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

Joanne L Kemp¹, Sally L Coburn¹, Denise M Jones¹, Kay M Crossley¹

¹ Latrobe Sport and Exercise Medicine Research Centre

@JoanneLKemp  e: j.kemp@latrobe.edu.au
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)

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

24 adults with FAIS (pain >3/10, >3 months duration; positive clinical impingement tests; alpha angle >60 on AP or Dunn radiograph) recruited from community

Targeted physiotherapy intervention group

Primary outcomes = Feasibility
Secondary outcomes = Symptoms and Quality of Life, strength, range, function

Control group

Blinded outcomes assessed = Baseline, 3/12 (primary end point)
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
Physical impairments in symptomatic femoroacetabular impingement: a systematic review

RESEARCH REPORT

JOANNE L. KEMP, PT, PhD1,2 • MAY ARNA RISBERG, PT, PhD3 • ANTHONY G. SCHACHE, PT, PhD4
MICHAEL MAKDISSI, MD, PhD5 • MICHAEL G. Pritchard, MD, PhD6 • KAY M. CROSSLEY, PT PhD2

Patients With Chondrolabral Pathology Have Bilateral Functional Impairments

- ปั้นช่อหัวเข่าทั้งสองข้างมีปัญหาการเจริญเติบโตที่มากขึ้น

Joanne L. Kemp1,2 • Michael Makdissi3 • Anthony G. Schache4 • Caroline F. Finch1 •
Michael G. Pritchard5 • Kay M. Crossley2
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

<table>
<thead>
<tr>
<th>Tidier Guidelines</th>
<th>Targeted physiotherapy</th>
<th>Control</th>
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</thead>
<tbody>
<tr>
<td><strong>Who provides</strong></td>
<td>Physiotherapists</td>
<td></td>
</tr>
<tr>
<td><strong>How</strong></td>
<td>Face-to-face individual sessions</td>
<td></td>
</tr>
<tr>
<td><strong>Where</strong></td>
<td>Physiotherapy clinic (&amp; clinic gym) in Regional Victoria</td>
<td></td>
</tr>
<tr>
<td><strong>When &amp; how much</strong></td>
<td>8x30 mins physiotherapy; and weekly 30 mins supervised gym sessions. Exercises progressed based on VAS &lt;3/10; Borg &lt;5/10</td>
<td></td>
</tr>
<tr>
<td><strong>Tailoring</strong></td>
<td>Individualised selection hip &amp; trunk strength, functional exercise and manual therapies&lt;br&gt;Progressive, tailored physical activity program</td>
<td>Standardised stretching&lt;br&gt;Standardised education and information on increasing physical activity</td>
</tr>
<tr>
<td><strong>How well</strong></td>
<td>Treatment response in files and adherence recorded in mobile phone app</td>
<td></td>
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</tbody>
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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).
<table>
<thead>
<tr>
<th>Participant characteristic</th>
<th>Mean</th>
<th>Standard deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>37</td>
<td>8</td>
</tr>
<tr>
<td>Gender (number (%) of women)</td>
<td>17 (71%)</td>
<td>NA</td>
</tr>
<tr>
<td>Height (metres)</td>
<td>1.70</td>
<td>0.08</td>
</tr>
<tr>
<td>Weight (kilograms)</td>
<td>73.7</td>
<td>11.6</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>25.4</td>
<td>3.4</td>
</tr>
</tbody>
</table>
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

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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

**Recruitment retention**: 
- 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

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

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

- **Blinding**
  - Randomisation procedure appropriate
  - The blinded outcome measurement assessor remained blinded
  - All participants remained blinded to group allocation

- **Integrity of protocol**

- **Recruitment retention**

- **Outcome measures**
Results: Feasibility

- Randomisation procedure appropriate
- The blinded outcome measurement assessor remained blinded
- All participants remained blinded to group allocation
Results: Feasibility

- **Integrity of protocol**
- **Recruitment retention**
- **Blinding**
- **Outcome measures**
- **Sample size calculation**

IHOT-33 (ES = 0.68) - PROM largest between-group effect sizes for difference in change scores. IHOT-33 therefore most appropriate.

Sample size for ES = 0.68 (20% drop out and 10% variation with multiple clinicians) = 164 (82 each group)
**Results: Feasibility**

**Integrity of protocol**

**Recruitment retention**

**Outcome measures**

**Blinding**

**Sample size calculation**

IHOT-33 (ES = 0.68) - PROM largest between-group effect sizes for difference in change scores. IHOT-33 therefore most appropriate. Sample size for ES = 0.68 (20% drop out and 10% variation with multiple clinicians) = 164 (82 each group)
Between group effect sizes of change scores for PROs and impairments

- IHOT-33
- HOOS-quality of life
- HOOS-pain
- Adduction strength
- Abduction strength
- Extension strength
- External rotation strength
- Flexion range of motion
- Single leg hop for distance
- Side bridge test of trunk endurance

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

IHOT-33

56 to 71 points
>MIC 9 points

Pre-intervention
Post-intervention
IHOT-33 Adduction strength Abduction strength Extension strength

Pre-intervention

Post-intervention

0.53 to 1.38 Nm/kg
160% change
IHOT-33 Adduction strength  Abduction strength  Extension strength

Pre-intervention

Post-intervention

1.27 to 1.33 Nm/kg  5% change
IHOT-33

Adduction strength

Abduction strength

Extension strength

Pre-intervention

Post-intervention

0.99 to 1.10 Nm/kg

10% change
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
@JoanneLKemp

e: j.kemp@latrobe.edu.au