The physioFIRST pilot study:

A pilot randomised clinical trial for the efficacy of a targeted physiotherapy intervention for femoroacetabular impingement syndrome (FAIS)

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Why do we need to do the physioFIRST study?

FAIS has large impact on affected individuals

While most people with cam morphology do not develop FAIS (ie: develop signs and symptoms), for those that do, the impact is enormous Agricola 2013, Kemp 2014, Hinman 2013

Quality of life scores similar to people with end stage hip OA. Clohisy 2013, kemp 2014

Young and middle aged people with large family and work commitments Griffin 2016, Kemp 2014

Unable to exercise = big consequences for general health Kemp 2014, Filbay 2015

Increased risk (10 times greater) of end stage hip OA and THA Agricola 2012, 2013

Pilot RCTs vital to avoid research funding wastage (wrong outcomes, wrong inclusion, wrong intervention…)

What are treatment options for FAIS?

Surgical RCTs of hip arthroscopy (registered)

Trial	Country	Sample Size	Interventions	Planned Reporting
UK FASHIoN	UK (Warwick)	344	Arthroscopic surgery vs physiotherapy	2017
Aus FASHIoN	Australia	120	Arthroscopic surgery vs physiotherapy	2018
FAIT	UK (Oxford)	120	Arthroscopic surgery vs physiotherapy	2017
FIRST	Canada and Finland	220	Arthroscopic surgery vs arthroscopic washout	2017
HIPARTI	Norway, Sweden Belgium, Canada and Australia	140	Arthroscopic surgery vs diagnostic arthroscopy	2020
US Army WA	USA	60	Arthroscopic surgery vs physiotherapy	unknown

Non-surgical treatment RCTs

No RCTs for physiotherapy, exercise or weight loss

Surgery should be last treatment option, even though it is often first….

Also, government no longer funding FAIS surgery…..

Given this, RCTs for non-surgical treatments urgently needed.

Aims

Primary aim: determine the feasibility of conducting a full-scale RCT evaluating the effects of a physiotherapy intervention compared to a control intervention to reduce pain and improve function in people with FAIS.

Secondary aims: explore the magnitude of effect sizes for the physiotherapy interventions compared to the control intervention for pain and function.

Methods

Study design:

Pilot, participant- and assessor-blinded RCT

Conforming to SPIRIT guidelines and Australian Good Clinical Practice guidelines.
Approved by the La Trobe University HREC (approval number: 15-076).
Registered with the Australian and New Zealand Clinical Trials Registry (number: ACTRN12615001218583).

Participants

Inclusion and Exclusion criteria

Inclusion:

Men and women aged 18-50 years

Hip or groin pain on impingement (>3/10 on visual analogue scale [VAS]) for ≥6 weeks)

Radiographic FAIS (Alpha angle ≥60˚ on either anterior-posterior (AP) pelvic or Dunn-45˚ hip radiographs.

Exclusion:

Physiotherapy treatment in the past three months;

Previous hip surgery or other major hip injury;

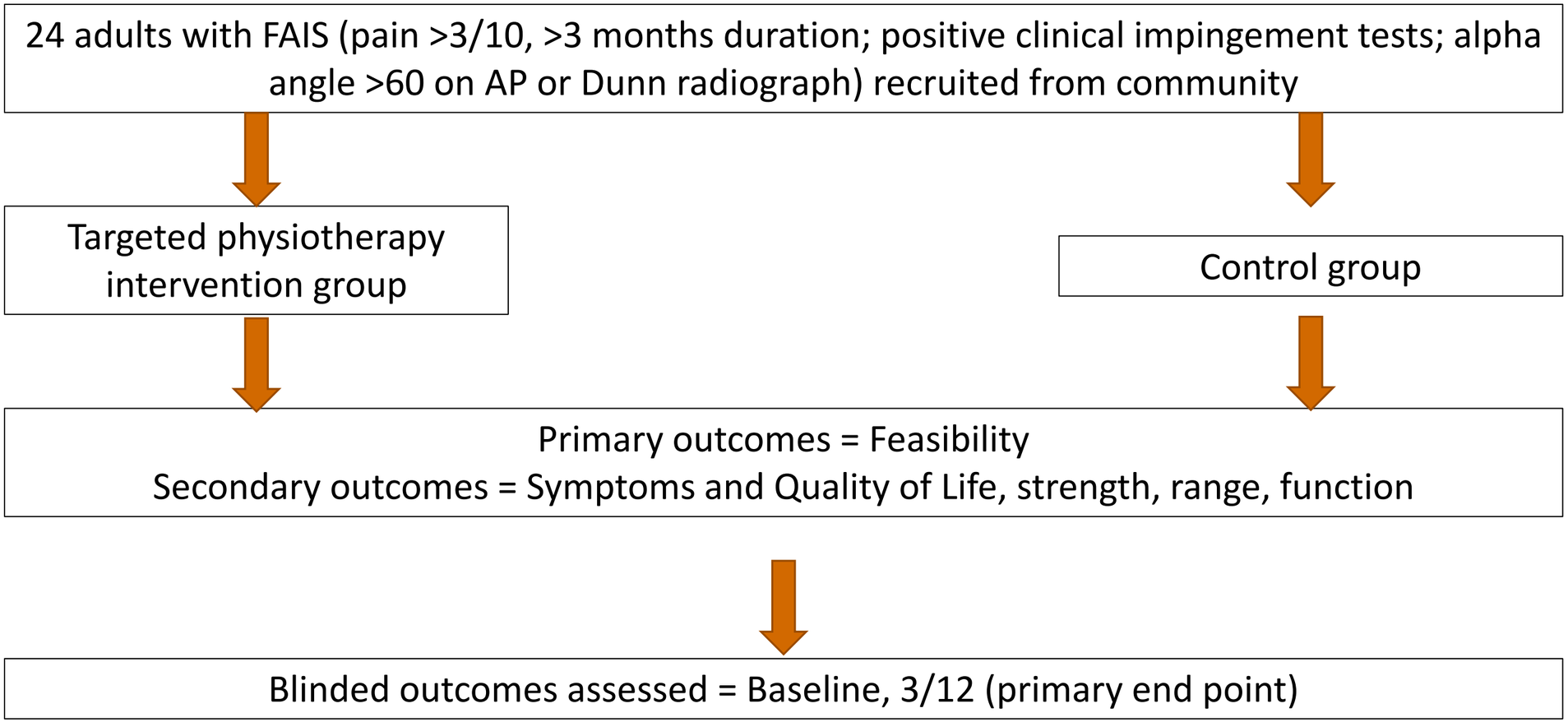
Other musculoskeletal conditions including rheumatoid arthritis;

Unable to perform testing procedures;

Unable to commit to a 12-week treatment program or baseline and follow-up assessments;

Contraindications to X-ray (including pregnancy)

physioFIRST pilot study procedure



Outcomes

Primary Outcome: feasibility of a full-scale RCT

Integrity of the study protocol

- Appropriateness of inclusion criteria
- Training of staff
- Accessibility of the intervention to participants,
- Acceptability of the intervention to participants and physiotherapists
- Time burden for participants
- Facilities required to deliver the intervention.

Recruitment and retention procedures

- Participant enrolment (at least 80% of eligible participants enrolled)
- Participant adherence with the intervention (at least 80% of participants attended 75% of appointments; and completed 75% of the prescribed exercises)
- Participant losses to follow-up (at least 80% of participants complete the follow-up)

Primary Outcome: feasibility of a full-scale RCT

Evaluation of outcome measurement collection

- Questionnaires
- Physical impairment measures

Blinding

- Appropriateness of randomisation & blinding methods
- Participants and Assessor awareness of group allocation
- Whether both treatment groups were credible

Outcome measure selection and sample size calculation

- PROM with largest between-group effect size, (>previously reported MIC);
- Estimate sample size - future fully-powered study (sample size calculations using the effect size data).

Secondary Outcomes: Between-group differences in change score

Hip-related Symptoms and QoL

iHOT-33 = reliable, valid, 0-100 points Thorborg 2015, Mohtadi 2012

HOOS pain and QoL subscales = reliable, valid, 0-100 points Thorborg 2015, Kemp 2013

Hip muscle strength

Abduction, adduction, extension, external rotation

Hand-held dynamometry, reliable methods, Nm/kg Kemp 2012

Hip joint range

Flexion range, inclinometer, reliable methods Hatton 2014

Functional task performance

Single leg hop for distance, Side bridge trunk endurance Kemp 2016

Interventions

Targeted intervention for FAIS: An impairment based model

BJSM Online First, published on June 14, 2016 as 10.1136/bjsports-2016-096152

Physical impairments in symptomatic femoroacetabular impingement: a systematic review

Ac

[RESEARCH REPORT]

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Paul
Clark

Patients With Chondrolabral Pathology Have Bilateral Functional Impairments

with chondrolabral pathology associated with impairments in hip strength or range of motion?

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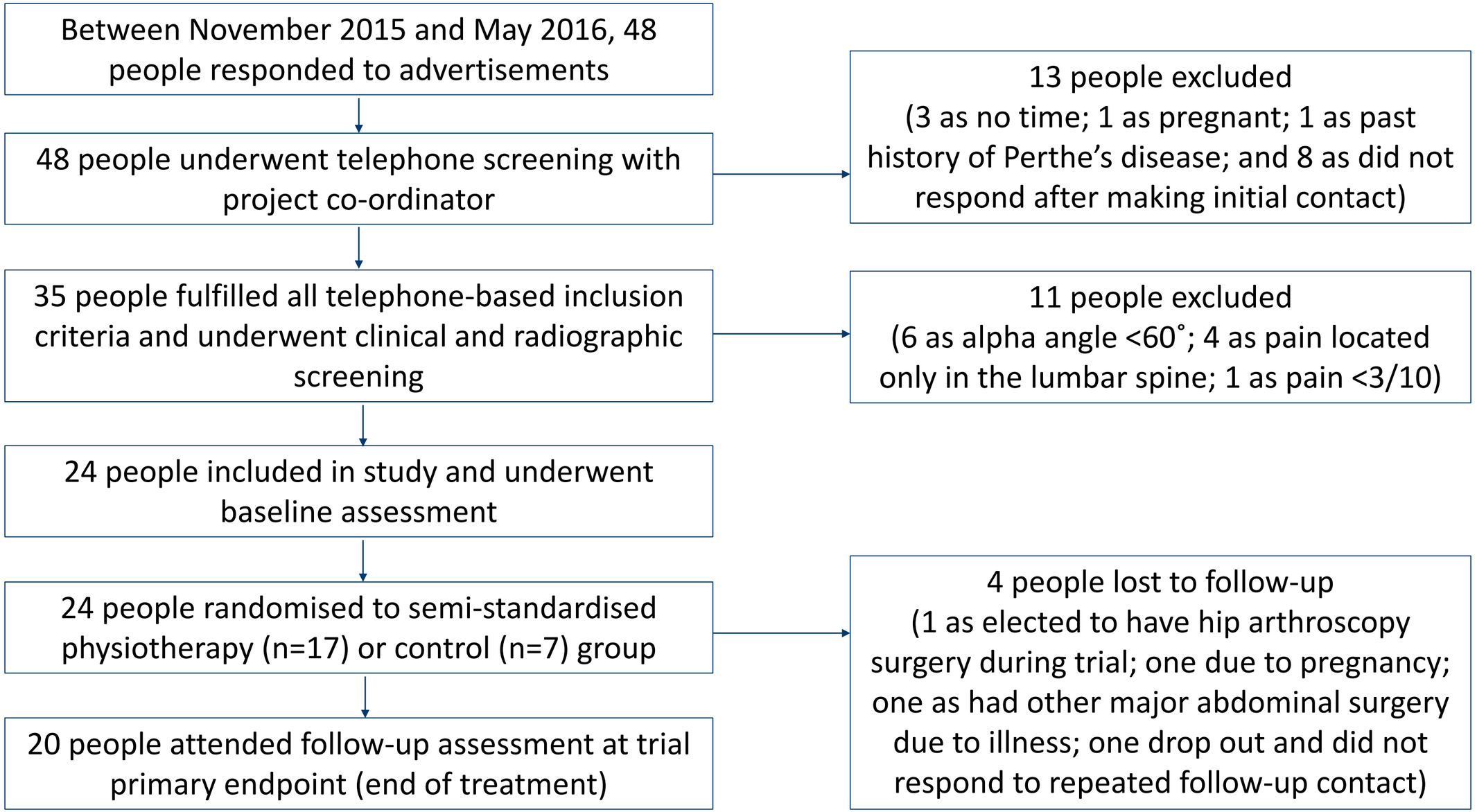
Elements of targeted physiotherapy intervention

Hip strength (AB, AD, EXT, ER)
Trunk strength
Functional and balance retraining
Sports specific retraining
ROM optimization
Education

Interventions: Tidier guidelines

	What	Targeted physiotherapy	Control
Tidier Guidelines	**Who provides**	Physiotherapists	
	How	Face-to-face individual sessions	
	Where	Physiotherapy clinic (& clinic gym) in Regional Victoria	
	When & how much	8x30 mins physiotherapy; and weekly 30 mins supervised gym sessions. Exercises progressed based on VAS <3/10; Borg <5/10	
	Tailoring	**Individualised** selection hip & trunk strength, functional exercise and manual therapies **Progressive, tailored** physical activity program	Standardised stretching Standardised education and information on increasing physical activity
	How well	Treatment response in files and adherence recorded in mobile phone app	

Results


Between November 2015 and May 2016, 48 people responded to advertisements
48 people underwent telephone screening with project co-ordinator
13 people excluded (3 as no time; 1 as pregnant; 1 as past history of Perthe's disease; and 8 as did not respond after making initial contact)
35 people fulfilled all telephone-based inclusion criteria and underwent clinical and radiographic screening
11 people excluded (6 as alpha angle <60˚; 4 as pain located only in the lumbar spine; 1 as pain <3/10)
24 people included in study and underwent baseline assessment
24 people randomised to semi-standardised physiotherapy (n=17) or control (n=7) group
4 people lost to follow-up (1 as elected to have hip arthroscopy surgery during trial; one due to pregnancy; one as had other major abdominal surgery due to illness; one drop out and did not respond to repeated follow-up contact)
20 people attended follow-up assessment at trial primary endpoint (end of treatment)

Participant characteristic	Mean	Standard deviation
Age (years)	37	8
Gender (number (%) of women)	17 (71%)	NA
Height (metres)	1.70	0.08
Weight (kilograms)	73.7	11.6
Body mass index (kg/m^2)	25.4	3.4

Results: Feasibility

Eligibility criteria conform with Warwick agreement

Pre-study training of therapists adequate

Protocol fidelity maintained through study duration

Accessibility of intervention was not adequate

Intervention credible to both groups, both groups would take part again

Time burden not excessive, clinic facilities adequate

Results: Feasibility

Eligibility criteria conform with Warwick agreement

Pre-study training of therapists adequate

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Accessibility of intervention was not adequate

Intervention credible to both groups, both groups would take part again

Time burden not excessive, clinic facilities adequate

Results: Feasibility

Recruitment

50% interested applicants eligible

100% of eligible people enrolled

17/24 attended all physiotherapy and supervised gym sessions

1/24 attended at least 80% of physiotherapy and supervised gym sessions

6/24 attended less than 80% of physiotherapy and supervised gym sessions

No adverse events were recorded

Results: Feasibility

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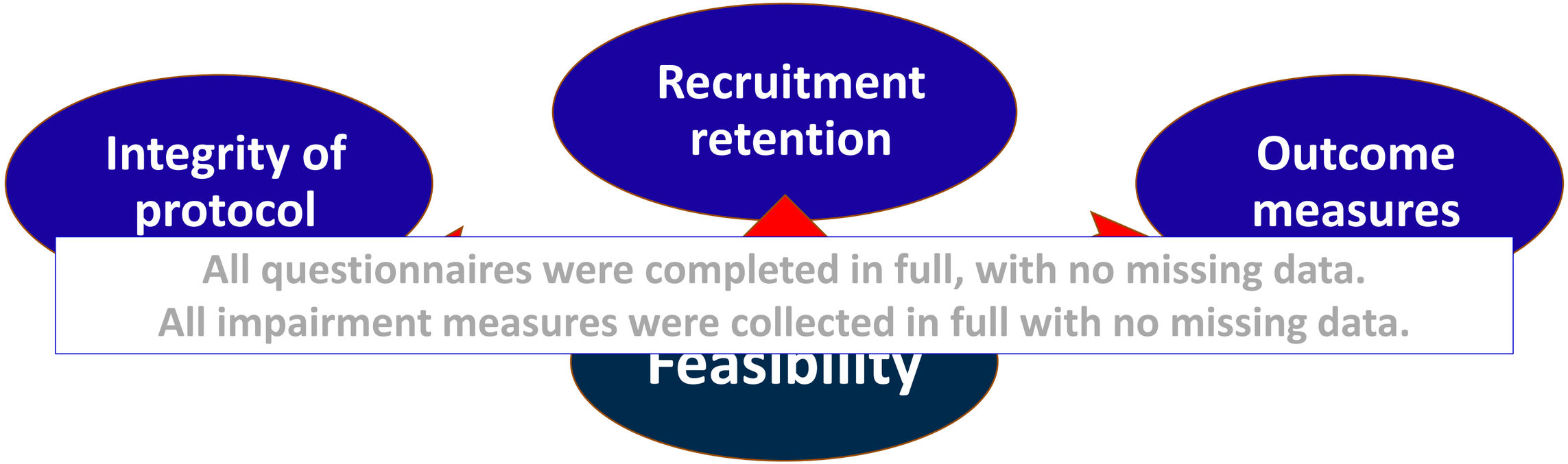
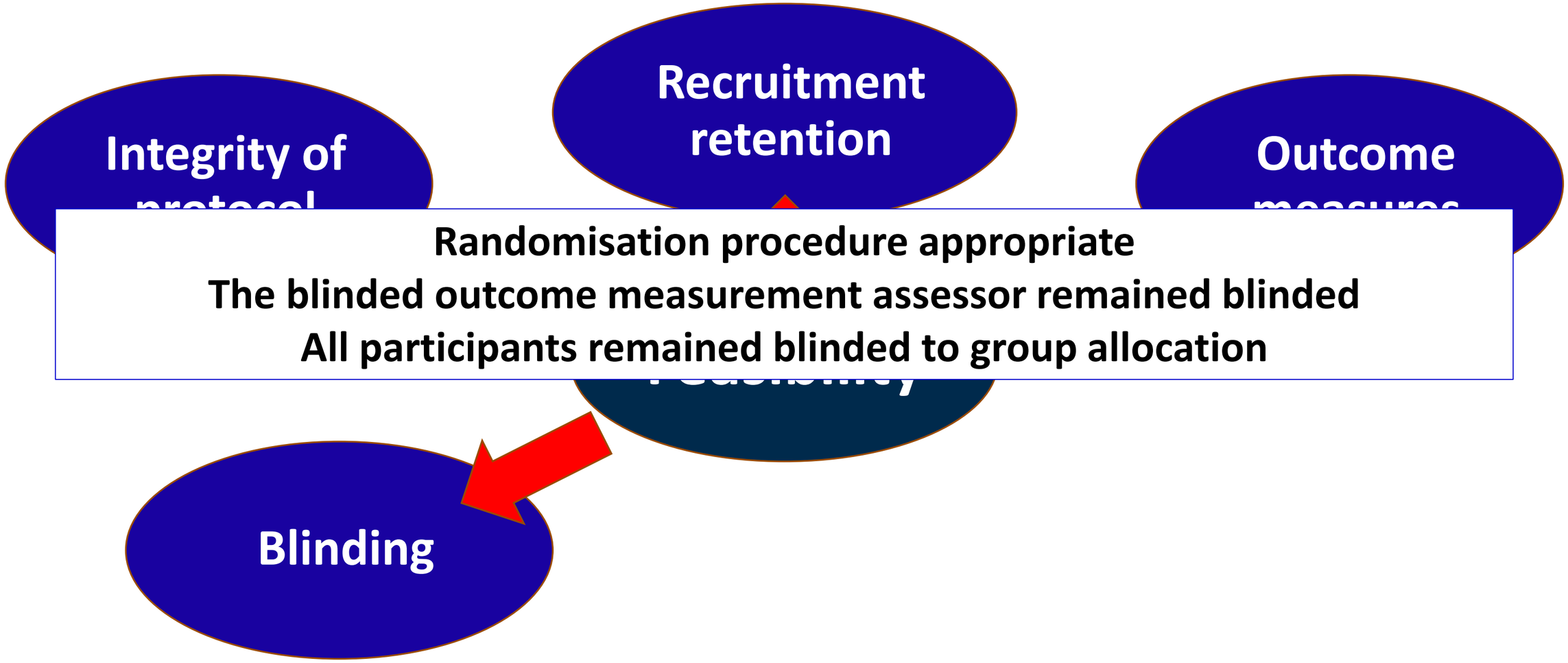
Results: Feasibility

All questionnaires were completed in full, with no missing data.
All impairment measures were collected in full with no missing data.

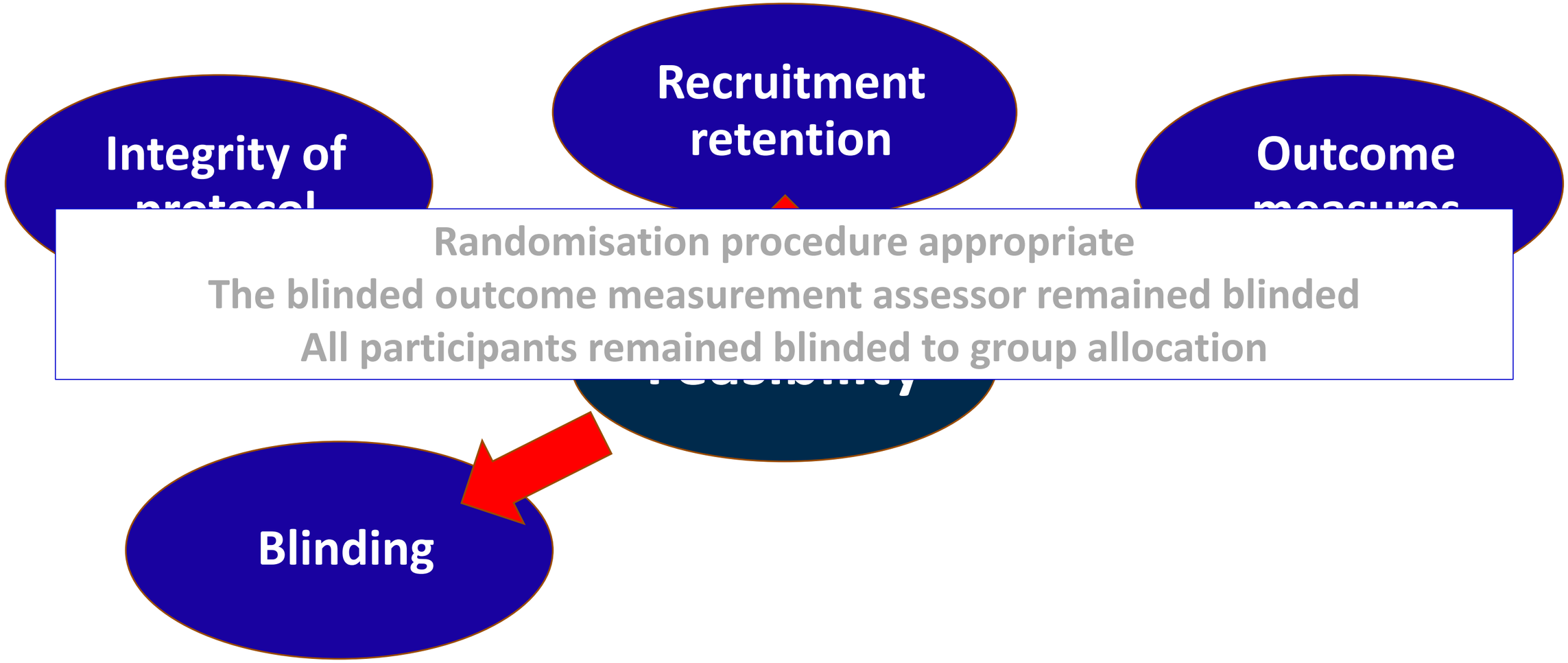
Results: Feasibility



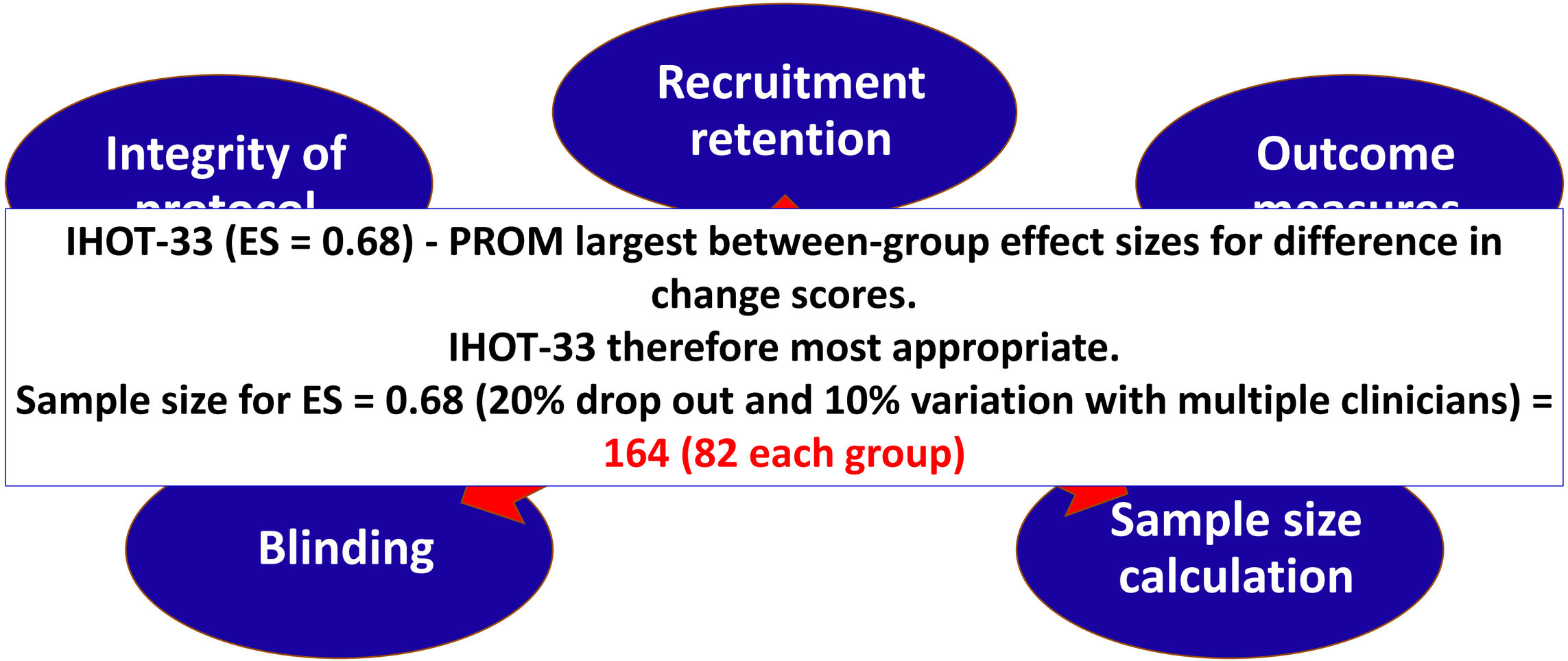
Results: Feasibility



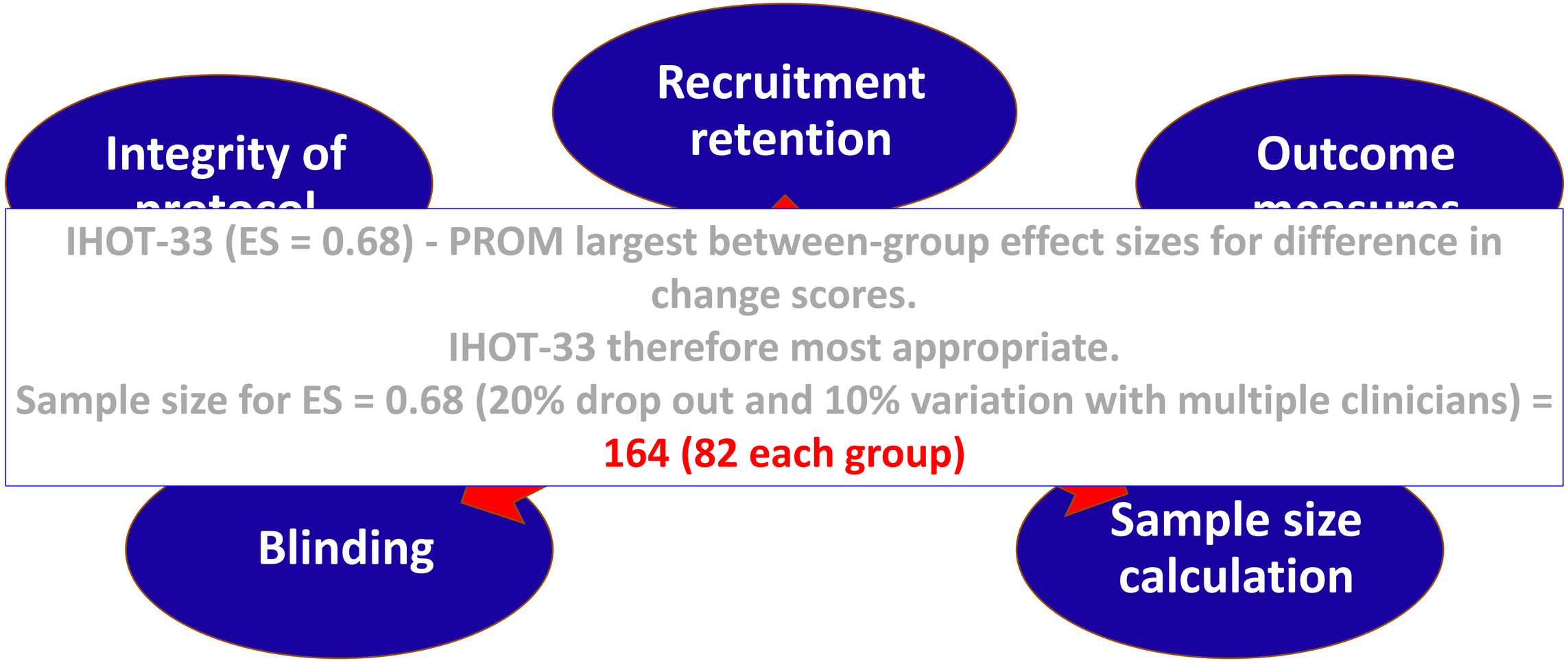
Results: Feasibility



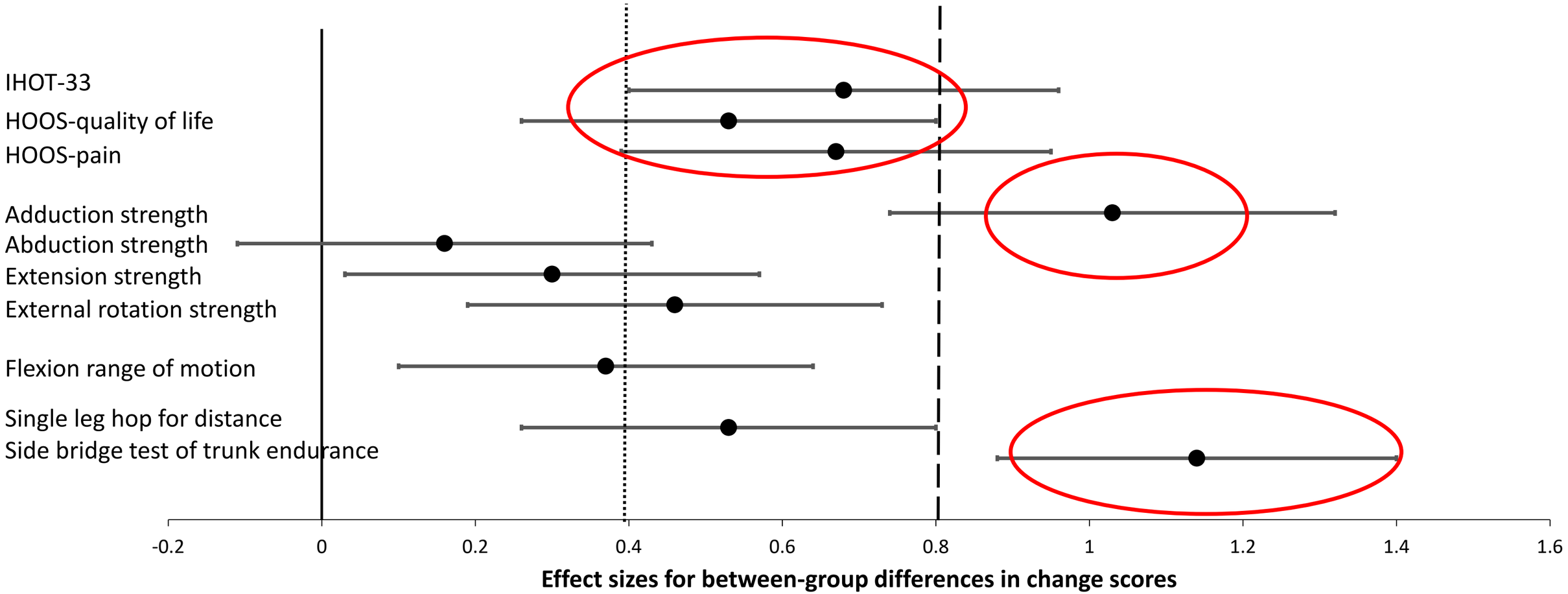
Results: Feasibility



Results: Feasibility



Between group effect sizes of change scores for PROs and impairments



Dashed line represents large effect size, dotted line represents moderate effect size

Positive effect size denotes difference in change score favouring the semi-standardised active physiotherapy intervention group

Discussion

Can we apply study findings in a clinical context?

Meet Mr X……

Mr X (study participant)

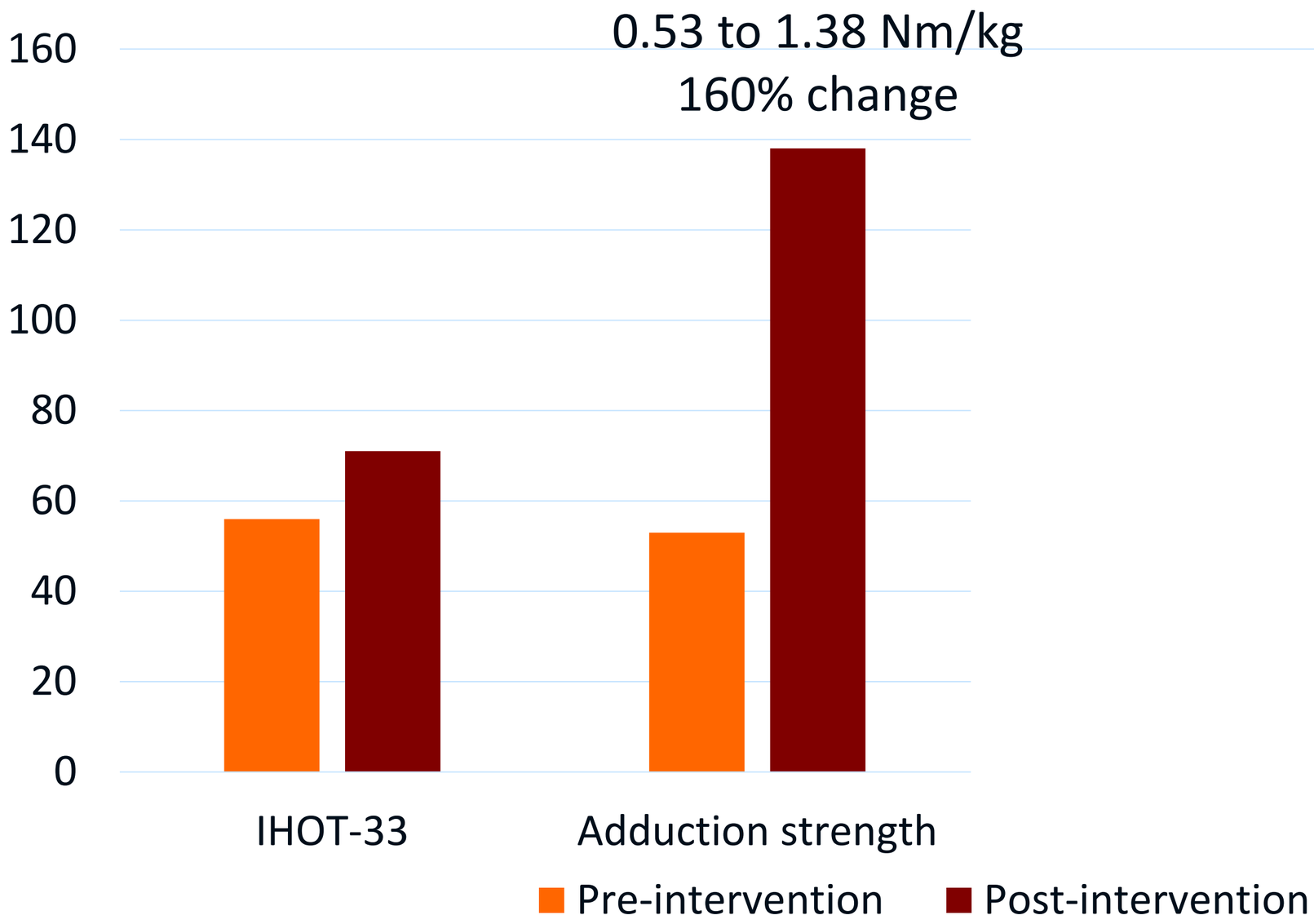
27 year old semi-professional footballer

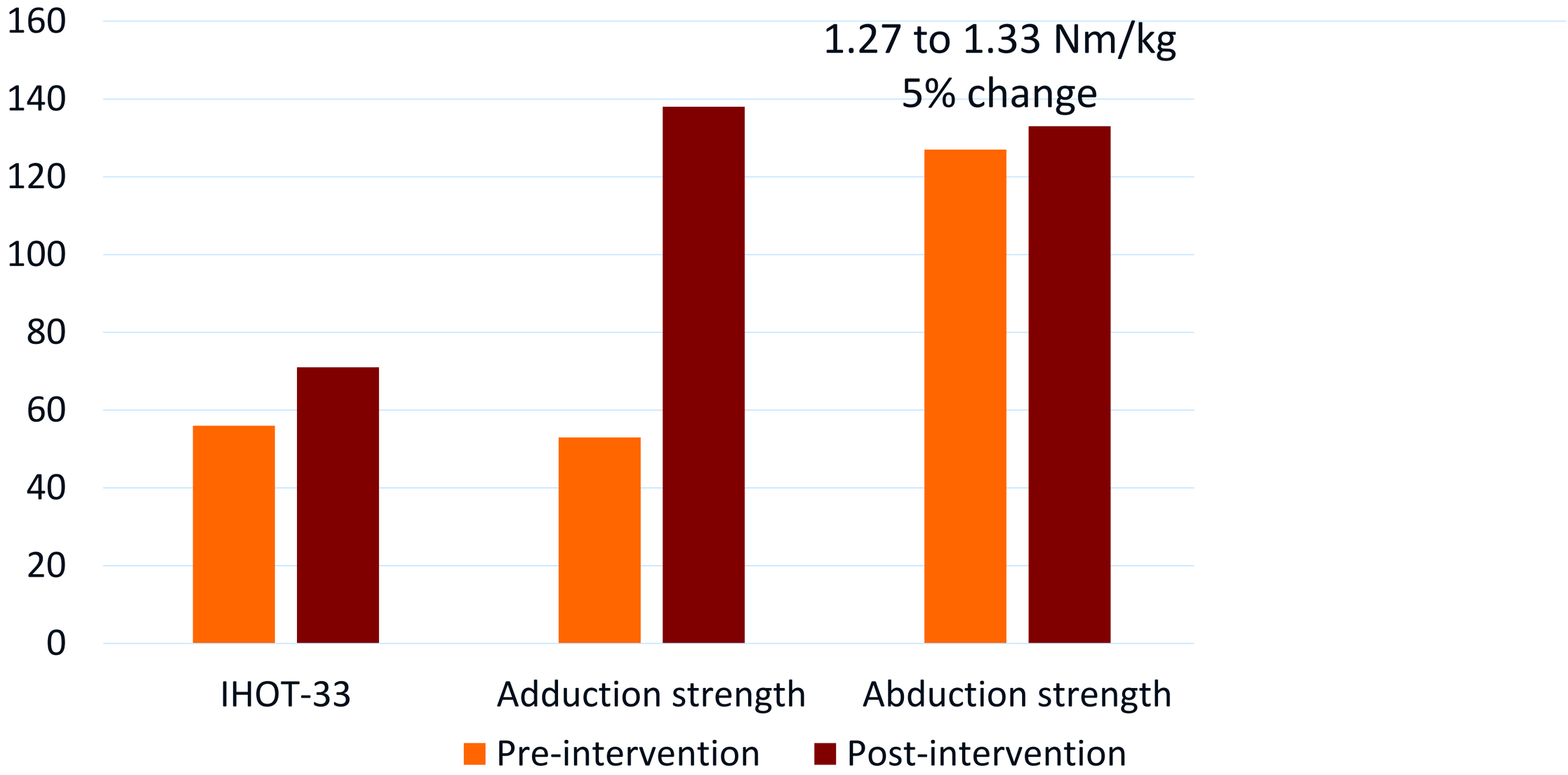
Had not played for 6 months at time of initial assessment

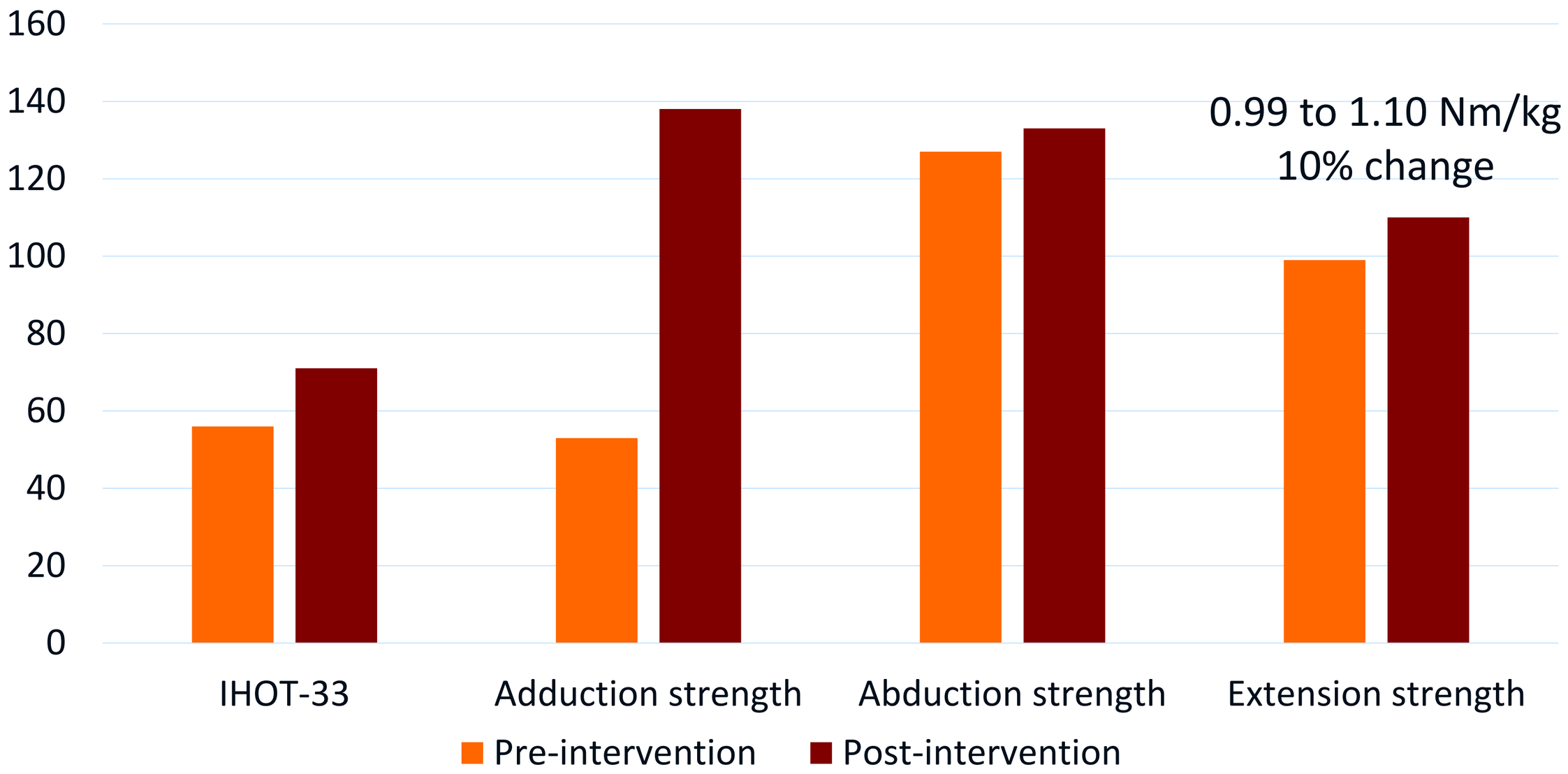
Met all eligibility criteria

Mr X results
(targeted physiotherapy group)

Change in primary and secondary outcomes


0.53 to 1.38 Nm/kg
160% change
160
140
120
100
80
60
40
20
0
IHOT-33
Adduction strength
Pre-intervention
Post-intervention


160
140
120
100
80
60
40
20
0
1.27 to 1.33 Nm/kg
5% change
IHOT-33
Adduction strength
Abduction strength
Pre-intervention
Post-intervention


160
140
120
100
80
60
40
20
0
0.99 to 1.10 Nm/kg
10% change
IHOT-33
Adduction strength
Abduction strength
Extension strength
Pre-intervention
Post-intervention

Return to Sport?

Able to train twice weekly and compete once weekly at full load at the completion of the rehabilitation program, with minimal hip and groin pain.

Conclusion and take home message

1. A full-scale RCT for FAIS is feasible and necessary
2. Future studies need 164 participants, at least 2 clinicians, appropriate strategies, such as incentives for retention
3. A targeted individualised physiotherapy intervention may improve function and reduce pain in people with FAIS
4. Due to the pilot nature of this study, these results must be interpreted with caution, until replicated in a full-scale study

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