Glazener CM, Boachie C, Buckley B, Cochran C, Dorey G, Grant A, Hagen S, Kilonzo M, McDonald A, McPherson G, Moore K, Norrie J, Ramsay C, Vale L, N'Dow J. **Urinary incontinence in men after formal one-to-one pelvic-floor muscle training following radical prostatectomy or transurethral resection of the prostate (MAPS): two parallel randomised controlled trials.** Lancet 2011;378(9788):328-337.

Title

Urinary incontinence in men after prostate surgery (MAPS): two randomised controlled trials of formal one-to-one pelvic floor muscle training after radical prostatectomy or TURP.

Clinical Trial registration number: **ISRCTN87696430**

Link to published protocol: http://www.thelancet.com/protocol-reviews/07PRT-588

Authors with degrees

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Conflict of interest

Disclosure forms provided by the authors are available.

Abstract

Background

Urinary incontinence (UI) is common immediately after prostate surgery. Men are often advised to perform pelvic floor exercises, but evidence to support this is inconclusive. The Men After Prostate Surgery (MAPS) study consisted of two randomised controlled trials testing whether formal one-to-one pelvic floor muscle training reduces incontinence.

Methods

Men who were incontinent six weeks after radical prostatectomy (Trial 1) or transurethral resection of the prostate (TURP, Trial 2) were randomly assigned, using remote computer allocation, to four sessions with a Therapist over three months (intervention group, N=205, 220 respectively), or standard care and lifestyle advice only (control group, N=206, 222). The primary endpoints, collected via postal questionnaires, were participants' report of UI, and incremental cost per quality-adjusted life year (QALY) after 12 months. Outcome assessors were blinded to group assignment, but this was not possible for participants or caregivers. Recruitment was completed in September 2008.

Findings

In the intervention group in Trial 1 (radical prostatectomy), the UI rate at 12 months was not significantly different compared with the control group: 75.5% (148/196, intervention) versus 77.4% (151/195, control): absolute risk difference (RD) -1.9% [-10% to 6%].

In Trial 2 (TURP), the difference in the UI rate at 12 months was not statistically significant: 126/194, 64.9% in the intervention group versus 125/203, 61.5% in the control group, RD 3.4% [-6% to 13%]. Adjusting for minimisation factors or performing 'treatment received' analyses did not change these results in either trial. No adverse effects were reported.

In both trials, the intervention resulted in higher mean costs per patient (£180 and £209 respectively) but there was no evidence of an economically important difference in QALYs (differences: 0.002 and 0.00003).

Interpretation

In settings where information about pelvic floor exercise is currently widely available, one-to-one conservative physical therapy for men who are incontinent after prostate surgery is unlikely to be effective or cost-effective. The high rates of persisting incontinence after one year indicate a significant level of unrecognised and unmet need for management amongst these men.

Clinical Trial registration number: ISRCTN87696430

Funding

National Institute of Health Research, Health Technology Assessment (NIHR HTA) Programme.

Background

Radical prostatectomy (RP) is a key treatment in localised (early stage) prostate cancer and may be performed by open surgical approaches (retropubic or less frequently, perineal) or by minimally invasive techniques using laparoscopic or robotic technologies. Men with lower urinary tract symptoms secondary to benign prostatic enlargement (BPE) who fail to respond to medical therapy are treated surgically by transurethral resection of the prostate (TURP). Although newer technologies continue to emerge, TURP remains the standard and most cost effective approach.(1-3)

Both groups of men are at risk of post-operative urinary incontinence (UI). Radical prostatectomy is associated with high rates, recently reported at around 16% at one year following surgery.(4;5) TURP for BPE is associated with a much lower prevalence of incontinence, 9% initially(1) and around 1% at 12 months postoperatively,(6) but as the operation is performed much more frequently, this still presents a significant public health burden.

Effectiveness of pelvic floor muscle training (PFMT) in women is relatively well established.(7;8) Analogous advice to perform pelvic floor muscle exercises is a typical early management strategy for men with stress UI after prostatectomy, but successive updates of Cochrane reviews concluded that there was insufficient evidence to demonstrate its effectiveness and hence cost-effectiveness.(9) Men who undergo TURP more often have overactive bladder syndrome or urgency urinary incontinence: bladder training (BT) is often recommended for these conditions, again without clear evidence of efficacy.(10)

The Men After Prostate Surgery (MAPS) trial was designed to compare a structured PFMT program with BT if indicated delivered in four one-to-one sessions, with current care that does not include formally taught PFMT. The primary outcome was UI reported by men at 12 months after randomisation.

Methods

Study Design

Men having prostate surgery were identified in 34 centres in the United Kingdom (UK) and invited to receive a screening questionnaire three weeks after surgery. Those who reported UI in their 'Screening' questionnaire were invited to be randomised. However, formal trial entry was limited to those men who were still incontinent as judged by their response to a further 'Baseline' questionnaire. This second questionnaire also contributed wider descriptive data as reported in Table 1. The methods were identical in the two parallel but separate trials (Trial 1 after radical prostatectomy and Trial 2 after TURP for BPE).

Randomisation was by remote computer allocation using the randomisation service of the Centre for Healthcare Randomised Trials (CHaRT, Health Services Research Unit, University of Aberdeen). Allocation was minimised based on centre, age and pre-existing UI. The process was independent of all clinical collaborators.

Participants and therapists could not be masked to the intervention. Outcome assessment was by participant-completed questionnaires and diaries, and data were entered by clerical staff blinded to group allocation.

Participants

Men were eligible if they had UI at six weeks after surgery for either prostate cancer or BPE. Incontinence was defined as any positive response to either of two screening questions from the International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form (ICIQ-UI SF) questionnaire.(11) Participants needed to be able to comply with the intervention and complete study questionnaires. Men were excluded if they had been referred for or received formal PFMT. Men who had TURP for lower urinary tract symptoms secondary to advanced prostate cancer ('channel TURP') or were to receive radiotherapy were excluded as these factors might independently affect bladder function or continence mechanisms.

Interventions

All randomised men received a Lifestyle Advice Leaflet that described the influence of fluid intake, caffeine, diet, constipation, fitness, lifting, chest problems and urinary tract infections on continence. No information was provided in the leaflet about pelvic floor exercises or techniques for dealing with urgency symptoms. Men having radical prostatectomy are commonly told about pelvic floor exercises by health care professionals and information is also widely available in the public domain, for example through the internet. No attempt was

made to prevent any participants from accessing such information independently, or from leaflets if these were part of standard care.

Men randomised to the intervention groups were invited to attend four one-to-one sessions held over a period of three months with a therapist and received a supplementary MAPS Pelvic Floor Exercise leaflet, aimed at establishing a home exercise regimen. The therapists were either specialist continence physiotherapists or specialist continence or urology nurses. Therapists were provided with standardised training in the management of male UI based on PFMT and BT. Details of the intervention and its rationale are described elsewhere.(12) Men in the control groups were not invited to one-to-one therapy and did not receive the MAPS Pelvic Floor Exercise leaflet.

Outcome measurements

The primary clinical endpoint was men's report of UI at 12 months after randomisation using the ICIQ-UI SF, a simple validated patient-completed instrument.(11) Incontinence was defined as any positive response to either of two screening questions from the ICIQ-UI SF questionnaire:(11) 'how often do you leak urine?' and 'how much urine do you leak? The primary measure of cost-effectiveness was incremental cost per quality-adjusted life year (QALY). Data at trial entry were collected by postal questionnaires and a 3-day urinary diary, and outcome data were collected by postal questionnaire and diary at 3, 6, 9 and 12 months after randomisation.

Data collected included: urinary outcomes (using the ICIQ-UI SF which measures frequency and severity of incontinence, the effect of incontinence on quality of life as a composite ICIQ score, the presence and type of incontinence)(11); use of pads and catheters; daytime and night time urinary frequency and incontinence; quality of life (EQ-5D and SF-12); use of health services in both primary and secondary care; QALYs derived from responses to the EQ-5D (13); and frequency of the practice of pelvic floor exercises. Data were also collected on bowel outcomes (such as faecal incontinence) and sexual function (such as erectile function). Data for all other secondary outcomes will be published in a forthcoming HTA Monograph.

Sample size and statistical analysis

We identified that achieving a difference of 15% in incontinence rates would be of clinical importance. Therefore, we aimed to identify an absolute difference between intervention and control groups of 15% (85% versus 70%) in the number of men who were still incontinent at 12 months: 174 men per arm of each trial would be needed to give 90% power to detect a statistically significant difference at the 5% level. This would also allow the

detection of a difference equivalent to 0.30 of a standard deviation for continuous measures, such as quality of life, with 80% power. Allowing for dropout after enrolment, we planned to recruit 200 men per arm of each trial.

Descriptive statistics were tabulated reporting baseline demographics and clinical characteristics using means and standard deviations (SD). We did not impute missing values for non-responders to questionnaires or diaries.

Intention-to-treat analyses (men analysed according to randomised group) were used to compare the primary outcome at 12 months using general linear models adjusting for age and pre-existing UI and trial entry data where appropriate. For the binary outcomes, a Poisson link function was used to estimate relative risks and robust standard errors were used to estimate the confidence intervals.(14) A secondary comparison was conducted to estimate the efficacy of the treatment received using a latent variable approach ('adjusted treatment received') (15) by the method described by Nagelkerke and colleagues.(16)

Planned subgroup analyses explored the effect on the primary outcome of potentially effect-modifying factors, such as pre-surgery incontinence, type of incontinence and type of therapist (physiotherapy or nursing background). Stricter levels of statistical significance (2P<0.01) were sought, reflecting the exploratory nature of these analyses.

Economic evaluation

The economic evaluation was a within-trial analysis at 12 months after recruitment. Direct health service costs associated with each treatment were derived by combining data on use of health services with unit cost data extracted from the literature or from relevant sources(17-20) to generate the total cost for each participant. QALYs were generated using the responses to the EQ-5D.

Mean costs for both intervention and control groups were compared using unpaired t tests and linear regression adjusted for data measured at trial entry. Non-parametric bootstrapping was used to estimate confidence limits. Differences in mean QALYs were estimated in a similar fashion and incremental cost-effectiveness ratios calculated, where appropriate.

Ethical approval

This trial was approved by the Multicentre Research Ethics Committee, Edinburgh, Scotland, and overseen by an independent trial steering committee and a separate independent data monitoring committee. All men gave signed informed consent to being screened, and

separately to being randomised: the trial was conducted in accordance with the Declaration of Helsinki.

Funding

The trial was funded by the National Institute of Health Research, Health Technology Assessment (NIHR HTA) Programme (project number 03-14-03) and will be published in full in Health Technology Assessment. The funder of the study had no role in study design, data collection, data analysis, data interpretation or writing of the report.

Author information

All authors agreed to submit the manuscript to the Lancet. Data was accessible to CB, CR, MK, LV, GMcP.

Results

Between January 2005 and September 2008, in 34 UK centres, we approached 1158 men having a radical prostatectomy of whom 780 met the inclusion criteria for screening and 95% (742/780) responded to the screening questionnaire. We also approached 5986 men having a TURP: of 2838 eligible for screening, 91% (2588/2838) responded. Of those eligible for randomisation at around six weeks after surgery, 87% (411/472) entered the radical prostatectomy RCT (Trial 1) and 86% (442/512) entered the TURP RCT (Trial 2, Figures 1A and 1B). Follow up rates for the primary outcome were high (95% (391/411) in Trial 1 and 90% (397/442) in Trial 2). No important clinical or demographic differences were identified between the randomised groups at entry in either trial (Table 1).

Exercise behaviour and treatment compliance

Many men had prior knowledge of pelvic floor exercises (380/411, 92%in Trial 1 and 183/442, 41% in Trial 2): 84% (346/411) of men in the former and 21% (93/442) in the latter claimed to be performing them at six weeks after operation but before randomisation (Table 1). Of the men allocated to the intervention groups, 189/205 (92%) and 189/220 (86%) respectively attended at least one therapy visit, while 175 (85%) and 158 (72%) respectively attended until the final visit (Table 4, though not necessarily all four appointments). Men in the intervention groups were more likely to report carrying out exercises at 12 months (Table 2): Trial 1: 128/191 (67%) versus 95/189 (50%), adjusted risk ratio (RR) 1.30 [95% CI 1.09 to 1.53]; Trial 2: 122/188 (65%) versus 39/193 (20%), adjusted RR 3.20 [2.37 to 4.32].

Urinary outcomes after radical prostatectomy (Trial 1)

At 12 months, 75.5% (148/196) of the intervention group and 77.4% (151/195) of the control group reported some UI, absolute Risk Difference (RD) -1.9% [-10% to 6%], far short of the pre-specified target difference of 15% (Table 3). Adjusting for minimisation factors or performing a 'treatment received' analysis did not change these results (Table 3).

Urinary outcomes after TURP (Trial 2)

At 12 months, 64.9% (126/194) of the intervention group and 61.6% (125/203) of the control group reported some UI, absolute RD 3.4% [-6% to 13%], again, far short of the pre-specified target difference of 15% (Table 3). Adjusting for minimisation factors or performing a 'treatment received' analysis did not change these results (Table 3).

In both trials, there were no statistically significant differences in the prevalence of UI or the mean ICIQ score between the groups at any of the time points (Figures 2, 3), nor in any of the other outcomes related to urinary leakage (Table 2). The majority of the improvement in

continence occurred within three months of trial entry (Figure 3). There was no evidence of a difference between trial groups in effect on faecal incontinence or erectile function (data not shown), or in any of the pre-specified subgroups (Figure 4).

Economic evaluation after radical prostatectomy (Trial 1)

The UK NHS provides universal health care coverage with care free at the point of use. The total trial-related NHS cost (interventions and subsequent NHS care) per participant was statistically significantly higher in the intervention group (difference estimate £181 [95% CI £107 to £255], US$287, [95% CI $170 to $404]).(21) This was almost entirely due to the cost of the one-to-one PFMT. On average, QALYs were virtually identical in the trial groups (difference: 0.002, [95% CI -0.027 to 0.023]), giving a mean incremental cost per QALY of £90,510 (US$143,458).

Economic evaluation after TURP (Trial 2)

The trial-related cost (interventions and the cost of subsequent NHS care) per participant was statistically significantly higher in the intervention group (difference estimate £209 [95% CI £147 to £271], US$332 [95% CI $233 to $430]) almost entirely due to the cost of PFMT. On average, the QALYs were lower for the intervention although not statistically significantly (-0.00003 [95% CI -0.026 to 0.026]). On average the intervention was dominated because it was more costly and there was no evidence that it was any more effective.

Adverse effects

No adverse effects were reported by any participant in the trials.

Overall incontinence rates

At six weeks after radical prostatectomy, 59% (429/742) of men reported incontinence (Figure 1a). Amongst the 411 randomised incontinent men, the rate of incontinence a year later, irrespective of management and assuming non-responders were dry, was 73% (299 men incontinent, Table 2). Of the original total population of 742 men, this translates to 40% (299) with any incontinence a year after radical prostatectomy (20% (152) severe, 18% (131) wearing pads). As expected, the incontinence rate at trial entry six weeks following TURP was lower (17%: 442/2590, Figure 1b), but of the 442 randomised men, 57% (251) were still wet 12 months later (Table 2). Of the original total population of 2590 men, this translates to 10% (251/2590) still wet a year after TURP (4% (97/2590) severe, 2% (48/2590) wearing pads).

Discussion

Summary of main findings

While the provision of one-to-one PFMT for men with UI after radical prostatectomy or TURP increased the number of men reporting they were performing pelvic floor exercises (compared to the control groups) in both trials, it did not result in better short or medium term continence rates or quality of life. It was significantly more costly to the NHS. Hence, provision of one-to-one PFMT was not cost-effective for UI after either radical prostatectomy or TURP in the UK health care context, where advice to perform pelvic floor exercises is widely available through other less intensive channels, such as verbally, in leaflets or via internet.

Stress urinary incontinence was more common after radical prostatectomy and urgency incontinence more common after TURP (Table 1). We treated the two populations as separate trials because of these clinical differences. Nevertheless, we did not find evidence of benefit of the intervention for either clinical group.

Strengths and weaknesses

The findings were consistent and robust. Validated outcome measures were used to assess men's subjective report of UI and pad use: arguably, these subjective outcomes are most relevant to men.(11) Independent of the statistical methods used to compare the groups, all the outcome measures concurred in failing to find clinically or statistically significant differences between the randomised groups in each trial. Where statistically significant differences in costs were identified, these were due to the higher cost of providing the intervention rather than any consequences of the intervention.

The randomised groups were comparable at trial entry on clinical and demographic characteristics (Table 1). The radical prostatectomy trial (Trial 1) included 87% (411/472) of the men who were still incontinent six weeks later and therefore eligible to be randomised. Similarly, the TURP trial (Trial 2) included 86% (442/512) of the men still eligible. These high participation rates, and the large number of UK centres contributing participants, suggest that the findings are generalisable to men with UI after radical prostatectomy or TURP in settings where information on PFMT is already available and accessed by men.

All men were analysed in the groups to which they were randomised. Once randomised, participants were compliant in attending treatment and in returning their questionnaires, while the withdrawal rates were low. There was little evidence of systematic differential

dropout from the randomised groups (Figures 1a and b), and incontinence rates remained similar even if the men lost to follow up were all assumed to be dry. This provided reassurance that the outcome data were representative of the men included in the trials, and that bias from differential attrition was minimal. We chose not to use objective measures of incontinence, such as pad tests, because of practical difficulties but, more importantly, because we felt that the men's rating of their incontinence was the more important clinical outcome.(22) The data entry was by clerks blinded to randomisation thus minimising detection bias. It was not possible to blind men or therapists to trial allocation. Performance of PFMT was reported by the men themselves in questionnaires, and thus may have been biased if they over-reported how many times they were expected to perform them rather than their actual practice. This information could not be verified objectively but was only used as a measure of the effect of attendance at therapy sessions on changing behaviour.

It is important to note that MAPS has not tested whether PFMT itself is an effective and efficient way of reducing incontinence in men. In the current health care system where information about incontinence after prostatectomy and PFMT is freely available, it would not be possible to identify a control group which was unaware of pelvic floor exercises.

The methods of the economic analysis were rigorous and reproducible. Although not reported in full here, we assessed the importance of uncertainties surrounding estimates of costs, effects and cost-effectiveness, and the conclusions were robust to these.

Meaning of the study

Despite the men's high attendance rate at therapy visits and self-reported adherence to performance of PFMT at home, there was no corresponding difference in UI rates in either clinical group. In contexts where advice to men about PFM exercise is widely available, this may be sufficient to instruct men in PFMT and adopt other behaviours aimed at improving their post-surgery continence. This trial found no extra benefit from the provision of one-to-one sessions with a therapist focusing on pelvic floor exercises and other aspects of conservative care such as BT and lifestyle advice for incontinent men after radical prostatectomy or TURP. There was also no evidence to suggest a different conclusion in sub-groups of men, such as those with pre-surgery incontinence, different types of incontinence or those receiving PFMT from a trained continence nurse rather than a trained physiotherapist (Figure 4).

The frequency of delivery of the intervention (four times in three months combined with home exercises) is typical of standard care in the NHS, and most men attended for the whole 3-month therapy period (Table 4). While other trials have used different frequencies

of contact with therapists after surgery, ranging from five sessions over 16 weeks (23), to three times a week for three weeks (24), to weekly as long as the incontinence persisted (25), there is little evidence that more frequent contacts in men would result in better incontinence outcomes.(9) However, the aim of therapy in all trials is to teach and motivate the men to perform pelvic floor exercises every day: MAPS showed that this was successful in both trials (128/191, 67% performing them in Trial 1, and 122/188, 65% in Trial 2, compared with 95/189, 50% and 39/193, 20% in the respective control groups, Table 2). The timing of the intervention (starting six weeks postoperatively) was dictated by the terms of the HTA commissioning brief, but it could be argued that starting earlier or before surgery would result in unnecessary treatment of men who would become dry spontaneously.

Before randomisation, there were considerably fewer men in the control group in the TURP trial performing PFMT compared to amongst the men after radical prostatectomy. This probably reflects the information supplied to men and the attitudes of staff around the time of prostate surgery. The underlying risk of becoming incontinent was much lower in the TURP group, so it may be that health professionals were less likely to recommend PFMT to men after TURP and indeed only around 40% (183/442) of men were aware of them, compared to over 90% (380/411) of men after radical prostatectomy. As a result, men in the Radical group were four times more likely to be actually performing PFMT before randomisation. The type of incontinence may also have affected the chance of men performing PFMT: this is recommended for stress urinary incontinence but men after TURP were more likely to have urgency urinary incontinence (Table 1). However, interestingly, the men in the intervention groups in both trials were equally likely to report that they were still performing PFMT at 12 months (around 65%).

We have only limited information about putative mechanisms for any effects of the intervention through men's reports of performing exercises and their daily frequency. Although we did see differential effects on these, the intervention might also be expected to have wider effects, such as improving the quality rather than the quantity of pelvic floor muscle contractions, the use of broader behavioural techniques such as BT, and generic quality of life, which were not measured directly.

The incontinence rates extrapolated to the original populations of men having prostatectomy (20% severe after radical prostatectomy and 10% after TURP) concur with those reported in recent surveys of quality of life after radical prostatectomy(4;5) and the 9% reported in a meta-analysis of RCTs of TURP compared with alternative surgical treatments for BPE.(1)

Conclusions

In settings where information about pelvic floor exercises is widely available, the provision of one-to-one conservative therapy for men with UI after radical prostatectomy or TURP is unlikely to be effective or cost-effective. Resources currently allocated to providing such a service might be better used elsewhere.

Research is needed to identify the best management for the large numbers of men who are left with persistent severe incontinence after radical prostatectomy, particularly the place of continence surgery for men. Similarly, research is needed to identify the best management for men with persistent incontinence following TURP.

Acknowledgements

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Disclaimer

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Appendix

Recruiting sites and Principal Investigators (MAPS Study group)

References

Pages 34-35

Research in Context

Systematic Review Panel:

The trial was commissioned because a Cochrane review in 1999 concluded that there was no reliable evidence on which to base treatment. The most recent update of this review (9) found six relevant RCTs but was still inconclusive, and only one trial (26) provided 12-month outcomes. The addition of MAPS to this review resulted in a Risk Ratio for urinary incontinence at 12 months of 0.97, 95% CI 0.87 to 1.09. A subsequent search of the Cochrane Incontinence Review group's register of trials found one more small trial (27) that provided outcomes at 12 months, but it had unexplained differential dropout from the control group. The addition of this trial introduced significant heterogeneity and widened the confidence interval (RR 0.92, 95% CI 0.81 to 1.03).

Interpretation Panel:

MAPS is the largest trial of formal one-to-one PFMT amongst men with urinary incontinence after radical prostatectomy, and the only trial in men incontinent after TURP. Of two other trials after radical prostatectomy, the results of one (26) were consistent with MAPS with similar rates of incontinence in the two trials groups at 12 months; the other smaller trial (27) showed lower rates of incontinence in the PFMT group but with high differential loss to follow-up.

Contributions of Authors

Professor Cathryn Glazener (Professor of Health Services Research, Chief Investigator), was the chief investigator of the study: she had complete involvement and oversight of the study design, execution and data collection, and was responsible for the writing of the final report.

Mr Charles Boachie (Statistician, statistical analysis) contributed to the statistical analysis of the study and writing of the results and discussion chapters.

Dr Brian Buckley (Chairman, Bladder and Bowel Foundation, consumer representative) contributed to the consumer aspect of the study and writing the final report.

Mrs Claire Cochran (Trial Manager) was responsible for the day to day management of the study and also contributed to the final report writing.

Professor Grace Dorey (Professor, The University of the West of England, intervention specialist) contributed to the design of the intervention component of the study, and was also responsible for training the therapists recruited to provide the intervention to study participants.

Professor Adrian Grant (Director of Research, trialist) contributed to the overall study design and gave expert guidance on the final report writing.

Professor Suzanne Hagen (Programme Director, trial design) contributed to the design of the study and also to the choice and design of the outcomes measures.

Miss Mary Kilonzo (Research Fellow, health economics) contributed to the analysis of the health economics component of the study and also to the writing of the health economics chapters.

Mrs Alison McDonald (Senior Trial Manager, trialist) contributed to the design of the study, organised the authorisation of the study and contributed to the writing of the final report.

Mrs Gladys McPherson (Senior IT Manager, programming) designed the programming of the study database, data analysis and writing of the final report.

Professor Katherine Moore (Vice Dean, trialist and therapist perspective) contributed to the design of the therapy intervention and to the writing of the final report.

Professor John Norrie (Director of ChaRT) contributed to the design, running and interpretation of the study,

Dr Craig Ramsay (Healthcare Assessment Programme Director, HSRU, statistical analysis) contributed to the statistical analysis of the study and also to the writing of the results chapters.

Professor Luke Vale (Professor of Health Technology Assessment, HERU, health economics) contributed to the writing of the health economics chapters and to the interpretation of the health economics findings.

Professor James N'Dow (Professor of Urology, clinician) contributed his clinical expertise to the design of the study and to the final report writing.

Table 1 Characteristics of the groups at trial entry after Radical Prostatectomy and TURP

	Trial 1 Radical prostatectomy		Trial 2 TURP	
	Intervent. N=205	**Control N=206**	**Intervent. N=220**	**Control N=222**
Time of randomisation after surgery (weeks) *Mean (SD) n*	7.8 (2.4) 205	8.1(2.9) 206	8.1(3.1) 220	8.6 (3.5) 222
Age in years *Mean, (SD) n [MIN, MAX]*	62.4 (5.8) 205 [47, 76]	62.3 (5.6) 206 [47, 75]	68.2 (7.7) 220 [47, 90]	67.9 (8.1) 222 [45, 86]
BMI, *Mean (SD) n [Min, Max]*	25.9 (2.9) 197 [19.4, 39.5]	26.3 (3.3) 202 [18.0, 36.2]	27.1 (4.1) 217 [15, 48]	27.1 (4.7) 215 [17, 44]
TURP before index surgery *n/N (%)*	12/205 (6)	4/201 (2)	23/217 (11)	26/218 (12)
Number of men not able to achieve erection before prostate surgery *n/N (%)*	17/205 (8)	18/202 (9)	67/214 (31)	71/215 (33)
Leakage of urine before prostate surgery	14/205 (7)	13/206 (6)	95/195 (49)	102/205 (50)
ICIQ Score [b] *Mean (SD) n*	11.2 (4.3) 205	11.5 (4.5) 206	8.6 (4.1) 219	8.7 (4.3) 222
Number of men with severe incontinence *n/N (%)* [c]	188/205 (92)	189/206 (92)	145/220 (66)	144/222 (65)
Number of men using pads n/N (%)	180/205 (88)	176/205 (86)	71/220 (32)	70/217 (32)
Urinary frequency (per day) *Mean (SD) n*	7.4 (2.9) 187	7.9 (3.7) 192	8.6 (5.2) 205	7.9 (3.1) 199
Urinary frequency (per night) *Mean (SD) n*	2.2 (1.2) 199	2.5 (1.6) 202	2.7 (1.6) 215	2.5 (1.5) 212
Number of men reporting carrying out any pelvic	176/205 (86)	170/206 (83)	47/220 (21)	46/222 (21)

floor exercises before randomisation				
EQ-5D *Mean (SD) n*	0.8 (0.2) 200	0.8 (0.2) 206	0.8 (0.3) 213	0.8 (0.3) 213
SF-12 Mental *Mean (SD) n*	50.8 (10.5) 201	49.3 (10.7) 201	49.9 (10.4) 216	50.3 (10.4) 212
SF-12 Physical Mean (SD) n	42.7 (9.9) 201	41.8 (10.6) 201	42.7 (11.0) 216	43.2 (11.9) 212
Type of incontinence *n/N (%)*				
SUI	195/205 (95)	195/206 (95)	148/220 (67)	136/222 (61)
UUI	135/205 (66)	156/206 (76)	186/220 (85)	183/222 (82)
MUI (both)	132/205 (64)	151/206 (73)	129/220 (59)	112/222 (50)
Post-micturition leakage	166/205 (81)	170/206 (83)	151/220 (69)	156/222 (70)
Other type of incontinence	72/205 (35)	91/206 (44)	57/220 (26)	44/222 (20)
Type of operation	**Radical prostatectomy** *n/N (%)* [a]		***Type of operation***	**TURP** *n/N (%)*
	204	***205***		***220*** ***222***
Abdominal	157/204 (77)	161/205 (79)	Standard TURP	210/220 (95) 207/222 (93)
Perineal	6/204 (3)	4/205 (2)	Laser TURP [e]	10/220 (5) 15/222 (7)
Laparoscopic [d]	41/204 (20)	40/205 (20)		

[a] Information missing in 2 cases

[b] ICIQ Score: 0=none, 21 = maximum (worst) score

[c] Severe incontinence defined as at least once a day AND a moderate or large amount of leakage on ICIQ-UI SF.(11)

[d] No procedures were performed robotically

[e] No procedures involved holmium enucleation (HoLEP)

Numbers as reported. SUI = Stress Urinary Incontinence. UUI = Urgency Urinary Incontinence. MUI = Mixed Urinary Incontinence.

Table 2 Outcomes at 12 months

	Trial 1 Radical prostatectomy			Trial 2 TURP		
	Intervent. N=205	**Control N=206**	**RR or MD [95% CI] p-value**	**Intervent. N=220**	**Control N=222**	**RR or MD [95% CI] p-value**
Incontinence outcomes						
Men with any incontinence [a] *n/N (%)*	148/196 (76)	151/195 (77)	0.97 [0.87 to 1.09] 0.64	126/194 (65)	125/203 (62)	1.06 [0.91 to 1.23] 0.47
Men with severe incontinence [b] *n/N (%)*	74/196 (38)	78/195 (40)	0.93 [0.73 to 1.19] 0.58	48/194 (25)	49/203 (24)	1.03 [0.73 to 1.45] 0.88
ICIQ Score at 12 months [c] *Mean (SD) n*	4.9 (4.1) 196	5.4 (4.5) 195	-0.34 [-1.05 to 0.38] 0.36	3.9 (3.7) 194	4.0 (4.3) 203	-0.04 [-0.78 to 0.71] 0.93
Number of men using pads *n/N (%)*	63/196 (32)	68/195 (35)	0.91 [0.69 to 1.20] 0.50	24/194 (12)	24/203 (12)	1.05 [0.62 to 1.78] 0.86
Daytime urinary incontinence episodes from diaries	1.7 (3.3) 183	1.7 (2.7) 181	0.04 [-0.65 to 0.72] 0.92	1.4 (2.3) 175	1.2 (2.2) 179	0.21 [-0.30 to 0.72] 0.42

Mean (SD) n						
Nocturnal urinary incontinence episodes from diaries	0.2 (0.6) 183	0.2 (0.8) 181	-0.05 [-0.27 to 0.16] 0.62	0.4 (0.9), 175	0.4 (0.9) 179	0.03 [-0.25 to 0.32] 0.81
Mean (SD) n						
Type of incontinence						
n/N (%)						
SUI	138/196 (70)	128/195 (66)	1.071 [0.94 to 1.22] 0.31	71/194 (37)	76/203 (37)	0.91 [0.72 to 1.17] 0.48
UUI	61/196 (31)	83/195 (43)	0.782 [0.61 to 1.00] 0.05	72/194 (37)	82/203 (40)	0.92 [0.72 to 1.17] 0.48
MUI (both)	59/196 (30)	74/195 (38)	0.843 [0.65 to 1.10] 0.21	46/194 (24)	58/203 (29)	0.77 [0.56 to 1.06] 0.12
Post-micturition leakage	102/196 (52)	106/195 (54)	0.924 [0.73 to 1.17] 0.51	92/194 (47)	87/203 (43)	1.13 [0.92 to 1.39] 0.25
Other type of incontinence	39/196 (20)	39/195 (20)	1.099 [0.74 to 1.63] 0.64	18/194 (9)	17/203 (8)	1.04 [0.55 to 1.95] 0.91
Urinary frequency (per day)	6.8 (2.1) 184	7.0 (2.8) 183	-0.24 [-0.73 to 0.26] 0.35	7.0 (4.3) 177	6.5 (2.1) 178	0.35 [-0.40 to 1.09] 0.36
Mean (SD) n						

Urinary frequency (per night) *Mean (SD) n*	1.3 (1.0) 180	1.4 (1.0) 185	-0.04 [-0.21 to 0.14] 0.68	1.7 (1.4) 177	1.8 (1.6) 181	-0.05 [-0.30 to 0.20] 0.70
Number of men reporting carrying out any pelvic floor exercises *n/N (%)*	128/191 (67)	95/189 (50)	1.30 [1.09 to 1.53] 0.0027	122/188 (65)	39/193 (20)	3.20 [2.37 to 4.32] 0.0001
Number of men reporting carrying out PFMT every day *n/N (%)*	67/192 (35)	51/190 (27)	0.85 [0.67 to 1.07] 0.17	51/188 (27)	15/193 (8)	0.90 [0.86 to 0.93] 0.0001
Number of contractions per day *Mean (SD) n*	12 (20) 191	19 (79) 189	-7.80 [-19.43 to 3.901] 0.19	11 (23) 188	4 (16)193	6.88 [2.91 to -10.86] 0.0007
Number of men with faecal incontinence *n/N (%)*	16/193 (8)	11/193 (6)	1.56 [0.74 to 3.29] 0.24	40/192 (21)	36/199 (18)	1.06 [0.74 to 1.52] 0.75

Number of men unable to achieve any erection 12 months after prostate surgery[d] *n/N (%)*	105/189 (56)	105/190 (55)	0.99 [0.83 to 1.19] 0.95	52/177 (29)	43/178 (24)	0.82 [0.58 to 1.16] 0.27
EQ-5D	0.879 (0.209)	0.887 (0.176)	-0.013 [-0.047 to 0.021]	0.784 (0.249)	0.791 (0.266)	-0.005 [-0.040 to 0.031]
Mean (SD) n	187	189	0.46	177	189	0.79
SF-12 Mental	52.9 (9.1)	53.6 (7.9)	-0.9 [-2.6 to 0.9]	52.6 (9.2)	51.7 (10.5)	-0.039 [-1.708 to 1.630]
Mean (SD) n	190	191	0.32	188	193	0.96
SF-12 Physical	51.4 (8.3)	51.2 (8.4)	0.0 [-1.6 to 1.6]	44.5 (11.1)	44.0 (13.3)	0.385 [-1.216 to 1.986]
Mean (SD) n	190	191	0.97	188	193	0.64

[a] Incontinence defined as any positive response to either: (1) How often do you leak urine? or (2) How much urine do you usually leak (whether you wear protection or not)? Derived from ICIQ-UI SF questionnaire.(11)

[b] Severe incontinence defined as at least once a day AND a moderate or large amount of leakage, as defined by the men in responses to these two questions derived from ICIQ-UI SF questionnaire.(11)

[c] ICIQ Score derived from the sum of the first three questions in the ICIQ-UI SF questionnaire.(11)

[d] Defined as: 'no erection possible'.

Numbers as reported. Data from postal questionnaires unless otherwise indicated.

Effect size is Mean Difference (MD) or Risk Ratio (RR) adjusted for age, urinary incontinence before surgery and baseline values

Table 3 Primary outcome, urinary incontinence at 12 months: further statistical analyses

	Trial 1 Radical prostatectomy	Trial 2 TURP
Urinary incontinence at 12 months	**148/196 (75.5%, intervention)**	**126/194 (64.9%, intervention)**
n/N (%)	**151/195 (77.4%, control)**	**125/203 (61.5%, control)**
Absolute Risk Difference [95% CI]	**-1.9% [-10% to 6%]**	**3.4% [-6% to 13%]**
	Risk Ratio [95% CI] p-value	**Risk Ratio [95% CI] p-value**
Intention to treat		
Unadjusted analysis	0.98 [0.88 to 1.09] 0.72	1.05 [0.91 to 1.22] 0.49
Analysis adjusted for minimisation factors [a]	0.97 [0.87 to 1.09] 0.64	1.06 [0.91 to 1.23] 0.47
Adjusted treatment received [b]		
Unadjusted analysis	0.98 [0.88 to1.09] 0.70	1.05 [0.90 to 1.22] 0.55
Analysis adjusted for minimisation factors [a]	0.98 [0.88 to 1.09] 0.68	1.05 [0.90 to 1.22] 0.54

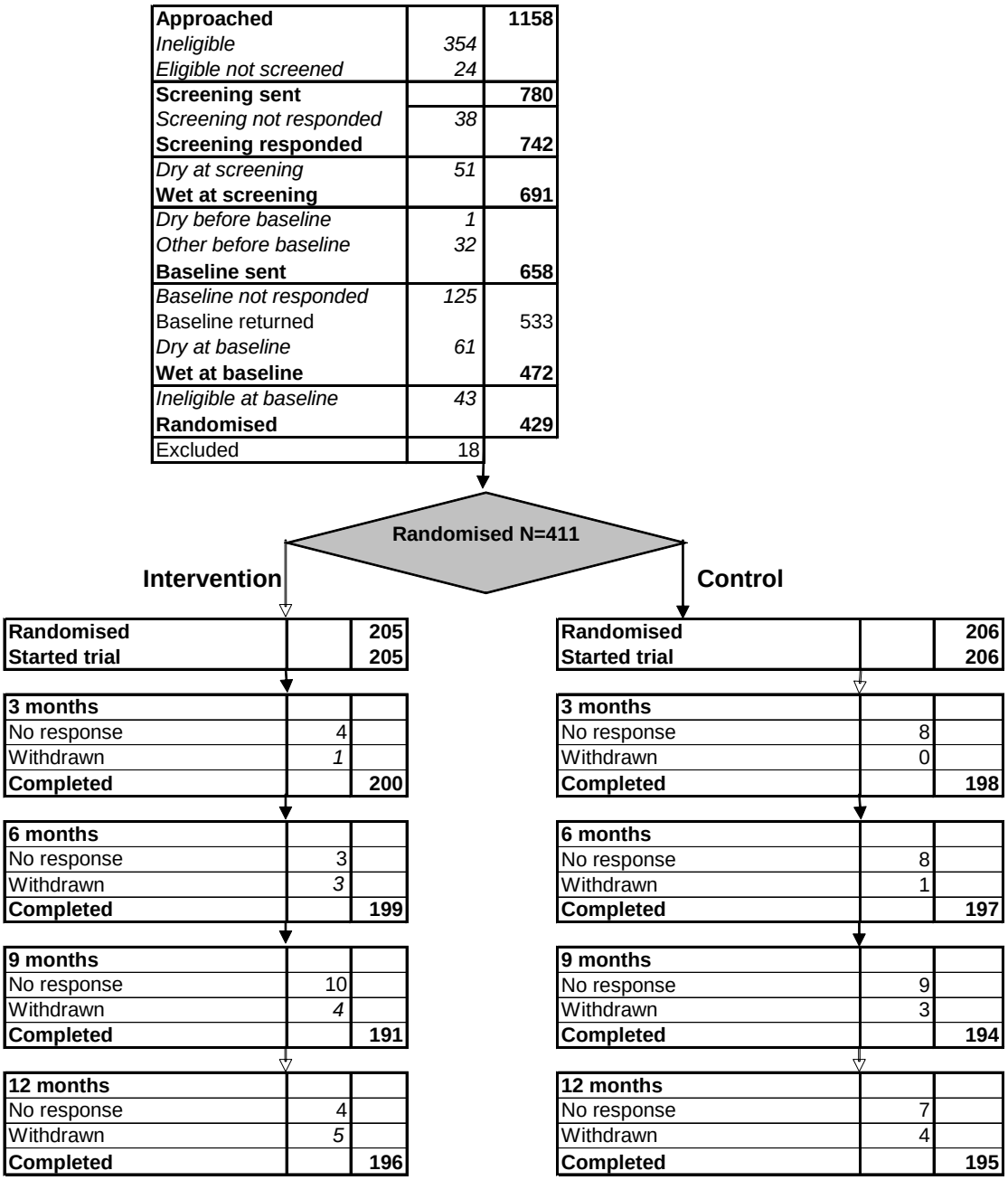
[a] Minimisation factors: age; pre-existing urinary incontinence

[b] Adjusted treatment received analysis, adjusted for actual attendance (compliance) with therapy

Table 4 Number of therapy visits attended by men randomised to the intervention groups

	First visit	Second visit	Third visit	Fourth visit
RADICAL(N=205)				
Number of men attending	189 (92%)	186 (91%)	177 (86%)	175 (85%)
TURP (N=220)				
Number of men attending	189 (86%)	173 (79%)	163 (74%)	158 (72%)

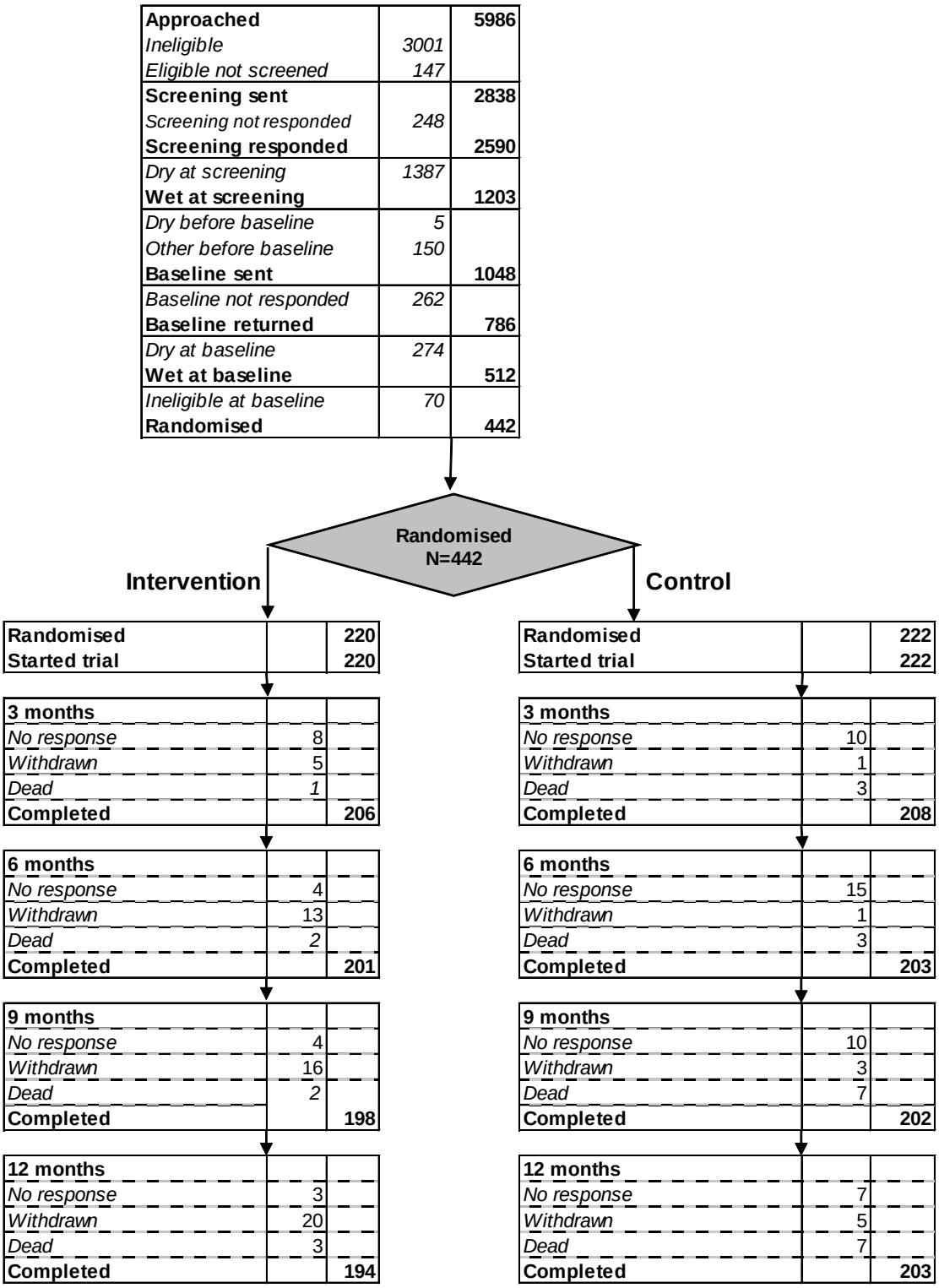
Figure 1a Flow Diagram Trial 1: Radical prostatectomy



[a] *Postrandomisation exclusion* — *Therapy was not available during some of the period of screening in one centre (18 men)*

Reasons for withdrawal after randomisation (Int / Control) — *Illness (1 / 1)*; *Dry (1 / 1)*; *No reason or other reason (3 / 2)*

Figure 1b Flow Diagram Trial 2: TURP

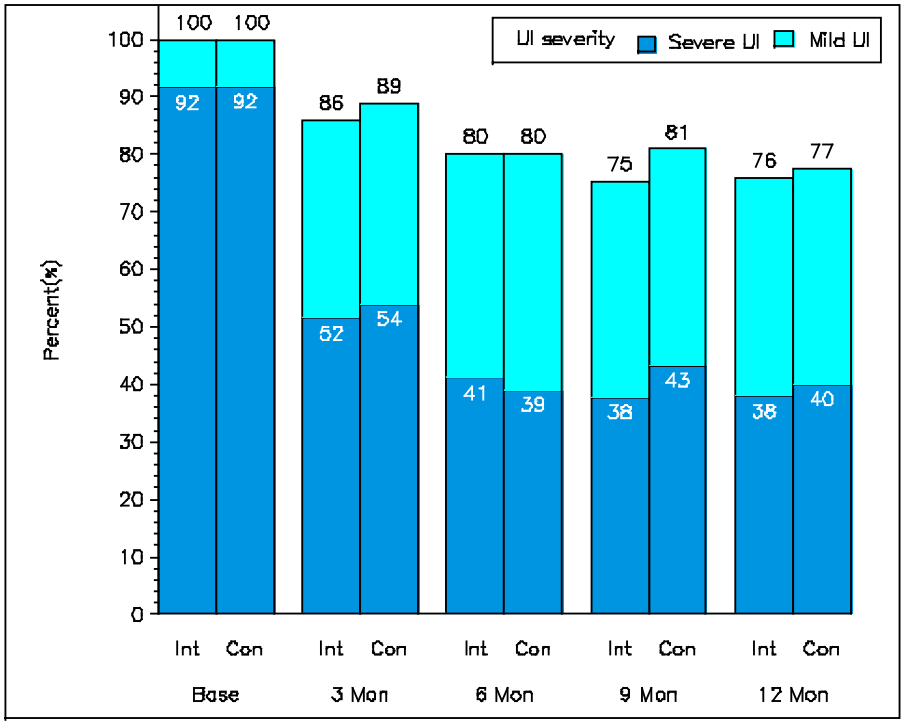


Reasons for withdrawal after randomisation (Int / Control):

Illness (6 / 2)
Dry (6 / 1)
No reason or other reason (8 / 2)

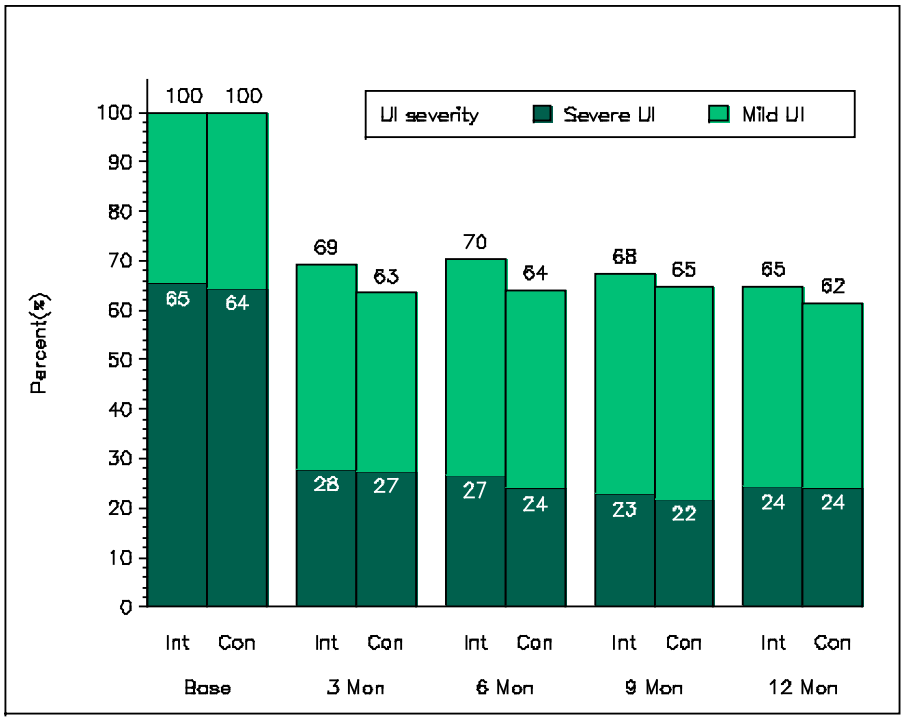
Figure 2 **Percentage of men incontinent and the severity* of the incontinence at each time point**

2a: Trial 1 Radical prostatectomy



Severe incontinence is defined as at least once a day AND a moderate or large amount of leakage. Int = Intervention group, Con = Control group

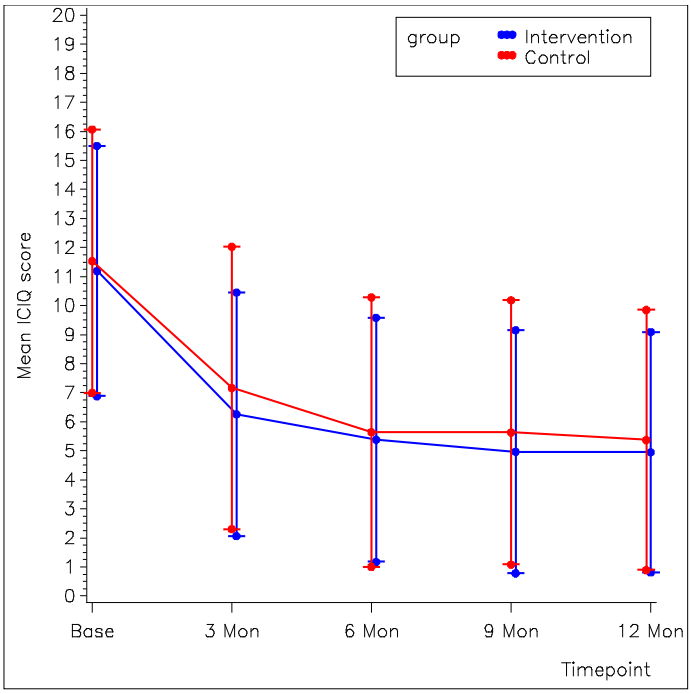
2b: Trial TURP



Severe incontinence is defined as at least once a day AND a moderate or large amount of leakage. Int = Intervention group, Con = Control group

Figure 3 **Mean ICIQ Score (+/- SD) at each time point** (a higher score = worse incontinence or effect on quality of life)

3a: **Trial 1 Radical prostatectomy**



3b: **Trial 2 TURP**

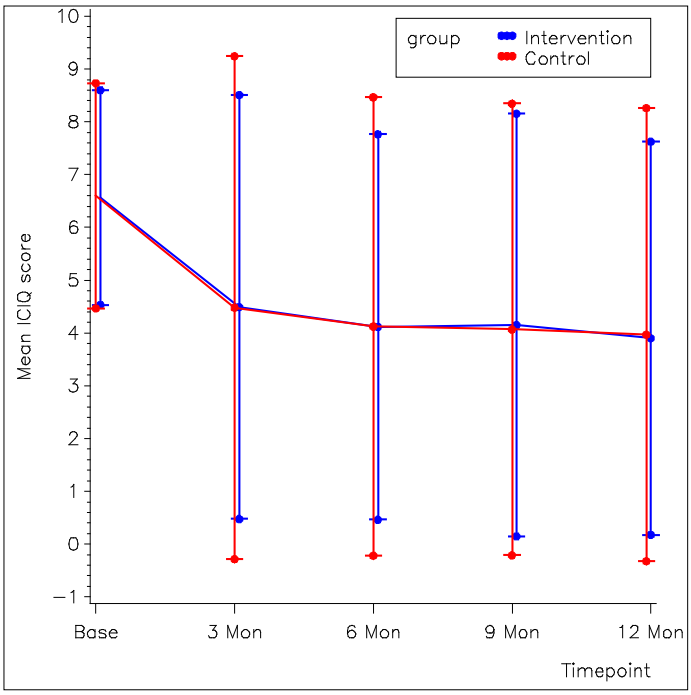
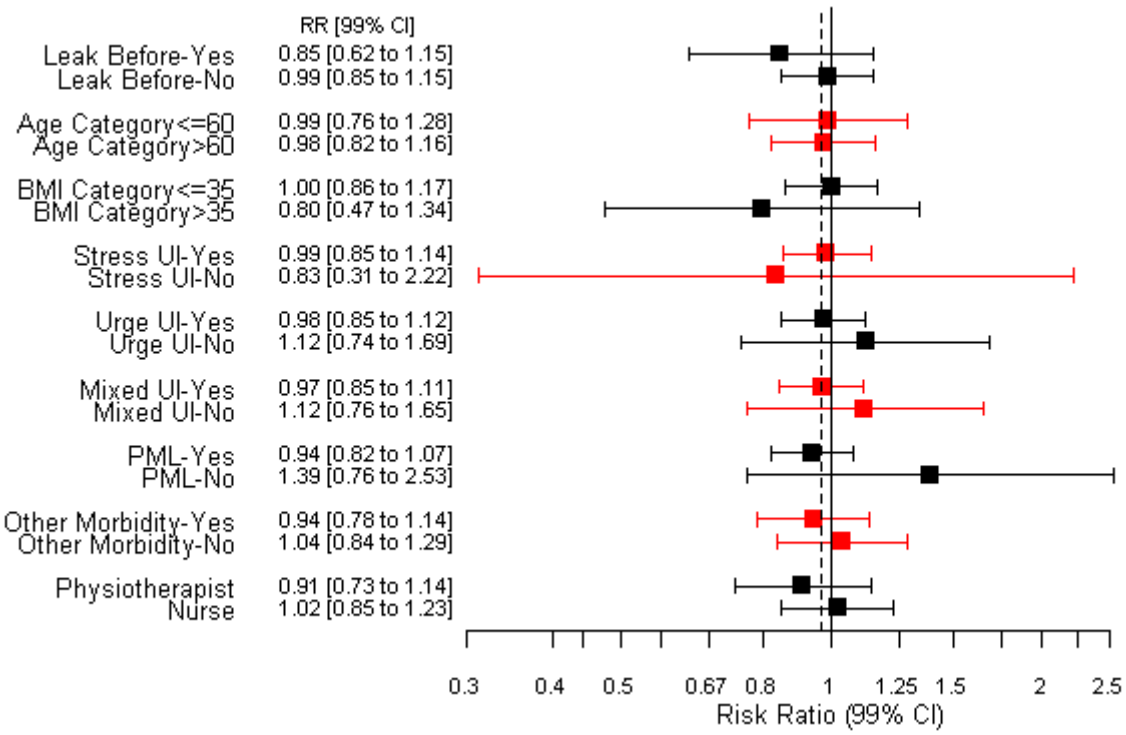


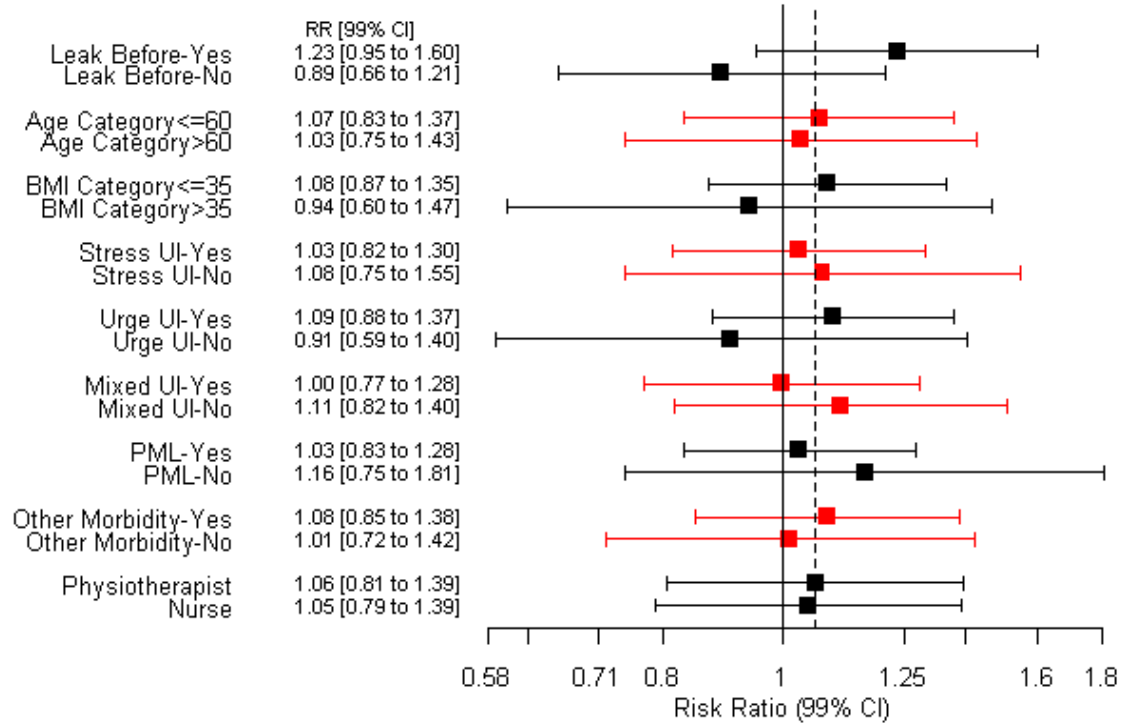
Figure 4 Forest plot of sub group analyses: Urinary Incontinence at 12 months

4a: Trial 1 Radical prostatectomy



Overall effect = 0.98, 95% CI [0.88 to 1.09], represented by broken line.

4b: Trial 2 TURP



Overall effect = 1.05, 95% CI [0.91 to 1.22], represented by broken line.

Explanatory footnote (for Figure 4):

Leak Before = urinary incontinence before surgery

Stress UI = stress urinary incontinence at randomisation after surgery

Urge UI = urgency urinary incontinence at randomisation after surgery

Mixed UI = both stress and urgency urinary incontinence after surgery

PML = post-micturition leakage at randomisation after surgery

Other morbidity = participant with other health problems at randomisation

Physiotherapist / Nurse = professional background of therapist delivering intervention

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