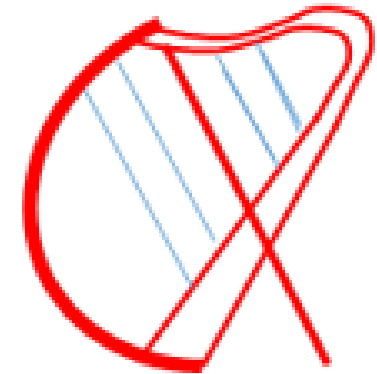


Randomised Control Trials



Osian Llwyd
Oxford University Hospitals
University of Oxford



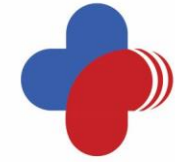
OxHARP study

Oxford haemodynamic adaptation to reduce pulsatility trial

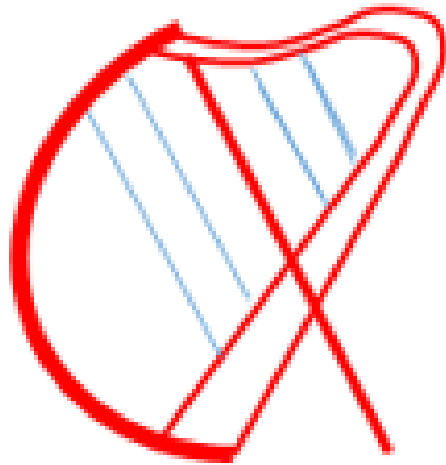
- Why you chose that methodology?
- Why it was a suitable study design for your project?
- The advantages and disadvantages to your study method

Randomised Control Trials

OxHARP study






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GREAT BRITAIN AND IRELAND



Study protocol

Design of a randomised, double-blind, crossover, placebo-controlled trial of effects of sildenafil on cerebrovascular function in small vessel disease: Oxford haemodynamic adaptation to reduce pulsatility trial (OxHARP)

Alastair Webb¹ , David Werring², Jesse Dawson³ ,
Alex Rothman⁴, Amy Lawson¹  and Karolina Wartolowska¹

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Why you chose that methodology?

- Affects over 50% of people over the age of 65 and the vast majority of people by the age of 80.

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- The number of people in the UK with dementia will increase from 1 million in 2025 to 2 million by 2050.

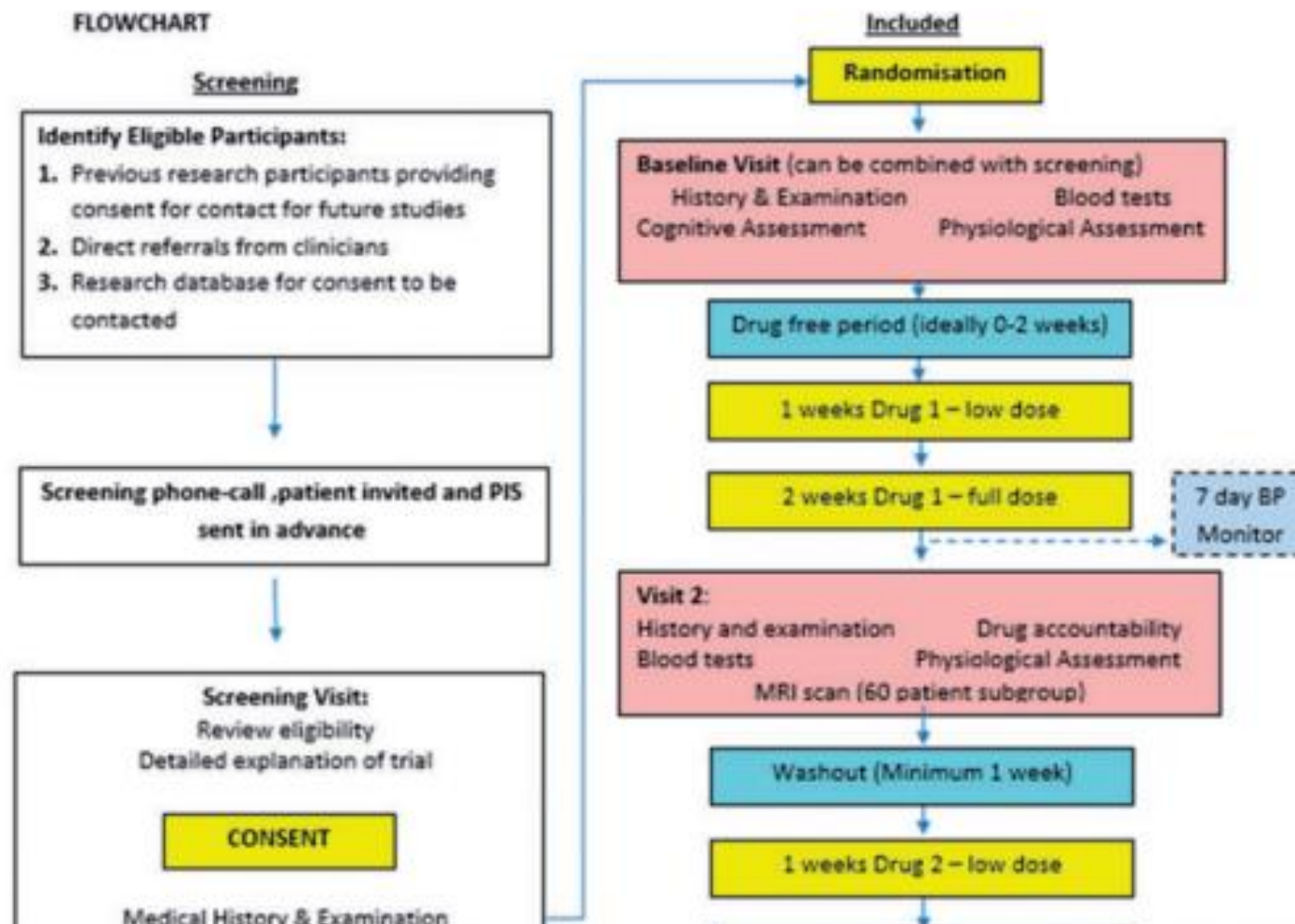
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- Associated with impaired control of cerebral blood flow.
- The number of people in the UK with dementia will increase from 1 million in 2025 to 2 million by 2050.
- Greater pulsations in blood pressure are transmitted to the brain through stiff blood vessels, resulting in increased pressure hitting the brain each time the heart beats and reduced blood flow between heart beats.

Why you chose that methodology?

Webb et al.

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Why you chose that methodology?

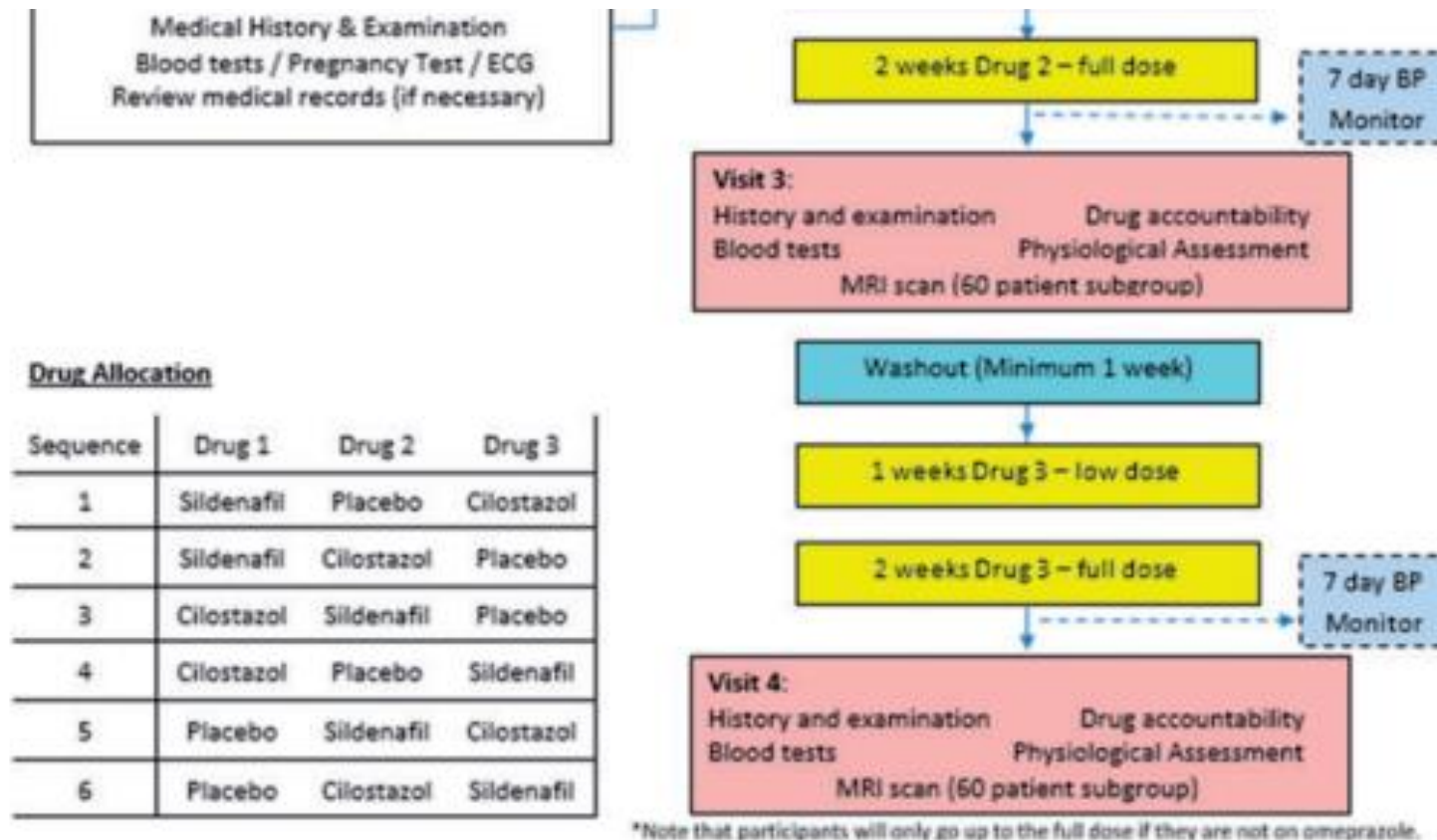


Figure 1. Flowchart of each patient's progress through the study.

Why you chose that methodology?

- Randomised
- Double-blind
- Crossover
- Placebo controlled trial

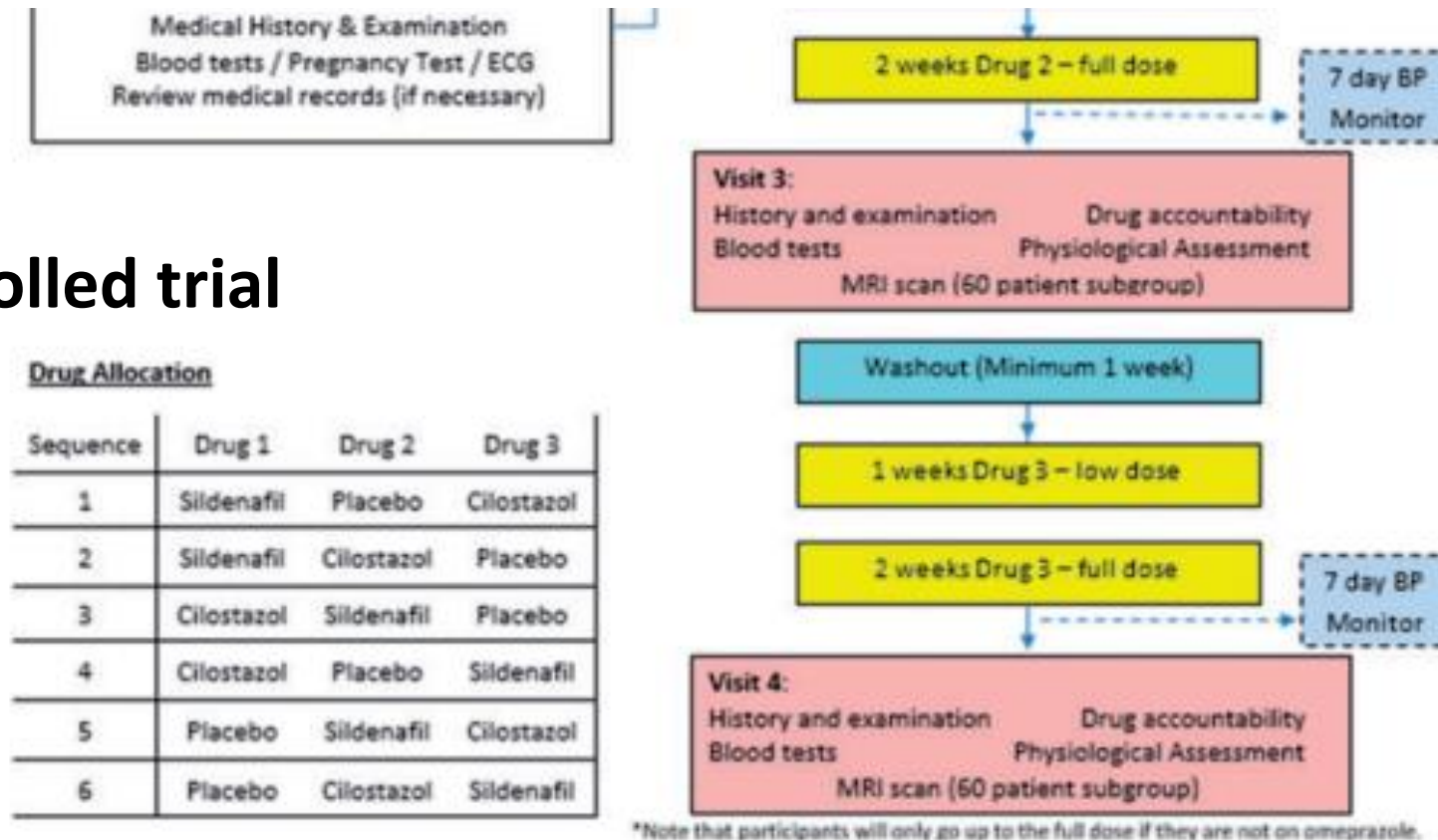
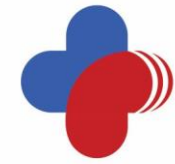


Figure 1. Flowchart of each patient's progress through the study.



Book of the day Science and nature books

Review

The Expectation Effect by David Robson review – mind-changing science

From exercise to old age, the latest research shows that what we believe can have some very concrete consequences


RADIO 4

Placebo

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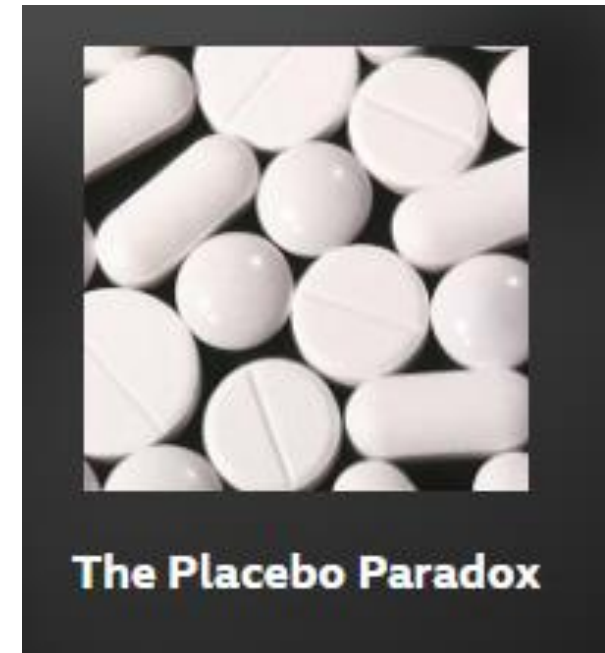
Episode 2

2/2 Ben asks if modern medicine is making the most of this strange phenomenon.

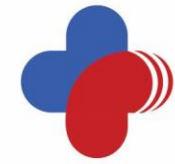


Episode 1

1/2 Our beliefs and expectations about medical treatments can have an impact on our health.



- <https://www.theguardian.com/books/2022/jan/06/the-expectation-effect-by-david-robson-review-mind-changing-science>
- <https://www.bbc.co.uk/sounds/play/m0002ngc>
- <https://www.bbc.co.uk/programmes/b00d1fv7/episodes/player>



Why it was a suitable study design?

- **Randomised** Control Trials removes the potential of bias
 - **Comparable groups** allow the statistical tests to have a valid significance level
 - **Comparable groups** should have similar characteristics and equally divided
- All participants were equally assigned to the intervention and **two types of controls**, a placebo and a drug comparator (Cilostazol)
- **Cross-over design** allowed each participant to serve as own control as they received intervention or control in the first period, then alternated for second and third period
- **Blindness** – participant and investigators blinded to assigned intervention.
 - = **Statistical Validity** - important covariates are balanced



The advantages and disadvantages to your study method

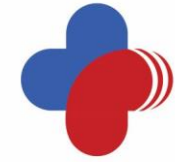
Advantages

- Study Design, all participants treated identically, $n = 75$

Disadvantages

- 3 weeks treatment time, 1-2 participants recruited per week
- $n < 100$, 80% male
- External Validity – To whom does the results apply to?

THE LANCET



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Volume 365, Issue 9453, 1 January 2005, Pages 82-93

Series

External validity of randomised controlled trials: “To whom do the results of this trial apply?”

Peter M Rothwell FRCP^a 

[External validity of randomised controlled trials: “To whom do the results of this trial apply?” - ScienceDirect](#)



Übersichten

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Randomized controlled trials: still the backbone of vascular surgery?

*All great men are gifted with intuition.
They know without reasoning or
analysis what they need to know*

Alexis Carrel (1873–1944)

the worst possible natural history studies for comparison and (iii) did not include strokes following angiography” when justifying a role for CEA. It would be fair to say that many surgeons (of that era) disagreed with his opinion and were high-

What is evidence-based medicine?

The ultimate goal of EBM is the delivery of optimal clinical care to patients, based upon the following tenets: (i) the accumu-

[772 2015 Article 100.pdf \(nih.gov\)](#)