

Good the intake of  
foods that is high in  
lycopene should  
lower inflammation in  
OV...

[Sociology](#), [Community](#)



**Q1. What is their hypothesis?**

Q2. What are the objectives and endpoints and are they clear?

Q3. What ethical permissions were obtained and are they suitable?

Ethical permissions for research involving human participants were approved by Ethics Committee of Human Experimentation of Tehran University of Medical Sciences.

**Q4. Is it double blind/placebo controlled and is the protocol appropriate in this area?**

It is not double blind/placebo controlled and the protocol was not appropriate, since only females from a single university were allotted. This could be a biased study.

**Q5. How suitable is the randomization?**

The randomization was not suitable for the sample, since it chosen via advertisement but there were a suitable randomization for choosing both groups (Gregory et al., 1993).

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**Q6. Has it recruited a suitable cohort of patients?**

Suitable cohorts of patient were recruited (Campbell et al., 1995).

**Q7. Has it recruited a suitable number of patients?**

Suitable cohorts of patient were recruited and they chose an equal number for both groups (Campbell et al., 1995).

Q8. Are the inclusion criteria suitable? Justify your comment.

Inclusion criteria are suitable. Participants were between 20-40 years old and

had a BMI of 25 and higher (Robergs, 2010).

Q9. Are the exclusion criteria suitable? Justify your comment.

Exclusion criteria are suitable. They excluded patient with inflammatory disease, smokers, and who are using any anti-inflammatory drugs (Robergs, 2010).

Q10. Does it clearly describe the trial's methods (sufficient relevant information to be reproducible by another research group).

Yes. The trial methods were appropriate. Another study showed similar results of lycopene and lower production of TNF- $\alpha$  (Hazewindus et al.)

### **Q11. Is there relevance to the non-compliance in the placebo group rather than the treatment group?**

No. The control group would not make any significant difference. Since only liquid water was given. This would however be taken on a daily basis as well.

Q12. Is there intention to treat? (in your answer explain the concept of intention to treat).

No. There was no prior treatment given. Intention of treatment also known as (ITT) analysis is based on when an initial treatment is given prior to actual treatment. In this case only tomato juice (lycopene) activity was checked for.

### **Q13. Does this study constitute the equivalent of a Phase 1/2/3/4 trial?**

The study constitutes of phase 2 and 3 trials, since direct recruitment and analysis of drugs or treatment on humans is involved. There is no marketing of any particular drug or novel protein and hence doesn't constitute to phase

4 trial.

Q14. Describe the statistical analyses used and discuss whether their methods of analysis are appropriate (e. g. parametric/non-parametric, have they used Significance? Confidence intervals? Both? What would be appropriate?).

The Statistical Package for Social Sciences (SPSS) was used. It was used to compare variables at baseline and also variables between two groups. Pearson's correlation coefficients were used to examine associations between change variables.

### **Using the SPSS program is most appropriate.**

Q15. Has a Post hoc test been used for multiple comparisons? Should there be?

No. No post hoc test has been used. I suggest there shouldn't be any since all appropriate test like SPSS, t test, Pearson's correlation test were used to compare variables.

### **Q16. What are the outcome measures and are they clear?**

Yes. It was clear and precise. The end results prove statistically that consumption of tomato juice could reduce inflammatory issues in obese individuals.

### **Q17. What are the limitations of this study?**

It only included females and only participants from The Tehran University of Medical Sciences.

This could result in population and gender bias and results can be

inappropriate if compared to a larger scale.

Q18. What methods are available to researchers to minimise confounding factors?

There are methods by which researches could use other samples containing antioxidants like green tea, citrus fruits etc.

Q19. Have they identified any possible risks?

No particular risk are found. Only in rare cases, individuals with tomato allergy should be warned.

### **Q20. How does the data justify their conclusions?**

The data is clear and precise. It is also compared to previous studies similar to the study plan. Also studies related to no consumption of tomato juice were compared and best results were obtained.