

An Exercise in Critically Evaluating Experimental Design: Can the “Peak Performance Pack” Benefit Adults of Every Age?

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Nutritional supplement companies often tout their products as having been “clinically tested” and demonstrated to “benefit adults of every age.” Bombarded daily with such advertising, students are expected to make informed decisions regarding the risks, benefits, and costs of nutritional supplements. This exercise will examine the “scientific evidence” presented on the internet by a supplement company. Participants are divided into groups, presented the materials provided publicly by the company, and asked to evaluate the experimental design used in each of two studies. Participants should evaluate the following: controls, sample size, placebo, single-blind, double-blind, definitions (“wellness,” “benefit,” “clinical trials”), dependent and independent variables. The evaluation should also consider the implications of peer-review and funding for the studies. Once completed, each group will share their evaluations with the entire class.

Keywords: critical thinking, hypothesis, experimental design, placebo, double-blind, clinical trial, peer review, variables.

Introduction

Nutritional supplement companies often tout their products as having been “clinically tested” and demonstrated to “benefit adults of every age.” Bombarded daily with such advertising, students are expected to make informed decisions regarding the risks, benefits, and costs of nutritional supplements. This exercise will examine the “scientific evidence” presented on the internet by a supplement company. The suggested example is *Melaleuca: The Wellness Company*. However instructors could encourage their students to select a company or supplement of interest.

Participants are divided into groups, presented the materials provided publicly by the company, and given a series of questions to evaluate the experimental design used in each of two studies. Studies presented in this workshop are “The Freiburg Study” (Freiburg, 2014) and the “Sterling Study” (Sterling Research Group, 2015).

Students should evaluate the following: controls, sample size, placebo, single-blind, double-blind, definitions (“wellness,” “benefit,” “clinical trials”), dependent and independent variables. The evaluation should also consider the implications of peer-review and funding for the studies. Once completed, each group will share their evaluations with the entire class.

Group sharing with the class is followed by a discussion of the four stage process of human clinical trials required to obtain approval of drugs by the Federal Drug Administration (FDA). These phases include trials of safety, efficacy, comparison of cohorts and various doses, and public monitoring for longitudinal impact in a broad population. Students then determine if the studies examined during class have met the rigorous requirements of human clinical trials for FDA approval. If time permits, students can be assigned the task of proposing a hypothesis regarding the supplement, designing an experiment to test the hypothesis, and writing a report describing the proposed experimental procedure.

Student Outline

Objectives

- Develop understanding of experimental design and clinical trials.
- Appreciate differences between science, weak science, and pseudoscience.
- Develop confidence to determine which over-the-counter nutritional supplements are worth purchasing (or not).

Introduction

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Working with your group, examine and evaluate the study assigned to you. Use the questions below to help guide your evaluation.

Study Assigned:

Who (names of researchers and the institution) conducted this study?

Who paid for this study?

Has this study been subjected to peer-review?

What is the underlying hypothesis of this study?

What is/are the dependent variable(s)?

What is/are the independent variable(s)?

If the study includes the following, please describe:

Controls

Placebo group

Definitions of “wellness” or “benefit”

Is this study a single-blind trial or is it a double-blind trial or is it neither? What are the strengths and weaknesses of the type of study used?

Please share any additional questions you have regarding the product or the research.

Materials

A computer with Internet access and LCD projector can be helpful for observing websites and presenting information regarding FDA clinical trials.

Whiteboards with dry erase markers for each working team promotes interaction among the students while answering the questions on the student sheet.

Suggested Studies to Evaluate:

“The Freiburg Study”

<http://www.freiburgstudy.com/>

<http://www.freiburgstudy.com/img/Freiburg%20Study%20Research%20Findings-2a.pdf>

<http://www.freiburgstudy.com/img/Freiburg%20Study%20Results-new.pdf>

“U.S. Based Sterling Study”

<http://sterlingclinicalresults.com/>

<http://sterlingclinicalresults.com/img/sterling-study-research-findings.pdf>

Notes for the Instructor

Instructors are encouraged to tailor this thoughtful discussion exercise to their particular course. Among introductory level courses, this exercise works well to demonstrate basic critical thinking skills and apply them to experimental design. Upper level or physiology courses could delve more deeply into the metabolism of supplements or statistical analysis of clinical trial data.

Cited References

Freiburg Study. 2014. The Freiburg Study. <http://www.freiburgstudy.com/>

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Acknowledgments

Thank you very much to all of my Contemporary Biology students and all of the mini-workshop participants for their enthusiastic participation.

About the Author

Lori has been the Freshman Biology Laboratory Coordinator at Sam Houston University since 1990, where she guides young lab instructors and enjoys finding new ways to encourage critical thinking in non-majors as well as botany, zoology, and environmental science students.

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Citing This Article

Rose LA. 2018. An Exercise in Critically Evaluating Experimental Design: Can the “Peak Performance Pack” Benefit Adults of Every Age? Article 53 In: McMahon K, editor. *Tested studies for laboratory teaching*. Volume 39. Proceedings of the 39th Conference of the Association for Biology Laboratory Education (ABLE). <http://www.ableweb.org/volumes/vol-39/?art=1>

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