

## Research Article

# Placebo - a strategy to improve physical fitness of normal adolescents: a randomized control trial.

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## ABSTRACT

**Background:** The capacity of the placebo effect to affect a range of physiological and psychological characteristics, including strength, endurance, and pain perception. Its use for teenage physical fitness, however, is still largely unknown.

**Objective:** To determine the effects of placebo drink administration on physical fitness among normal-weight adolescents compared to plain water.

**Methods:** This randomized control trial with n=60 adolescents aged 10-19 years, of both genders and normal weight was conducted at Shifa Tameer-e-Millat University, Islamabad from May 2021 to August 2021. Randomization was performed using the envelope method dividing the sample into an experimental group who were given a placebo drink (water + red food colour) and a control group who were given water. Tools used for data collection included the Physical Activity of Leisure Motivation Scale for motivation level determination, the Physical Activity Questionnaire, and four fitness tests including 20 m running, a broad jump, a reach test, and a reduced cooper test.

**Results:** Post-intervention results revealed a significant difference in means for experimental and control groups for reduced Cooper test ( $P=0.003$ ), pulse rate ( $p=0.033$ ), and exertion level ( $p<0.001$ ). post-intervention palms score revealed significantly better results in the experimental group for mastery ( $p=0.004$ ) physical ( $p=0.008$ ) and psychological levels ( $p<0.001$ ). the results also indicate that the experimental group showed a more significant mean difference regarding the affiliation subscale with ( $p<0.001$ ) and total PALMS score ( $p<0.001$ ).

**Conclusion:** Administered placebo drink boosts physical performance by increasing motivational levels and decreasing the exertion of normal-weight adolescents.

**Keywords:** Adolescent; exercise; health; heart rate; placebo; physical fitness; water.

**IRCT #** 20211052405138N1

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## INTRODUCTION

In the current era, adolescents are facing challenges including growing academic competition, excessive exposure to the internet, consumption of junk food, and lack of opportunities for physical activity in daily routine. Declining physical fitness has beefed up serious concerns regarding upcoming challenges with health and physical functional capacity [1, 2].

Physical activity regularly improves the body's growth as well as development thus beneficially affecting social, psychological, mental as well as physical health which also contributes to learning [3]. Placebo & nocebo are also among the factors with their effects still waiting to be estimated and researched with placebo signifying positive beneficial effects [4]. Placebos, inactive substances, or processes that have no pharmacological impact, are becoming more and more popular in a variety of fields including clinical trials, where they are employed to assess the efficacy of various treatments [5].

Studies have demonstrated the impact of placebos on conditions including migraines [5-7]. Recent studies on their effects on fatigue have raised concerns that they could have an impact on exercise and physical performance. It has been seen that placebos have physiological and psychological effects, such as variations in heart rate, pain perception, and anxiety levels [8, 9]. There are brain regions involved in pain reduction, as well as the endogenous opioid system [10]. The use of placebos raises ethical questions; however, it is thought that doing so serves to assess therapeutic efficacy [11, 12]. Promoting regular physical activity is essential for growth and development, given the risks associated with inactivity, especially among adolescents. Both intrinsic and extrinsic motivation are essential for maintaining levels of physical activity [13, 14].

Keeping in view the dearth of literature on the subject, and the declining health status of adolescents, to determine ways to motivate adolescents to enhance physical activity and to determine the effect of placebo-like coloured water in non-clinical settings, it was hypothesized that administration of a placebo has both positive psychological and physiological outcomes to enhance physical activity. With this hypothesis, a current study was conducted to determine the effects of placebo administration on physical fitness among normal-weight adolescents. This study has significant importance, since proving the hypothesis of the study true, placebo administration methods can be used in non-clinical settings to foster the health of the younger generation. This study will also be a significant addition to the literature and a base for further research.

## METHODOLOGY

This randomized control trial (IRCT # 20211052405138N1) was conducted at the Department of Rehabilitation Sciences, Shifa Tameer-e-Millat University, Islamabad, Pakistan following approval of the Institutional Review Board and Ethics Committee (IRB & EC), Shifa International Hospital Ltd. & Shifa Tameer-e-Millat University with Reference IRB # 066-21 dated 9th April, 2021 Sample was recruited using non-probability convenient sampling from Decent Public School, Islamabad, Pakistan over 4 months from 1st May 2021 to 31st August, 2021, after obtaining permission from the Principal of the School. Informed consent of participants was taken from their parents/guardians and ethical concerns were addressed.

The study participants included adolescents aged 10-19 years of either gender with normal BMI, who were less motivated, and who were residents of Islamabad were included in the study. Adolescents with any acute or chronic disease, deformity or psychological illness, family history of sudden cardiac death, comorbidities like asthma and diabetes, history of exercise-associated dizziness, pre-syncope, or collapse were excluded from the study.

A study sample of  $n=60$  was utilized for the study. The sample was calculated using OpenEpi, Version 3, and an open-source calculator with a significance level of 95, power of 80, and Odds Ratio of 10. This revealed a total sample size of  $n=58$  (29 in each group) hence, a sample of  $N=60$  was taken for the study. To get this sample  $n=68$  participants were enrolled of which 08 were excluded and a sample of  $N=60$  was utilized for the study which was randomized into two groups with blinding using the envelope method with  $n=30$  in the Experimental and  $n=30$  in the control group (Figure 1).

The tools used to collect the data were a demographic sheet that inquired about age, gender, BMI, and comorbidity. Physical Activity of Leisure Motivation Scale (PALMS) and Physical Activity Questionnaire for Adults (PAQ-A) and Children (PAQ-C) for measuring physical activity [15-18]. The Rate of Perceived Exertion Scale (RPE) assesses exercise intensity; a digital pulse oximeter (model TCPOC L213) is used to measure heart rate.

Moreover, Physical fitness was measured with the Cooper 6-minute run test, for assessing aerobic fitness and endurance, the standing broad jump test is a measure of lower body strength and explosive power, and running as fast as possible for 20 meters test is a measure of speed and acceleration, and sit and reach test is a measure of flexibility hamstring muscles. Participants completed questionnaires and performed fitness tests measuring flexibility, endurance, speed, and jump. We continuously

tracked heart rate and exertion. Participants were ultimately categorized based on the information gathered.

Group A (Experimental Group): participants received a placebo drink (red food colouring added to water) and a leaflet with phrases that reinforced the placebo's possible impact on performance improvement within a half-hour time (30 minutes) frame. These assurances included a range of physical tests, including the sit-and-reach test, the running test, the standing broad jump, and the reduced Cooper test, which would be administered under close supervision with performance assessments; an energy drink being given; to repeat the aforementioned tests following the energy drink's consumption, with readings to be retaken; and The plan to compare performance during the physical activities both before and after consuming the energy drink, looking for any differences in results.

Group B. (Control Group): Participants of the control group were given water.

This whole procedure was done by the first investigator whereas the second investigator was

blinded. This was necessarily done because to administer a placebo drink, which was coloured to bring a placebo effect, the first investigator could not be used for post-intervention result measurements for which a blinded investigator was used. All tests were repeated under the supervision of a second investigator and again exertion level and pulse rate were monitored. The difference between pre and post-reading was evaluated.

The statistical analysis of done by SPSS Version 21. The mean and standard deviation were used for descriptive statistics of continuous variables, while frequency and percentages were described for categorical variables. As the data assumed that assumption of parametric test. The paired sample t-test was performed to determine within-group changes. While an independent t-test was used to investigate the difference between the Experimental and Control groups as well as for the affiliation, competition, and total score of PALMS these were not comparable at the baseline, so the mean of mean differences of these variables were compared. The  $p < 0.05$  was considered significant.

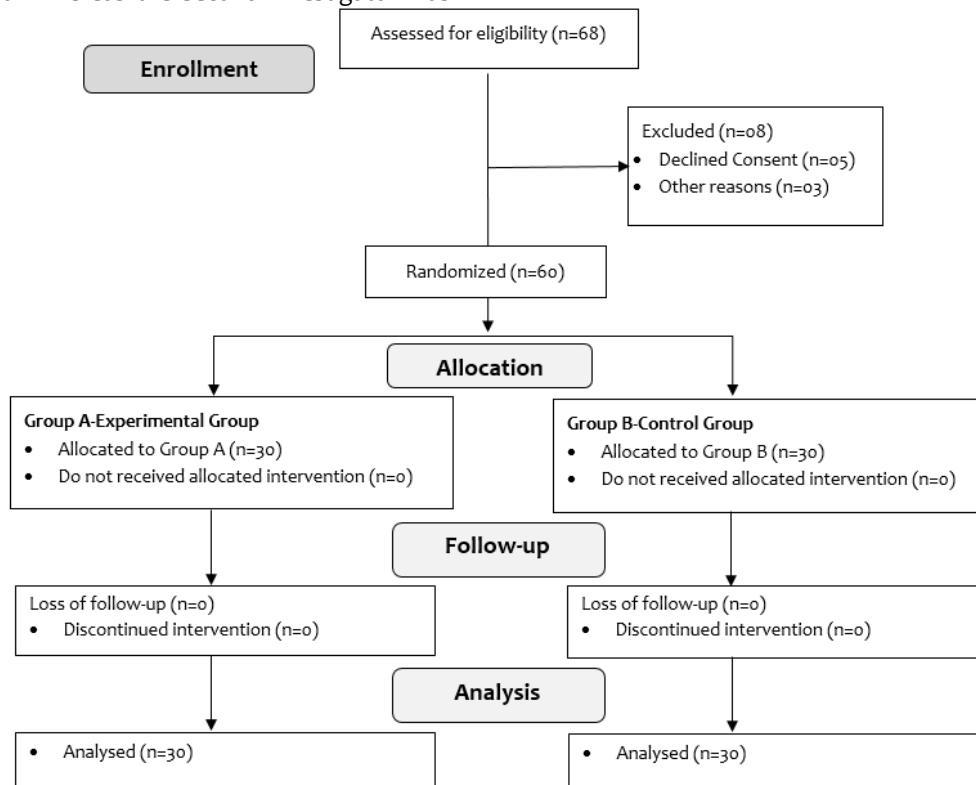


Figure 1: Consort Diagram

**RESULTS**

The mean age of the participants was 14.03±1.913 years, including 29(48.3%) boys and 31(51.7%) girls with no significant ( $p = .077$ ) difference between the experimental and control groups.

The result of paired sample t-test showed that group A (Experimental) which received a placebo drink significant improvement in the pre-post analysis of all variables including lower body strength with broad jump test ( $p < 0.001$ ), speed through running as fast as possible for 20 meters test ( $p = 0.001$ ), flexibility of hamstring muscle with sit and reach test ( $p < 0.001$ ), aerobic fitness and

endurance with reduced cooper test ( $p=0.002$ ), Rate of Perceived Exertion (RPE) for assessing exercise intensity ( $p<0.001$ ) and heart rate measurement with a digital pulse oximeter ( $p=0.002$ ). In group B (Control), all variables were significantly improved ( $p<0.05$ ) except pulse rate ( $p=0.23$ ) and rate of perceived exertion ( $p=0.28$ ) in pre-post analysis. The

pre-post analysis of Physical Activity and Leisure Motivation Scale (PALMS) items and the total score showed that each group significantly improved ( $p<0.001$ ) in the emotional motivation of participants undergoing physical activity after the interventions. (Table 1)

**Table 1: Pre & Post Test Comparative Statistics**

	Experimental Group (n=30)			Control Group (n=30)		
	Pre-Test	Post-Test	P-value	Pre-Test	Post-Test	p-value
Broad jump test (cm)	161.17 ± 23.07	166.30 ± 21.78	0.000***	161.97 ± 22.43	163.80 ± 21.42	0.002**
20-m running test (sec)	3.97 ± 1.01	3.62 ± 0.69	0.001**	4.22 ± 1.06	3.97 ± 0.81	0.009**
Sit and reach test (cm)	99.39 ± 11.15	101.51 ± 11.25	0.000***	98.64 ± 10.09	100.25 ± 9.63	0.000***
Reduced cooper test (m)	339.60 ± 99.33	361.37 ± 89.54	0.002**	340.83 ± 105.76	296.80 ± 73.42	0.001**
Pulse Rate	131.47 ± 22.80	129.6 ± 22.61	0.002**	141.10 ± 19.83	141.63 ± 19.82	0.23
Rate of Perceived Exertion	8.00 ± 1.01	6.77 ± 1.10	0.000***	7.93 ± 0.86	8.10 ± 0.80	0.28
<b>PALMS Sub Scales</b>						
Mastery	8.27 ± 1.41	14.50 ± 1.87	0.00***	8.80 ± 1.88	13.07 ± 1.81	0.00***
Physical condition	7.63 ± 1.40	13.07 ± 2.10	0.00***	8.23 ± 1.43	11.67 ± 1.80	0.00***
Affiliation	9.90 ± 2.09	18.03 ± 1.71	0.00***	12.77 ± 2.67	17.60 ± 2.44	0.00***
Psychological condition	8.07 ± 2.28	13.70 ± 3.14	0.00***	7.30 ± 2.07	9.87 ± 2.75	0.00***
Appearance	6.53 ± 1.22	9.80 ± 2.65	0.00***	6.40 ± 1.49	8.93 ± 2.21	0.00***
Enjoyment	12.07 ± 1.89	17.77 ± 2.81	0.00***	12.93 ± 2.31	17.17 ± 2.00	0.00***
Competition	8.53 ± 1.81	16.17 ± 1.82	0.00***	9.57 ± 1.99	16.10 ± 2.59	0.00***
Total	61.00 ± 5.23	103.47 ± 5.60	0.00***	66.0 ± 7.00	94.57 ± 6.92	0.00***

Significance level:  $p<0.05^*$ ,  $p<0.001^{**}$  &  $p<0.001^{***}$ ; PALMS- Physical activity and leisure motivation scale

When comparing the groups after intervention significant improvement in group A (experimental) was observed as compared to group B (Control) in aerobic endurance ( $p=0.003$ ), pulse rate ( $p=0.03$ ), and rate of perceived exertion ( $p<0.001$ ). But no significant difference was observed when comparing the lower limb strength ( $p=0.656$ ), speed ( $p=0.079$ ), and flexibility ( $p=0.64$ ) were not significantly improved. When comparing the

Physical activity and leisure motivation after the intervention, the result showed that subscales including mastery ( $p=0.004$ ), physical condition ( $p=0.008$ ), and psychological condition ( $p<0.001$ ) were significantly better in the experimental group. But no significant difference in sub-scale appearance ( $p=0.175$ ) and enjoyment ( $p=0.345$ ) after intervention. (Table 2)

**Table 2: Experimental & Control Group Comparative Statistics**

	Pre-Test		p-value	Post-Test		p-value
	Experimental Group (n=30)	Control Group (n=30)		Experimental Group (n=30)	Control Group (n=30)	
Broad jump test (cm)	161.17 ± 23.074	161.97 ± 22.438	0.892	166.30 ± 21.780	163.80 ± 21.426	0.656
20-m running test (sec)	3.97 ± 1.017	4.22 ± 1.064	0.356	3.62 ± 0.691	3.97 ± 0.819	0.079
Sit and reach test (cm)	99.40 ± 11.156	98.64 ± 10.096	0.782	101.52 ± 11.251	100.25 ± 9.637	0.64
Reduced cooper test (m)	339.60 ± 99.335	340.83 ± 105.766	0.963	361.67 ± 89.542	296.80 ± 73.425	0.003**
Pulse Rate	131.47 ± 22.805	141.10 ± 19.833	0.086	129.63 ± 22.619	141.63 ± 19.826	0.033*
Rate of Perceived Exertion	8.00 ± 1.017	7.93 ± 0.868	0.786	6.77 ± 1.104	8.10 ± 0.803	0.000***
<b>PALMS Sub Scales</b>						
Mastery	8.27 ± 1.413	8.80 ± 1.883	0.220	14.50 ± 1.871	13.07 ± 1.818	0.004**
Physical condition	7.63 ± 1.402	8.23 ± 1.431	0.106	13.07 ± 2.100	11.67 ± 1.807	0.008**
Affiliation	9.90 ± 2.090	12.77 ± 2.674	0.00***	18.03 ± 1.712	17.60 ± 2.444	0.43
Psychological condition	8.07 ± 2.288	7.30 ± 2.070	0.179	13.70 ± 3.142	9.87 ± 2.751	0.00***
Appearance	6.53 ± 1.224	6.40 ± 1.499	0.707	9.80 ± 2.657	8.93 ± 2.212	0.175
Enjoyment	12.07 ± 1.893	12.93 ± 2.318	0.118	17.77 ± 2.812	17.17 ± 2.001	0.345
Competition	8.53 ± 1.814	9.57 ± 1.995	0.04*	16.17 ± 1.821	16.10 ± 2.591	0.909
Total	61.00 ± 5.239	66.00 ± 7.007	0.003**	103.47 ± 5.606	94.57 ± 6.922	0.00***

Significance level:  $p<0.05^*$ ,  $p<0.001^{**}$  &  $p<0.001^{***}$ ; PALMS- Physical activity and leisure motivation scale

Moreover, the affiliation, competition, and total score of PALMS were not comparable at the baseline, so the mean differences of these variables were compared. The result showed that the placebo group showed more significant mean difference regarding the affiliation subscale ( $-8.13 \pm 2.33$  vs.  $-4.83 \pm 2.08$ ,  $p<0.001$ ) and total PALMS score ( $-$

$42.46 \pm 4.66$  vs.  $-28.56 \pm 6.53$ ,  $p<0.001$ ). While the competition subscale showed no significant ( $p=0.06$ ) difference between groups.

**DISCUSSION**

The current study determined the effectiveness of a placebo on physical fitness and motivation

regarding exertion and pulse rate among adolescents. The study outcomes concluded that physical fitness was enhanced in the experimental group receiving a placebo, whereas the control group receiving water did not show much difference in results. This might be due to several underlying neuro-biological impacts of placebo with studies researching the mediators like opioids, dopamine, serotonin, etc., [19]. Though evidence on the exact mechanisms involved is deficient, the literature reveals that a placebo as a stimulating agent increases dopamine levels in mesocortical (pre-frontal) & mesolimbic regions of the brain [20].

In the current study, four different activities were performed including broad jump, 20m running, sit and reach test, and reduced cooper test. The experimental group showed a marked increase in all activities, reduced Cooper test post measurement showed mean value maximum difference. Whereas the control group didn't show the makeable difference in all activities. Similar results were reported in a study by Shira Fanti-Oren and Daphna Birenbaum-Carmeli in Israel, in 2019, which concluded that a placebo has beneficial outcomes on physical fitness. In that study, the effect of placebo was achieved by information, provided regarding a water drink consumed before testing-standard information (water) vs. deliberate positive information (presumed energy drink, placebo). When given in the form of administration and information. In this study, the treadmill test was performed twice, and results were based on exertional level, heart rate, and recovery time [21]. Whereas the current study concluded results based on variables including exertional level, pulse rate, motivational level, and post-activity measurements (speed, time, and distance).

Similarly, in another study by Crum & Langer at Harvard University, information on work-related exercise acted as a placebo resulting in a reduction in weight, fat, blood pressure, ratio of hip to waist, and body mass index. In that study, subjects in the experimental group were told that the work they do is good exercise and satisfies the Surgeon General's recommendations for an active lifestyle. Subjects in the control group were not given this information. The placebo effect is any effect that is not attributed to an actual pharmaceutical drug or remedy but rather is attributed to the individual's mindset (mindless beliefs and expectations). The experimental group was given information about how their work is a good exercise; this information was conveyed in the form of a verbal presentation, through individual handouts, and on larger posters tacked to the bulletin boards in their lounge in the hope that they would be reminded of how much exercise they were getting each day. The control group was not given this information [22]. Current

study outcomes also showed the significance of a placebo in driving motivation. Similarly, a study conducted by Alves et al. in 2017 in Brazil, concluded that in the case of a placebo. In this study they evaluated the effect of a recognized brand (versus an unrecognized brand) in the placebo effect, subjects who were more motivated and had high expectancy showed improved results [14]. Another study was conducted by Davis et al. in 2019 in the UK, which explained motivation comes from giving cues i.e., rewards and benefits can boost physical performance or sports activity. Social information gleaned from competitors and teammates can also elicit a placebo effect and can change the optimal physical output strategies for athletes and exercisers. [23]. Hence there is a highly significant relationship between motivation and performance. Similarly, Hyland suggested that conditioning, the expectancy of response, and activation of goal have resulted in a placebo effect on a short-term basis only, while a long-term impact is obtained through goal satisfaction and the hypothalamic-pituitary-adrenal axis [24].

The current study utilized PALMs, which is a reliable, measure of participants' motivation, to study the various factors of motivation that are mastery, affiliation, physical condition, enjoyment, appearance, and psychological condition [23]. There was a significant difference in the pre and post-subcategory of enjoyment and competition among the experimental group, whereas the control group only showed a slight increase in enjoyment. In another study most respondents i.e., 97% believed, and 73% experienced placebo-impacted performance in competitive sports. The athletes who falsely believed that they had been administered anabolic or that they had ingested carbohydrate, caffeine, or a hypothetical 'new ergogenic' or who believed they were using a respiratory training device, performed better than baseline or controls. [25]. Similarly, a systematic review that investigated studies to see the impact of placebo and nocebo revealed a small to moderate impact on performance in sports[26].

The current study also concluded that high motivational level and expectancy leads to decreased exertion levels and pulse rate. Participants after receiving a placebo showed a noticeable decline in exertion level, whereas subjects receiving water were more exhausted after performing exercise. Similarly, a study conducted in the United Kingdom in 2019, revealed a marked decrease in exertional level in the experimental group after receiving a placebo & subjects were able to perform more with less fatigue. In this study, the researcher compared the effect of information on physical fitness metrics in overweight or obese to normal-weight children. Each participant performed a treadmill exercise stress test twice under identical

conditions except for the difference in the information provided regarding a drink consumed before testing. Before each testing session, the participants drank a glass of water. In one session, they were given standard information that they were drinking water. In the other session, deliberate positive information was given, and the water drink was described by the researchers as a drink that increases energy levels, strengthens muscles and therefore is likely to improve exercise performance. The water bottles were also styled differently for the two sessions; during the standard information session, plain transparent water bottles were used, whereas during the deliberate positive information sessions, the water bottles were opaque and blue-coloured, and included a label proclaiming the content to be an energy drink that strengthens muscles and improves athletic performance [21].

The present study has also inferred a slight decrease in pulse rate which might be associated with elevated motivational level and decreased exertional level. This complies with a study conducted by Crawford et al. in the United States in 2019, in which authors concluded that variability in heart rate drives motivation reduces fatigue and allows a person to perform high-intensity exercise for prolonged periods. Hence it can be assumed that the pulse rate might be altered with variations in motivation and fatigue [27]. Similarly, a study by Thai Tuong involving a virtual reality exergame reported significant ( $p < 0.05$ ) improvement in mean heart rate, intrinsic motivation & time spent exercising [28]. This is also in line with a study by Stöckel & Grimm, in which running with real-time feedback of heart rate seemed to augment motivation in running at increased exertional level [29]. Berdi M et al noted that in 14 studies involving different sports, the impact of placebo on physiological and performance indicators like the power of muscles, heart rate, speed, and psychological factors show significant [30].

**Limitations:** The results of the study cannot be generalized since the study was conducted at a local school in one city due to COVID-19 restrictions.

## CONCLUSION

The study concludes that administering a placebo drink boosts physical performance by increasing motivational levels and decreasing the exertion of normal-weight adolescents. Hence it can be recommended for boosting physical performance in less motivated adolescents to avoid the unnecessary use of energy drinks.

## DECLARATIONS & STATEMENTS

### Author's Contribution

FB, NF, MA and AA: substantial contributions to the conception and design of the study.

MA, AA and MK: acquisition of data for the study.  
MA, AA and FB: analysis of the data for the study.  
MA, AA and NF: interpretation of data for the study.  
FB and GS: drafted the work.

MK, GS, FB, NF, MA and AA: revised it critically for important intellectual content.

MK, GS, FB, NF, MA and AA: final approval of the version to be published and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All authors contributed to the article and approved the submitted version.

### Ethical Statement

The study was conducted after approval of the Institutional Review Board and Ethics Committee (IRB & EC), Shifa International Hospital Ltd. & Shifa Tameer-e-Millat University with Reference IRB # 066-21 dated 9<sup>th</sup> April 2021.

### Consent Statement

Informed consent of participants was taken from their parents/guardians and ethical concerns were addressed.

### Conflicts of Interest

None to declare.

### Funding

None to declare.

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