# *Randomization*

# *Goals of Participatory Randomization*

- Model a randomization procedure
- Identify issues in randomization for smaller samples
- Look at distribution of demographic factors using different randomization strategies
- Create academic product to pad Tutor CV's to allow successful promotion (it's not easy to get grants these days)

# *Tutor Brainstorming – what to study*

- Efficiency of PubMed searches: RCT comparing trained ringtail lemurs vs EBM tutors
- The effects of alcohol consumption on study validity: understanding the Friday night journal club effect using a cohort methodology
- The impact of climate change on EBM education and practice: Miami beach versus Durham - a multisite education and outcome study

# SEQUESTRATION

# *POPP-DM: RT*

***P**lain **O**r **P**eanut:*

***P**revention of Diabetes Mellitus*

***R**andomized **T**rial*

# Nut and Peanut Butter Consumption and Risk of Type 2 Diabetes in Women

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**Context** Nuts are high in unsaturated (polyunsaturated and monounsaturated) fat and other nutrients that may improve glucose and insulin homeostasis.

**Objective** To examine prospectively the relationship between nut consumption and risk of type 2 diabetes.

**Design, Setting, and Participants** Prospective cohort study of 83 818 women from 11 states in the Nurses' Health Study. The women were aged 34 to 59 years, had no history of diabetes, cardiovascular disease, or cancer, completed a validated dietary questionnaire at baseline in 1980, and were followed up for 16 years.

**Main Outcome Measure** Incident cases of type 2 diabetes.

**Results** We documented 3206 new cases of type 2 diabetes. Nut consumption was inversely associated with risk of type 2 diabetes after adjustment for age, body mass index (BMI), family history of diabetes, physical activity, smoking, alcohol use, and total energy intake. The multivariate relative risks (RRs) across categories of nut consumption (never/almost never, <once/week, 1-4 times/week, and ≥5 times/week) for a 28-g (1 oz) serving size were 1.0, 0.92 (95% confidence interval [CI], 0.85-1.00), 0.84 (0.95% CI, 0.76-0.93), and 0.73 (95% CI, 0.60-0.89) (*P* for trend <.001). Further adjustment for intakes of dietary fats, cereal fiber, and other dietary factors did not appreciably change the results. The inverse association persisted within strata defined by levels of BMI, smoking, alcohol use, and other diabetes risk factors. Consumption of peanut butter was also inversely associated with type 2 diabetes. The multivariate RR was 0.79 (95% CI, 0.68-0.91; *P* for trend <.001) in women consuming peanut butter 5 times or more a week (equivalent to ≥140 g [5 oz] of peanuts/week) compared with those who never/almost never ate peanut butter.

**Conclusions** Our findings suggest potential benefits of higher nut and peanut butter consumption in lowering risk of type 2 diabetes in women. To avoid increasing caloric intake, regular nut consumption can be recommended as a replacement for

TYPE 2 DIABETES AFFECTS APproximately 16 million people in the United States[1] and 135 million people worldwide[2]; the number of people with diabetes will reach an estimated 300 million worldwide by 2025.[2] Because management of diabetes and its complications such as cardiovascular disease, amputation, blindness, and renal failure imposes enormous medical and economic burdens, primary prevention has become a public health imperative.

Recent studies have shown that diet and lifestyle modifications are important means of preventing type 2 diabetes.[3-5] Evidence indicates that specific

# *The Evidence and the Question…*

- Nut and Peanut Butter consumption associated with decreased risk of diabetes in women
- National Nurses Health Study: Prospective Cohort with 16 years of follow up (JAMA 2002:288;2554-60)
- 83,818 women from 11 states
- Adjusted for age, BMI,FH DM, physical activity, smoking
- Does Nut consumption decrease hyperglycemia in other health professionals, both men and women?

# *The Setting and Study Design…*

- 96 participants at an EBM conference in Durham NC
- Randomized controlled trial: Plain vs. Peanut M&Ms
- Seating by random assignment: Plain v. Peanut→ outcome Blood Glucose Monitoring

# *Population Demographics…*

Total Sample Size: 96

- Gender:

  59 men (61%); 37 women (39%)

- Participant / Faculty:

  62 P (65%); 34 F (35%)

- NC / Out of State:

  NC 40 (42%); Out 56 (58%)

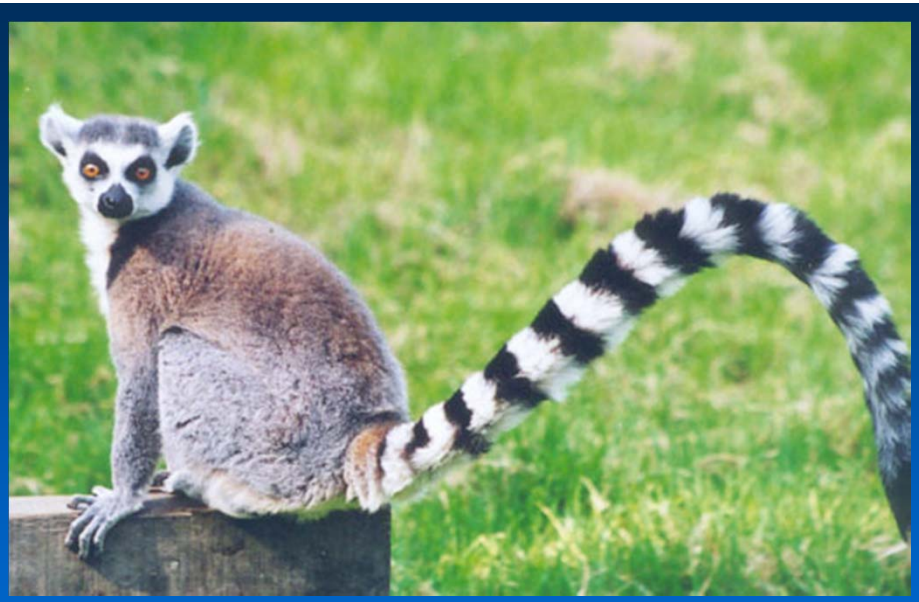
# *Population Demographics…*

- Gender
- Participant / Faculty
- In State / Out of State

Might these factors matter?

What are possible effects of sample size?

How would you try to minimize impact of bias?



# *The Randomizations*

# *POPP-DM RT Simple Randomization*

96 participants

| Plain | Peanut |
| --- | --- |
| N=52 | N=44 |
| Female: 15 (29%) | Female: 22 (50%) |
| Faculty: 22 (42%) | Faculty: 12 (27%) |
| In State: 19 (36%) | In State: 21 (47%) |

*Things should be made as simple as possible, but not any simpler.*

**Albert Einstein**

# *8 Stratification Groups*

Female

| | Faculty | Participant |
|---|---|---|
| NC | 12 | 5 |
| Out of State | 8 | 12 |

Male

| | Faculty | Participant |
|---|---|---|
| NC | 7 | 16 |
| Out of State | 7 | 29 |
| TOTAL | 34 | 62 |

# *POPP-DM RT Stratified Randomization*

96 participants

| Plain | Peanut |
| --- | --- |
| N=48 | N=48 |
| Female: 29 (60 %) | Female: 30 (62%) |
| Faculty: 17 (35%) | Faculty: 19 (39 %) |
| In State: 19 (40 %) | In State: 19 (40%) |

# *Other randomization approaches…*

- Block randomization
- Unequal randomization

*Questions?*

# *The End*

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