 

years and started with the fresh orange juice intervention. After this four week intervention, there was a period of no orange juice consumption for eight weeks. Then subjects switched the type of orange juice and drank it for another four weeks.

To be included in the study, participants had to maintain the same lifestyle, not take any medications or antioxidant supplements to control blood pressure, and not drink any type of orange juice within the preceding 30 days. The exclusion criteria was: diabetic, smoked cigarettes, marijuana or electronic cigarettes, drink alcohol more than once a week, allergic to oranges, and/or diagnosed as hypotensive or hypertensive. The Institutional Review Board of Loma Linda University approved all methods and procedures. Risks of this study included a possible breach of confidentiality. Although subjects may not personally benefit from this study, their participation may help practitioners provide scientific information that may benefit men in managing blood pressure with citrus sinensis juice.

## PSS

Perceived Stress Scale (PSS) is a widely used psychological instrument for measuring perception of stress. It is a measure of the degree to which situations in one's life are perceived as stressful. Emotional stress has been linked to increased blood pressure. The PSS is an easy-to-use questionnaire with established internal consistency (Cronbach's  $\alpha$ =0.87) and positive test-retest reliability (ICC=0.86, p<.001).<sup>11</sup>

## **Blood Pressure**

The blood pressure monitor that we used for this study was Omron, 5 series, Model: BP742N. Subjects came in four times throughout the study at the beginning and end of the first four weeks, and the beginning and end of the second four weeks. We took three readings each time and averaged them.

## **Orange Juice**

We bought fresh oranges and commercial orange juice from Sysco. We squeezed the fresh oranges at the kitchen of the School of Allied Health Professional with a reamer type juicer on the same day as distribution. The juice was not treated with additional preservatives or sugar. To produce eight ounces of fresh orange juice, approximately three oranges were needed. One part of concentrated orange juice needed four parts of water to reconstitute. Then we measured the reconstituted orange juice and put them into 32 fluid ounces water bottles, and stored them in the refrigerator. We gave subjects orange juice every three or four days.

## Procedure

- Visit 1 Beginning of the first four weeks: Upon arrival, subjects were given a consent form. Student investigators went over the layout of the research study with them, such as procedures and compliance . Then subjects were asked if they agreed to drink orange juice daily for two months. If they agreed, they were asked to relax for five minutes, and student investigators took their blood pressure reading three times using a blood pressure monitor. Subjects completed the PSS survey before leaving. Subjects had to drink eight ounces of the specified juice daily for four weeks.
- ∉ Visit 2 End of the first four weeks: Subjects met with student investigators at a convenient location. Subjects were asked to rest for five minutes. Then student investigators took their blood pressure reading three times using a blood pressure monitor. Subjects completed the PSS survey before leaving.
- ∉ Between visit 2 and 3: There was a washout period of eight weeks with no consumption of any type of orange juice.

- Visit 3 Beginning of the second four weeks: Subjects met with the student investigators at a convenient location and were asked to rest for five minutes. Then, student investigators took their blood pressure reading three times using a blood pressure monitor. Subjects completed the PSS survey before leaving. Subjects had to drink orange juice for the second four weeks and came in every three or four days to pick up orange juice.
- ✓ Visit 4 End of the second four weeks: Subjects met with student investigators at a convenient location and were asked to rest for five minutes. Then student investigators took their blood pressure reading three times using a blood pressure monitor. Subjects completed the PSS survey and were given gift cards as compensation before leaving.

## **Data Analysis**

Mean and standard deviation were computed for quantitative variables, while median as well as minimum and maximum ranges were computed for ordinal variables. A paired t-test was performed to analyze data obtained by the crossover design before and after juice supplementation in order to determine possible significant differences in blood pressure between time points. A paired t-test between baseline values (either natural or commercial orange juice supplementation) was used to establish correct performance of the washout. A paired t-test was also used to compare the mean values obtained before and after the experiment period. To examine the effect of the type of intervention on SBP and DBP over time (pre versus post), a mixed model was conducted within and between groups. Data was analyzed using SPSS Statistics Software version 24.0 (SPSS Inc, Chicago, IL, USA). All analyses were performed at an alpha level of .05.

## Results

Overall, 18 subjects began the study, but only 17 completed the study in its entirety. One subject was dropped due to lack of compliance. Table 1 shows that 12% of subjects were vegetarians. Table 1 also shows the diet, exercise frequency, and occupation of each subject at baseline. Four out of the 17 subjects were physically active greater than five times per week. Of the 17 subjects, 13 were students at Loma Linda University (Table 1). In the commercial group, no significant change occurred in systolic (119.1 ± 5.8 to 119.8 ± 5.7; 0.6% change; p = 0.547) and diastolic blood pressure (72.8 ± 9.3 to 75.4 ± 6.8; 3.6% change; p = 0.197) over four weeks. In the fresh group, no significant change was observed in systolic (119.2 ± 7.0 to 116.2 ± 5.3; - 2.5% change; p = 0.146) and diastolic blood pressure (73.7 ± 7.6 to 75.1 ± 8.7; 1.9% change; p = 0.419) over four weeks. No significant change occurred in stress levels of both fresh and commercial orange juice groups over four weeks (P = 0.063 and P = 0.413, respectively). No significant change occurred in stress levels between fresh and commercial orange juice groups over four weeks (P = 0.416).

Characteristics	Frequency (%)
Age <sup>†</sup> (years)	$27.6\pm5.3$
Diet:	
Regular	15(88.2)
Vegetarian	2(11.8)
<b>Exercise (frequency):</b>	
0-3 days per week	9(52.9)
4-5 days per week	4(23.5)
>5 days per week	4(23.5)
Occupation:	
Student	13(76.5)
Non-student	4(23.5)

Table 1. Frequency (%) of selected demographics of participants at baseline (N = 17)

 $^{\dagger}$  Values are presented as mean  $\pm$  standard deviation

	Commercial				Fresh				
	Pre	Post	Percent change	P-value	Pre	Post	Percent change	P-value	P-value*
SBP	119.1 (5.8)	119.8 (5.7)	0.6	0.547	119.2 (7.0)	116.2 (5.3)	-2.5	0.146	0.063
DBP	72.8 (9.3)	75.4 (6.8)	3.6	0.197	73.7 (7.6)	75.1 (8.7)	1.9	0.419	0.413
PSS	13 (3, 24)	13 (2, 25)	0.0	1.000	11 (2, 22)	11 (0,19)	0.0	0.586	0.416

**Table 2.** Mean (SD) of blood pressure and median (minimum, maximum) of stress level by group overtime (N=17)

SBP: Systolic Blood Pressure, DBP: Diastolic Blood Pressure, PSS: Perceived Stress Scale P-value\* for between groups

## Discussion

The purpose of this study was to determine the effects of drinking 8 fluid ounces of fresh versus commercial orange juice on blood pressure in healthy normotensive males ages 18 - 59 years. Consumption of citrus fruits such as oranges, grapefruit, and lemon may reduce blood pressure. Oranges are a good source of several vitamins and minerals, especially vitamin C, thiamine, folate, and potassium. High intake of potassium can lower blood pressure in people who already have high levels and may reduce risk of heart disease.<sup>2</sup>

The main finding of our study was that the four week consumption of commercial and fresh orange juice did not affect blood pressure in normotensive male subjects. In comparison to the Asgary study, we used the same four week duration, but we tested 8 fluid ounces of orange juice instead of one liter (34 fluid ounces). We hypothesized that fresh orange juice would cause a significant decrease in blood pressure because the pasteurization process used in commercial orange juice would destroy some of the flavonoid content. However, Asgary reported that commercial citrus sinensis juice significantly decreased SBP and DBP.<sup>10</sup> Asgary mentioned that the amount of flavonoid is higher in commercial orange juice compared to fresh hand squeezed

orange juice. Commercial orange juice has a higher flavonoid (polymethoxylated flavones, hesperidin, and naringin) content compared to fresh orange juice. This is due to the grinding process, which uses the entire fruit to produce the juice. Producing fresh orange juice, on the other hand, requires the separation of juice from the flesh of the orange. One of the limitations of our study could be the equipment that was being used to extract juice. The flesh of the orange contains flavonoids and the equipment used may not have been able to extract as many flavonoids as needed to impact results.

It has been reported that water extract from lemon peels have a suppressive effect on blood pressure.<sup>8</sup> A study was conducted by Kato (2014) in which 101 subjects consumed a lemon with the peel and walked daily for five months.<sup>8</sup> Study results showed a significant decrease in systolic blood pressure. Furthermore, pectin and essential oils contained in the peel were also found in greater amounts in commercial juice (skin is separated when fresh squeezed). Flavonoids naringin and hesperidin are mainly present in the peel and essential oils of grapefruits and oranges. They have been reported to possess antioxidant, antihypertensive, and hypocholesterolemic effects. Flavonoids also offer some kind of protection against mutagenesis and lipid peroxidation.<sup>8</sup> Morand (2014) studied twenty-four healthy overweight men ages 50 – 65 years of age who consumed a 500 milliliter drink that contained orange flavoring and hesperidin capsules daily for four weeks.<sup>12</sup> Results showed a drop in diastolic blood pressure.

We believe the results of our study were not significant due to the amount of juice subjects consumed. With a daily consumption of 8 fluid ounces of orange juice, subjects would not receive as many flavonoids as those drinking one liter. Additionally, significant changes on blood pressure may have been observed had the duration of the intervention phases been prolonged. Long term exposure to ascorbate is known to increase endothelial nitric oxide

11

synthase activity by stabilizing its cofactor tetrahydrobiopterin. Ascorbate derives from ascorbic acid and acts as a water soluble reducing agent and an antioxidant. Low levels of plasma ascorbate has been linked to increased oxidative stress which has been related to hypertension.<sup>13</sup> Lastly, the oranges that we bought from Sysco could have altered the results since there was a period where the oranges used were not as ripe which may have altered the number of available flavonoids.

A future study could be done in which essential oils of orange could be put into capsules and used to evaluate possible change to blood pressure. This would be a method where additional calorie and sugar intake from orange juice would be eliminated. Another future study could examine effects of alternative amounts and duration of orange juice being consumed to reduce blood pressure.

## Conclusion

Some studies indicate orange juice can possibly lower blood pressure. Our study's findings showed that neither fresh nor commercial orange juice was able to significantly decrease systolic or diastolic blood pressure in a four week period of time. In general, more research on orange juice and blood pressure is needed.

## References

- Drawz PE, Abdalla M, Rahman M. Blood pressure measurement: clinic, home, ambulatory, and beyond. *Am J Kidney Dis.* 2012;60(3):449-462.
- Yang Q, Liu T, Kuklina EV, et al. Sodium and potassium intake and mortality among US adults: prospective data from the Third National Health and Nutrition Examination Survey. *Arch Intern Med.* 2011;171(13):1183-1191.
- Mosca L, Benjamin EJ, Berra K, et al. Effectiveness-based guidelines for the prevention of cardiovascular disease in women--2011 update: a guideline from the American Heart Association. J Am Coll Cardiol. 2011;57(12):1404-1423.
- Williams PT, Thompson PD. Walking versus running for hypertension, cholesterol, and diabetes mellitus risk reduction. *Arterioscler Thromb Vasc Biol.* 2013;33(5):1085-1091.
- 5. AlSaleh A, Maniou Z, Lewis FJ, et al. Interaction between a CSK gene variant and fish oil intake influences blood pressure in healthy adults. *J Nutr*. 2014;144(3):267-272.
- Ried K, Frank OR, Stocks NP. Aged garlic extract reduces blood pressure in hypertensives: a dose-response trial. *Eur J Clin Nutr*. 2013;67(1):64-70.
- Dosoky NS, Setzer WN. Biological Activities and Safety of Citrus spp. Essential Oils. *Int J Mol Sci.* 2018;19(7).
- Kato Y, Domoto T, Hiramitsu M, et al. Effect on blood pressure of daily lemon ingestion and walking. *J Nutr Metab.* 2014;2014:912684.
- Dow CA, Going SB, Chow HH, Patil BS, Thomson CA. The effects of daily consumption of grapefruit on body weight, lipids, and blood pressure in healthy, overweight adults. *Metabolism.* 2012;61(7):1026-1035.

- Asgary S, Keshvari M. Effects of Citrus sinensis juice on blood pressure. ARYA Atheroscler. 2013;9(1):98-101.
- 11. Vernon H, Mior S. The Neck Disability Index: a study of reliability and validity. *Journal of manipulative and physiological therapeutics*. 1991;14(7):409-415.
- Morand C, Dubray C, Milenkovic D, et al. Hesperidin contributes to the vascular protective effects of orange juice: a randomized crossover study in healthy volunteers. *Am J Clin Nutr*. 2011;93(1):73-80.Ladurner A, Schmitt CA, Schachner D, et al. Ascorbate stimulates endothelial nitric oxide synthase enzyme activity by rapid modulation of its phosphorylation status. *Free Radic Biol Med*. 2012;52(10):2082-2090.

## Appendix

PERCEIVED STRESS SCA	LE					
The questions in this scale ask you about your feelings and In each case, you will be asked to indicate by circling how certain way.	thoughts w often yo	durin; u felt	g the or tl	last houg	mor ht a	nth.
Name	_ Date _			_		
Age Gender ( <i>Circle</i> ): M F Other	-	-		-		
0 = Never 1 = Almost Never 2 = Sometimes 3 = Fair	ly Often	4 = Ve	ry O	ften		
<ol> <li>In the last month, how often have you been upset be something that happened unexpectedly?</li> </ol>	cause of	0	1	2	3	4
<ol><li>In the last month, how often have you felt that you were u control the important things in your life?</li></ol>	inable to	0	1	2	3	4
3. In the last month, how often have you felt nervous and "stres	sed"?	0	1	2	3	4
4. In the last month, how often have you felt confident ab ability to handle your personal problems?	out your	0	1	2	3	4
5. In the last month, how often have you felt that things we your way?	ere going	0	1	2	3	4
5. In the last month, how often have you found that you could with all the things that you had to do?	not cope	0	1	2	3	4
7. In the last month, how often have you been able to control i n your life?	rritations	0	1	2	3	4
3. In the last month, how often have you felt that you were o hings?	on top of	0	1	2	3	4
9. In the last month, how often have you been angered be hings that were outside of your control?	cause of	0	1	2	3	4
10. In the last month, how often have you felt difficulties were so high that you could not overcome them?	piling up	0	1	2	3	4
info@mindgarden.com	n	Lom Insti App	a Lind itution roved	a Univ al Revi 10/3	ersity . ew Bo	Healt ard 8

References The PSS Scale is reprinted with permission of the American Sociological Association, from Cohen, S., Kamarck, T., and Mermelstein, R. (1983). A global measure of perceived stress. *Journal of Health and Social Behavior*, 24, 386-396. Cohen, S. and Williamson, G. Perceived Stress in a Probability Sample of the United States. Spacapan, S. and Oskamp, S. (Eds.) *The Social Psychology of Health*. Newbury Park, CA: Sage, 1988.

Subject #				
		Compliance	Log Sheet	
		Please circle if you	drank orange juice 🕲	Comments
Week 1	Day 1	Yes	No	
	Day 2	Yes	No	
	Day 3	Yes	No –	
	Day 4	Yes	No –	
	Day 5	Yes	No	
	Day 6	Yes	No	
	Day 7	Yes	– No	
Week 2	Day 1	Yes	No	
	Day 2	Yes	No	
	Day 3	Yes	No	
	Day 4	Yes	No –	
	Day 5	Yes	No	
	Day 6	Yes	No	
	Day 7	Yes	No –	
Week 3	Day 1	Yes	No –	
	Day 2	Yes	No	
	Day 3	Yes	No	
	Day 4	Yes	No	
	Day 5	Yes	No	
	Day 6	Yes	No	
	Day 7	Yes	No	
Week 4	Day 1	Yes	No	
	Day 2	Yes	No	7.000
	Day 3	Yes	No	
	Day 4	Yes	No	
		Loi Ins	na Linda University Health titutional Review Board comment 9/13/12018	

IN: Pro Loma Lin (909	INSTITUTIONAL REVIEW BOARD Authorization for Use of Protected Health Information (PHI) Per 45 CFR §164.508(b) RESEARCH PROTECTION PROGRAMS LOMA LINDA UNIVERSITY   Office of the Vice President of Research Affairs 24887 Taylor Street, Suite 202 Loma Linda, CA 923150 (909) 558-4531 (vice) / (909) 559-0131 (dayle-mail: ubb@llu adu				
TITLE OF STUDY:	THE EFFTCTS OF 8 OZ OF FRESH VS. COMMERCIAL ORANGE JUICE ON BLOOD PRESSURE IN NORMOTENSIVE MALES AGED 18-59				
PRINCIPAL INVESTIGATOR:	Cory Gheen, MS, RD, Assistant Professor				
Others who will use, collect, or share PHI:	All authorized personnel				

The study named above may be performed only by using personal information relating to your health. National and international data protection regulations give you the right to control the use of your medical information. Therefore, by signing this form, you specifically authorize your medical information to be used or shared as described below.

The following personal information, considered "Protected Health Information" (PHI) is needed to conduct this study and may include, but is not limited to: <u>name, address, telephone</u> number, date of birth, and past and current medical history of your blood pressure.

The individual(s) listed above will use or share this PHI in the course of this study with the Institutional Review Board (IRB) and the Office of Research Affairs of Loma Linda University.

The main reason for sharing this information is to be able to conduct the study as described earlier in the consent form. In addition, it is shared to ensure that the study meets legal, institutional, and accreditation standards. Information may also be shared to report adverse events or situations that may help prevent placing other individuals at risk.

All reasonable efforts will be used to protect the confidentiality of your PHI, which may be shared with others to support this study, to carry out their responsibilities, to conduct public health reporting and to comply with the law as applicable. Those who receive the PHI may share with others if they are required by law, and they may share it with others who may not be required to follow national and international "protected health information" (PHI) regulations such as the federal privacy rule.

Subject to any legal limitations, you have the right to access any protected health information created during this study. You may request this information from the Principal Investigator named above but it will only become available after the study analyses are complete.

Lona Linda University Health Institutional Review Board Approved <u>9/13/18</u>\_void After<u>9/12/20</u>/9 IRB 5720291 The authorization expires upon the conclusion of this research study.

200

You may change your mind about this authorization at any time. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal health information will be used for this study. However, study personnel may continue to use the health information that was provided before you withdrew your permission. If you sign this form and enter the study, but later change your mind and withdraw your permission, you will be removed from the study at that time. To withdraw your permission, please contact the Principal Investigator or study personnel at (909) 558-1000 ext: 42727

You may refuse to sign this authorization. Refusing to sign will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are entitled. However, if you do not sign this authorization form, you will not be able to take part in the study for which you are being considered. You will receive a copy of this signed and dated authorization prior to your participation in this study.

I agree that my personal health information may be used for the study purposes described in this form.

Signature or Patient's Lega	of Patient Il Representative	Date			
Printed Name of Le (if a	egal Representative ny)	Representative's Authority to Act for Patient			
Signature of Inves Author	tigator Obtaining ization	Date			
		Lama Linda University Bealth			
		Institutional Review Board American 9/13/18 Vold After 9/12/2019			
		IRB# 5780291			
		IRI3 6/207	2014		



### INFORMED CONSENT

### THE EFFECTS OF 8 OZ OF FRESH VS. COMMERCIAL ORANGE JUICE ON BLOOD PRESSURE IN NORMOTENSIVE MALES AGED 18-59

PRINCIPAL INVESTIGATOR: Cory Gheen, MS, RD, Assistant Professor Graduate Student Investigators: Cheng Yi Wong and Izac Dinio

### WHY IS THIS STUDY BEING DONE?

The purpose of this graduate student research study is to determine the effects of drinking eight ounces of fresh vs. commercial orange juice on blood pressure in males with normal blood pressure.

You are invited to be in this study because you are a healthy 18-59 years old male, willing to keep the same lifestyle, not taking any medications or antioxidants to control blood pressure, and do not drink any types of orange juice within 30 days.

You are excluded from the study if you are diabetic, smoke cigarettes, marijuana or electronic cigarettes, drink alcohol more than once a week, allergic to oranges, and diagnosed with low blood pressure or high blood pressure.

Approximately 20 subjects will participate in this study at the comfort of your own home apart from four visits. You will attend four visits at a convenient location at Loma Linda University. Visit 1 takes 45 minutes, visit 2, 3, and 4 takes 10 minutes each over the course of four months which will entail two four-week sessions of drinking orange juice with eight weeks of no consumption of any types of orange juice in between.

### HOW WILL I BE INVOLVED?

Participation in this study involves the following:

Visit 1 - Beginning of the first four-week session

- · You will sign an informed consent.
- · We will go over the procedures and compliance with you.
- You will be asked if you agree with drinking 8 oz of orange juice daily for two 4 weeks sessions,

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Page 1 of 4 DEPARTMENT OF NUTRITION AND DIETETICS | Loma Linda, California 92350 909-558-4593 · www.lluhealth.org

- If you agree, you will be asked to relax for five minutes and your blood pressure will be taken by the student investigators. If your blood pressure is considered high or low, you will be excluded from the study and we suggest you see your primary physician.
- You will need to complete a stress survey (5 minutes).
- You will need to drink orange juice for 28 days, and come in every 3 or 4 days to pick up your orange juice.

Visit 2 - End of the first four-week session

- You will be asked to rest for five minutes and blood pressure will be taken by the student investigators. If your blood pressure is considered too high or low, you will be dropped from the study and we suggest you see your primary physician.
- You will need to complete the stress survey (5 minutes).

Between visit 2 and 3 - Eight weeks of no consumption of any types of orange juice.

Visit 3 – Beginning of the second four-week session

- You will be asked to rest for five minutes and blood pressure will be taken by the student investigators. If your blood pressure is considered high or low, you will be dropped from the study and we suggest you see your primary physician.
- You will need to complete the stress survey (5 minutes).
- You will need to drink orange juice for 28 days, and come in every 3 or 4 days to pick up orange juice.

Visit 4 - End of the second four-week session

- You will be asked to rest for five minutes and blood pressure will be taken by the student investigators. If your blood pressure is considered high or low, you will be dropped from the study and we suggest you see your primary physician.
- · You will need to complete the stress survey (5 minutes).

# WHAT ARE THE REASONABLY FORESEEABLE RISKS OR DISCOMFORTS I MIGHT HAVE?

This study may involve a possible risk of breach of confidentiality.

To minimize the risk of breach of confidentiality, we will store all your data in a locked cabinet, in a locked office.

All records and research materials that identify you will be held confidential. Any published document resulting from this study will not disclose your identity without your permission. Information identifying you will only be available to the study personnel.

Page 2 of 4

Lona Linda University Health Institutional Review Soard Approved 9/13/18 void After 9/12/2019 Rss 5180291

### WILL THERE BE ANY BENEFIT TO ME OR OTHERS?

Although you may not personally benefit from this study, your participation may help practitioners provide scientific information that may help men and the healthcare setting in terms of managing blood pressure with citrus sinensis juice.

### WHAT ARE MY RIGHTS AS A SUBJECT?

Your participation in this study is entirely voluntary. You may refuse to participate or withdraw once the study has started. If at any time you feel uncomfortable, you may refuse to answer questions.

### WHAT COSTS ARE INVOLVED?

There is no cost to you for participating in this study. The fresh and commercial orange juice, water bottles, and measuring cup will be provided to you at no cost. At the end of the study, you are allowed to keep the water bottles and measuring cup at no cost to you.

### WILL I BE PAID TO PARTICIPATE IN THIS STUDY?

You will be given a \$50 gift card at the completion of the entire study period.

### WHO DO I CALL IF I HAVE QUESTIONS?

Call 909-558-4647 or e-mail <u>patientrelations@llu.edu</u> for information and assistance with complaints or concerns about your rights in this study.

#### SUBJECT'S STATEMENT OF CONSENT

• I have read the contents of the consent form and have listened to the verbal explanation given by the investigator.

· My questions concerning this study have been answered to my satisfaction.

Signing this consent document does not waive my rights nor does it release the investigators, institution or sponsors from their responsibilities.

I may call Cory Gheen at (909) 558-1000 ext: 42727 if I have additional questions or concerns.

· I hereby give voluntary consent to participate in this study.

Signature of Subject

Printed Name of Subject

Date

Page 3 of 4

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### INVESTIGATOR'S STATEMENT

I have reviewed the contents of this consent form with the person signing above. I have explained potential risks and benefits of the study.

Signature of Investigator

Printed Name of Investigator

Date



## Subject #

Demographic Questionnaire

- 1. Age
  - 2. Diet: Regular Vegetarian Vegan Paleo Keto Other\_\_\_\_\_
  - 3. Types of exercise:
    - a. Days per week:
  - b. Duration of exercise in minutes or hours:
- 4. Occupation:
- 5. Education level: High school College undergraduate Graduate

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