



UNIVERSIDAD DE COLIMA

School of Medicine

**Effect of coconut water compared with oral electrolytes on hydration status
in adolescents who perform physical exercise of aerobic competition.
Randomized, double-blind controlled clinical trial.**

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PRESENTS:

LN. Alexis Adan Lopez Maria

ADVISORS:

D in C Carmen Alicia Sánchez Ramírez

D in C Fabian Rojas Larios

CO-ADVISOR:

D on C Yunue Flores Ruelas

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INDEX

1	ABSTRACT:	7
2	INTRODUCTION	7
3	THEORETICAL FRAMEWORK	8
3.1	Water	8
3.1.1	Composition and structure	8
3.1.2	Functions	10
3.1.3	Distribution of Total Body Water (TBW)	11
3.1.4	Water homeostasis	12
3.1.5	Thirst mechanism	13
3.1.6	Renin Angiotensin Aldosterone System (RAAS)	13
3.2	Hydration Status	14
3.2.1	Prevalence of dehydration	15
3.2.2	Classification of dehydration based on the loss of water and sodium	15
3.2.3	Fluid requirements in athletes	17
3.2.4	Consequences of dehydration	18
3.3	Physical exercise as an important factor of dehydration	19
3.3.1	Types of physical exercise	20
3.3.2	Exercise intensity	20
3.3.3	Prevalence of dehydration in athletes	22
3.4	Factors that alter hydration status	22
3.4.1	Obesity	22
3.4.2	Climate	23
3.4.3	Feeding Habits	24
3.5	Diagnostic methods of dehydration	25
3.5.1	Gold standard	26
3.5.2	Urine Specific Gravity (USG)	27
3.5.3	Total Body Water Loss by bioimpedance (PACT)	27
3.5.4	Total Body Mass Loss (TWBC)	29
3.6	Hydrating drinks	30
3.6.1	Oral electrolytes	31
3.6.2	Disadvantages of using industrialized beverages	32
3.6.3	Coconut water	32

3.6.4	Chemical composition of coconut water	33
3.6.5	Chemical comparison between oral electrolytes, Coconut water and Electrolit®	35
4	BACKGROUND	36
5	PROBLEM STATEMENT	39
6	JUSTIFICATION	40
6.1	Research question	41
7	MATERIAL AND METHODS	41
7.1	Hypothesis	41
7.1.1	Work hypothesis	41
7.1.2	Null hypothesis	41
7.1.3	Alternate hypothesis	42
7.2	Objectives	42
7.2.1	General objective	42
7.2.2	Specific objectives	42
7.3	Trial design	42
7.3.1	Study universe	43
7.3.2	Inclusion criteria	43
7.3.3	Exclusion criteria	44
7.3.4	Elimination criteria	44
7.4	Operationalization of variables	44
7.4.1	Independent Variable: Hydrating Drinks	44
7.4.2	Dependent variable: Hydration status	44
7.4.3	Variable box	46
7.5	Sample size	47
7.6	Randomization	47
7.7	Masking or blinding	48
7.8	Interventions	48
7.8.1	Flowchart	49
7.8.2	Execution protocol taking into account the epidemiological situation of CoVid-19	49
7.8.3	Hydrating drinks	52
7.8.4	Meal plan	53

7.9	Methods and statistical analysis.....	53
8	ETHICAL ASPECTS.....	54
9	RESULTS.....	55
9.1	Description of the subjects prior to the exercise sessions.....	56
9.2	RR, RRR and NNT tests.....	58
9.3	Frequency of hydration status per exercise session.....	58
9.4	Comparison between groups using Chi square test.....	59
9.5	Intragroup comparison in the different sessions.....	59
10	DISCUSSION.....	60
10.1	Limitations.....	61
11	CONCLUSION.....	62
12	PERSPECTIVES.....	62
13	REFERENCES.....	62
14	ANNEXES.....	68
14.1.1	Annex 1: Urine collection technique, conservation and analysis.....	68
14.1.2	Annex 2: Aspects to be evaluated to measure physical health as an inclusion criterion.68	
14.1.3	Annex 3: Criteria for measuring mental health in sports performance.....	69
14.1.4	Annex 4: Health protocol to be followed by the educational institution.....	69
14.1.5	Annex 5: Personal information collection sheet for each subject.....	70
14.1.6	Annex 6: CPRD Test.....	70
14.1.7	Annex 7: Correct weighing according to ISAK guidelines.....	78
14.1.8	Annex 8: Study authorization letter issued by the ISFPG institution.....	78
14.1.9	Annex 9: Request letter to carry out research within the ISFPG.....	80
14.1.10	Annex 10: Informed consent letter for father, mother, or guardian.....	82
14.1.11	Annex 11: Informed assent letter for the minor.....	83
14.1.12	Annex 12: Letter approved by the Research Ethics Committee of the State Institute of Cancerology in Spanish and English.....	84
14.2	Viability.....	86
14.2.1	Feasibility.....	86
14.2.2	Human Resources.....	86
14.2.3	Financial resources.....	86
14.2.4	Financing.....	86

14.3	Schedule of activities	87
14.3.1	CONSORT check list	88

INDEX OF FIGURES.

Figure 1.	Atomic structure of water.	9
Figure 2.	Electrostatic relationship of water.	9
Figure 3.	Mechanism of RAAS.....	14
Figure 4.	Graphical derivation of the phase angle and its relationship with resistance R , reactance (X_c) and impedance (Z).	28
Figure 5.	Parallel design of an RCT.....	43
Figure 6.	Randomization using the balanced block method.....	48
Figure 7.	Flowchart of the progress of the phases of a parallel RCT of two groups.....	49

TABLE INDEX.

Table1.	Percentage of water contained in the different tissues of the human body.	10
Table3.	Net body fluid balance and your average volume (mL) of water gain or water loss.	12
Table4.	Classification of AD based on clinical signs and symptoms.....	15
Table5.	AD classification with respect to Na^+ and water loss and its most common etiologies.	16
Table6.	Physiological responses of the organism to dehydration.	18
Table7.	Classification of PA and its intensity with respect to the METs used.	21
Table8.	Intensity classification according to the METs used in each sport per 1 hour of PA(30).	21
Table9.	Area of the state of Colima by type of climate and annual temperature in $^{\circ}C$	23
Table10.	Cut-off points for euhydration in the different indicators.	26
Table12.	Hydration status with respect to ACT loss by bioimpedance.	29
Table13.	State of hydration with respect to the percentage of weight loss (%PP).....	29
Table14.	Classification of hydrating drinks	30
Table16.	Chemical comparison between powdered oral electrolytes, Coconut Water and Electrolit $^{\circ}$ per 100 ml.	35
Table17.	Variable box	46
Table18.	Nutritional composition of the sports drink that will be used in the project (Electrolit $^{\circ}$).	52
Table19.	Description of the study population.	55
Table22.	Comparison of pre and post hydration indicators in the CW group.....	57
Table23.	Comparison of pre and post hydration indicators in the OE group.....	57
Table24.	General cross table of the state of hydration with respect to the assigned treatment.	57
Table25.	Estimation of RA, RR, RAR, NNT and RRR	58
Table26.	General table of sessions regarding treatment and hydration status.....	58
Table27.	Chi square broken down by sessions.....	59

ABBREVIATIONS:

CW: Coconut water.

TBW: Total Body Water.

ADH: Antidiuretic hormone.

PA: Physical activity

HD: Hydrating drinks.

EBI: Electrical bioimpedance.

GI: Glycemic load.

CRPD: Psychological Characteristics related to Sports Performance.

PE: Physical exercise.

ENSANUT: National Survey of Health and Nutrition.

OE: Oral Electrolytes

USG: Urine Specific Gravity.

USGf: Final Urine Specific Gravity.

USGi: Initial Urine Specific Gravity.

HCO: Carbohydrates.

IG: Glycemic index.

BMI: Body Mass Index.

ISFPG: Fray Pedro de Gante Salesian Institute.

LEC: extracellular fluid

LIC: intracellular fluid

BM: Body mass

UCol: Urine color.

WHO: World Health Organization

UOsm: Urine osmolality.

Wf: final weight

Wi: initial weight

WL: Weight loss

TBWL: Total body water loss

OW: Overweight

RAAS: Renin Angiotensin Aldosterone System.

1 ABSTRACT:

Introduction: Dehydration is a very common problem that is often not identified. The pediatric population is more susceptible to dehydration due to its physiological characteristics. Proper hydration is crucial for health since any degree of dehydration causes a reduction in physical and mental work capacity, hence the importance of preventing it by considering the type of drink. There are multiple beverage options, including industrial oral electrolytes (OE), on the other hand, coconut water (CW) has been studied as a natural alternative beverage with characteristics that can help maintain a state of euhydration.

Purpose: To determine if CW has a greater effect on hydration status than EO in adolescents who perform physical exercise. **Materials and methods:** RCT, double blind. 34 subjects aged 13.02 ± 1.08 years were selected, assigned to treatment with either OE (Electrolit®) or CW. They received a weekly physical exercise session (4 weeks). Hydration was personalized (ml x kilograms of weight) and hydration was evaluated by Urine Specific Gravity (USG), Total Body Water (TBW) by bioimpedance and changes in body mass.

Results: There were no significant differences in hydration in the first 3 exercise sessions ($p > 0.05$), however, in the last session there was a significant difference between treatments ($p = 0.003$). **Conclusion:** CW and OE have the same effect on hydration levels in adolescents who perform physical exercise, except for the last session where the effect was beneficial with CW compared with OE.

2 INTRODUCTION

Sports nutrition is a specialized branch of nutrition, which is responsible for taking care of nutrition and hydration before, during and after exercise or competition in athletes. Physical activity has been related to the prevention of chronic non-communicable diseases thanks to its protective health benefits, however, dehydration is a very common problem that occurs in the population that performs physical activity, exercise, or sports. Hydration status is difficult to measure because it is a dynamic process; that is to say, it is constantly modified and varies in each individual so, to measure the state of hydration, what is actually examined is the variation instead of the absolute degree of hydration through different methods such as plasma osmolality, isotopic dilution, bioimpedance, urine specific gravity, urine color, and

changes in body mass. Many times, it is not possible to identify dehydration because there are no signs or symptoms in its first stages and when the thirst mechanism is activated there is already a degree of dehydration.

The pediatric population is more susceptible to dehydration due to its physiological characteristics and its low capacity for thermoregulation. Proper hydration is crucial for health since any degree of dehydration causes a reduction in physical and mental work capacity, hence the importance of preventing it by considering the type of drink, quantity, and administration times. There are currently multiple beverage options, including industrial oral electrolytes, which have been shown in different studies to induce weight gain due to the high amounts of added sugar they contain and tooth wear due to acidic pH (1,2). On the other hand, Coconut Water (AC) is a natural alternative drink with chemical characteristics that can favor an optimal state of hydration in addition to being a fruit that is easily found in the state of Colima.

3 THEORETICAL FRAMEWORK

3.1 Water

The common name applied to the liquid state of the compound of hydrogen and oxygen: H_2O (3). Water is the most abundant component of the human body, by itself the organism is unable to produce it in sufficient quantities to cover its needs, for which it must be considered as an essential nutrient for life.(4).

3.1.1 Composition and structure.

It is made up of two hydrogen atoms covalently bonded to one oxygen atom.(4). The oxygen atom and the two hydrogen atoms occupy the vertices of an isosceles triangle (Figure 1). The electrons of the molecule are arranged in such a way that accumulations of positive and negative charges are produced alternately arranged in space. This separation of charges causes the molecule to form an electric dipole.(3).

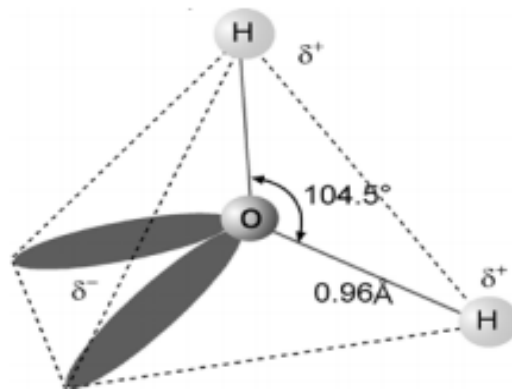


Figure1. Atomic structure of water.

Source: Aranalde, G (2015). Kidney Physiology.

This bond profoundly affects the physicochemical properties of water and is the basis of a series of essential functions for life. In fact, biological structures such as proteins and phospholipid membranes maintain their shape and structure through an electrostatic relationship with the water that surrounds them (Figure 2)(3).

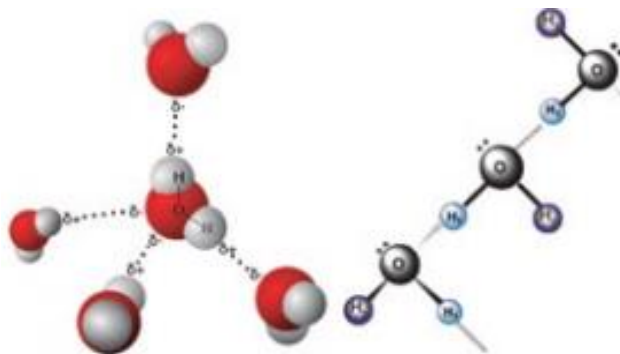


Figure two. Electrostatic relationship of water.

Source: Aranalde, G (2015). Kidney Physiology.

3.1.2 Functions

It is the main indispensable constituent of all cells, animal and plant, and life cannot exist in its absence even for a limited period.(3). Water fulfills many functions inside and outside our body, among the main ones is that it serves as a reactive and transport medium. It is the main cellular and blood component that transports nutrients, hormones and oxygen throughout the body, in addition to facilitating waste substances as well as giving structure to the body through the rigidity it provides to body tissues.(5). Water has thermal properties, so in physically active people it helps to maintain a constant body temperature balance, especially during prolonged exercise in a hot and humid environment.(6). Its high specific heat makes it an exceptional shock absorber and thermoregulator, thus maintaining constant body temperature. On the other hand, its high value of vaporization heat allows large amounts of heat to be eliminated through sweat, avoiding problems in organic systems and preserving us from “heat strokes”(7)In addition, studies have linked adequate water consumption with better quality eating plans, better health habits and a lower risk of developing chronic diseases(8). Water is found in all tissues in different percentages (table 1) and is essential for life, for this reason, human beings can live for several weeks without eating any food, but with water deprivation they could only survive a few days. The loss of just 10% of body water can already cause very serious disorders in the individual and the loss of 20% of water can cause death(9).

Table1. Percentage of water contained in the different tissues of the human body.

Body Tissue	Water (%)	Water (L)
Kidney	83	0.25
Lung	80	0.40
Blood	76	4.65
Brain	75	1
Muscle	76	22.10
Skin	72	10
Bone	22	2.45
fat cells	10	0.70

Source: Gonzalez MJ (2006). Water.

3.1.3 Distribution of Total Body Water (TBW)

The water content is variable between organisms of the same species. Young tissues have a greater amount of water, this is lost as they age. Table 2 shows the variations of the percentage of body water with respect to the total body mass according to age and sex.(3).

Table two. Evolution of the percentage of ACT according to age and sex.

Population	ACT (% body weight)	ACT (% body weight)
	women	males
>50 years	47 (39-57)	56 (47-67)
19-50 years	50 (41-60)	59 (39-57)
12-18 years	56 (49-63)	59 (52-66)
1-12 years	60 (49-75)	60 (49-75)
6 months-1 year	60 (57-64)	60 (57-64)
newborn-6 months	47 (39-57)	47 (39-57)

Source: Aranalde, G (2015). Kidney Physiology.

In parentheses is the normal body water percentage range for age and sex.

On average, 63% of the weight in an adult man is water, while in women, water is equivalent to between 50 and 55% of the total body mass because they have a higher proportion of body fat. In newborns, water occupies up to 75% of the weight(10). In adolescence they decrease slowly, being more pronounced in women, who after reaching puberty present 2%-10% less ACT(eleven). There are two large compartments into which the distribution of water in the body is divided and which differ in their volume and composition, they are called intracellular fluid (ICF) and extracellular fluid (ECF).(3). Approximately 65% of the water content in organisms is found in the cells and 35% in the extracellular space.(12). This last compartment is divided into interstitial fluid and plasma (aqueous content of the blood), which are equivalent to 75% and 25%, respectively, of the ECF.

3.1.4 Water homeostasis

Homeostasis is the exact regulation of the volume and composition of fluids in the body. Water balance is essential because small changes in water balance can cause major changes in metabolic processes. The human body is in homeostasis when it contains optimal concentrations of gases, nutrients, ions, and water. When this homeostasis is altered, it can cause health effects.(3.13). The daily water balance depends on the net difference between the gain and loss of water. Water gain comes mainly from 3 components: a) the water ingested through the thirst mechanism, b) the water contained in food and c) the water generated from metabolism, this last component provides very little water to the body (500 ml/day), so adequate daily water intake is important to maintain the body in homeostasis(5). On the other hand, body water losses have 4 main routes: a) insensible water losses that include breathing and evaporation through the skin, b) loss through sweat, c) losses from the digestive tract or feces and d.) loss through urine giving a water balance as shown in table 3(3).

Table2. Net body fluid balance and your average volume (mL) of water gain or water loss.

Source	Volume (ml)
Profits	
• Oral intake	2000
• from metabolism	500
Total	2500
Losses	
• Insensible skin losses	400
• Insensible respiratory tract losses	400
• sweat losses	100
• Fecal losses	100
• urine losses	1500
Total	2500

Source: Aranalde, G (2015). Kidney Physiology.

3.1.5 Thirst mechanism

The human body has developed a precise control system to maintain water balance through physiological adaptations, such as decreasing water through excretion through urine or increasing it through mechanisms that regulate thirst.(4.5). Thirst is stimulated when cell volume or extracellular space decreases. This mechanism is activated by decreasing the volume of water in the body causing plasmatic hyperosmolality, this is compensated by the outflow of water from the cells due to the osmotic gradient. Small changes in plasma osmolality, such as a 1% or 5% decrease in plasma fluid, stimulate secretion of antidiuretic hormone (ADH)(5), the osmoreceptors of the pituitary cells detect these changes as well as other similar receptors, in this way, two relatively separate mechanisms are activated, one that activates thirst and the other that prevents the escape of renal fluid through the Renin Angiotensin Aldosterone System (RAAS). These mechanisms can compensate each other when one of the two fails.(9).

The hypothalamus and adjacent preoptic regions play an essential role in the mechanisms of thirst, which is a sensation that occurs when there is a change in the internal environment that leads to cellular hypohydration (dehydration), thus thirst; appears when it is already too late, because there is already a degree of dehydration which is normally reached when there is a loss between 1-2% of the loss of body weight(12), however, there is an anticipation mechanism regarding stopping dehydration, where the water is still in the stomach and from there and even from the tongue the rehydration signal is sent to the brain, anticipating blood dilution by 10 to 20 min. If there is a thermal overheating, sweating immediately begins(9).

3.1.6 Renin Angiotensin Aldosterone System (RAAS)

The Renin-Angiotensin-Aldosterone System (RAAS) is a proteolytic cascade connected to a signal transduction system, establishing it as one of the most important elements involved in the regulation of blood pressure as well as the hydro-electrolytic balance of a human being(14).When there is a decrease in plasma volume, the renal baroreceptors sensitive to pressure changes activate the RAAS, increasing renin secretion, which will act on angiotensinogen by splitting this decapeptide from the liver to form Angiotensin I (AG I),

since obtained AG I, is proteolytically converted into angiotensin II (AG II) by Angiotensin Converting Enzyme (ACE), mainly at the pulmonary level. However, it is now known that many tissues, including blood vessels, kidney, heart, and brain, are also capable of locally generating AG II via non-ACE-dependent pathways. AG II acts through at least two classes of receptors, the AT-1 and AT-2 receptors. Once the AT-1 receptor is stimulated by AG II, expressed mainly in the adrenal cortex,(9.15)(Figure 3).

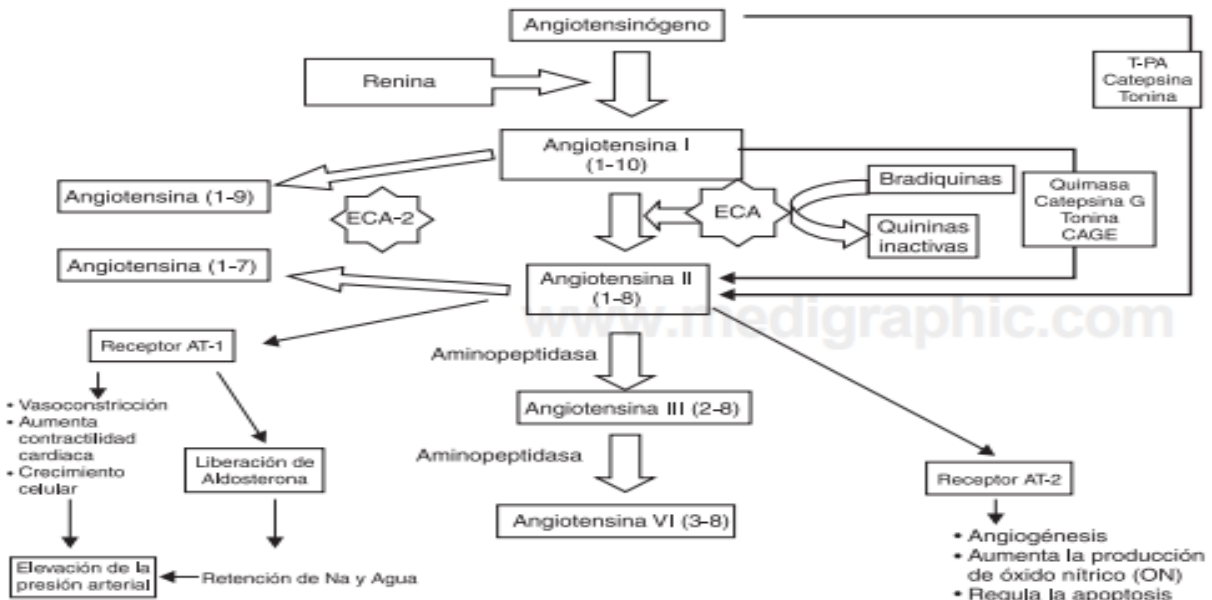


Figure2. RAAS mechanism.

Source: Contra, HS (2008). The renin-angiotensin-aldosterone system and its functional role beyond blood pressure control.

3.2 Hydration Status

The body's water remains constant in its levels in the healthy individual, however it does not mean that it is a static system, on the contrary, there is a constant dynamic state where there are mechanisms responsible for its internal and external regulation, between the individual and his environment, and on the other hand between the various fluid compartments of the body(3). The state of optimal water balance is called the state of euhydration in the English literature, which is defined as the normal storage and distribution of water in the body in total percentages inside and outside the cells to meet the physiological demands of the organism. according to their age, physical activity and health status, which were previously written in

the distribution section of the ACT(16). On the other hand, acute dehydration (AD) is defined as the clinical state following the loss of water and solutes(17). It is an acute process in which water losses are equated to sudden weight loss(18).

3.2.1 Prevalence of dehydration

The general population, athletes or non-athletes and of different age groups, come to suffer dehydration without presenting signs or symptoms and therefore without being aware of it, which is why its incidence or prevalence is difficult to determine.(2.10). According to Arredondo et al, 2017, it was shown that in countries with dry or hot climates, 70% of children were found to be in a state of chronic dehydration with levels of dehydration of at least 2% with a significant deterioration of mental functions. (arithmetic ability, motor-visual tracking and short-term memory)(4).

3.2.2 Classification of dehydration based on the loss of water and sodium.

The classification of dehydration is based on the loss of water and electrolytes (mainly sodium and potassium) or by weight loss and its clinical signs as shown in Table 4.(18).

Table3.Classification of AD based on clinical signs and symptoms.

Signs and symptoms	mild AD	moderate AD	severe AD
Awareness	normal/alert	irritable/restless	clouded
Eyes	normal	sunken	Very sunken/dry
Tears	presents	Missing	Missing
mouth/tongue	pasty	dry	Very dry
Thirst	regular baby	Thirsty	unable to drink
Skin	negative fold	positive fold	very positive fold
Weight loss	<5%	5-10%	>10%
Fontanelle	Normal	depressed	depressed

Tachypnea	No	Mild	moderate
Blood pressure	Normal	Decline	hypotension/shock
Increased pulse	No	Mild	rapid and weak pulse
skin perfusion	Normal	cold	Acrocyanosis
urine flow	normal/poor	Oliguria	Oliguria/anuria
Urinary density	>1,020	>1,030	>1,035
blood pH	7.30-7.40	7.10-7.30	<7.10

Source: Trevino, SJ (2006). Acute dehydration. Rehydration.

Based on serum sodium levels, dehydration is classified as:

- Hypotonic: Hypotonic dehydration occurs when sodium is less than 130 mEq/L, indicating that fluid loss is less than electrolyte loss.
- Isotonic: plasma sodium ranges between 130-150 mEq/L, deducing that the loss of water and electrolytes is the same or similar.
- Hypertonic: sodium is greater than 150 mEq/L and the loss is mostly water.

There are several important electrolytes in acid-base regulation and hydration maintenance, however, sodium and potassium are the ones that are most involved in the state of hydration. Sodium is the main electrolyte present in the ECF while potassium is found in greater quantity inside the cell or ICF, therefore, potassium may be important to achieve rehydration by helping to retain water in the intracellular space(6). This distribution is important to maintain chemical-electrical gradients and ensure the correct function of the cell and its electrical communication with the whole body.(5). In the first two classifications, dehydration (hypotonic and isotonic) is eminently extracellular, since more sodium is lost than potassium, yet the last one it is fundamentally intracellular and potassium losses are greater than sodium losses(18,19). Regarding the etiology of these classifications, they are shown in Table 5.(Twenty).

Table4. AD classification with respect to Na⁺ and water loss and its most common etiologies.

	Na ⁺ in blood	H ₂ O loss	cases
--	--------------------------	-----------------------	-------

isotonic dehydration	Normal	Increased + electrolyte loss	Bleeding, fasting, anorexia, vomiting and/or diarrhea.
hypertonic dehydration	Increased	augmented	Diabetes insipidus, sweating, heat stroke.
hypotonic dehydration	Diminished	No loss	Excessive intake of liquids.

Source: Escudero, O (2010). Hydration

3.2.3 Fluid requirements in athletes

The Institute of Medicine (IOM, 2004) published the daily dietary reference for water consumption, where the Committee established the recommended daily intake of water for children and adolescents, which indicates that children from 1 to 3 years should consume 1.3 L/day; those 4-8 years old 1.7 L/day; those 9-13 years old 2.4 L/day; male adolescents between 14-18 years 3.3 L/day; girls 9-13 years old 2.1 L/day and female adolescents 14-8 years old 2.3 L/day(twenty-one). If the water deficit is moderate (200 ml/h), water needs can be met, but if the deficiency increases, ingestion will be less effective, since the digestive absorption of water cannot exceed 800 ml/h. One way to try to speed up the absorption of water is to add glucose and sodium.(9). Some practical recommendations are(22):

- Drink 5 to 7 ml/kg of weight 4 hours before the competition or physical exercise, in case of not urinating or dark urine, add 3 to 5 extra ml per kg of weight 2 hours before exercise.
- Immediately before physical exercise consume 200 to 400 ml of drink with a concentration of 5-8% HCO.
- During training consume 1.5 to 3 ml/kg every 15 to 20 minutes during the first hour of exercise.
- In competitions or exercises that last less than 2 hours but are of moderate to vigorous intensity, the same drink can be consumed in the final 4 times of the competition.
- After the competition, if you have lost 2% or more of body mass, you should consume more fluids, even if you are not thirsty, recommending 1.2 to 1.5 per kg of weight lost during exercise.

Although proper hydration should be based on the body weight of each individual; general recommendations have been established for practical purposes in clinical practice, such as the recommendations mentioned above by the IOM.

3.2.4 Consequences of dehydration

The loss of body water causes different alterations in the organism for which these alterations can suppose a degree of dehydration. It has been shown that dehydration during exercise causes significant changes in the physiology of the body's systems: cardiovascular, thermoregulatory, metabolic, and endocrine. As a result, the perceived exertion of activity may be increased when exercising in a dehydrated state and exercise discontinuation due to fatigue is accelerated. The alterations caused by the loss of water and solutes in these systems can in turn cause the advancement of fatigue during prolonged exercise, so the most outstanding effects of dehydration on a person's body are presented below. When 2% of water is lost, the ability to regulate body temperature decreases and there is an increase in temperature. With a 3% loss, cramps and dizziness occur and resistance to exercise decreases with the possibility of fainting and a greater increase in body temperature that reaches 38°. When reaching 4 to 6%, muscle strength decreases, and the muscles suffer contractures. Headaches appear and the temperature rises to 39°. When a 7 or 8% level of dehydration is reached, contractures are very present, with generalized physical exhaustion, paresthesia's (strange sensations in the limbs, such as cramps, tremors, etc.) with possible organ failure and heat stroke. Table 6 shows the physiological effects caused by dehydration in a person's body, therefore,(13).

Table5. Physiological responses of the organism to dehydration.

Gastric emptying rate	decreases
Incidence of gastrointestinal upset	increases
Splanchnic and renal blood flow	decreases
plasma volume	decreases

Plasma osmolality	increases
blood viscosity	increases
core blood volume	decreases
central venous pressure	decreases
Cardiac filling pressure	decreases
heart rate	increases
stroke volume	decreases
minute volume	decreases
Sweat rate at a given core temperature	decreases
Internal temperature at which sweat appears	increases
Maximum sweat rate	decreases
Skin blood flow at a given internal temperature	decreases
Internal temperature at which skin blood flow increases	increases
Maximum blood flow to the skin	decreases
Core temperature at a given exercise intensity	increases
Muscle glycogen utilization	increases
Endurance performance (simulated races)	decreases
Endurance capacity (exercise to exhaustion)	decreases

Source: Merida, WTO (2010). The importance of hydration in sport.

3.3 Physical exercise as an important factor of dehydration

It is important to establish the difference between PA and physical exercise (PE). PA is understood as any bodily movement that increases energy expenditure(23). On the other hand, PE is planned, structured, repetitive and purposeful physical activity with the final or intermediate objective of improving or maintaining physical condition.(24). During AF or EF, coupled with weather conditions, the muscles generate a large amount of heat that must be dissipated. This heat production by the muscles is proportional to the intensity of the work, so that in activities of short duration and high intensity (team sports) as those of longer duration and lower intensity (half marathon, marathon, cycling stages, triathlon, etc.) carried out in adverse temperature conditions, represent a risk of heat-induced injuries and, in turn,

this physiological process induces a loss of fluids and minerals in our body (dehydration), which we have to recover to establish organic homeostasis(25).

3.3.1 Types of physical exercise

There are two main types into which we can classify physical exercise, which are the aerobic type and the anaerobic type. Aerobic exercises are also known as dynamic exercises, within this classification, are low and medium intensity exercises, which are commonly used to lose weight, since it allows you to burn fat more quickly, for example, cycling, run or swim. By putting this method (aerobic) into practice, the body has a higher oxygen consumption, helps prevent cardiovascular diseases, lower blood pressure, cholesterol levels and blood glucose. On the other hand, anaerobic exercise, also known as "static", deals with those physical activities that require more effort, characterized by being of high intensity, such as lifting weights or another type of activity for skeletal muscle toning; are carried out in short series. The benefits it provides list the improvement of flexibility, elasticity and resistance of the body, this due to the repetitions of the exercise, as well as reducing the amount of fat and strengthening the joints(26). There are many different types of physical activity that serve to develop various aspects of physical fitness. The most important types of physical activity for child and youth health are activities related to cardiovascular (aerobic) work, those related to strength and/or muscular endurance, flexibility and, lastly, coordination exercises.(27). The global recommendations of the World Health Organization (WHO) suggest that children and adolescents should spend at least 60 minutes a day in physical activities of moderate to vigorous intensity, mainly aerobics, and perform muscle and bone strengthening activities, at least 3 times a week(28).

3.3.2 Exercise intensity

The measurement of the quantity and quality of AF or EF has become increasingly important, for this, accelerometry seems the most reliable objective instrument, that is, valid and reproducible to be able to measure the intensity of the exercise, however, a drawback of this instrument or technique is hardly applicable for clinical use, in primary care practice, office or other settings. On the other hand, epidemiological studies require a large number of subjects, resulting in a cost problem.(29). Intensity involves time and volume and is classified

with respect to the energy required based on the basal energy. There are simpler (reliable and inexpensive) methods to measure exercise intensity, for example, the metabolic equivalent task or MET for its acronym in English. METs is the unit used to describe the energy expenditure of a specific activity with respect to the expenditure at rest, for example, a MET is the energy index considered for the energy expenditure at rest, therefore an activity of 3 METs means an expenditure 3 times higher than the energy at rest(24). Tables 7 and 8 show the classification of intensity in PA and intensity performed by sport, respectively.

Table6. Classification of PA and its intensity with respect to the METs used.

intensity level	Absolute intensity: METs	Relative intensity: perception scale, where 0= rest and 10=maximum effort.
Short	1.1-2.9	
moderate	3.0-5.9	5-6 (45-64% aerobic capacity)
vigorous	6.0 METs or more	7-8 (65-84% aerobic capacity)

Source: Boullosa, B & Casas, I (2011). Physical activity for health. In: nutrition applied to sport.

Table7. Intensity classification according to the METs used in each sport per 1 hour of PA(30).

<i>Exercise</i>	<i>MET</i>	<i>Classification</i>
Yoga (Surya Namaskar)	3.3	moderate
Baseball	4.0	moderate
Golf	4.3	moderate
volleyball	4.5	moderate
Dance (Jazz, Ballet)	5.0	moderate
Basketball	6.5	vigorous
Playing football (soccer)	7.0	vigorous
Jogging	7.0	vigorous
Running (7.5Km/H)	13.0	vigorous

Bicycle (heavy duty)	14.0	vigorous
Swimming (vigorous pace)	15.6	vigorous
Running (10Km/H)	16.0	vigorous

Source: Muntané, M (2017). How to measure exercise intensity: METs.

According to the previous tables (Tables 7 and 8), it was considered unnecessary to use an accelerometer, heart rate or oximetry instrument since the exercise to be performed is already categorized as vigorous intensity.

3.3.3 Prevalence of dehydration in athletes

During PE in a cool, dry environment, sweat loss can be as little as 250 milliliters per hour; on the contrary, in a hot and humid environment, the amount of sweat of a physically trained and well-acclimatized athlete can exceed 2,500 milliliters per hour. Due to climatic conditions, exercise, hydration habits and chronic-degenerative diseases, it is difficult to determine the prevalence of dehydration in the general population due to the constant changes in composition since it is a dynamic process and varies in each individual(31). Dehydration is cumulative, in other words, it is understood as a progressive process of the athlete in successive days of physical exercise if he does not hydrate completely.(Two).

3.4 Factors that alter hydration status

3.4.1 Obesity

Childhood obesity has emerged as one of the main public health problems, alarmingly increasing its prevalence and its multiple and serious comorbidities. The term obesity refers to an excess of body fat.(32). In the last three decades, the prevalence of global overweight and obesity has increased worldwide, with an estimated 170 million children (under 18 years of age) due to sedentary lifestyle and poor eating habits(33). Therefore, it is imperative to consider exercise and physical activity as prevention and a way to combat the epidemic of childhood obesity.(3. 4). The 2018 Health and Nutrition Survey has reported a combined

prevalence of overweight and obesity in the population aged 12 to 19 years of 38.4%, where overweight was 23.8% and obesity 14.6%, that is, it increased 3.5% with respect to the data of 2012 in the combined prevalence. Taking into account the premise that the ACT in the organism can vary between 55% and 70% in individuals due to the different characteristics of body composition(35), that is, the water content in fatty tissue is approximately 10–15%, while in muscle tissue it is approximately 75%, so the aqueous fraction of body mass varies inversely with the degree of obesity . This value is much lower when calculated as the fraction of lean mass where skeletal muscle tissue contains more than 75% water.(3).

3.4.2 Climate

In the state of Colima there are 4 types of climates, predominantly the warm sub-humid climate in 78.52%, with 12.42% of its territory presenting dry and semi-dry climate, on the other hand, the semi-warm sub-humid climate has 7.58% of the territory, and In the northern part of the state, on the slopes of the Colima Volcano, the temperature decreases, so it presents a Subhumid Temperate climate with the minimum percentage of 1.48%. The average annual temperature is 25°C with maximum temperatures greater than 30°C and minimum temperatures of 18°C, as shown in table 9.(36).

Table8. Area of the state of Colima by type of climate and annual temperature in °C.

Type or subtype			Symbol	Total R
Warm sub-humid with summer rains			A(w)	78.52
Semi-warm sub-humid with rains in summer			AC	7.58
Subhumid temperate with summer rains			C(w)	1.48
Very warm and warm semi-dry			BS1(h')	12.42
Station	Period	Average temperature	coldest temperature	hottest temperature
Cauhtémoc	1981-2016	23.7	21.4	25.5
Manzanillo (observatory)	1961-2016	26.6	20.3	33.0
Callejones	1946-2016	26.6	23.5	29.3

Comala ETA	1987-2016	24.3	22.9	26.1
Los Otates veladero	1966-2016	25.1	21.5	26.7
Colima (observatory)	1966-2016	25.6	23.8	28.1
Minatitlan	1965-2016	23.2	21.3	26.3
Armory	1948-2016	26.6	23.5	28.7

Source: National Water Commission. Monthly record of average temperature in °C.

Weather conditions are a strong factor in altering hydration status, especially in climates with high temperatures. In hot climates (31 to 32°C) the rate of sweating increases and therefore dehydration of 2% of body weight can be obtained in 60 min of intense exercise, reducing sports performance in addition to reducing cognitive/mental performance(5). Any rise in ambient temperature of 1 °C greater than 30 °C increases water requirements (30 ml/kg). If the heat is extreme and sweating is very important, the feeling of thirst is not as intense as it would correspond to the greater need for water, so it should be prevented by considering the amount and type of drink(9). Extreme environmental conditions (both hot and cold) represent a challenge to the body's thermoregulatory mechanisms and cause serious damage to the health of the athlete, for this reason it is essential to establish adequate hydration guidelines to improve and prevent possible problems, as well as how to increase sports performance. The main cardiovascular and thermoregulatory adaptations occur during the first few days of training in the heat, with full adaptation being achieved within 14 days. However, 75% of physiological acclimatization responses occur by the end of the first week. To do this, it is necessary to train in hot environments at temperatures between 25-35°C, intensities between 60-75% of VO₂max (above the Aerobic Threshold),(25).

3.4.3 Feeding Habits

Within the branch of medicine, specifically nutrition, hydration has become a leading country in Spain, a science in itself. One of the most pioneering and representative definitions of hydration is "the contribution of water, as an essential non-caloric nutrient, from food and beverages"(8). Studies have shown that athletes can recover the fluid lost by sweating during

training or competition, which shows that this problem is a voluntary cause. Some of the risk factors for dehydration are the daily eating and hydration habits and the state of hydration with which they arrive at the practice, secondly, the lack of hydration or insufficient hydration during this time(37). Some of the guidelines on daily water needs have shown that children and adolescents drink less than the adult population, coupled with their low consumption of foods high in water (fruits and vegetables) since children do not feel the need to drink enough amount of water to replenish the loss of liquids lost during prolonged exercise, making them more susceptible to dehydration, this being the main cause of the excessive increase in body temperature, which predisposes the person to suffer from heat stroke(21,38).

3.5 Diagnostic methods of dehydration

Selection of an appropriate hydration assessment method is a controversial aspect of fluid balance science. All hydration assessment techniques vary greatly in their applicability due to methodological limitations such as the circumstances required for measurement (reliability), ease and cost of application (simplicity), sensitivity to detect small but significant changes in the state of hydration (accuracy) and the type of dehydration expected(39). Hydration status is difficult to measure because it is a dynamic process; that is, it is constantly modified and varies in each person. Another problem is that in many tests to measure hydration status, what is actually examined is "the variation" rather than the absolute degree of hydration.(31). When greater precision of acute changes in hydration is sought, plasma osmolality, isotope dilution, and changes in body mass, used in an appropriate context, provide the precise gradation of measurements frequently required in scientific research.(Twenty-one). Table 10 shows defined thresholds for complex and simple indicators of hydration recommended in athletes to guide the distinction between euhydration and dehydration. For the present study, 3 indicators will be used (GEO, change in ACT and change in body mass) where the fluid balance will be considered adequate when the results of any two evaluations are consistent with the euhydration thresholds (Table 10).(39).

Table9. Cut-off points for euhydration in the different indicators.

Evaluation technique	Practicality for the athlete	Acceptable euhydration cutoff point
Change in total body water (L)	Short	<2%
Plasma osmolality (mOsm)	Half	<290
GEO (g/mL)	high	<1,020
Urine osmolality (mOsm)	high	<700
Urine color (#)	high	<4
Changes in body mass (kg)	high	<1%

Source: Cheuvront, SN (2005). Evaluation of hydration in athletes.

3.5.1 Gold standard

The combination of total body water by estimation of the dilution of trace amounts of an isotope (usually deuterium oxide, $2H_2O$) and plasma osmolality provides the "gold standard" for hydration assessment. higher accuracy and reliability(39,40). The isotope dilution method is the most accurate and widely used way of determining ACT. The word isotope (“same place”) of an element in the periodic table refers to an element that differs from the parent element in atomic weight without affecting chemical properties. Despite being an easy method to perform and not using radiation, it is a time-consuming and expensive study. This makes it hardly applicable in clinical practice, although being the reference method for estimating body water, it can be used to confirm the data obtained by simpler methods.(41). Blood plasma osmolality accurately identifies a person's hydration status and is sensitive to changes in hydration status, during acute dehydration and rehydration.(40). Plasma osmolality is determined by the concentrations of sodium, potassium, glucose and urea nitrogen and its calculation is obtained with the following formula:

- Plasma osmolarity = $2(Na^+ + K^+) + \text{glucose}/18 + \text{BUN}/2.8$

Normal plasma osmolality is between 280 and 295 mOsmo/L(42). These “gold standards” of hydration assessment are good for sports science, medicine, or benchmarking, but because they require considerable methodological control, they are expensive, and they require skill.

analytical, they are not of practical use for monitoring hydration status on a day-to-day basis during training or competition(39).

3.5.2 Urine Specific Gravity (USG)

GEO or urinary specific density is a technique (whose collection, conservation and analysis are described in Annex 1) that measures the concentration of particles in urine and the density of urine compared to that of water. Measuring GEO is an easy and convenient method of estimating a patient's hydration status as well as the functional capacity of their kidneys.(43). Urinalysis is a frequently used clinical measurement to distinguish between normal and pathological conditions. Urinary indicators of dehydration include decreased urine volume, high UGE, high urine osmolality (OOsm), and dark urine color (OCol).(39). Normal GEO results in adults' range between 1010 and 1020 gr/cm³. Abnormal results are usually those below 1,010 or above 1,020(43). A child is relatively hydrated when the density is less than 1010g/l and relatively dehydrated when it is greater than 1020g/l. Urine with a urinary density of less than 1010g/l is called hyposthenuria, isosthenuria with a urinary density of 1010-1020g/l, and hyposthenuria with a urinary density greater than 1020g/l. The GEO results can classify the level of dehydration that a person may have as shown in table 11(44).

Table eleven. Hydration status with respect to GEO.

GEO (g/cm ³)	Hydration Status
>1,030g/cm ³	severe dehydration
1,020 to 1,030 g/cm ³	moderate dehydration
<1,020g/cm ³	Euhydrated

Source: Lozano, Triana (2016). General urine test: a useful test in children.

3.5.3 Total Body Water Loss by bioimpedance (PACT)

Numerous methods are known to estimate ACT, including bioimpedance, anthropometry, and the use of stable isotopes. Another estimation formula, widely used clinically, is the calculation of 60% of body weight or (Kg)*0.6(41). ACT loss is one of the most reliable indicators to measure and diagnose the degree of dehydration. There are two techniques to measure total body water, which can be isotope dilution or can be estimated by BIE(40). This is a technique that in some research is recommended as a method that accurately estimates

the hydration status of a person, however, the EIB is not a good method if it is used as a reference criterion or isolated, it can already show contradictory results(39). The BIE is an indirect technique to estimate body composition using the ACT with its advantages of being simple, fast, and non-invasive. By deduction of the water constants of the tissues, the fat-free mass (FLM) is obtained and by derivation, the fat mass (FM), through the equation based on two components ($\text{FFM kg} = \text{total weight kg} - \text{MG kg}$). These 2 vectors would agree with the equation $Z^2 = R^2 + X_c^2$. The R represents the resistance of the tissues to the passage of an electric current and X_c is the additional opposition due to the capacitance of those tissues and cell membranes (it is the so-called dielectric component), and these values depend on the frequency of the electric current. .(Four. Five).

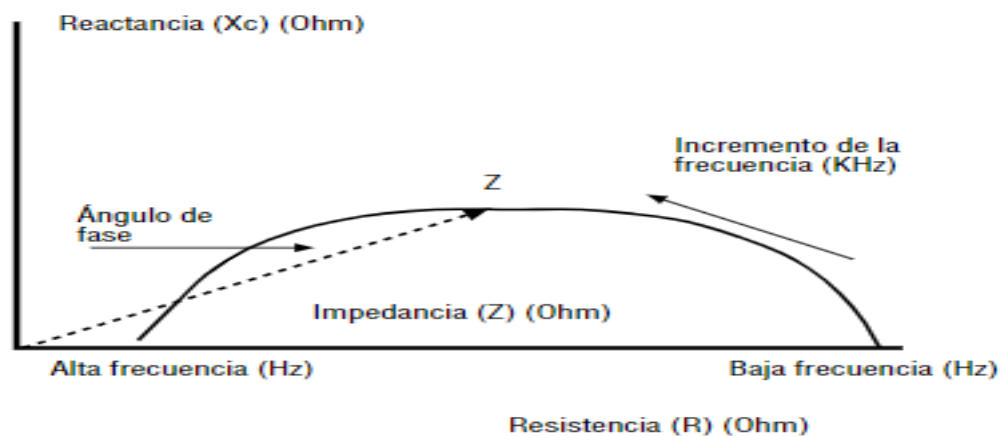


Figure3. Graphical derivation of the phase angle and its relationship with the resistance R , the reactance (X_c) and the impedance (Z).

Source: Alvero-Cruz JR; et al. (2011). Electrical bioimpedance as a method for estimating body composition, practical rules of use.

EIB can be affected by many different situations that must be considered, such as: body position, hydration, intake of food and drink, ambient air and skin temperature, recent physical activity and the conductance of the place where it is performed. Physical activity increases cardiac output and vascular perfusion, with a subsequent increase in blood flow to the muscle, as well as an increase in muscle and skin temperature, resulting in a decrease in

muscular endurance and an overall decrease of body impedance(Four. Five). The degree of dehydration can be classified based on the loss of ACT as shown in table 12(46).

Table10. Hydration status with respect to ACT loss by bioimpedance.

Percentage of water loss.	Hydration Status
>7%	severe dehydration
4 to 6%	moderate dehydration
2 to 3%	mild dehydration
<2%	Euhydrated

Source: Cirigliano, H (2018). Hydration and physical activity.

3.5.4 Total Body Mass Loss (TWBC)

Rapid and accurate estimation of changes in fluid balance is very important. It is difficult to determine the total volume of water with precision in each case, but an extremely useful and sensitive indicator of changes in body water content is the daily measurement of body mass.(3). Likewise, the percentage of weight loss is a good indicator of the state of hydration, classifying the state of hydration according to the percentage of body mass lost, as shown in Table 13. A loss of 1% of body weight causes a decrease 2.5% in plasma volume and represents mild dehydration(twenty-one). Acute changes in hydration are calculated as the difference in body mass before and after exercise and the percentage lost is subsequently calculated. The level of dehydration is best expressed as a percentage of initial body mass rather than a percentage of ACT, since the latter varies widely. The use of this technique implies that 1 g of mass lost is equivalent to 1 mL of body water lost.(39). The formula to calculate the percentage of weight lost considers the initial weight (Pi) and final weight (Pf), expressed as follows:

- $(P_i - P_f) * 100 / P_i$

Table11. State of hydration with respect to the percentage of weight loss (%PP).

Weight change percentage	Hydration Status
>5%	severe dehydration
3.1% to 5%	moderate dehydration
>1% to 3%	mild dehydration
< or equal to 1%	Euhydrated

Source: Mayol, L (2011). Thermoregulation and hydration in exercise. In: Nutrition applied to sport.

3.6 Hydrating drinks

With the advances in science and technology, new forms or strategies of sports preparation called ergogenic are born, which seek an improvement in physical capacity reflected in better sports performance. Ergogenic aids include substances, methods, drugs, equipment, and the improvement of those innate or acquired conditions. These aids are divided into non-nutritional and nutritional. Nutritional ergogenic aids include micronutrient supplementation and macronutrient supplementation in which hydrating drinks are included.(47). Hydration drinks are drinks that contain water, glucose and electrolytes to replenish the loss of liquids and mineral salts, in addition, they regulate body temperature, lubricate the joints and facilitate the absorption and transport of the nutrients necessary to obtain energy(48). In Mexico, the Federal Consumer Protection Agency (PROFECO) in the moisturizing beverage market has been classified into three different groups (Table 6).

Table12. Classification of hydrating drinks

type of drink	Characteristic
sports drinks	Made with the dissolution of mineral salts, sweeteners, or other ingredients in order to replenish the water, energy and electrolytes lost by the human body during exercise.
rehydration drinks	These types of products are solutions that contain electrolytes without sugars.

oral electrolytes	According to the General Health Law, in its article 226 section VI, they are "medicines that do not require a prescription to be purchased and that can be sold in establishments other than pharmacies", and that generally contain glucose and electrolytes, such as sodium and potassium.
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Source: Characteristics of the types of hydrating drinks according to PROFECO. Adapted from "Moisturizing Drinks", by PROFECO, 2018.

3.6.1 Oral electrolytes

According to the General Health Law, in its article 226 section VI, oral electrolytes can be defined as "medications that do not require a prescription to be purchased and that can be sold in establishments other than pharmacies", and that generally contain glucose and electrolytes, such as sodium and potassium(49). Being classified as a medicine, its use is based on the prevention and treatment of dehydration of different causes, mainly vomiting and diarrhea. Its administration provides sufficient amounts of water, sodium, chloride and potassium necessary to compensate for the losses in many mild to moderate cases that do not require parenteral therapy, and thus restore the fluid and electrolyte balance.(Fifty). Based on the results of a meta-analysis, in 2002, the WHO changed the formulation of oral rehydration salts to a lower osmolality (245 mosmol/kg) with a lower glucose concentration (13.5 g/L [75 mmol/L]. l]) and sodium (75 meq/L) while maintaining a 1:1 molar ratio of sodium and glucose. This new formula replaces the original, and is the only one used worldwide by the WHO(51). Currently the solution for oral hydration is constituted (in g/L) by: 3.5 sodium chloride, 2.9 trisodium citrate dihydrate, 1.5 potassium chloride and 20 glucose. This solution provides (in mmol/L): sodium 90, chlorine 80, potassium 20, citrate 10, and glucose 111 (total osmolality, 311 mosm/L). The administration and dose of oral electrolytes in children under two years of age consists of giving the necessary spoonful in a 24-hour period. Not to exceed 1200 ml in 24 h. In older than two years, the necessary tablespoons in a period of 8 to 24 hours. Thirst is a good guide to restore the required volume(fifty).

Hydrating drinks of any kind are consumed mostly by sportsmen or athletes, since they were designed to delay the depletion of glycogen stores during training or physical exercise, providing sufficient carbohydrates to maintain glucose levels in blood in addition to replenishing essential electrolytes such as sodium and potassium, which promote fluid retention and help prevent dehydration and are often more easily lost through sweat(52).

3.6.2 Disadvantages of using industrialized beverages

The prevalence of overweight and obesity in Mexico has been related to the high consumption of hyperenergetic beverages that are sweetened with added sugars, favoring positive energy balances that result in an increase in body weight(1). According to a study by the National Institute of Public Health of Mexico (INSP), beverages provide more than 20% of the calories in the Mexican diet, although it is recommended that they do not exceed 10%. In addition, 70% of the added sugars consumed by Mexicans come from sugary drinks, which has caused a serious problem of overweight, obesity and diabetes in our country.(53). Studies conducted by the University of Birmingham have found that sports drinks wear down the tooth enamel and dentin beneath them. Its high levels of acidity imply that the wear of tooth enamel is 30 times greater compared to plain water. Drinking these drinks during exercise worsens the situation since, since there is a shortage of saliva, there is no buffer against the acidity of the drink.(Two) in addition, the influence of advertising on the diet of children and adolescents that favors the consumption of foods and beverages with a high content of sugars, fats and/or sodium, directly linked to obesity. In another cohort study of adolescents in the USA, the research focused on the consumption of sports drinks and its relationship with weight gain. Each daily serving of sports drink was found to predict a 0.3-point increase in BMI in women and 0.33 in men. Therefore, its consumption was associated with greater weight gain and risk of obesity.(54).

3.6.3 Coconut water

The coconut plant belongs to the Arecaceae family, whose scientific name is *Cocos nucifera* and commonly known as coconut palm. It is a plant native to the Pacific Islands, and today cultivated throughout the tropics. It is the most cultivated and important palm in the world, since it is currently the main species that produces vegetable fat. It is one of the plants that provides the greatest diversity of products in the world, being a primary source of food and drink.(55). In Mexico, the commercial cultivation of coconut palms is over a hundred years old and for decades it was the engine of the economy of the coastal regions of the Pacific (Guerrero, Colima, Oaxaca, Michoacán, Sinaloa, Jalisco and Chiapas) and the Gulf and Caribbean (Tabasco, Veracruz, Campeche, Yucatan and Quintana Roo)(56).Coconut water is the liquid found naturally inside the fruit surrounded by the pulp of the coconut. It is transparent in color, sometimes a little opaque, and has a characteristic sweet flavor when it reaches its ripening point.(53). Coconut water has a low caloric value, however, most of its composition is sugars, and it is considered a natural isotonic drink, being highly appreciated for its little manipulation since it is taken by extracting it directly from the fruit, which is why it is recommended among athletes for promote recovery after physical activity. This food also has antioxidant properties that help delay cell aging.(55).

3.6.4 Chemical composition of coconut water

Coconut water can vary by species, place of origin and maturity of the coconut (young or green coconut water is fresher and more functional)(53). The average nutritional composition is shown in table 15.

Table fifteen. Average nutritional contribution of natural coconut water in 100 ml.

Component	Coconut water
Energy (kcal)	twenty
Proteins (gr)	0.1
HCO (gr)	5.5
Lipids (gr)	0.05
Sodium (mg)	25

Potassium (mg)	160
Chlorine (mg)	twenty
Calcium (g)	5
Phosphorus (mg)	0.4
Magnesium (mg)	0.45

Source: FAO.

The chemical composition of coconut water is affected by several factors. Coconut water from different varieties of coconut contains different concentrations of compounds, and since the chemical content also varies in addition to the different stages of maturity, the soil and environmental conditions also affect its composition.(57). Coconut plantations are established in the coastal zone, on sandy soils, poor in organic matter and N. The soil has a sandy texture with 90.92, 3.28 and 5.80% sand, silt and clay, respectively. The low productivity results in low income per unit area, so the application of appropriate fertilizers is a viable alternative to increase the yield of the coconut crop using essential elements such as N and K, giving variability to the chemical composition of the coconut, especially in you go out(58). A study carried out in Brazil showed that the physical properties of AC were affected by the variable application of nitrogen and potassium(57). The differences in the concentration of potassium and salts (WHO/UNICEF) contain 20 mmol/L and the green AC ranges between 32.6 and 53.5 mmol/L(59).

Currently AC has been widely studied since it contains electrolytes and an osmolality similar to that of intestinal content, which facilitates its absorption, reducing the possibility of dehydration.(53). AC contains cytokinin that promotes cell regeneration, in addition, its high content of potassium and other electrolytes promotes adequate blood pressure, helping to prevent heart disease. This electrolyte (K⁺) is extremely important for the prevention and treatment of dehydration, since losses are high and if not corrected it can aggravate dehydration, so coconut water can be used as a moisturizing and rehydrating solution due to its content of this electrolyte(53.59), has also been used successfully in various parts of the world as a therapy for oral rehydration, treatment of childhood diarrhea, gastroenteritis and cholera(60). Other applications and benefits of coconut water are:

- Its consumption in fresh represents an important source of energy for the human organism, but in addition the pulp offers is a protagonist in the elaboration and manufactures of confectionery.
- Coconut water is used as a refreshing drink and as an ingredient for stews, ice cream and dishes.
- In the beekeeping sector it plays an important role, as the flowers are excellent food for bees.
- In medicine it has many applications, among which are: antiseptic, astringent, bactericide, diuretic, etc.
- In many tropical countries it is used as a popular remedy against asthma, bronchitis, bruises, burns, constipation, dysentery, cough, fever, flu, etc.

Within all these uses and benefits of coconut and coconut water, it should be kept in mind that the best way to consume coconut is fresh (freshly cut and opened).(53).

Although AC is already well studied in terms of its chemical content, there may still be unknown solutes that contribute to its special biological effects. With the development of more advanced detection techniques, the detection can be intensified to detect new compounds of medicinal value present in it, therefore, future studies should be carried out to determine the factors that produce the desirable chemical composition for a specific purpose. Breeding studies can also be carried out to produce AC enriched with specific chemical compounds(57).

3.6.5 Chemical comparison between oral electrolytes, Coconut water and Electrolit®

Table13. Chemical comparison between powdered oral electrolytes, Coconut Water and Electrolit® per 100 ml.

	oral electrolytes	Coconut water	Electrolit®
Energy (kcal)	8	22	twenty
Proteins (gr)	-	0.1	-
HCO (gr)	two	5.5	5
Lipids (gr)	-	0.05	-
Sodium (mg)	35	25	12
Potassium (mg)	150	160	149
Chlorine (mg)	284	twenty	106
Calcium (g)	-	5	0.03
Phosphorus (mg)	-	0.4	-
Magnesium (mg)	-	0.45	14.2

Own source

4 BACKGROUND.

There are currently few studies on the effect of AC on hydration status in athletes, in addition to being studies on adults, since the bibliography on the comparison of beverages (coconut water vs. sports drink) is almost null, and it is null when comparing oral electrolytes.

In a study conducted by Castro-Sepúlveda, et al. 2015 in Chilean professional soccer players, a prevalence of dehydration of 98% was reported by Urine Specific Gravity (USG) before training, of the 156 athletes evaluated, only one subject (0.6%) presented euhydration. 9% (14 subjects) showed mild dehydration, 76.9% (120 subjects) moderate dehydration, and 13.5% (21 subjects) severe dehydration(61)so this study clearly shows us the lack of habits in terms of hydration. Cheuvront S. and Sawka M. in their 2005 study that aimed to evaluate several common methods for assessing hydration status found that although measurements of plasma osmolality and total body water are currently the best assessment measurements of hydration, there is currently no consensus to prefer any proposal over the other in sports contexts. In most circumstances, the use of body mass measurement combined with some measurement of urine concentration (GEO, OOSm, and OCol), offers a simple method of evaluation and allows a wide sensitivity to detect significant deviations in urine concentration. fluid balance (>(39). In the Yucatan Peninsula, Mexico, Pérez NGU carried

out a study in 2014 where the consumption preferences of coconut derivatives (*tuba*, coconut water and virgin coconut oil) were evaluated through sensory tests, surveys, and tastings at food events. Dissemination, with the main objective of contributing to the knowledge of the behavior of the coconut palm consumer and, specifically, of *tuba*, virgin oil, and coconut water, where an acceptance of 93.9%, 94% and 87% respectively was obtained. Both consumers and non-consumers of coconut water expressed their interest in incorporating bottled coconut water into their habits. 52.67% reported that they would do it weekly, among the factors they mentioned, the flavor and nutritional properties stand out.(56).

Among the studies carried out where AC is compared with other hydrating drinks is the study by Saat, M, et al. 2002 which is entitled "Rehydration after exercise with fresh young coconut water, carbohydrate-electrolyte beverage and plain water" where 8 healthy subjects aged 22.4 ± 3.3 years were included with the aim of comparing plain water, coconut water and beverage with carbohydrates and electrolytes. To measure rehydration status, they used blood samples, urine samples, and evaluated body mass before and after exercise. A volume of liquids equivalent to 120% of water loss was administered, dosed as follows: 50% before exercise (781 ± 47 ml), 40% during exercise (625 ± 33 ml) and 30% post exercise (469 ml). ± 28 ml) resulting in 120%. The drinks were administered randomly. The percentage of weight lost and regained after rehydration was not statistically significant in the different sessions. On the other hand, blood volume was measured, and fluid restoration was much better with coconut water, although it was not statistically significant between the other two drinks used. The accumulated urine was not different between the sessions, in addition to there being no difference with the osmolality of sodium and chloride in serum, the only significant thing was the concentration of plasmatic glucose that was elevated compared to plain water when the periods of hydration were with coconut water and sports drink On the other hand, blood volume was measured and fluid restoration was much better with coconut water, although it was not statistically significant between the other two drinks used. The accumulated urine was not different between the sessions, in addition to there being no difference with the osmolality of sodium and chloride in serum, the only significant thing was the concentration of plasmatic glucose that was elevated compared to plain water when the periods of hydration were with coconut water and sports drink On the other hand, blood volume was measured and fluid restoration was much better with coconut water, although it was not statistically

significant between the other two drinks used. The accumulated urine was not different between the sessions, in addition to there being no difference with the osmolality of sodium and chloride in serum, the only significant thing was the concentration of plasmatic glucose that was elevated compared to plain water when the periods of hydration were with coconut water and sports drink(62). On the other hand, the study entitled “Coconut Water Does Not Improve Markers of Hydration during Sub-Maximal Exercise and Performance in a Subsequent Time Trial Compared to Water Alone” was carried out with the purpose of comparing markers of hydration during sub-maximal exercise and performance. Of sub-maximal exercise and subsequent to the study time consuming plain water or coconut water. There was also a secondary objective which evaluated coconut water palatability during exercise and voluntary consumption during vigorous exercise. Ten men aged 27.9 ± 4.9 years, body mass 78.1 ± 10.1 kg, and mean maximum minute of power 300.2 ± 28.2 were evaluated completing 60 minutes of submaximal cycling, followed by 10 km against the clock on two occasions. During the tests, the participants consumed plain water or coconut water randomly, drinking 250 ml of the assigned drink between 10-15 min, 25-30 min and 40-45 min, and then drinking at will from minute 55 until finishing. The proof. Body mass and urine osmolality were recorded before exercise and then after 30 min, 60 min, and after the time trial. During each drink period, blood glucose, lactate, heart rate, rate of perceived exertion (RPE; 6-20), and ratings of thirst, sweetness, nausea, satiety, and upset stomach (1 = very high) were recorded. Low / not at all, 5 = very high). Coconut water did not significantly improve time trial performance compared to water alone (971.4 ± 50.5 and 966.6 ± 44.8 seconds, respectively; $P = 0$).(63).

It is important to note that a very low sample size was used in both studies, so studies with a larger sample size are required to allow us a more accurate or adequate determination of the effects on our study variables. In addition, it should be noted that both studies were carried out in the adult population, unlike the present research work, which will work with the pediatric population, who, due to their different physiological characteristics, could yield different results.

5 PROBLEM STATEMENT

The objective of sports-related nutrition is to cover all stages related to sports, including training, competition, recovery, and rest. Proper hydration, especially in pediatric stages, benefits sports performance and is crucial for health, since during physical exercise, children are at greater risk of dehydration due to their physiological characteristics that make them less effective at eliminating heat. bodily(two)In addition, due to the established recommendations, where children should perform at least 60 minutes of moderate or vigorous intensity aerobic physical activity per day, it is necessary to emphasize that dehydration according to Bean A. 2010, in the complete athlete's guide, mentions that it is cumulative, so if children and adolescents do not receive proper daily hydration, the risk of suffering a higher degree of dehydration increases(2.28). Hydration is an aspect that should not be taken lightly by health personnel and by personnel who remain in contact with children when they perform physical exercise within their sport, this personnel includes parents, teachers or coaches(12). There are currently multiple beverage options available to the consumer, including isotonic beverages. These drinks, thanks to their content of carbohydrates and electrolytes (mainly sodium), contribute to maintaining the athlete's hydration at all stages of training and/or competition (before, during and after). Keep in mind that plain water is not the ideal beverage for post-exercise rehydration when rapid and complete restoration of fluid balance is necessary and where all consumption is in liquid form. Plain water ingestion after exercise-induced dehydration of 4% of body mass causes a large decrease in plasma osmolality followed by copious diuresis.(6). In recent years, a new technique for using these drinks has been developed that consists of rinsing the mouth with them and then expelling the liquid without ingesting it. Although it is still under study, the purpose of this technique is to obtain the benefits of sports drinks, avoiding some of the adverse effects derived from their ingestion. The problem with the wide range of beverages available to the consumer is the lack of knowledge on the part of the latter of how to use them correctly, which can lead to the appearance of adverse effects derived from misuse or excessive consumption.(52).

6 JUSTIFICATION

The purpose of this study is to compare the hydration effects of AC as an alternative drink to industrial EOs in adolescents who perform physical exercise. Currently there are no studies that have evaluated AC in adolescent athletes, so this study can generate knowledge of this drink in an unstudied population.

Water is the most abundant component of the human body, which by itself is unable to produce in sufficient quantities to satisfy its needs; That is why it is vital to consume an adequate amount to maintain homeostasis, since small changes in the water balance can cause important modifications in metabolic processes.(4). This non-caloric nutrient is involved in almost all functions of the human body, particularly important in thermoregulation and physical and cognitive performance.(10) On the other hand, a lack of hydration has disadvantages and these are more evident when carrying out prolonged or high-intensity exercise in hot conditions. A deficit of less than 2% of the athlete's body mass has been shown to decrease exercise capacity and performance by detectable amounts. It has been commonly reported that performance declines when the individual becomes dehydrated to as little as 2% of body weight, and that losses in excess of 5% of body weight can decrease work capacity by approximately 30%.(37). Experts indicate that regular consumption of water maintains good health and even helps prevent non-contagious diseases related to nutrition, so the absence of this nutrient can be fatal in days. children who play sports in hot climates such as the state of Colima, they are especially susceptible to the development of involuntary dehydration(4). The sweating rate is lower in children, for this reason their core temperature increases to compensate for the production of sweat, causing heat stroke, for this reason it is possible that the hydro electrolytic needs in children are higher than in an adult(5).

Industrial hydration drinks (sports drinks or oral electrolytes), although they can help maintain water and electrolyte levels in adolescents who perform vigorous physical activities, have different disadvantages such as the Acidic pH and high content of added sugars that is closely related to the prevalence of overweight and obesity in Mexico. This has led to opt for alternatives in the type of beverages used by children and adolescents, considering AC an alternative to hydrate the pediatric population due to the chemical composition Of the C. AC is currently considered a hydration option due to containing a higher average contribution of

K⁺ than conventional EO. This electrolyte is essential for the prevention and treatment of hypertonic or intracellular dehydration, which is more common in exercise due to high sweating. In which water and electrolytes are lost. The deficiency of the electrolyte K⁺ translates into muscle weakness in addition to presenting cardiac arrhythmias, for this reason, AC causes manifestations of hypokalemia to be less frequent and can maintain a better general state, in addition to its osmolality (255 and 333 mOsm/ kg of water) similar to that of the intestinal content (210 and 330 mOsm/kg of water) facilitates its absorption and due to its limited handling and its composition(53), considering that it is a better option for athletes for their hydration and better sports performance, without adverse effects as with EOs, which gives rise to the research question.

6.1 Research question

What is the effect of coconut water compared to conventional oral electrolytes on the state of hydration in adolescents who perform physical exercise belonging to the *Fray Pedro de Gante* Salesian Institute (ISFPG)?

7 MATERIAL AND METHODS

7.1 Hypothesis

7.1.1 Work hypothesis

AC has a greater hydration effect than EO in adolescents who perform competitive physical exercise.

7.1.2 Null hypothesis

AC does not have a greater hydration effect than EO in adolescents who perform competitive physical exercise.

7.1.3 Alternate hypothesis

EOs have a greater hydration effect than AC in adolescents who perform competitive physical exercise.

7.2 Objectives

7.2.1 General objective

To determine the effect of AC vs EO on the state of hydration in adolescents who perform competitive physical exercise belonging to the ISFPG.

7.2.2 Specific objectives

- Administer AC in the experimental group and EO in the control group in adolescents who perform competitive physical exercise belonging to the ISFPG.
- Determine the state of hydration using the following indicators:
 - ✓ To calculate the percentage of weight change through the initial weight and final weight in adolescents who perform competitive physical exercise belonging to the ISFPG.
 - ✓ To determine the percentage of ACT through BIE before and after physical exercise in adolescents belonging to the ISFPG.
 - ✓ To quantify and compare the GEO by means of a refractometer before and after each training session in adolescents who perform physical exercise belonging to the ISFPG.
- To compare the state of hydration between the groups that received AC vs. EO in adolescents who perform competitive physical exercise belonging to the ISFPG.
- To compare the intra-group hydration status in adolescents who perform competitive physical exercise belonging to the ISFPG.

7.3 Trial design

The present study is presented as a Randomized Controlled Clinical Trial (RCT), double-blind, and parallel design (Figure 5).

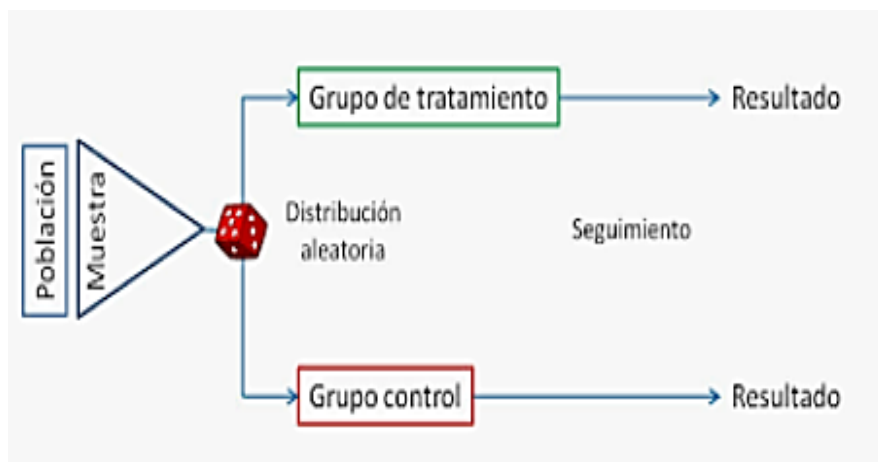


Figure4. Parallel design of an RCT.

Source: Lazcano-Ponce E, et al. (2004). Randomized clinical trials: variants, randomization methods, analysis, ethical considerations, and regulation.

7.3.1 Study universe

Adolescents from 12 to 17 years old who belong to the ISFPG and perform competitive aerobic physical exercise.

7.3.2 Inclusion criteria

- That the adolescent is a student belonging to the private institution ISFPG.
- That the adolescent perform competitive physical exercise of an aerobic type (soccer, basketball, volleyball, cycling, among others).
- Those students who are 12 years old and who are under 18 years old.
- The parent or guardian of the adolescent and the student himself must agree to participate and comply with the autograph authorization of the informed consent letter.
- The adolescent must be in good physical (Annex 2) and mental (Annex 3) health.

7.3.3 Exclusion criteria

- Adolescents suffering from a chronic disease such as obesity, hypertension, DM, asthma, COPD, cancer, injuries or physical disabilities.
- That the adolescent is allergic to any component of the treatments.

7.3.4 Elimination criteria

- Adolescents who do not complete physical training sessions.
- That the adolescent presents a serious sports injury (fracture or sprain) during any of the physical exercise sessions.
- That the adolescent decides to withdraw once the practical stage of the investigation has begun.

7.4 Operationalization of variables

7.4.1 Independent Variable: Hydrating Drinks

- **Conceptual definition:** Hydrating drinks are those intended to replenish mineral salts, glucose and water through hydration before, during and after intense physical activity(64).
- **Operational definition:** AC and EO drink
- **Indicator:** milliliters
- **Nature:** dichotomous nominal qualitative

7.4.2 Dependent variable: Hydration status

- **Conceptual definition:** the state of water balance is called in the English literature the state of euhydration; the process of water loss is known as dehydration, and the final state of water deficit reached is called hypohydration(65).
- **Operational definition:** euhydrated or dehydrated

- **Indicator:** Any 2 or more indicators (GEO, %PACT or %PP) with consistent values of euhydration or dehydration.
- **Nature:** dichotomous nominal qualitative

7.4.2.1 Urine Specific Gravity

- **Conceptual definition:** Urine Specific Gravity is a practical way to measure urine, to associate with the state of hydration at the time of physical exercise(twenty-one).
- **Operational definition:** Urine Specific Gravity.
- **Indicator:** g/cm³ (Euhydrated: when GEO is less than 1,020 g/ cm³ and Dehydrated: when GEO is equal to or greater than 1,020 g/ cm³)
- **Nature:** continuous quantitative.

7.4.2.2 Total Body Water

- **Conceptual definition:** element that represents 50-70% of the human body weight and comprises the two largest water compartments (intracellular (2/3) and extracellular water (1/3))(66).
- **Operational definition:** percentage of total body water loss (%PACT).
- **Indicator:** percentages (euhydrated: when the %PACT is less than 2% and dehydrated: when the %PACT is equal to or greater than 2%)
- **Nature:** continuous quantitative.

7.4.2.3 Body mass

- **Conceptual definition:** is the measurement of body mass at two different times. Since 1 mL of water has a mass of 1 g, variations in body mass can be used to quantify water gain and loss.(31).
- **Operational definition:** percentage weight loss (%PP).

- **Indicator:** Euhydrated: when the %PP is equal to or less than 0.9% and Dehydrated: when the %PP is equal to or greater than 1%
- **Nature:** continuous quantitative

7.4.3 Variable box

Table14. Variable box

			INDICATORS TO MEASURE HYDRATION STATUS		
VARIABLES	HYDRATING DRINKS	HYDRATION STATUS	URINE SPECIFIC GRAVITY	PERCENTAGE OF WEIGHT CHANGE	LOSS OF BODY WATER
INTERRELATION	INDEPENDENT	DEPENDENT	DEPENDENT	DEPENDENT	DEPENDENT
CONCEPTUAL DEFINITION	Drinks that, due to their composition, provide water, electrolytes and sugar, and are used above all by athletes or physically active people.	The state of water balance is called in the English literature the state of euhydration; the process of water loss is known as dehydration, and the final state of water deficit reached is called hypohydration.	Specific gravity measurement is a practical way of measuring urine to associate with hydration status at the time of physical exercise.	It is the measurement of body mass at two different times. Since 1 mL of water has a mass of 1 g, changes in body mass can be used to quantify water gain and loss.	Element that represents 50-70% of the human body weight and comprises the two largest water compartments (intracellular (2/3) and extracellular water (1/3).
OPERATIONAL DEFINITION	Milliliters of AC or EO	Euhydrated or Dehydrated	Euhydrated or Dehydrated	Euhydrated or Dehydrated	Euhydrated or Dehydrated
NATURE	Qualitative	Qualitative	quantitative	quantitative	quantitative
MEASUREMENT LEVEL	dichotomous nominal	dichotomous nominal	Reason	Reason	Reason
INDICATOR	AC or EO	Euhydrated: when any 2 indicators (GEO, %PP or %PACT) agree with the euhydration thresholds Dehydrated: When any 2 or more indicators (GEO, %PP or %PACT) are consistent with	Euhydrated: when the GEO is $\leq 1,020$ g/cm ³ Dehydrated: when the GEO is $> 1,020$ g/cm ³	Euhydrated: when the %PP is equal to or less than 1% Dehydrated: when the %PP is greater than 1%	Euhydrated: when the %PACT is less than 2%. Dehydrated: when the %PACT is equal to or greater than 2%.

		the dehydration values.			
STATISTICAL TEST	χ^2 or Fisher's test	χ^2 or Fisher's test	χ^2 or Fisher's test	χ^2 or Fisher's test	χ^2 or Fisher's test

Font:

7.5 Sample size

For the sample size, the sample calculation formula was used to test hypotheses in studies that compare two means(67):

$$n = 2 \left[\frac{(Z\alpha + Z\beta)\sigma}{X1 - X2} \right]^2$$

The formula was made with a confidence level of 95% (1.96) and a beta error of 95% (1.28), in addition, to clear the formula, 2 articles based on adults who administered AC were used (Saat M, et al 2012 and Peart J, et al., 2016) since there are no studies in which AC has been administered to adolescent athletes or those who perform physical exercise. The first study administered a mean of 1875 ml of AC and the second study 1420 ml of AC. A Standard Deviation (SD) of 412 ml was used. The formula was replaced, which yielded a result of 17 subjects, of which a loss of 30% was taken into account, that is, 22 adolescents per group, 5 participants per group could not participate, so a total of 17 adolescents per group were evaluated.

$$n = 2 \left[\frac{(1.96 + 0.84)412}{1875 - 1420} \right]^2 = 17.2 \quad 17 + 30\% = 22 \text{ per group}$$

7.6 Randomization

The primary purpose of randomization was to ensure that the possible causal inference observed at the end of the study was not due to other factors. The balanced block method was used based on the assigned treatment (A or B) as shown in figure 6. This method consisted of assembling a series of blocks, formed by a certain number of cells, in which the different types of treatment. The number of blocks was determined by the number of participants to include and the number of cells that it was decided to include in each block. Each block had

in each cell one of the treatment alternatives and within each block there was a balanced number of possible treatments.

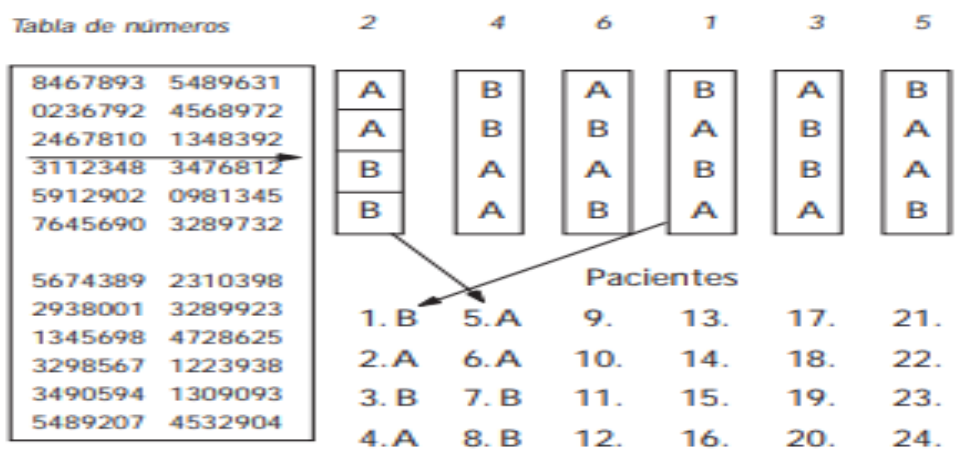


Figure5. Randomization using the balanced block method.

Source: Lazcano-Ponce E, et al. (2004). Randomized clinical trials: variants, randomization methods, analysis, ethical considerations, and regulation.

7.7 Masking or blinding

For the present investigation, a double blind was used, which consists first of blinding the study subjects so that they do not know the type of treatment they are receiving (AC or EO), so it was considered that the EOs used in the study were flavored. To coconut so that both treatments had similar flavors, and that they had the same color appearance. The researcher was blinded with the help of a person external to the study who was in charge of labeling the treatment containers, which were letters A and B, without specifying the type of treatment (AC or EO).

7.8 Interventions

34 healthy adolescents between 12 and 17 years old were selected through simple sampling and the treatment they received was randomly assigned, whose treatment was the same

during the 4 sessions of physical exercise, which lasted 60 ± 10 min. approximately per session, whose characteristics of the exercise per session are described later.

7.8.1 Flowchart

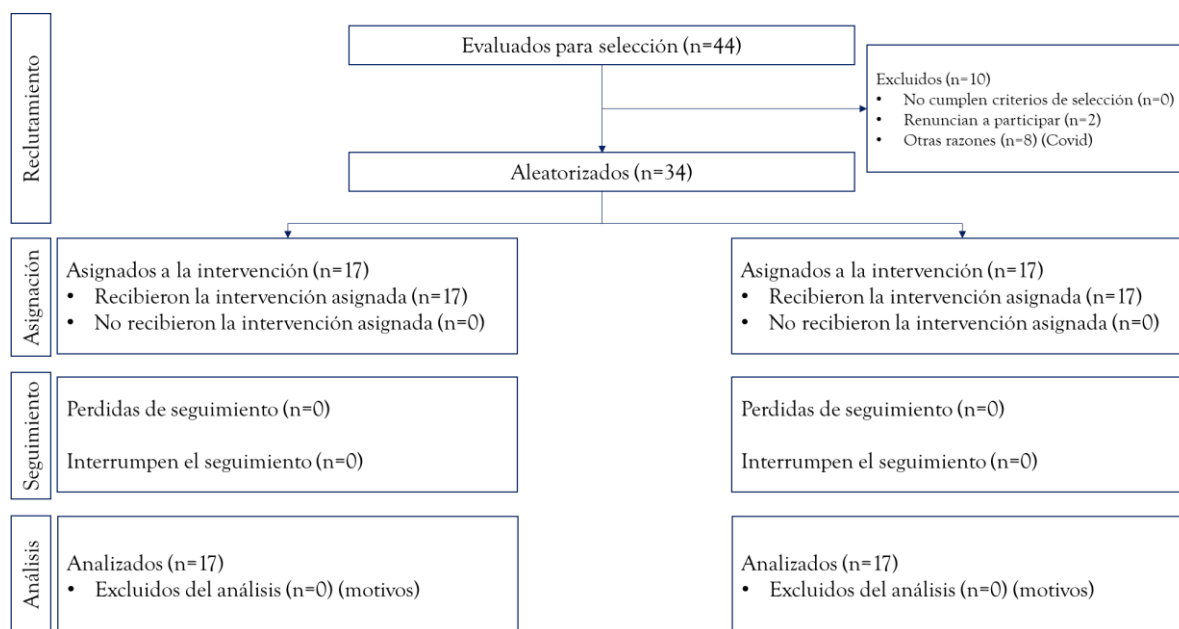


Figure6. Flowchart of the progress of the phases of a parallel RCT of two groups.

Source: CONSORT (2010)

7.8.2 Execution protocol taking into account the epidemiological situation of CoVid-19

1. Due to current epidemiological reasons of CoVid-19, the subjects were divided into two groups of 17 subjects, this in order to reduce population and risk of contagion, following the health protocols established by the institution mentioned in Annex 4. They were summoned at 12:00 pm on Mondays or Tuesdays only according to the group assigned to start with the collection of personal data (Annex 5) and a mental test called Psychological Characteristics related to Sports Performance (CPRD) (Annex 6) whose test was applied by an expert in the area of psychology.

2. After taking personal data, hydrating drinks were immediately administered before training (6 ml x kg of weight) 4 hours before. At 2:00 p.m., the corresponding hydrating drink (4 ml x kg of weight) was administered again. Each study participant was provided with a 1000 ml graduated glass given by the researcher to keep track of the drink administered at the different times of each session.
3. Then, a 200 ml dose of hydrating drink was administered immediately before exercise (10-15) min, and anthropometry and urine samples were taken just before exercise to ensure a state of euhydration. To record body mass, the protocol developed by the International Society for the Advancement of Kinanthropometry (ISAK) (Annex 7) was followed.(68). The study subjects were weighed in sports shorts and barefoot before starting the physical exercise, having been instructed that, in the case of urinating or defecating, they should do so before the initial weighing. Simultaneously with taking the body mass, the % of ACT was determined by electrical bioimpedance. For the recording of body mass and % of water ACT, the Tanita BC-533 bioimpedance scale was used with a reliability of 97%, precision of 0.1kg and with a measurement range of 0-150kg.
4. Urine was analyzed immediately (less than 30 min at room temperature) using a manual refractometer by nutrition students previously trained in the care and analysis of urine samples.
5. The physical exercise protocol was continued, receiving one session per week with a duration of 60 ± 10 min each session for 4 sessions. The exercise sessions were carried out in the *Domingo Savio* sports fields and were taught under the charge of the main researcher who has worked as a sports coach in the soccer area for 4 years, in addition to being trained for this purpose in the same institution in which the study will be carried out. Days prior to the start of the practical execution of the protocol, parents and selected students were summoned virtually to a meeting where the dynamics of the research were widely explained. The physical exercise sessions consisted of 4 parts:
 - a. The first part of the 10-minute warm-up and stretching workout to increase your baseline HR and prepare the body for the next high-intensity stages and

prevent injury in teens. The heating had a rest of 5 minutes and hydration of 2 ml x kg of weight.

- b. This second part was developed in 12 min of continuous jogging around the field at a medium pace with the objective of going around the soccer field every 1 minute 36 seconds, giving a total of 7 and a half laps (Cooper test). 8 min of rest for the total recovery of energy systems and hydration of 2 ml x kg of weight.
 - c. In the third part of the training, the adolescents ran from one line to another, twenty meters apart, at the rhythm of a tape recorder. This race pace will increase every minute. Subjects began the test at a speed of 8 km/hr, the first minute they increased to 9 km/hr, and each minute thereafter they increased the pace by $\frac{1}{2}$ km/hr. The test ended in approximately 10 min and there was a rest of 8 min and hydration of 2 ml x kg of weight.
 - d. In the last part of the training session, it was a type of exercise based on Tabatha, which consisted of performing 8 different exercises for 20 seconds with a 10-second rest to the rhythm of the marked music, giving a time of 4 minutes per Tabatha. . Two Tabatha's were made with an intermediate rest of 3 min between each Tabatha and hydration of 2 ml x kg of weight.
6. At the end of this last stage of the training session, anthropometry was taken and information was collected where the percentage of weight change, ACT by bioimpedance and GEO were determined immediately to avoid bias of the samples at room temperature before to begin the final hydration, since, if it had been done in reverse, it was very likely that no one would come out in a dehydrated state. After the anthropometry, they were administered the corresponding post-exercise hydration (1.5 ml x kg of weight). The calculation of the percentage of lost weight will be calculated using the following formula: % Lost Weight or Dehydration = $[(\text{Initial weight} - \text{Final weight}) / \text{Initial weight}] \times 100$.

7.8.3 Hydrating drinks

Previously it was mentioned that hydration must be according to the weight of the study subject, so following the personalized hydration guidelines, a format was created in the Excel program where the milliliters to be consumed by each subject were automatically calculated and a person in charge was placed in beverage containers serving the right amount, not too much or too little.

- 4 hours before: 7 ml x kg of weight
- 2 hours before: 4 ml x kg of weight
- Immediately before: 200 ml
- During (4 breaks): 2 ml x kg of weight
- Post-exercise: After the exercise, once the MC, ACT and GEO measurements were taken, 1.5 ml/kg of weight were administered to recover weight and lost water.

Among the aspects that were also taken into account for adequate hydration in adolescents, apart from the guidelines and recommendations for fluid intake in both quantity and distribution mentioned above, CHO concentrations (5-8%) at temperature (8 -10 °C), and the taste of the drink. Electrolit® coconut flavor was used as the sports drink to be administered, whose nutritional composition is described in Table 18.

Table15. Nutritional composition of the sports drink that will be used in the project (Electrolit®).

Component	Content in 100 ml of formula
Sodium chloride	12mg
Potassium chloride	149mg
Calcium chloride dihydrate	30mg
Magnesium chloride hexahydrate	41mg
sodium lactate	314mg
Glucose	5mg
%HCO	5%

Source: Electrolit®

Hydrating drinks were administered under the same conditions and temperature as mentioned above. The drinks were poured by the person in charge of the masking into two 19-liter thermos coolers with a dispenser, of the igloo® brand, labeled with the type of treatment assigned.

7.8.4 Meal plan

We established a feeding plan which was standardized and carried out by the LN Alexis Adan Lopez Maria (investigator of the present study). To standardize the food plan, the general needs of the age group and the average age, weight and height of the participants were taken into account, using the Harris Benedict formula as a predictive equation, since in a study carried out in 2015 by Becerril Marlu, this formula was the closest to the average measured resting energy expenditure, with a difference of 12.1 kcal/day in Mexican children(69).How I mentioned previously eating and hydration habits is a factor in altering the state of hydration, so the meal plan indicated had the purpose of eliminating the bias that the different eating habits in each subject could intervene, in addition about what It was not necessary to keep track of the intake of water ingested in the foods and the quantity of liquids in each individual, since the hydration guidelines considering the time, quantity and type of drink 4 hours before the physical test ensured the state of euhydration in the study subjects.

7.9 Methods and statistical analysis

1. The Shapiro Wilk test (small samples <50) was applied to determine the distribution of the data, which showed an asymmetric distribution with a positive bias in the age of the subjects.
2. For descriptive statistics, qualitative variables were presented as numbers, percentages (%), frequencies, or interquartile ranges, as the case may be, and quantitative variables were expressed as mean ($\bar{X}$), $\pm$ standard deviation (SD).
3. Student's t-test was used to compare the pre- and post-exercise hydration indicators in general and by treatment received (AC and EO).

4. Regarding inferential statistics, the statistical significance test was performed to compare two independent qualitative means (AC and EO) using X².
5. Fisher's exact test was used in exercise sessions with frequencies less than 5 in any cell.
6. The analysis of relative risk (RR), absolute risk (AR), relative risk reduction (RRR), absolute risk reduction (ARR) and the number needed to treat (NNT) was performed. Calculation of the aforementioned analyzes helped us determine the clinical significance of the study results.
7. For the contrast of the means of the independent variables on the different mean of the dependent variable, the X² test was carried out.
8. A 95% confidence interval (CI) with a standard error of ± 1.96 was used.
9. Statistical significance was established when $p \leq 0.05$.

8 ETHICAL ASPECTS

The present study adheres to the guidelines of the Declaration of Helsinki and respect for the principles of beneficence, non-maleficence, justice and autonomy of decision. (Ethical Principles for Medical Research Involving Human Subjects 64th version, October 2013). In addition, in accordance with the General Health Law on Health Research Title II, Chapter I, Articles 17. III (1997), the present study is classified as greater than minimum risk in those that use: radiological studies and with microwaves, trials with medications and modalities defined in article 65 of the regulation, trials with new devices, studies that include surgical procedures, extraction of blood greater than 2% of the circulating volume in neonates, amniocentesis and other invasive techniques or procedures greater, those that use random methods of assignment to therapeutic schemes and those that have placebo control, among others. The signing of a letter of informed consent in writing will be requested from the institutional director to carry out the study in the academic institution (Annex 8) by means of a letter issued by the coordination of the postgraduate degree in medical sciences and by the advisor in charge. Of the study (Annex 9). Parents or guardians will also be asked to sign the informed consent letter (Annex 10) as well as the study subjects' informed assent letter

(Annex 11). Likewise, the anonymity of the study subjects is taken care of, clarifying to the parents of the minors that the data obtained is only for research purposes.

The Research Ethics Committee may waive compliance with these requirements for justified reasons. Article amended DOF 04-02-2014. This study was submitted for evaluation to the Research Ethics Committee of the State Institute of Cancerology, whose verdict was approving under registration CEICCI06082021-AGCOHID-12 and the letter is shown attached in Annex 12. The same project continues in the registration process in the clinical trials.

9 RESULTS

34 male adolescent subjects with an age range of 12 to 17 years were recruited and analyzed, whose characteristics of age, weight, height and BMI are described in Table 19. The study subjects were selected and assigned to a drinking treatment at random by means of the balanced block method. The experimental protocol consisted of 4 hydrated training sessions 4 hours before training (345.03 ± 74.51 ml), 2 hours before (230.02 ± 49.67 ml) and immediately before starting the dehydration process (200.00 ± 0.00 ml) which had a duration of $65 \text{ min} \pm 5 \text{ min}$. During the exercise, the subjects were hydrated on 3 occasions (every 20 min) where the treatment corresponding to each individual was administered (115.01 ± 24).

Table16. Description of the study population.

	Half	Dev. half	Asymmetry
AGE (YEARS)	13.03	1,087	1,444
WEIGHT (KG)	57.50	12.41	.507
SIZE (CM)	162.50	10,936	.320
BMI	21.58	3.03	.605

The asymmetry statistic indicates a positive bias in the variables as they are greater than 0, with a greater bias in the age of the subjects.

9.1 Description of the subjects prior to the exercise sessions

The 34 subjects presented to each training session in a euhydrated state with an average initial weight of 56.74 ± 13.32 kg, USG of 1.028 ± 0.011 g/cm³ and TBW of $68.47 \pm 5.40\%$. At the end of the 4 sessions, the subjects had the following data on average: final weight of 56.24 ± 13.14 kg, USGf of 1.032 ± 0.012 g/cm³ and TBWf of $68.37 \pm 5.22\%$, which indicates that the subjects had a weight loss average of 0.50 ± 0.19 kg, USGf of 0.004 ± 0.001 g/cm³ and TBWf of $0.11 \pm 0.19\%$. Table 20 breaks down the results obtained before and after the physical test of the hydration status indicators, and Table 21 shows the differences obtained between these indicators with their significance.

Table twenty. Description of the initial and final hydration status according to the indicators evaluated per session.

	Body mass (kg)		USG (g/cm ³)		%TBW	
	Pre	post	Pre	post	Pre	post
Session 1	56.61 ± 13.33	56.35 ± 13.27	1.027 ± 0.011	1.035 ± 0.011	69.59 ± 5.170	68.76 ± 5.270
Session 2	56.75 ± 13.26	55.95 ± 12.90	1.030 ± 0.012	1.035 ± 0.013	67.36 ± 05.35	67.13 ± 05.56
Session 3	56.59 ± 13.12	56.06 ± 13.01	1.029 ± 0.011	1.034 ± 0.011	68.09 ± 6.431	68.72 ± 5.253
Session 4	57.03 ± 13.60	56.61 ± 13.38	1.026 ± 0.012	1.029 ± 0.012	68.86 ± 4.679	68.86 ± 4.782

USG= Urine Specific Gravity. TBW= Total Body Water. Data is presented as mean $\pm$ SD.

Table twenty. T test for pre and post comparison in indicators of hydration status

Indicator	Half OF	Significance
Pesoi - Pesof	0.50 ± 0.23	.021
ACTi - ACTf	0.10 ± 0.60	.749
GEOi - GEOf	0.005 ± 0.002	.015

Next, the comparisons of the hydration indicators before and after physical exercise are shown, separated by intervention groups (CW and OE) in tables 22 and 23. The indicators

show a better trend of hydration in the pre and post exercise values. With AC than with OE, although with no significant difference between sessions.

Table17. Comparison of pre and post hydration indicators in the CW group

	Body mass (kg)		GEO (g/cm3)		%ACT	
	Pre	post	Pre	post	Pre	post
Session 1	53.38 ± 10.93	53.25 ± 10.74	1.023 ± 0.009	1.032 ± 0.011	69.62 ± 4.529	68.95 ± 4.370
Session 2	53.74 ± 11.69	53.09 ± 11.47	1.028 ± 0.012	1.032 ± 0.015	68.69±5,7 11	68.53 ± 5.626
Session 3	52.80 ± 10.80	52.25 ± 10.67	1.027 ± 0.013	1.033 ± 0.011	68.40 ± 7.934	69.42±5,7 82
Session 4	53.58 ± 11.53	53.39 ± 11.54	1.022 ± 0.012	1.025 ± 0.012	69.86 ± 4.297	70.28 ± 3.531

GEO= Urine Specific Gravity. ACT= Total Body Water. It is observed that in session 3 and 4 there was a gain in %ACT, although not in body mass, on the contrary, it is shown that in all sessions the subjects showed a pre-exercise GEO greater than 1,020 and less than 1,030 g/ cm3 classified as mild to moderate dehydration.

Table18. Comparison of pre and post hydration indicators in the OE group

	Body mass (kg)		GEO (g/cm3)		%ACT	
	Pre	post	Pre	post	Pre	post
Session 1	59.85 ± 14.99	59.46 ± 15.07	1.032 ± 0.011	1.039 ± 0.009	69.56 ± 5.876	68.57 ± 6.175
Session 2	59.76 ± 14.38	58.81 ± 13.93	1.033 ± 0.011	1.038 ± 0.011	66.04 ± 4.775	65.74 ± 5.289
Session 3	60.39 ± 14.42	59.88 ± 14.29	1.032 ± 0.009	1.036 ± 0.010	67.79 ± 4.706	67.83 ± 4.668
Session 4	60.47 ± 14.94	59.82 ± 14.64	1.029 ± 0.011	1.034 ± 0.010	67.85 ± 4.954	67.44 ± 5.514

GEO= Urine Specific Gravity. ACT= Total Body Water. We can observe that in session 3 there was a slight gain in %ACT, on the other hand, the GEO pre-exercise shows that in most sessions the subjects showed a value greater than 1,030 g/cm3, which is classified as severe dehydration.

Table 24 shows the frequency of the hydration status of the subjects post-exercise during the 4 training sessions that the study lasted.

Table19. General cross table of the state of hydration with respect to the assigned treatment.

			Hydration Status		Total
			Euhhydrated	Dehydrated	
Tx Assigned	AC	not observed	53	15	68
	EO	not observed	36	32	68
Total		not observed	89	47	136

9.2 RR, RRR and NNT tests

The absolute risk (AR), the relative risk (RR), the absolute risk reduction (ARR), the relative risk reduction (RRR) and the number needed to treat (NNT) were estimated, whose values are shown in Table 25. And they indicate that the probability of having the dehydration event with any treatment was 35% as well as the probability of ending the sessions dehydrated in 47% when receiving the OE treatment. The ARR indicates a 25% reduction in dehydration in subjects treated with AC compared to those who received EO. Finally, the NNT throughout the study shows that 4 subjects needed to be treated to obtain 1 euhydration effect after physical exercise treated with AC.

Table20. Estimation of RA, RR, RAR, NNT and RRR

AR	0.35
RR	0.47
RAR	0.25
RRR	0.53
NNT	4

Clinical data show a favorable trend for AC hydration to prevent dehydration and its adverse effects.

9.3 Frequency of hydration status per exercise session

Table 26 shows the frequencies of hydration status broken down by exercise sessions and according to the assigned treatment.

Table21. General table of sessions regarding treatment and hydration status

Hydration Status	Treatment	Physical exercise sessions				
		Session 1	Session 2	Session 3	Session 4*	Total
	AC					68
Euhydrated		12	12	13	16	53
Dehydrated		5	5	4	1	15

	EO					68
Euhydrated		8	7	13	8	36
Dehydrated		9	10	4	9	32

During the first 3 sessions, no significant difference in hydration is seen between AC and EO; however, a greater trend of hydration is shown with AC, being significantly higher in the last session of the study.

*Session with statistical significance between treatments.

9.4 Comparison between groups using Chi square test

The chi-square test was performed for each of the sessions, accepting H0 in the first 3 sessions and accepting H1 in the last session. The p obtained in table 27 are shown below. Fisher's exact test, alternative to the Chi square test, was used in the last session because a frequency of less than 5 was obtained in one of the boxes of the cross table.

Table22. Chi square broken down by sessions

	Significance Session 1	Significance Session 2	Significance Session 3	Significance Session 4
Pearson chi-square	0.163	0.084	1,000	0.003*
Continuity Correction	0.296	0.167	1,000	0.008
Fisher exact test	-	-	-	0.007*
likelihood ratio	0.161	0.082	1,000	0.001

*P<0.05 showing statistical significance between treatments.

-Does not apply

9.5 Intragroup comparison in the different sessions

To find out the variations in the frequencies of a single treatment in the 4 different exercise sessions, Cochran's Q was performed in each study group. In treatment group A (CW), the frequencies of hydration between sessions did not show significant differences with a value of Q= 3.909 and p>0.005.

With relation to treatment B (EO) a greater variation of the frequencies in the state of hydration was observed, obtaining a $Q=5.739$, however, there were no significant differences in the treatment in each of the sessions ($p>0.05$).

10 DISCUSSION

Coconut water has been widely studied for its antimicrobial properties, for its uses in the culinary field and the benefits it offers as a natural drink for athletes. Dehydration is a very common problem in both athletes and the general population, and a low level of hydration can affect physical and mental health. In the pediatric population there is a risk of heat stroke due to their low sweating rate and thermoregulation capacity, so the present study aimed to compare the effect of AC vs EO (Electrolit®) on hydration status in adolescents who perform physical exercise.

There are few studies that compare coconut water on hydration levels in adolescent athletes, so the characteristics of the populations in different studies found are compared below, but with similar objectives in people who perform physical exercise (soccer, treadmill, cycling, volleyball, etc.). Previous studies such as: Daniel J. Peart, et al 2016; Kalman, et al. 2012; Saat M, et al. 2002 and Pérez and Aragón 2011, evaluated trained adults with samples of less than 12 participants. On the other hand, this study recruited 34 subjects from the pediatric population (adolescents) aged 13.03 ± 1.09 years with different physiological characteristics that can contribute to providing new knowledge that can be used in later studies. Added to this,

Going back to the 4 studies mentioned above, all carried out physical exercise of approximately 60 min comparing 3 or 4 hydrating drinks (natural coconut water, bottled coconut water, simple bottled water and/or sports drink) using in some of them bottled coconut, knowing that bottled products are added with sugars and preservatives to prolong the shelf life of the product and may further affect the health of athletes. In the present study, natural or plain water was not compared with the other hydrating drinks since it was considered unnecessary to include it due to its electrolyte deficit, which makes it a drink not

suitable for sports since, when consumed and does not contain electrolytes, plain water dilutes the few remaining electrolyte concentrations in the blood,

Among the similarities found was that no study mentioned above found significant differences between the drinks compared. Saat M, et al, 2002 performed only one exercise session, which does not allow the study to find significant differences compared to the other studies that, unlike this one, performed 3, 4 and 3 sessions in the studies by Daniel J Peart, et al 2016; Kalman, et al 2012 and Pérez and Aragón 2011 respectively. In the present study, 4 sessions of physical exercise with a duration similar to 60 ± 10 min were carried out, as in the study carried out by Kalman, et al 2012, where the previously presented results show a trend of greater hydration with AC in each session. Without being statistically significant during the first 3 sessions ($p > 0$).

An important part in the comparative studies are the techniques and instruments for evaluating hydration, since they vary greatly in their applicability due to methodological limitations such as the circumstances necessary for measurement such as reliability, ease of application and cost (simplicity), sensitivity to detect small but significant changes in hydration status (precision). In all the studies, indirect methods were used that were the same or similar in the present study, with body mass and USG being one of the most used methods due to their practicality in the field of clinical research; on the other hand, the gold standard was not included. In no study since it includes, in addition to blood osmolality, the isotopic dilution for TBW and they are mostly invasive methods,

10.1 Limitations

There were some limitations in the study of intervening variables that could affect hydration levels and that, for financial reasons or external to the researchers in charge, could not be controlled or included in the study. In this case, the climate was an environmental factor that could not be controlled due to the facilities where the study was carried out. Another factor was that the gold standard of hydration was not applied for reasons of practicality and finances, in addition, hydration levels change in a matter of minutes and waiting for anthropometric and urine measurements could have been an intervening factor.

On the other hand, the acceptance of beverages was something that was not contemplated since the participating adolescents did not have a hydration habit with CW or OE coconut flavor, and there were even subjects who had tried the assigned hydrating drink for the first time.

11 CONCLUSION

CW and OE have the same effect on hydration levels in adolescents who perform physical exercise, however, a significant difference was found in the last session, the effect being greater with CW compared to OE.

12 PERSPECTIVES

Session 4 of this study with significant results may give rise to future research on AC due to the trend shown for euhydration in each session.

Prolonging the number of sessions can show greater significant results due to the physiological adaptation to exercise and acceptance of AC in the body.

Applying the gold standard in conjunction with the methods used in the present study can give a more accurate diagnosis of hydration status.

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14 ANNEXES

14.1.1 Annex 1: Urine collection technique, conservation and analysis.

It is necessary to process the sample in the clinical laboratory as soon as possible. If the sample cannot be analyzed within the first 30 minutes of collection, it should be refrigerated in the refrigerator door at 4 degrees Celsius for a maximum of 24 hours. hours, otherwise there is a risk that the substances contained in it will be altered due to the effects of ambient temperature and sunlight after 2 hours of collecting the sample(44). For a regular urinalysis with urine specific gravity, about 20 ml should be collected. Urine specific gravity can be tested with one of these methods: hydrometer or urinometer, a multi-test dipstick, and by means of a refractometer or total solids meter. This last method is the most reliable and the measurement technique is as follows: place a drop of urine on the glass of the urinometer and put another glass on top. The path of light bends (as it passes through the sample and gives the refractive index, that is, the ratio between the speed of light in air and the speed of light in the sample. The degree of refraction is directly proportional to urine density(43).

14.1.2 Annex 2: Aspects to be evaluated to measure physical health as an inclusion criterion.

- A. BMI will be evaluated in order not to include subjects with obesity that may affect exercise performance and the percentage of total body water in the body.
- B. The physical examination will determine through observation conditions that make it impossible to perform physical exercise (lack of some limbs).

14.1.3 Annex 3: Criteria for measuring mental health in sports performance.

Athletes can be classified in any of the following risk profiles, if their scores are below the 25th percentile on the scales marked in the results table shown in Annex 6. The authors indicate profile one as the maximum risk profile. And the lowest risk number seven.

Risk profile:

1. Scores are below the 25th percentile in Stress Management, Influence of Performance Evaluation, and Motivation.
2. Scores are below the 25th percentile on the Stress Control and Influence of Performance Assessment.
3. Scores are below the 25th percentile in Stress Management and Motivation.
4. Scores are below the 25th percentile on Influence of Performance and Motivation Assessment.
5. Scores are below the 25th percentile in Stress Management and Mental Ability.
6. Scores are below the 25th percentile on Motivation.
7. Scores are below the 25th percentile in Team Cohesion(70).

14.1.4 Annex 4: Health protocol to be followed by the educational institution.

1. Only teachers, students and study managers will be allowed to enter the sports facilities.
2. Access to the facilities must be mandatory with a face mask wearing it correctly (covering the nose and mouth).
3. The body temperature of everyone entering the facility will be recorded.
4. Once the temperature is registered and it is optimal, it will be atomized with sanitizer and anti-material gel will be put on them.
5. Within the facilities, the healthy distance between students and educational staff will be kept.
6. The sports material to be used will be disinfected before and after each training session.

7. A disinfected glass will be given to each study subject that will bear their name in order not to confuse glasses.
8. Any student with signs or symptoms of COVID will be denied entry and therefore excluded from the study.

14.1.5 Annex 5: Personal information collection sheet for each subject.

CÓDIGO	PESO I (KG)	PESO F (KG)	%PP	GEO INICIAL	GEO FINAL	DIF DE GEO	%ACT INICI	%ACT FINA	%PACT	ESTADO DE	Tx ASIGNADO
AMJP01	48.6	49.8	-2.46314	1.040	1.048	0.008	74.7	72.9	2.409639	2	B
BMAG04	46.9	46.9	0	1.055	1.05	-0.005	74.1	73.3	1.079622	1	B
CEF05	47.3	47.3	0	1.022	1.026	0.004	80	79.1	1.125	1	A
CCCE06	47.2	46.6	1.27186	1.015	1.034	0.019	68.8	68.9	-0.14535	2	A
CDLMJR07	40.9	41.6	-1.71143	1.022	1.042	0.020	77.9	77	1.155327	1	A
DAAMD09	74.7	73.2	2.008032	1.02	1.028	0.008	70	68	2.857143	2	B
DLMHM10	60.4	61.6	-1.98675	1.034	1.038	0.004	69.4	68.3	1.585014	1	B
DRNA11	37.2	36.8	1.075269	1.018	1.02	0.002	65.3	65.1	0.306279	1	A
EAJJ12	73.4	73	0.544959	1.03	1.017	-0.013	68.3	65.4	4.245974	1	A
GRGG13	63.5	62.8	1.102362	1.034	1.043	0.009	66.7	66.9	-0.29985	2	A
GJJR14	45.1	45	0.221729	1.01	1.02	0.010	73.5	72.8	0.952381	1	A
GCIE15	48.5	48	1.030928	1.042	1.046	0.004	74.5	75.1	-0.80537	1	B
GLGA16	89.2	85	-2.16346	1.039	1.04	0.001	63.2	62.7	0.791139	1	B
LLPM17	64.5	65.7	-1.66047	1.038	1.038	0.000	66.1	66.5	-0.60514	1	B
MCR18	85.1	83.4	1.93765	1.017	1.03	0.013	68.3	65.4	4.245974	2	B
MSG19	55.9	55.2	1.252236	1.032	1.042	0.010	75.2	76.5	-1.72872	2	B
MMHA20	55.5	55.2	0.540541	1.033	1.048	0.015	69.4	68.3	1.585014	1	B
MHD21	58.3	57.6	1.200686	1.015	1.034	0.019	70.1	70.2	-0.14265	1	A
NLCE22	60.2	61.3	-1.62724	1.02	1.042	0.022	64.6	63.6	1.547988	1	A
OG023	42.9	43.9	-2.331	1.036	1.041	0.005	75.8	74.1	2.242744	2	B
PAE24	67.4	67	0.593472	1.032	1.046	0.014	63.9	63.2	1.095462	1	A
RLRS26	54.1	52	3.881701	1.025	1.018	-0.007	70.1	68	2.99572	2	B
RCA27	59.8	58.6	2.006689	1.01	1.018	0.008	68.4	69.4	-1.46199	1	A
RSPS28	47.1	45.1	4.246285	1.015	1.028	0.013	73.4	73.4	2.52324	2	B
RR29	63.5	62.8	1.102362	1.015	1.018	0.003	65	65	0	1	A
VDJE30	51.8	53.1	-2.50965	1.017	1.034	0.017	72	70.5	2.083333	2	A
YBAS31	55.3	55.6	-0.5425	1.036	1.041	0.005	69.7	69.9	-0.28694	1	A
ZRO32	56.6	55.9	1.236749	1.042	1.046	0.004	67.3	67.2	0.148588	2	A
LGS33	34.5	34.7	-0.57971	1.026	1.04	0.014	68.7	67.3	2.037846	2	A
JRGA34	55.7	54	3.052065	1.02	1.032	0.012	61.4	60	2.28013	2	B
YUYUS35	62.3	60	3.691814	1.03	1.038	0.008	60	58	3.333333	2	B
GAP36	42.3	42	0.70922	1.038	1.042	0.004	76.4	76.9	-0.65445	1	B
RBFJ37	89.8	89.8	0	1.022	1.05	0.028	58.7	58.3	0.681431	1	B
EVP38	45.4	45.5	-0.22026	1.03	1.03	0.000	79.4	79.3	0.678474	1	A

14.1.6 Annex 6: CPRD Test

Dear athlete:

Amateur or professional competitive sport requires, increasingly, that the training and preparation methods of athletes whose objective is to achieve success at the highest level, evolve taking into account the physical, technical and psychological characteristics of the athletes who they must be trained, as well as their opinion regarding issues related to their participation in tests, matches and competitions. For this reason we are writing to you as we believe that, as a competitive athlete, your answers will be of great help to us. Specifically, it is about knowing certain characteristics and opinions of adolescent athletes belonging to the ISFPG in relation to their participation in sports training and competitions. To this end, we would be grateful if you would answer the questions attached. There are no right or wrong answers, each athlete is different, which is why we ask you to answer with the utmost

sincerity. The questionnaire is strictly confidential; if he wants to put his name he can do it and in that case we will be able to inform you about his answers later. If you do not want to put your name, you can leave the corresponding space blank. We look forward to your valuable and kind cooperation. If you do not want to put your name, you can leave the corresponding space blank. We look forward to your valuable and kind cooperation. If you do not want to put your name, you can leave the corresponding space blank. We look forward to your valuable and kind cooperation.

Thank you very much.

***INSTRUCTIONS:**

Please respond to each of the following statements indicating how much you agree or disagree with the statements in question.

In each sentence, 6 response options are shown, represented by a circle. Fill in the circle that you choose according to the position of agreement or disagreement with the sentence. If you do not understand a sentence, please fill in the circle in the last column.

Date:	Colima, Col. On _____ of the month of _____
	year _____
	Surname name: _____
	Age: _____

Sport in which you participate: _____

Playing position: _____

Category: _____

	strongly disagree	Disagreement	Neutral	In agreement	totally agree	I don't understand
1. I often have trouble concentrating while competing.	☐	☐	☐	☐	☐	☐
2. While I sleep I usually think about the match or competition in which I am going to participate.	☐	☐	☐	☐	☐	☐
3. I have great confidence in my technique.	☐	☐	☐	☐	☐	☐
4. Sometimes I don't find myself motivated to train.	☐	☐	☐	☐	☐	☐
5. I get along very well with other team members.	☐	☐	☐	☐	☐	☐
6. I rarely feel tense enough for tension to negatively interfere with my performance.	☐	☐	☐	☐	☐	☐
7. I often mentally rehearse what I should do just before I start my participation in a competition.	☐	☐	☐	☐	☐	☐
8. In most competitions I am confident that I will do well.	☐	☐	☐	☐	☐	☐
9. When I do it wrong, I tend to lose concentration.	☐	☐	☐	☐	☐	☐
10. It doesn't take much to shake my self-confidence.	☐	☐	☐	☐	☐	☐
11. I care more about my own performance than the performance of the team.	☐	☐	☐	☐	☐	☐
12. I am often “scared to death” in the moments before the start of a competition.	☐	☐	☐	☐	☐	☐
13. When I make a mistake I have a hard time forgetting it to concentrate on what I have to do.	☐	☐	☐	☐	☐	☐
14. Any little injury or bad training can weaken my self-confidence.	☐	☐	☐	☐	☐	☐
15. I set goals that I must achieve and I usually achieve them.	☐	☐	☐	☐	☐	☐

16. Sometimes I feel intense anxiety while participating in a test.	☐	☐	☐	☐	☐	☐
17. During my performance in a competition my attention seems to fluctuate back and forth between what I have to do and other things.	☐	☐	☐	☐	☐	☐
18. I like to work with my teammates.	☐	☐	☐	☐	☐	☐
19. I have frequent doubts about my chances of doing well in a competition.	☐	☐	☐	☐	☐	☐
20. I spend a lot of energy trying to be calm before a competition starts.	☐	☐	☐	☐	☐	☐
21. When I start doing it wrong, my confidence drops quickly.	☐	☐	☐	☐	☐	☐
22. I think team spirit is very important	☐	☐	☐	☐	☐	☐
23. When I mentally practice what I have to do, I “see” myself doing it as if I were looking at myself on a television monitor.	☐	☐	☐	☐	☐	☐
24. Generally, I can continue to participate (play) with confidence, even if it is one of my worst performances.	☐	☐	☐	☐	☐	☐
25. When I prepare to participate in a test, I try to imagine, from my own perspective, what I will see, do or notice when the situation is real.	☐	☐	☐	☐	☐	☐
26. My self-confidence is very unstable.	☐	☐	☐	☐	☐	☐
27. When my team loses I feel bad regardless of my individual performance.	☐	☐	☐	☐	☐	☐
28. When I make a mistake in a competition I get very anxious.	☐	☐	☐	☐	☐	☐
29. Right now, the most important thing in my life is to do well in my sport.	☐	☐	☐	☐	☐	☐
30. I am effective in controlling my stress.	☐	☐	☐	☐	☐	☐
31. My sport is my whole life.	☐	☐	☐	☐	☐	☐

32. I have faith in myself.	☐	☐	☐	☐	☐	☐
33. I usually find myself motivated to improve myself day by day.	☐	☐	☐	☐	☐	☐
34. I often lose concentration during the competition as a result of decisions by referees or judges that I consider unwise and go against me or my team.	☐	☐	☐	☐	☐	☐
35. When I make a mistake during a competition (or during a match) I often worry about what other people like the coach, teammates or someone in the audience think.	☐	☐	☐	☐	☐	☐
36. The day before a competition I am usually too nervous or worried.	☐	☐	☐	☐	☐	☐
37. I usually set myself goals whose achievement depends 100% on me instead of goals that do not depend only on me	☐	☐	☐	☐	☐	☐
38. I believe that the specific contribution of all the members of a team is extremely important for the success of the team.	☐	☐	☐	☐	☐	☐
39. It is not worth devoting as much time and effort as I dedicate to sport	☐	☐	☐	☐	☐	☐
40. In competitions I usually encourage myself with words, thoughts or images.	☐	☐	☐	☐	☐	☐
41. I often lose concentration during a competition because I worry or think about the final result	☐	☐	☐	☐	☐	☐
42. I usually accept criticism well and try to learn from it.	☐	☐	☐	☐	☐	☐
43. I easily concentrate on what is most important at each moment of a competition.	☐	☐	☐	☐	☐	☐
44. I find it hard to accept that the work of other team members is highlighted more than mine.	☐	☐	☐	☐	☐	☐
45. When a competition ends, I analyze my performance objectively and specifically (that is, considering real	☐	☐	☐	☐	☐	☐

events and each section of the competition or match separately.						
46. I often lose focus on the competition as a result of unsportsmanlike performance or comments from opponents.	☐	☐	☐	☐	☐	☐
47. I am very concerned about the decisions that the coach may make regarding me during a competition.	☐	☐	☐	☐	☐	☐
48. I do not mentally rehearse, as part of my training plan, situations that I need to correct or improve.	☐	☐	☐	☐	☐	☐
49. During training I am usually very focused on what I have to do.	☐	☐	☐	☐	☐	☐
50. I usually set priority goals before each training session and each competition.	☐	☐	☐	☐	☐	☐
51. My confidence in the competition depends to a large extent on the successes or failures in the previous competitions	☐	☐	☐	☐	☐	☐
52. My motivation largely depends on the recognition I get from others.	☐	☐	☐	☐	☐	☐
53. The coach's instructions, comments and gestures often negatively interfere with my concentration during the competition.	☐	☐	☐	☐	☐	☐
54. I usually trust myself even in the most difficult moments of a competition.	☐	☐	☐	☐	☐	☐
55. I am willing to make any effort to be better and better.	☐	☐	☐	☐	☐	☐

CPRD Answer Sheet

Date: Colima, Col. On _____ of the month of _____ year _____ Surname name: _____ Age: _____
--

Sport in which you participate: _____

Playing position: _____

Category: _____

stress management						Influence of performance evaluation						Motivation					
item or question	strongly disagree	Disagreement	Neutral	In agreement	totally agree	item or question	strongly disagree	Disagreement	Neutral	In agreement	totally agree	item or question	strongly disagree	Disagreement	Neutral	In agreement	totally agree
1	4	3	2	1	0	9	4	3	2	1	0	4	4	3	2	1	0
3	0	1	2	3	4	16	4	3	2	1	0	15	0	1	2	3	4
6	0	1	2	3	3	28	4	3	2	1	0	29	0	1	2	3	4
8	0	1	2	3	4	34	4	3	2	1	0	31	0	1	2	3	4
10	4	3	2	1	0	35	4	3	2	1	0	33	0	1	2	3	4
12	4	3	2	1	0	42	0	1	2	3	4	39	4	3	2	1	0
13	4	3	2	1	0	44	4	3	2	1	0	49	0	1	2	3	4
14	4	3	2	1	0	46	4	3	2	1	0	55	0	1	2	3	4
17	4	3	2	1	0	47	4	3	2	1	0	Direct score:					
19	4	3	2	1	0	51	4	3	2	1	0						
20	4	3	2	1	0	52	4	3	2	1	0						
21	4	3	2	1	0	53	4	3	2	1	0						
24	0	1	2	3	4	Direct score:											
26	4	3	2	1	0												
30	0	1	2	3	4												
32	0	1	2	3	4												
36	4	3	2	1	0												
41	4	3	2	1	0												
43	0	1	2	3	4												
54	0	1	2	3	4												

Direct score:	
---------------	--

Mental ability						team cohesion					
item or question	strongly disagree	Disagreement	Neutral	In agreement	totally agree	item or question	strongly disagree	Disagreement	Neutral	In agreement	totally agree
2	4	3	2	1	0	5	0	1	2	3	4
7	0	1	2	3	4	11	4	3	2	1	0
23	4	3	2	1	0	18	0	1	2	3	4
25	0	1	2	3	4	22	0	1	2	3	4
37	0	1	2	3	4	27	0	1	2	3	4
40	0	1	2	3	4	38	0	1	2	3	4
45	0	1	2	3	4	Direct score:					
48	4	3	2	1	0						
50	0	1	2	3	4						
Direct score:											

	stress management	Influence of evaluation on performance	Motivation	Mental ability	team cohesion
99	77-80	42-45	30-31	31-34	24
95	69	38	27	28	-
90	64	3. 4	26	26	23
85	61	33	25	25	22
80	58	31	23	24	-
75	56	29	-	-	21
70	54	28	22	23	-
65	52	27	21	-	20
60	50	-	20	22	-

55	48	26	-	21	19
50	46	24	19	-	-
45	44	23	18	20	18
40	42	22	17	-	-
35	40	21	-	19	17
30	39	20	16	18	16
25	36	19	15	17	-
20	3.4	18	-	16	15
15	30	16	14	-	14
10	27	15	12	15	13
5	21	12	11	13	11
1	0-14	0-7	0-8	0-11	0-1

14.1.7 Annex 7: Correct weighing according to ISAK guidelines

The measurement of the taking of body weight is without clothes. This can be estimated by weighing the clothing or clothing similar to that of the subject to be measured whose value is subtracted from the previously recorded on the scale. Generally, body mass in minimal clothing is accurate enough. Your mass should be evenly distributed on both feet on the scale.

14.1.8 Annex 8: Study authorization letter issued by the ISFPG institution.

Colima, Colima, on _____, _____

I _____ director of the school
 _____ domiciled at
 _____ authorize the student of the Master of
 Medical Sciences at the University of Colima Alexis Adan Lopez Maria with identification
 number 20106199 to apply the corresponding procedures for his research study *"Effect of
 water of coconut compared with oral electrolytes on hydration status in adolescents who
 perform competitive aerobic physical exercise. RCT, double blind."* towards all the students
 trained under my command in inter-institutional issues. In the same way, I promise to be

accessible in the required times and the established space. This document is issued for subsequent purposes.

Attentively:

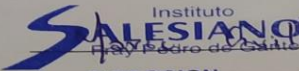
Name and signature of the director of the institution

CARTA DE AUTORIZACIÓN DEL ESTUDIO

Colima, Col. A. 21 de Septiembre del año 2021

Yo: Maric Guillermo de Anda Chávez director del colegio Instituto Salesiano Fray Pedro de Gant con domicilio en Medellin 504 Colima Centro Autorizo al alumno de la Maestría en ciencias Médicas de la Universidad de Colima Alexis Adan Lopez Maria con n° de identificación 20106199 a la aplicación de los correspondientes procedimientos para su estudio de investigación "*Eficacia del Agua de coco vs bebida deportiva sobre el estado de hidratación en adolescentes que realizan ejercicio físico.*" hacia todos los alumnos entrenados bajo mi mando en temas interinstitucionales. De la misma manera, me comprometo a ser accesible en los tiempos requeridos y el espacio establecido. Se expide el presente documento para fines consiguientes.

ATENTAMENTE

 Maric Guillermo de Anda Chávez
DIRECCION Nombre y firma del director de la Institución

14.1.9 Annex 9: Request letter to carry out research within the ISFPG

Colima, Colima, on _____, _____

P.SBD Enrique Gonzalez Tapia

Academic director Mario Guillermo de Anda Chavez

We hereby request authorization so that the student Alexis Adan Lopez Maria student of the third semester of the Master in Medical Sciences with identification number 20106199 can carry out the application of the corresponding procedures to carry out the research project entitled "*Effect of water of coconut compared with oral electrolytes on hydration status in adolescents who perform competitive aerobic physical exercise. RCT, double blind.*" within the facilities of the educational institution (DOSA). The project is attached to the ethical considerations of the Declaration of Helsinki and the Law General Health and was approved by the Research Ethics Committee of the Institute State of Colima Cancerology whose letter is attached to the document.

Without more for the moment, we appreciate the attention provided and we hope for a prompt response. Best regards.

Attentively

Master's coordinator

Student advisor

Petición para la realización de investigación en el Instituto Salesiano Fray Pedro de Gante

Colima, Col. A 23 de agosto del 2021

P. SDB Enrique González Tapia

Mtro. Mario de Anda Chávez

Por medio de la presente solicitamos autorización para que el alumno Alexis Adán López María estudiante del tercer semestre de la Maestría en Ciencias Médicas con n° de identificación 20106199 pueda llevar a cabo la aplicación de los procedimientos correspondientes para realizar el proyecto de investigación titulado *"Eficacia del agua de coco vs bebida deportiva sobre el estado de hidratación en adolescentes en adolescentes que realizan ejercicio físico. Ensayo clínico, doble ciego"* dentro de las instalaciones de la institución educativa (DOSA). El proyecto está apegado a las consideraciones éticas de la declaración de Helsinki y de la Ley General de Salud y fue aprobado por el Comité de Ética en Investigación del Instituto Estatal de Cancerología de Colima cuya carta se encuentra adjunta en el documento.

Sin más por el momento agradecemos la atención brindada y esperamos pronta respuesta.
Saludos cordiales.

ATENTAMENTE



Coordinadora de la maestría en ciencias médicas

DCM. Luz Margarita Baltazar Rodríguez



Asesora del alumno

DCM. Carmen Alicia Sánchez Ramírez

14.1.10Annex 10: Informed consent letter for father, mother, or guardian.

INFORMED CONSENT LETTER

Colima, Col. On _____ of _____ the year _____

I _____ declare that I have been fully explained by the student of the Master of Medical Sciences of the University of Colima: Alexis Adan Lopez Maria with identification 20106199 about the research process which leads to title “Effect of coconut water compared to oral electrolytes on hydration status in adolescents who perform physical exercise. Clinical trial, double-blind” with the objective of comparing 2 drinks on the state of hydration, in this way in full use of my faculties, I give consent for my son _____ to participate in the research study, agreeing with the performance of the process where 4 sessions of aerobic physical training will be carried out without any compensation and with benefits for my son's health since the quantity, type of drink and hydration times will be taken care of at all times, ensuring proper hydration, as well as being aware of possible risks such as: cramps, headache, nausea, vomiting, dizziness, or sports injury. I accept that the researcher performs anthropometric measurements such as: weight, height and total body water through bioimpedance, in addition to the administration of hydrating drinks and urine collection. By signing this document, I agree to provide personal information, providing my full name, age, and/or any information requested to carry out the research study, taking care of the anonymity of the identities and clarifying that the data obtained is only for research purposes.

Without prejudice to the procedures to be carried out, I declare that I have full capacity, conscience, and lucidity to decide and accept the aforementioned procedures under my full responsibility.

Father's name and signature

Mother's name and signature

14.1.11Annex 11: Informed assent letter for the minor.

Colima, Col. On _____ of _____ the year _____

Me, Alexis Adan Lopez Maria, responsible for the research project “Effect of coconut water compared to oral electrolytes on hydration status in adolescents who perform physical exercise. Clinical trial, double blind” I offer the following information in order to obtain the consent of the subjects that will be studied in the program. The objective of this research project is to compare the effect of coconut water vs oral electrolytes in adolescents under a test of physical exercise. To carry out the study, patients must ingest a weekly dose of the aforementioned beverages, they must also comply with physical exercise sessions, follow a meal plan, perform anthropometric measurements (weight, height and total body water by bioimpedance), urine collection and mental health screening, plus routine follow-up. Likewise, the anonymity of the identities is taken care of, clarifying that the data obtained is only for research purposes.

All study subjects who agree to participate in this study assume the risk of having some side effects related to the intake of beverages, exercise or food plan. Among the symptoms that could present are: generalized fatigue, drowsiness, dizziness or vomiting.

The duration of the study will be a period of 4 sessions, in which the subjects must drink the drink assigned to them within the facilities on a weekly basis. If the subject presents any disease or severity during the course of the study that makes it impossible for him to continue, the treatment will be suspended.

I, _____ after having read and understood the entire procedure to be carried out, I accept to be part of the aforementioned research project and being aware that I can withdraw from the study without being forced to continue.

[Signature of the participant]

[Signature of the person in charge]

[Witness signature 1]

[Witness signature 2]

14.1.12Annex 12: Letter approved by the Research Ethics Committee of the State Institute of Cancerology in Spanish and English.



SECRETARÍA DE SALUD
Y BIENESTAR SOCIAL

SERVICIO DE SALUD DEL ESTADO DE COLIMA
INSTITUTO ESTATAL DE ONCOLOGÍA DE COLIMA
COMITÉ DE ÉTICA EN INVESTIGACIÓN
Registro Contáctico (Vale vigente) 1872
Oficio: CECOCOMI (ACCORD) 1/2021
Asunto: Notificación Aprobación Protocolo

D. en C. CARMEN ALICIA SÁNCHEZ RAMÍREZ
D. en C. FABIAN ROJAS LABIOS

ESTIMADOS INVESTIGADORES

Notificamos a ustedes que en sesión ordinaria N° 04/CED/2021 del Comité de Ética en Investigación del Instituto Estatal de Cancerología de Colima se presentó a su solicitud, revisión y en su caso aprobación del protocolo, "EFICACIA DEL AGUA DE COCO VS BEBIDA DEPORTIVA SOBRE EL ESTADO DE HIDRATACIÓN EN ADOLESCENTES QUE REALIZAN EJERCICIO FÍSICO. ENSAYO CLÍNICO ALBERTOZADO DOBLE CIEGO." bajo registro: CECOCOMI-ACCORD-12 de acuerdo a los siguientes:

DATOS TÉCNICOS	
INVESTIGADORES RESPONSABLES	D. en C. CARMEN ALICIA SÁNCHEZ RAMÍREZ D. en C. FABIAN ROJAS LABIOS Profesores Investigadores de la Facultad de Medicina de la Universidad de Colima UN. ALBERTO ADAM LOPEZ MARIA Estudiante de Maestría en Ciencias Médicas, Facultad de Medicina de la Universidad de Colima
PROTOCOLO INVASIVO	EFICACIA DEL AGUA DE COCO VS BEBIDA DEPORTIVA SOBRE EL ESTADO DE HIDRATACIÓN EN ADOLESCENTES QUE REALIZAN EJERCICIO FÍSICO. ENSAYO CLÍNICO ALBERTOZADO DOBLE CIEGO.
INSTITUCIÓN PARTICIPANTE	Facultad de Medicina de la Universidad de Colima Av. Universidad 333 colonia Las Viboras Colima Colima C. P. 29040.

Hacemos de su conocimiento que este Comité de Ética en Investigación del Instituto Estatal de Cancerología revisó el protocolo detallado en el anterior cuadro técnico. La evaluación fue realizada con apego a la regulación nacional e internacional vigente, tomando en cuenta para esta revisión los aspectos éticos mínimos exigidos por la Comisión Nacional de Bioética y contemplados en la Guía Nacional para la Integración y el Funcionamiento de los Comités de Ética en Investigación tales como: valor científico; pertinencia científica en el diseño y conducción del estudio; selección de los participantes; proporcionalidad de los riesgos y beneficios; evaluación independiente; respeto a los participantes; y consentimiento informado; dado el apego a los principios anteriormente expuestos, se notifica a los investigadores que este cuerpo colegiado otorga a este protocolo el carácter:

APROBATORIO	
Registro de la aprobación	CECOCOMI-ACCORD-12
Fecha de aprobación	06/08/2021
Vigente hasta	06/08/2022
Versión revisada	Segunda

Esta aprobación tiene vigencia de 1 año a partir de la fecha de aprobación; comunicarle a los investigadores que al término del primer semestre y a la conclusión del mismo, se deberán presentar de manera obligatoria los reportes correspondientes generados por el desarrollo del proyecto, en los que consignará el grado de avances así como la información más relevante haciéndose énfasis en los aspectos técnicos y éticos. Este reporte deberá hacerse llegar de forma física o electrónica a los datos que se consignaron al final de la presente carta de aprobación. De no encontrarse ninguna razón para ser nuevamente evaluado y de contar con la documentación completa, se procederá al refrendo o renovación de la vigencia **en caso de requerirse o solicitarse.**

ATENTAMENTE
Colima, Colima, a los 6 días del mes de Agosto del año 2021

DRA. BERTHA ALICIA CUSIDO BUENROSTRO
Presidenta del Comité
Presidente Comité de Ética en Investigación



DR. IVÁN DELGADO ENCISO
Secretario Comité de Ética en Investigación

"2021, Año de Graciela Bernal (Pionera de León)"
Servicios de Salud del Estado de Colima
Instituto Estatal de Cancerología
Av. Llave de Varadero 401, Col. La Esperanza, C. P. 29040, Colima, Colima, México
Mail: etec@institutoestataldecancerologia.com



CONBIOÉTICA-06-CEI-001-20200721
Colima, Col. August 6 2021

Protocol Approval Notification

We notify you that in ordinary session of the Research Ethics Committee of the State Institute of Cancerology of Colima was presented at your request, review and, where appropriate, approval of the protocol "EFFECT OF THE COCONUT WATER COMPARED WITH ORAL ELECTROLYTES ON HYDRATION STATUS IN ADOLESCENTS WHO EXERCISE PHYSICAL DOUBLE-BLIND RANDOMIZED CLINICAL TRIAL." under registration CECC106082021-AGCOHID-12 according to the following:

TECHNICAL DATA	
RESPONSIBLE INVESTIGATORS	D. en C. CARMEN ALICIA SANCHEZ RAMIREZ D. en C. FABIAN ROJAS LARIOS Research advisors L.N. ALEXIS ADAN LOPEZ MARIA Student of de Master of Medical Sciences
EVALUATED PROTOCOL	PROJECT TITLE "EFFECT OF THE COCONUT WATER COMPARED WITH ORAL ELECTROLYTES ON HYDRATION STATUS IN ADOLESCENTS WHO EXERCISE PHYSICAL DOUBLE-BLIND RANDOMIZED CLINICAL TRIAL."
INSTITUTION PARTICIPANT	Faculty of Medicine of the University of Colima. Av University 333

This approval is valid for 1 year from the date of approval, starting from August 6, 2021 until August 6, 2022, being within the marked time.



Bertha Olmedo

DRA. BERTHA ALICIA OLMEDO BUENROSTRO
President of the
Research Ethics Committee

Iván Delgado Enciso

DR. IVÁN DELGADO ENCISO
Secretary of the
Research Ethics Committee

14.2 Viability

14.2.1 Feasibility

This project is feasible since, according to the financial calculation that was estimated, the total inputs could be covered by the student, in addition to the fact that it is planned to attend the call for the CONACYT scholarship plus other external sources of financing. Additionally, it complies with ethical aspects, classifying itself as minimal risk, without compromising the patient's health.

14.2.2 Human Resources

Those responsible for the project: D in C Carmen Alicia Sánchez Ramírez, D in C Fabian Rojas Larios, D in C Yunue Flores Ruelas and LN Alexis Adan Lopez Maria, student of the Master of Medical Sciences at the University of Colima, with the present project.

14.2.3 Financial resources

For the development of this research project, a good part of the resources to carry it out are already available, and they are mentioned in the following table. In relation to the costs of computer equipment, software and office supplies, they will be covered by the principal investigator.

14.2.4 Financing

ITEM NO.	DESCRIPTION OF THE ARTICLE	PRESENTATION	AMOUNT	PRICE
STATIONERY				
1	WHITE BOND SHEETS LETTER SIZE	PACK OF 100 SHEETS	1	\$55.00
two	HALF EYEBROW LETTER SIZE FOLDER	PACKAGE W/100 PCS	1	\$82.00
3	PEN MEDIUM POINT 1.0 MM	PACKAGE WITH 3	two	\$56.00
4	MEDIUM POINT PENCIL NO. 2	PACKAGE W/6 PCS	1	\$28.00
5	YELLOW TEXT MARKER	PACKAGE WITH 2 PCS	1	\$25.00
6	LIQUID CORRECTOR PEN	PART	1	\$30.00
7	RUBBER TO ERASE	PACKAGE WITH 2 PCS	1	\$11.00
8	PENCIL SHARPENER	PART	1	\$18.00
9	STAPLER	PART	1	\$47.00
10	STANDARD STAPLES	PACK W/5,040 PCS	1	\$25.00
eleven	SONY VAIO BRAND 15" LAPTOP	PART	1	\$10,000.00

HYDRATING DRINKS				
12	COCONUT WATER	LITERS	156	\$5,300.00
13	ELECTROLIT 1.115 ML COCO® FLAVOR	PART	156	\$5,183.00
LAB'S MATERIAL				
14	TANITA MODEL BC-601 SCALE	PART	1	\$7,150.00
fifteen	SECA STADIMETERS MODEL 21317210092	PART	two	\$5,740.00
16	HERMETIC JARS FOR SAMPLES	BOX W/200	300	\$1,500.00
17	MEASURING GLASSES	PART	44	\$2,860.00
INFRASTRUCTURE MATERIAL				
18	REFRIGERATOR	PART	1	\$4000.00
19	HANDHELD REFRACTOMETER	PART	1	\$3000.00
TOTAL PROJECT COST				\$45,110

14.3 Schedule of activities

ACTIVITIES	2020		2021							2022						
	SEP-OCT	NOV-DEC	JAN-FEB	MAR-APR	MAY-JUN	JUL	AUG-SEP	OCT-NOV	DEC	JAN-FEB	MAR-APR	MAY-JUN	JUL	AUG-SEP	OCT-NOV	DEC
Development and evaluation of the research project protocol.																
Evaluation of the study population.																
Selection of adolescents who will participate in the research.																
Realization of the protocol in the field.																
Analysis of results																
Thesis writing.																
Obtaining the degree of Master in Medical Sciences																

Writing and submission of article for publication.																	
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14.3.1 CONSORT check list

CONSORT				
<i>Section / Topic</i>	<i>Question (37)</i>	<i>Check list</i>	<i>Evaluator 1</i>	<i>Evaluator 2</i>
<i>Title and abstract</i>	<i>1st</i>	<i>Identification in title as randomized</i>		
	<i>1 B</i>	<i>Structured summary of the design, methodology, results and conclusions</i>		
<i>Introduction</i>				
<i>Background and objectives</i>	<i>2nd</i>	<i>scientific background</i>		
	<i>2b</i>	<i>Specific objectives or hypothesis</i>		
<i>methods</i>				
<i>Study design</i>	<i>3rd</i>	<i>Description of trial design, including allocation ratio</i>		
	<i>3b</i>	<i>Important changes in methods before the start of the trial with reasons for them</i>		
<i>Participants</i>	<i>4th</i>	<i>Selection criteria.</i>		
	<i>4b</i>	<i>Conditions and locations where the data was collected</i>		
<i>Interventions</i>	<i>5</i>	<i>Interventions for each group with sufficient detail to allow replication, including how and when they were administered</i>		
<i>Results</i>	<i>6th</i>	<i>Prespecified definition of primary and secondary outcomes, including how and when they were assessed</i>		
	<i>6b</i>	<i>Any changes to the trial after the start of the trial, with reasons</i>		
<i>Sample size</i>	<i>7th</i>	<i>How was the sample size determined?</i>		
	<i>7b</i>	<i>When applicable, explanation of interim analysis and detention guidelines.</i>		
<i>randomization</i>				

<i>Sequence of generation, assignment and implementation</i>	<i>8th</i>	<i>Method used to generate the randomized allocation sequence</i>		
	<i>8b</i>	<i>Randomization type, restriction details (blocks and size)</i>		
	<i>9</i>	<i>Mechanism used for the random assignment sequence describing the steps taken to hide the sequence until the interventions were assigned</i>		
	<i>10</i>	<i>Who generated the assignment sequence, who recruited the participants, who assigned the participants to the interventions?</i>		
<i>blinding</i>	<i>11th</i>	<i>If done, who was blinded after allocation of interventions (participants, investigators, those assessing outcomes) and how.</i>		
	<i>11b</i>	<i>If relevant, description of similarity of interventions</i>		
<i>Statistical methods</i>	<i>12th</i>	<i>Statistical methods used to compare groups for primary and secondary outcomes</i>		
	<i>12b</i>	<i>Methods for additional analyses, such as subgroup analyzes and adjusted analyzes</i>		
Results				
<i>Flow of participants (Develop CONSORT diagram)</i>	<i>13th</i>	<i>For each group, the number of participants who were randomly assigned, with the intention to receive treatment, and who were analyzed for the primary outcome</i>		
	<i>13b</i>	<i>For each group, losses and exclusions after randomization, with reasons.</i>		
	<i>14th</i>	<i>Dates defining the recruitment and follow-up periods.</i>		
	<i>14b</i>	<i>Why the trial stopped or was stopped</i>		
	<i>fifteen</i>	<i>Table showing the baseline demographic and clinical characteristics of each group</i>		
	<i>16</i>	<i>For each group, number of participants (denominator) included in each analysis and whether analysis was by original allocation of groups</i>		

	17th	<i>For each primary and secondary outcome, results for each group, the estimated sample effect, precision (confidence interval)</i>		
	17b	<i>For binary outcomes, presentation of absolute and relative effect is recommended.</i>		
	18	<i>Results of any other analysis carried out, including subgroups and adjustments, distinguishing by default from the exploratory one.</i>		
	19	<i>All deleterious or unexpected effects in each group</i>		
	twenty	<i>Study limitations, sources of potential bias, imprecision and, if relevant, multiplicity of analyses.</i>		
	twenty-one	<i>Generalization of the study findings (external validity)</i>		
	22	<i>Interpretation, consistency with results, balance between benefits and harms, and consideration of different relevant evidence</i>		
	23	<i>Registration number and trial name.</i>		
	24	<i>If available, the full trial protocol can be accessed.</i>		
	25	<i>Sources of sponsorship and other support, role of sponsors.</i>		