NKR 33 Urininkontinens, PICO 6: Bør kvinder med stress urininkontinens tilbydes bækkenbundstræning frem for operation med midturethral slynge?

Review information

Authors

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Citation example: S. NKR 33 Urininkontinens, PICO 6: Bør kvinder med stress urininkontinens tilbydes bækkenbundstræning frem for operation med midturethral slynge? Cochrane Database of Systematic Reviews [Year], Issue [Issue].

Characteristics of studies

Characteristics of included studies

Labrie 2013

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Intervention ● *Age*: 50 (8.2) ● *BMI*: 26.9 (5.0) ● *Postmenopausal*: 67/196 ● *Number of voidings/24h*: 8 (3-17) ● *Patient Global Impression of Severity - not severe*: 12/196 ● *UDI score: urinary incontinence*: 41.1 (19.2)

	● *UDI score: overactive bladder*: 18.4 (20.3) ● *UDI score: discomfort or pain*: 9.9 (14.1) ● *IIQ score: physical functioning*: 15.4 (17.3) ● *IIQ score: social functioning*: 11.9 (20.6) ● *IIQ score: embarrassment*: 29.1 (24.1) Control ● *Age*: 50 (8.2) ● *BMI*: 26.9 (5.0) ● *Postmenopausal*: 67/196 ● *Number of voidings/24h*: 8 (3-17) ● *Patient Global Impression of Severity - not severe*: 12/196 ● *UDI score: urinary incontinence*: 41.1 (19.2) ● *UDI score: overactive bladder*: 18.4 (20.3) ● *UDI score: discomfort or pain*: 9.9 (14.1) ● *IIQ score: physical functioning*: 15.4 (17.3) ● *IIQ score: social functioning*: 11.9 (20.6) ● *IIQ score: embarrassment*: 29.1 (24.1) **Included criteria:** Women were 35 to 80 years of age and had been referred to an outpatient gynecology or urology clinic after presenting with stress urinary incontinence classified as moderate or severe according to the severity index developed by Sandvik et al.In women presenting with mixed incontinence (involuntary loss of urine associated with urgency [urge incontinence] and also on physical exertion, sneezing, or coughing), stress incontinence was classified as predominant if there were more episodes of stress than urge incontinence, as reported on the validated Dutch version of the Urogenital Distress Inventory. **Excluded criteria:** Treatment or physiotherapy 6 months prior to randomization.Women who had undergone previous incontinencesurgery or who had concomitant pelvicorganprolapse of stage 2 or higher (according tothe Pelvic Organ Prolapse Quantification system)were excluded.
Interventions	**Intervention Characteristics** Intervention ● *Description*: A supervised program to help women build up to 8 to 12 maximal contractions three times per day was provided. Treatment was given at 1-week or 2-week intervals, depending on the severity of symptoms, treatment goals, adherence, and the ability of the women to learn to perform the muscle contractions. The physiotherapist deter-mined the number of sessions, with an intended number of nine sessions in 9 to 18 weeks (the standard

	number at the time). If a woman was unable to contract her pelvic-floor muscles, touch, tapping, and massage were applied to increase awareness of these muscles. Biofeedback-assisted or functional electrostimulation therapy could be used. ● *Follow-up*: 12 months ● *Duration*: 9-18 weeks Control ● *Description*: e treatment assignments were not concealed.Surgical procedures were performed by 49 gyne-cologists and urologists. Before participating in this trial, each surgeon had performed a mini-mum of 20 procedures. Both retropubic and trans-obturator midurethral-sling surgical techniques were allowed. ● *Follow-up*: 12 months ● *Duration*:
Outcomes	*Hæmatom* ● **Outcome type**: AdverseEvent ● **Measure names**: ["End of treatment", "Follow up 12 months"] ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *De novo inkontinens* ● **Outcome type**: AdverseEvent ● **Measure names**: ["End of treatment", "Follow up 12 months"] ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Inkontinensrelateret livskvalitet - social functioning* ● **Outcome type**: IIQ-7 (range 0-100, lower is better) ● M**easure names**: ["End of treatment", "Follow up 12 months"] ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint ● **Notes**: den angivne værdi er den rapporterede ændring fra baseline. Dvs jo større negativ ændring desto bedre.

Infektion

- **Outcome type**: AdverseEvent
- **Measure names**: ["End of treatment", "Follow up 12 months"]
- **Reporting**: Not reported

Stranguri med residualurin

- **Outcome type**: AdverseEvent
- **Measure names**: ["End of treatment", "Follow up 12 months"]
- **Reporting**: Not reported

Bensmerter

- **Outcome type**: AdverseEvent
- **Measure names**: ["End of treatment", "Follow up 12 months"]
- **Reporting**: Not reported

Underlivssmerter

- **Outcome type**: AdverseEvent
- **Measure names**: ["End of treatment", "Follow up 12 months"]
- **Reporting**: Not reported

Antal tilfælde af inkontinens

- **Outcome type**: ContinuousOutcome
- **Measure names**: ["End of treatment", "Follow up 12 months"]
- **Reporting**: Not reported

Patientoplevet effekt

- **Outcome type**: DichotomousOutcome
- **Measure names**: ["12 months follow-up"]
- **Reporting**: Fully reported
- **Scale**: PGI-I: improvement
- **Unit of measure**: no/total no.
- **Direction**: Higher is better
- **Data value**: Endpoint

Inkontinensrelateret livskvalitet - physical functioning

- **Outcome type**: IIQ-7 (range 0-100, lower is better)

	● **Measure names**: ["End of treatment", "Follow up 12 months"] ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint
Identification	**Sponsorship source:** Supported by a grant from ZonMw, the Netherlands Organizationfor Health Research and Development (80-82310-98-08203). **Country:** Holland **Setting:** **Comments:** **Authors name:** Labrie J **Institution:** University Medical Centre Utrecht **Email:** j.labrie@umcutrecht.nl. **Address:**
Notes	*Birgitte Holm Petersen* on 12/08/2015 02:08 **Baseline Characteristics** alle angives i mean (SD) frasetpostmenopausal: antal postmenopausale n/Nnumber of voidings/24h: median (range)Patient Global Impression of Sevirity - not severe: antal not severe n/N *Irina Goukasian* on 16/08/2015 19:59 **Baseline Characteristics** Kirurgisk behandling kaldes Intervention. Bækkenbundstræning kaldes Control. *Irina Goukasian* on 16/08/2015 21:57 **Continuous Outcomes** s. 1128: In the physiotherapy group, 99 women(49.0%) crossed over to the surgery group, aftera mean (±SD) time of 31.7±12.7 weeks.s. 1129: jeg kan ikke finde den tabel, som der henvises til: "ThePGI-I and PGI-S responses for all follow-up assessments,including the assessment at 18 months,are shown in Table S2 in the Supplementary Appendix."Spørgsmål til Jimmi: der er stor gruppe på 99 kvinder, der skiftede til kirurgisk behandling efter 5-10 mdr. (s. 1128). Hvor skal vi placere dem?

Risk of bias table

Bias	Authors' judgement	Support for judgement
Allocation concealment	High risk	Quote: "Women were assigned in a 1:1 ratio to the surgery group or the physiotherapy group, with blocks of four per center, stratified according to the severity of incontinence (moderate or severe). The treatment assignments were not concealed."
Sequence Generation	Low risk	Quote: "After written informed consent was obtained, research nurses on site performed computerized randomization on a central server. An indepen- dent data manager designed the randomization table."
Blinding of participants and personnel All outcomes	High risk	Judgement Comment: Både deltagere og behandlere vidste, hvilket intervention man blev randomizeret til. Hvis nogle kvinder på forhånd mente, at de blev bedst hjulpet ved operation, kunne dette påvirke deres vurdering af inkontinens efter intervention, hvis de blev randomizeret til BB træning.
Blinding of participants and personnel Påvirkbar	High risk	Judgement Comment: Blinding af deltagerne ikke muligt. Alle outcomes er påvirkbare fraset hæmatom. Derfor high risk of bias.
Blinding of outcome assessors	High risk	Judgement Comment: Manglende blinding af deltagerne. Deltagerne er outcome assessors ved alle outcomes end hæmatom. Derfor high risk of bias
Incomplete outcome data	Low risk	Quote: "in the study, of whom 460 gave written informed consent. These wom- en were randomly assigned to the surgery group (230) or the physiotherapy group (230) (Fig. 1). Analyses were performed for 215 women assigned to the surgery group and 202 women as- signed to the physiotherapy group; at 12 months, outcome data were available for 196 (91.2%) 460 Provided written consent and"
Selective outcome reporting	Low risk	
Other sources of bias	Low risk	

Footnotes

References to studies

Included studies

Labrie 2013

Labrie, J.; Berghmans, B. L.; Fischer, K.; Milani, A. L.; van, der Wijk I.; Smalbraak, D. J.; Vollebregt, A.; Schellart, R. P.; Graziosi, G. C.; van der Ploeg, J. M.; Brouns, J. F.; Tiersma, E. S.; Groenendijk, A. G.; Scholten, P.; Mol, B. W.; Blokhuis, E. E.; Adriaanse, A. H.; Schram, A.; Roovers, J. P.; Lagro-Janssen, A. L.; van der Vaart, C. H.. Surgery versus physiotherapy for stress urinary incontinence. New England Journal of Medicine 2013;369(12):1124-1133. [DOI: http://dx.doi.org/10.1056/NEJMoa1210627]

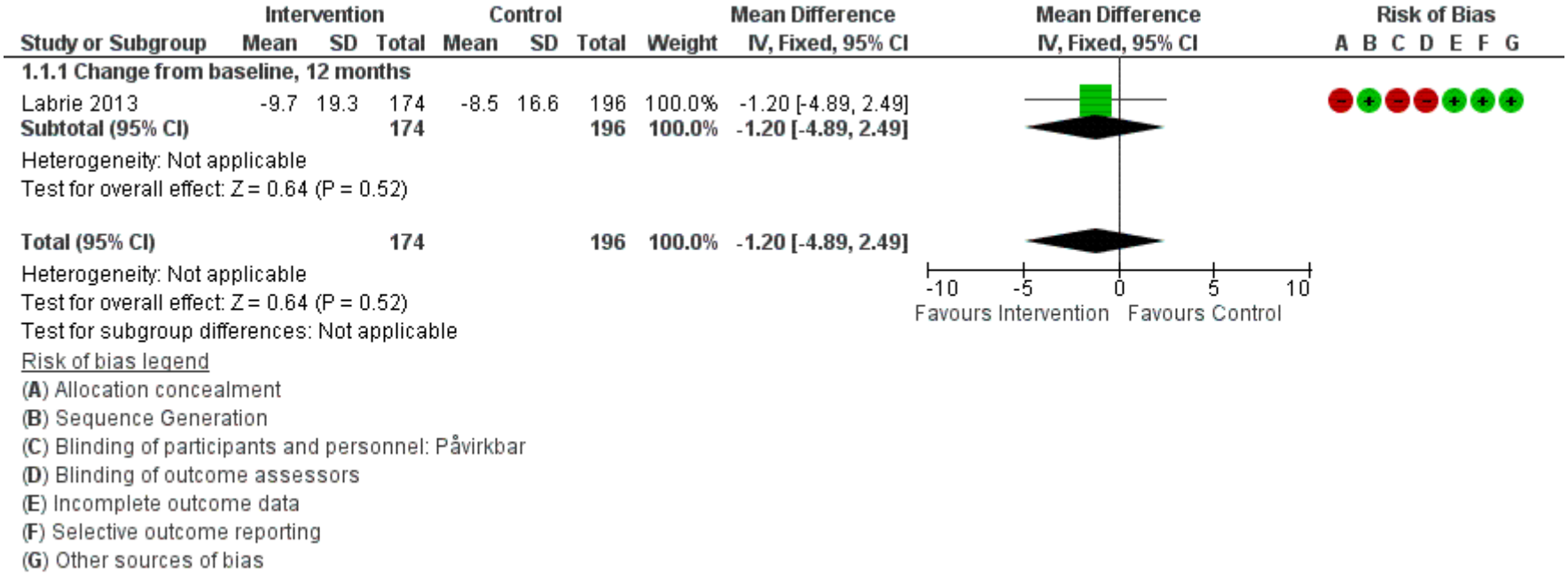
Data and analyses

1 Intervention vs Control

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Inkontinensrelateret livskvalitet - social functioning	1	370	Mean Difference (IV, Fixed, 95% CI)	-1.20 [-4.89, 2.49]
1.1.1 Change from baseline, 12 months	1	370	Mean Difference (IV, Fixed, 95% CI)	-1.20 [-4.89, 2.49]
1.2 Inkontinensrelateret livskvalitet - physical functioning	1	370	Mean Difference (IV, Fixed, 95% CI)	2.90 [-0.59, 6.39]
1.2.1 Change from baseline, 12 months	1	370	Mean Difference (IV, Fixed, 95% CI)	2.90 [-0.59, 6.39]
1.3 Patientoplevet effekt	1	369	Risk Ratio (IV, Fixed, 95% CI)	0.71 [0.63, 0.80]
1.3.1 12 months follow-up	1	369	Risk Ratio (IV, Fixed, 95% CI)	0.71 [0.63, 0.80]
1.4 Antal tilfælde af inkontinens	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable

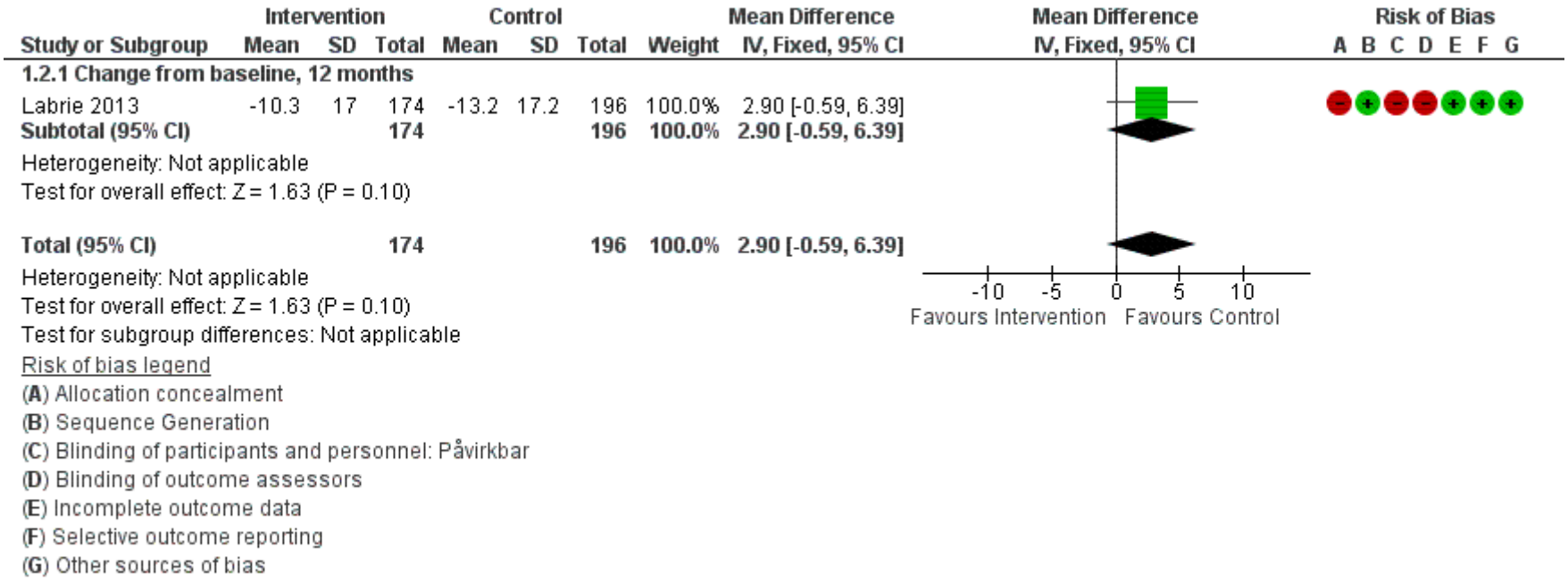
Figures

Figure 1 (Analysis 1.1)



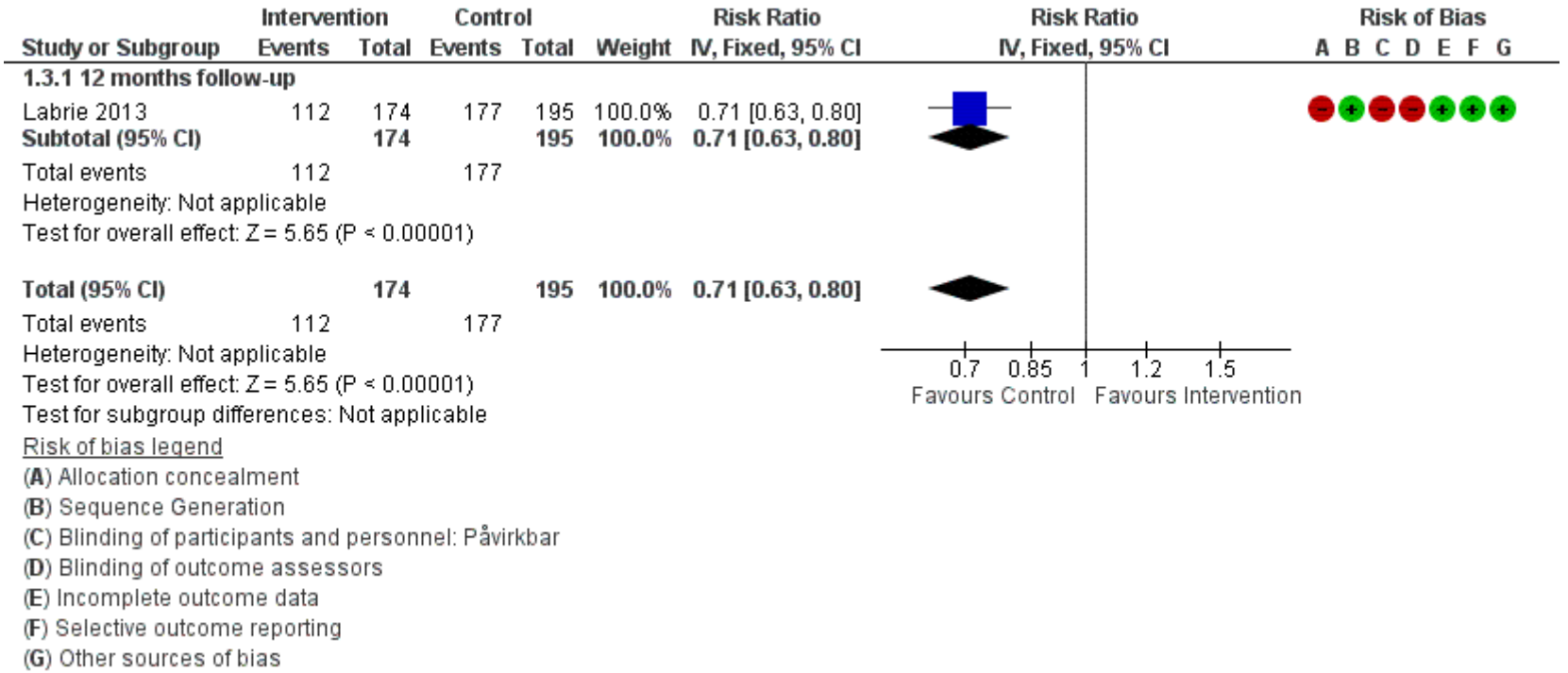
Forest plot of comparison: 1 Intervention vs Control, outcome: 1.1 Inkontinensrelateret livskvalitet - social functioning.

Figure 2 (Analysis 1.2)



Forest plot of comparison: 1 Intervention vs Control, outcome: 1.2 Inkontinensrelateret livskvalitet - physical functioning.

Figure 3 (Analysis 1.3)



Forest plot of comparison: 1 Intervention vs Control, outcome: 1.3 Patientoplevet effekt.