Improving the effectiveness of exercise therapy for older adults with knee pain: a pragmatic randomised controlled trial (the BEEP trial)

NIHR Professor Nadine Foster on behalf of the BEEP trial team
Background

• Knee Osteoarthritis

• Clinical trials, systematic reviews and guidelines consistently recommend exercise

• Benefits of exercise tend to be small to moderate and decline over time

• ? Linked to insufficient individualisation of exercise and limited attention to adherence over time ?
Aim: Test whether pain and function outcomes can be improved by changing the characteristics of the exercise programme in comparison to usual physiotherapy care.
**Design:**
- Multi-centre, pragmatic superiority RCT
- Comparison of 3 physiotherapy-led exercise-based interventions

**Setting:**
- Participants recruited from:
  - 65 general practices
  - 5 NHS physiotherapy services

**Recruitment:**
- Those consulting their GP with knee pain
- Physiotherapy referrals
- A survey to all registered adults at GP practice
## Participants

### Inclusion
- Aged ≥ 45 years
- Current knee pain and/or stiffness
- Met criteria for clinical diagnosis of knee OA
- Able to read and write in English
- Willing to participate
- Able to give full informed consent
- Access to a telephone

### Exclusion
- THR/TKR on affected side
- On waiting list for THR/TKR
- Potentially serious pathology (e.g. inflammatory arthritis or malignancy)
- Exercise interventions contraindicated
- Received an exercise programme from a physiotherapist in the last 3 months
## Interventions

<table>
<thead>
<tr>
<th>Key features</th>
<th>Usual Physiotherapy Care (UC)</th>
<th>Individually Tailored Exercise (ITE)</th>
<th>Targeted Exercise Adherence (TEA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment sessions</td>
<td>Up to 4 sessions over 12 weeks</td>
<td>6-8 sessions over 12 weeks</td>
<td>8-10 contacts over 6 months</td>
</tr>
<tr>
<td>General education</td>
<td>Advice booklet</td>
<td>Advice booklet</td>
<td>Advice booklet</td>
</tr>
<tr>
<td>Exercise focus</td>
<td>Lower limb exercise</td>
<td>Lower limb exercise</td>
<td>Lower limb exercise, general physical activity</td>
</tr>
<tr>
<td>Individualisation</td>
<td>Exercises individually prescribed /selected from template</td>
<td>Exercises individually prescribed</td>
<td>Exercises individually prescribed</td>
</tr>
<tr>
<td>Progression and supervision</td>
<td>Minimal</td>
<td>Good</td>
<td>Good</td>
</tr>
<tr>
<td>Adherence focus</td>
<td>Minimal</td>
<td>Exercise diary, ‘selling’ of exercise</td>
<td>Use of an ‘adherence enhancing toolkit’</td>
</tr>
</tbody>
</table>
Outcomes

• Primary outcomes:
  – **Pain and function** using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

• Postal questionnaires with reminders
  – at baseline, 3, 6, 9, 18 months follow-up
Secondary outcomes

• Responders to treatment: OMERACT-OARSI criteria
• Exercise adherence
  - “I have been doing my exercises as often as I was advised”
    - Physical Activity Scale for the Elderly (PASE)
    - Accelerometry with subsample (n=90)
• Cost-effectiveness
• Knee-related health resource use
• Safety
Flow chart

Potentially eligible
n=1530

Eligible, consent and
randomised
n=514

UC
N=175
6 month follow-up
89%

ITE
n=176
6 month follow-up
86%

TEA
n=163
6 month follow-up
85%
## Baseline characteristics

- Similar across all treatment arms

<table>
<thead>
<tr>
<th>Key characteristics</th>
<th>UC</th>
<th>ITE</th>
<th>TEA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (years)</td>
<td>62</td>
<td>63</td>
<td>64</td>
</tr>
<tr>
<td>Female gender</td>
<td>50%</td>
<td>52%</td>
<td>52%</td>
</tr>
<tr>
<td>Mean BMI (kg/m2)</td>
<td>29.4</td>
<td>29.4</td>
<td>30.0</td>
</tr>
<tr>
<td>Physical Activity level (PASE)</td>
<td>176</td>
<td>175</td>
<td>180</td>
</tr>
<tr>
<td>WOMAC Pain (0-20)</td>
<td>8.2</td>
<td>8.5</td>
<td>8.5</td>
</tr>
<tr>
<td>WOMAC Function (0-68)</td>
<td>27.5</td>
<td>27.8</td>
<td>29.1</td>
</tr>
</tbody>
</table>
Clinical effectiveness

WOMAC pain

WOMAC function
Clinical effectiveness

WOMAC pain

WOMAC function

Data are means and 95% confidence intervals
Clinical effectiveness

**WOMAC pain**

- Usual physiotherapy care (UC)
- Individually Tailored Exercise (ITE)
- Targeted Exercise Adherence (TEA)

**WOMAC function**

- Usual physiotherapy care (UC)
- Individually Tailored Exercise (ITE)
- Targeted Exercise Adherence (TEA)
## Clinical effectiveness

OMERACT-OARSI responders

<table>
<thead>
<tr>
<th></th>
<th>3-mths</th>
<th>6-mths</th>
<th>9-mths</th>
<th>18-mths</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UC</strong></td>
<td>44%</td>
<td>50%</td>
<td>45%</td>
<td>48%</td>
</tr>
<tr>
<td><strong>ITE</strong></td>
<td>46%</td>
<td>51%</td>
<td>49%</td>
<td>50%</td>
</tr>
<tr>
<td><strong>TEA</strong></td>
<td>45%</td>
<td>55%</td>
<td>50%</td>
<td>51%</td>
</tr>
</tbody>
</table>
Exercise adherence

“I have been doing my exercises as often as advised” – % agree/strongly agree

PASE and accelerometers: differences between groups were not statistically significant
Treatment fidelity

• Number of treatment sessions
  – UC      median 3 sessions
    • 89% were judged to be in line with protocol
  – ITE     median 6 sessions
    • 62% were judged to be in line with protocol
  – TEA     median 7 sessions
    • 48% were judged to be in line with protocol
Health economics

- **UC both more effective and cheaper** over 18 months
  - UC slightly higher QALYs (difference 0.009) vs. ITE or TEA

- ITE and TEA groups both more costly than UC
  - ITE: mean cost difference of £273 per person
  - TEA: mean cost difference of £141 per person

- Cost differences due to
  - more physiotherapy sessions in ITE and TEA groups
  - more surgical procedures/ NHS consultant visits in ITE
Summary

- On average, patients did well with all three physiotherapy-led exercise interventions over time.
- No differences between groups in patient’s pain and function.
- Exercise behaviour was back to baseline levels by 18 months follow-up.
- Exercise interventions were safe:
  - No serious adverse events
  - Rare expected minor adverse events (n=4)
Conclusion

- More individual tailoring of, and targeting adherence to, exercise were not more effective than usual NHS physiotherapy care.

- Economic analysis suggests usual care is “treatment of choice”.

- Older adults with knee OA do not sustain increases in exercise and physical activity behaviours in the long-term.

- Whilst 50% or more of participants responded well to exercise, up to half did not.

- **Future research**: better identification of those who respond to exercise, rather than changing the characteristics of exercise programmes.
Acknowledgements

Participating patients and clinicians


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