

MSC / MA SUPERSATURDAY

SATURDAY 16TH OCTOBER 2021

APPLIED RESEARCH AND ETHICS

SCHEDULE FOR THE DAY

HOUSEKEEPING

PROFESSIONAL ETIQUETTE

INTRODUCTION



A LITTLE BIT ABOUT ME...

Health Care Professions Council Registered Health Psychologist

Research experience in applied and educational settings
(government, NHS and University)

Expertise in psychoncology, genetics, dementia and intervention
and service evaluation

Over 15 years experience in successful NHS ethics applications
including large multicentre RCTs of complex interventions

Expert committee member of NHS Research Ethics Committee

Board member of Welsh Govt Health and Care Research Wales,
Research for Public & Patient Benefit Board.



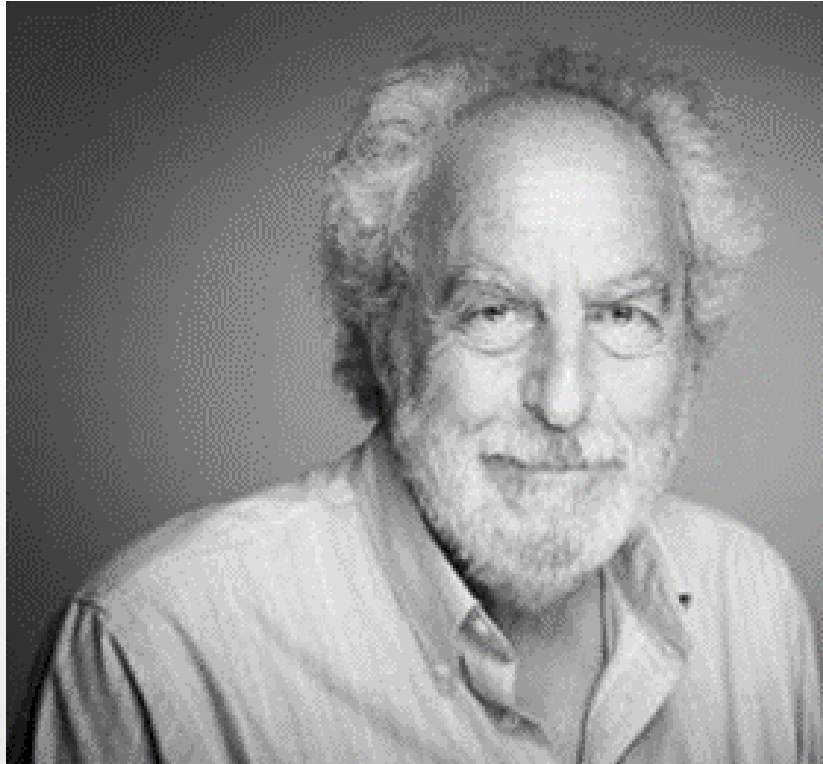
WHAT IS APPLIED RESEARCH?



‘research’ means the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods.



Health Research Authority, 2016



“

“To maximise the benefit to society, you need to not just do research but do it well.

- Professor Doug Altman

Medical research hero and statistics game-changer

RESEARCH, SERVICE EVALUATION OR AUDIT?

“Patients expect health professionals to undertake audit and service evaluation as part of quality assurance. These involve minimal additional risk, burden or intrusion for participants, and are regulated as standard clinical practice outside of the Research Ethics Service.”

“Research may involve greater risk, burden or intrusion for participants than standard clinical practice. It may generate conflicts of interest for the researcher, which will require review by an ethics committee. With some exceptions, research requires review by a REC.”

<http://www.hra.nhs.uk/documents/2016/06/defining-research.pdf>

RESEARCH GOVERNANCE FRAMEWORKS

Set out appropriate responsibilities and standards that apply to research in a specific context e.g.

- ***Research Governance Frameworks for Health and Social Care in Wales***

<http://gov.wales/docs/dhss/publications/governance/090929researchen.pdf>

- ***British Psychological Society Code of Human Research Ethics***

http://www.bps.org.uk/sites/default/files/documents/code_of_human_research_ethics.pdf

- ***BACP Ethical Guidelines for researching counselling and psychotherapy***

https://www.bacp.co.uk/docs/pdf/e_g.pdf

CODES OF HUMAN RESEARCH ETHICS

The moral principles by which we conduct ourselves as researchers



- BPS Code of Human Research Ethics (2021)
- BPS Ethics Guidelines for Internet-mediated Research (2021)
- BACP Ethical Guidelines for Research in the Counselling Professions (2019)

BASIC ETHICAL PRINCIPLES IN RESEARCH

- Respect for the autonomy, privacy and dignity of individuals and communities
- Scientific integrity
- Social responsibility
- Maximising benefit and minimising harm.
- **As researchers we have we have a moral obligation**
 - To our participants
 - To the academic/professional field
 - To our employers/funding body
 - To ourselves

BASIC ETHICAL PRINCIPLES IN RESEARCH

- **Beneficence and Nonmaleficence**

- ☐ The benefits of research versus the harm that can be caused by the research
- ☐ In human research we aim for no harm...
- ☐ Is temporary discomfort harmful? What if the research is highly significant?

- **Responsibility**

- ☐ We are in positions of trust
- ☐ Must not abuse this

KEY ETHICAL CONSIDERATIONS

Written informed consent – at appropriate levels

Clarity and comprehension of research materials

No potential coercion

Right to withdraw

Debriefing

Potential for harm/discomfort/distress

Confidentiality/Data Protection

SESSION ONE: APPLIED RESEARCH DESIGN

REFRESHER:

COMMON
DISTINCTIONS IN
RESEARCH

Basic versus applied
research

Qualitative versus
quantitative

Experimental V non-
experimental

Qualitative versus Quantitative Research

Quantitative research:

- We are not really interested in the sample that we study – we are interested in the target population
- Ability to generalise results to target population

Qualitative research:

- Interested in the specific experiences of our sample - the “life-world” of our participants
- Do not attempt to generalise to larger populations

NB: Growing role of “Mixed Methods” research!



INTERVIEWS

- Structured V Unstructured V Narrative
- Telephone, face-to-face, on-line
- Semi-structured interviews:
 - neutral open-ended questions, aimed at eliciting in-depth responses from participants
 - questions form a prompt to the interviewer
 - should enable participants to express their beliefs, opinions and feelings freely

J Genet Counsel (2008) 17:394–405

DOI 10.1007/s10897-008-9158-z

ORIGINAL RESEARCH

“I Wouldn’t Classify Myself as a Patient”: The Importance of a “Well-being” Environment for Individuals Receiving Counseling about Familial Cancer Risk

Ceri Phelps • Debra Horrigan • Liwsi Kim Protheroe •
Janina Hopkin • Wendy Jones • Alexandra Murray



FOCUS GROUPS

- group discussions of a small number of people who have something in common and are an ideal method eliciting people's own meanings and understanding of health and illness (Wilkinson, 2005).
- allow individuals to interact with each other in response to a particular topic,
- make use of group dynamics to stimulate discussion, generate ideas and gain insights

J Genet Counsel (2010) 19:487–496
DOI 10.1007/s10897-010-9300-6

ORIGINAL RESEARCH

“The Bigger the Network the Bigger the Bowl of Cherries...”: Exploring the Acceptability of, and Preferences for, an Ongoing Support Network for Known BRCA 1 and BRCA 2 Mutation Carriers

Lisa Hughes • Ceri Phelps

PSYCHO-ONCOLOGY

Psycho-Oncology (in press)

Published online in Wiley InterScience (www.interscience.wiley.com). DOI: 10.1002/pon.937

THE DEVELOPMENT OF A DISTRACTION-BASED COPING INTERVENTION FOR WOMEN WAITING FOR GENETIC RISK INFORMATION: A PHASE 1 QUALITATIVE STUDY

CERI PHELPS^{a,*}, PAUL BENNETT^b, RACHEL IREDALE^a, SALLY ANSTEY^c and JONATHON GRAY^c

^a*Cancer Genetics Service for Wales, Institute of Medical Genetics, Cardiff University, UK*

^b*Department of Psychology, University of Wales, Swansea, UK*

^c*Cancer Genetics Service for Wales, Institute of Medical Genetics, Cardiff and Vale NHS Trust, Cardiff, UK*

S U M M A R Y

TYPES OF QUESTIONNAIRE STUDY

Cross-sectional

Longitudinal/Prospective

Randomised controlled trials

Quasi-Experimental*

Illness representations and distress in women undergoing screening for familial ovarian cancer

D. Lancaster^{a*}, K. Brain^b and C. Phelps^{c†}

^aDepartment of Psychology, University of Glamorgan, Treforest, Pontypridd CF37 1DL, UK; ^bInstitute of Medical Genetics, Clinical Epidemiology Interdisciplinary Research Group, Cardiff University School of Medicine, Heath Park, Cardiff CF14 4XN, UK;

^cSchool of Psychology & Counselling, Swansea Metropolitan University, Townhill Campus, Swansea SA2 0UT, UK

(Received 8 March 2010; final version received 13 January 2011)

Women with a familial or genetic predisposition to ovarian cancer are at significantly increased risk of developing the disease, and this warrants effective risk management strategies. A clinical trial of ovarian cancer screening (OCS) is being conducted to establish the effectiveness of this risk management strategy. This article reports data from its psychological partner study which aims to evaluate the psychological effects of OCS.

Original Research

Knowledge and Expectations of Women Undergoing Cancer Genetic Risk Assessment: A Qualitative Analysis of Free-Text Questionnaire Comments

C. Phelps,^{1,5} F. Wood,² P. Bennett,³ K. Brain,¹ and J. Gray⁴

Individuals undergoing cancer genetic risk assessment have been found to have a poor understanding of the process, which may affect how well they cope with learning their risk. This paper reports free-text data from questionnaires completed by women undergoing a randomised controlled trial of a psychological intervention. Of the 268 women undergoing genetic assessment for familial breast/ovarian cancer risk who were invited to take part in the trial, 157 women returned research questionnaires. Of these, 97 women provided free-text comments upon referral to a cancer genetics clinic, 62 provided com-

ments on the intervention, 10 provided comments on the genetic assessment process.



EXPERIMENTAL RESEARCH

- Experiments: three characteristics
 - Researcher manipulates (controls) one or more variables
 - Researcher measures whether this manipulation influences other variables
 - Researcher attempts to control extraneous factors that might influence the outcome of the experiment

A close-up photograph of a chessboard with several dark wooden pieces standing. In the foreground, a light-colored piece is lying on its side. A semi-transparent dark rectangle is overlaid in the center, containing the text 'RANDOMISED CONTROLLED TRIALS' in white, bold, sans-serif capital letters. A thin horizontal line is positioned below the text.

RANDOMISED CONTROLLED TRIALS

A self-help coping intervention can reduce anxiety and avoidant health behaviours whilst waiting for cancer genetic risk information: results of a phase III randomised trial

Ceri Phelps^{1*}, Paul Bennett², Kerenza Hood³, Kate Brain⁴ and Alexandra Murray⁵

¹School of Psychology and Counselling, Swansea Metropolitan University, Wales, UK

²Psychology Department, Swansea University, Wales, UK

³South East Wales Trials Unit, School of Medicine, Cardiff University, Wales, UK

⁴Institute of Medical Genetics, School of Medicine, Cardiff University, Wales, UK

⁵Institute of Medical Genetics, Cardiff and Vale University Health Board, UK

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Abstract

Objective: The objective of this study is to evaluate the effectiveness of a self-help coping intervention in reducing intrusive negative thoughts while waiting for cancer genetic risk information.

Methods: Between August 2007 and November 2008, 1958 new referrals for cancer genetic risk assessment were invited to participate in a randomised trial. The control group received standard information. The intervention group received this information plus a written self-help coping leaflet. The primary outcome measure was the intrusion subscale of the Impact of Event Scale.

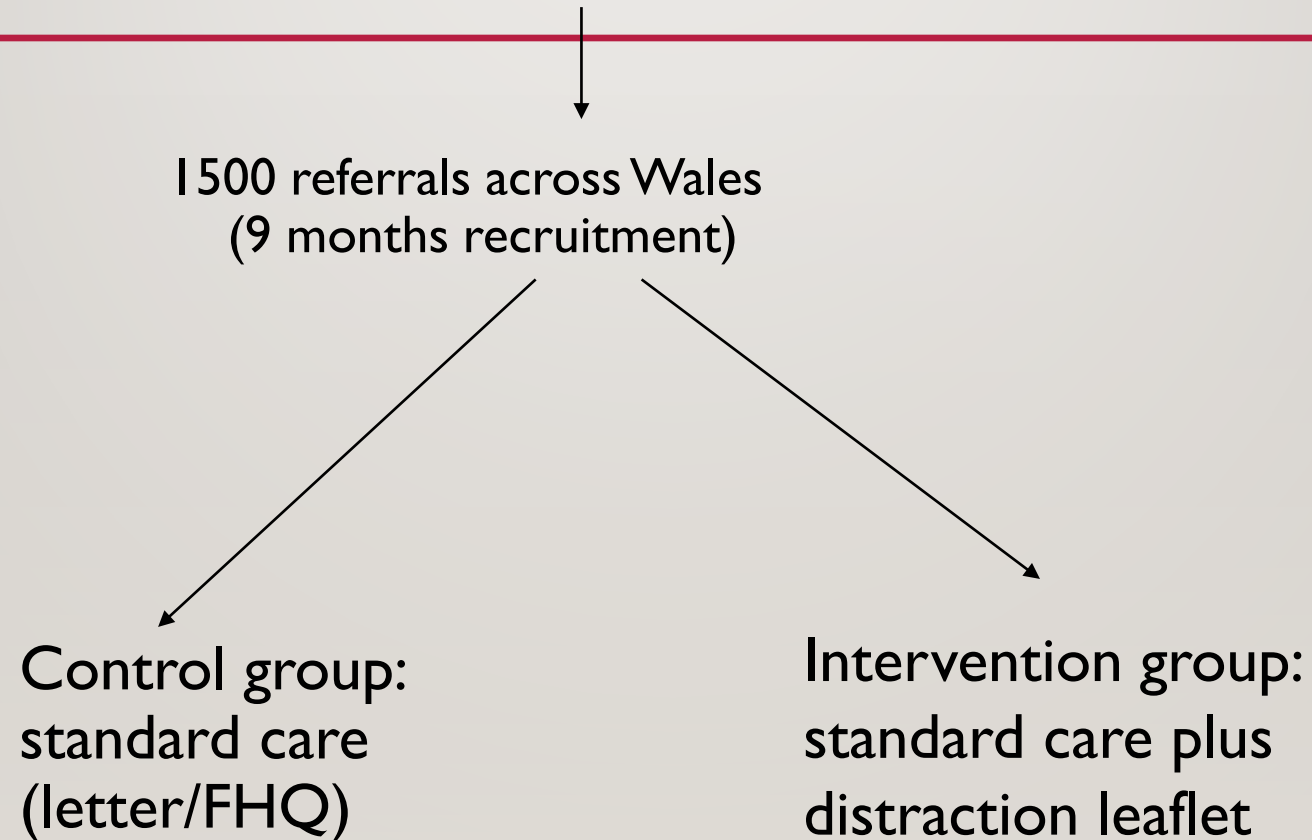
Results: The intervention significantly reduced intrusive thoughts during the waiting period in those reporting moderate baseline levels of intrusion ($p = 0.03$). Following risk provision, those in the inter-

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Phase III: The CARIAD Trial

28

MRC Phase III Randomised Controlled Trial



SESSION TWO: DOING
APPLIED RESEARCH WELL:

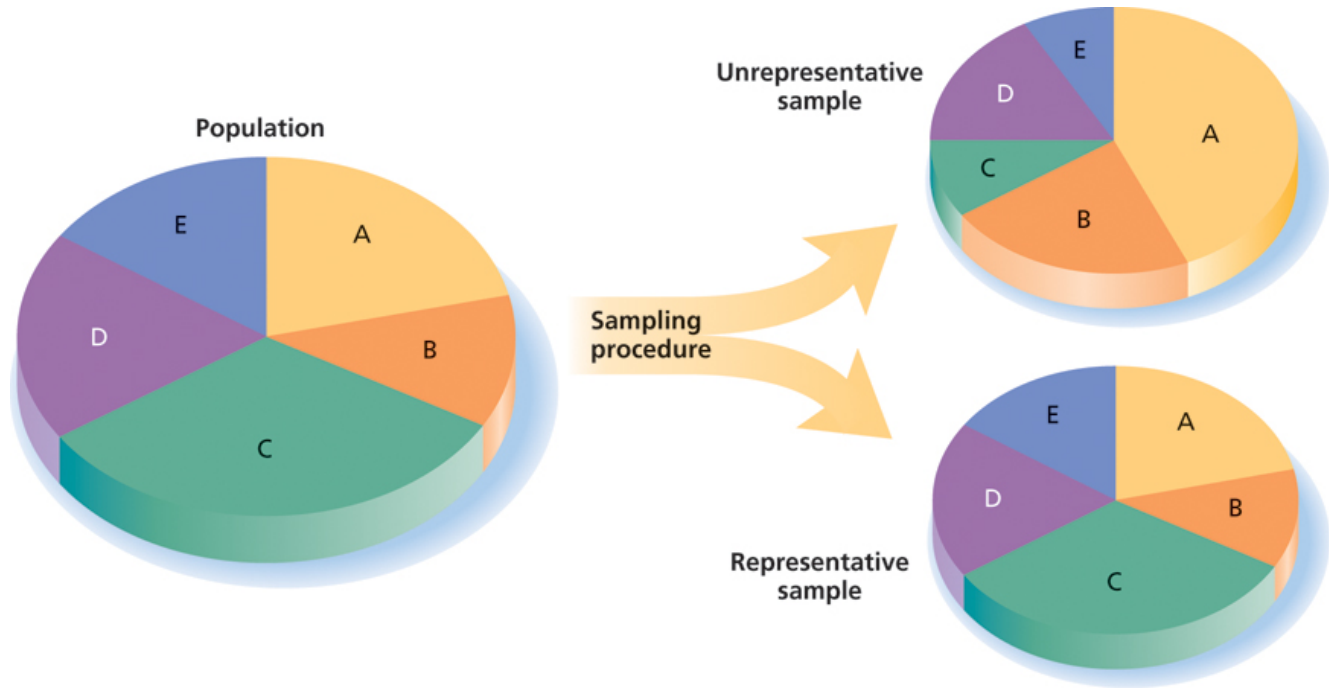
FROM GOOD RESEARCH
QUESTIONS TO GOOD
RESEARCH DESIGN

ASKING GOOD QUESTIONS

Good research questions in applied research are:

- clear and simple
- relevant, necessary and timely
- appropriate psychological concepts and variables that are clearly defined and can be measured
- answerable

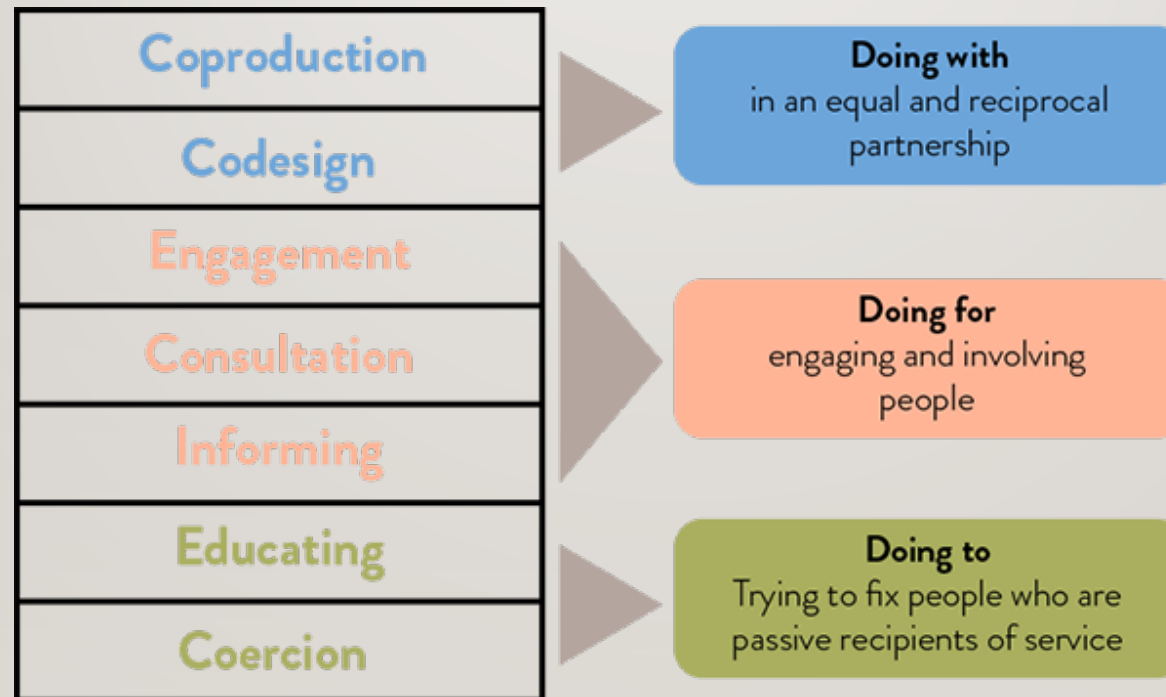
IDENTIFYING YOUR TARGET POPULATION AND YOUR SAMPLE



FROM RESEARCH THOUGHT TO RESEARCH QUESTION

- The challenge is to break that initial research thought/question down in order to be able to answer:
- Why? Why is this needed? Context? Evidence base? Novelty?
- How? How will you actually design a study to enable you to answer this question in the most appropriate way?
- What? What are you measuring and how are you capturing this information
- Who? Who are you interested in and how will you access this group?

INVOLVING PEOPLE IN RESEARCH



<https://knowhow.ncvo.org.uk/organisation/collaboration/coproduction-and-service-user-involvement>

INVOLVING PEOPLE IN RESEARCH

Patient & Public Involvement in Research (PPI)

https://www.diabetes.org.uk/resources-s3/2017-10/0983_PPI%20resource_guidance-document_DL_v5.pdf

involve people affected by diabetes in their research.

Participation, engagement or involvement

There is a difference between patient and public **involvement**, **participation** and **engagement** in research.

1. **Involvement** refers to people with a health condition inputting into stages of a research proposal. It **doesn't** refer to researchers raising awareness of their research, sharing knowledge or engaging with the public. It also **doesn't** refer to the recruitment of patients as participants in research. However, these different activities – involvement, engagement and participation – can complement each other.

Examples of involvement

- Commenting on and helping with the development of the grant application.
- Involvement in identifying research priorities relevant to the health condition.

2. **Participation** means recruiting people to take part in your study – this **isn't** patient and public involvement.

Examples of participation

- People being recruited to a clinical trial, or volunteering in observational, intervention or other research as study participants.
- Completing a questionnaire or participating in a focus group as part of a research study.

3. **Engagement** is sharing information and knowledge about your research which is important for demonstrating the importance of research to both the general public and individuals affected by the health condition. Engagement also builds confidence in your research by the people affected by the condition. Engagement **isn't** patient and public involvement

Examples of engagement

- Attending local diabetes groups and/or presenting your research at an event or conference.
- Raising awareness of research through the media such as social media or television.
- Dissemination of your research findings to research participants, colleagues or members of the public.

BREAKOUT SESSION

(30 MINS)

Identify three different research questions that could explore “the impact of **COVID-19** on mental health” and break each question down into:

- **Why?**
- **How?**
- **What?**
- **Who?**

Each group to prepare a brief five minute presentation to the class for 11.30am



SESSION THREE: CRITICALLY EVALUATING RESEARCH

30 minute breakout session

☐ Is it clear why this research is necessary and timely? Is it clear what this study will add to the existing evidence base? Does it seem sufficiently novel and does it have enough potential impact to fund?

☐ Does the proposal demonstrate sufficient engagement with appropriate literature – theory and evidence?

☐ Is it clear from reading the proposal what is actually going to be done, to who, how, in what order, and why?

☐ Is it clear how the data will be captured, measured and analysed in such a way that it will answer the question?

☐ Are you satisfied that the research team have recognised the ethical considerations and put steps in place to minimise any potential ethical concerns?

☐ Does the researcher/research team have sufficient expertise to carry out this study?

☐ Is it clear what the outcomes of the study will be?



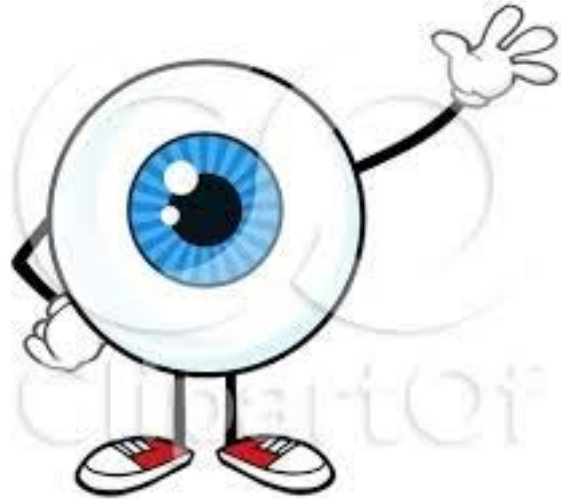
ETHICAL CONSIDERATIONS

- Think about.... What are the key ethical considerations that an ethics committee would want to see consideration of when carrying out applied research?
- How many can you think of...?



LUNCH BREAK

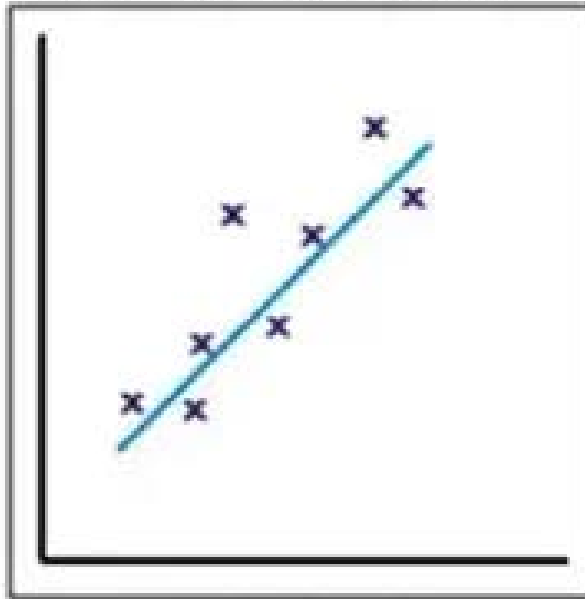




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SESSION FOUR: KNOWING YOUR DATA

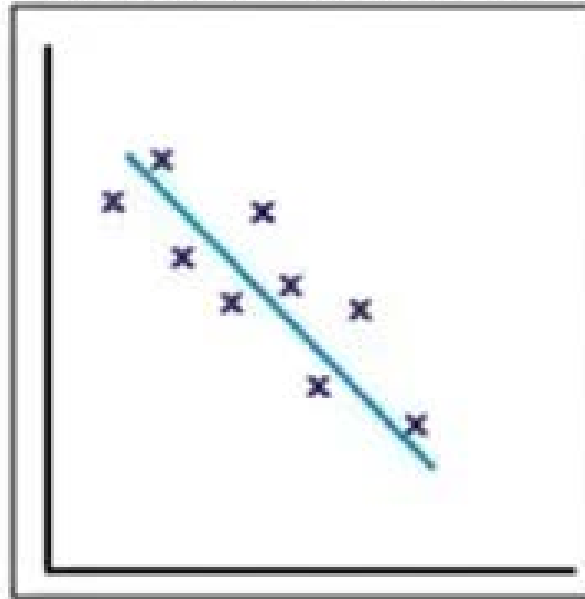
Positive correlation



The points lie close to a straight line, which has a positive gradient.

This shows that as one variable **increases** the other **increases**.

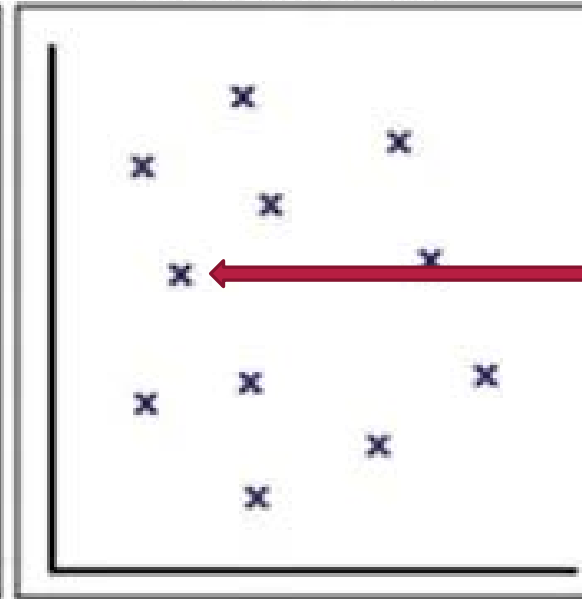
Negative correlation



The points lie close to a straight line, which has a negative gradient.

This shows that as one variable **increases**, the other **decreases**.

No correlation



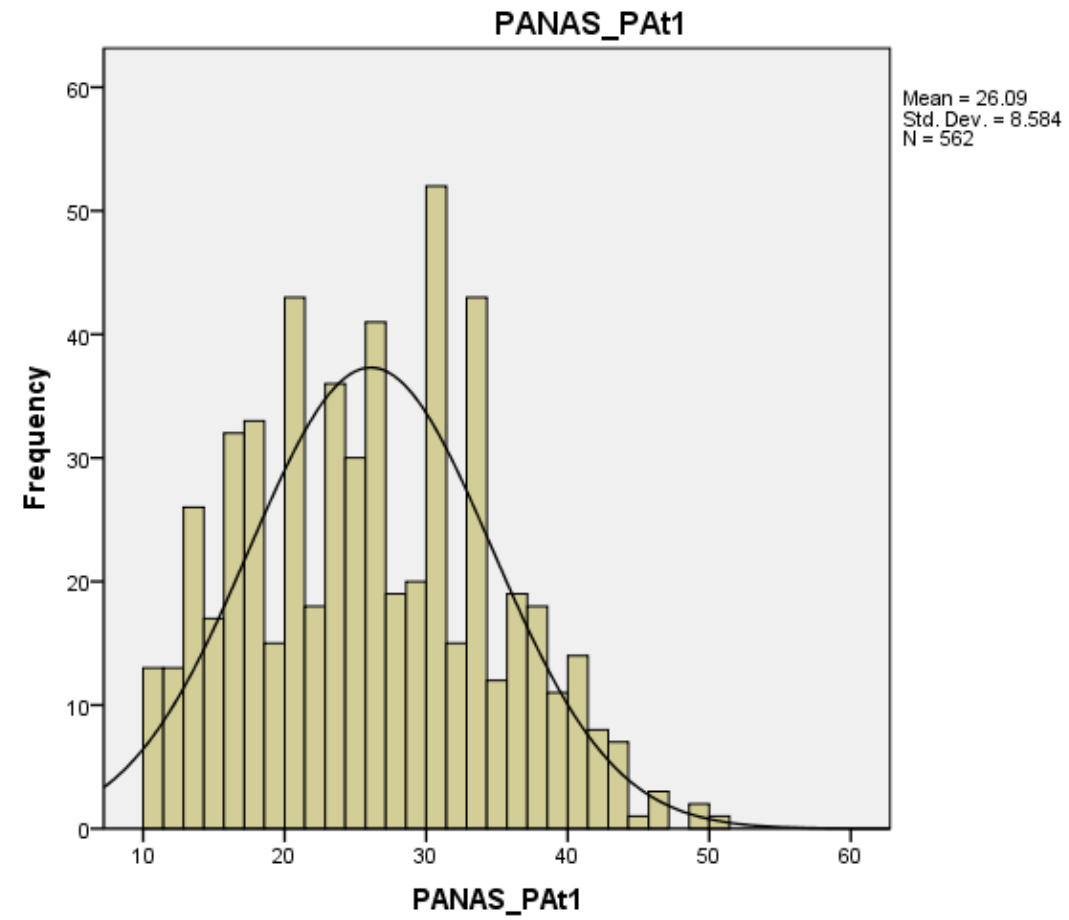
There is no pattern to the points.

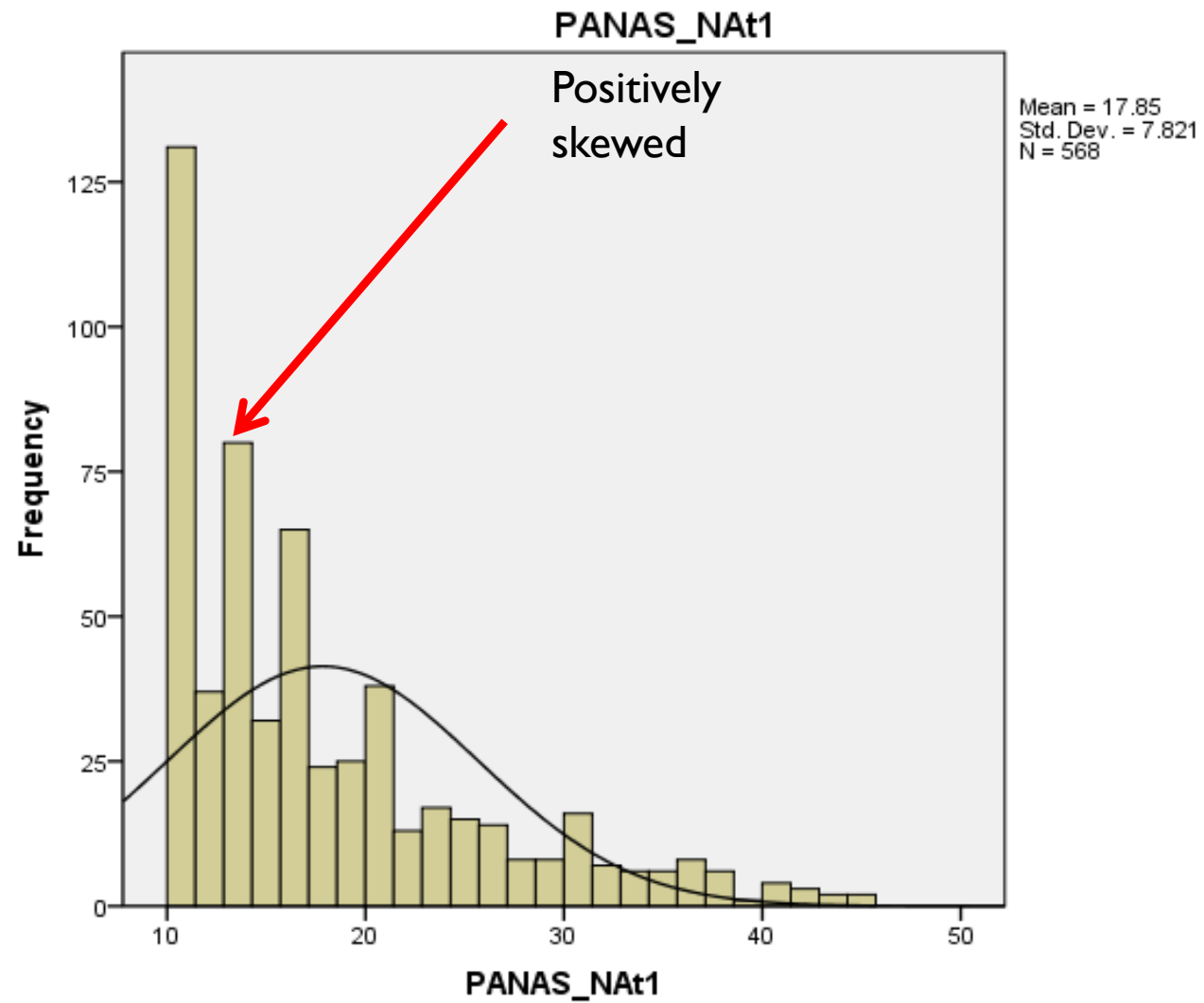
This shows that there is **no connection** between the two variables.

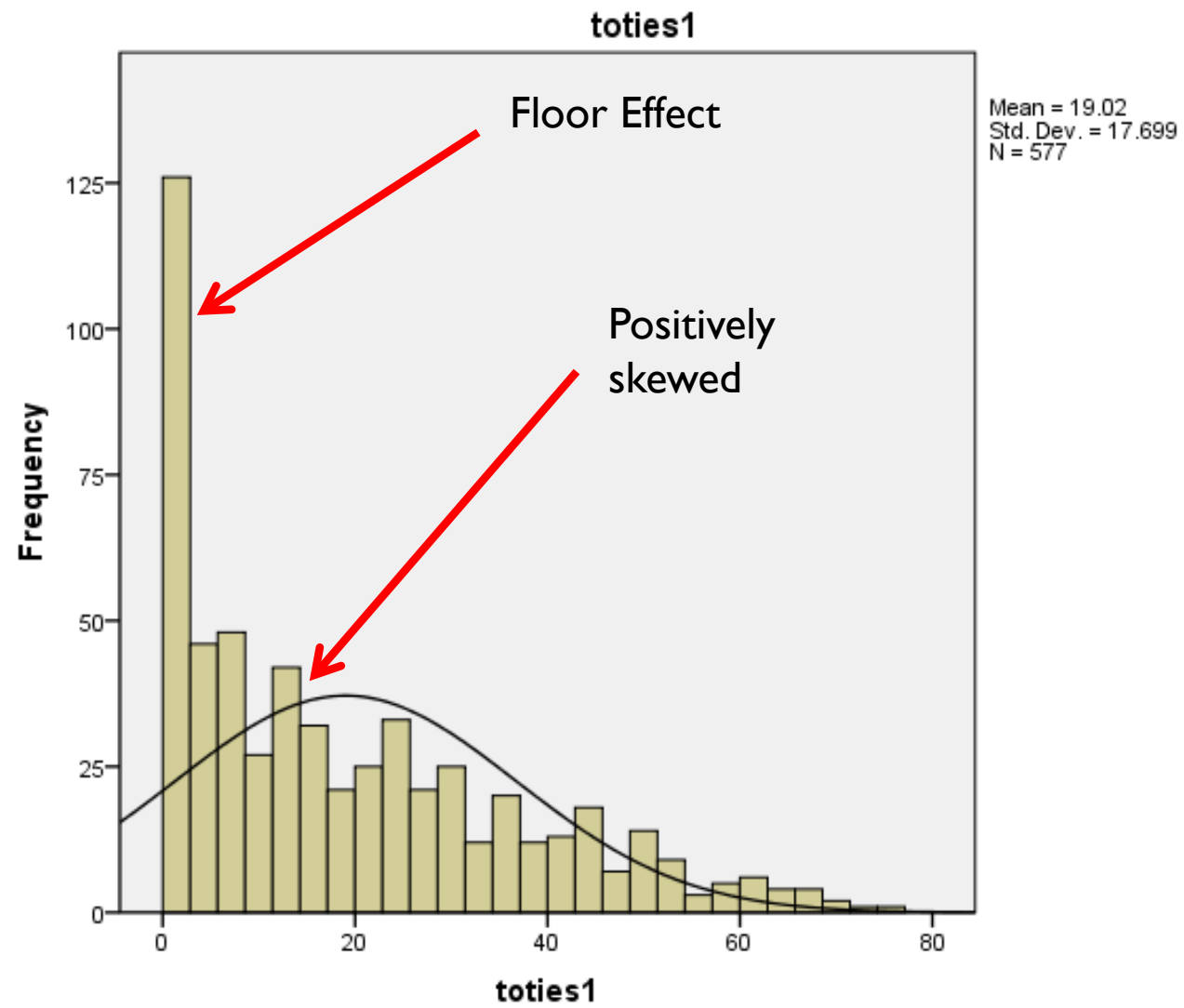
A data point = a person!

Statistics

		PANAS_Nat1	PANAS_Pat1	toties1
N	Valid	568	562	577
	Missing	22	28	13
Mean		17.85	26.09	19.02
Median		16.00	26.00	14.00
Mode		10	18	0
Std. Deviation		7.821	8.584	17.699
Variance		61.174	73.680	313.254
Range		35	40	75
Minimum		10	10	0
Maximum		45	50	75







Does participants' levels of psychological distress change over time?

Statistics				
		toties1	toties2	
N	Valid	577	424	
	Missing	13	166	
Mean		19.02	16.05	
Median		14.00	10.00	
Mode		0	0	
Std. Deviation		17.699	16.416	
Variance		313.254	269.471	
Range		75	69	

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	toties1	18.02	416	17.120	.839
	toties2	16.06	416	16.516	.810

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	toties1 & toties2	416	.725	.000

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Pair 1 toties1 - toties2	1.957	12.484	.612	.754	3.161	3.198	415	.001

Statistical vs Clinical Significance

Statistical
Significance

Is this difference
unlikely?

$p < .05$



Does it matter to a statistician?

Clinical
Significance

Is this difference
important?

?



Does it matter to a clinician?

<https://www.youtube.com/watch?v=E7934CSKkN4>



SESSION FIVE:
INTERVENTIONS: EFFECTIVENESS AND IMPACT

FINAL BREAK OUT SESSION (40 MINUTES)

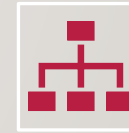
- In small groups, using the provided review table, work through the Jorm, Kitchener, Sawyer, Scales and Cvetkovski paper and make notes on the following:



Sample & recruitment strategy



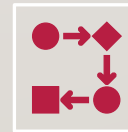
Appropriate follow-up duration?



Theory base of intervention explained?



Appropriate outcome measures?



Was the intervention effective? For what outcomes?



Intervention fidelity and implications for real-world implementation



Overall rating/comment: does it have a positive effect on wellbeing?



SHORT BREAK



SESSION SIX: PRESENTING RESEARCH FOR DIFFERENT AUDIENCES

Simple tips for writing a lay summary: simplify and reduce

- Answer the questions what, where, when, why and how
- Keep it short
- Imagine you're talking to the reader
- Get rid of any jargon
- Make it human
- Use person centred language such as 'people with breast cancer' rather than 'breast cancer sufferers'.
- Put your research in context
- Explain the study's impact – what are you hoping to achieve
- Don't oversimplify your research
- Get a colleague and a non scientist to read it

<https://acmedsci.ac.uk/more/news/10-tips-for-writing-a-lay-summary>



Rule	Sign it is violated
1: Focus on one big idea	Readers cannot give 1-sentence summary.
2: Write for naive humans	Readers do not “get” the paper.
3: Use context, content, conclusion structure	Readers ask why something matters or what it means.
4: Optimize logical flow	Readers stumble on a small section of the text.
5: Abstract: Compact summary of paper	Readers cannot give the “elevator pitch” of your work after reading it.
6: Introduction: Why the paper matters	Readers show little interest in the paper.
7: Results: Why the conclusion is justified	Readers do not agree with your conclusion.
8: Discussion: Preempt criticism, give future impact	Readers are left with unanswered criticisms and/or questions on their mind.
9: Allocate time wisely	Readers struggle to understand your central contribution despite your having worked hard.
10: Iterate the story	The paper’s contribution is rejected by test readers, editors, or reviewers.

<https://doi.org/10.1371/journal.pcbi.1005619.t001>

Writing a good abstract:

- Look at the format for an appropriate journal abstract
- Has to be written last
- Need to be written in academic manner
- Needs to be a succinct summary of the entire report/paper
- Should be less than 250 words
- Takes time!

THE END!!