Ethics, Society and Responsible Science Communication

SPICE 2024

Neuroscience & Computational Psychiatry Module

Class IX

12th of July 2024

Mount Sinai

Center for Computational Psychiatry

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Research ethics

- **Definition**: Research ethics involves the applicati
of fundamental ethical principles to scientific resea
- **Importance**: Ensures the protection of participant
integrity of research, and credibility of findings.

Image: VectorStock

Research ethics highlights

Nuremberg Code (1948) “The voluntary informed consent of the human subject is absolutely essential.”

Tuskegee Syphilis Study (1932-72)

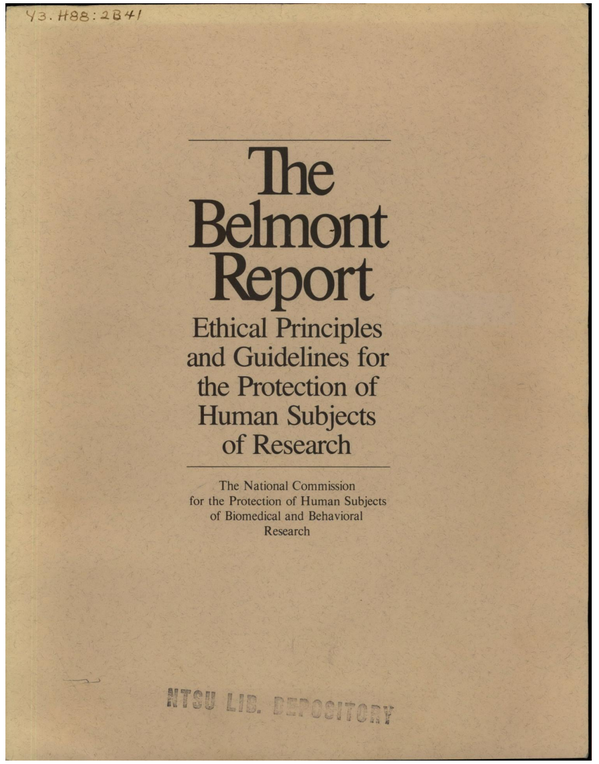
Declaration of Helsinki (1964) “This protocol should be submitted…to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence.”

National Research Act (1974)

Source: Berkeley University of California

Research ethics highlights: the Belmont Report

- The Belmont Report identifies the ethical principles upon which the federal regulations for human subject protections are based.
  - **Respect for persons**
  - **Beneficence**
  - **Justice**
- Reading this short document is highly recommended; see “Additional Resources” (final slide).



Source: Berkeley University of California

Research ethics highlights: the Belmont Report - Respect for Persons

- The autonomy of the individual must be acknowledged and respected.
  - Informed consent
  - Voluntariness – ability to decide to participate in research *and* to withdraw at any time, without coercion or undue influence from others.
- Individuals with limited autonomy must receive additional protections. The limits
  - May be inherent (e.g., limited capacity to understand and process information).
  - May be situational (e.g., prisoners, children, and pregnant women and fetus/neonates)

Source: Berkeley University of California

Research ethics highlights: the Belmont Report – Beneficence, Justice

Beneficence

- Benefits may be
  - To individual subjects; and/or
  - To others (e.g., to basic research, to a community, or to society as a whole).

Justice

- Treat individuals fairly.
- Design research such that its burdens and benefits are shared equitably.

Source: Berkeley University of California

Informed Consent

- Informed Consent (IC) is often misinterpreted as merely obtaining an individual's signature on a form (or a "yes" response in a verbal consent process).
- IC is a process of education and decision-making that begins with the very first contact with a potential study subject (i.e., during recruitment).

Recruiting

- Study staff who recruit subjects should keep in mind that this step is also part of the IC process.
- Regulations permit initial discussions about the study to occur in a group setting or one-on-one. A setting can be selected for reasons that are practical or based on cultural considerations.

Study Process

- For those individuals who decide to participate, the IC process continues throughout the study.
- It is entirely up to them whether they participate or not.
- They have to make an informed decision and be able to.
- They are free to skip parts of the experiment or stop participating in the study at any time without having to share their reason(s) for doing so.

Privacy and Confidentiality

These terms are sometimes confused.

- ***Privacy*** pertains to control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

- ***Confidentiality*** pertains to the treatment of information that an individual discloses in a relationship of trust. It involves the expectation that information will not be divulged to others- without permission- in ways that are inconsistent with the understanding of the original disclosure.

Institutional Review Board (IRB)

- **Definition**: An IRB is a committee that reviews and monitors research involving human participants to ensure ethical standards.
- **Purpose**: Protect the rights and welfare of human research participants.

Composition of the IRB

- **Diverse Membership**: Composed of scientists, non-scientists, and community members to provide varied perspectives.
- **Qualifications**: Members should have the expertise to evaluate specific aspects of the research and ensure ethical standards are met.

IRB Responsibilities

- **Review Research Proposals**: Evaluate study design, informed consent process, and risk-benefit ratio.
- **Monitor Compliance**: Ensure ongoing adherence to ethical standards and regulations throughout the research.
- **Continuing Review**: Regularly review ongoing studies, typically at least annually, to ensure continued protection of participants.

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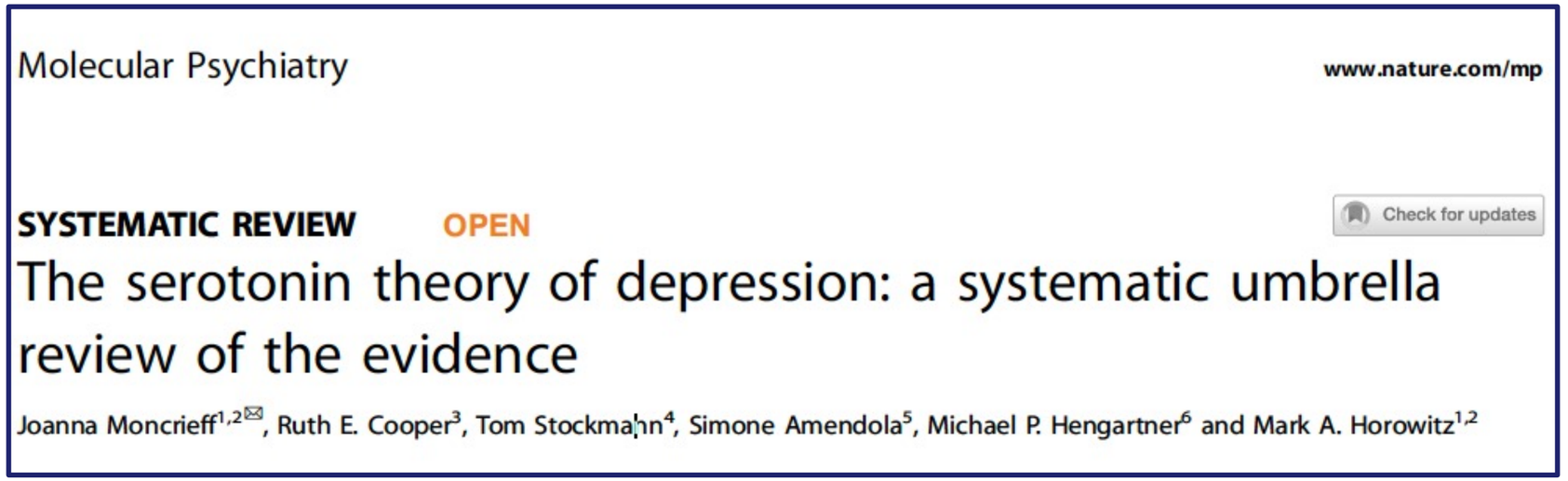
Paper discussion



Molecular Psychiatry www.nature.com/mp

SYSTEMATIC REVIEW OPEN

Check for updates

The serotonin theory of depression: a systematic umbrella review of the evidence

Joanna Moncrieff[1,2✉], Ruth E. Cooper[3], Tom Stockmann[4], Simone Amendola[5], Michael P. Hengartner[6] and Mark A. Horowitz[1,2]

1. **What are the main research questions and how are they motivated?**
2. **What are the main methods?**
3. **What are the main findings?**
4. **What do these findings mean?**

Paper discussion

Research Question and Motivation

1. Is depression associated with low serotonin concentration or activity?

- Motivated by the longstanding serotonin hypothesis influencing antidepressant prescriptions.

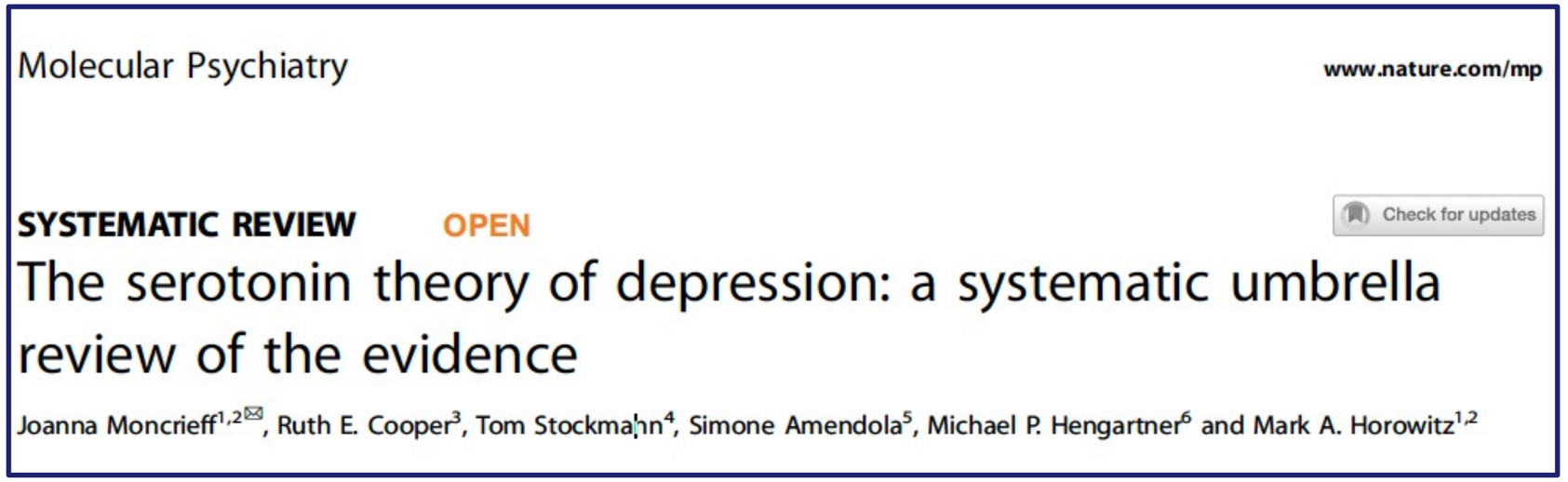
Methods

- Systematic Umbrella Review: Synthesized findings from existing systematic reviews and meta-analyses.
- Search Strategy: Searched PubMed, EMBASE, and PsycINFO for relevant studies.
- Quality Assessment: Used AMSTAR-2 and STREGA tools.

Main Findings

- No consistent evidence linking serotonin levels to depression.
- Inconsistent results from serotonin receptor and transporter studies.
- Genetic studies show no association with depression.

Paper discussion



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Criticism? What could have been improved?

How do you think this was perceived by the public?

Paper discussion – media coverage

Little evidence that chemical imbalance causes depression, UCL scientists find

Researchers question use of antidepressants, prescribed to one in six UK adults

The antidepressant drug Prozac. 'There is no convincing evidence that depression is caused by serotonin abnormalities,' the researchers said. Photograph: Christian Hopewell/Alamy

The Guardian

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'I ended up staying depressed for a decade longer than I needed to': Prozac users shocked by new study

By Jeanette Settembre

Published July 28, 2022 | Updated July 29, 2022, 5:46 p.m. ET

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Science

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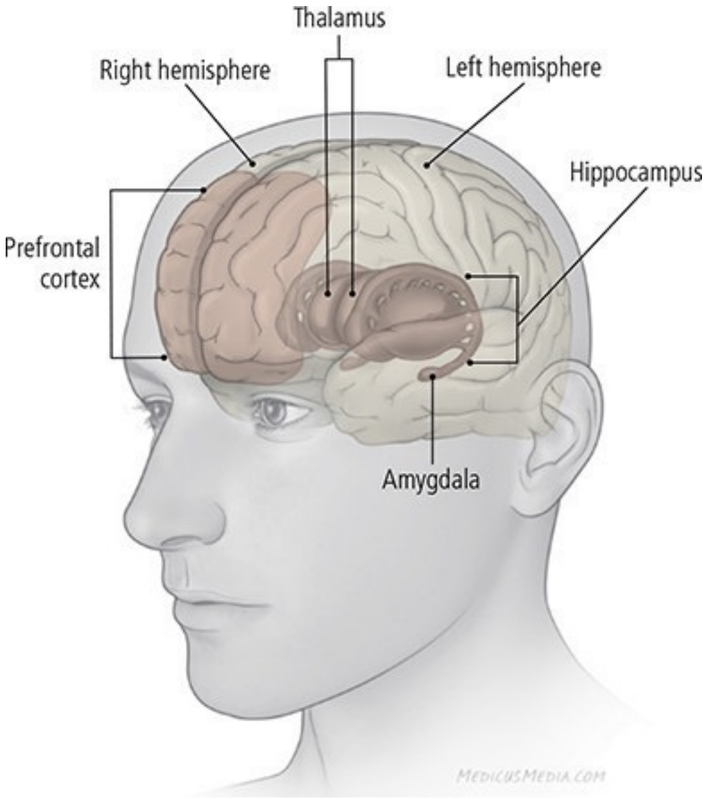
New study: low serotonin does not cause depression

Psychiatrists recall that clinical trials show the efficacy of antidepressants and that they are a useful complement to treatments such as psychotherapy

Paper discussion

- Treatment is often trial and error
- 42-53% response rate for antidepressants
- All antidepressants were more efficacious than placebo in adults with major depressive disorder.



Study claims to find first direct evidence of a link between low serotonin and depression

Exclusive: Results add to debate over decreased serotonin response and depression

Arroll et al., 2009; Taliaz et al., 2021

Images: Guardian; Health.Harvard.edu

Science Communication

Integrity and Honesty:

- Scientists must ensure that their research and findings are reported truthfully and accurately. Misleading information can have significant negative impacts on public health and policy.

Public Engagement:

- Scientists have a duty to communicate their findings in a way that is accessible and understandable to the general public.
- Researchers often cannot control media coverage and studies might be misrepresented!

Accountability:

- Scientists must be accountable for their work, including acknowledging errors and rectifying them. Transparency in methods and data is crucial for maintaining credibility and public trust.

Science Communication

Impact on Public Health & Science Itself:

- Accurate and responsible communication of scientific findings can improve public health outcomes.
- Communication with the public can inform research questions and ideas and make it more relevant.

Policy and Regulation:

- Policymakers rely on scientific evidence to create regulations and laws. Misinformation or poorly communicated research can lead to ineffective or harmful policies.

Trust in Science:

- Maintaining public trust is essential for the continued support and funding of scientific research. Trust is built through transparency, honesty, and effective communication.

Thank you!

Any Questions?

Thank you and good luck with your research projects!

Any Questions?

Social: Today 12-2pm