NKR 33 Urininkontinens, PICO 3: Bør kvinder med urininkontinens tilbydes behandling med et vaginalt hjælpemiddel?

Review information

Authors

Sundhedsstyrelsen[1]

[1]The Danish Health and Medicines Authority

Citation example: S. NKR 33 Urininkontinens, PICO 3: Bør kvinder med urininkontinens tilbydes behandling med et vaginalt hjælpemiddel? Cochrane Database of Systematic Reviews [Year], Issue [Issue].

Characteristics of studies

Characteristics of included studies

Cornu 2012

Methods	Prospective randomised parallel-group trial.
Participants	N = 55. Withdrawal = 14. Stress urinary incontinence (SUI) assessed by clinical examination (stress test) or mixed incontinence with predominant SUI. Mean age = 58.7 (range 29-88). Inclusion: Aged 18 or more, SUI assessed by clinical examination (stress test) or mixed incontinence with predominant SUI (at least 4 incontinence episodes per week), postmenopausal/contraception, no vaginal delivery in the past 2 months, no bladder/vaginal disease, no acute or recurrent urinary infection, no pelvic organ prolapse >stage II according to POPQ classification, no surgical intervention for SUI in the past 6 months, no drug treatment for UI in the last month, no pelvic floor muscle training underway Exclusion: None. Multi-centre, France.
Interventions	Use of intravaginal device (75NC007) for up to 24 hours a day for 14 days 1. 75NC007 (n = 29) 2. wearing no mechanical device (n = 26) 75NC007 is made of thermoplastic elastomer supplied in two sizes: medium and small. Inserted into the vagina with or without an applicator. It automatically locates beneath the urethra and bladder, removed by pulling string on cylindrical part of device. The device can be inserted by the woman and must be discarded and replaced with a new device after 24 hours

Outcomes	1. Incontinence Episode Frequency (IEF) according to bladder diaries. 2. Urinary Symptom Profile score 3. 24 hour pad weighing test 4. CONTILIFE questionnaire
Notes	Phase two data only analysed. Change from baseline scores were used for all measures Description + Risk of Bias assessment is from review by Lipp et al 2014

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computerised randomisation was centralised by the data coordinating centre
Allocation concealment (selection bias)	Low risk	Computerised randomisation was centralised by the data coordinating centre
Blinding of participants and personnel (performance bias)	Unclear risk	Not stated
Blinding of outcome assessment (detection bias)	Unclear risk	Not stated
Incomplete outcome data (attrition bias)	High risk	14/55 dropouts (25%), ITT analysis performed.
Selective reporting (reporting bias)	Low risk	Prespecified outcomes reported on, but the trial protocol not assessed
Other bias	Low risk	Study funded by B. Braun Medical SAS. Consultancy honoraria from B. Braun by one of the authors (S Mouly)

Nygaard 1995

Methods	Crossover RCT to examine the effects of Hodge pessary with support, a super tampon on urinary incontinence during exercise. Duration: three exercise sessions
Participants	N = 20. Withdrawal = 2. Stress incontinence by stress test. Age range = 33-73. Inclusion: History of exercise incontinence, physical ability to perform 40 minutes exercise and positive stress test. Exclusion: prolapse of uterus or vagina, stenotic vagina and pelvic mass. Single centre, Department of Obstetrics & Gynaecology, USA.

Interventions	All participated in each of 3 separate standardised exercise sessions: 1. wearing a Hodge pessary with support (n= 18). 2. wearing a Tampax super tampon (n= 18). 3. wearing no mechanical device (n= 18) The Hodge vaginal pessary is a ring, in this case with support, placed at the neck of the cervix and is plastic coated with wires that allow it to be shaped for different anatomies. The Tampax super tampon is placed in the vagina and is a commercially available tampon. The tampon string was 'hidden' as participants were blinded to treatment. Both devices were placed by the investigator
Outcomes	1. Pad weighing test. 2. Patient self reported discomfort
Notes	4 patients were continent during the control exercise despite positive stress test initially Description + Risk of Bias assessment is from review by Lipp et al 2014

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	'Women were randomly allocated by blocked randomization in groups of four'
Allocation concealment (selection bias)	Low risk	'blocked randomization in groups of four'
Blinding of participants and personnel (performance bias)	Low risk	Paticipants and outcome assessors were blinded to the intervention. It was unclear whether care providers were blinded
Blinding of outcome assessment (detection bias)	Low risk	Paticipants and outcome assessors were blinded to the intervention. It was unclear whether care providers were blinded
Incomplete outcome data (attrition bias)	Low risk	2 withdrew before the start of the study.
Selective reporting (reporting bias)	Low risk	Prespecified outcomes reported on, but the trial protocol not assessed
Other bias	Low risk	Participants formed both intervention and control group.

Footnotes

Characteristics of excluded studies

Footnotes

References to studies

Included studies

Cornu 2012

[Empty]

Nygaard 1995

[Empty]

Excluded studies

Data and analyses

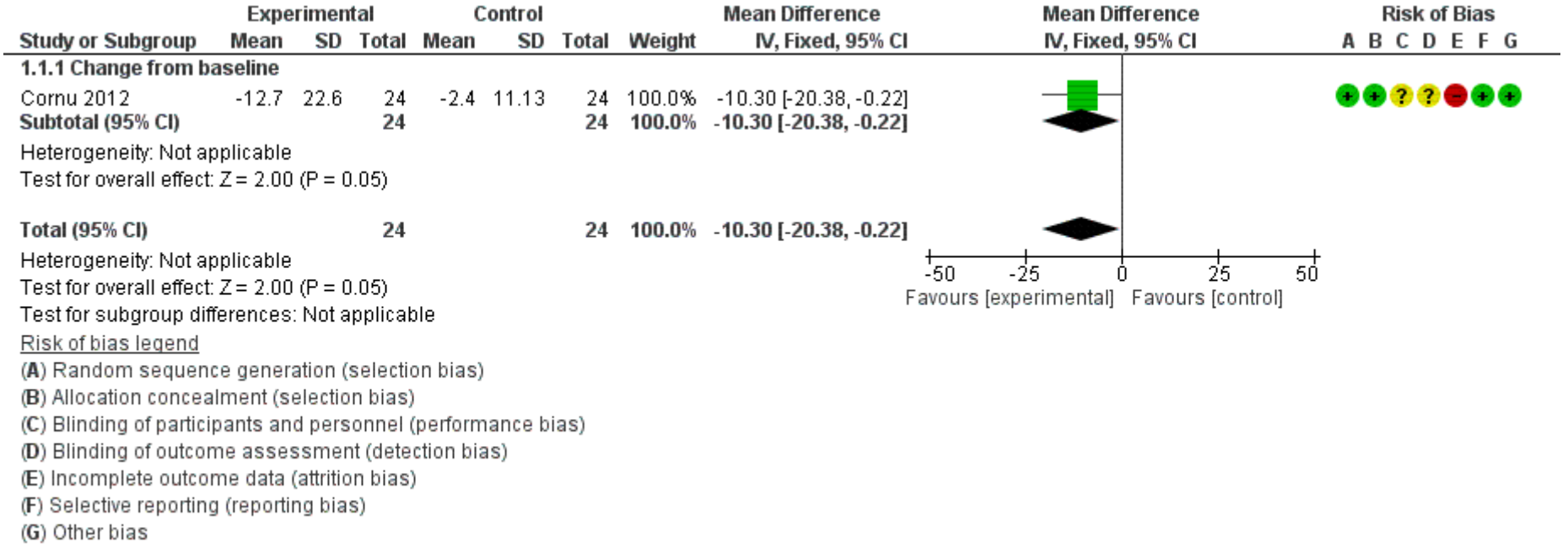
1 Intervention vs Control

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Inkontinensrelateret livskvalitet	1	48	Mean Difference (IV, Fixed, 95% CI)	-10.30 [-20.38, -0.22]
1.1.1 Change from baseline	1	48	Mean Difference (IV, Fixed, 95% CI)	-10.30 [-20.38, -0.22]
1.2 Patientoplevet effekt	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.3 Antal tilfælde af inkontinens	1	55	Mean Difference (IV, Fixed, 95% CI)	-24.10 [-49.60, 1.40]
1.4 Udflåd, Lugtgener	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable

1.5 Underlivssmerter/ubehag - antal med underlivssmerter	1	54	Risk Ratio (M-H, Fixed, 95% CI)	6.68 [0.40, 112.31]
1.5.1 End of use	1	54	Risk Ratio (M-H, Fixed, 95% CI)	6.68 [0.40, 112.31]
1.6 Frafald	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
1.7 Sår	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable

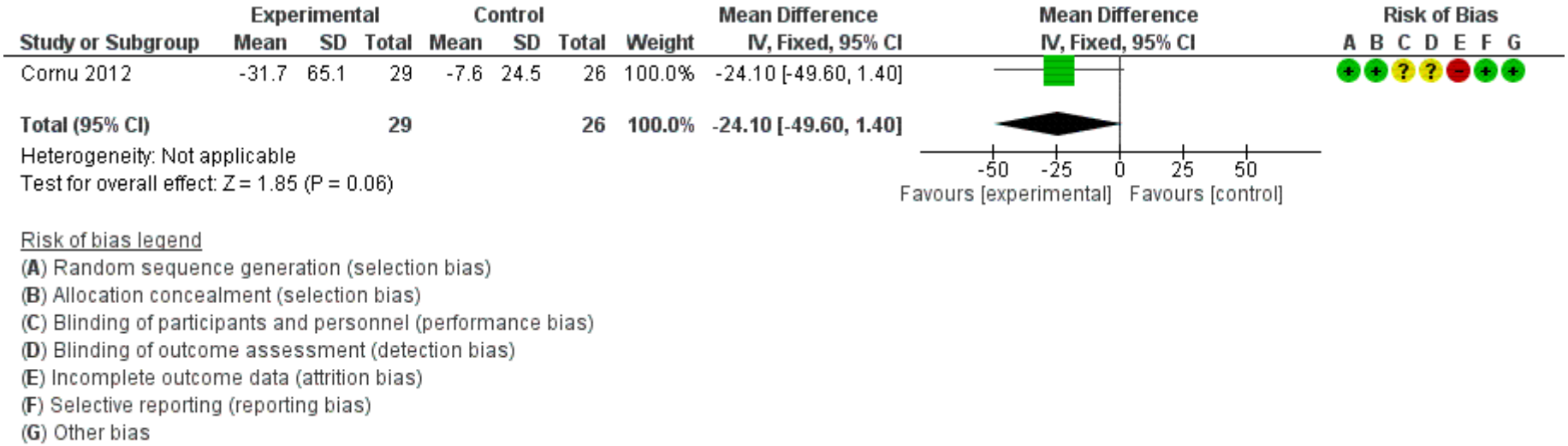
Figures

Figure 1 (Analysis 1.1)



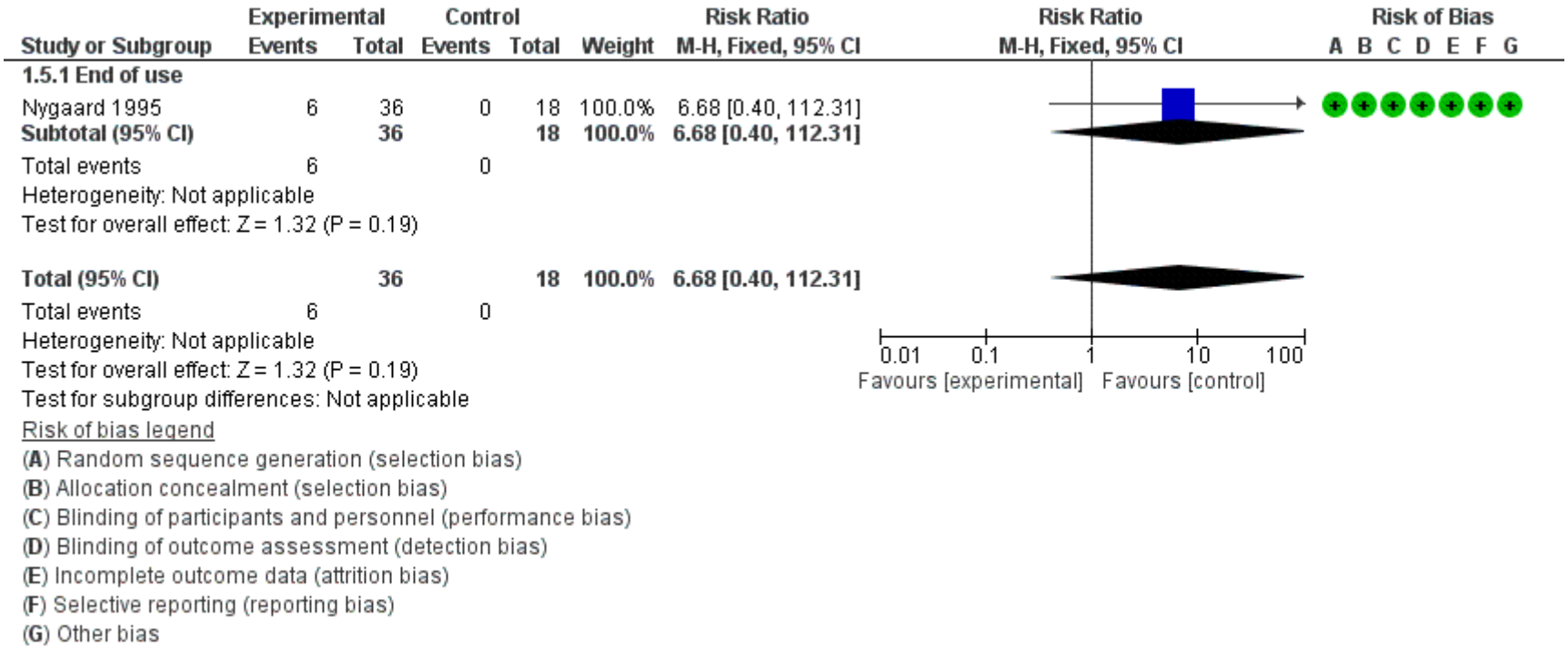
PICO 3: Forest plot of comparison: 1 Intervention vs Control, outcome: 1.1 Inkontinensrelateret livskvalitet.

Figure 2 (Analysis 1.3)



PICO 3: Forest plot of comparison: 1 Intervention vs Control, outcome: 1.3 Antal tilfælde af inkontinens.

Figure 3 (Analysis 1.5)



PICO 3: Forest plot of comparison: 1 Intervention vs Control, outcome: 1.5 Underlivssmerter, antal med underlivssmerter.