



# Designing an RCT protocol (ii) Group activity

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▶ WOMEN'S BENEFITS ▶ MEN'S BENEFITS

### FITFLOP™ BENEFITS▶

MICROWOBBLEBOARD™ TECHNOLOGY CAN HELP

- ↓ REDUCE LOWER BACK STRAIN
- ↓ REDUCE HIP JOINT STRESS
- ↑ INCREASE QUADRICEP MUSCLE ACTIVATION (UP TO 16%)
- ↓ REDUCE KNEE JOINT STRESS
- ↑ INCREASE GALE MUSCLE ACTIVATION (UP TO 11%)
- ↓ REDUCE ANKLE JOINT STRESS
- ↓ REDUCE FOOT PRESSURE CONCENTRATION

▶ WOMEN'S BENEFITS ▶ MEN'S BENEFITS

### FITFLOP™ BENEFITS▶

MICROWOBBLEBOARD™ TECHNOLOGY CAN HELP

- ↓ REDUCE BACK STRESS
- ↑ INCREASE BOTTOM MUSCLE ACTIVATION (UP TO 30%)
- ↑ INCREASE HAMSTRING MUSCLE ACTIVATION (UP TO 16%)
- ↓ REDUCE KNEE JOINT STRESS
- ↑ INCREASE LOWER LEG MUSCLE ACTIVATION (UP TO 11%)
- ↓ REDUCE ANKLE JOINT STRESS
- ↓ REDUCE FOOT PRESSURE CONCENTRATION

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## PICO Clinical question

- Participant:
  - ?
- Intervention:
  - ?
- Comparison:
  - ?
- Outcome:
  - ?



## Participants

- Source:
  - ?
- Inclusions:
  - ?
- Exclusions:
  - ?
- Eligibility for therapists:
  - ?



## Intervention

- Exp
  - ?
- Dose
  - ?
- Treatment fidelity (standardisation/quality)
  - ?

## Comparison

- Control
  - ?
- Dose
  - ?
- Treatment fidelity (standardisation/quality)
  - ?

## Outcomes\_1

- Primary outcome:
  - ?
- Secondary outcomes:
  - ?
- Adverse events:
  - ?



## Outcomes\_2

- Data quality:
  - ?
- Data capture:
  - ?
- Data storage:
  - ?



## Sample size estimation

- Basic parameters
  - the smallest effect worth detecting
  - the variability of outcomes
  - tolerance of Type II errors (usually  $\beta = 0.2$ )
  - tolerance of Type I errors (usually  $\alpha = 0.05$ )
- Others
  - Loss to follow-up
  - Treatment non-compliance
- *Rob Herbert's excel file*

## Allocation

- Randomisation-sequence generation
  - ?
- Allocation concealment
  - ?
- Implementation
  - ?

## Blinding

- Participant
  - ?
- Therapist
  - ?
- Assessor
  - ?
- Statistician
  - ?
- GP
  - ?



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## Statistical methods

- Baseline comparability
  - ?
- Primary outcome
  - ?
- Secondary outcome
  - ?



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## Documentation

- Registering the trial  
–?
- Trial manuals/documents  
–?
- Publishing trial protocol  
–?