Surgery and Physiotherapy for prolapse Research: a feasibility study – ‘SUPER’

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Prolapse

Pelvic organ prolapse (POP) - symptomatic descent of the vaginal walls and/or uterus or vaginal vault from their normal anatomical position.
Background

• In a sample of 2,979 women between 45 and 86 years of age, reported in 2010, 21% were found to be symptomatic

• Symptoms include bladder, bowel and sexual dysfunction, lower back pain, feeling of a bulge

Slieker-ten et al 2009
Jelovsek et al 2007
Confirmed risk factors

- Age
- Race
- Family history
- BMI
- Parity
- Vaginal delivery
- Constipation

Doshani et al 2007
Pessary

Pessaries offer a good non-invasive option in POP management for women unfit for surgery, those who have not yet completed childbearing, or those who do not desire surgical repair.

Jones & Harmanli 2010
Conservative management – pre surgery

- Evidence in non-surgical populations that pelvic floor muscle training (PFMT) can prevent worsening of POP - One-to-one pelvic floor physiotherapy for women with stage I to III prolapse of any type is likely to be effective in improving prolapse symptoms and cost-effective

Hagen et al 2011
Braekken et al 2013
Management - Surgery

- Women have an 11% risk of undergoing at least one surgical intervention for POP by the age of 79.
- The long-term outcome following surgical correction of POP is poor, and in a prospective study 41% of women had recurrence of POP at 5 years and 10% of women had undergone a repeat POP operation within five years of their index operation.

Miedel et al 2008
Olsen et al 1997
Surveys- post operative physiotherapy

• In 2008 a UK survey of members of the Association of Chartered Physiotherapists in Women's Health (ACPWH) was undertaken.
• It was evident that there is wide variation in practice amongst physiotherapists.
• Many felt dissatisfied with this situation.
• International surveys of physiotherapy practice following surgery for POP, have reported similar findings.

McClurg et al 2008
Peri-op Literature

- Jarvis et al (2004) - 2 group RCT (n=30)
- Neither reported on prolapse specific OCM
Hypothesis - PFMT

Bø reviewed basic research and case-control studies and put forward two hypotheses:-

• Women can build up 'muscle tone' and structural support of the pelvic floor muscles through regular strength training over time.

• Women can learn to contract their pelvic floor muscles (PFMs) consciously before and during an increase in intra-abdominal pressure and will continue to make such contractions as a behavioural modification in order to prevent descent of the pelvic contents

• In addition a study by Braekken et al (2010) demonstrated elevation of the pelvic organs after PFM training and assumed that PFMT can be used in prevention of POP.

Bo K 2006
Braekken et al. 2010
Aims and Objectives

• To develop the methods and assess the feasibility of a multi-centre RCT of peri-operative PFMT and lifestyle advice for women undergoing surgical intervention POP

• To collect pilot data to inform sample size calculations and optimal health economics methods in preparation for undertaking a multi-centre pragmatic randomised controlled trial.
Methods

- 2 group RCT - Intervention and Control
- 30 per group, from 3 centres – Newcastle, Southampton and Belfast
- Patients approached at the gynaecology appointment
- Consented and randomised using remote computer programme
- Outcome assessors were blinded to group allocation
Outcome measures

**Primary outcome measure**
Pelvic Organ Prolapse Symptom Score (POP-SS) at 12 months.  
(Hagen et al 2009 2010)

**Secondary outcome measures**
POP-Q - Measurement of prolapse  
(Stark et al 2010)
Pelvic floor muscles assessment (PERFECT and Modified Oxford Scale)  
(Laycock & Jerwood 2001)
ICIQ-SF for urinary incontinence  
(Abrams et al 2006)
ICIQ bowel questionnaire  
(Abrams et al 2006)
PISQ-12 for sexual dysfunction  
(Rogers et al 2003)

All outcomes were measured at 0, 6 and 12 months.
Reasons for ineligibility:
- Previous surgery n=12
- Previous PFMT n=3
- Operated before seen n=5
- Unwilling n=15
- Other n=7

Approached 111 women at 3 centres

- Eligible n=69
- Ineligible n=42

Number randomised n=57

Surgery

Treatment Group n=28
- One pre-op appointment
- Withdrew n=2
- Post-op/surgery complications

Advice leaflet posted at week 1
- 6 out-patient appointments over a 16 week period
- Home PFMT program with advice

6 month follow-up
- Withdrew n=3

12 month follow-up
- 8 ran out of time
- 1 lost to follow-up

Control Group n=29
- No pre-op appointment

Withdrawn n=2
- Post-op/surgery complications

Advice leaflet posted at week 1
- No further contact

6 month follow-up
- Withdrew n=2

12 month follow-up
- 12 ran out of time
- 1 lost to follow-up
Results

• Information on study processes such as recruitment rates and difficulties with knowing the dates of surgery, for a future definitive trial has been gathered.

• Data were returned which have enabled us to undertake a sample size calculation for a definitive study.

• When compared to the control group (n=29), benefits to the intervention group (n=28) were observed in terms of fewer prolapse symptoms at 12 months (mean difference between groups in change from baseline symptom score (MD 3.94; 95% CI [1.35, 6.75]; t=3.24, p=0.006), however these results must be viewed with caution due to possible selection bias.
# Results

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Treatment group baseline Mean/SD</th>
<th>Control group baseline Mean/SD</th>
<th>Treatment group 6 months Mean/SD</th>
<th>Control group 6 months Mean/SD</th>
<th>Treatment group 12 months Mean/SD</th>
<th>Control group 12 months Mean/SD</th>
<th>Between group diff 0 to12 months 95%CI, t, p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>POP-SS</td>
<td>13.38 (5.76)</td>
<td>14.69 (5.40)</td>
<td>3.27 (4.50)</td>
<td>5.41 (5.96)</td>
<td>2.45 (2.42)</td>
<td>6.40 (3.40)</td>
<td>(1.358,6.750) t=3.248 p=0.006</td>
</tr>
<tr>
<td>ICIQ-UI</td>
<td>6.30 (7.69)</td>
<td>6.30 (4.47)</td>
<td>3.54 (4.69)</td>
<td>3.84 (3.69)</td>
<td>1.30 (1.60)</td>
<td>3.23 (3.60)</td>
<td>(-.337,4.183) t=1.75 p=0.92</td>
</tr>
<tr>
<td>ICIQ Bowel</td>
<td>14.53 (5.36)</td>
<td>13.92 (3.64)</td>
<td>12.90 (5.02)</td>
<td>12.85 (3.95)</td>
<td>11.40 (4.52)</td>
<td>11.38 (3.01)</td>
<td>(-4.221,-3.001) t=-.348 p=.731</td>
</tr>
<tr>
<td>SF 12</td>
<td>35.20 (0.92)</td>
<td>34.83 (6.01)</td>
<td>42.82 (3.68)</td>
<td>40.20 (5.20)</td>
<td>42.58 (3.60)</td>
<td>35.70 (6.29)</td>
<td>(-11.344,-2.431) t =-3.218 p = 0.004</td>
</tr>
<tr>
<td>PISQ</td>
<td>42.69 (23.90)</td>
<td>38.53 (19.91)</td>
<td>36.23 (26.56)</td>
<td>36.84 (22.69)</td>
<td>31.07 (23.19)</td>
<td>29.38 (17.76)</td>
<td>(-13.65,21.96) t=.481 p=.635</td>
</tr>
</tbody>
</table>
'I feel that all women after childbirth should be advised about the importance of pelvic floor exercises so that they become part of a daily routine like brushing teeth. It has taken the research programme to make me aware of how valuable exercises are'.

'I have felt in the past 3 months that I have a slight bulge coming back. I would have a lot of lifting in my job which I have kept moderate at work, but still feel that it is to blame. I am quite active and continue walking but don't feel I can go back to the gym yet for fear of doing damage'.

'So pleased to have had the operation and so pleased to have been included in this study'.

'I still cannot understand what exactly I am supposed to be able to do and often overdo it and then have symptoms/discomfort.'
Conclusions

With modifications to design, for example

- Dedicated site recruiter
- Better communication on waiting list times
- Possibly reduce the number of visits
- Long term follow-up with strategies to increase retention and completion of all OCM e.g.
- payment of parking for repeat vaginal assessments; more flexibility with appointments

an RCT is practical.
The Definitive RCT

200 per group

20 sites with 10 per group

Long-term follow-up of 10 years (Access NHS data and consent for questionnaires at 5 and 20 years)

Provide evidence from which clinical guidance on the place of peri-operative PFMT to limit POP recurrence could be developed

However
Additional knowledge as to the most effective advice on return to ADL is also required – Delphi study
References


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Thank you for your attention

Any Questions?

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