

# Writing strong proposals

*Ngaira Kerse PhD, FRNZCGP*

## Gone with the NHMRC

The greatest  
screen entertainment  
of all time!

Frankly my dear I  
don't give a damn

But what will  
happen to my  
proposal

CLARK GABLE • VIVIEN LEIGH • LESLIE HOWARD • OLIVIA DEHAVILLAND

A SELZNICK INTERNATIONAL PICTURE • VICTOR FLAming

FOUR STAR METRO GOLDWYN MAYER METROCOLOR

REGISTERED TRADEMARK OF THE GENERAL ELECTRIC COMPANY

# Aiming for success

- Read the instructions
- Address the review criteria
- Organisation
  - Start early
- Clarity
- Preparedness
  - Quotes, consultation, support letters
- Pilot study
- Peer review



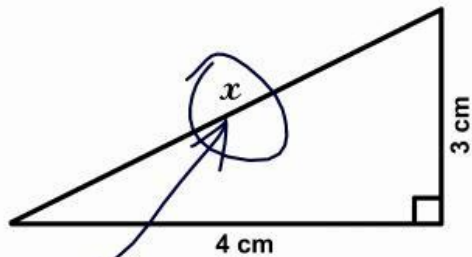
# Problems with proposals (NIH)

- **Lack of new or original ideas**
- **Absence of an acceptable scientific rationale**
- **Lack of experience in the essential methodology**
- **Questionable reasoning in experimental approach**
- **Uncritical approach**
- **Diffuse, superficial, or unfocused research plan**
- **Lack of sufficient experimental detail**
- **Lack of knowledge of published relevant work**
- **Unrealistically large amount of work**
- **Uncertainty concerning future directions**

# Outline

- Summary page
- Rationale
- Methods
- Health significance

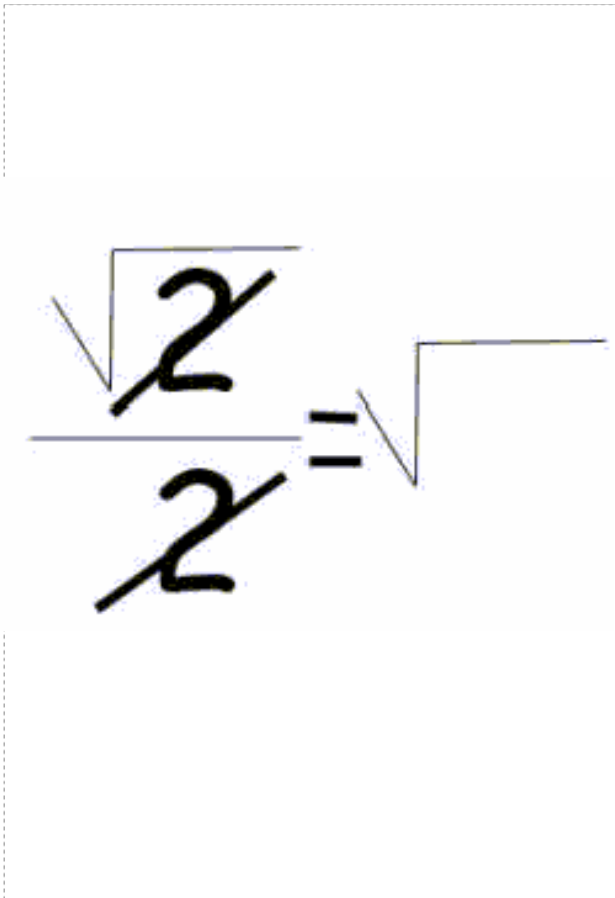
3. Find  $x$ .



*Here it is*

Ocular Trauma - by Wade Clarke ©2005

# Summary



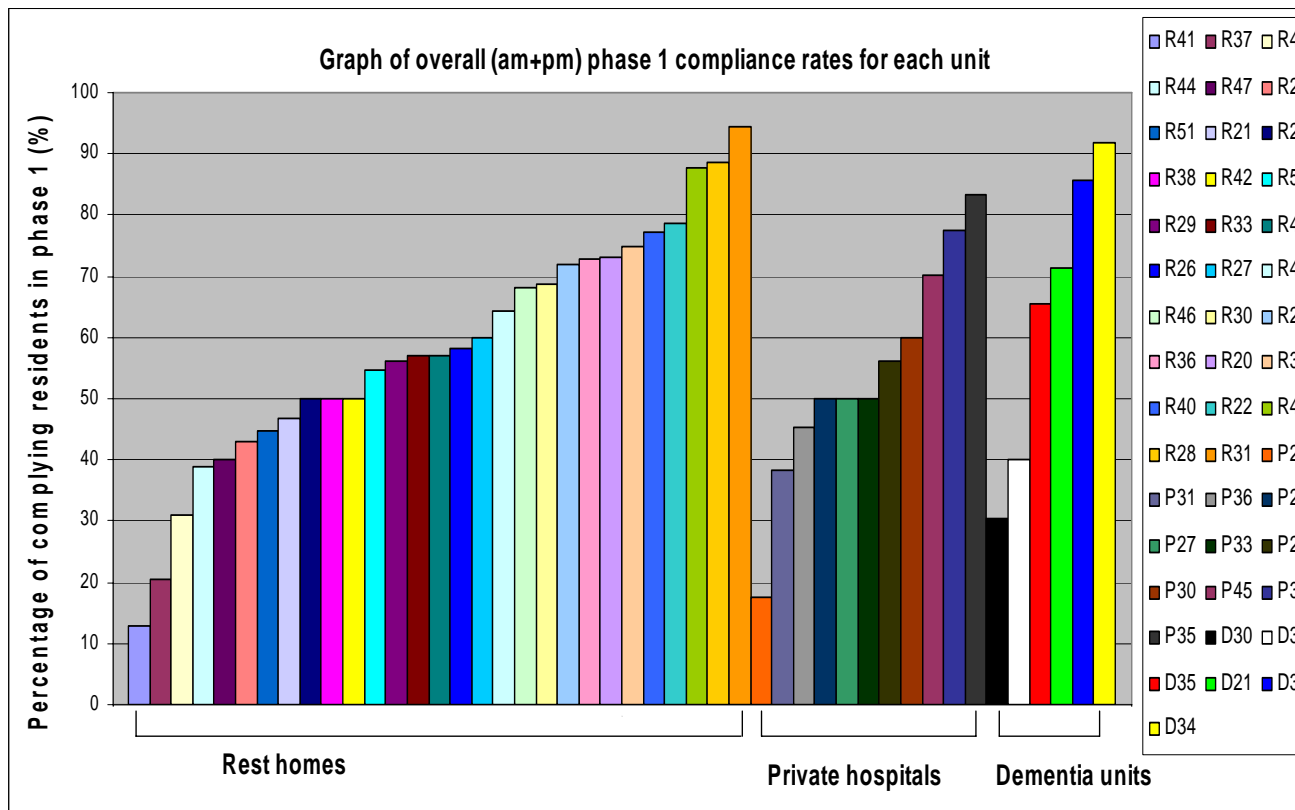
The image shows a handwritten mathematical equation enclosed in a dashed rectangular box. The equation is  $\frac{\sqrt{2}}{2} = \frac{1}{\sqrt{2}}$ . The numbers and symbols are written in a cursive, handwritten style. The fraction on the left has a square root symbol over a '2', and the denominator is another '2'. An equals sign follows, and the fraction on the right has a '1' in the numerator and a square root symbol over a '2' in the denominator.

- Most important
- Clarity
- Language
- Correct

# Rationale/background

- Justify the need
- Point out the potential impact
- Relate to national strategies
- Work towards your specific study
- Identify the gap
- Show your grasp on the literature
- Justify your population
- Justify your method and outcomes
- Show you have experience in them
- Report your pilot study
- How will this study make a difference
  - to what and for whom

# Rationale - use tables and graphs



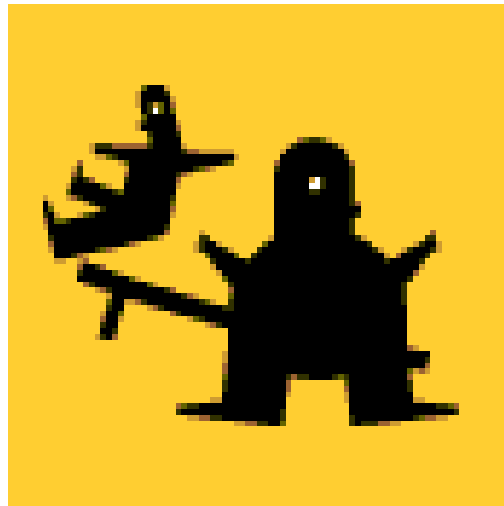
# Aim

- Succinct
- Clear
- Achievable



# Methods

- Match the aim
- Population
- Sampling
- Measures/  
outcomes
- Analysis



# Population

- Who is of interest
- How will you access them
- Have you been able to do this successfully before



# Measures/ outcomes



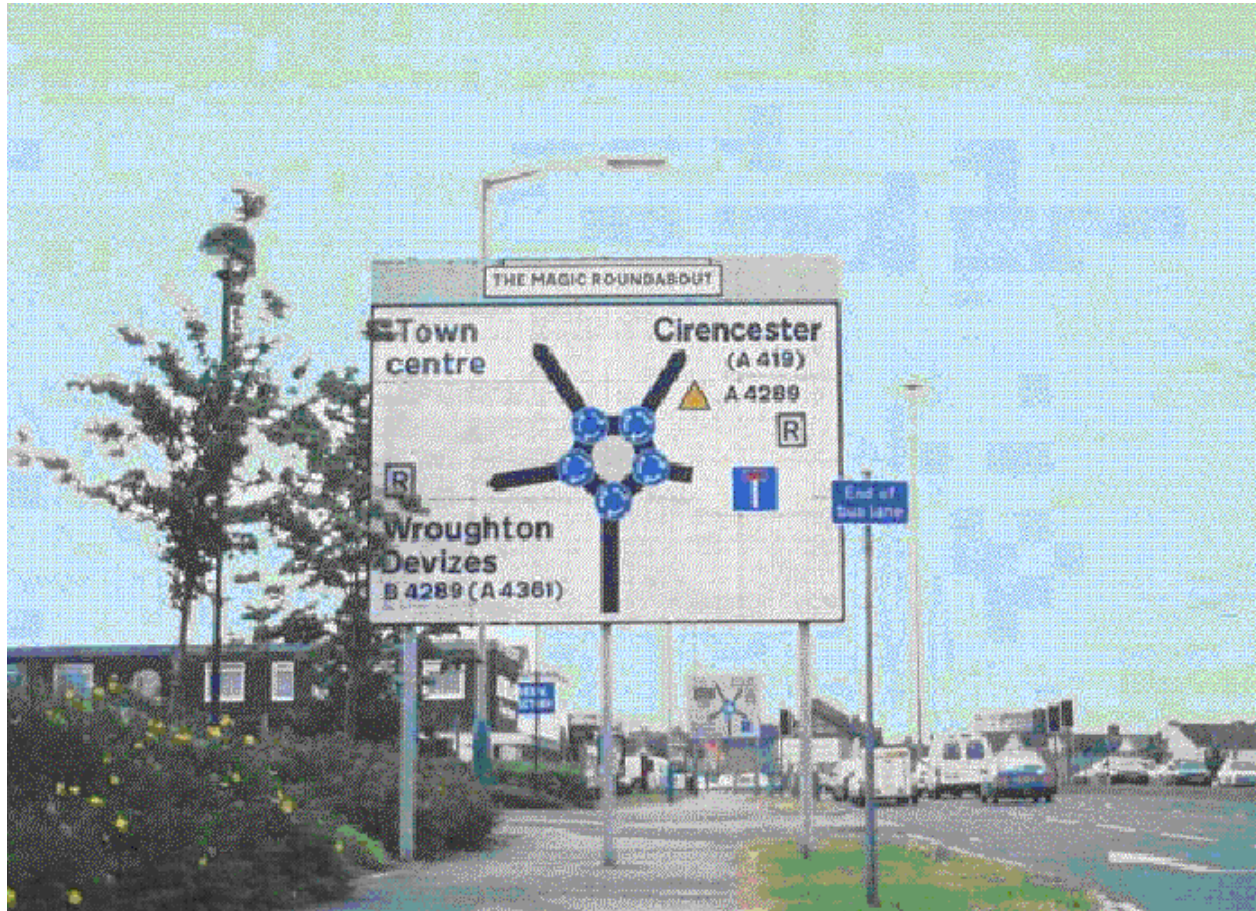
- What is the outcome and does this measure it
- How is it measured
- Is it a reliable measure
- Is it right for this population
- Can it be done

# Analysis

- Accepted
- Enough detail
- Understandable
- Satisfy specialist reviewer
  - Qual
  - Quant
  - Mixed



# Simple in theory



Clockwise on the edges,  
counterclockwise in the middle

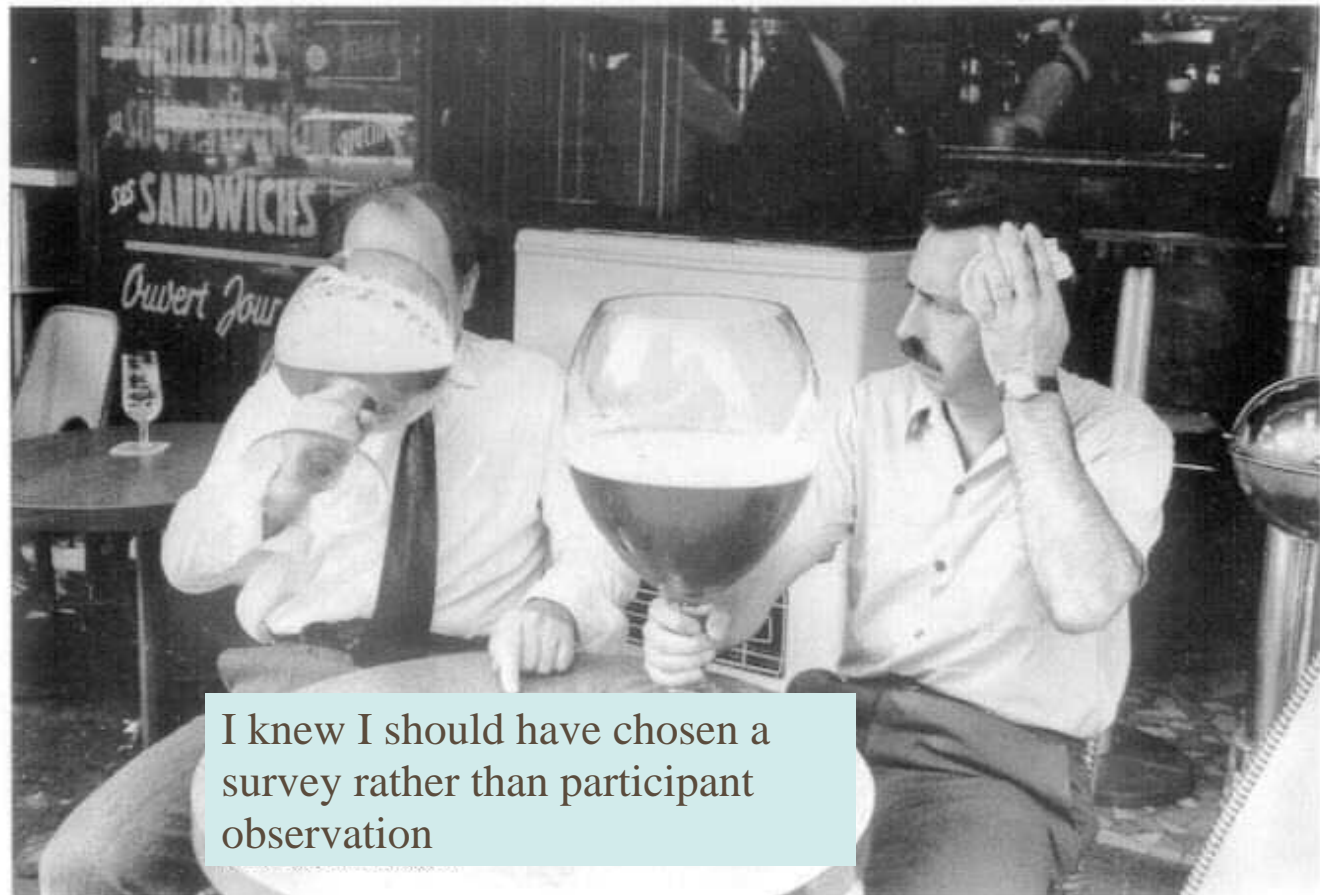




# Significance

- Does this study address an important problem?
- If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced?
- What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventive interventions that drive this field?

# Specific methods



I knew I should have chosen a survey rather than participant observation

# Cross sectional studies



- Cross sectional studies are the best way to determine prevalence
- Are relatively quick
- Can study multiple outcomes
- Do not themselves differentiate between cause and effect or the sequence of events

# Cohort studies

<http://emj.bmj.com/cgi/content/full/20/1/54>

- Cohort studies describe incidence or natural history.
- They analyse predictors (risk factors) thereby enabling calculation of relative risk.
- Cohort studies measure events in temporal sequence thereby distinguishing causes from effects.
- Retrospective cohorts where available are cheaper and quicker.
- Confounding variables are the major problem in analysing cohort studies.
- Subject selection and loss to follow up is a major potential cause of bias.

# Why randomise?

- To see if something makes a difference
- Each study unit (patient, GP, practice, facility) equal chance of being/not being in the intervention group
- Reduces bias
  - researchers unable to consciously/unconsciously load the intervention group with ‘good’ GPs, good communicators, high SES patient groups
- Evenly distribute known/unknown factors associated with certain outcomes

**Notes to slide 21**

By randomising we can ensure that each study unit has an equal chance of being or not being in the intervention group and as a researcher we are unable to consciously or unconsciously load the intervention group with desirable features.

And one of the key advantages is the opportunity to evenly distribute known/unknown factors that may affect the outcome between the groups.

I would like to highlight the importance of the unknown factors. It is possible, yet difficult, to distribute known factors using a non-randomised design. However, it is impossible to distribute unknown factors using the non-randomised design. This feature is one of the strongest reasons for using the randomised trial design and it probably accounts for the observation that an intervention tested using a non-randomised design appears to work better than when it is tested using a randomised design.

# When to randomise?

- Uncertainty about benefits of intervention
- Outcomes have clinical and real-life significance
- Sample size is large enough
- Harm acceptable in relation to benefits
- Trial is feasible, researchers competent and sufficient funds

**Notes to slide 22**

Clear guidelines have been developed for the ethical conduct of randomised trials.

Perhaps some of our reluctance to use the randomised design stems from some of the unethical studies that have been performed.

Queen Caroline using prisoners and orphans, the NAZI experiments of the 2nd world war and 20th century examples of women with breast cancer who were unaware they had been randomised to not receive counselling support.

A randomised design should be considered whenever there is a

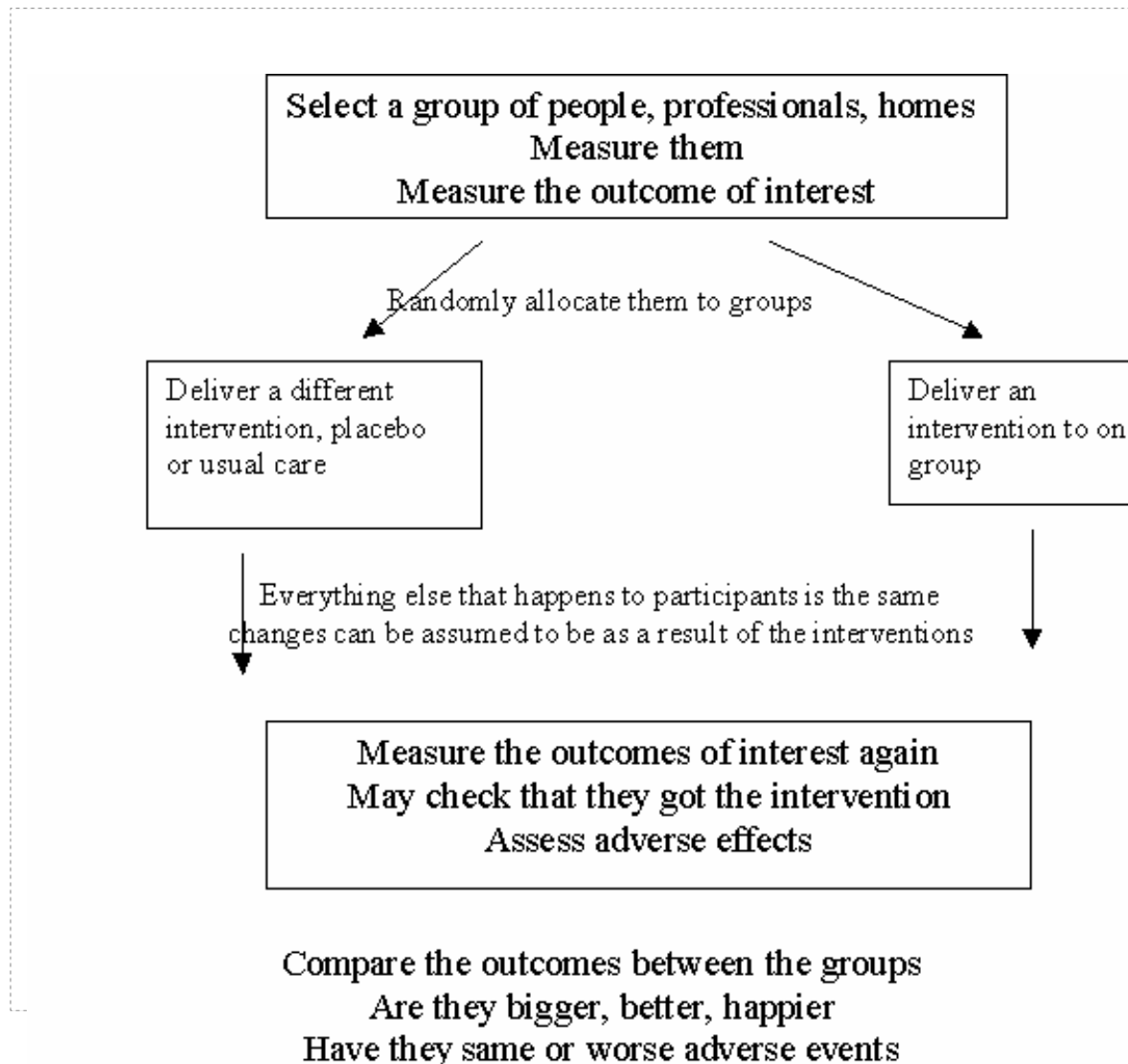
Genuine uncertainty about the benefits of the intervention

When outcomes can be measured that are of clinical and real-life significance

Sample size is large enough to detect worthwhile effects with confidence

When the potential harm is acceptable in relation to potential benefits

When the trial is feasible, the researchers are technically competent and there are sufficient funds to complete the trial



# Some key points

- Defined condition and outcomes
- Equal groups
- Single, double blinded
- Blinded outcomes assessment
- Equal treatment of all groups
- Generalisability
- Confounders unequally distributed
- Systematic bias
- Measurement bias
- Effect not due to the intervention.



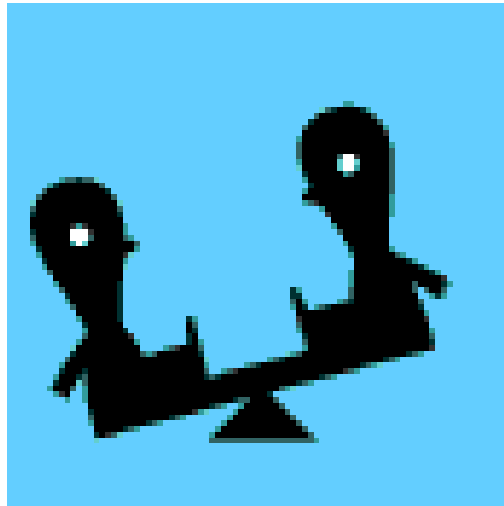
- Be open to the prospect of unexpected results
- Understand the context of the research



# Randomised trials- consort statement – BMJ website

- Moher D. Schulz KF. Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. Lancet. 357(9263):1191-4, 2001 Apr 14.
  - Use the headings
    - Eligibility criteria
    - Interventions
    - Objectives
    - Outcomes
    - Sample size estimate
    - Randomisation
    - Blinding
    - Adverse events

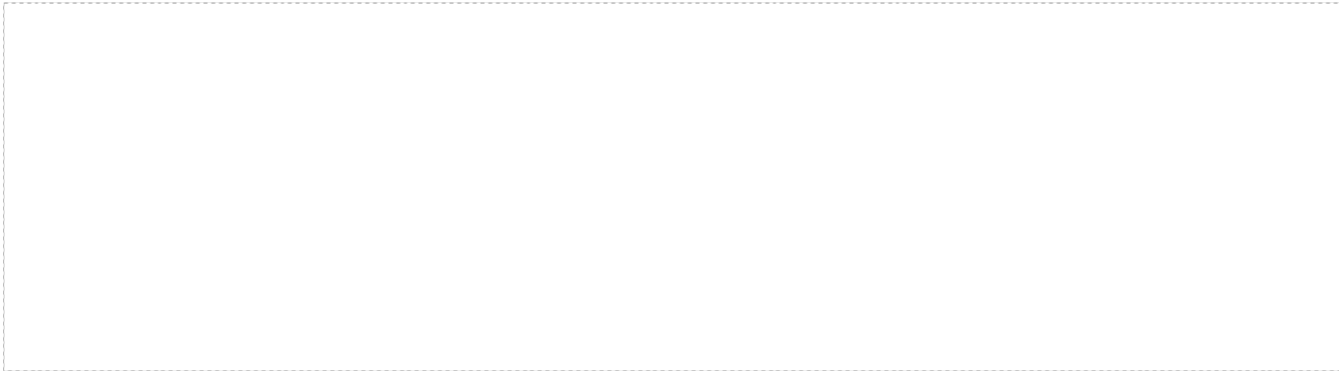
<http://www.consort-statement.org/Downloads/checklist.pdf>



[http://grants.nih.gov/grants/grant\\_tips.htm](http://grants.nih.gov/grants/grant_tips.htm)



# Scales and measures in Dementia Research



# Issue to be considered

- What Measures could be considered?
- What Scales are available already?
  - Validity, Utility etc
- How do the scale match up with the Goals?

# Problems observed

- What are the primary outcome measures?
- Are these able to be directly or indirectly measured, ie are surrogates being used?
- Are more measures better?
- Is the instrument to be used appropriate in the environment?
  - Self assessment scales in LTC setting?
- Who is using them?
  - Training, blinding etc, who are the observers, and are they likely to be consistent and reliable?

# Depression

- Observed, vs reported, especially in the LTC setting (highly problematic)
- How observant are the informers, do they need ‘training’?
- Self rated eg GDS vs observed eg Depressive Symptom Scale
- Mixed eg Cornell Scale for Depression in Dementia

# Neuropsychiatric Scales

- Global or domain orientated?
  - Eg BEHAVE-AD / NPI etc
  - Watch for overlap with other scales (eg Depression
  - Can be exhausting for subject and observer
  - If interviewing a ‘carer’ are they good observers and are they likely to be consistently available

# ADLS

- Useful for measure of ‘Direct Outcome’
- Environmental effects, especially IADLs
- Observer based vs Performance based
  - Time and training costs for performance testing are high
- Observer consistency
- Mixed causes for lowered performance

# Memory / Cognitive

- Usually over valued, but still helpful as obviously a core feature of Dementia.
- Participant vs Observed
- Short vs long term studies
  - Pencil & Paper
  - Computerised

