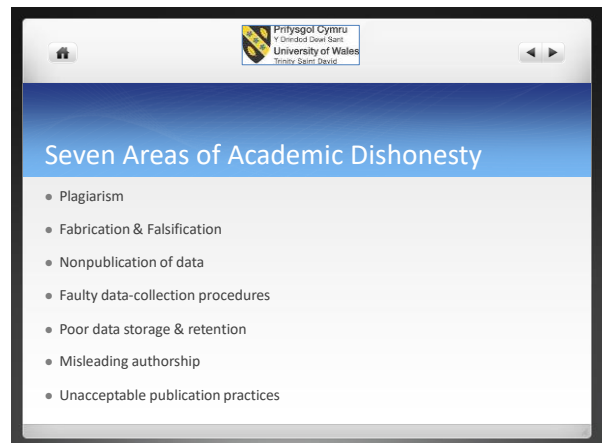
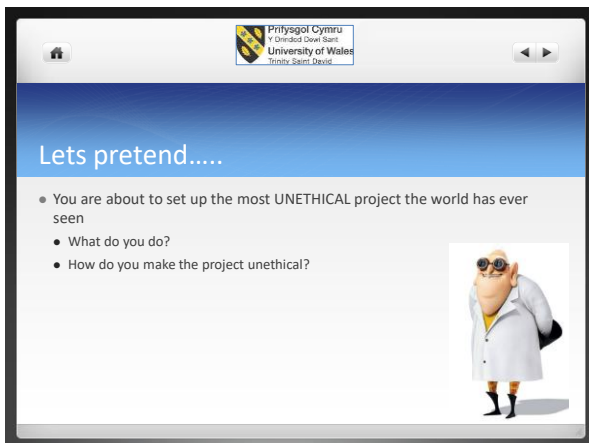
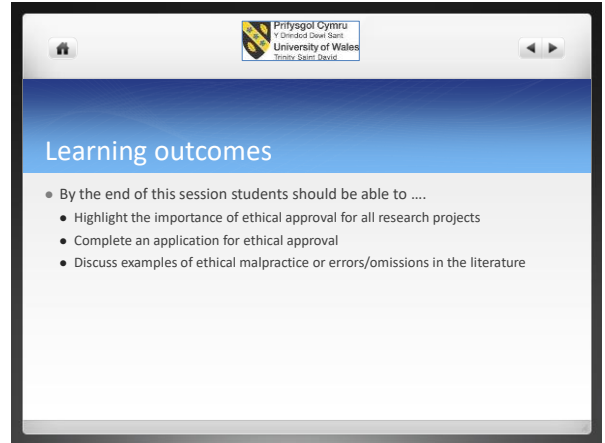






Ethical issues in research

Prior to the study

- Consider the following :
 - Professional body standards
 - University standards
 - Permission from stakeholders
 - Risk assessment of site if testing off-site
 - Negotiate authorship for publication
 - Child protection issues where applicable



Ethical issues in research

At the start of the study

- Consider the following :
 - Identify how the research proposal will benefit the participants
 - Disclose the purpose of the study
 - Be sensitive to the needs of vulnerable participants (e.g. children)
 - Informed consent
 - Informed ascent
 - Parental consent



Participant rights:

- Right to privacy or nonparticipation
- Remain anonymous
- Confidentiality
- Expect experimenter responsibly

Informed consent

- Can only be given if participant has been given ALL the information
 - Participant information sheet
 - Initial that the understand & had the opportunity to ask questions & give consent
- Parent/guardian must also go through this process for U18
- U18 give ascent NOT consent



Ethical issues in research

- During data collection:
 - Respect the site, disrupt as little as possible
 - Ensure each participant has the same testing experience
 - Avoid deceiving participants
 - Make sure participants and stakeholders are aware of risks and take every step to minimise the risk
 - Respect the participants right to withdraw consent AT ANY TIME FOR ANY REASON
 - Do not exploit participants
 - Gather data then leave
 - Consider confidentiality
 - Who has access to data?

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Ethical issues in research

- Data analysis
 - Be objective
 - Do not favour participants
 - Do not DELETE data that is outlying or skewing results
 - Do not FALSIFY data
- Respect the privacy and anonymity of participants
 - Number rather than name participants
 - NEVER PRESENT INDIVIDUAL PARTICIPANT DATA

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Ethical issues in research

- Reporting, sharing and storing data
 - Avoid falsifying authorship, evidence, data, findings and conclusions
 - Do NOT plagiarise
 - Avoid disclosing information that would harm participants
 - Only share data if participants CONSENTED
 - Keep raw data
 - For 7 years post age of 21?
 - Do not duplicate or piecemeal publications
 - State conflict of interest
 - State who OWNS the data from a study

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University Ethics Forms

PG2 E1 Form

- <http://www.uwtsd.ac.uk/media/uwtsd-website/content-assets/documents/academic-office/quality-handbook/PG2-E1-Ethics-Form-v6.docx>

UWTSd Research Ethics website

- <http://www.uwtsd.ac.uk/research/research-ethics/>

Research Integrity and Ethics Codes of Practice Policy

- <http://www.uwtsd.ac.uk/media/uwtsd-website/content-assets/documents/research/research-ethics-integrity-code-practice.pdf>

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Bad Research Practices: Researchers are dishonest!

BAD RESEARCH PRACTICES

John, L. K., Loewenstein, G., & Prelec, D. (2002). Measuring the prevalence of questionable research practices with incentives for truth telling. *Psychological science*, 23(9), 524-532.

63%	Unreported measures In a paper, failing to report all of a study's dependent measures	38%	Data exclusion Deciding whether to exclude data after looking at the impact of doing so on the results
56%	Increasing sample size Deciding whether to collect more data after looking to see whether the results were significant	28%	Unreported conditions In a paper, failing to report all of a study's conditions
46%	Publication bias In a paper, selectively reporting studies that "worked"	27%	HARKING In a paper, reporting an unexpected finding as having been predicted from the start

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Examples of unethical research

2016 President's Dignity of Research

P-1127 - MINIMAL INVASIVE PSYCHOSURGERY TECHNIQUE FOR AUTISM PATIENTS

A.I. Stodolovskiy
Neurology and Neurosurgery, Alexandria Clinic, Moscow, Russia

Introduction: Investigation of cerebral blood flow (CBF) using SPECT for decades revealed hypoperfusion/hypoxemia in different part of the brain in many psychiatric patients, including Autism. Studies were of purely academic interest of the scientists without end user practice.

Objectives: We study and implement neurosurgery 4 patients with autism diagnosis which earlier has been confirmed by psychiatrists. All patients made age 3.5-6 years old. Histories of patients signed agreements with Clinic and gave free will informed consent to the offered cure.

Aims: Create minimal invasive psychosurgery method for treatment Autism.

Methods: Patients (single those with hyperactivity) examined by Transcranial Doppler Ultrasound (TCD) of middle cerebral arteries (MCA) on both sides. In pre-surgery period TCD showed ischaemic disturbances of blood flow velocity and Cerebral Pulse Index (CPI) results and patterns. Method for Treating Brain Ischemia (patent RF 2312618, patent US110931007). Method used not in temporary and absence any manipulation on brain tissue. Treatment consists in introduction of external blood flow due to single-stage sequential ligation of all branches of external cerebral artery for reduction blood flow in internal cerebral artery system.

Results: In post surgery period we seen restoration of TCD values on MCA in both sides with initial dysregulation signs of postoperative hyperperfusion. During 3.6 month and more, till 3.6 years, we seen good positive psychoneurological dynamics, but observed any seriously complication and lethal cases. Complication was followed up 1.5-6.6 years.

Conclusions: We support ichthyosis signs of CBF in Autism is closely related to pathophysiology course and outcome of disease. Neurosurgery of the Brain by our method showed significant improvement of clinical status and regions TCD values 10 tested.

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Examples of unethical research

Walnuts for Weight Loss?

By NICHOLAS BAKALAR AUGUST 18, 2017

A handful of walnuts may be an effective weight loss tool. Walnuts are rich in omega-3 fatty acids and other substances and, in moderation, have been linked to reduced risk of obesity and diabetes. They may also efficiently reduce appetite.

Researchers now may have found out why. They had nine hospitalized obese patients drink, on five consecutive days, either a smoothie containing 48 grams of walnuts (2.7 ounces), or about 14 walnut halves and 315 calories) or a placebo smoothie identical in taste and calorie content. Then, after a month on their regular diet, the patients returned for a second five-day trial, with placebo drinks on the first trial receiving a walnut smoothie, and vice versa.

The participants underwent M.R.I. brain scans while looking at pictures of high-fat food (cake, for example), low-fat food (vegetables) or neutral pictures of rocks and trees. The study, published in *Diabetes, Obesity and Metabolism*, found that when people looked at pictures of high-fat food, activation in the basala, a part of the brain involved in appetite and impulse control, increased among those who drank the walnut smoothie, but not among placebo drinkers. The study was funded in part by the California Walnut Commission.

"Walnuts can alter the way our brains view food and impact our appetite," said the lead author, Olivia K. Park, of Beth Israel Deaconess Medical Center in Boston. "Our results reinforce the current recommendations to include walnuts as part of a healthy diet."

Abstract

Aims: The use of walnuts is recommended for obesity and type 2 diabetes, although the mechanisms through which walnuts may improve appetite control and/or glycaemic control remain largely unknown.

Materials and Methods: To determine whether short-term walnut consumption could alter the neural control of appetite using functional magnetic resonance imaging, we performed a randomized, placebo-controlled, double-blind, cross-over trial of 10 patients who received, while living in the controlled environment of a clinical research center, either walnuts or placebo (using a validated smoothie delivery system) for 5 days each, separated by a wash-out period of 1 month.

Results: Walnut consumption decreased feelings of hunger and appetite, assessed using visual analog scales, and increased activation of the right insula to highly desirable food cues.

Conclusions: These findings suggest that walnut consumption may increase salience and cognitive control processing of highly desirable food cues, leading to the beneficial metabolic effects observed.

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Examples of unethical research

Ohio CrossFit Article

The Journal of Strength and Conditioning Research has retracted the article entitled "CrossFit-based High Intensity Power Training Improves Maximal Aerobic Fitness and Body Composition" by Smith, MM, Sommer, AJ, Starckoff, BE, and Dvorc, ST, published in the November 2013 issue of the Journal of Strength and Conditioning Research (Vol. 27, pp. 3159-3172). The Journal of Strength and Conditioning Research was advised on May 4, 2017 by one of the authors that the study was not conducted under an IRB approved protocol for that study, as was stated in the article. **Because the study was performed without proper IRB approval, the article has been retracted.**

A federal judge ruled in September of 2016 that the injury data reported by the authors in the article was false.

Judge Sammartino noted that the NSCA had "commercial motivation" to make the false statement about study participant injuries in the Ohio State study and that it had made that statement "with the intention of disparaging CrossFit and thereby driving consumers to the NSCA."

The retractions issued today by the NSCA is the very same relief that Mr. Potter and Ohio Fit Club sought long before even filing suit over the article. We are gratified that, albeit years later, the NSCA has finally acknowledged what has been the truth all along - that some of the study participants were injured at Mr. Potter's gym, nor did they drop out of the study as a result of injury or overuse caused by Mr. Potter or Ohio Fit Club.

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Examples of unethical research

- A judge said the two sports science students probably only survived because they were fit and active young men
- The pair had volunteered to take part in a test aiming to measure the effect of caffeine on exercise, but a basic calculation error meant the second-year students were given 100 times the correct dosage.
- The pair should have been given 0.3g of caffeine in the orange juice mix, but were in fact given 30g.
- There is 0.1g in the average cup of coffee
- Newcastle Crown Court heard the calculation had been done on a mobile phone, the decimal point being put in the wrong place and there being no risk assessment for the test.
- Death has previously been reported after consumption of just 18g and the students were left in a "life-threatening condition".
- Student 1 was kept in hospital for six days, reported short-term memory loss and lost 26.5lb (12kg) in weight.
- Student 2 was treated for two days in intensive care and lost 22lb (10kg) in weight.

The Telegraph News

Students left fighting for lives after taking enough caffeine for 3000 cups of coffee in bottled university experiment

Northumbria University

