# Evaluation of a Novel Curriculum in Evidence-Based Medicine for Year 2 Medical Students

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# Evidence based medicine

- “Tools to understand EBM should be developed in concert with learning in pathophysiology and clinical medicine, ideally integrated across and through the curriculum”

# The problem…

- Healthcare students are expected to be able to locate, review and interpret evidence to inform clinical decisions
- Students at our school have had little opportunity to learn, practice and receive feedback on these skills in their first two years

# Our learning assumptions

- We believe that students learn best
  - By being active, in small groups
  - When they are self-directed
  - When the material is relevant to current learning
  - When the provider is credible
  - When they get feedback
  - When they are energized
- Students will value the evidence if they understand how it is generated
- Confidence and familiarity with EBM will enhance its utilization

# Our Learning Objectives

- Appreciate the importance of critical appraisal when searching for answers to clinical questions
- Recognize how basic science and animal research can inform and validate clinical research
- Identify different study designs and recognize their strengths and weaknesses.
- Understand the basic principles of statistical analysis as they pertain to selected research studies and clinical trials.
- Understand the concept of power, and the strength of randomization
- Understand the process and importance of peer review before publication

# Three Modules

- Student as Clinician
- Student as Reviewer
- Student as Researcher

# Research Plan


Model #1
Students as Clinicians

# Model #1: Students as clinicians

## Learning Objectives

- Understand difference between review and original material
- Identify trial designs
- Understand effect of subject selection
- Differentiate clinically and statistically significant differences

## Process

- Comparison of two trials examining role of N-acetylcysteine in preventing contrast nephropathy
- Comparison with other sources (texts etc)
- Series of questions provided to be worked on in tutorial groups
- 1 hour facilitated session

# Model #1: Students as clinicians

Compare

The New England Journal of Medicine

PREVENTION OF RADIOGRAPHIC-CONTRAST-AGENT–INDUCED REDUCTIONS IN RENAL FUNCTION BY ACETYLCYSTEINE

MARTIN TEPEL, M.D., MARCUS VAN DER GIET, M.D., CAROLA SCHWARZFELD, ULF LAUFER, M.D., DIETER LIERMANN, M.D., AND WALTER ZIDEK, M.D.

to

UpToDate ONLINE 12.2

**Acetylcysteine** — Among patients with chronic renal failure, the administration of acetylcysteine, a thiol-containing antioxidant, in combination with saline hydration and a nonionic, low osmolal contrast agent has protected against contrast nephropathy in some studies [47]:

And to textbook, review article, and consensus recommendations

# Model #1: Students as clinicians

Students receive

1. Learning objectives
2. Guiding questions
3. Referent material

5 days to work on material

Tutorial group meets to discuss and answer questions

~2hrs

1hr

Larger group-based facilitated discussion, learning objectives reviewed

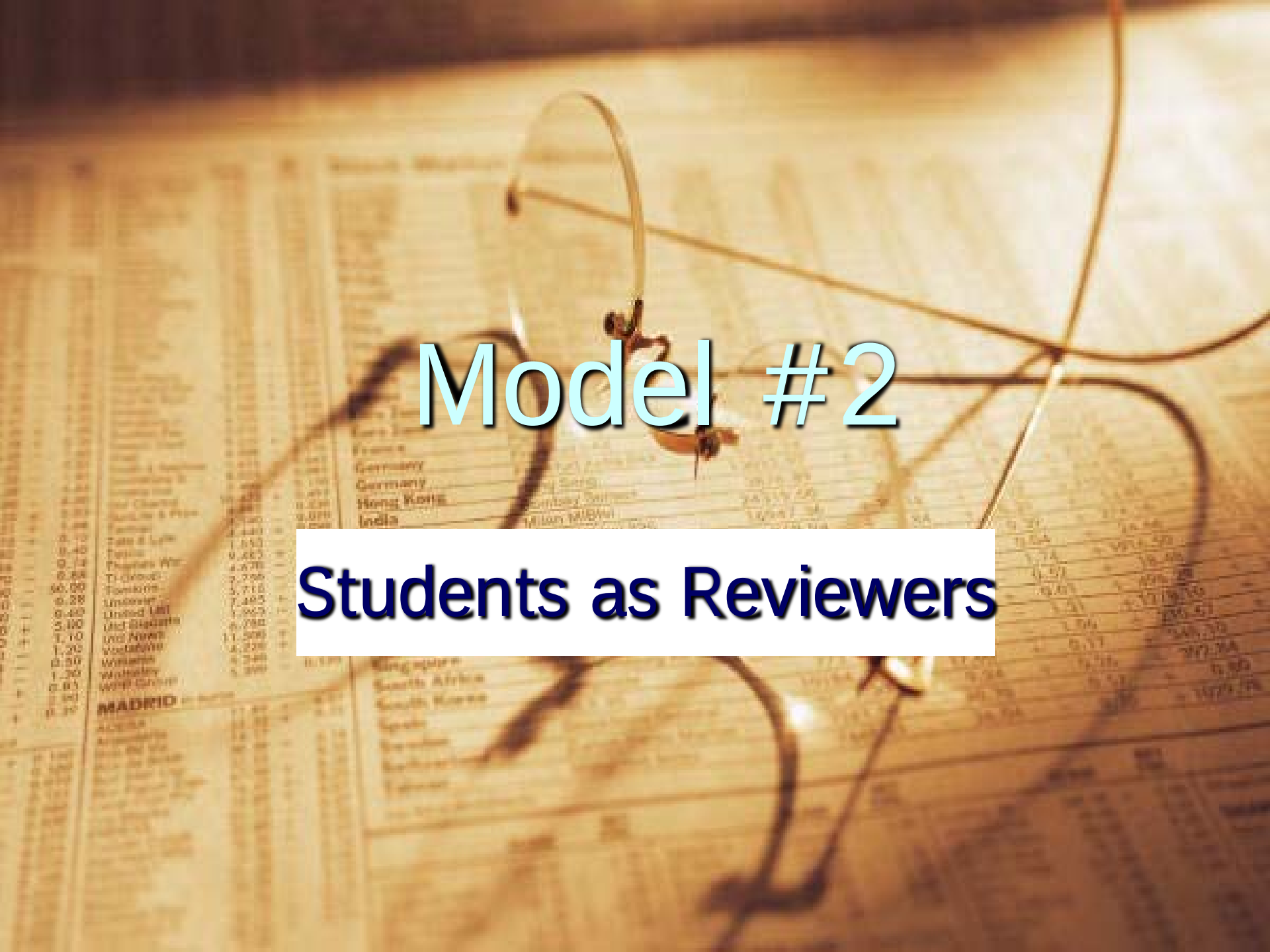
# Students' Response to Model #1

- Outcome data
  - Felt stimulated
  - Learned a great deal
  - Good use of time
  - Clearer about the role of literature
  - Plan to read more
  - Studied the papers
- Agreement* (n=115)
  - 74%
  - 68%
  - 56%
  - 81%
  - 88%
  - 86%

- Clinical vs. statistical significance
- Utility of different study designs
- Differences between various sources

- ↑ from baseline
  - 3.36 vs 3.11, p=0.018
  - 3.38 vs. 3.31, p=NS
  - 3.48 vs. 3.02, p<0.001

*Agreement = score ≥4 on 5-point agreement scale


Model #2
Students as Reviewers

# Model #2: Students as reviewers

## Learning Objectives

- Understand the importance of peer review
- Understand impact of statistical analysis on conclusions
- Develop insight into how the media interprets trial results

## Process

- Review the original submission of a low-carb diet trial
- Receive editorial reviews
- Answer a series of questions, exploring the effect of the editorial process on final publication
- Discuss answers in facilitated session
- Compare two papers, discuss statistics, editorial decisions, media impact

Half of class receive

1. Lea
2. Ori
3. Gui

Half of class receive

- Learning objectives
- mission B
- tions B

New England Journal of Medicine MS#02-2637

Samaha et al; Randomized trial to compare the effects of a carbohydrate restricted diet versus a fat- and calorie-restricted diet on weight loss and atherosclerotic risk factors in severely obese subjects

This study compared the effects on weight loss and cardiovascular disease risk factors of a low carbohydrate (LC) with a low fat (LF) diet in a six month trial. The authors demonstrate that subjects in the LC group had greater weight losses, improvements in triglyceride levels, insulin levels, and a greater increase in insulin sensitivity than subjects in the LF group. The study was well designed, and the manuscript is well written. The tables and figures appear appropriate.

Several problems require further elaboration.

1. The authors anticipated a 25% dropout rate, but observed a 40% dropout rate. The number of dropouts from the LF group was greater than that in the LC. The reasons for the dropout rate are not addressed, although the study results were not compromised by the increased dropout rate. It would be useful if the authors could provide more information as to why their dropout rate was so high, even if this information is anecdotal. Furthermore, it would be useful to know more about the ethnic and gender characteristics of those who left the study.
2. What explains the differences in weight loss between Caucasians and African Americans?
3. Was uric acid measured and were levels affected as anticipated by the LC diet? Regardless, if uric acid was measured, the results should be included in Table 3. If not, the authors should comment on why they did not monitor uric acid levels, insofar as elevated uric acid is common on low carbohydrate diets.

article & media impact

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

# A Low-Carbohydrate as Compared with a Low-Fat Diet in Severe Obesity

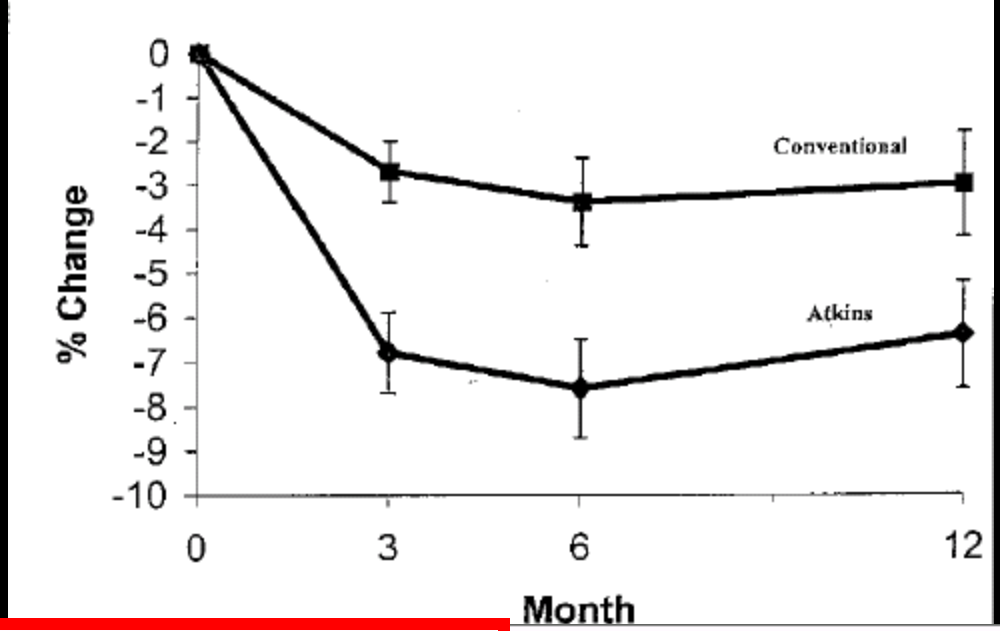
Frederick F. Samaha, M.D., Nayyar Iqbal, M.D., Prakash Seshadri, M.D., Kathryn L. Chicano, C.R.N.P., Denise A. Daily, R.D., Joyce McGrory, C.R.N.P., Terrence Williams, B.S., Monica Williams, B.S., Edward J. Gracely, Ph.D., and Linda Stern, M.D.

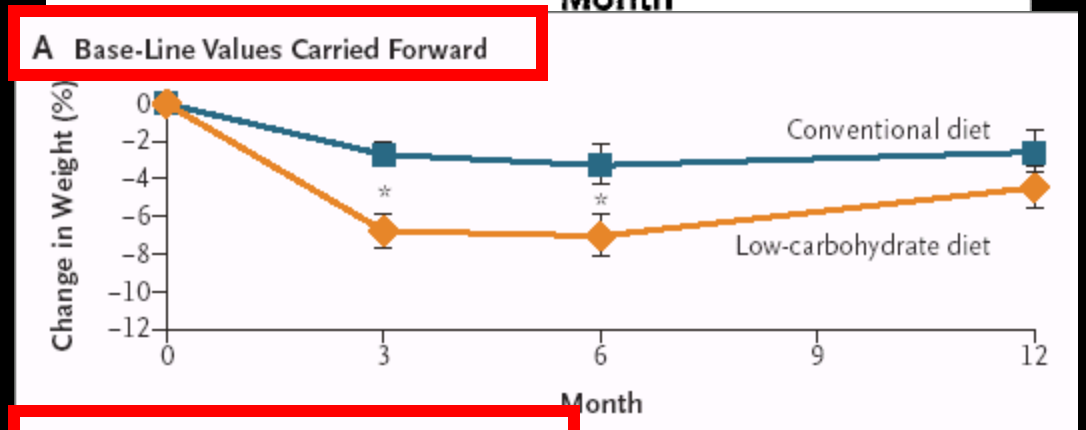
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

# A Randomized Trial of a Low-Carbohydrate Diet for Obesity

Gary D. Foster, Ph.D., Holly R. Wyatt, M.D., James O. Hill, Ph.D., Brian G. McGuckin, Ed.M., Carrie Brill, B.S., B. Selma Mohammed, M.D., Ph.D., Philippe O. Szapary, M.D., Daniel J. Rader, M.D., Joel S. Edman, D.Sc., and Samuel Klein, M.D.


0
-1
-2
-3
-4
-5
-6
-7
-8
-9
-10
% Change
Conventional
Atkins
0
3
6
12
Month


A Base-Line Values Carried Forward
Change in Weight (%)
0
-2
-4
-6
-8
-10
-12
Conventional diet
Low-carbohydrate diet
*
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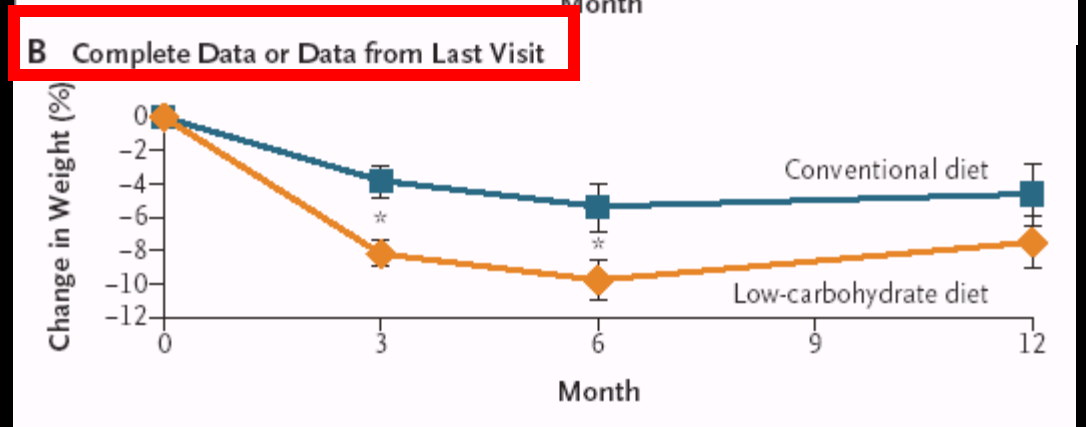
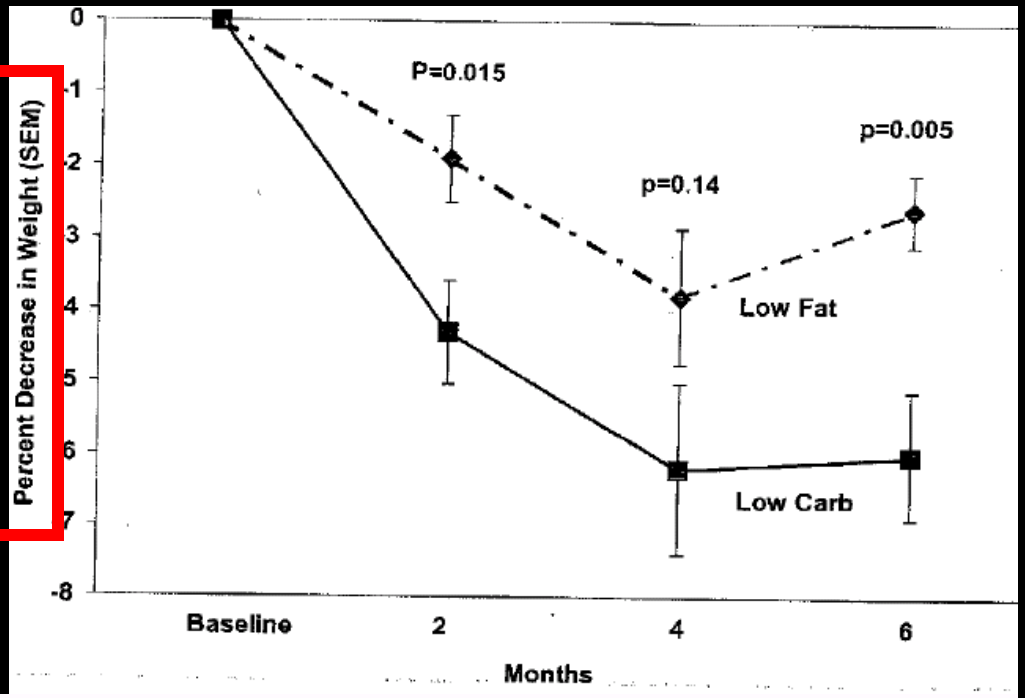
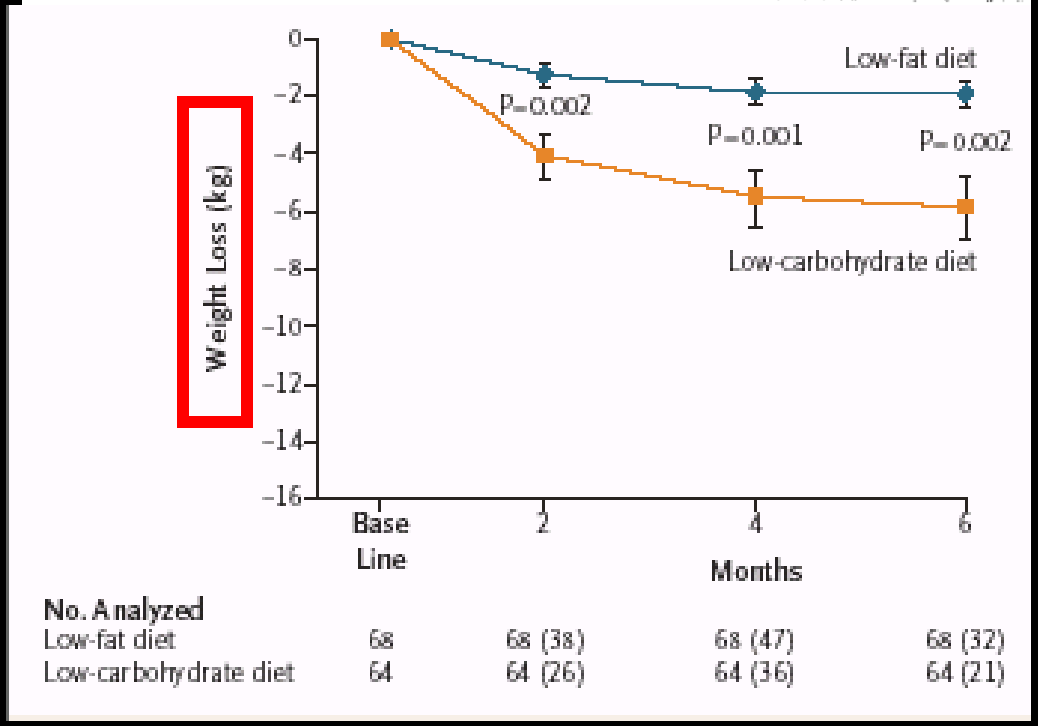
0
3
6
9
12
Month


B Complete Data or Data from Last Visit
Change in Weight (%)
0
-2
-4
-6
-8
-10
-12
Conventional diet
Low-carbohydrate diet
*
*
0
3
6
9
12
Month

Foster




Note scale




Numbers provided

Samaha

# Conclusions: Foster

## Original

These results demonstrate that the Atkins' diet produces greater weight loss than a conventional diet for up to 1 year, when both are prescribed in a self help format. In addition, treatment with the Atkins' diet decreased some risk factors for CHD.

## Final

The low-carb diet produced a greater weight loss (absolute difference ~4%) than did the conventional diet for the first six months, but the differences were not significant at one year. The low-carbohydrate diet was associated with a greater improvement in some risk factors for coronary heart disease. Adherence was poor and attrition was high in both groups.

# Conclusions: Samaha

## Original

Severely obese subjects with a high prevalence of diabetes or metabolic syndrome achieved greater weight loss, with a shift to a more favorable cardiovascular risk profile, on a carbohydrate-restricted diet compared with a calorie- and fat-restricted diet at six months.

## Final

Severely obese subjects with a high prevalence of diabetes or the metabolic syndrome lost more weight during six months on a carbohydrate-restricted diet than on a calorie and fat-restricted diet, with a relative improvement in insulin sensitivity and triglyceride levels, even after adjustment for the amount of weight lost. This finding should be interpreted with caution, given the small magnitude of overall and between-group differences in weight loss in these markedly obese subjects and the short duration of the study.


**Video #1:**
http://tinyurl.com/a38vt
**Studies support Atkins' diet**

**Video #2:**
http://tinyurl.com/7ab3z
**Atkins get the health high five**

May 5, 2004

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- File Cabinet
- Shopping List
- Journal

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Resources

Glossary of Terms

# Grounded in Research

A growing body of clinical research on controlled carbohydrate nutrition includes literature on chronic disease risk factors. This section provides supporting research in several different formats.

**How appropriate is the commercial conclusion?**

[ SCIENCE OVERVIEW ]

### Latest Research

**Very-Low Carbohydrate Weight-Loss Diets Revisited**

Much scientific and anecdotal data demonstrate favorable metabolic responses to very-low-carbohydrate diets.

Read More ▹

### Articles About Research

Read some reports supporting the Atkins Nutritional Approach™.

- New Research, New Directions
- Research Update, March 2004
- Research Update, January

### Practitioners' Forum

**Q: How appropriate is the Atkins Nutritional Approach™ for adolescents?**

Read the Answer ▹

- More Questions
- Submit Your Question

The Science Behind Atkins
Research Supporting Atkins
Science Overview
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Research Summaries



Resources
Glossary of Terms
Carb Gram Counter
View FAQs



# Research Supporting Atkins

The Science Behind Atkins > Research Supporting Atkins

## Research Supporting Atkins

Print This Email This Save This

Below you will find a list of selected research studies that have been published on the topic.

### References

Bailes, J.R., Strow, M.T., Werthammer, J., et al., "Effect of Low-Carbohydrate, Unlimited Calorie Diet on the Treatment of Childhood Obesity: A Prospective Controlled Study", *Metabolic Syndrome and Related Disorders,* 1(3), 2004, pages 221-225.
view summary

Brehm, B.J., Seeley, R.J., Daniels, S.R., et al., "A Randomized Trial Comparing a Very Low Carbohydrate Diet and a Calorie-Restricted Low Fat Diet on Body Weight and Cardiovascular Risk Factors in Healthy Women," *The Journal of Clinical Endocrinology and Metabolism*, 88(4), 2003, pages 1617-1623.
view summary

Dansinger, M.L., Gleason, J. L., Griffith, J.L., et al., " One Year Effectiveness of the Atkins, Ornish, Weight Watchers, and Zone Diets in Decreasing Body Weight and Heart Disease Risk,"Presented at the American Heart Association Scientific Sessions November 12,2003 in Orlando, Florida.
view summary

Foster, G.D., Wyatt, H.R., Hill, J.O., et al., "A Randomized Trial of a Low-Carbohydrate Diet for Obesity," *The New England Journal of Medicine*, 348(21), 2003, pages 2082-2090.
view summary

Greene, P., Willett, W., Devecis, J., et al., "Pilot 12-Week Feeding Weight-Loss Comparison: Low-Fat vs Low-Carbohydrate (Ketogenic) Diets," Abstract Presented at The North American Association for the Study of Obesity Annual Meeting 2003, *Obesity Research*, 11S, 2003, page

# Students' Response to Model #2

- Outcome data
  - Felt stimulated
  - Learned a great deal
  - Good use of time
  - Clearer about lit role
  - Plan to read more
  - Studied the papers
- Agreement (n=142)
  - 87%
  - 86%
  - 67%
  - 81%
  - 89%
  - 95%

- Clinical vs. statistical significance
- Utility of different study designs
- Concept of Power
- Meaning of intent to treat

- ↑ from baseline
  - 3.53 vs. 3.11, $p<0.001$
  - 3.49 vs. 3.31, $p=0.036$
  - 3.19 vs. 2.94, $p=0.014$
  - 3.48 vs. 2.57, $p<0.001$

# Model #3

## Students as Scientists

# Model #3: Students as scientists

## Learning Objectives

- Recognize how basic science and animal research can inform and validate clinical research
- Understand the elucidation of the genetic etiology of rare diseases

## Process

- A basic science paper illustrating the discovery and validation of a new mutation controlling reproduction
- Each tutorial group asked to design a trial to build on this knowledge
- Each submitted trial reviewed and discussed by lead author from original research

ORIGINAL ARTICLE

# The GPR54 Gene as a Regulator of Puberty

Stephanie B. Seminara, M.D., Sophie Messager, Ph.D.,
Emmanouella E. Chatzidaki, B.Sc., Rosemary R. Thresher, Ph.D.,
James S. Acierno, Jr., B.S., Jenna K. Shagoury, B.S., Yousef Bo-Abbas, M.D.,
Schwinof, M.A., Alan G. Hendrick, Ph.D.,
on, B.A., Ursula B. Kaiser, M.D.,
F. Gusella, Ph.D., Stephen O'Rahilly, M.D.,
, William F. Crowley, Jr., M.D.,
., Ph.D., and William H. Colledge, Ph.D.

**Basic & translational science need not be intimidating and can be clinically informative**

STRACT

BACKGROUND

Puberty, a complex biologic process involving sexual development, accelerated linear growth, and adrenal maturation, is initiated when gonadotropin-releasing hormone begins to be secreted by the hypothalamus. We conducted studies in humans and mice to identify the genetic factors that determine the onset of puberty.

METHODS

We used complementary genetic approaches in humans and in mice. A consanguineous family with members who lacked pubertal development (idiopathic hypogonadotropic hypogonadism) was examined for mutations in a candidate gene, GPR54, which encodes a G protein–coupled receptor. Functional differences between wild-type and mutant

From the Reproductive Endocrine Unit (S.B.S., J.S.A., J.K.S., K.M.S., W.F.C.) and the Molecular Neurogenetics Unit, Center for Human Genetic Research (S.A.S., J.F.G.), Massachusetts General Hospital; the Division of Endocrinology, Diabetes, and Hypertension, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School (W.K., U.B.K.); and the Harvard Institute of Human Genetics, Harvard Medical School (S.A.S., J.F.G.) — all in Boston; Paradigm Therapeutics (S.M., R.R.T., A.G.H., D.Z., J.D., M.B.L.C., S.A.J.R.A, W.H.C.); the

# The Challenge...design a study

- Could kisspeptin-1, acting through *GPR54*, and then GnRH, be the "switch" that turns on or turns off the reproductive cascade? If so, what are the implications of this discovery for other reproductive disorders besides IHH?
- The **CHALLENGE** for this week is to answer that question! Ope out the creative investigator insi
- Imagine that you are an author o the next set of experiments you role of kisspeptin-1/metastin and Money and manpower are no objects—you have every reagent, including purified metastin. You can work in *in vitro* or *in vivo* systems.

**Designing a study requires students to understand the material and explore its implications**

# Model #3: Students as scientists

Students receive

1. Learning objectives
2. Discussion Paper & editorial
3. Invited to design new trial

Tutorial group meets to discuss and create trial based on research

Facilitated discussion with lead author, after review of submitted trials

# Students' Response to Model #3

| Outcome data | Agreement (n=125) |
| --- | --- |
| Felt stimulated | 66% |
| Learned a great deal | 60% |
| Good use of time | 44% |
| Clearer about role of literature | 71% |
| Plan to read more | 86% |
| Studied the papers | 82% |
| Understand how basic science can inform clinical decision-making | 91% |
| Use of genetic approaches to find novel genes involved in human disease | 88% |
| Methods to determine whether specific base pair changes in a gene represent true "mutations." | 70% |

# Outcome Measures: Opinions

**Positives**

- Creative
- Interesting
- Integrated
- Necessary
- Fun
- Authoritative speakers

**Negatives**

- Too late
- Too little
- Too much work
- Conflict with board studying & exams

# What now?

- Longitudinal 3-yr curriculum in EBP
  - Integrating interactive online modules (dispersed students) & intermittent in-person tutorials
  - Progressively more challenging cases
  - Knowledgeable consistent tutorial staff
  - Include strategies to practicing application
  - Keep diary of progress, own searches, and how their practice changed
  - Students will be graded & evaluated

# Conclusions

- A majority of our students appreciate the opportunity to learn about EBM and request more time.
- A clearer appreciation of evidence based medicine can result from careful introduction of relevant interactive material
- An opportunity exists to facilitate student learning in this important area by collaborating across courses, years and disciplines to create a longitudinal curriculum

# Media Impact: Foster & Samaha

- ABC news
- CBS news
- NBC nightly news
- NPR
- Good Morning America
- American Morning
- CNN live today
- Voice of America
- Dateline
- Fox News
- New York Times
- Washington Post
- Boston Globe
- Wall street Journal
- USA Today
- Los Angeles Times
- Time Magazine
- US News
- New Zealand Herald
- London Times
- Guardian
- Toronto Star
- Australian Bulletin
- Tagesspiegel
- Berliner Zeitung
- Cape Argus (s. afr)
- Straits Times

**417 Media Articles**

## Top Ten List for Media Coverage - Total Citations for 2003

| Article Title | Issue Date | No. Of Original Citations | No. Picked Up By | Total Citations |
|---|---|---|---|---|
| **1.** A Randomized Trial of a Low-Carbohydrate Diet for Obesity | 5/22/2003 | 207 | 210 | 417 |
| A Low-Carbohydrate as Compared with a Low-Fat Diet in Severe Obesity | 5/22/2003 | 207 | 210 | 417 |
| **2.** The Influence of Finasteride on the Development of Prostate Cancer | 7/17/2003 | 98 | 149 | 247 |
| **3.** Effect of Anti-IgE Therapy in Patients with Peanut Allergy | 3/13/2003 | 62 | 149 | 211 |
| **4.** Overweight, Obesity, and Mortality from Cancer in a Prospectively Studied Cohort of U.S. Adults | 4/24/2003 | 66 | 133 | 199 |
| **5.** A Randomized Trial of Letrozole in Postmenopausal Women after Five Years of Tamoxifen Therapy for Early-Stage Breast Cancer | 11/6/2003 | 85 | 113 | 198 |
| **6.** Estrogen plus Progestin and the Risk of Coronary Heart Disease | 8/7/2003 | 62 | 109 | 171 |

# Sources

- When you have a clinical question, where do you turn to first?
  - Online databases 45%
  - Texts 25%
  - PubMed 7%
  - From survey of 142 Year 2 HMS students during this program

# Two studies provide scientific backing for the Atkins diet

Associated Press, 5/22/2003

A month after Dr. Robert C. Atkins's death, his controversial low-carbohydrate diet has received its most powerful scientific support yet: Two studies in one of medicine's most distinguished journals show it really does help people lose weight faster without raising their cholesterol. The research, in today's **New England Journal of Medicine**, found that people on the high-protein, high-fat, low-carbohydrate Atkins diet lose twice as much weight over six months as those on the standard low-fat diet recommended by most major health organizations.

# Atkins Diet Does Well in Tests

David Armstrong, Wall Street Journal 05/22/2003

The popular but controversial low-carbohydrate Atkins diet helped obese patients lose weight faster and with potentially more health benefits than the conventional low-fat diet, according to two studies published in this week's **New England Journal** of **Medicine** .

The researchers involved were quick to say there were several caveats and that they weren't endorsing the diet. Still, the appearance of the studies in a prestigious medical journal is certain to give a boost to the often-derided approach designed by Robert Atkins, who died last month.

# Atkins Similar to Low-Fat Diets

## Study: Long-Term Results Differ Little

Sally Squires, Washington Post 5/22/2003

Two new studies suggest that the low-carbohydrate Atkins diet may trim pounds faster than the traditional low-fat approach without raising risks for heart disease. But one year after losing weight, the Atkins group had regained more pounds than the low-fat group, leaving no significant weight difference between the two.