COMP320

RESEARCH PRACTICE

Ethics in Research

Objectives for Today

After this session, you should be able to:

- **Recognise** the role of ethics in human research
- **Discuss** the philosophical basis and historical context of research ethics
- **Explain** the ethical review process

Objectives for Today

After this session, you should be able to:

- **Anticipate** ethical issues associated with different research methods
- **Prepare** an adequate information document and consent form
- **Justify** your sample size with a statistical power analysis using G*Power

Further Learning

You will need to:

- **Identify** a suitable methodology and data analysis technique
- **Justify** these methodologies and analysis techniques
- **Prepare** a presentation on your work-in-progress and draft proposal

Objectives for Today

1. Role of Ethics in Human Research

- What are research ethics?
- Why do we need ethics?
- Key historical events

2. Ethical Review

- Positions in Ethical Review
- Review Process

3. Rights of Research Participants

- Human Dignity and Research

4. Information and Consent Forms

- Preparing an Appropriate Form

5. Power Analysis

- Principles and Measures of Effect Size
- Using G*Power

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Role of Ethics in Human Research

What are Ethics?

- Ethic
  - "A body of moral principles or values"
- Ethical
  - "of or pertaining to ethics"
  - "in accordance with professional or moral standards for right conduct or practice"
- Ethics
  - "a system of moral principles"
  - "the right and wrong of certain actions and the good and bad of such actions often embedded in a code"

What are Ethics?

- Research

  A systematic investigation to establish facts, principles or generalizable knowledge.

- Ethics in Human Research

  The values and moral principles associated with the manipulation and/or collection of data from persons, through intervention or otherwise

What are Ethics?

Research involving humans is premised on a fundamental moral commitment to advancing human welfare, knowledge, and understanding, and to examining cultural dynamics

Why Do We Need Ethics in Human Research?

- Human participants have not always been well protected
- Correct past, and prevent, new problems and abuses
  - Learn from dangerous and naiive research practices
- Research is big business with enormous amounts of money involved
  - Conflicts of interest (e.g. financial gain)
  - Dishonesty

Why Do We Need Ethics in Human Research?

- Monitoring the potential future impact of controversial issues (e.g. genetic engineering, cloning, gene therapy, etc.)
- Privacy issues for individuals is a growing societal concern.
  - Anonymity
  - Security and protection of data
- High standards of research ethics (and engagement in reflective practice) promote high quality research

Key Historical Events

- **Tuskegee Scandal**

  From 1932, 399 men (African-Americans from Alabama with poor literacy) suffering from syphilis were observed to track the natural progression of the disease.
- They were not told they had syphilis
- They infected their wives and their children were born with congenital syphilis
- Although penicillin had become the standard treatment by 1947, such treatment was deliberately withheld from research participants in order not to undermine the study.

Key Historical Events

- **Nazi Experimentation**

  Through 1940's experiments were carried out on prisoners of war
- Many experiments resulted in death, disfigurement, or life-changing injuries:
  - Freezing/hypothermia – deliberately killed people to see how long they would last
  - Malaria – tests of immunization and vaccines, most attempts unsuccessful
  - Mustard gas – testing how to treat chemical burns by deliberately injuring people
  - Sulfonamide – deliberately giving people "battlefield wounds" to test different treatments

Key Historical Events

- **Harvard Radiation Scandal**

  From 1946 to 1956, 19 boys who thought they were participating in a science club were fed radioactive milk by researchers who wanted to learn about the digestive system.
- The experiments were performed at the Fernald State School in Massachusetts. Researchers from Harvard University and MIT fed radioactive forms of iron and calcium to the boys, sometimes in their breakfast milk, to study the body's ability to digest minerals.

Key Historical Events

- **Willowbrook Scandal**

  In 1955, Krugman iimed to study the natural history of infectious diseases (e.g., hepatitis).
- Subjects were all children who were *deliberately* infected.
  - Defended by saying that the vast majority of them acquired the infection anyway and it was better for them to be infected under controlled research conditions.
  - School closed to new residents - but study took new patients - parents only able to place children at school if they participated in study.

Key Historical Events

- Hippocratic Oath ~AD275.
  - Earliest known set of principles outlining right and acceptable conduct
  - An oath sworn by Greek physicians to uphold a set of ethical standards
  - "I will use treatment to help the sick according to my ability and judgment, but never with a view to injury and wrong-doing. Neither will I administer a poison to anybody when asked to do so, nor will I suggest such a course." (extract, translated)

Key Historical Events

- Nuremberg Code 1947.
  - War trials by the Allies
  - Prompted by the use of prisoners of war in research
  - First international code of research ethics
- Declaration of Helsinki 1964.
  - World Medical Association
- Belmont Report 1979.
  - U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Key Historical Events

- Scandals relating to the abuse of research participants continued to arise occurred public attention in the U.S. between 1953 and 1972
- Even as recent as 2010, the *Lancet* withdrew a high profile medical article that contained falsified data about vaccination and autism
- Such incidents lead many to conclude that researchers should not be trusted to conduct studies involving humans without some form of accountability

Why Protect Research Participants?

It is unacceptable to treat persons solely as means (mere objects or things), because doing so fails to respect their intrinsic dignity and thus impoverishes all of humanity.

Tri-Council i.5

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Ethical Review

Ethical Review

- Any research involving human participants is subject to ethical review
  - Includes observation, questionairres, etc.
- Often follows this process:
  - Research is designed
  - Proposal is written
  - Proposal is assessed by an ethics committee
  - Comments sent to author
  - Amendments made to design and proposal
  - Proposal is approved or rejected
  - Research is conducted
- Mandatory at all UK universities, including Falmouth University, to get ethical approval for any research involving human participants

Positions in Ethical Review

- Deontological
  - The use a Universal code when making ethical decisions. An action is either ethical or not ethical, without exception.
- Ethical Skepticism
  - Concrete and inviolate ethical or moral standards cannot be formulated. Ethical standards are not universal but are relative to one's particular culture, time, etc.
- Utilitarianism
  - The practical position: decisions about the ethics should be based on an examination and comparison of the costs and benefits that may arise from an action.

Principles of Ethical Research

- **Social value**
  finding is worth something, results generalisable, is likely to be disseminated, has a potential impact on practice/culture/economy/politics/education/etc.
- **Scientific Validity**
  clear scientific objective, design of study appropriate to objectives, reliable methodology, is practically feasible, qualified research team
- **Fair Participant Selection**
  justice, no discrimination on protected characteristics, care taken with vulnerable populations
- **Favourable risk-benefit ratio**
  the benefits outweigh the risks
- **Independent Review**
  minimise conflicts of interest, and enables public accountability.
- **Informed Consent**
  voluntary consent based on a clear understanding of the objectives, risks, benefits, and alternatives to the research; able to withdraw at any point without penalty.
- **Respectful**
  ensure privacy, minimise disruption/impact, maintain anonymity, etc.

Group Activity

- Discuss which ethical position you take and why
- Which do you is more useful for research practice?

- Deontological
- Ethical Skepticism
- Utilitarianism

- Reading (2 minutes)
- Discussion (4 minutes)
- Notes (2 minutes)
- Presentation (2 minutes)

Rights of Research Participants

Key Rights of Research Participants

Although not deontological in nature, research participants are entitled to many rights:

- Respect for Human Dignity
- Free and Informed Consent
- Vulnerable Persons
- Privacy and Confidentiality
- Justice and Inclusiveness
- Balancing Harms and Benefits
- Minimizing Harm and Maximizing Benefit

Human Dignity

- Research participants are real people
  - They are not simply a *means*
  - They are not merely *objects*
- Participants bear the risks associated with the research

Free and Informed Consent

- Respecting participants' capacity and right to make free and informed choices
- Informing participants about the research through formal requirements
- A continual dialogue: it starts when prospective subjects are first approached and ends when their actual involvement is over
- Freedom to decline or withdraw from a research project without penalty

Vulnerable Persons

- Often unable to provide consent themselves
  - Children
  - Critically injured or ill
  - Cognitive impairment or mental illness
- Rather than consent, assent is often obtained from a guardian
- Studies involving vulnerable persons are often evaluated with significantly more rigor

Privacy and Confidentiality

Dignity and autonomy of human subjects is the ethical basis of respect for the privacy of research subjects

- The type of data to be collected;
- The purpose for which the data will be used;
- Limits on the use, disclosure and retention of the data;
- Appropriate safeguards for security and confidentiality;
- Any modes of observation;
- Any anticipated secondary uses of identifiable data from research;
- Any anticipated linkage of data gathered in the research with other data about subjects, whether those data are contained in public or personal records;
- Provisions of confidentiality of data resulting from the research

Justice and Inclusiveness

- Researchers have a duty to do everything within their power to make sure the benefits of their research is widely distributed
- Fairness and equity in the way that benefits and risks of research are distributed among individual participants, communities, and society
  - The benefits should not be restricted from or unjustly exclude any particular group of people
  - Any risks should be fairly distributed

Balancing Harms and Benefits

- If potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subjects in those aspects of his or her everyday life that relate to the research,
- Then the research can be regarded as within the range of minimal risk.

Group Activity

An experiment was conducted where students in a class were randomly allocated into two groups: one using a new teaching tool and one without. During the experiment, the students complained that they had not received access to the new tool and that the other group had an unfair advantage on the forthcoming exam. The researcher decided to continue the research irrespectively of the students' wishes.

- What are the ethical issues associated with this research?
- Was the research was ethical?

- Reading (5 minutes)
- Discussion (5 minutes)
- Notes (2 minutes)
- Presentation (3 minutes)

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Information & Consent Forms

Information and Consent Form

- You must include in your ethics application:
  - Information sheet
  - Consent form
- You seek consent only after the participant has received and adequately understood all of the necessary information and the consequences of participation in your research
- The information sheet must be clear and easily understood
- If written, consent should be obtained by signing on the consent form
- These need to be kept for your records, and destroyed when no longer needed in line with GDRP rules

Example Information and Consent Form

- Review the following example: https://www.soscisurvey.de/cs-ed-research-2018/
- The information and consent form typically contains:
  - Self-introduction
  - Purpose of the research
  - Benefits (if any, if not state)
  - Risks (if any, if not state)
  - Commitment required
  - Remuneration (if any, if not state)
  - Declaration of confidentiality
  - Anticipated outputs (if quotations likely, state)
  - Right to withdraw
  - Researchers' contact details

Group Activity

In your research groups, design a consent form for your studies.

Use your own research areas, questions, hypotheses, and methodologies as guides.

- What information should be included?
- Is there sufficient detail?
- Is it written using simple enough terms?

- Thinking (5 minutes)
- Drafting (5 minutes)
- Discussion (5 minutes)
- Presentation (2 minutes)

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Power Analysis

Make Your Work Meaningful!

Statistical Power

Statistical Power is the probability of detecting an effect, given that the effect is really there.

Our ethics suggest it is critically important that when we conduct research, we are not wasting time on underpowered studies that will not likely find anything!

Statistical Power

For example, let's say that we have a simple A|B study with design A and design B, and that the design B truly is better; the power is the probability of finding a difference between the two designs.

So, imagine that we had a power of .5 and that this simple study was conducted many times.

Statistical Power

Having power of .5 means that 50% of the time, we would get a statistically significant difference between the groups testing version A and version B when there is a real difference.

This also means that 50% of the times that we run this experiment, we will not obtain a statistically significant effect between the two groups, *even though there really is an effect in reality*.

Statistical Power

- The **statistical power** of a hypothesis test is the probability of making the correct decision if the alternative hypothesis is true.

- That is, the **power** of a hypothesis test is the probability of rejecting the null hypothesis when the alternative hypothesis is true.

Statistical Power

- Consider a usability trial testing two different control schemes for the same game. You might want to know which control scheme contributes to RSI, but unfortunately, only a few cases report problems. You can only test each scheme on a hundred play testers, but only a few in each group suffer serious effects.

- A researcher finds their p-value greater than 5%. They write:

  "*There was no statistically significant difference in adverse effects between groups*"

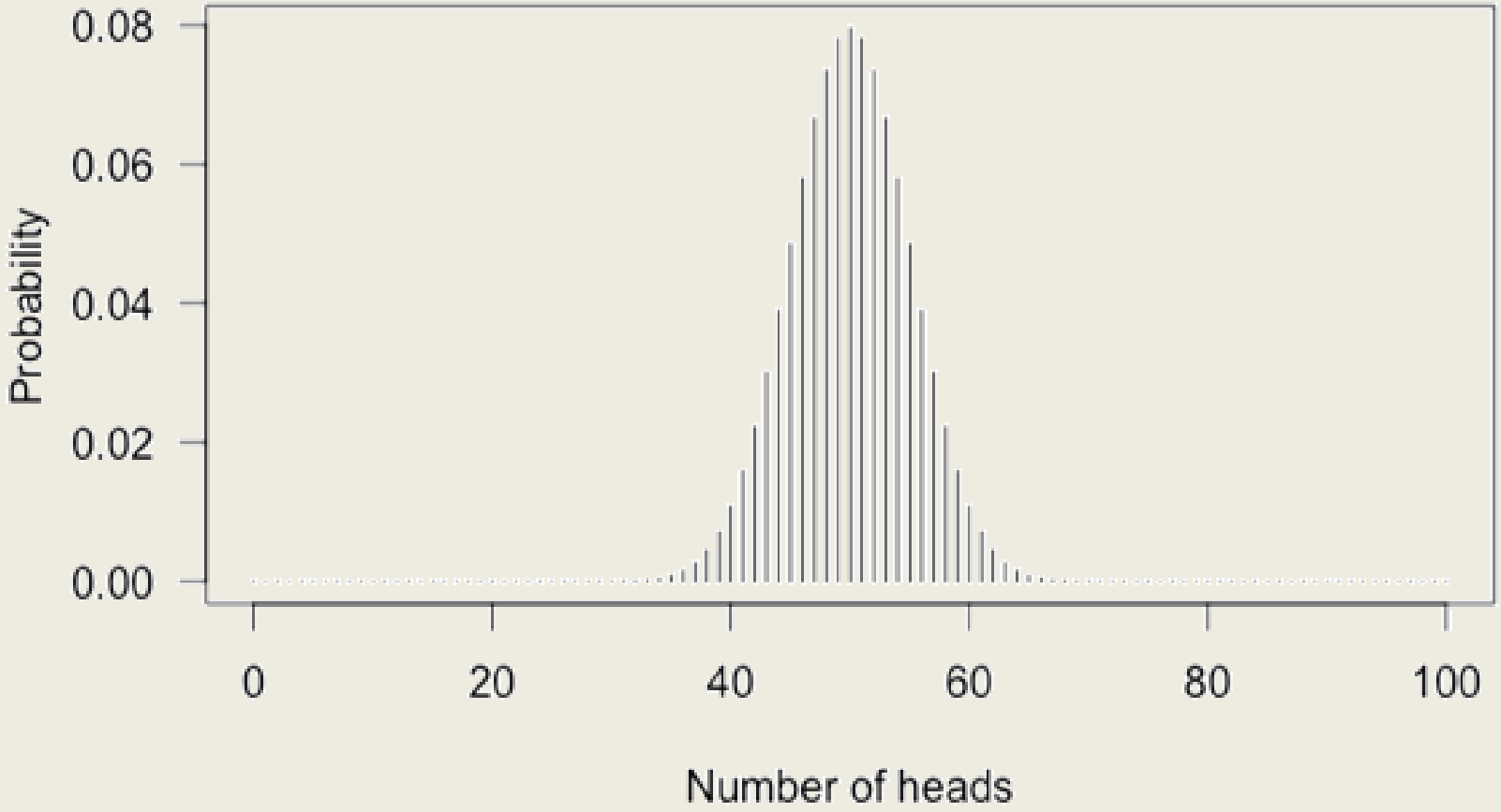
- Is there likely to be **no** difference? **Discuss.**

Statistical Power

Let's consider a simple scenario to explore:

- A gambler is convinced that an opponent has an unfair coin: rather than getting heads half the time and tails half the time, the proportion is different!
- How to prove it?
- You can't just flip the coin a hundred times and count the heads. Even with a perfectly fair coin, there won't be exactly fifty heads because of random error!

Statistical Power

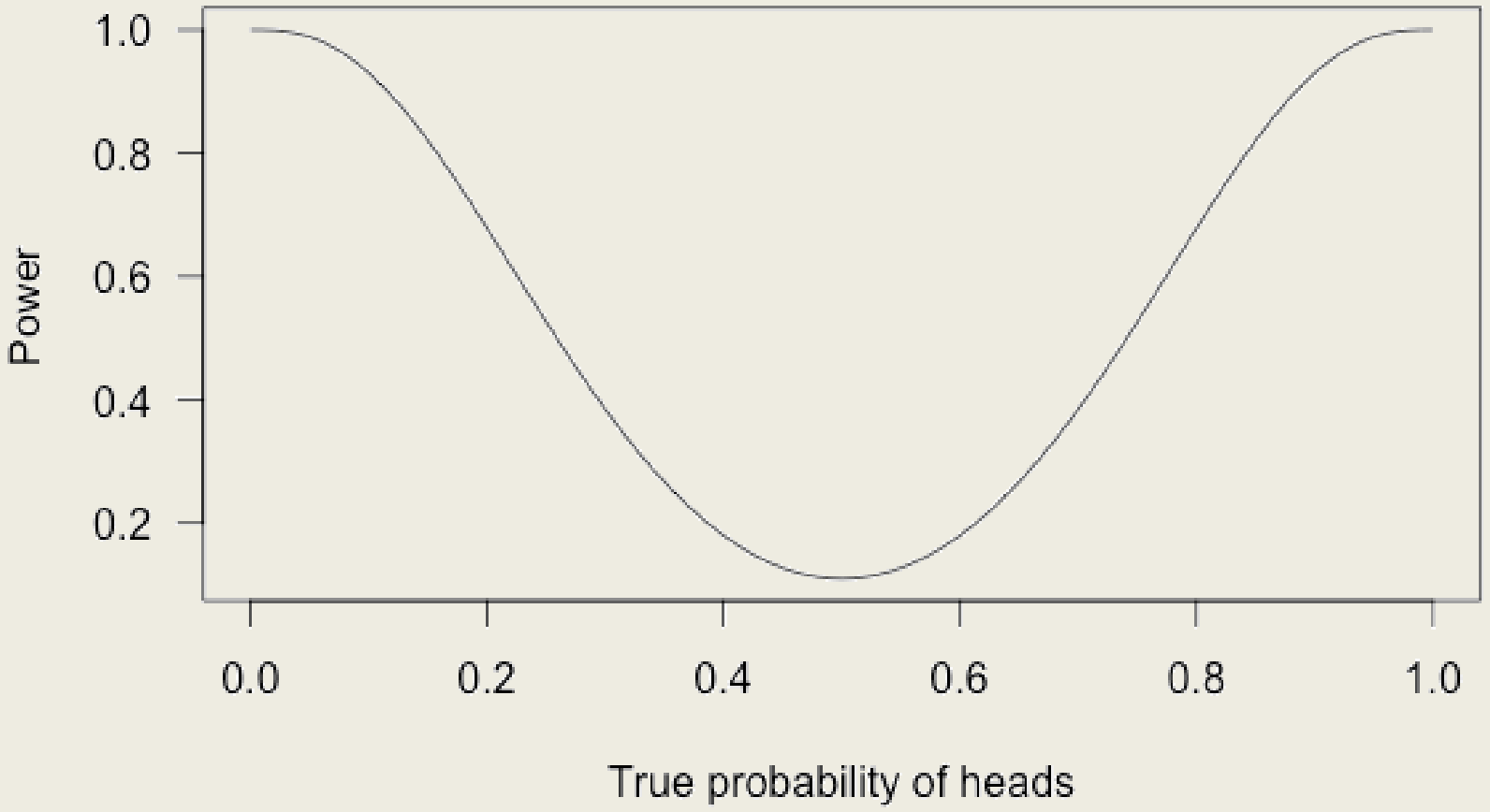


Statistical Power

The simulation with a fair coin shows:

- You can see that 50 heads is the most likely observation.
- It's also reasonably likely to get 43 or 57. The coin might be rigged, but you might just be lucky.
- Consider a *p*-value of 5% --- under the assumption the null hypothesis is true (a fair coin), there is only a 5% chance of observing those numbers, or more extreme values, with a fair coin.

- If it's less than a 5% chance, the it is not a fair coin.
- Otherwise, I can conclude nothing.


1.0
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Power
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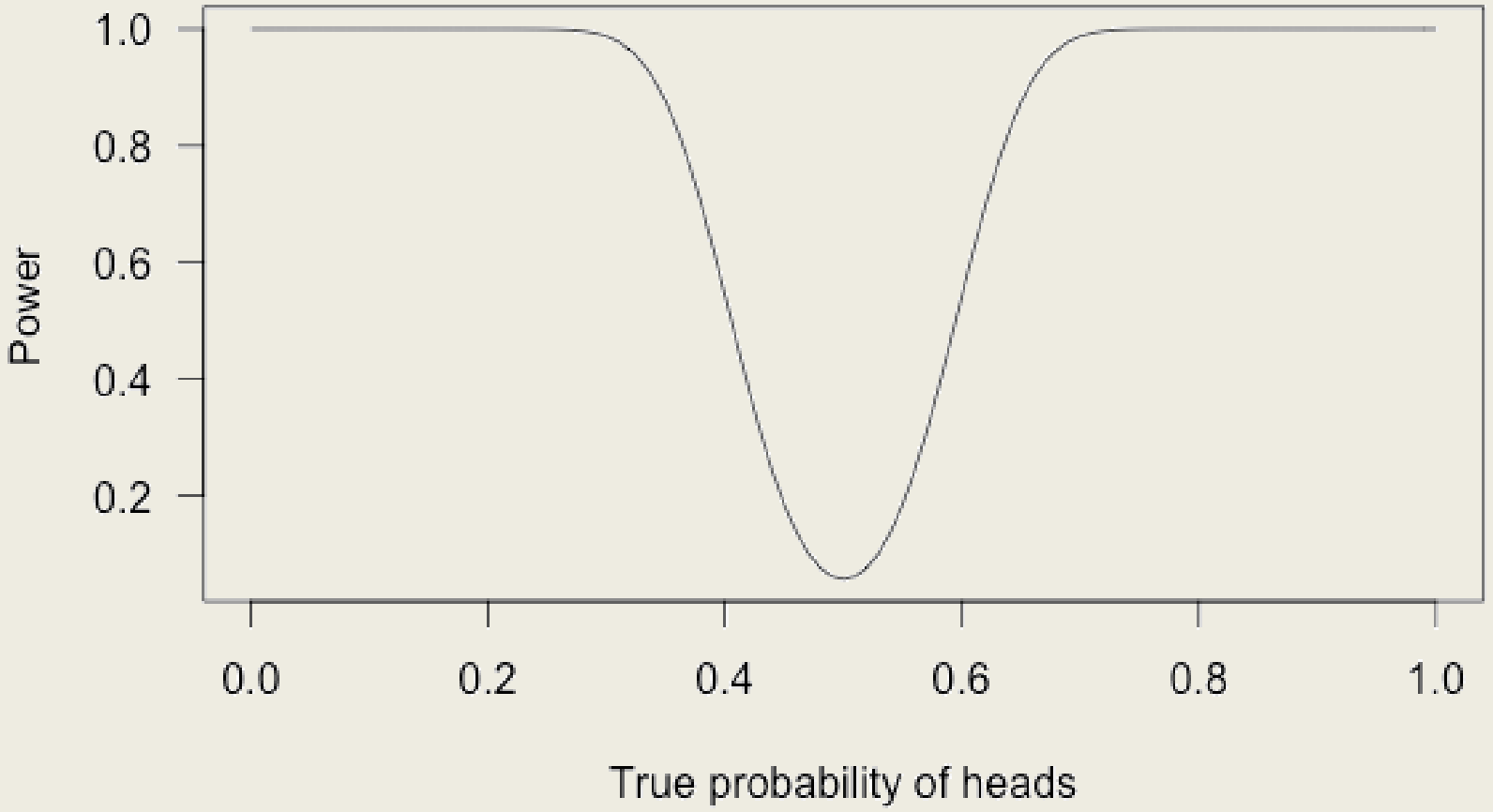
True probability of heads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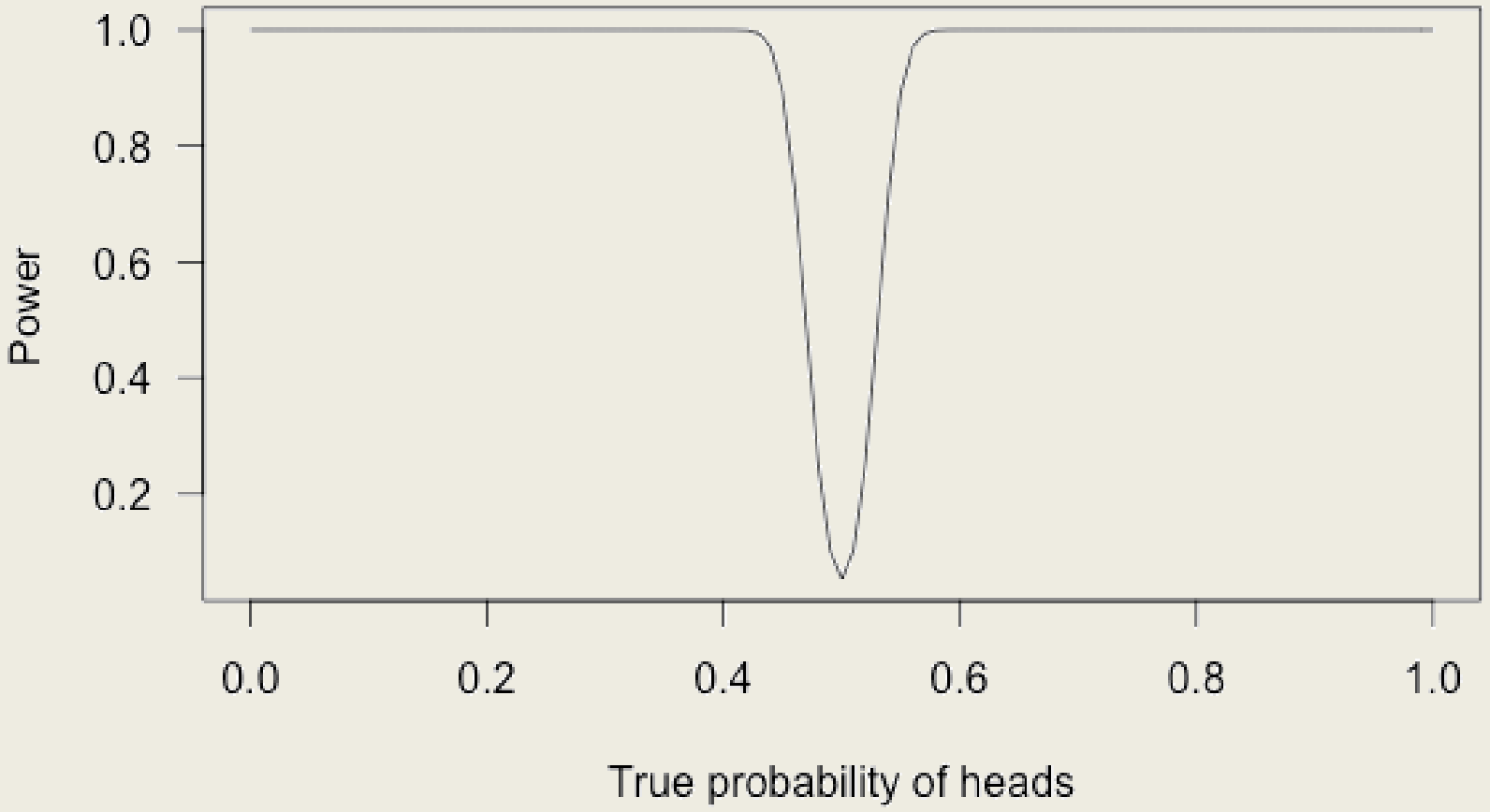
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1.0
True probability of heads

Statistical Power

- With one thousand flips, it is easy to determine if the coin is rigged. It is overwhelmingly unlikely that flipping a fair coin 1,000 times will result in more than 600 heads.

Statistical Power

Notes (adapted from Reinhart's analysis of medical trials):

> *27% of randomized controlled medical trials that were conducted to find effects on RSI gave negative results, but 64% of these didn't collect enough data to detect a 50% difference [...] between groups [using different control schemes]. Fifty percent! Even if one [scheme] decreases symptoms by 50% more than the other medication, there's insufficient data to conclude [that it was safer].*

Statistical Power

- Now, reconsider the usability trial testing two different control schemes for the same game. You might want to know which control scheme contributes to RSI, but unfortunately, only a few cases report problems. You can only test each scheme on a hundred play testers, but only a few in each group suffer serious effects.

- A researcher finds their p-value greater than 5%. They write:

  "*There was no statistically significant difference in adverse effects between groups*"

- Is there likely to be **no** difference? **This is a Type-II Error due to insufficient sample size!**

Statistical Power

- The sensitivity of particular statistical tests is known, and they scale with the amount of data being analysed.
- Random error cancels itself out as the number of observations is increased.
- So, with more data, smaller effect sizes can be reliably detected
- Where “reliable” is often considered an 80% chance. If you know the effect size, you can calculate the minimum sample size.

Effect Size

- Pearson's *r*

$$r = r_{xy} = \frac{n\sum x_i y_i - \sum x_i \sum y_i}{\sqrt{n\sum x_i^2 - (\sum x_i)^2}\sqrt{n\sum y_i^2 - (\sum y_i)^2}}.$$

- Cohen's *d*

$$d = \frac{|\mu_1 - \mu_2|}{\sigma} \qquad d = \frac{|\bar{x}_1 - \bar{x}_2|}{\sqrt{\frac{s_1^2 + s_2^2}{2}}}$$

- Cohen's *f*-ratio

$$f = \frac{\sigma_{means}}{\sigma} \qquad f = \sqrt{\frac{eta^2}{1 - eta^2}}$$

- Cohen's *w*

$$w = \sqrt{\sum \frac{(\pi_0 - \pi_1)^2}{\pi_0}} \qquad w = \sqrt{\sum \frac{(p_0 - p_1)^2}{p_0}}$$

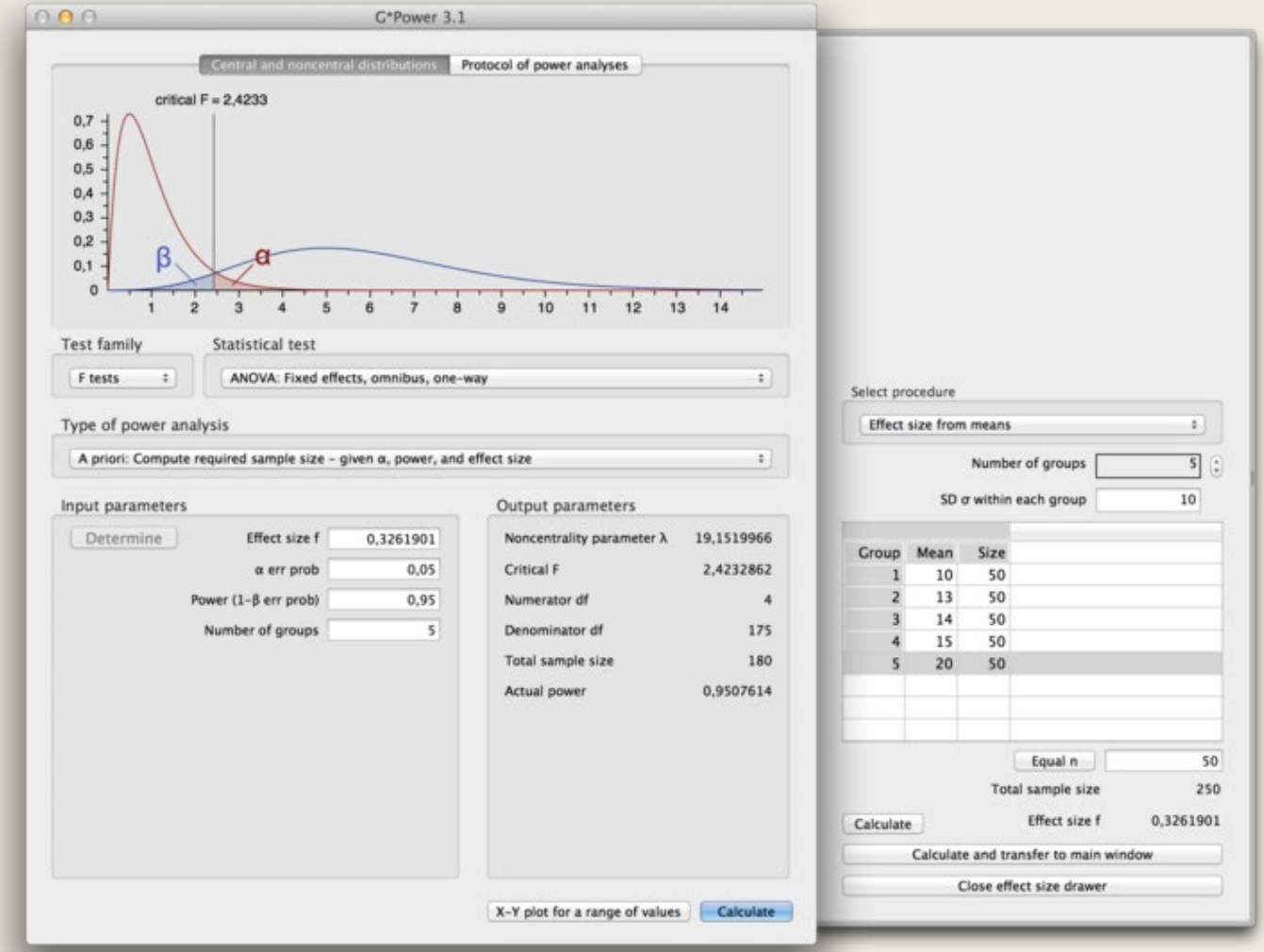
Power Analysis

- There are many tools that can be used to determine sample size --- G*Power is the one I recommend for beginners:

  http://www.gpower.hhu.de/en.html

- More sophisticated data analyses can be powered in *R* using pwr package:

  https://www.statmethods.net/stats/power.html


G*Power 3.1
Central and noncentral distributions
Protocol of power analyses
critical F = 2,4233
0,7
0,6
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0
β
α
1 2 3 4 5 6 7 8 9 10 11 12 13 14
Test family
F tests
Statistical test
ANOVA: Fixed effects, omnibus, one-way
Type of power analysis
A priori: Compute required sample size – given α, power, and effect size
Input parameters
Determine
Effect size f 0,3261901
α err prob 0,05
Power (1–β err prob) 0,95
Number of groups 5
Output parameters
Noncentrality parameter λ 19,1519966
Critical F 2,4232862
Numerator df 4
Denominator df 175
Total sample size 180
Actual power 0,9507614
X-Y plot for a range of values
Calculate
Select procedure
Effect size from means
Number of groups 5
SD σ within each group 10
Group Mean Size
1 10 50
2 13 50
3 14 50
4 15 50
5 20 50
Equal n 50
Total sample size 250
Calculate
Effect size f 0,3261901
Calculate and transfer to main window
Close effect size drawer

Power Analysis

- There are many tools that can be used to determine sample size --- G*Power is the one I recommend for beginners:

  http://www.gpower.hhu.de/en.html

- More sophisticated data analyses can be powered in *R* using pwr package:

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Important Note: Error Inflation

- Error inflation occurs when you test multiple hypotheses
- G*Power assumes only a single hypothesis test, you need to *increase* sample size for multiple hypothesis testing
- The Bonferroni adjustment: divide the alpha value (usually .05) by the number of hypotheses being tested

Important Note: Representativeness

- Not the same as a representative sample
- This is the minimum for statistical sense making, but if the sample doesn't adequately represent the population you're studying, then the research is still moot!
- http://www.academia.edu/download/35450631/bartlett_kotrlik_higgins_sampling_size.pdf