NKR 38: PICO 5, Sexologisk rådgivning

Review information

Authors

Sundhedsstyrelsen[1]

[1][Empty affiliation]

Citation example: S. NKR 38: PICO 5, Sexologisk rådgivning. Cochrane Database of Systematic Reviews [Year], Issue [Issue].

Characteristics of studies

Characteristics of included studies

Chambers 2015

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Intervention - Sexologisk rådgivning ● *Age - Mean (SD)*: 62.70 (6.8) ● *Number of men on ADT*: 0 ● *Number of men with prostatectomy*: 54 Kontrol - Vanlig behandling ● *Age - Mean (SD)*: OVERALL ● *Number of men on ADT*: 0 ● *Number of men with prostatectomy*: 53 **Included criteria:** Patients who were scheduled for or undergone surgery for prostate cancer within 12 months and their female partners:Study inclusion criteria were as follows: (a)newly diagnosed with localised prostate cancer and hav-ing radical prostatectomy OR less than 12 months post-surgery; (b) in a heterosexual cohabitating couple relation-ship; (c) able to read and speak English; (d) no previoushistory of head injury, dementia or psychiatric illness;and (e) no other concurrent cancer.

	Excluded criteria: Der foreligger ikke specifikke eksklusions kriterier udover det faktum at såfremt patienterne ikke overholder ovenstående inklusionskriterier, da er de ekskluderede **Pretreatment:** Ingen forskelle i de 3 grupper, hverken i de to interventionsgrupper eller i standardgruppen.
Interventions	**Intervention Characteristics** Intervention - Sexologisk rådgivning ● *Description*: Nurse counselling interventionThe nurse counselling followed principles of cognitive–behavioural sex and couples therapy with an adult learningapproach where couples self-selected goals [16,21].Content included education about prostate cancer, menopauseand sexuality; behavioural homework including increasingexpression of affection and non-demandingsexual touch; challenging negative beliefs about prostatecancer, ageing and sexuality; and helping the couplechoose a medical treatment for ED and integrating thisinto their sexual relationship. Additional componentstargeting the challenges of the early treatment phase(e.g. urinary incontinence, pain and sleep disturbance)were selected if relevant.The intervention was delivered by two experiencedprostate cancer nurse counsellors, who received additionaltraining. This included a 1 day workshop on communicatingwith couples and 7 hours of training with an experiencedclinical psychologist covering problem solving,decision support, working with couples, communicationand research protocols. ● *Follow up*: 12 mdr ● *Personel*: sygeplejerske Kontrol - Vanlig behandling ● *Description*: Couples in usual care received standard medical managementand a set of published patient education materials. ● *Follow up*: 12 mdr. ● *Personel*: ?
Outcomes	*Livskvalitet - kontinuert outcome EOT* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Not reported *Seksuel relateret livskvalitet - kontinuert outcome EOT* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Not reported *Tilfredshed med seksuel funktion - kontinuert outcome EOT* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Scale**: International Index of Erectile Function - ● **Range**: ? 0-75

	● **Unit of measure**: Points ● **Direction**: Higher is better ● **Data value**: Endpoint *Tilfredshed med seksuel funktion - Dikotomt outcome (antal tilfreds/antal i gruppe) EOT* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Not reported
Identification	**Sponsorship source:** National Health and Medical Research Council: This project was funded by the National Health and Medical Re-search Council (ID496001) and Andrology Australia. We gratefullyacknowledge the support of the Urological Society of Australia andNew Zealand; Mr Bill McHugh and Mr Spence Broughton as con-sumer advisors; Sylvia Burns and Brigid Hanley as prostate cancernurse advisors; and all of our peer support volunteers in the under-taking of this research. **Country:** Australia and New Zealand **Setting:** School of Applied Psychology, Griffith University, Brisbane, Australia **Comments:** NR **Authors name:** Suzanne K. Chambers **Institution:** School of Applied Psycology, Griffith University **Email:** chambers@griffith.edu.au **Address:** School of Applied Psychology,Griffith University, Qld 4222,Australia.
Notes	*Annamaria Giraldi* on 07/03/2016 03:23 **Select** Meget general psykosocial rådgivning, men der fokuseres bla på bivirkninger til behandlingen og der er rapporteret seksuelt endpoint

Risk of bias table

Bias	Authors' judgement	Support for judgement
Blinding of outcome assessors	High risk	Judgement Comment: Not possible to blind as participants fillout qustionaires
Sequence Generation	Low risk	Quote: "Randomisation occurred in blocks of 12, with each condition randomly generated four times within each block to ensure an unpredictable allocation sequence with equal numbers of couples in each group at the completion of each block." Judgement Comment: Det er lykkedes at finde beskrivelsen af randomiseringen.

Allocation concealment	Low risk	Quote: "This sequence was undertaken by the project manager and concealed from investigators." Judgement Comment: Se venligst fagkonsulentens svar. Jeg er enig.
Blinding of participants and personnel	High risk	Judgement Comment: Not possible to blind intervention
Incomplete outcome data	Low risk	Judgement Comment: Frafrald i de 3 grupper var fuldstændig ens. Outcome data burde derfor være sammenlignelige. Og der ser ikke ud til at være patienter eller outcomes der ikke kan redegøres for.
Selective outcome reporting	High risk	Judgement Comment: Quality of life outcomes are missing,
Other sources of bias	Unclear risk	Judgement Comment: Grundlæggende er det er problem, at over 700 kunne deltage i undersøgelsen, men at man får så mange gange nej til deltagelse, at man ender med en patientpopulation på 200. Det er en risiko for bias, at de mest "syge" har takket nej, og at der derfor bliver forvredne resultater.

Titta 2006

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Intervention - Sexologisk rådgivning ● *Age - Mean (SD)*: 63.5 (range 55-72) ● *Number of men on ADT*: NR ● *Number of men with prostatectomy*: na Kontrol - Vanlig behandling ● *Age - Mean (SD)*: Overall ● *Number of men on ADT*: na ● *Number of men with prostatectomy*: na **Included criteria:** Histological proved localized prostate cancer or mucle invasive bladder cancer, good preoperative sexual performance and in a stable heterosexual relationship for at least 6 months, and PGE1-responsive. **Excluded criteria:** NR **Pretreatment:** NR

Interventions	**Intervention Characteristics** Intervention - Sexologisk rådgivning ● *Description*: The participants in the sexual counselling group, with their female partner if in attendance,completed an unvalidated semi-structured questionnaire on sexual history and difficultiesand satisfaction with drug administration using the ICISexual counselling tailored (based on questionnaire response) to each participant involvedsix sessions over 18 months with a therapist to discuss drug administration and couplecommunication about sexual problems and psychodynamic-oriented sexual therapy to placetherapy within the couples' sexual behaviours and relationship (it is unclear if all maleparticipants had their female partner in attendance). Sessions were held at three, six, nine,12 and 18 months. The intervention also involved a telephone session aimed to identifythe lowest efficacious PGE1 home dose and to facilitate home sildenafil tests prior to followup sessions ● *Follow up*: We performed 18-month ambulatory follow-up(at 3, 6, 9, 12, and 18 months after surgery); ● *Personel*: Kontrol - Vanlig behandling ● *Description*: Participants were instructed to performICI twice a week. Before each assessment, tomeasurecompliance with ICI, participants were invited to attempt sexual intercourse after takingsildenafil 100mg one hour beforehand. Same as the Intervention group ● *Follow up*: ● *Personel*:
Outcomes	*Livskvalitet - kontinuert outcome EOT* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Not reported *Seksuel relateret livskvalitet - kontinuert outcome EOT* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Not reported *Tilfredshed med seksuel funktion - kontinuert outcome EOT* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Scale**: The International Index of Erection Function(IIEF) ● **Unit of measure**: points ● **Direction**: Higher is better ● **Notes**: Overall satisfaction IIEF mean scores p.269 *Tilfredshed med seksuel funktion - Dikotomt outcome (antal tilfreds/antal i gruppe) EOT*

	● **Outcome type**: DichotomousOutcome ● **Reporting**: Not reported
Identification	**Sponsorship source:** NR **Country:** Italy **Setting:** Single center **Comments:** **Authors name:** Matteo Titta **Institution:** University of Padova - department of Urology **Email:** matteo.titta@libero.it **Address:** via Giustiniani 2, Padova 35128, Italy
Notes	*Annamaria Giraldi* on 07/03/2016 03:57 **Select** Er lidt i tvivl om denne. Intervention er medicinsk behandling inkl rådgivning sammenlignet med medicinsk behandling. man kan argumentere for at medicinsk behandling er "treatment as usual" *Henning Keinke Andersen* on 09/03/2016 01:26 **Population** Det er problematisk at der ikke er nogen baseline værdier for dette studie. Ej heller data om hvor mange patienter med blærekræft der indgår i de to IV grupper. Principielt kunne samtlige 7 indgå i den samme gruppe. Så stratificering umuliggjort.Ideelt havde man undladt cystectomierne... *Henning Keinke Andersen* on 09/03/2016 01:26 **Population** Det er problematisk at der ikke er nogen baseline værdier for dette studie. Ej heller data om hvor mange patienter med blærekræft der indgår i de to IV grupper. Principielt kunne samtlige 7 indgå i den samme gruppe. Så stratificering umuliggjort.Ideelt havde man undladt cystectomierne... *Henning Keinke Andersen* on 09/03/2016 01:47 **Outcomes** Der er en betydelig drop-out rate i kontrol gruppen (-SC), og der er ikke angivet om analyser er udført efter ITT princip. Derfor har jeg valgt at anføre N - dropouts (8) fra kontrol-gruppen.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Blinding of outcome assessors	High risk	Judgement Comment: selfreported outcomes meauseres therefore not possible
Sequence Generation	Unclear risk	Judgement Comment: method not stated, and no protocol preceeds this study
Allocation concealment	Unclear risk	Judgement Comment: method not stated to permit a judgement
Blinding of participants and personnel	High risk	Judgement Comment: Participants were definitely not blinded to the IV, and as no methods nor attempts to describe blinding of personnel have been stated, I assume there is high risk of bias
Incomplete outcome data	High risk	Judgement Comment: There is a relative large number of dropouts in the control group (8/28), 28,6%, and no information on whether authors have used ITT principle
Selective outcome reporting	Low risk	Judgement Comment: The purpose was to evaluate the effect of sexual conselling on outcomes of injection of PGE1 in patients with confirmed ED. Three parametres were evaluated; efficacy, compliance and drop-out rates. All three reported. However it must be noted that there was no preceeding protocol to this study.
Other sources of bias	Unclear risk	Judgement Comment: It's a problem that the study mix two group of patients without stratification. No baseline values presented. In principle, all cystectomized patients could have been 'randomised' into one and the same group, maybe affecting compliance to the intervention, and wrong estimation of the efficacy of the IV.

Footnotes

References to studies

Included studies

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Excluded studies

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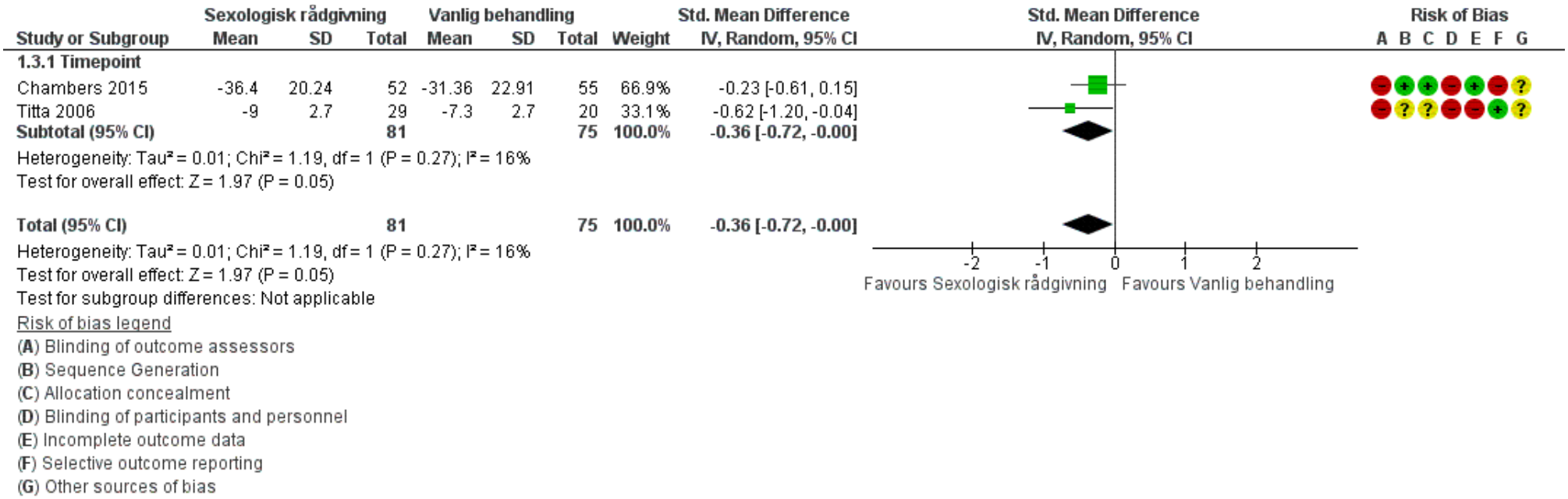
Data and analyses

1 Sexologisk rådgivning vs Vanlig behandling

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Livskvalitet - kontinuert outcome EOT	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.2 Seksuel relateret livskvalitet - kontinuert outcome EOT	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.3 Tilfredshed med seksuel funktion - kontinuert outcome EOT	2	156	Std. Mean Difference (IV, Random, 95% CI)	-0.36 [-0.72, -0.00]
1.3.1 Timepoint	2	156	Std. Mean Difference (IV, Random, 95% CI)	-0.36 [-0.72, -0.00]

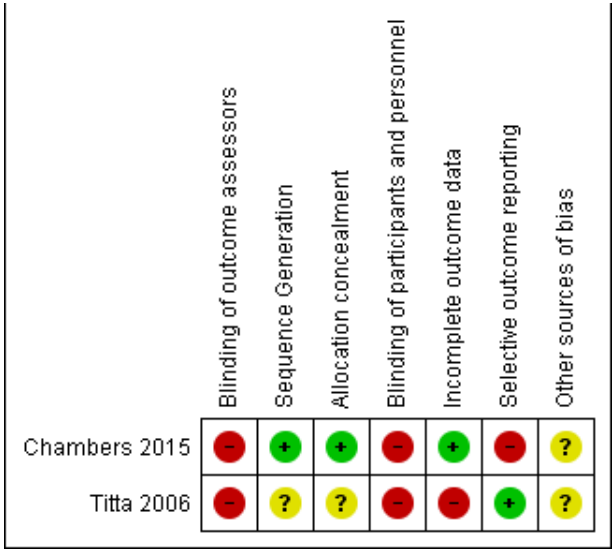
Figures

Figure 1 (Analysis 1.3)



Forest plot of comparison: 1 Sexologisk rådgivning vs Vanlig behandling, outcome: 1.3 Tilfredshed med seksuel funktion - kontinuert outcome EOT.

Figure 2



Risk of bias summary: review authors' judgements about each risk of bias item for each included study.