Change Management in Animal Research

NIH National Institutes of Health
Office of Laboratory Animal Welfare

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Speakers

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The speaker(s) declare that they have no conflicts of interest for this presentation.

Driving change: sex inclusive research as a case study

Natasha Karp

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Disclosure

- AstraZeneca
- Member of the UK – Medical Research Council (MRC) Working Group on Sex in Experimental Design of Animal Research
- NC3Rs
  - The National Centre for the Replacement, Refinement and Reduction of Animals in Research
  - Working group for ARRIVE (Animal Research: Reporting of In Vivo Experiments)
  - Working group for Experimental Design Assistant

Outline

1. Driving Change
2. Case study: Sex Inclusive Research
3. Case study: Understanding the barriers
4. Case study: A nudge strategy
5. Conclusions

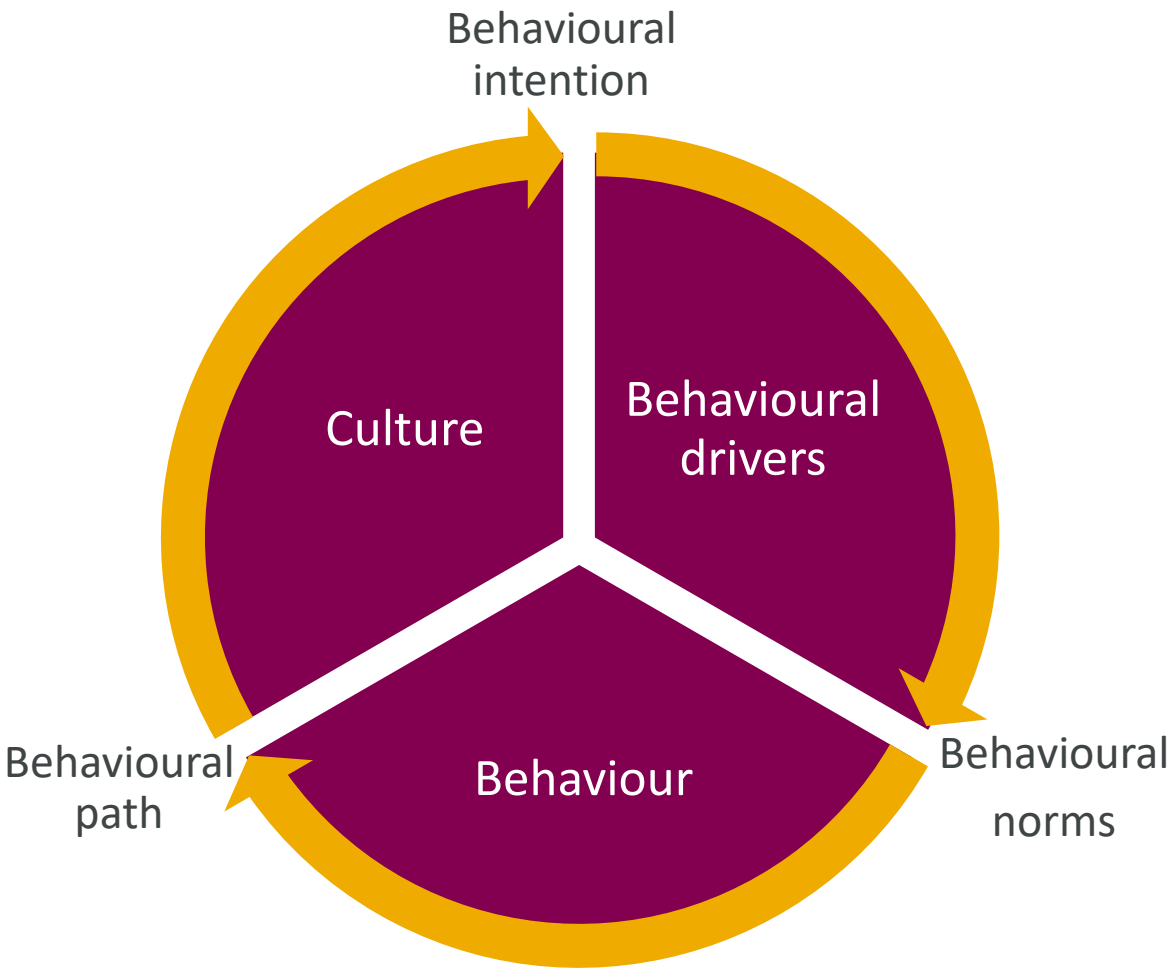
1

Driving change

My personal driver

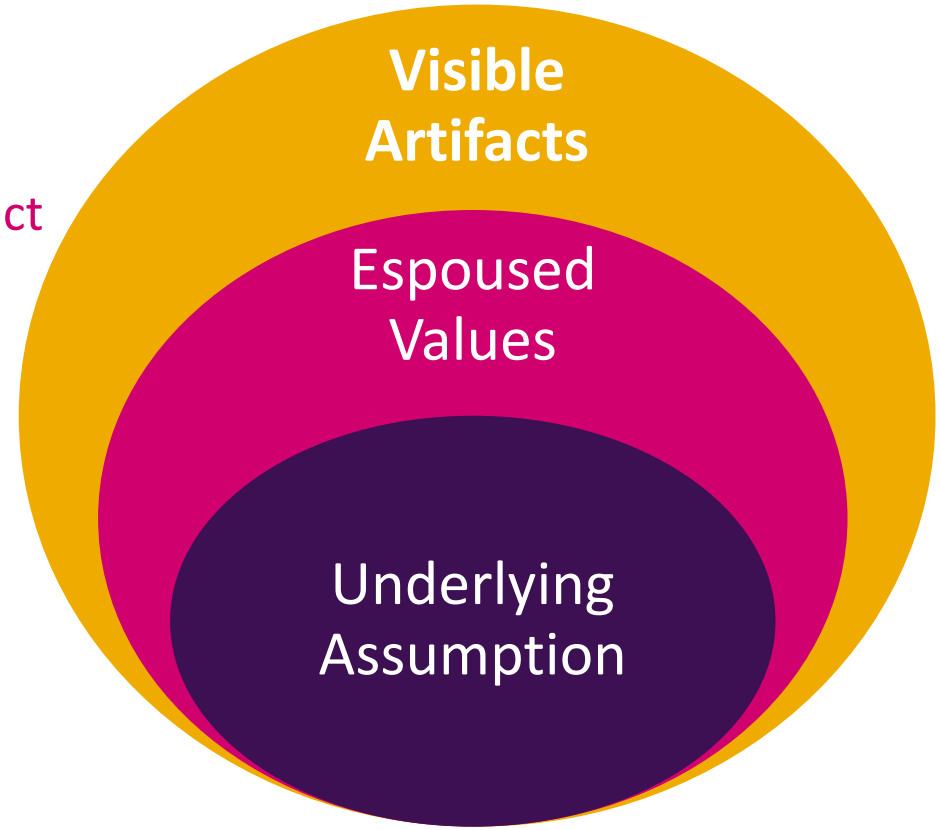
"It is lovely to see you. I haven't seen you in so long. You are doing so well. Still banging on about experimental design"

Organisational Culture: ‘the way we do things around here”.



Mission/vision statement
Formal guidelines & processes

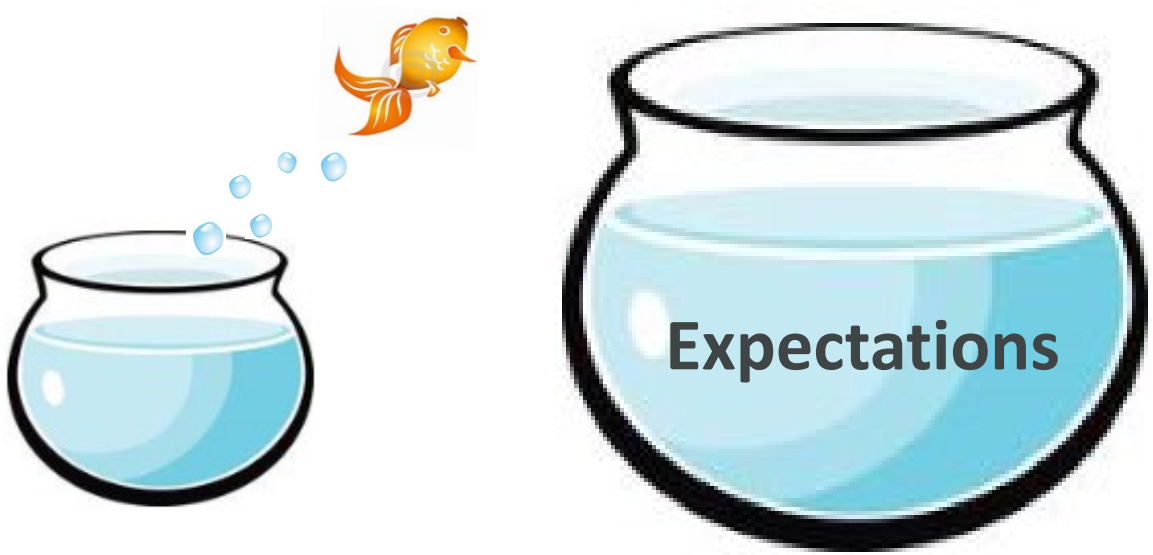
Rules of conduct
Values
Standards



Self-evident and unconscious behaviour.

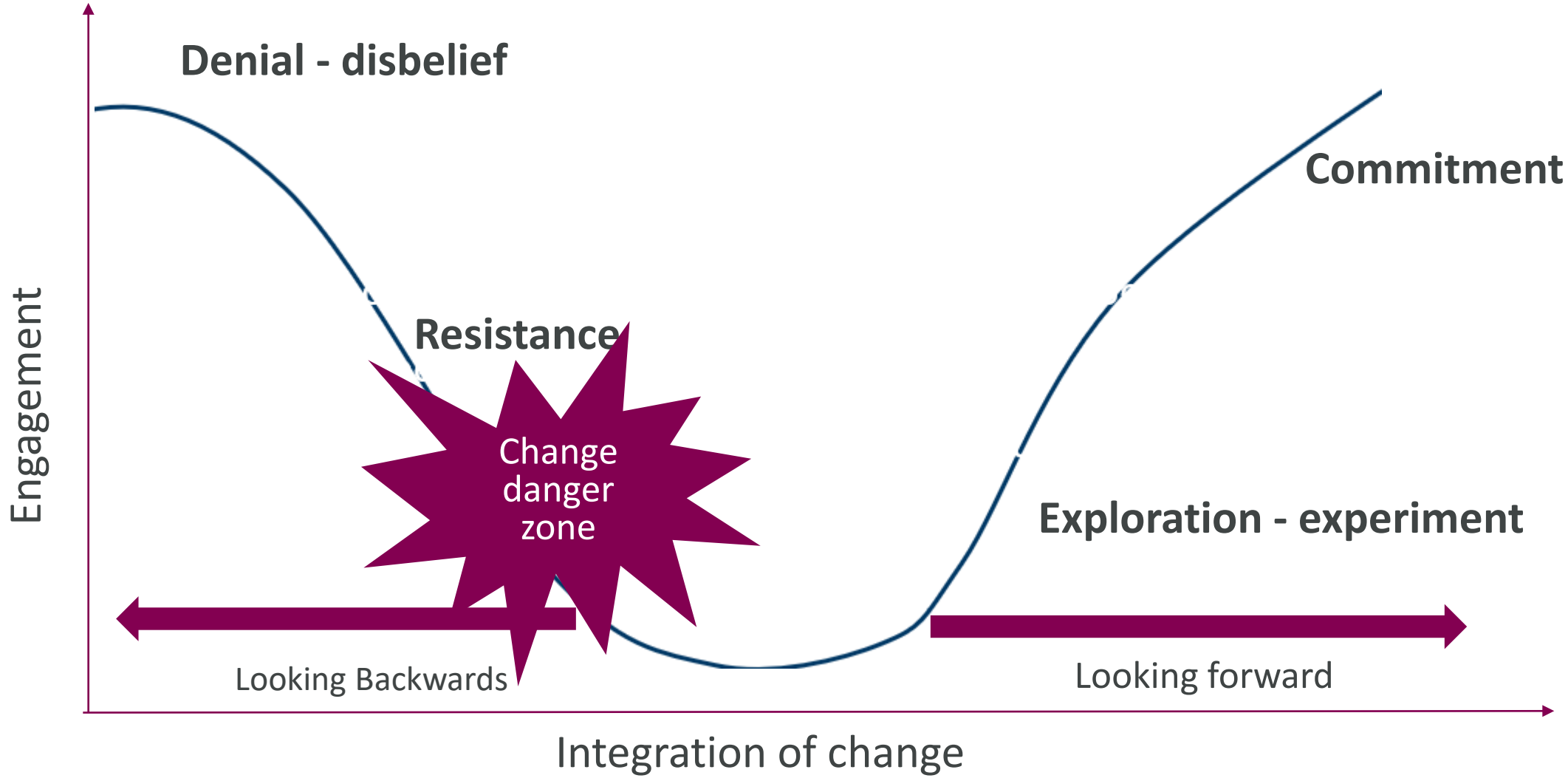
SCHEIN, E. H. 2010 Organisation Culture and Leadership

Step 1 - recognising that this is CHANGE



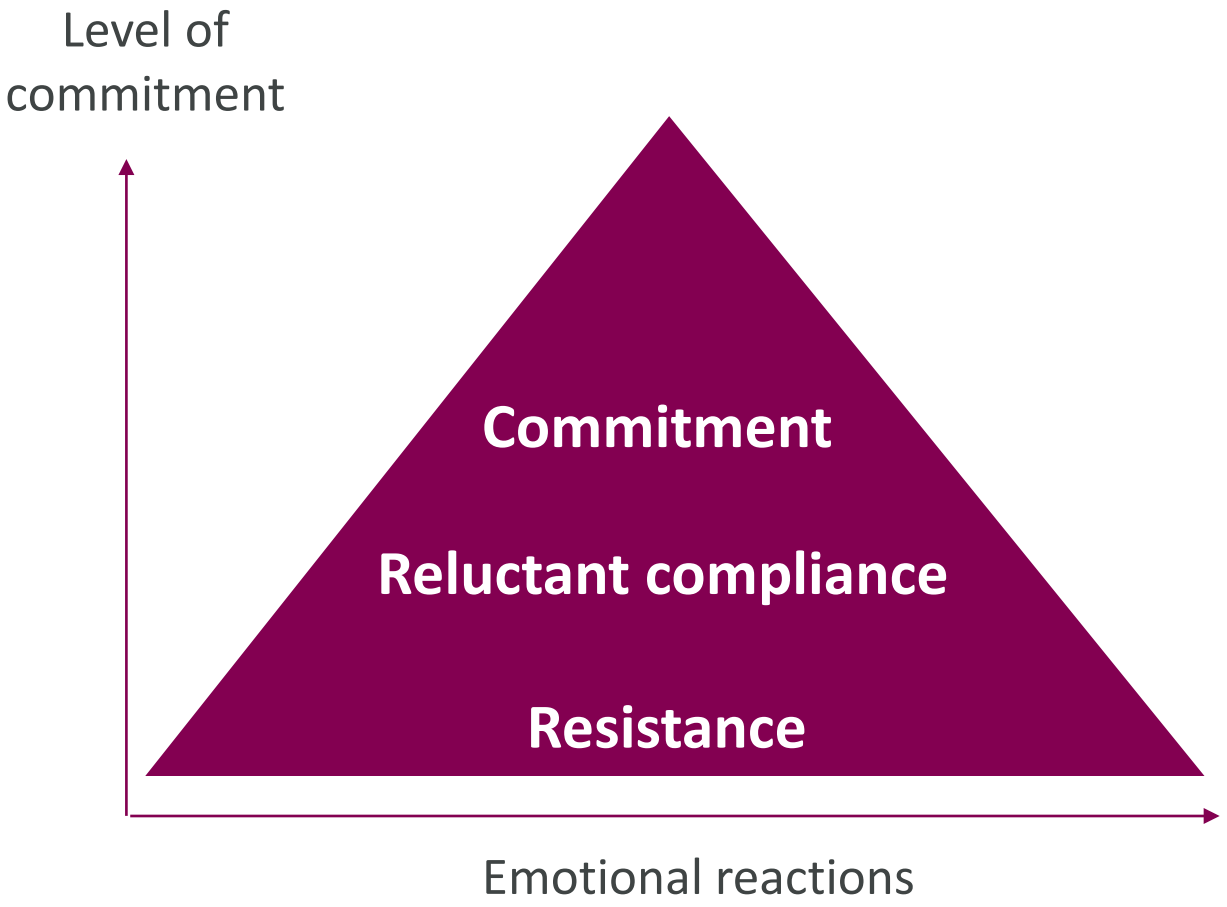
- You need a plan
- You need a community / support
- Need realistic expectations

Personal reaction to change



Scire, P. (2007) Applying Grief Stages to Organizational Change

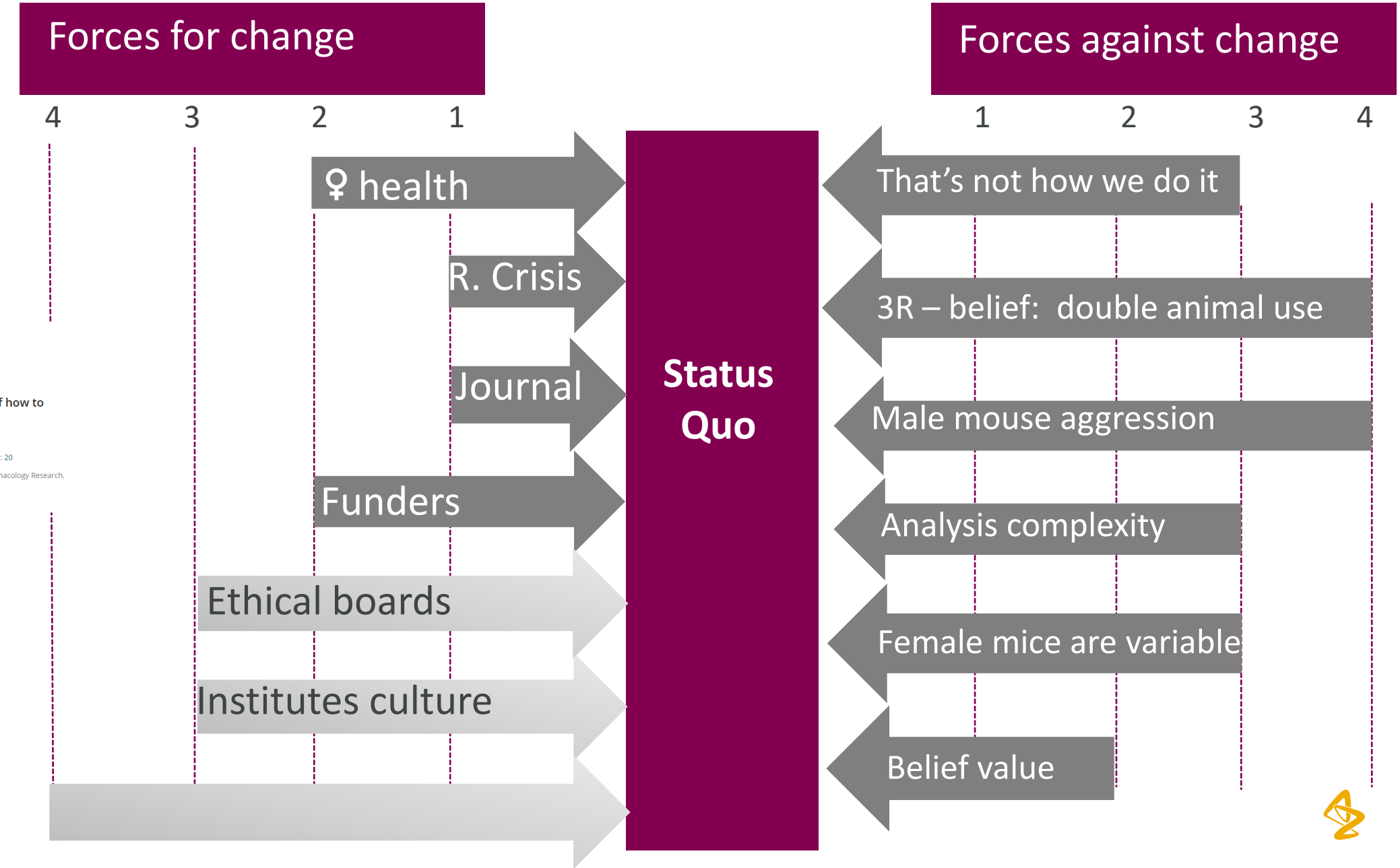
What strategies can we use to drive engagement?



Tactics	
Positive	Rational Persuasion
	Exchange
	Consultation
	Inspirational Appeal
Negative	Pressure
	Legitimising
	Coalition Building

Gary Yukl (1981) Leadership in organization.

Lewin's Force field analysis



BJP British Journal of Pharmacology

REVIEW ARTICLE | Free Access

Sex bias in preclinical research and an exploration of how to change the status quo

Natasha A Karp ✉ Neil Reavey

First published: 12 November 2018 | https://doi.org/10.1111/bph.14539 | Citations: 20

This article is part of a themed section on The Importance of Sex Differences in Pharmacology Research. To view the other articles in this setion visit http://onlinelibrary.wiley.com/doi/10.1111/bph.v176.21/issuetoc

Institute level plan

	Kotter - 8 step change process
Leadership	1: Create Urgency
	2: Form a Powerful Coalition
	3: Create a Vision for Change
	4: Communicate the Vision
Management	5: Remove Obstacles
	6: Create Short-Term Wins
	7: Build on the Change
	8: Anchor the Changes in Institute Culture

John P. Kotter (1995) Leading Change

2

Case study: sex inclusive research

Gender / Sex – does terminology matter?

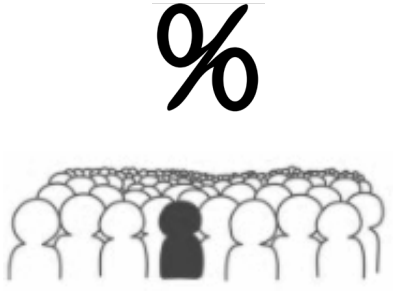
Sex refers to

- “the different biological and physiological characteristics of males and females, such as reproductive organs, chromosomes, hormones, etc” World Health Organisation

Gender refers to

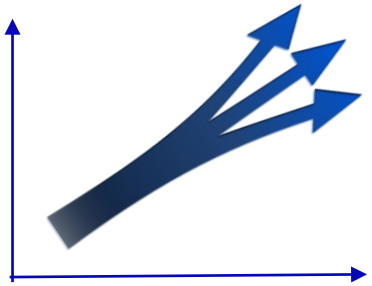
- “the socially constructed characteristics of women and men – such as norms, roles and relationships of and between groups of women and men. It varies from society to society and can be changed.” World Health Organisation

Sex and gender matters

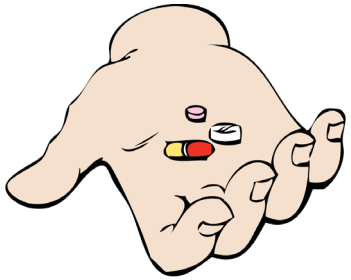


Prevalence

Symptoms



Progression

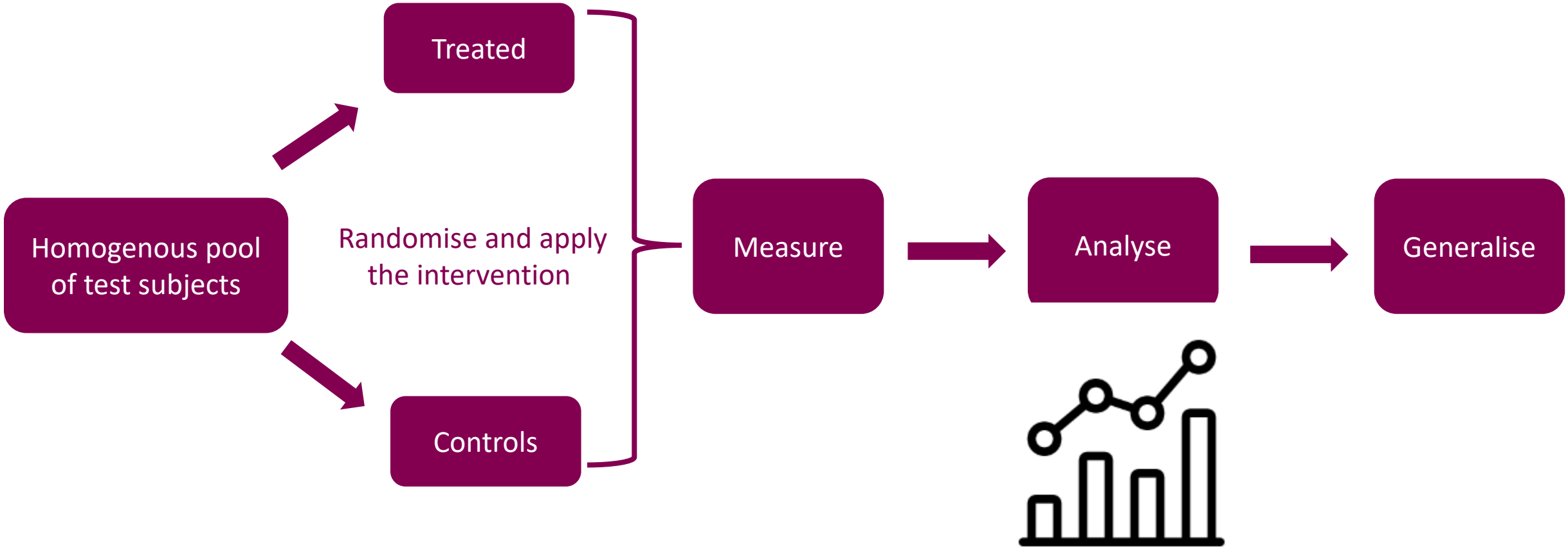


Side Effects

COVID-19 [Bwire 2020; Doerre & Doblhammer 2022]

- Prevalence higher in ♀ but higher morbidity and mortality in ♂
  - Biological differences ?
    - Higher expression ACE 2 receptor for coronavirus in ♂
    - Immunological differences driven by sex hormone and X chromosome
- Gender differences
  - ♀ - more contacts, work in care roles
  - ♂ higher rates of smoking and drinking
  - ♂ Lower uptake of preventative measures

Simplification underpins experimental research



We typically discarded sex a long with other sources of variation

Embedded neglect of sex within preclinical research

- Reporting:
  - *In vivo*: 22% did not specify the sex (Yoon 2014)
  - *In vitro*: 75% did not specify the sex (Shah 2014)
- Experimental design:
  - *In vivo*: Meta analysis across 9 fields of biology 2009 and then again 2019 (Woitowich 2020)
    - Average increased from 26 to 48%
    - 6/9 fields significant improvement, 1 -pharmacology reduced to 29%.
  - *In vitro*: 69-80% male only (Taylor 2011, Shah 2014)
- Analysis (In vivo)
  - When both sexes collected, only 42% sex-based analysis (Woitowich 2020)
  - Those reporting sex differences, 1/3 not backed statistically (Garcia-Sifuentes 2021)

Take home: Two problems – including both sexes and appropriate analysis

Sex matters but it isn't perceived as a doable problem

Sociological exploration

- Generalizability Important to embrace variation to understand biological difference
- Avoiding complexity To make progress in science reduce complexity
- Practicality
- Tension between the above. Impractical

Gompers, Annika. Genderscilab, 2018. www.genderscilab.org/blog/three-years-in-sex-as-a-biological-variable-policy-in-practice-and-an-invitation-to-collaborate

UK MRC survey

- 95% researchers saw benefit
  - Translatability
  - Reproducibility
  - Detecting sex specific effects
- But there were barriers/concerns
  - Cost of experiments
  - Complexity of research design
  - Compliance with 3Rs

www.ukri.org/wp-content/uploads/2022/03/MRC-090322-SexInExperimentalDesign-SummaryReport.pdf

3

Case study: understanding the barriers

The 2hr workshop intervention

Section	Content
Lecture	Reflection clinical sex matters Exploration of the status in preclinical research Exploration of what is sex inclusive research Factorial analysis role in sex inclusive research
Interactive	Multiple choice activity on analysis of inclusive designs
Lecture	Exploration of the perceived barriers to sex inclusive research
Resource	Sex Inclusive Research Framework (SIRF) tool to evaluate research proposals.
Interactive	Multiple choice activity using the SIRF

Awareness of changing expectation

Challenge misconceptions

Link to new resources

Upskill in design considerations

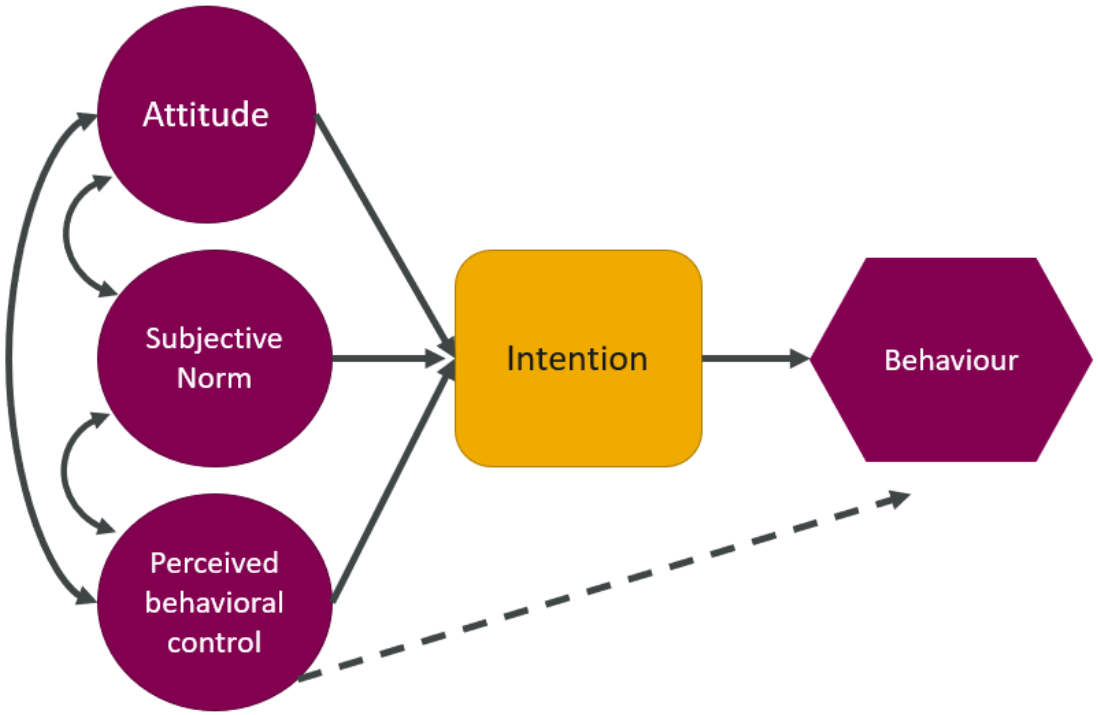
Upskill in data analysis

Survey delivers?

Outcomes

- We can quantify the scale of the issues/misconceptions
- We can statistically assess if
  - there was an improvement in knowledge
  - the intervention can rescue the embedded cultural and knowledge barriers to sex inclusive research.
  - what is driving behaviour and where we can focus our resources to further drive change

Theory of planned behaviour



Survey construct – total 39 questions

Consent

Checked Inclusion criteria

Personal Demographics

Workplace Demographics

Current experience of inclusion

Advantages?

Barriers?

Knowledge (analysis, design) N=5)

Future intention N=3

Their attitude N=4

Behav. Control N=3

Society expectation N=3

Example TPB question construct

Perceived behavioural control questions

I feel **confident in my ability to include** both sexes into an *in vivo* experimental design

- Strongly disagree =7
- Disagree =6
- Somewhat disagree =5
- Neither agree nor disagree =4
- Somewhat agree =3
- Agree =2
- Strongly agree =1

Whether or not I include both sexes in an *in vivo* experimental design **is completely up to me**

- Strongly disagree **=7**
- Disagree **=6**
- Somewhat disagree **=5**
- Neither agree nor disagree **=4**
- Somewhat agree **=3**
- Agree **=2**
- Strongly agree **=1**

Overall, using both sexes in an *in vivo* experimental design

- Extremely difficult = **1**
- Moderately difficult **=2**
- Slightly difficult **=3**
- Neither easy nor difficult **=4**
- Slightly easy **=5**
- Moderately easy **=6**
- Extremely easy **=7**

Data study 1

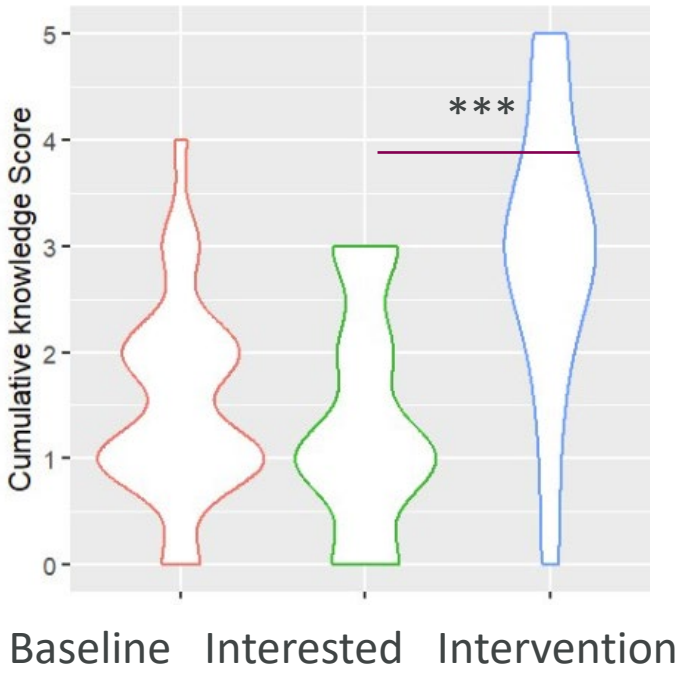
Dataset?

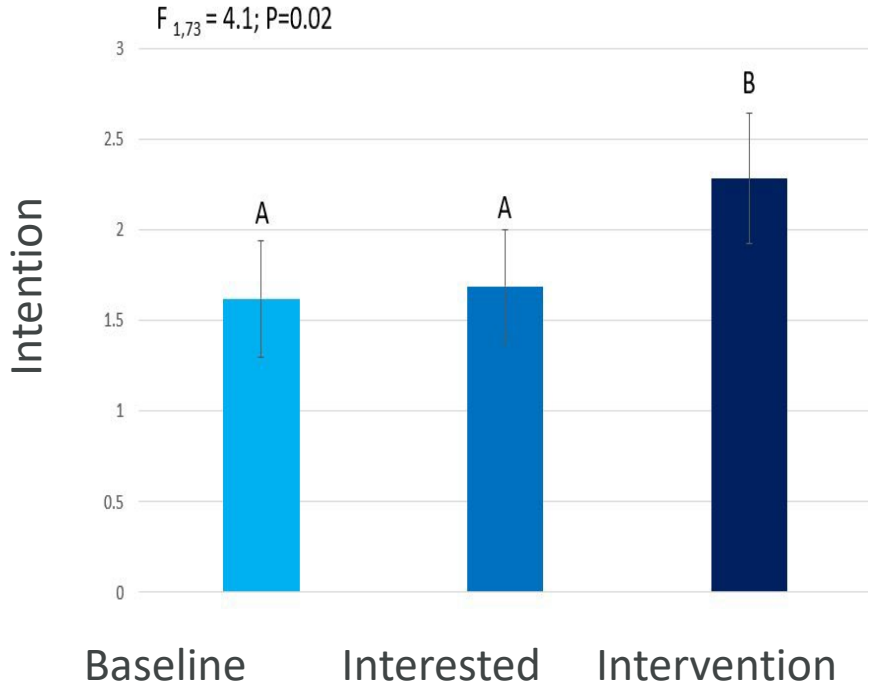
- 194 people started the survey
  - 102 met the inclusion criteria questions and answered sufficient questions
    - N = 35 Baseline research community
    - N = 48 Researchers interested in sex inclusive research
    - N = 15 Intervention group

Inference space?

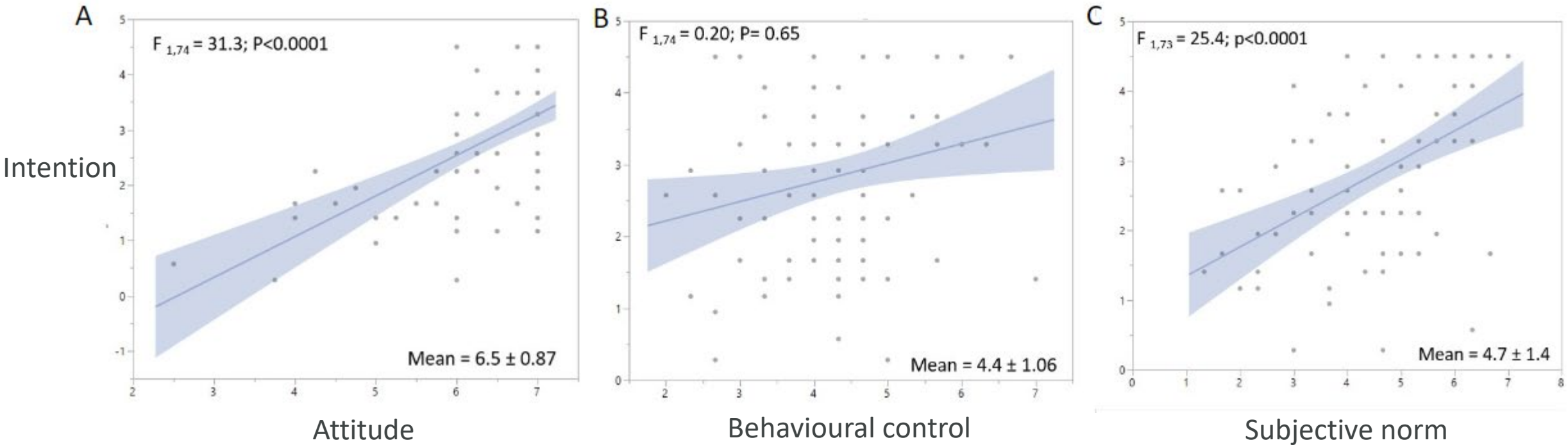
- The majority of the population evaluated were female (61%), had a PhD (63%), and worked at an **academic** institution (97%) in Europe (58%). On average the participants had been involved with animal research for **13.8 years**.
- Whilst 63% of participants are always, or often, involved, or can influence, the planning of experimental designs, the majority (62%) have only incorporated both sexes in 50% or less of their studies.

The workshop rescued embedded cultural and knowledge barriers



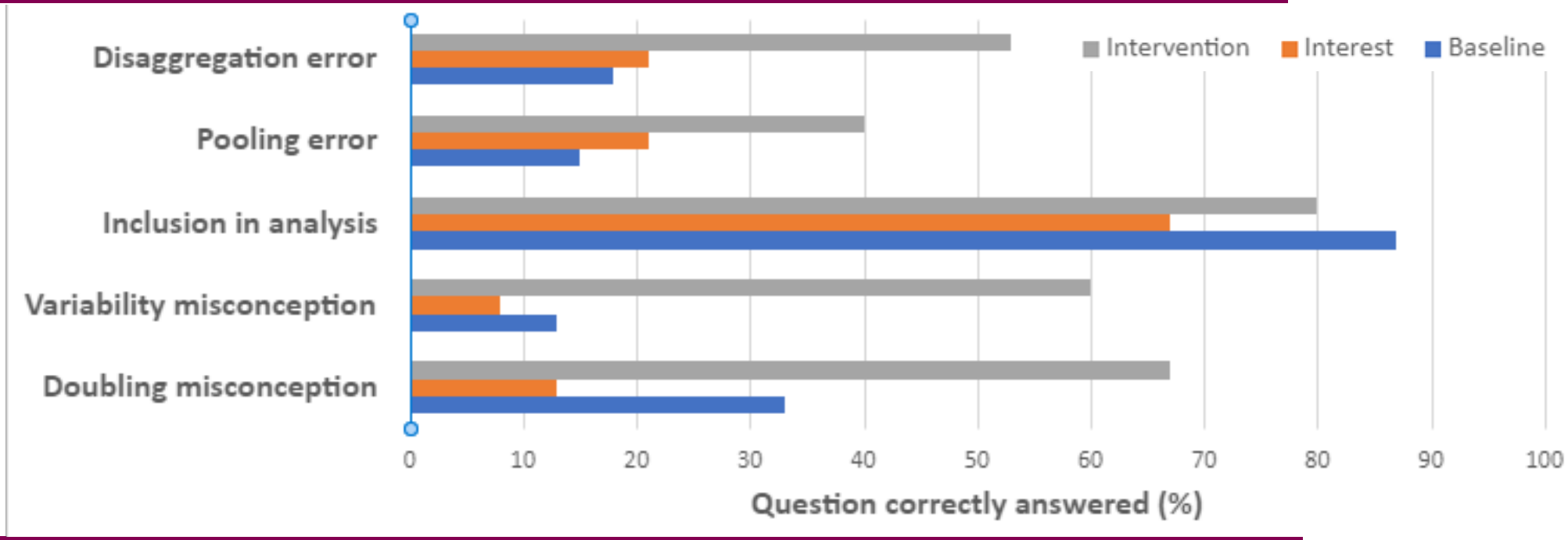


Intention positive correlates with attitude and subjective norm



No one selected “data analysis concerns” as a barrier but

- 68% of researchers thought data could be pooled
- 71% of researchers thought data should be disaggregated



The scale of the misconceptions was staggering

- 69% thought inclusion would double the N
- 79% though inclusion increases variability

Take home message for your change project?

- Value of understanding the barriers
  - Believe in value of sex is high – talks highlighting the value will have little impact
  - Need to address the barriers and cultural expectation
  - Strategies?
    - Listen carefully to concerns
    - Conduct a root causes analysis to understand the resistance
    - Look for themes
    - Pilot before implementation

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Case study: a nudge strategy

SIRF: Sex Inclusive Research Framework

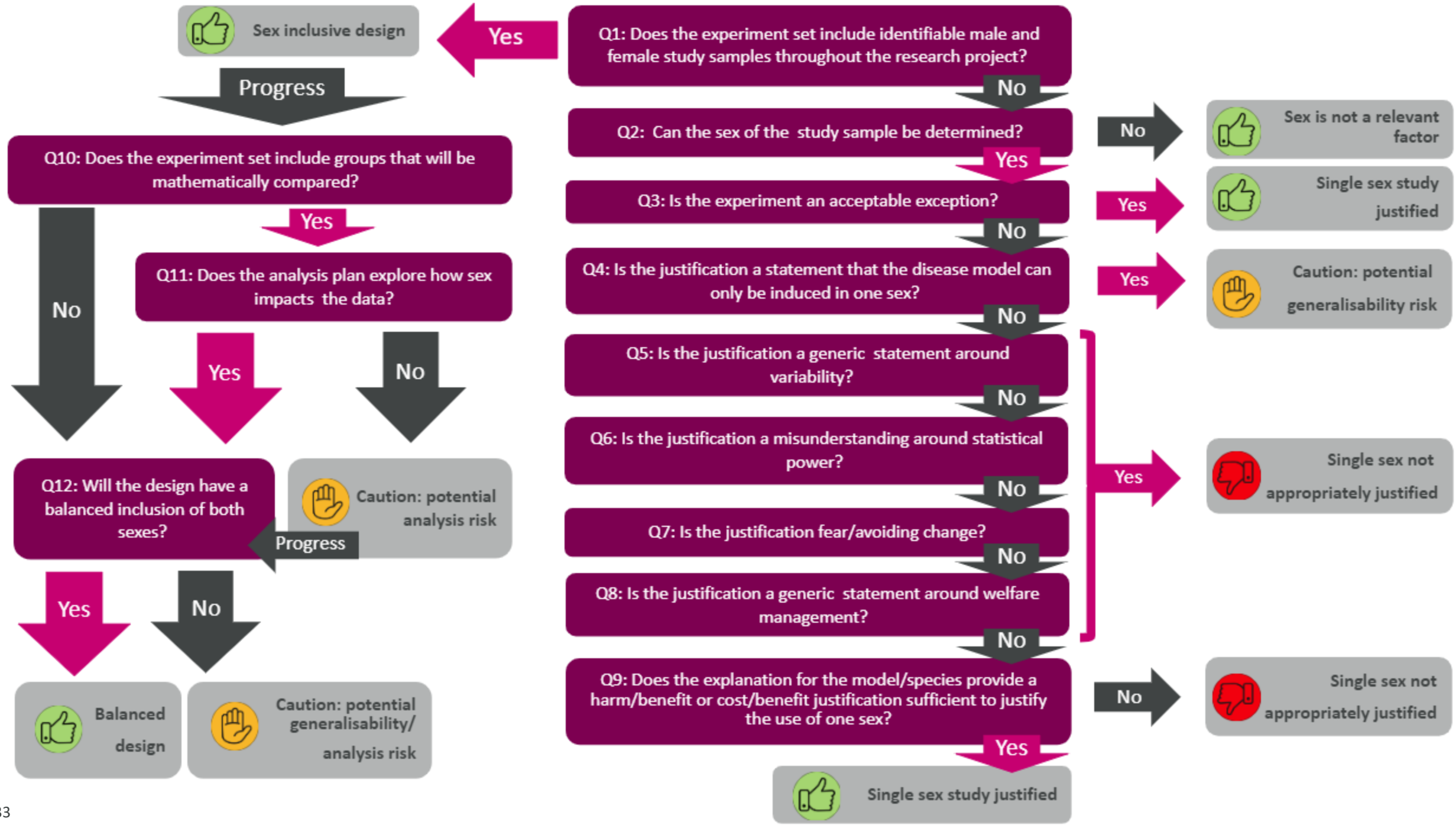
Why?

- Funders/regulatory bodies need to assess whether a research proposal is appropriate from a sex inclusive position.
- Frequently barriers are misconceptions
- Need transparency in the decision-making process
- We need educational resource to help move into considered justification to assess whether sex inclusion is a possibility.
- “Behavioural Nudging” and raising awareness of expectation.

What?

- Decision tree of twelve questions and associated supporting information
- Delivers evaluation outcome
- Options:
  - **Green**: Proposal is appropriate
  - **Amber**: Caution is required (I.e., the proposed design/analysis carries some risk)
  - **Red**: Justification for single sex study in the proposal is not sufficient

Manuscript: https://osf.io/preprints/mxg3e/


Sex inclusive design
Yes
Q1: Does the experiment set include identifiable male and female study samples throughout the research project?
No
Progress
Q2: Can the sex of the study sample be determined?
No
Sex is not a relevant factor
Yes
Q3: Is the experiment an acceptable exception?
Yes
Single sex study justified
No
Q4: Is the justification a statement that the disease model can only be induced in one sex?
Yes
Caution: potential generalisability risk
No
Q5: Is the justification a generic statement around variability?
No
Q6: Is the justification a misunderstanding around statistical power?
No
Q7: Is the justification fear/avoiding change?
No
Q8: Is the justification a generic statement around welfare management?
No
Yes
Single sex not appropriately justified
Q9: Does the explanation for the model/species provide a harm/benefit or cost/benefit justification sufficient to justify the use of one sex?
No
Single sex not appropriately justified
Yes
Single sex study justified
Q10: Does the experiment set include groups that will be mathematically compared?
Yes
Q11: Does the analysis plan explore how sex impacts the data?
No
Yes
No
Q12: Will the design have a balanced inclusion of both sexes?
Caution: potential analysis risk
Progress
Yes
No
Balanced design
Caution: potential generalisability/ analysis risk

Examples "Caution is required"

Arises?

- Unbalanced inclusive designs
  - **Generalisability/analysis risks**
- Inclusive designs that do not consider sex in the analysis
  - **Analysis risks**
- Studies for disease which effects both sexes but the model can only be induced in one
  - **Generalisability risk**

Example scenario

'In all experiments, male and female littermates will be pooled together and analyzed as one group"

- Q1 – inclusive? Yes
- Q10 – Groups compared? Yes
- Q11 – analysis considers sex? No

Sex inclusive design

Caution: potential analysis risk

Decision to proceed depends on reflection on the risk

Examples "Single sex not appropriately justified"

Arises?

Misconceptions

- "Females are more variable"
- "Including both sexes will increase the variation in my data"
- "Including both sexes will double the sample size needed"

Fear/Avoiding change

- "My previous data is all in one sex"
- "Sex hasn't been shown to date to matter"

Example scenario

We plan to use male mice, as female mice tend to have twice the levels of circulating CORT as males, and these levels may shift in response to stage of the estrus cycle.

Q1 – inclusive? No

Q2 – Can the sex be determined? Yes

Q3 – acceptable exception? No

Q4 – disease model induction issue? No

Q5 – generic statement around variability Yes

Single sex not appropriately justified

Examples "proposal is appropriate outcomes"

Exception?

Female mice implanted with patient derived ovarian cancer tumours

Q1 – inclusive? No

Q2 - Can the sex be determined? Yes

Q3 – acceptable exception? Yes

Single sex study justified

Harm &/or Cost evaluation versus benefit

Th9 transfer experiments will be done in male mice because Foxp3Sf donor Th9 cells are obtained from male mice and could not be transferred to female recipients due to risk of rejection.

Q1 – inclusive? No

Q2 – can the sex be determined? Yes

Q3 – acceptable exception? No

Q4 – disease model induction issue? No

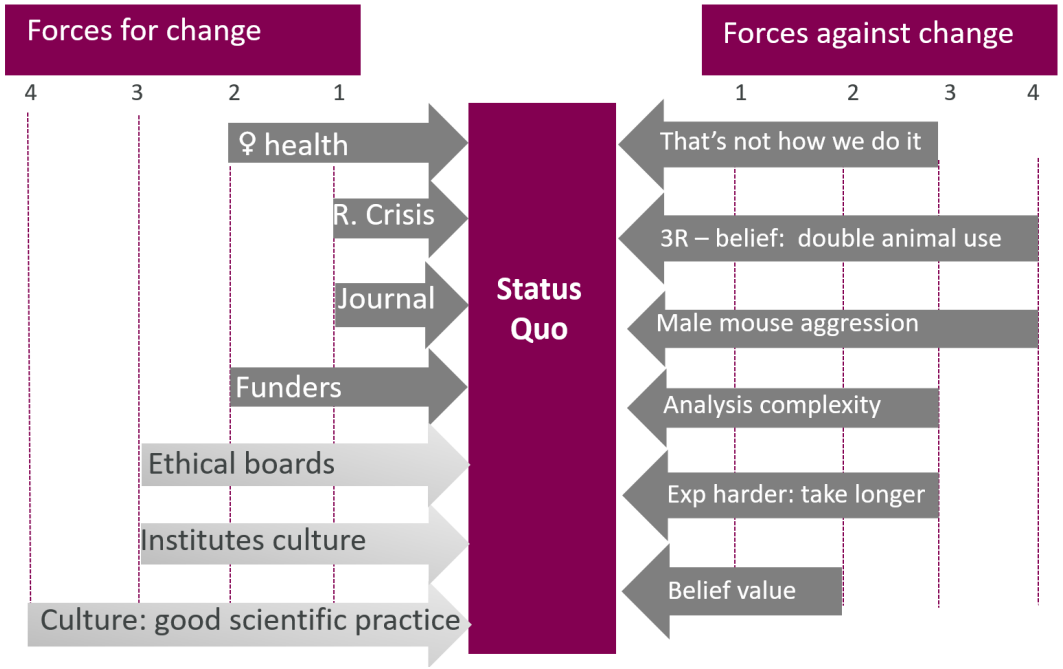
Q5:8 – misconceptions/fear of change? No

Q9: Cost &/or harm versus benefit? Yes

Single sex study justified

What is the SIRF trying to do?

Culture position: Inclusion is the default and justification for exclusion



Strengthen driving forces

Weaken resisting force

https://openinnovation.astrazeneca.com/preclinical-research/sex-inclusive-research-framework.html

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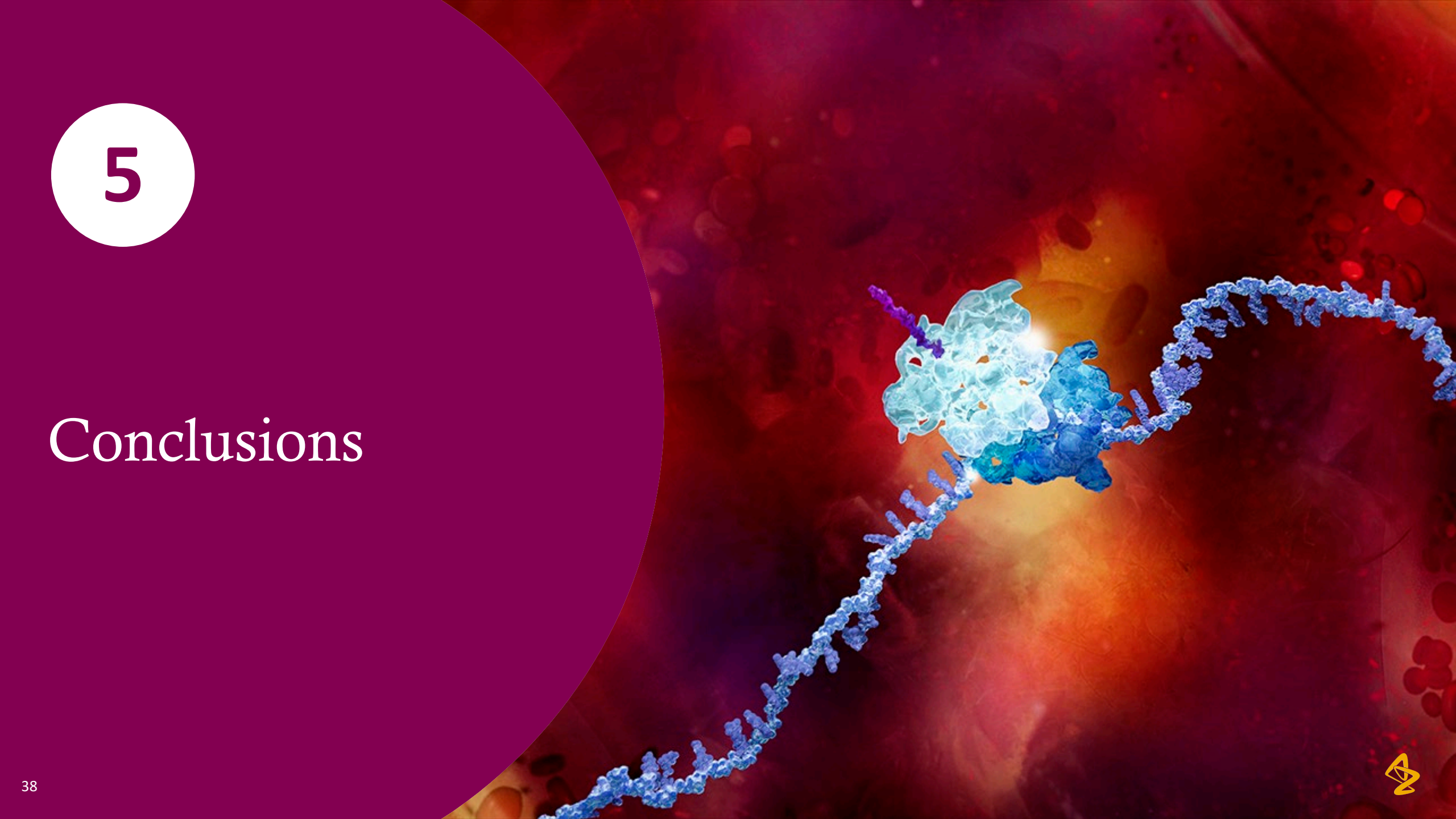
Conclusions



Conclusions

- I have been talking about sex inclusive research for many years, and suddenly the tide is turning.
- Don’t be disheartened. Incrementally you can drive change.
- But you do need a strategy. Business change management strategies are useful to develop your plan and communicate the approach to management.
- The first step is to understand the barriers and the drivers for change.
- Find wins on the way and celebrate the progress you are making.
- Then we can be solution focused and deliver real impact in scientific practice.

Acknowledgement

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Changing human behavior to improve animal welfare: rat tickling as a case study

Brianna Gaskill, PhD

Disclosure

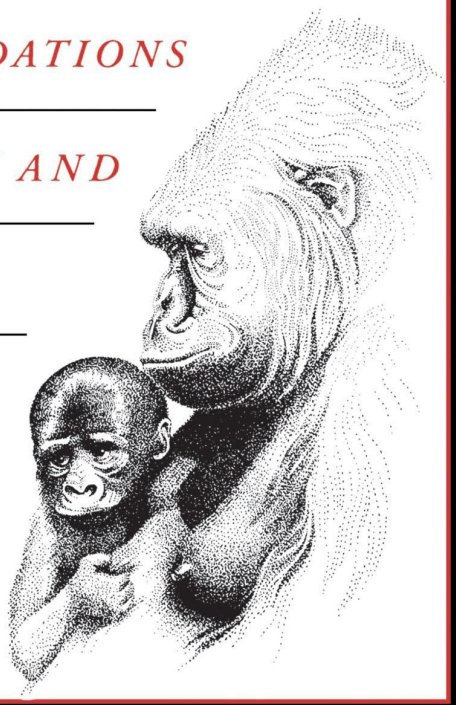
Opinions and information expressed within the content of this talk are my own and do not necessarily reflect the opinions or beliefs of my current employer.

How does change happen in laboratory animal science?

SERIES IN AFFECTIVE SCIENCE

AFFECTIVE NEUROSCIENCE

THE FOUNDATIONS OF HUMAN AND ANIMAL EMOTIONS



Jaak Panksepp

Video courtesy of S. Cloutier

Rat play has 2 key components

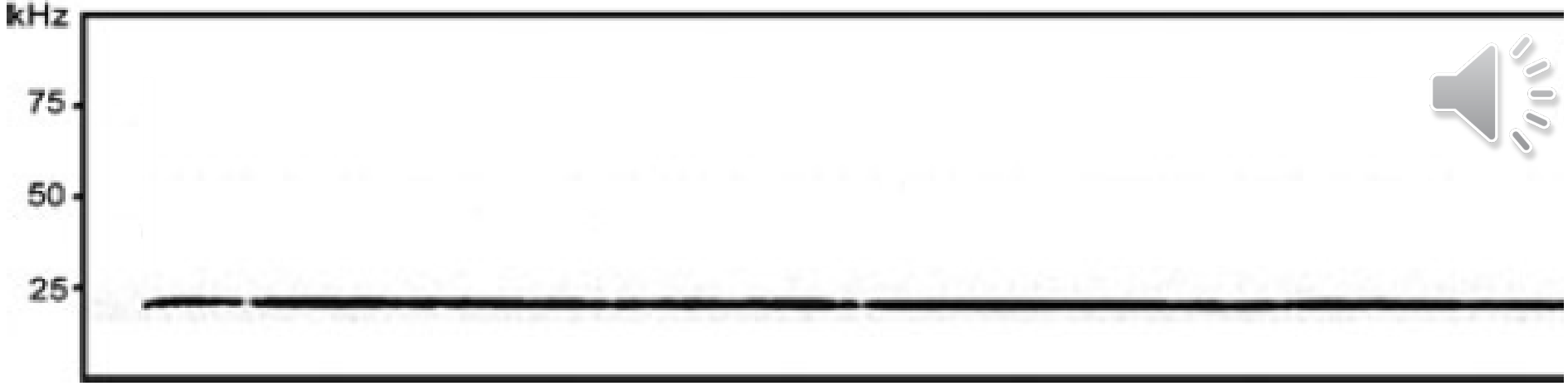
Dorsal Contact

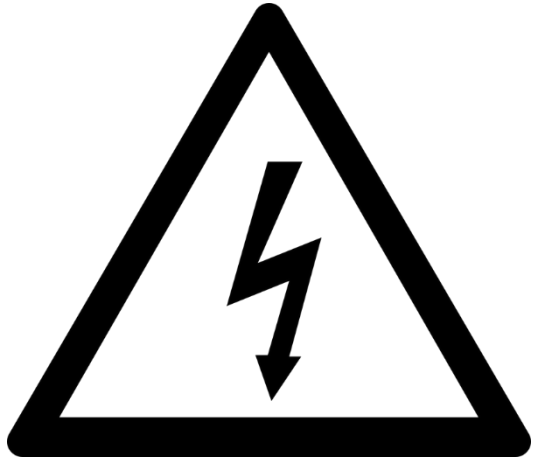
Trezza et al., 2010; Panksepp 1999

Rat tickling mimics 2 key aspects of rat rough-and-tumble play

Trezza et al., 2010; Panksepp 1999

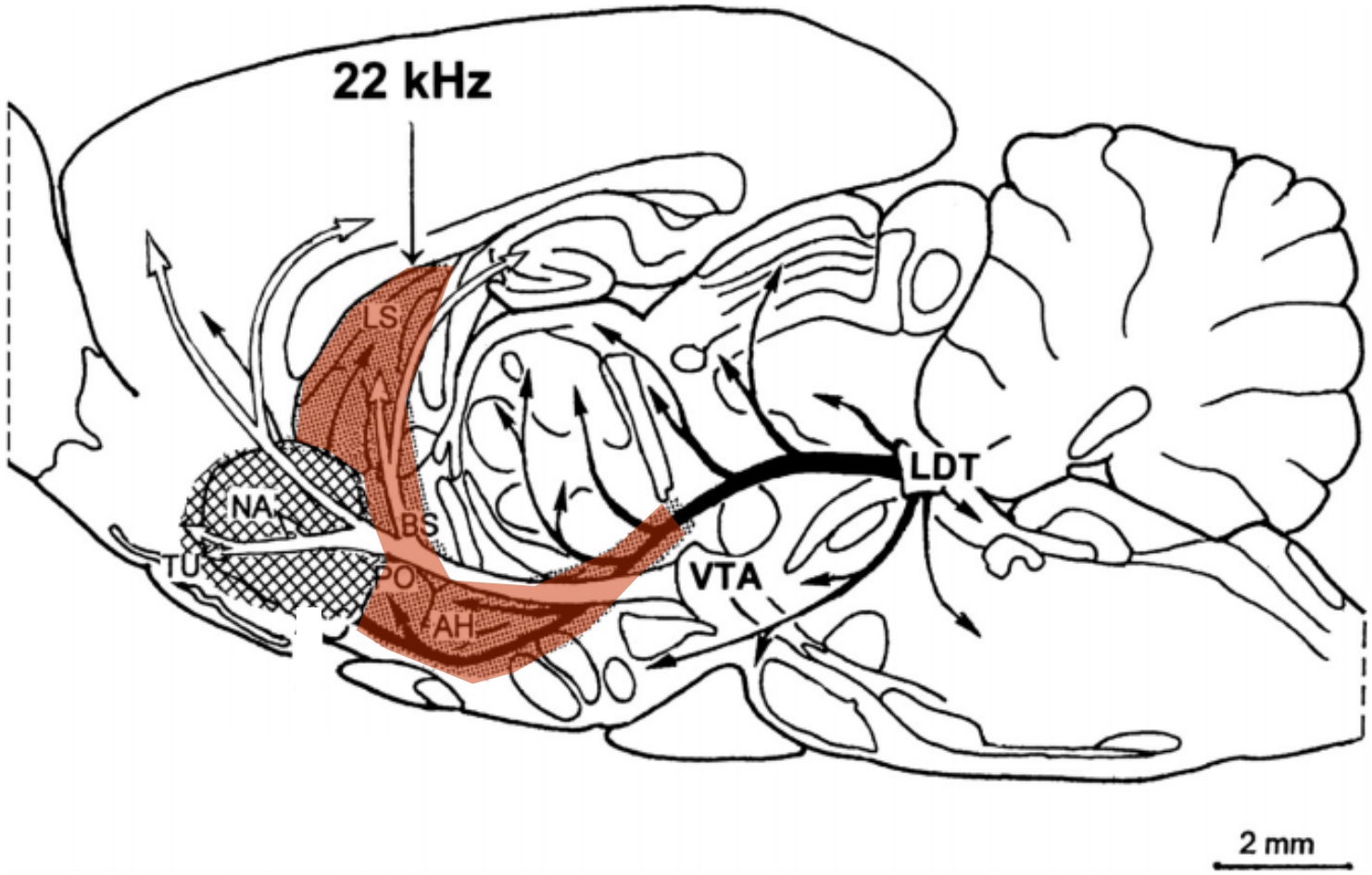
22-kHz vocalizations reflect **negative affect**





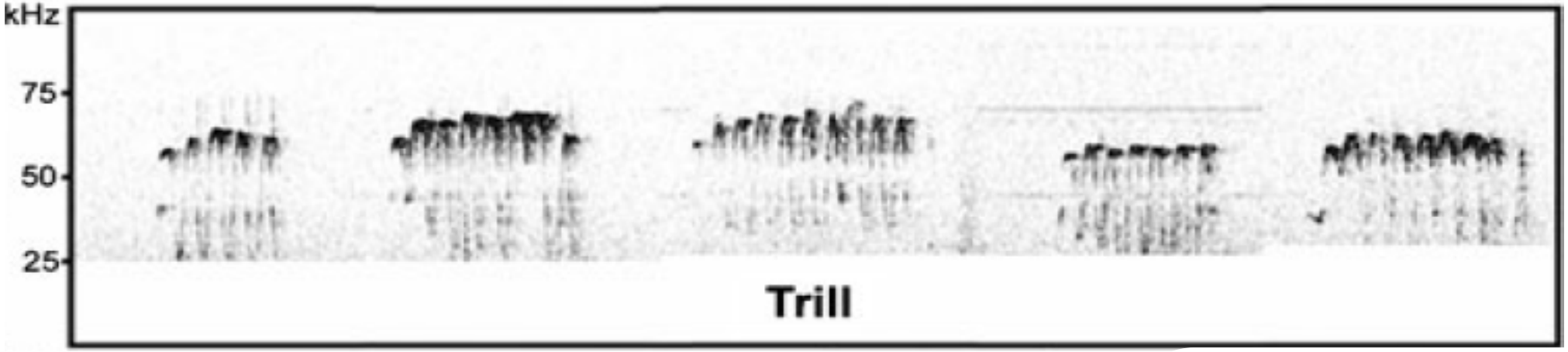
Knutson and Panksepp, 2002; Burman 2007; Brudzyski 2018; Burgdorf 2018

22-kHz = cholinergic activity & are correlated with magnitude of anxiety

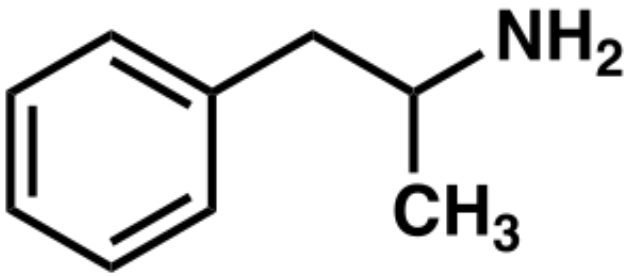


Brudzynski 2007; Simola 2018

50-kHz vocalizations reflect **positive affect**

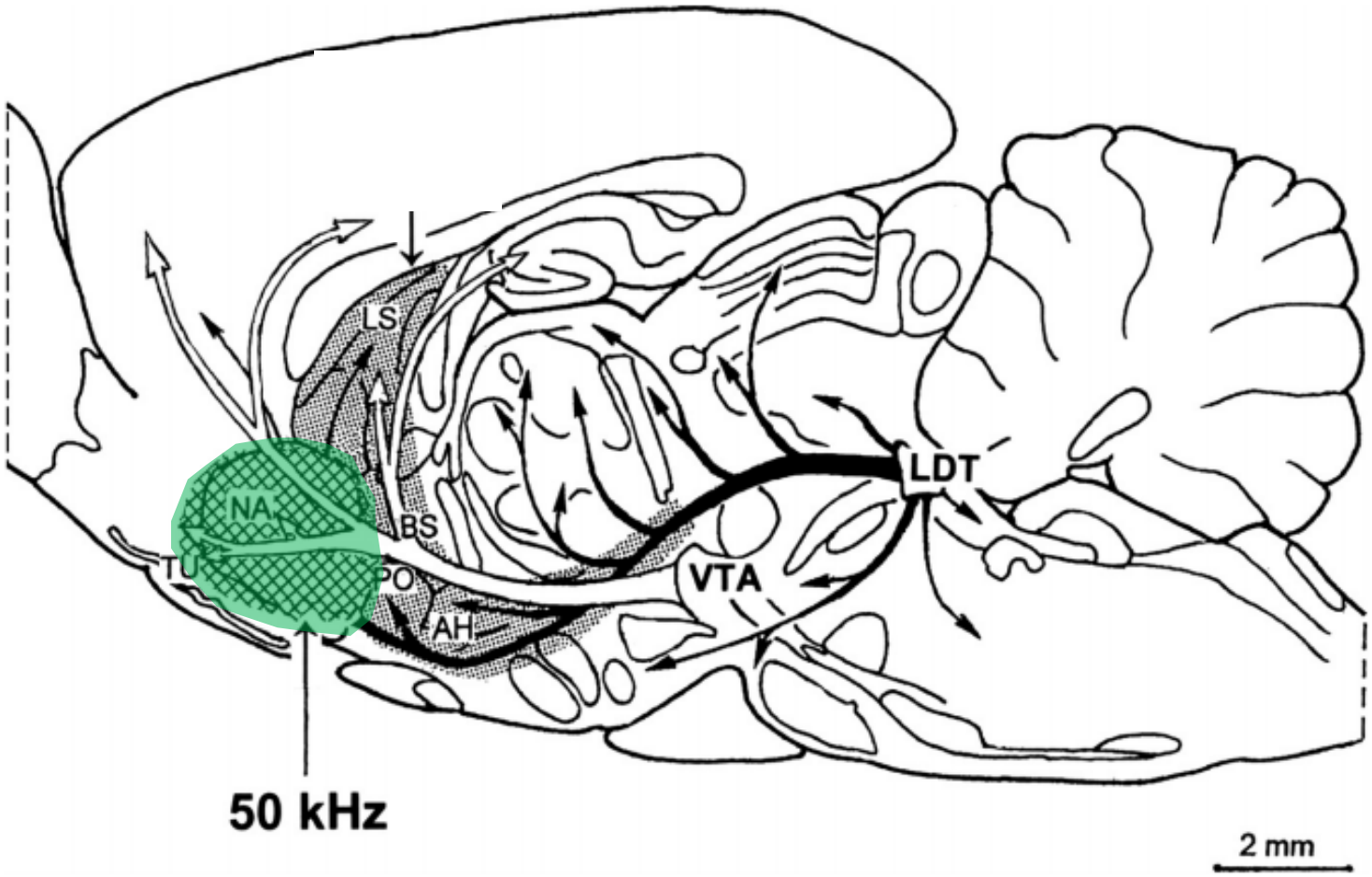


AMPHETAMINE



Knutson and Panksepp, 2002; Burman 2007; Burgdorf 2018

50-kHz = dopaminergic activity & are correlated with magnitude of reward

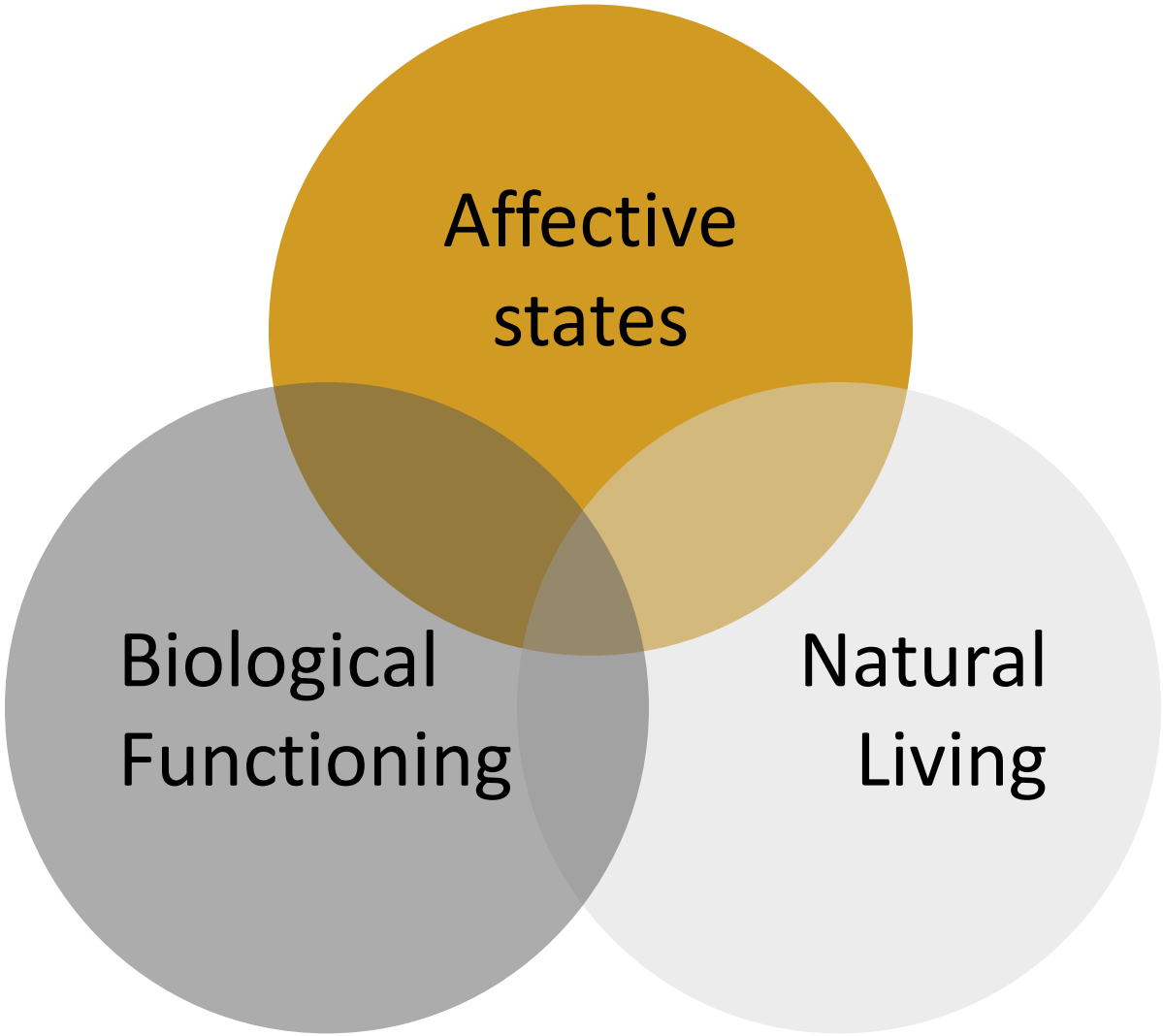


Brudzynski 2007; Knutson and Panksepp, 2002; Burman 2007; Burgdorf 2018

That's cool but....

why should I tickle rats?

…the vocalizations tell us how a rat is feeling!



Fraser 1997

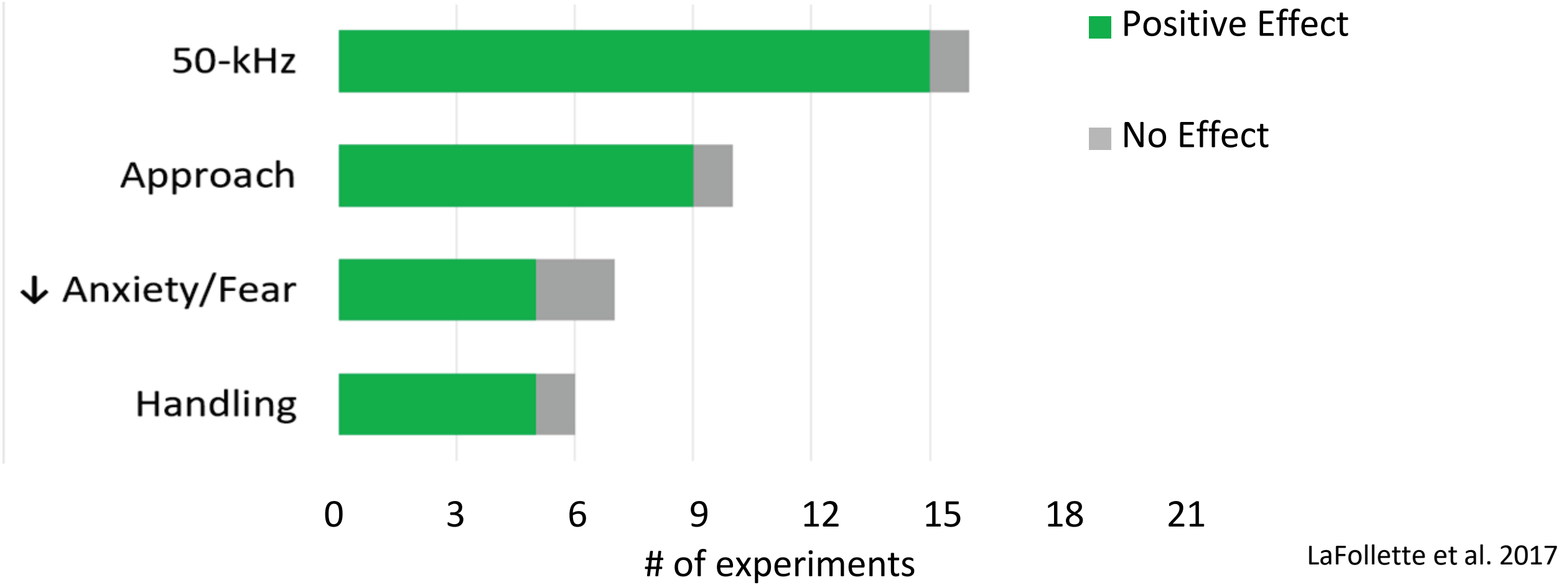
Rats experience stress during handling

Changes rat behavior, hormones, & brain structure

Harms rat welfare, experimental validity, & reliability.

Davis and Perusse, 1988; Gartner et al., 1980; Balcombe et al., 2004

Rat tickling is an effective intervention



LaFollette et al. 2017

Does anyone use it?

Cross-sectional survey at a single-time point of laboratory animal personnel across the United States & Canada.

LaFollette et al. 2019

Measures: 3 main sections

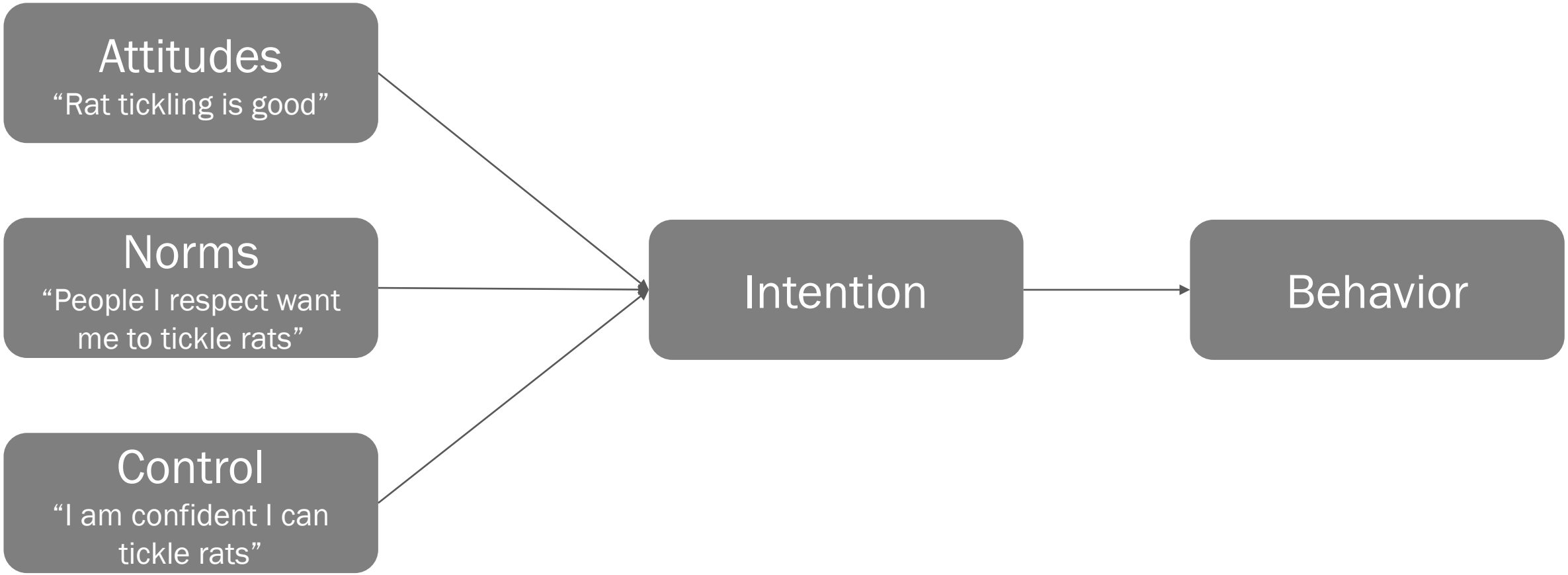
Demographics

Rat Tickling Frequency (Hoy et al. 2010)

Theory of Planned Behavior (Francis et al. 2004 & Ajzen 1991)

Intention & Beliefs about Rat Tickling

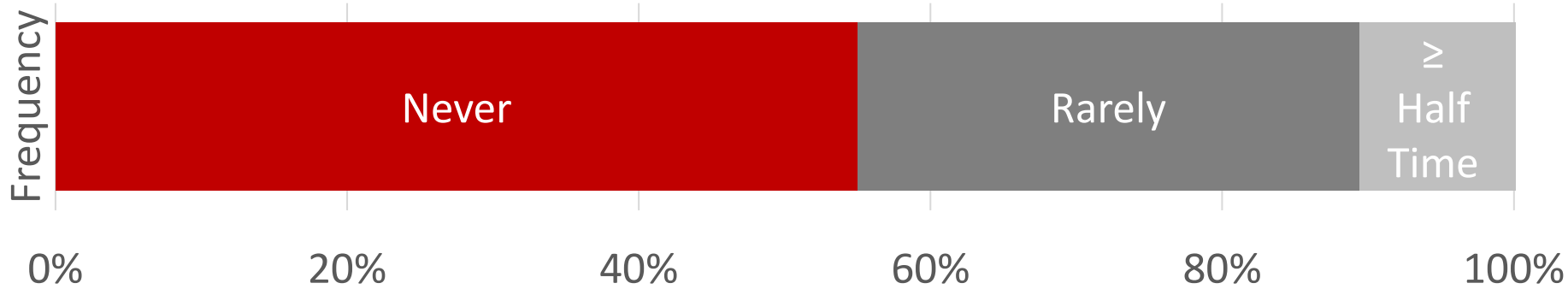
Theory of planned behavior



Ajzen 1991; Hemsworth & Coleman 2011

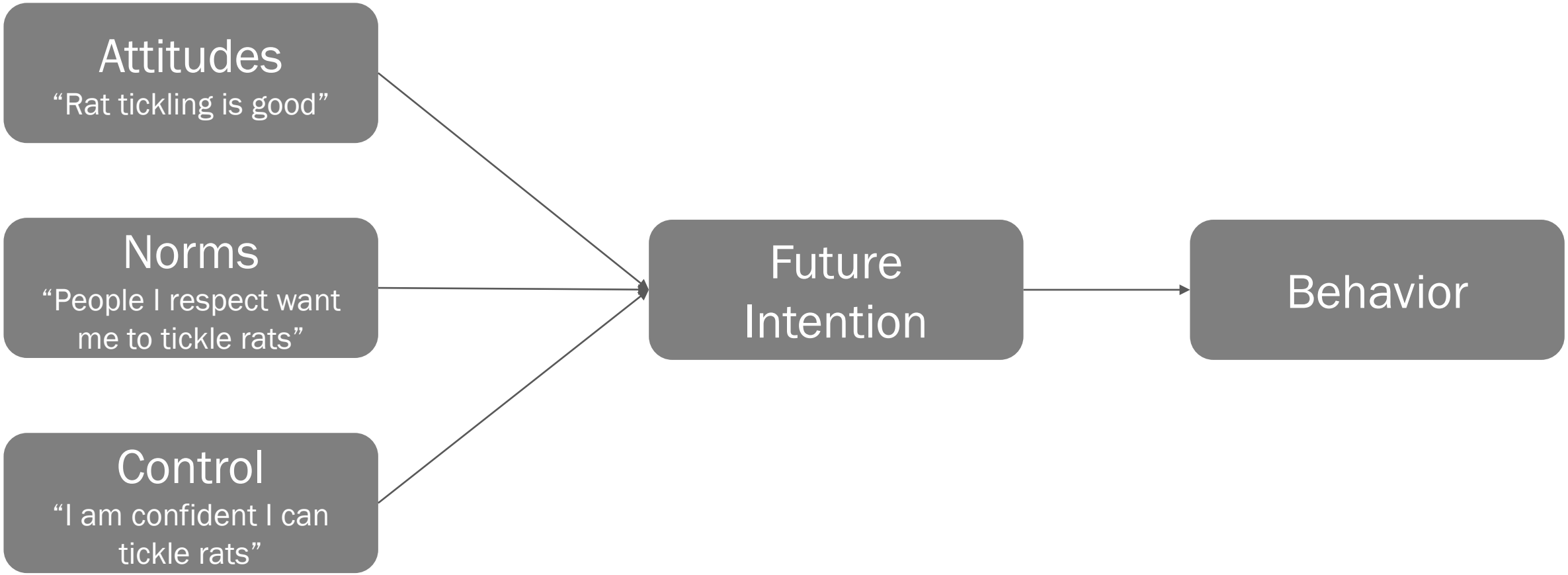
Lab personnel tickle rats infrequently

89% of personnel **never or rarely** tickle their rats



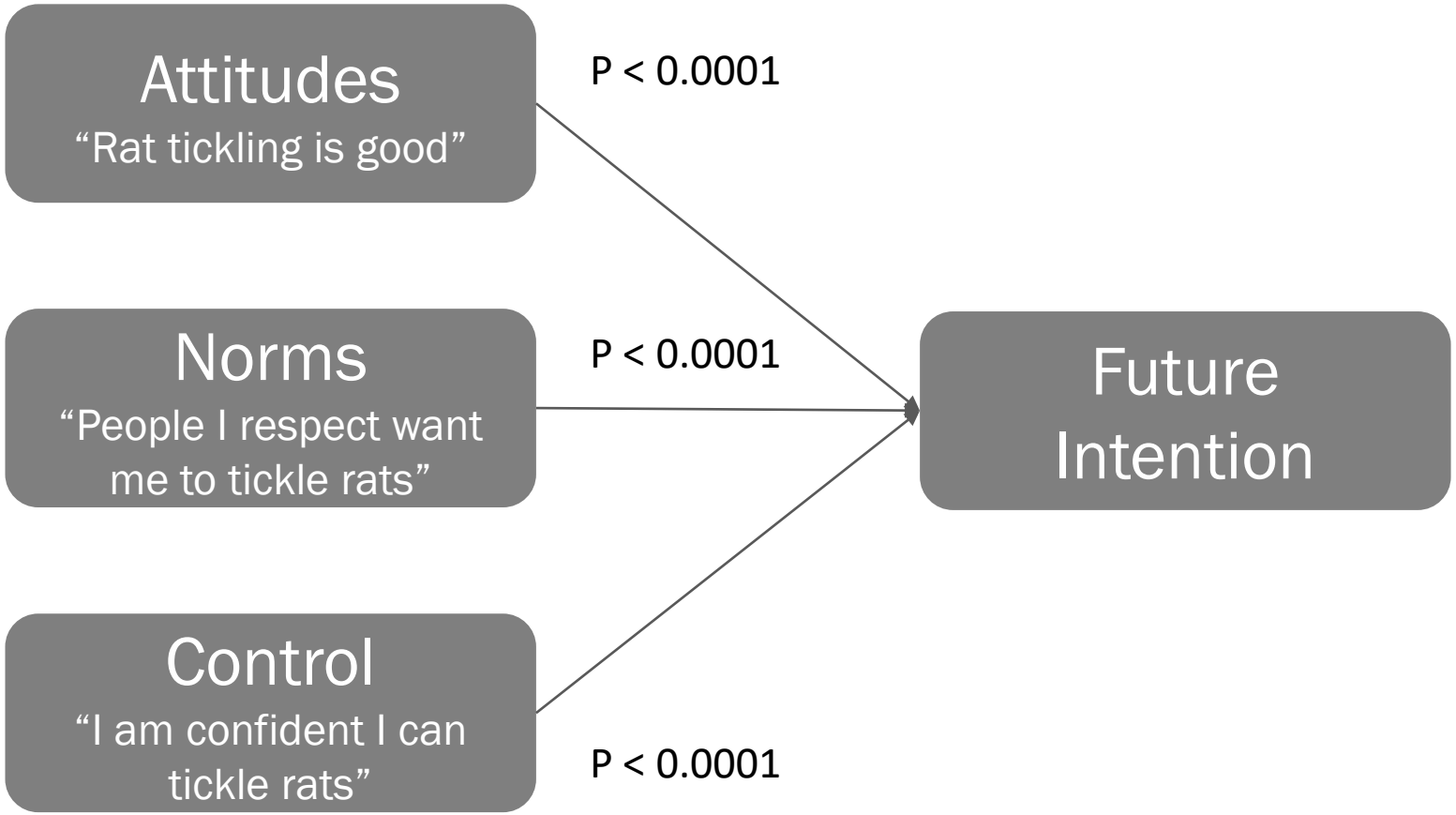
LaFollette et al. 2019

Theory of planned behavior



Ajzen 1991; Hemsworth & Coleman 2011

Beliefs are associated with rat tickling intention

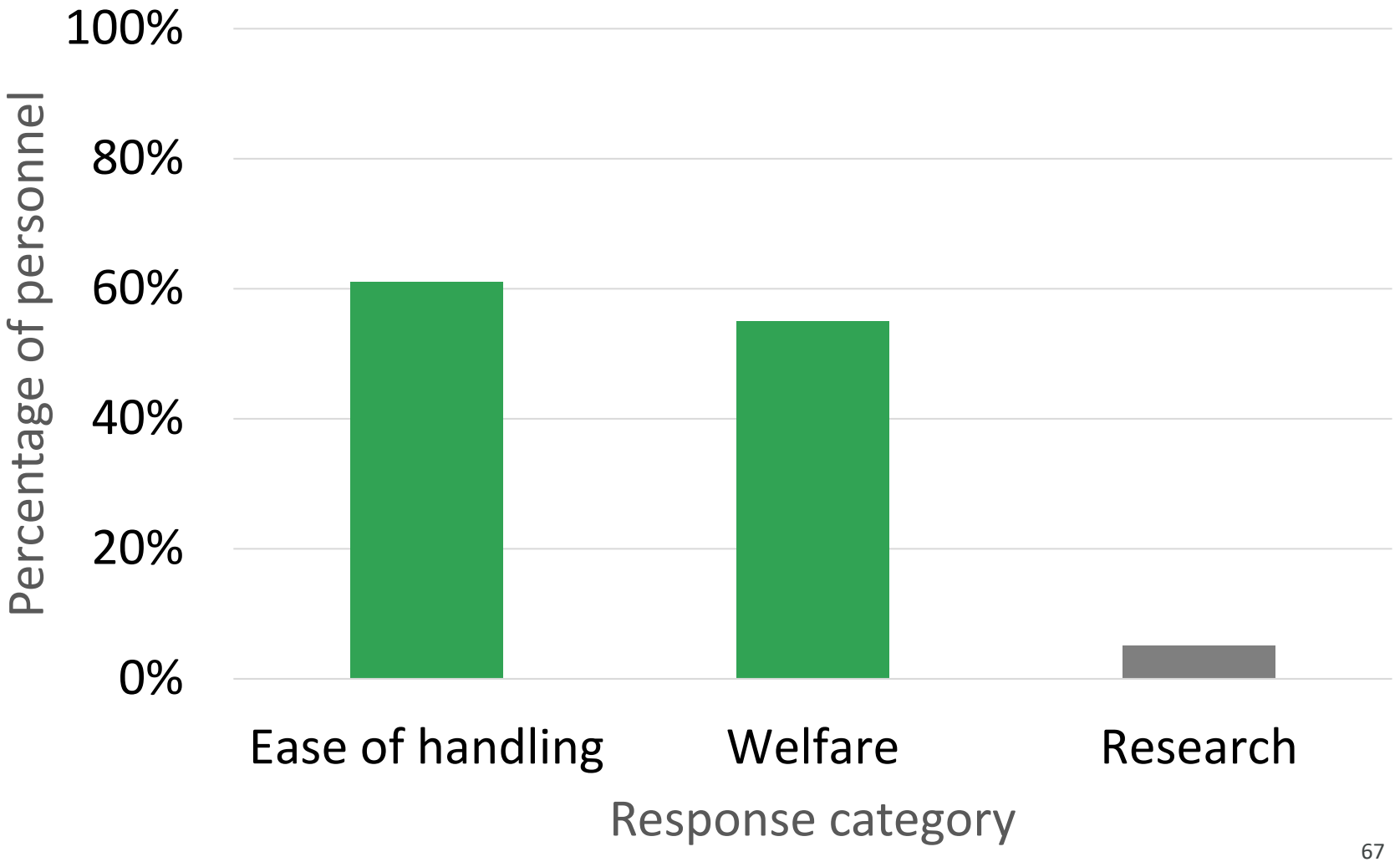


LaFollette, 2019

Handling & welfare was a benefit of tickling

≥55%

of personnel mentioned tickling increased ease of handling and rat welfare

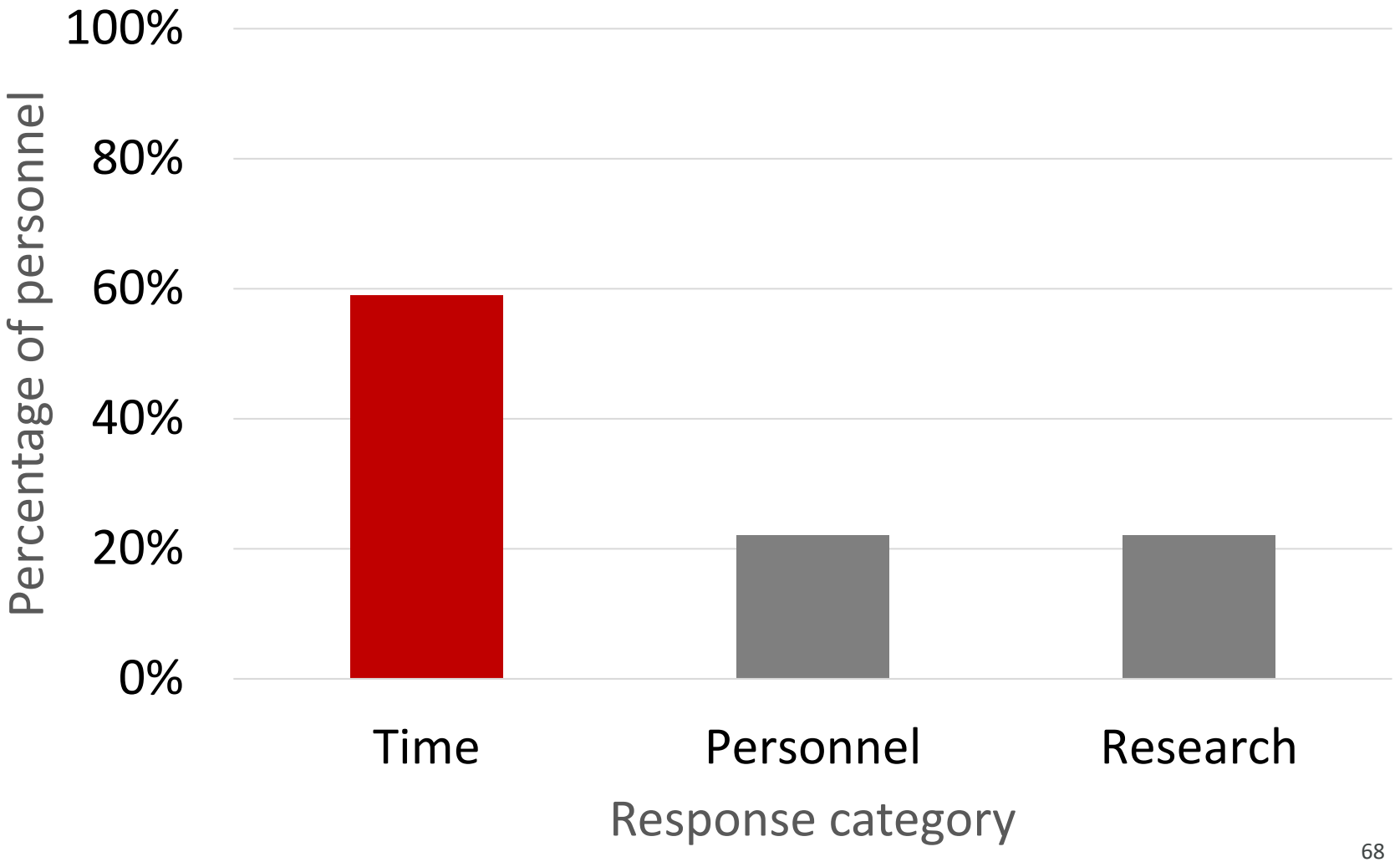


LaFollette et al. 2019

Time was the biggest barrier to rat tickling

59%

of personnel mentioned time related phrase

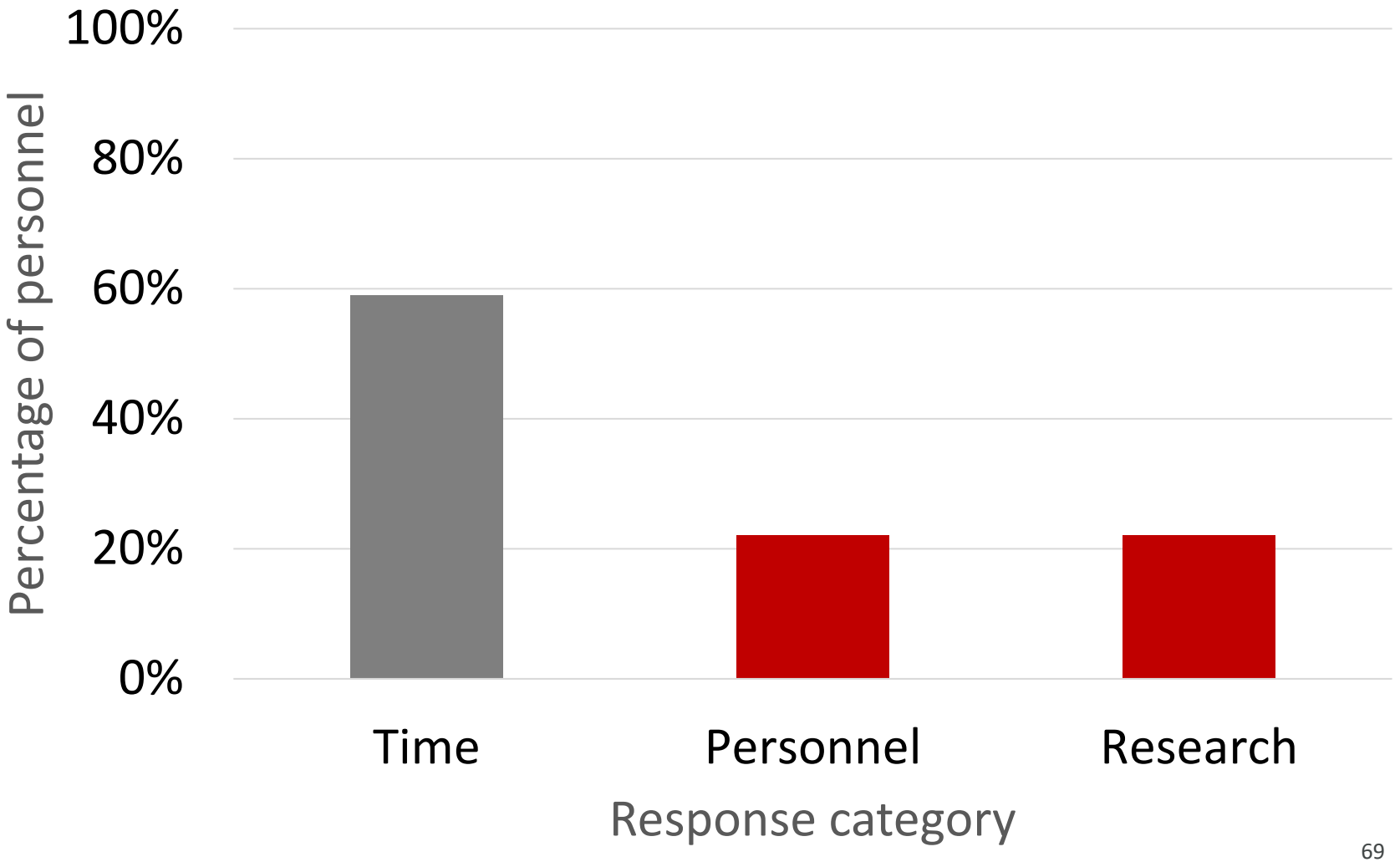


LaFollette et al. 2019

Personnel & Research were other barriers

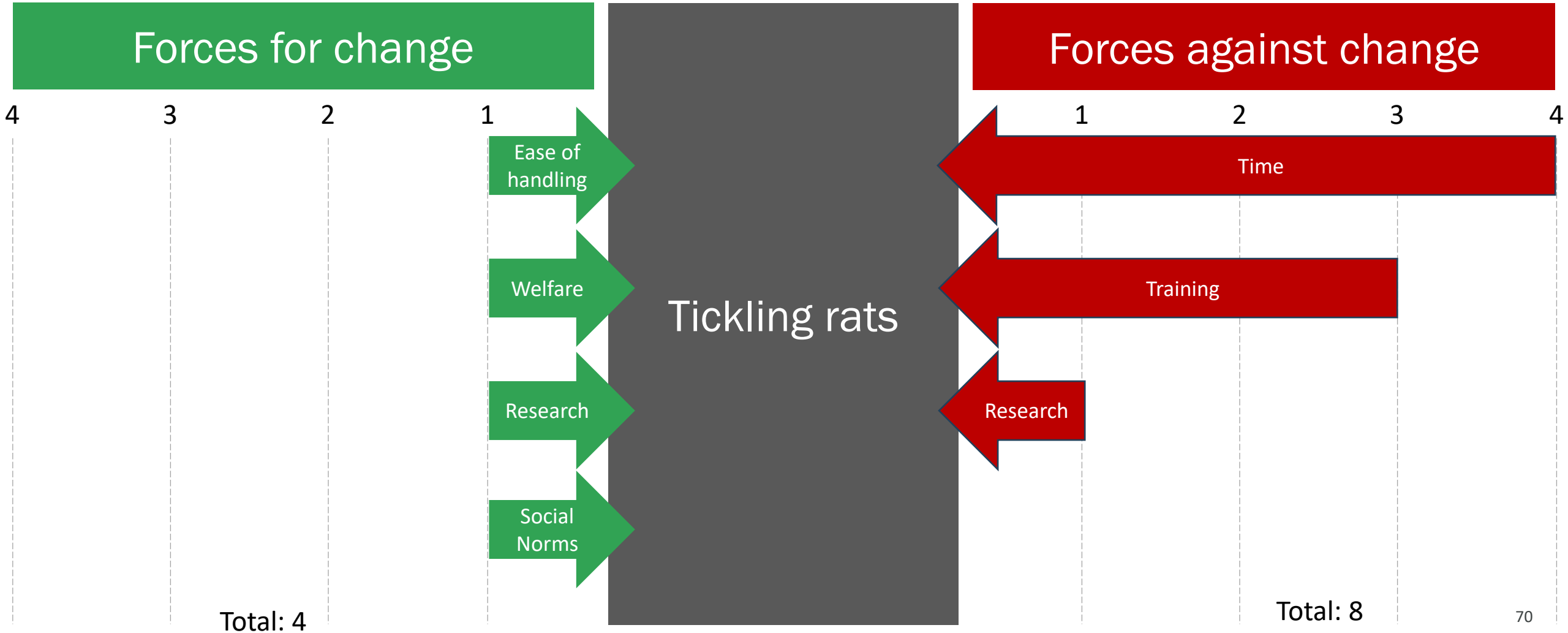
22%

of personnel mentioned personnel and research related phrase



LaFollette et al. 2019

Forcefield analysis



Can we address these forces against change and improve implementation?

Current tickling practices are time-intensive

2 min

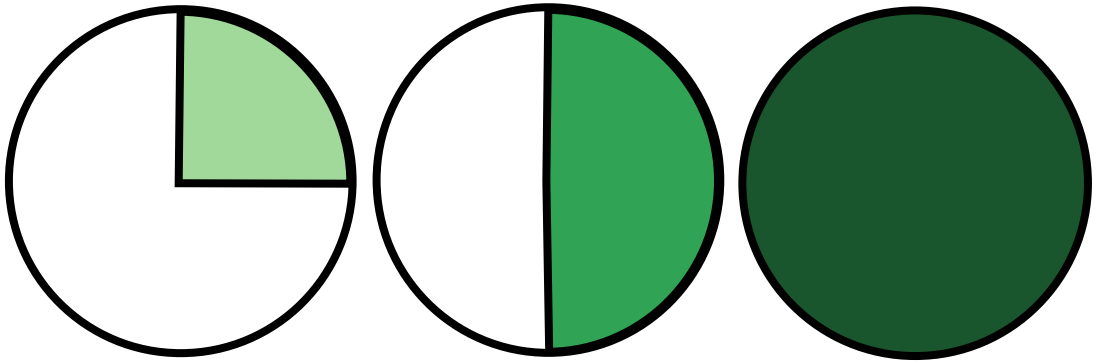
5 days

50 rats

=5 hours/study

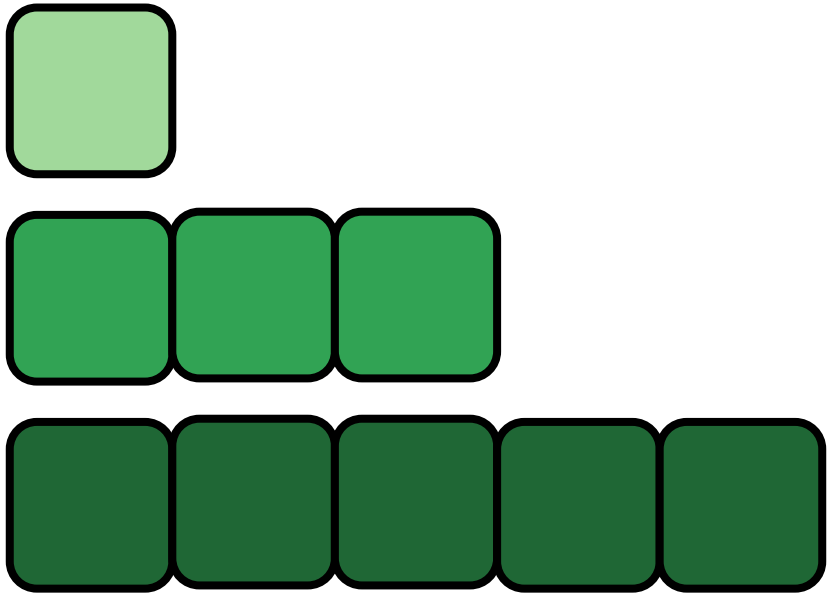
What dose of tickling is sufficient?

Duration



15, 30, or 60 seconds

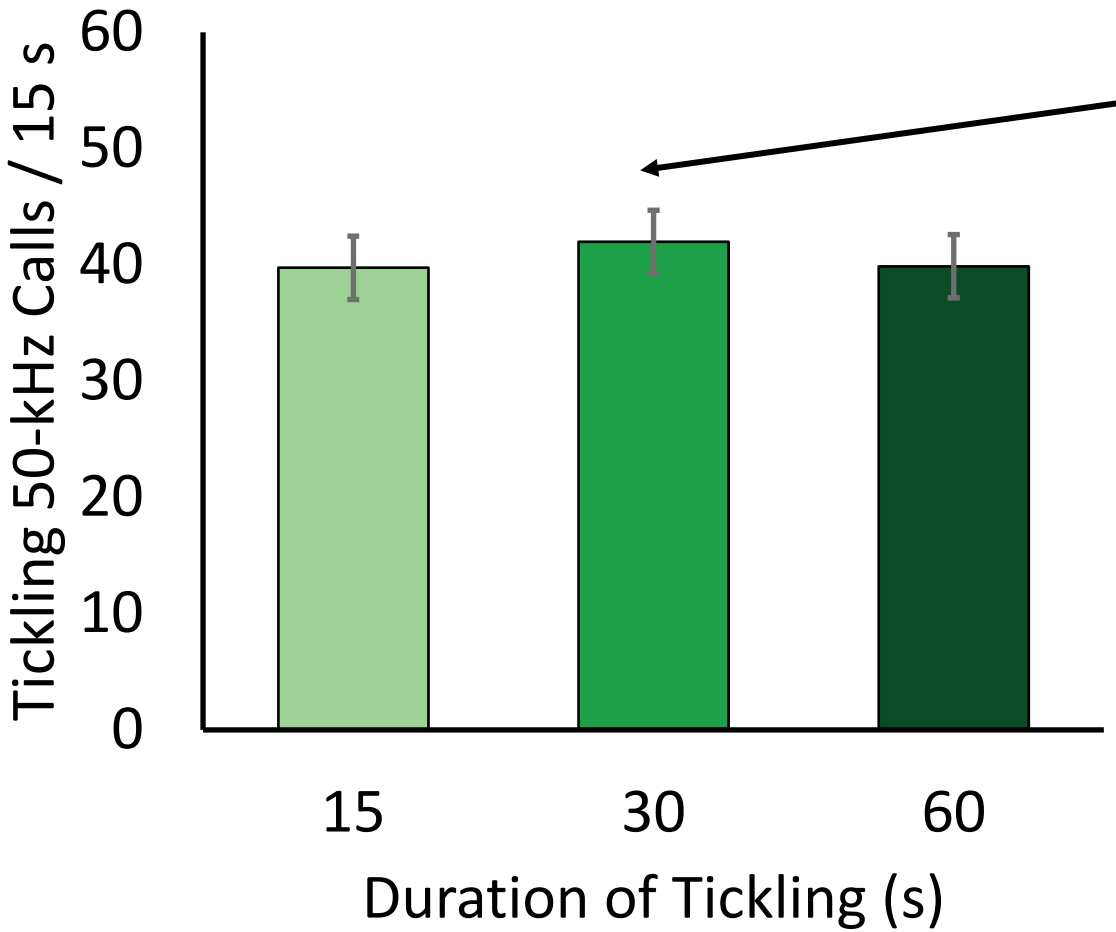
Frequency



1, 3, or 5 days

LaFollette et al, 2018

Tickling for 15 s was most efficient & effective

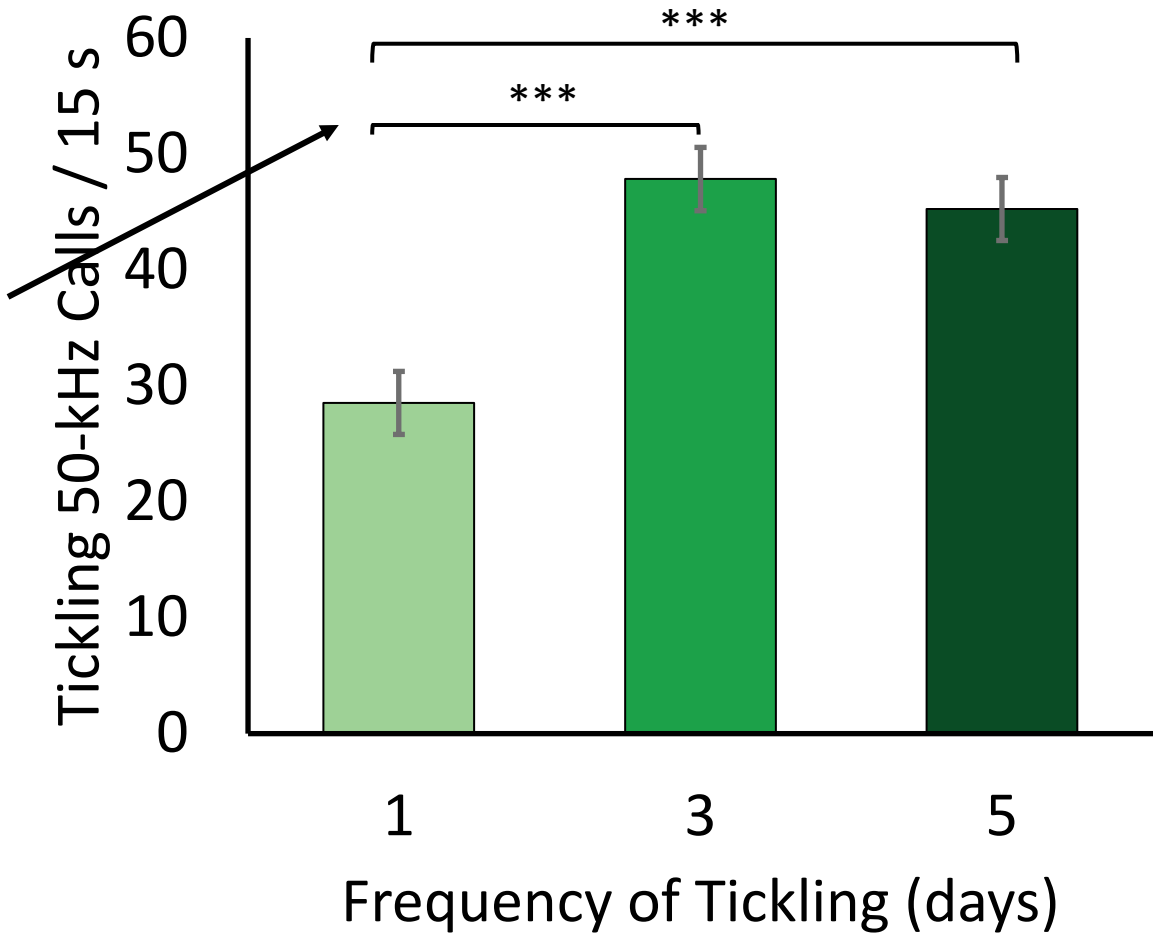


No difference between durations of 15, 30, or 60 s.

LaFollette et al, 2018

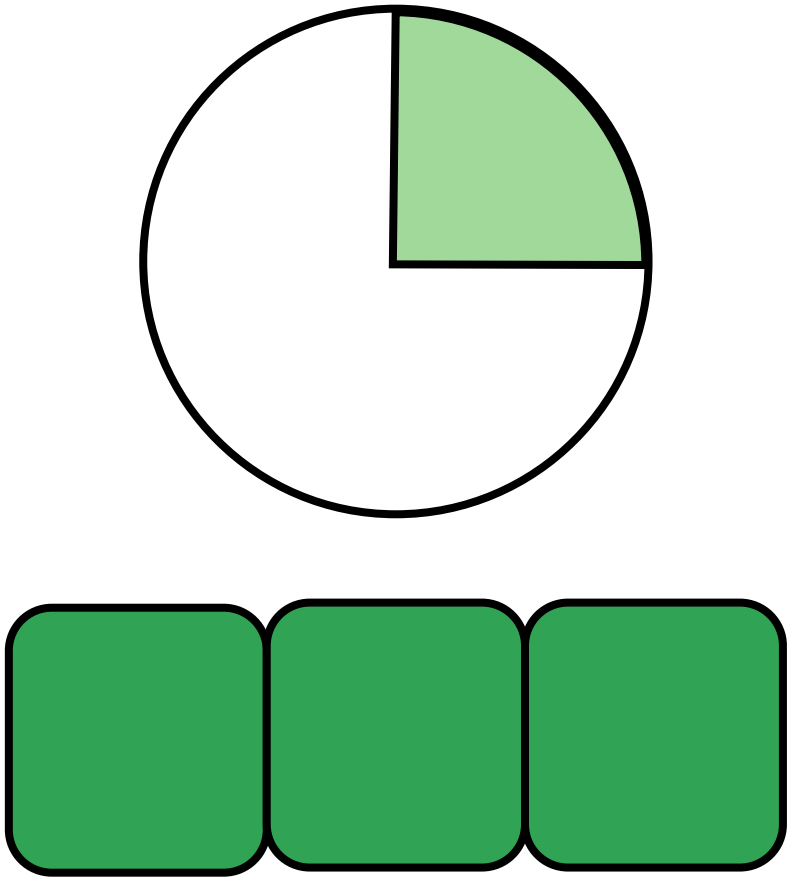
Tickling for 3 days was most efficient & effective

70% more
50-kHz calls
during tickling
after 3 days



LaFollette et al, 2018

Tickling for 15 s over 3 days was the most efficient & effective tickling dosage



Initial time investment

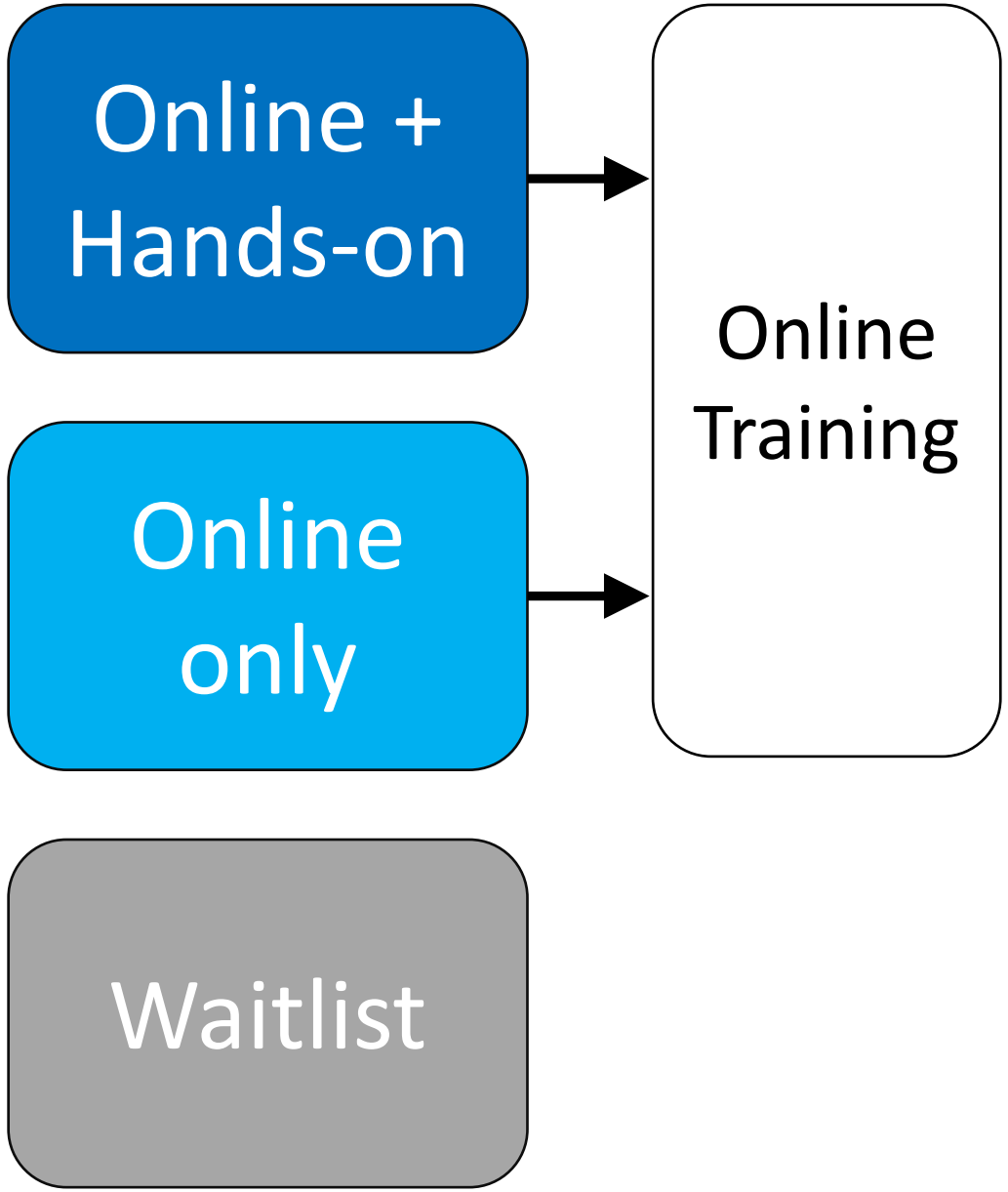
5hrs

↓

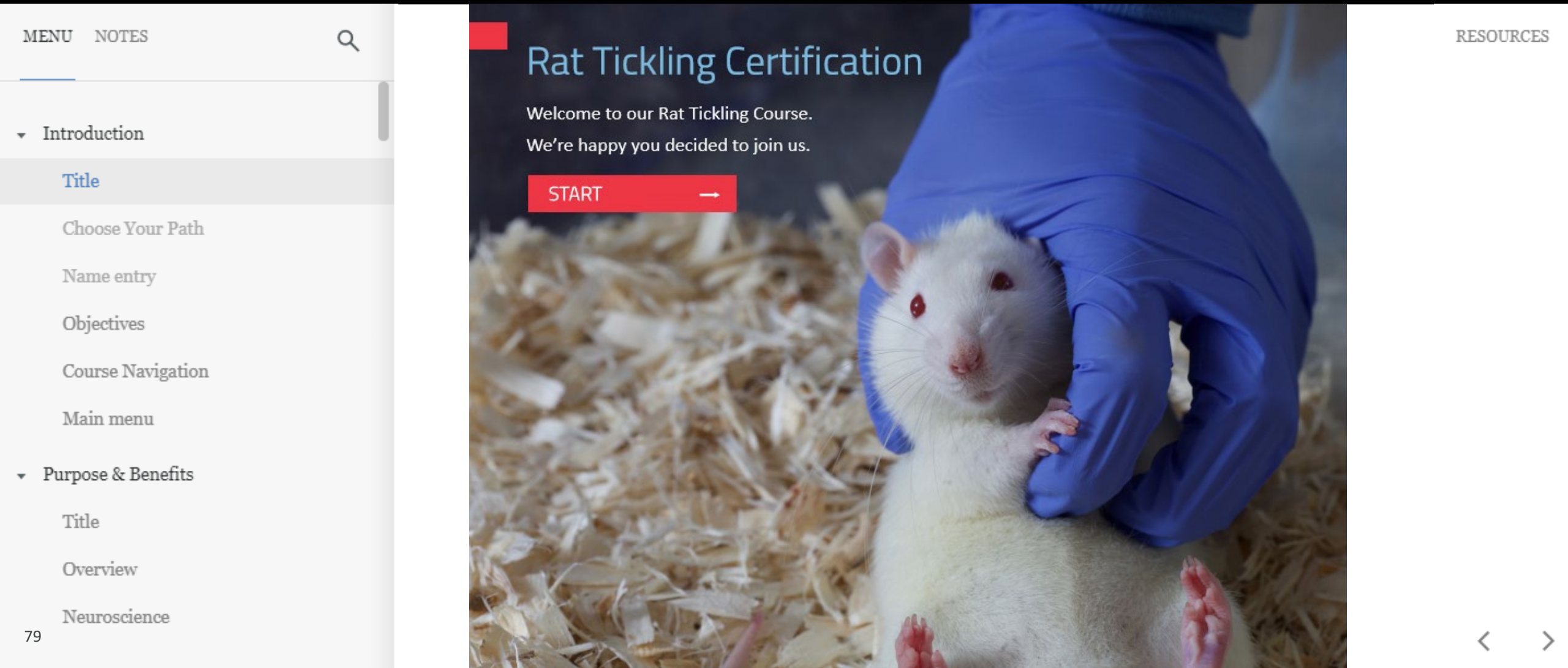
38m

LaFollette et al, 2018

Can we address personnel barriers through training?


Online +
Hands-on
Online
only
Online
Training
Waitlist

Online tickling training



Practical explanations

Step 2b

The Flip Grip

Practice on a stuffed or well-habituated rat before trying on a naive rat.

Imagine supporting the rat under its "armpits" with your thumb & middle finger. Then use your pointer finger in front of the rats collar bone to prevent it from just running out of your hand when new to tickling.

Consider tucking you pinky & ring fingers out of the way during the flip (show below) and actually using them to push the rat through.

How to fit tickling into your study

How can tickling fit into a study timeline?

Example 1: Short Study

Day 0: Rats Arrive at Facility

Allow rats at least one day to recover from transportation stress before tickling.

Days 1-3: Habituation Period

Tickle rats on day 1, 2, and 3.

Days 4-7: Daily Injections

Tickle just before daily injections.

Example 2: Long Study

Day 0: Rats Arrive at Facility

Allow rats at least one day to recover from transportation stress before tickling.

Days 1-7: Habituation Period

Tickle rats on day 4, 5, and 6.

On day 7 when you need to mark rats for individual identification, tickle them just before marking.

Days 8-50: Weekly Manipulations

Tickle rats during weekly cage changes or just before weekly manipulations. If time is an issue, aim to tickle about once a month.

These are just examples. Feel free to modify tickling to your individual circumstances and time allowance. If you have more time flexibility, tickle more. If you have less, tickle less. Just remember the principles & that even if you have to stop tickling before major procedures (implantation, surgery, etc.) it may be beneficial to tickle first to establish positive human-animal interactions.

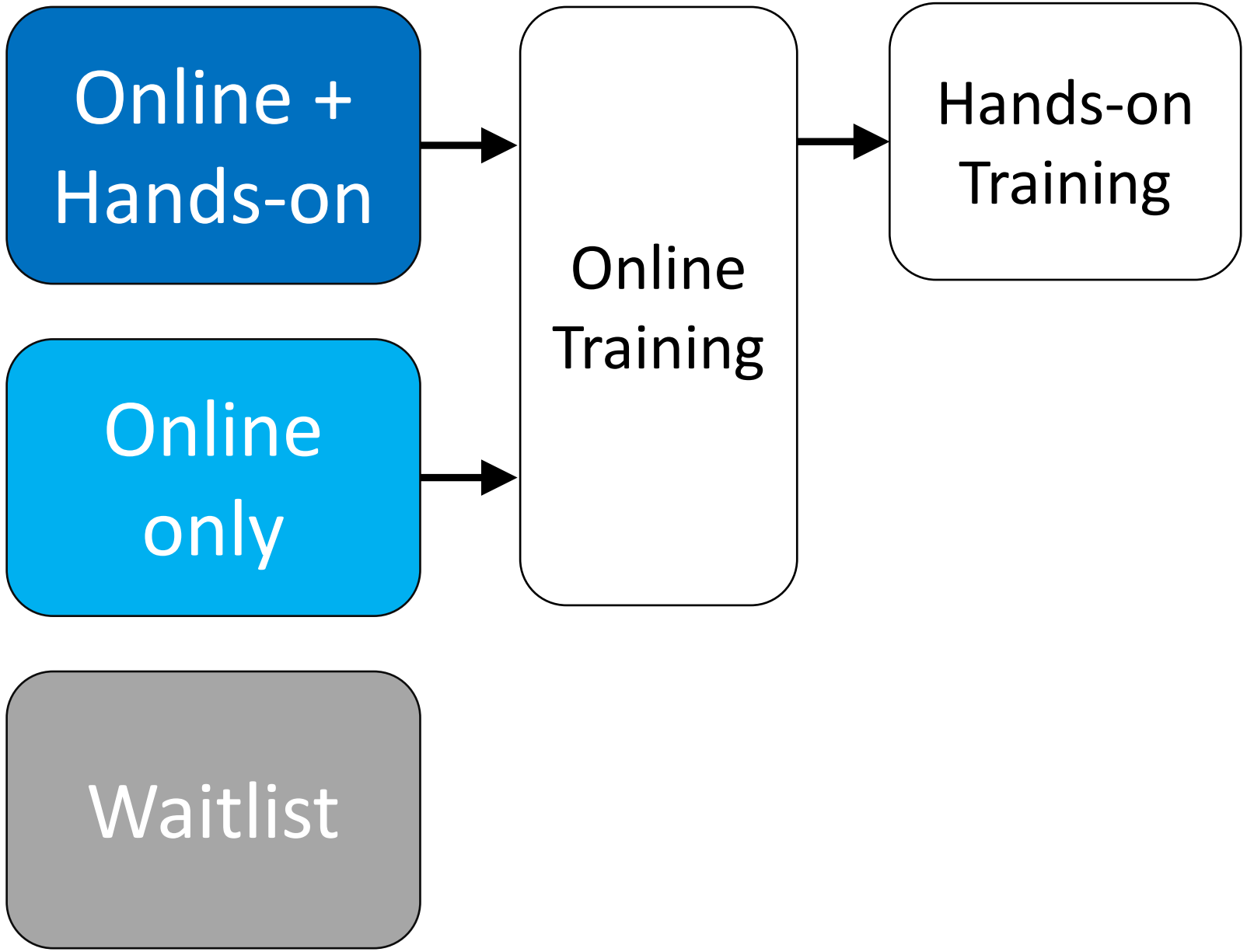
FAQs and tips!

#2

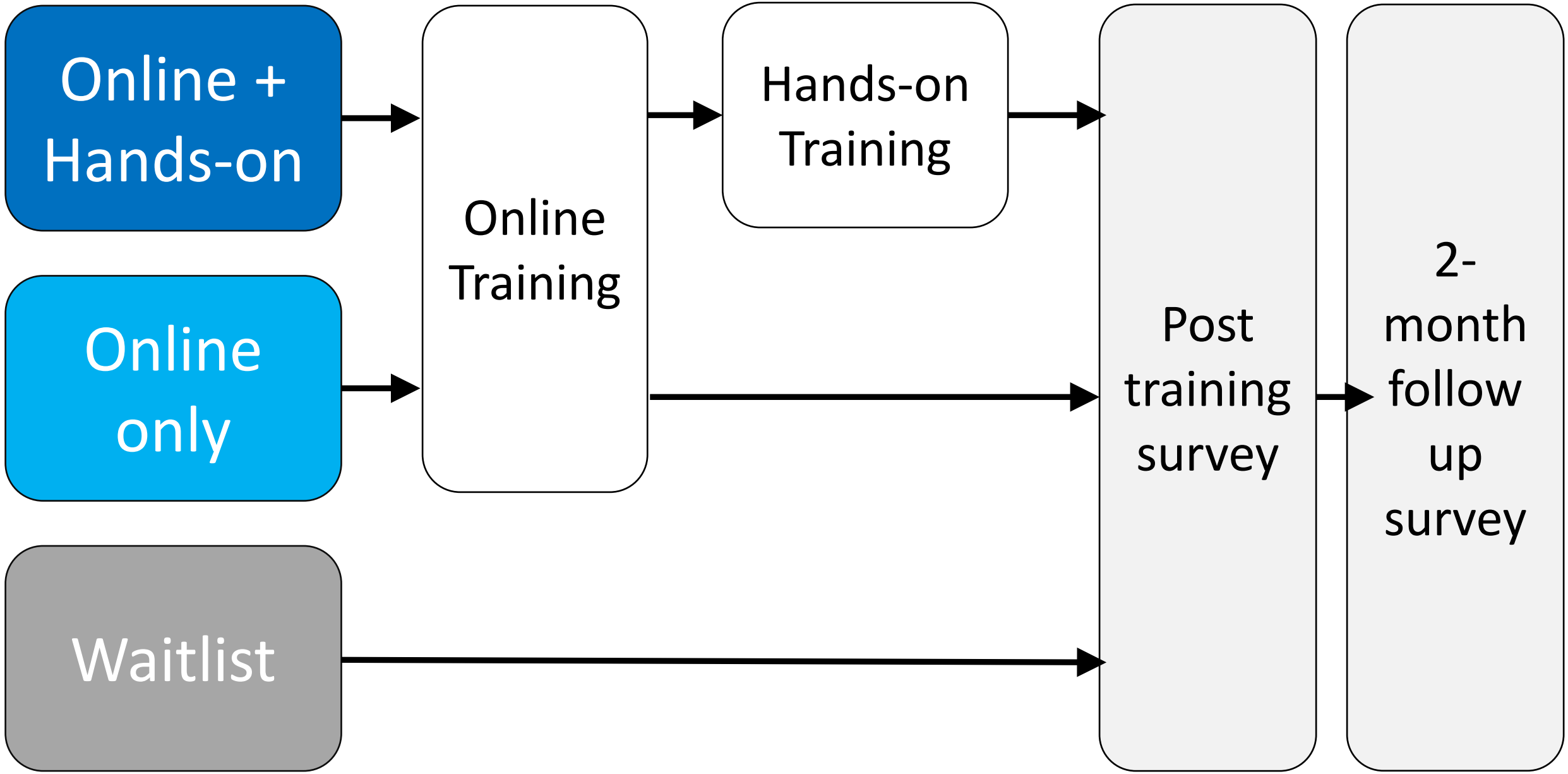
Tickle first, manipulate later

- Tickle for 3 days before doing any potentially aversive procedures like marking or injections.
- On the day of procedures make sure to tickle rats *before* rather than after. When rats are tickled before a procedure this induces positive emotions/affect and will contribute to minimizing the impact of the procedure.
- Don't try to tickle after aversive procedures such as having injection, rats may not be in the mood to play.

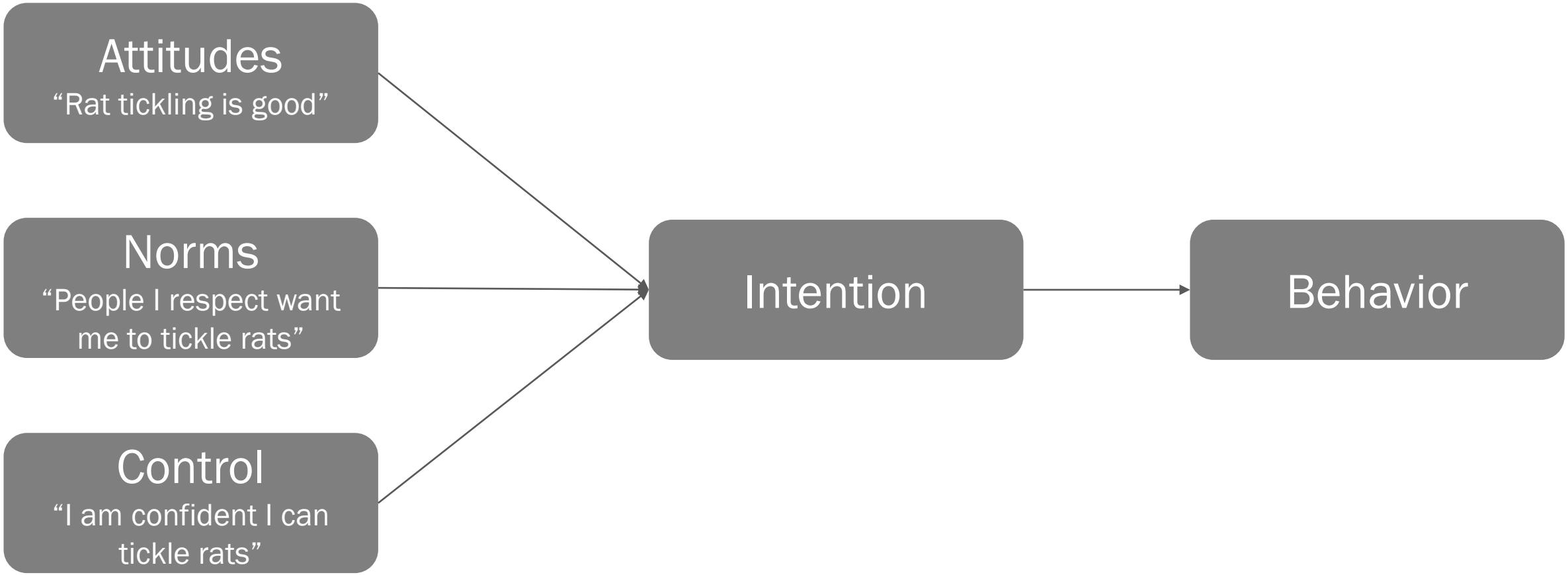

Certificate of Completion
This certifies that
Jane Doe
has successfully completed
Rat Tickling Certification Course
PURDUE
UNIVERSITY


Online + Hands-on
Online only
Waitlist
Online Training
Hands-on Training


CANADA
PACIFIC OCEAN
UNITED STATES
SAINT PIERRE & MIQUELON
ATLANTIC OCEAN
IFES


Online + Hands-on
Online only
Waitlist
Online Training
Hands-on Training
Post training survey
2-month follow up survey

Theory of planned behavior



Ajzen 1991; Hemsworth & Coleman 2011

Beliefs about tickling

Attitudes
"Rat tickling is good"

Norms
"People I respect want me to tickle rats"

Control
"I am confident I can tickle rats"

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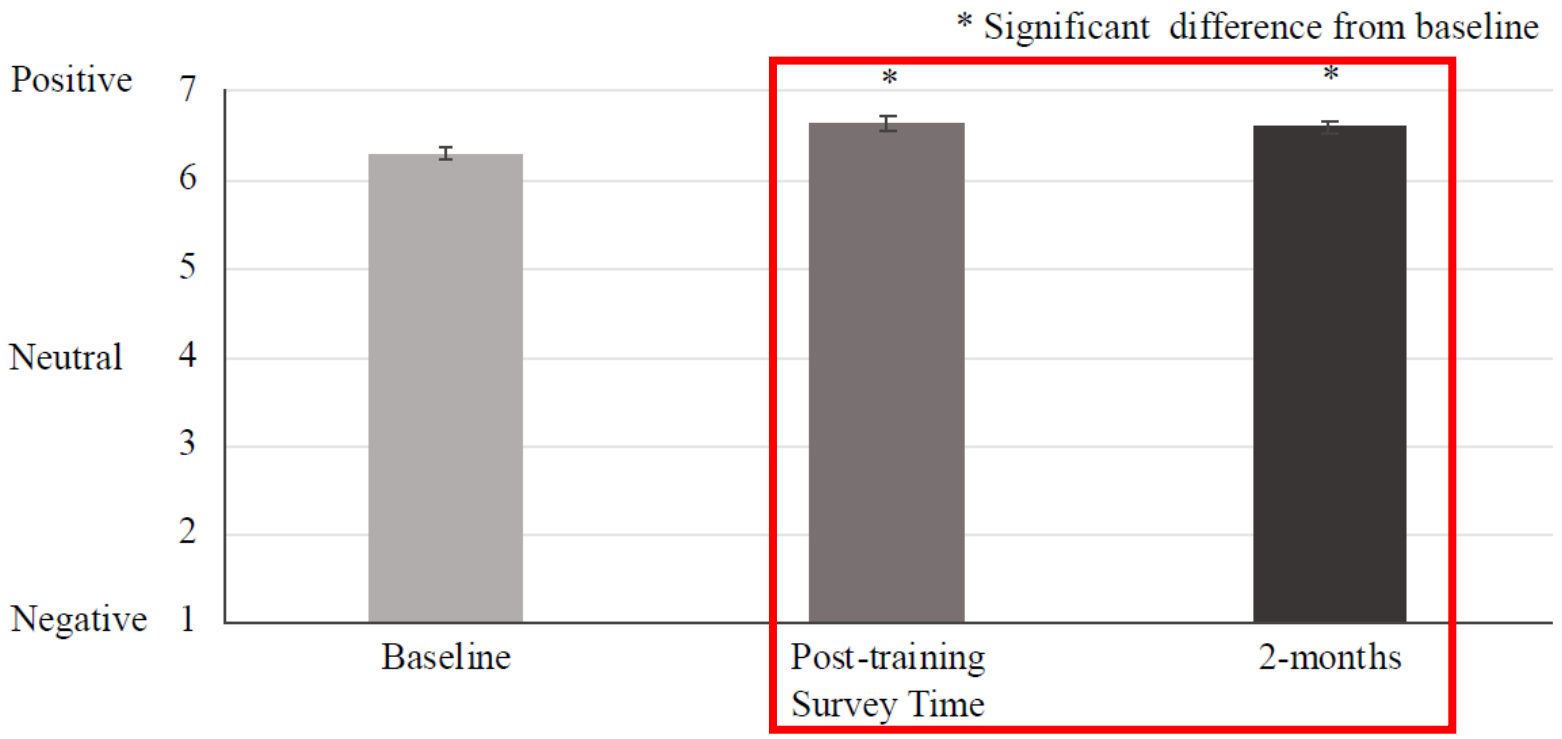

Timepoint: $F_{2,178} = 13.5$; $P < 0.0001$

LaFollette et al, 2020

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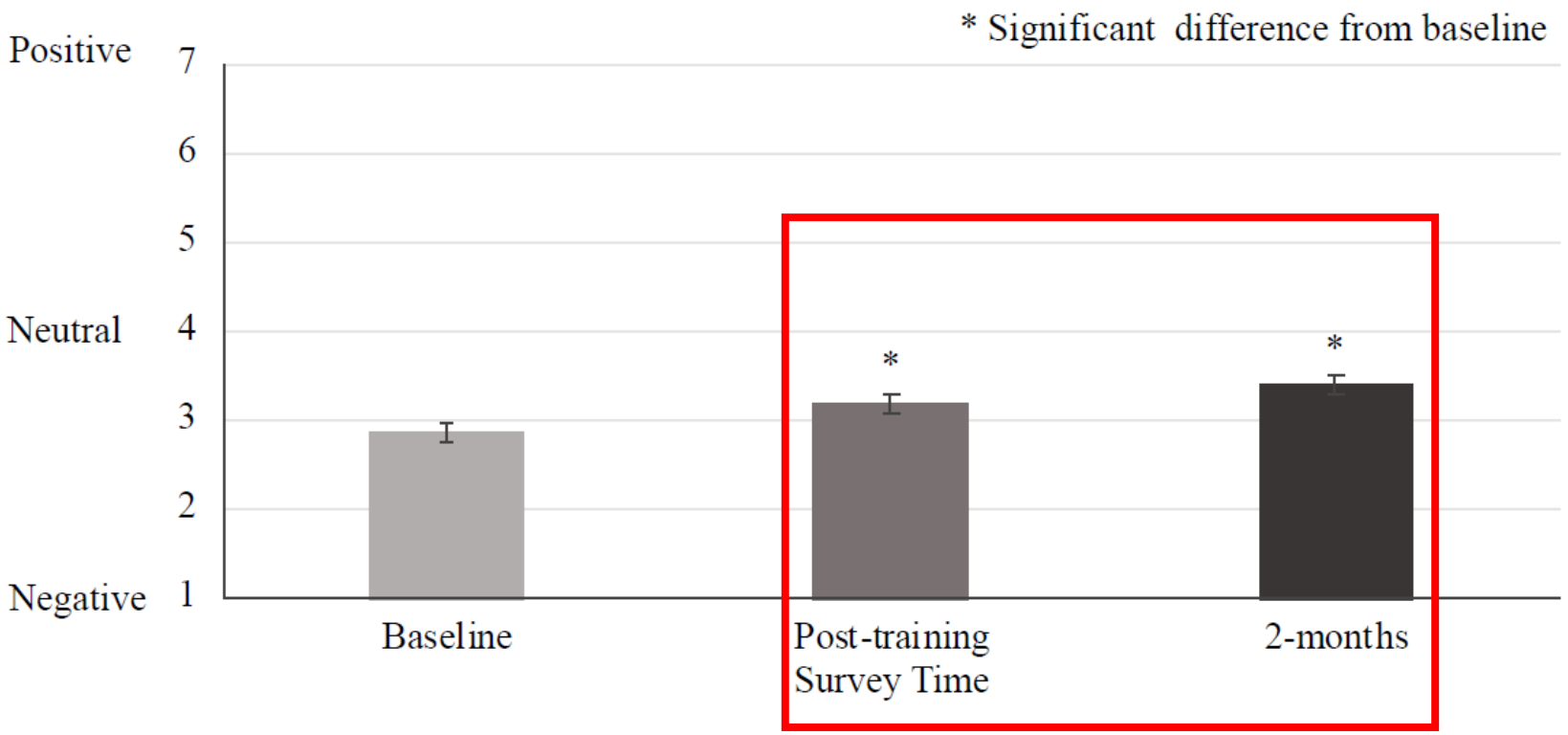

Timepoint: $F_{2,179} = 14.0$; $P < 0.0001$

LaFollette et al, 2020

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LaFollette et al, 2020

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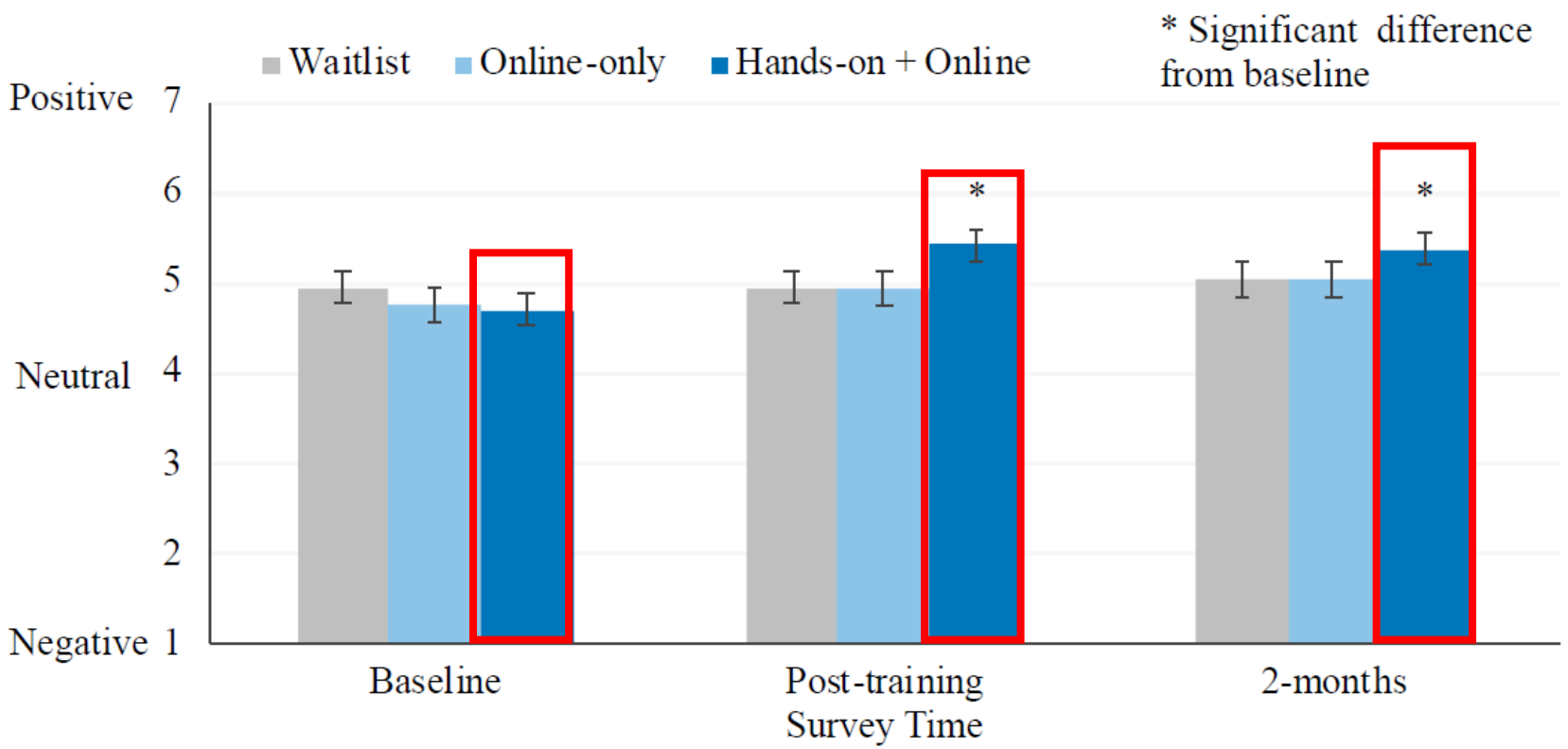
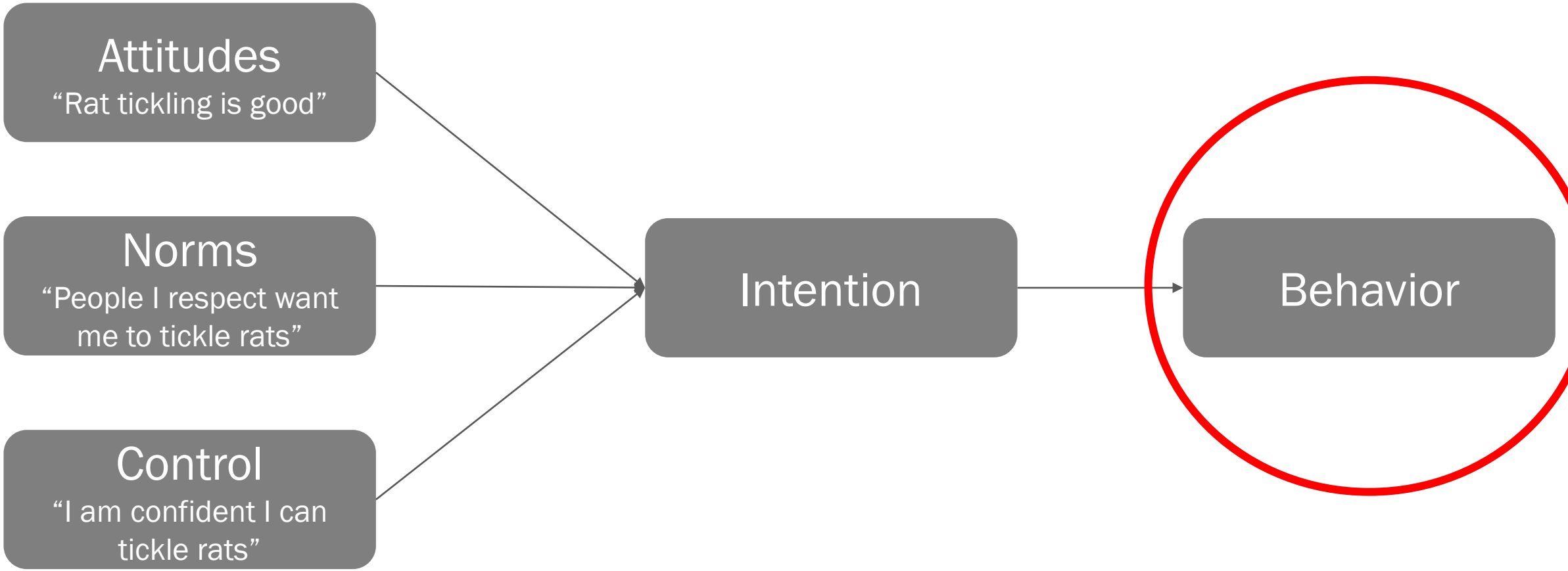


Timepoint*Treatment: $F_{4,178} = 3.5$; $P = 0.009$

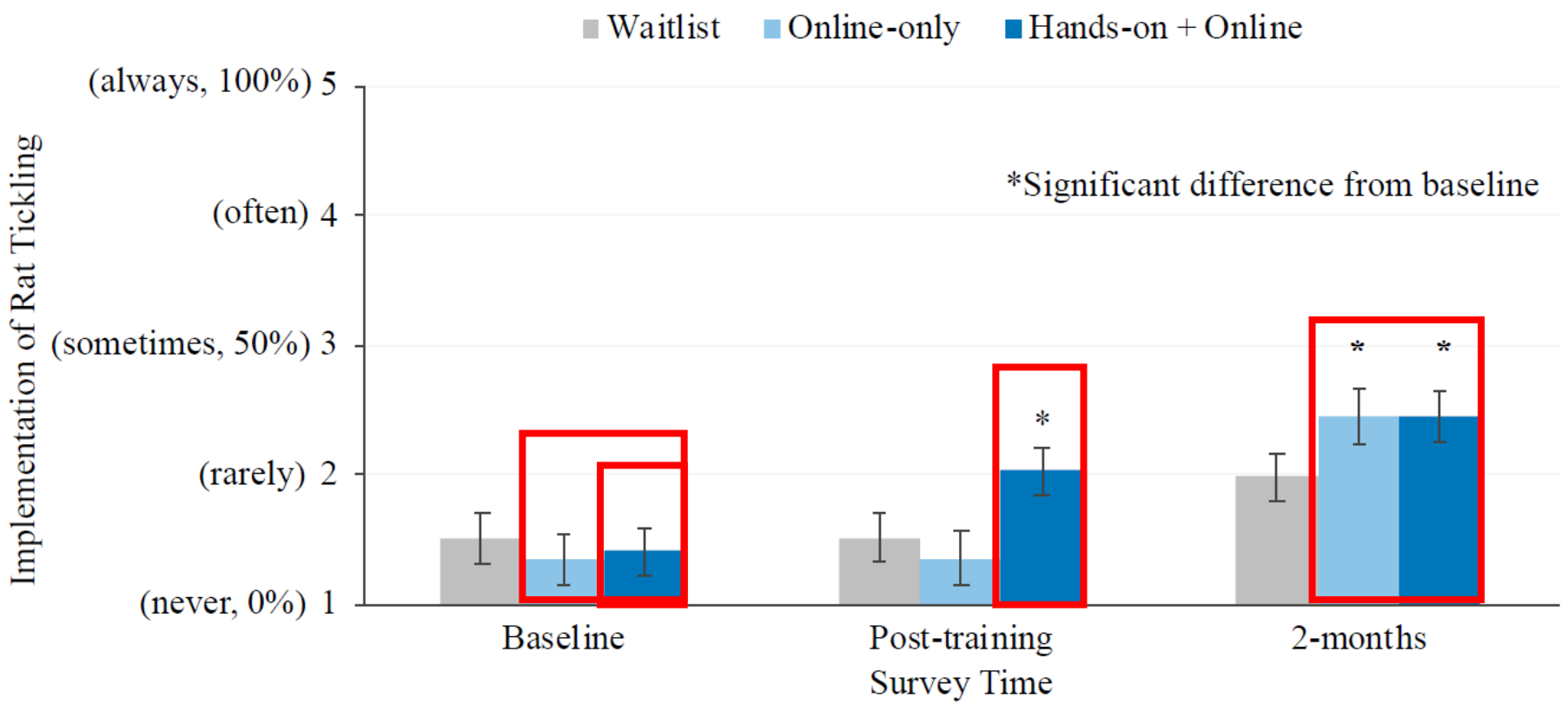
LaFollette et al, 2020

Theory of planned behavior



Ajzen 1991; Hemsworth & Coleman 2011

Training improved implementation

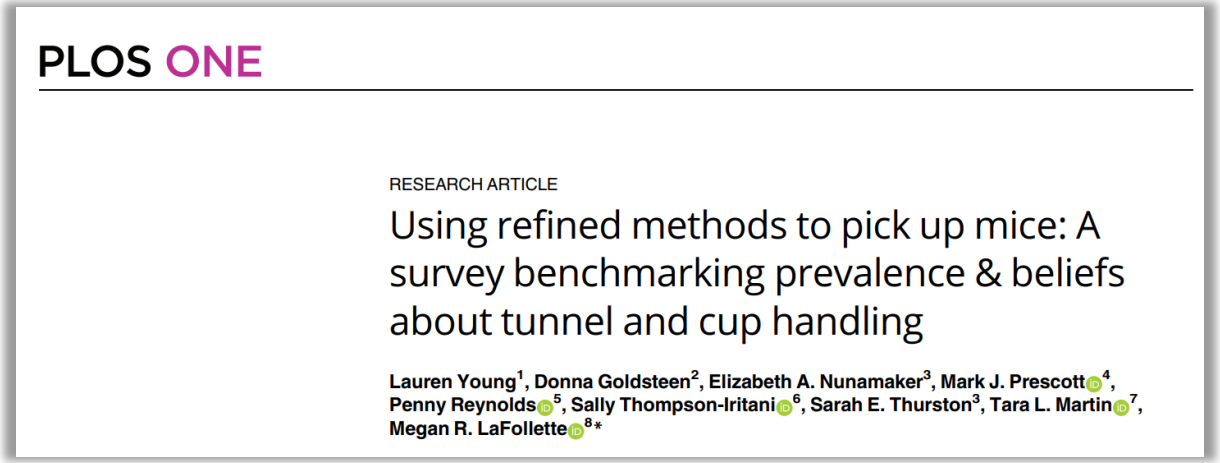


LaFollette et al, 2020

Other applications for welfare change

The 3Rs Collaborative

Refined mouse handling



PLOS ONE

RESEARCH ARTICLE

Using refined methods to pick up mice: A survey benchmarking prevalence & beliefs about tunnel and cup handling

Lauren Young[1], Donna Goldsteen[2], Elizabeth A. Nunamaker[3], Mark J. Prescott[4], Penny Reynolds[5], Sally Thompson-Iritani[6], Sarah E. Thurston[3], Tara L. Martin[7], Megan R. LaFollette[8]*

Environmental health monitoring

Journal of the American Association for Laboratory Animal Science
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Vol 62, No 1
January 2023
Pages 64–73

A Cross-sectional Survey on Rodent Environmental Health Monitoring Practices: Benchmarking, Associations, and Barriers

Kerith R Luchins,[1,‡,*] Kate V Gates,[2,‡] Caroline B Winn,[3] Christopher A Manuel,[4] Christina Pettan-Brewer,[5] Patricia L Foley,[6] Norman C Peterson,[7] Joseph P Garner,[8] Wai Hanson,[9] and Megan R LaFollette[10]

Conclusions

- People are barriers to animal welfare improvements
- A social science framework can be utilized to improve implementation
  - Listen to stakeholders and identify barriers and benefits
  - Scientifically address barriers and provide solutions
  - Provide data and experiences back to end user

Acknowledgements

Megan LaFollette
Sylvie Cloutier
Maggie E. O'Haire
Colleen Brady

PURDUE UNIVERSITY

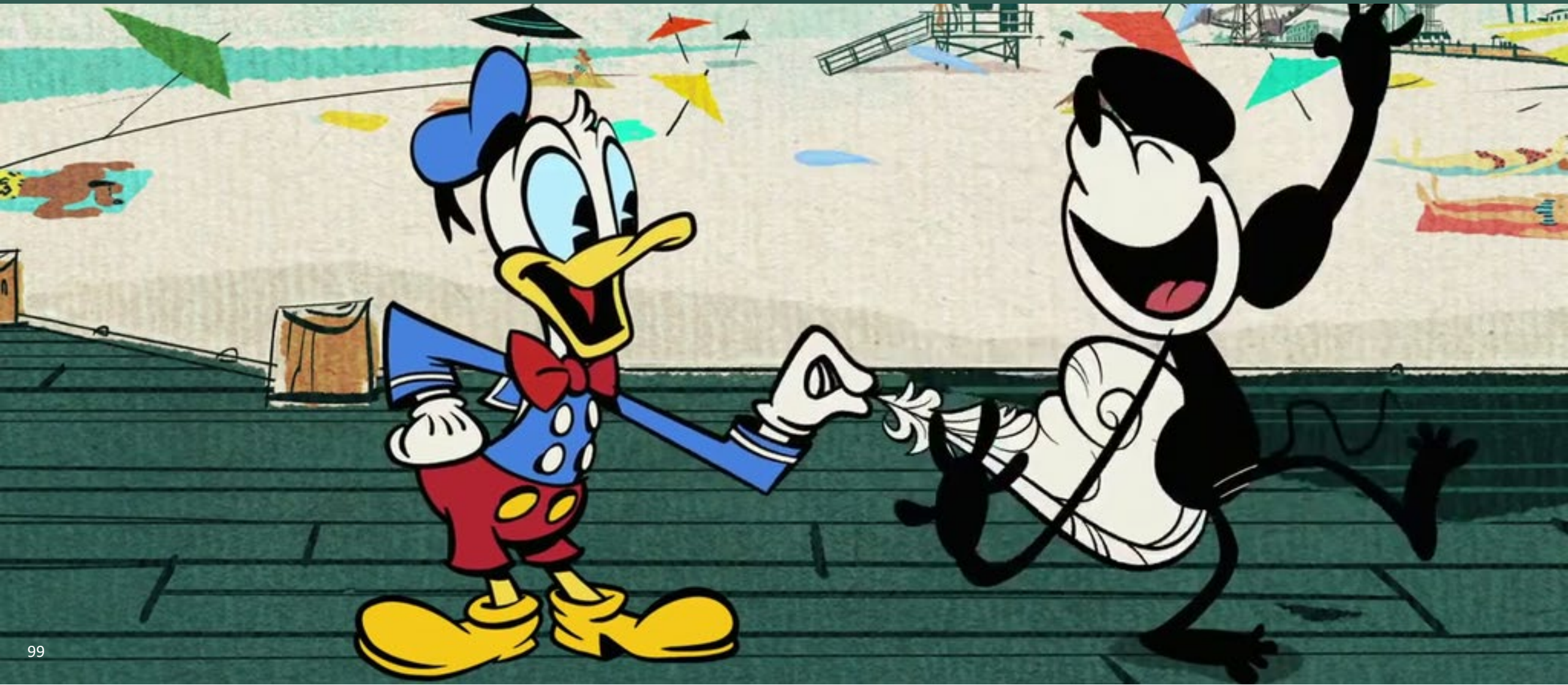
Funders

glas
Grants for Laboratory Animal Science

Animal Welfare Institute

bit.ly/RatTicklingCertificate

Can I tickle other species?



Applying the technique

Control

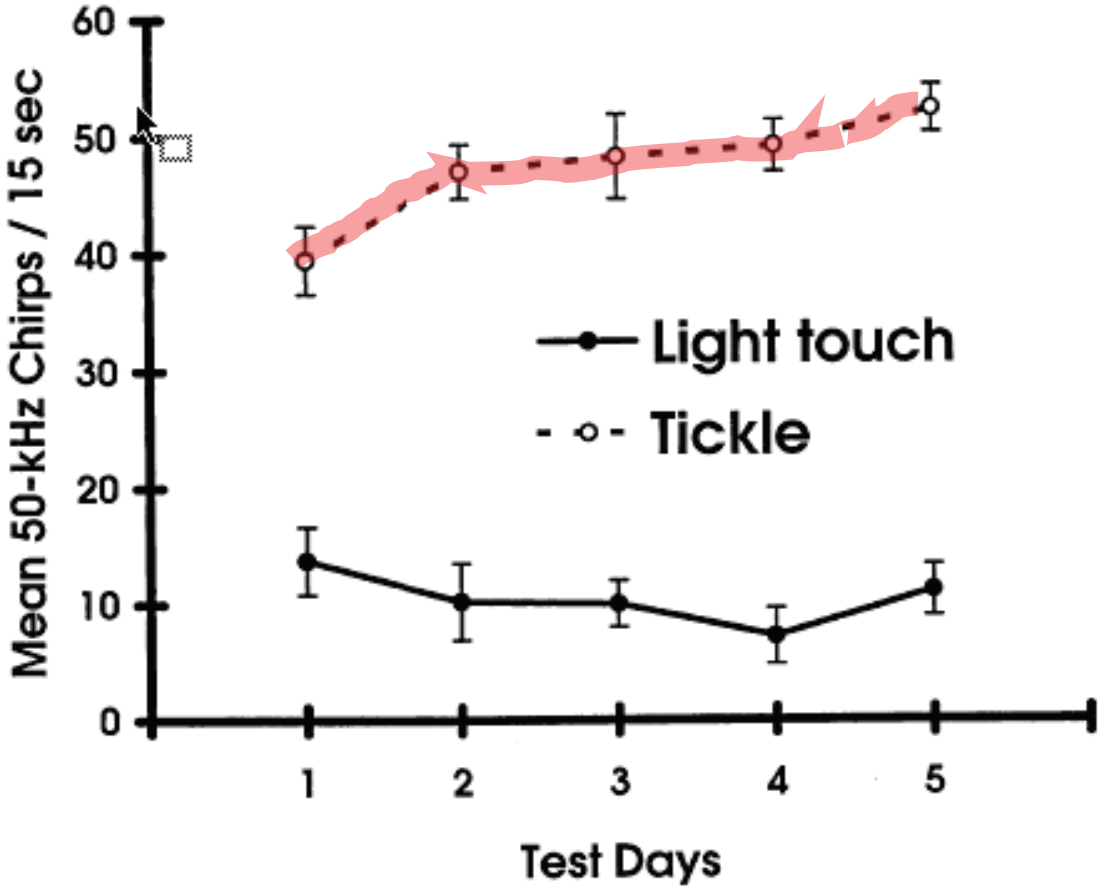
Cloutier 2015

Applying the technique

Tickled

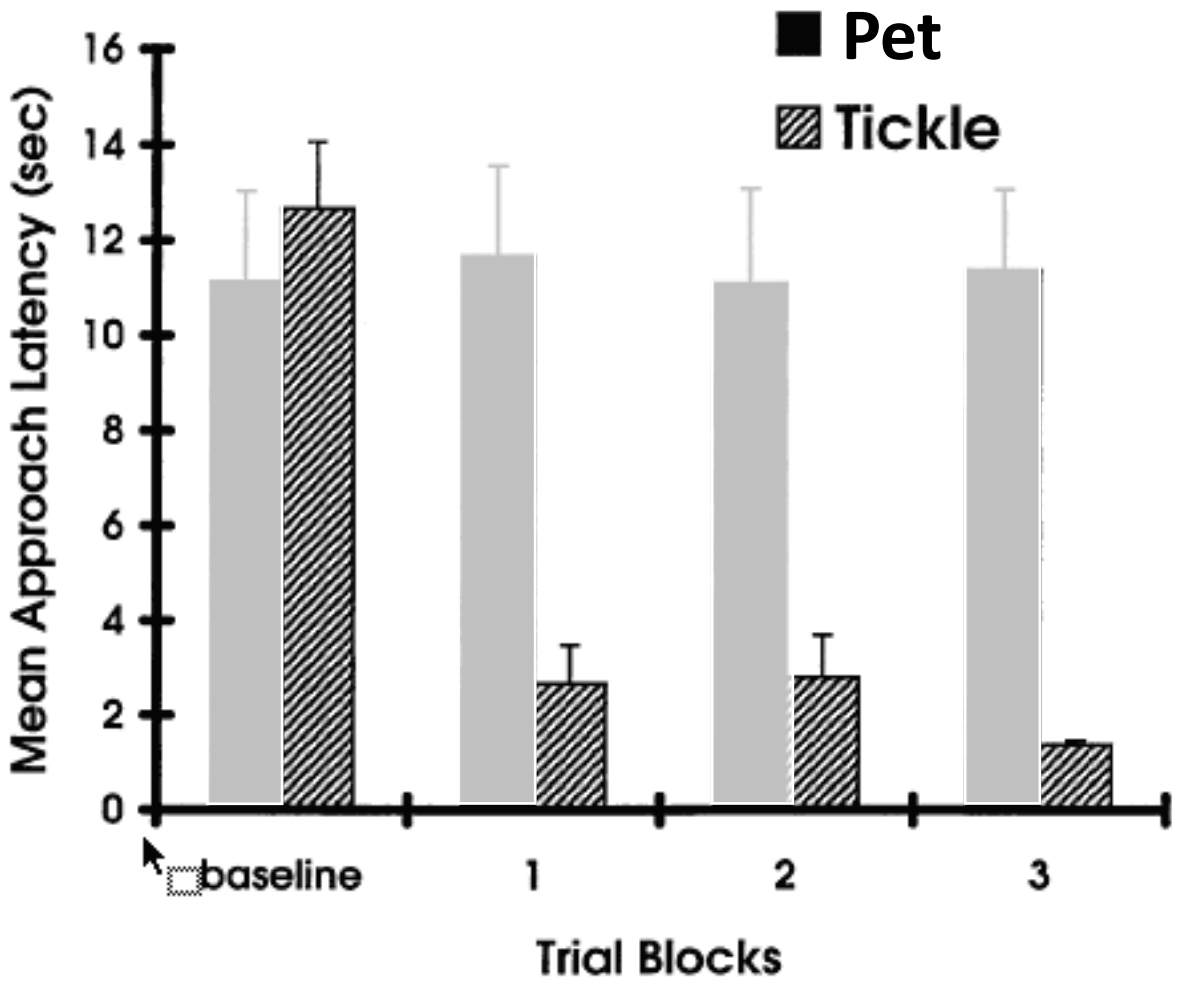
Cloutier 2015

Tickling is better than petting



Burgdorf 2001

Tickling is better than petting



Burgdorf 2001

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Autumn 2024

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