

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

Glazener, Cathryn; Boachie, Charles; Buckley, Brian; Cochran, Claire; Dorey, Grace; Grant, Adrian; Hagen, Suzanne; Kilonzo, Mary; McDonald, Alison; McPherson, Gladys

Published in:
Lancet

DOI:
[10.1016/S0140-6736\(11\)60751-4](https://doi.org/10.1016/S0140-6736(11)60751-4)

Publication date:
2011

Document Version
Author accepted manuscript

[Link to publication in ResearchOnline](#)

Citation for published version (Harvard):

Glazener, C, Boachie, C, Buckley, B, Cochran, C, Dorey, G, Grant, A, Hagen, S, Kilonzo, M, McDonald, A & McPherson, G 2011, '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*, vol. 378, no. 9788, pp. 328-337 . [https://doi.org/10.1016/S0140-6736\(11\)60751-4](https://doi.org/10.1016/S0140-6736(11)60751-4)

General rights

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

Take down policy

If you believe that this document breaches copyright please view our takedown policy at <https://edshare.gcu.ac.uk/id/eprint/5179> for details of how to contact us.

1 **Title**

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

4
5 Clinical Trial registration number: **ISRCTN87696430**

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

7
8 **Authors with degrees**

9 Cathryn Glazener PhD^{1*}, Charles Boachie MSc¹, Brian Buckley PhD², Claire Cochran MSc¹,
10 Grace Dorey PhD³, Adrian Grant DM⁴, Suzanne Hagen PhD⁵, Mary Kilonzo MSc⁶, Alison
11 McDonald MSc¹, Gladys McPherson MSc¹, Katherine Moore PhD⁷, John Norrie MSc(Econ)⁸,
12 Craig Ramsay PhD¹, Luke Vale PhD,⁶ James N'Dow FRCS(Urol)⁹

13
14 ¹Health Services Research Unit, University of Aberdeen, Foresterhill, Aberdeen, AB25 22D,
15 UK

16 ²Bladder and Bowel Foundation, SATRA Innovation Park, Kettering NN16 9JH, UK

17 ³Faculty of Health and Life Sciences, The University of the West of England, Bristol, BS16
18 1DD, UK

19 ⁴College of Life Sciences and Medicine, University of Aberdeen, Foresterhill, Aberdeen,
20 AB25 22D, UK

21 ⁵Nursing, Midwifery and Allied Health Professions Research Unit, Glasgow Caledonian
22 University, Cowcaddens Road, Glasgow, G4 0BA, UK

23 ⁶Health Economics Research Unit, University of Aberdeen, Foresterhill, Aberdeen, AB25
24 22D, UK

25 ⁷Faculty of Nursing, University of Alberta, Edmonton, Canada

26 ⁸Robertson Centre for Biostatistics, University of Glasgow, Boyd Orr Building University
27 Avenue, Glasgow, G12 8QQ, UK

28 ⁹Academic Urology Unit, University of Aberdeen, Foresterhill, Aberdeen, AB25 22D, UK

29

30 ***Corresponding author:** Cathryn Glazener

31

32 **Conflict of interest**

33 Disclosure forms provided by the authors are available.

34

35 **Abstract**

36 **Background**

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

41 **Methods**

42 Men who were incontinent six weeks after radical prostatectomy (Trial 1) or transurethral
43 resection of the prostate (TURP, Trial 2) were randomly assigned, using remote computer
44 allocation, to four sessions with a Therapist over three months (intervention group, N=205,
45 220 respectively), or standard care and lifestyle advice only (control group, N=206, 222).
46 The primary endpoints, collected via postal questionnaires, were participants' report of UI,
47 and incremental cost per quality-adjusted life year (QALY) after 12 months. Outcome
48 assessors were blinded to group assignment, but this was not possible for participants or
49 caregivers. Recruitment was completed in September 2008.

50 **Findings**

51 In the intervention group in Trial 1 (radical prostatectomy), the UI rate at 12 months was not
52 significantly different compared with the control group: 75.5% (148/196, intervention) versus
53 77.4% (151/195, control): absolute risk difference (RD) -1.9% [-10% to 6%].

54 In Trial 2 (TURP), the difference in the UI rate at 12 months was not statistically significant:
55 126/194, 64.9% in the intervention group versus 125/203, 61.5% in the control group, RD
56 3.4% [-6% to 13%]. Adjusting for minimisation factors or performing 'treatment received'
57 analyses did not change these results in either trial. No adverse effects were reported.

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

61 **Interpretation**

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

67

68 **Clinical Trial registration number:** ISRCTN87696430

69

70 **Funding**

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

73

74

75

76

77 **Background**

78

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

86

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

93

94 Effectiveness of pelvic floor muscle training (PFMT) in women is relatively well established.
95 (7;8) Analogous advice to perform pelvic floor muscle exercises is a typical early
96 management strategy for men with stress UI after prostatectomy, but successive updates of
97 Cochrane reviews concluded that there was insufficient evidence to demonstrate its
98 effectiveness and hence cost-effectiveness.(9) Men who undergo TURP more often have
99 overactive bladder syndrome or urgency urinary incontinence: bladder training (BT) is often
100 recommended for these conditions, again without clear evidence of efficacy.(10)

101

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

106

107

108

109

110

111

112

113

114

115 **Methods**

116

117 ***Study Design***

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

125

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

130

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

134

135 ***Participants***

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

145

146 ***Interventions***

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

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

155

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

164

165 ***Outcome measurements***

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

174

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

184

185 ***Sample size and statistical analysis***

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

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

194

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

198

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

206

207 Planned subgroup analyses explored the effect on the primary outcome of potentially effect-
208 modifying factors, such as pre-surgery incontinence, type of incontinence and type of
209 therapist (physiotherapy or nursing background). Stricter levels of statistical significance
210 ($2P < 0.01$) were sought, reflecting the exploratory nature of these analyses.

211

212 ***Economic evaluation***

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

218

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

224

225 ***Ethical approval***

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

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

231

232 ***Funding***

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

237

238 ***Author information***

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

241

242

243

244

245

246

247 **Results**

248

249 Between January 2005 and September 2008, in 34 UK centres, we approached 1158 men
250 having a radical prostatectomy of whom 780 met the inclusion criteria for screening and 95%
251 (742/780) responded to the screening questionnaire. We also approached 5986 men having
252 a TURP: of 2838 eligible for screening, 91% (2588/2838) responded. Of those eligible for
253 randomisation at around six weeks after surgery, 87% (411/472) entered the radical
254 prostatectomy RCT (Trial 1) and 86% (442/512) entered the TURP RCT (Trial 2, Figures 1A
255 and 1B). Follow up rates for the primary outcome were high (95% (391/411) in Trial 1 and
256 90% (397/442) in Trial 2). No important clinical or demographic differences were identified
257 between the randomised groups at entry in either trial (Table 1).

258

259 ***Exercise behaviour and treatment compliance***

260 Many men had prior knowledge of pelvic floor exercises (380/411, 92% in Trial 1 and
261 183/442, 41% in Trial 2): 84% (346/411) of men in the former and 21% (93/442) in the latter
262 claimed to be performing them at six weeks after operation but before randomisation (Table
263 1). Of the men allocated to the intervention groups, 189/205 (92%) and 189/220 (86%)
264 respectively attended at least one therapy visit, while 175 (85%) and 158 (72%) respectively
265 attended until the final visit (Table 4, though not necessarily all four appointments). Men in
266 the intervention groups were more likely to report carrying out exercises at 12 months (Table
267 2): Trial 1: 128/191 (67%) versus 95/189 (50%), adjusted risk ratio (RR) 1.30 [95% CI 1.09
268 to 1.53]; Trial 2: 122/188 (65%) versus 39/193 (20%), adjusted RR 3.20 [2.37 to 4.32].

269

270 ***Urinary outcomes after radical prostatectomy (Trial 1)***

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

275

276 ***Urinary outcomes after TURP (Trial 2)***

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

281

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

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

288

289 ***Economic evaluation after radical prostatectomy (Trial 1)***

290 The UK NHS provides universal health care coverage with care free at the point of use. The
291 total trial-related NHS cost (interventions and subsequent NHS care) per participant was
292 statistically significantly higher in the intervention group (difference estimate £181 [95% CI
293 £107 to £255], US\$287, [95% CI \$170 to \$404]).(21) This was almost entirely due to the
294 cost of the one-to-one PFMT. On average, QALYs were virtually identical in the trial groups
295 (difference: 0.002, [95% CI -0.027 to 0.023]), giving a mean incremental cost per QALY of
296 £90,510 (US\$143,458).

297

298 ***Economic evaluation after TURP (Trial 2)***

299 The trial-related cost (interventions and the cost of subsequent NHS care) per participant
300 was statistically significantly higher in the intervention group (difference estimate £209 [95%
301 CI £147 to £271], US\$332 [95% CI \$233 to \$430]) almost entirely due to the cost of PFMT.
302 On average, the QALYs were lower for the intervention although not statistically significantly
303 (-0.00003 [95% CI -0.026 to 0.026]). On average the intervention was dominated because it
304 was more costly and there was no evidence that it was any more effective.

305

306 ***Adverse effects***

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

308

309 ***Overall incontinence rates***

310 At six weeks after radical prostatectomy, 59% (429/742) of men reported incontinence
311 (Figure 1a). Amongst the 411 randomised incontinent men, the rate of incontinence a year
312 later, irrespective of management and assuming non-responders were dry, was 73% (299
313 men incontinent, Table 2). Of the original total population of 742 men, this translates to 40%
314 (299) with any incontinence a year after radical prostatectomy (20% (152) severe, 18% (131)
315 wearing pads). As expected, the incontinence rate at trial entry six weeks following TURP
316 was lower (17%: 442/2590, Figure 1b), but of the 442 randomised men, 57% (251) were still
317 wet 12 months later (Table 2). Of the original total population of 2590 men, this translates to
318 10% (251/2590) still wet a year after TURP (4% (97/2590) severe, 2% (48/2590) wearing
319 pads).

320

321

322 **Discussion**

323

324 ***Summary of main findings***

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

333

334

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

339

340 ***Strengths and weaknesses***

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

348

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

356

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

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

372

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

377

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

381

382 ***Meaning of the study***

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

394

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

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

408
409 Before randomisation, there were considerably fewer men in the control group in the TURP
410 trial performing PFMT compared to amongst the men after radical prostatectomy. This
411 probably reflects the information supplied to men and the attitudes of staff around the time of
412 prostate surgery. The underlying risk of becoming incontinent was much lower in the TURP
413 group, so it may be that health professionals were less likely to recommend PFMT to men
414 after TURP and indeed only around 40% (183/442) of men were aware of them, compared
415 to over 90% (380/411) of men after radical prostatectomy. As a result, men in the Radical
416 group were four times more likely to be actually performing PFMT before randomisation.
417 The type of incontinence may also have affected the chance of men performing PFMT: this
418 is recommended for stress urinary incontinence but men after TURP were more likely to
419 have urgency urinary incontinence (Table 1). However, interestingly, the men in the
420 intervention groups in both trials were equally likely to report that they were still performing
421 PFMT at 12 months (around 65%).

422
423 We have only limited information about putative mechanisms for any effects of the
424 intervention through men's reports of performing exercises and their daily frequency.
425 Although we did see differential effects on these, the intervention might also be expected to
426 have wider effects, such as improving the quality rather than the quantity of pelvic floor
427 muscle contractions, the use of broader behavioural techniques such as BT, and generic
428 quality of life, which were not measured directly.

429 The incontinence rates extrapolated to the original populations of men having prostatectomy
430 (20% severe after radical prostatectomy and 10% after TURP) concur with those reported in
431 recent surveys of quality of life after radical prostatectomy(4;5) and the 9% reported in a
432 meta-analysis of RCTs of TURP compared with alternative surgical treatments for BPE.(1)

433

434 **Conclusions**

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

439

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

444

445

446 **Acknowledgements**

447 The MAPS study group would like to thank all the men who willingly participated in the
448 MAPS trial and completed their questionnaires, diaries and attended their therapy
449 appointments. We are also very grateful to the staff at each of our centres for recruiting and
450 motivating our participants.

451

452 Thanks to the MAPS Study Office staff (Louise Campbell, Diane Collins, Janice Cruden and
453 Julie Murdoch) for administration of the trial.

454

455 **Disclaimer**

456 The trial was funded by the National Institute of Health Research Health Technology
457 Assessment Programme, Project number 03-14-03. HSRU, HERU and NMAHP RU are
458 funded by the Chief Scientist Office of the Scottish Government Health Directorates.
459 However, the views expressed in this publication are those of the authors and not
460 necessarily those of the funding bodies or the Department of Health, UK. The authors
461 accept full responsibility for the research.

462

463 **Appendix**

464 Recruiting sites and Principal Investigators (MAPS Study group)

465

466 **References**

467 Pages 34-35

468

469 **Research in Context**

470

471 **Systematic Review Panel:**

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

481

482

483 **Interpretation Panel:**

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

490

491

492

493 **Contributions of Authors**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

529 Professor James N'Dow (Professor of Urology, clinician) contributed his clinical expertise to
530 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) <i>Mean (SD) n</i>	7.8 (2.4) 205	8.1(2.9) 206	8.1(3.1) 220	8.6 (3.5) 222
Age in years <i>Mean, (SD) n [MIN, MAX]</i>	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, <i>Mean (SD) n [Min, Max]</i>	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 <i>n/N (%)</i>	12/205 (6)	4/201 (2)	23/217 (11)	26/218 (12)
Number of men not able to achieve erection before prostate surgery <i>n/N (%)</i>	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 <i>Mean (SD) n</i>	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 <i>n/N (%)</i> ^c	188/205 (92)	189/206 (92)	145/220 (66)	144/222 (65)
Number of men using pads <i>n/N (%)</i>	180/205 (88)	176/205 (86)	71/220 (32)	70/217 (32)
Urinary frequency (per day) <i>Mean (SD) n</i>	7.4 (2.9) 187	7.9 (3.7) 192	8.6 (5.2) 205	7.9 (3.1) 199
Urinary frequency (per night) <i>Mean (SD) n</i>	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 (%)		Type of operation	TURP n/N (%)	
	^a				
		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 <i>n/N (%)</i>	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 <i>n/N (%)</i>	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 <i>Mean (SD) n</i>	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 <i>n/N (%)</i>	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

<i>Mean (SD) n</i>							
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
<i>Mean (SD) n</i>							
Type of incontinence							
<i>n/N (%)</i>							
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	
<i>Mean (SD) n</i>							



Urinary frequency (per night) <i>Mean (SD) n</i>	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 <i>n/N (%)</i>	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 <i>n/N (%)</i>	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 <i>Mean (SD) n</i>	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 <i>n/N (%)</i>	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 <i>n/N (%)</i>	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 <i>Mean (SD) n</i>	0.879 (0.209) 187	0.887 (0.176) 189	-0.013 [-0.047 to 0.021] 0.46	0.784 (0.249) 177	0.791 (0.266) 189	-0.005 [-0.040 to 0.031] 0.79
SF-12 Mental <i>Mean (SD) n</i>	52.9 (9.1) 190	53.6 (7.9) 191	-0.9 [-2.6 to 0.9] 0.32	52.6 (9.2) 188	51.7 (10.5) 193	-0.039 [-1.708 to 1.630] 0.96
SF-12 Physical <i>Mean (SD) n</i>	51.4 (8.3) 190	51.2 (8.4) 191	0.0 [-1.6 to 1.6] 0.97	44.5 (11.1) 188	44.0 (13.3) 193	0.385 [-1.216 to 1.986] 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
<i>Intention to treat</i>		
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
<i>Adjusted treatment received</i> ^b		
Unadjusted analysis	0.98 [0.88 to 1.09] 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

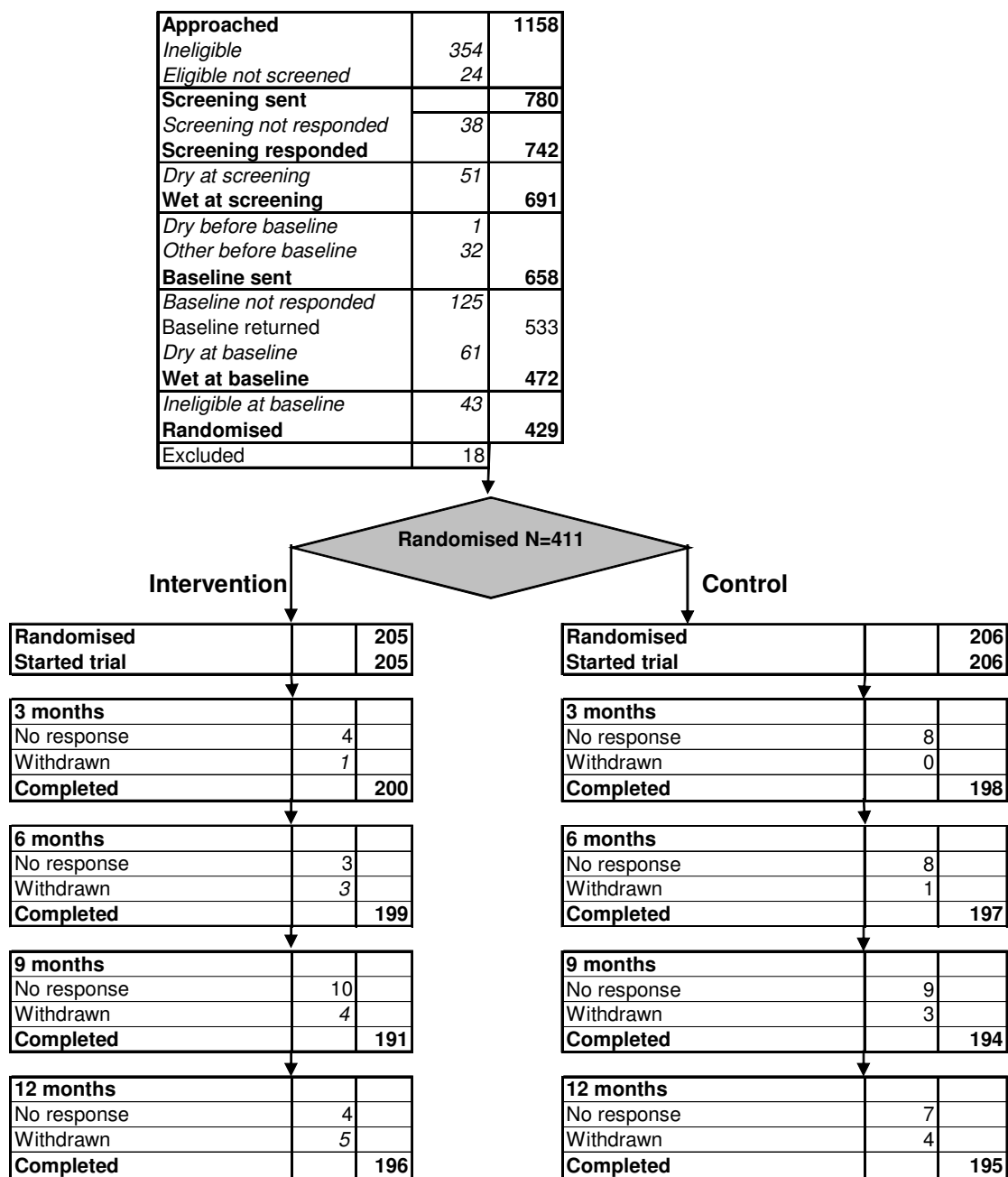
^b Adjusted treatment received analysis, adjusted for actual attendance (compliance) with therapy



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

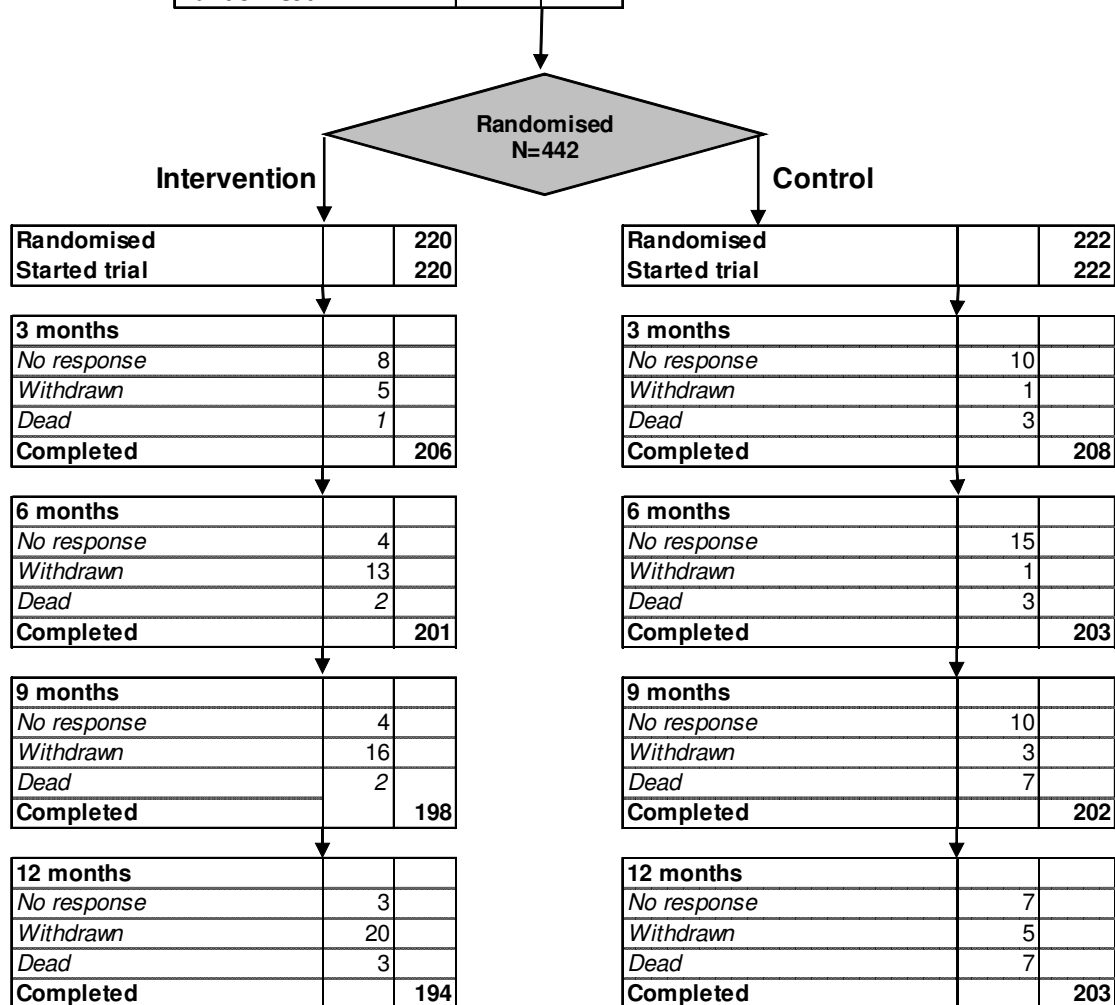


^a *Postrandomisation exclusion* Therapy was not available during some of the period of screening in one centre (18 men)

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

Approached		5986
<i>Ineligible</i>	3001	
<i>Eligible not screened</i>	147	
Screening sent		2838
<i>Screening not responded</i>	248	
Screening responded		2590
<i>Dry at screening</i>	1387	
Wet at screening		1203
<i>Dry before baseline</i>	5	
<i>Other before baseline</i>	150	
Baseline sent		1048
<i>Baseline not responded</i>	262	
Baseline returned		786
<i>Dry at baseline</i>	274	
Wet at baseline		512
<i>Ineligible at baseline</i>	70	
Randomised		442

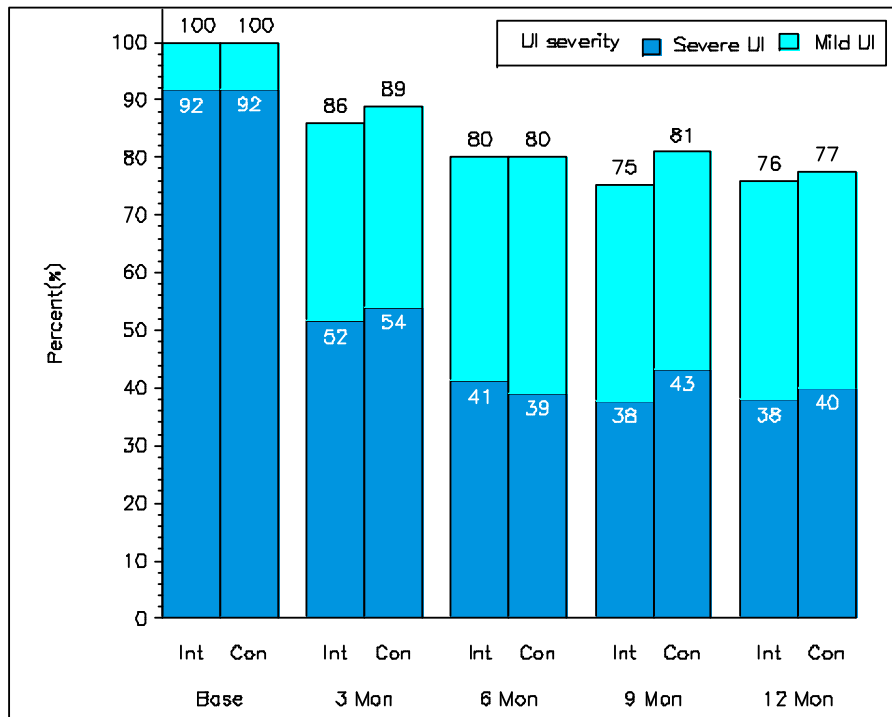


Reasons for withdrawal after randomisation (Int / Control):

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

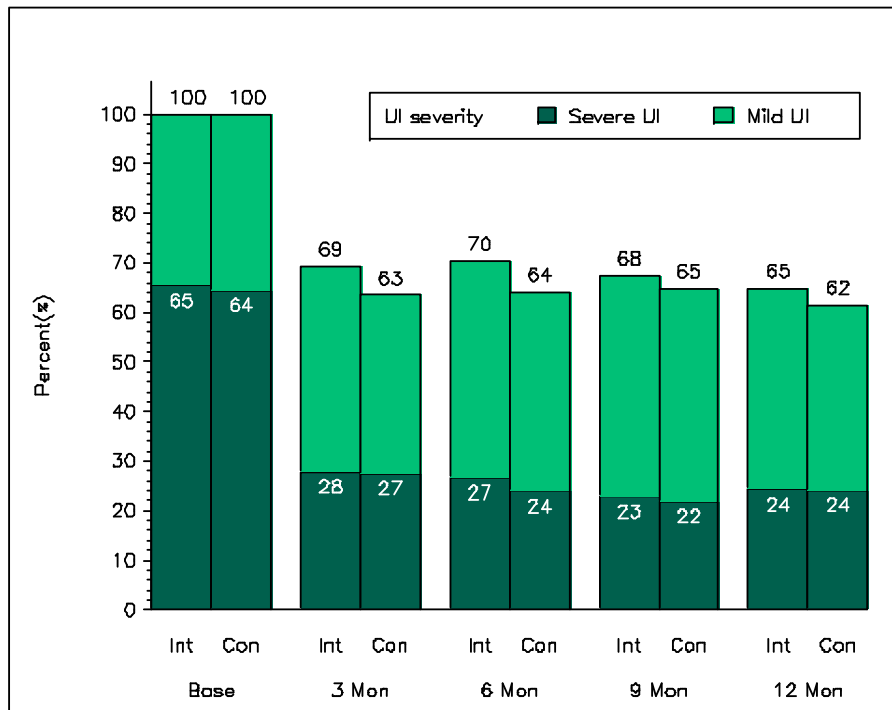
Figure 2 Percentage of men incontinent and the severity* of the incontinence at each time point

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

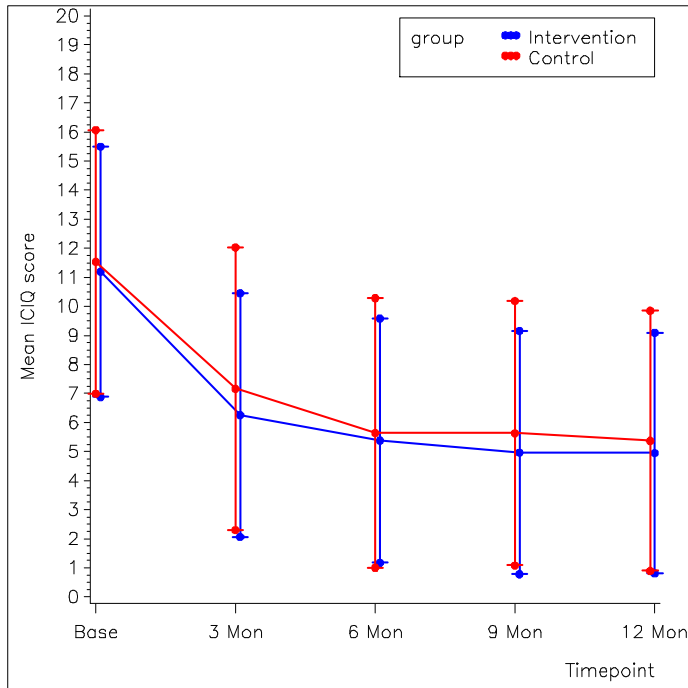
2b: Trial TURP



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

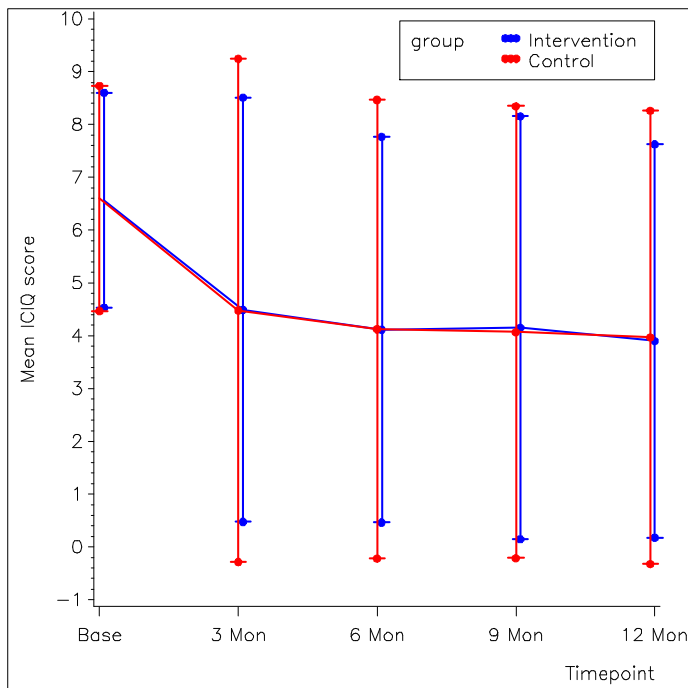
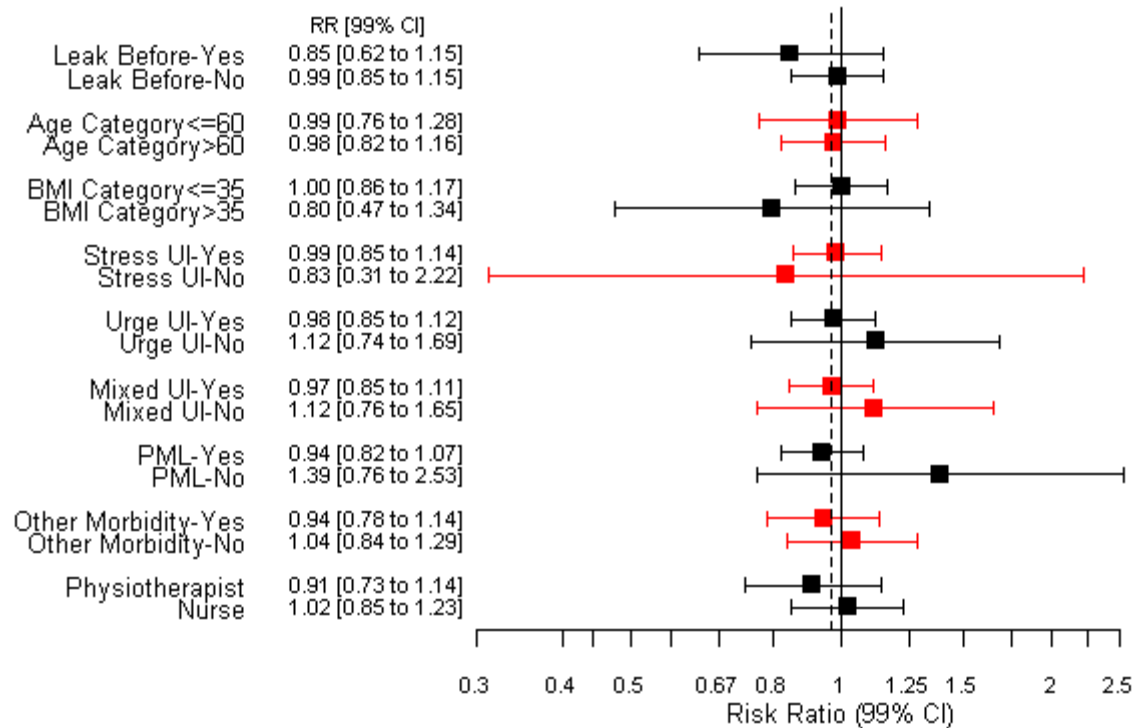


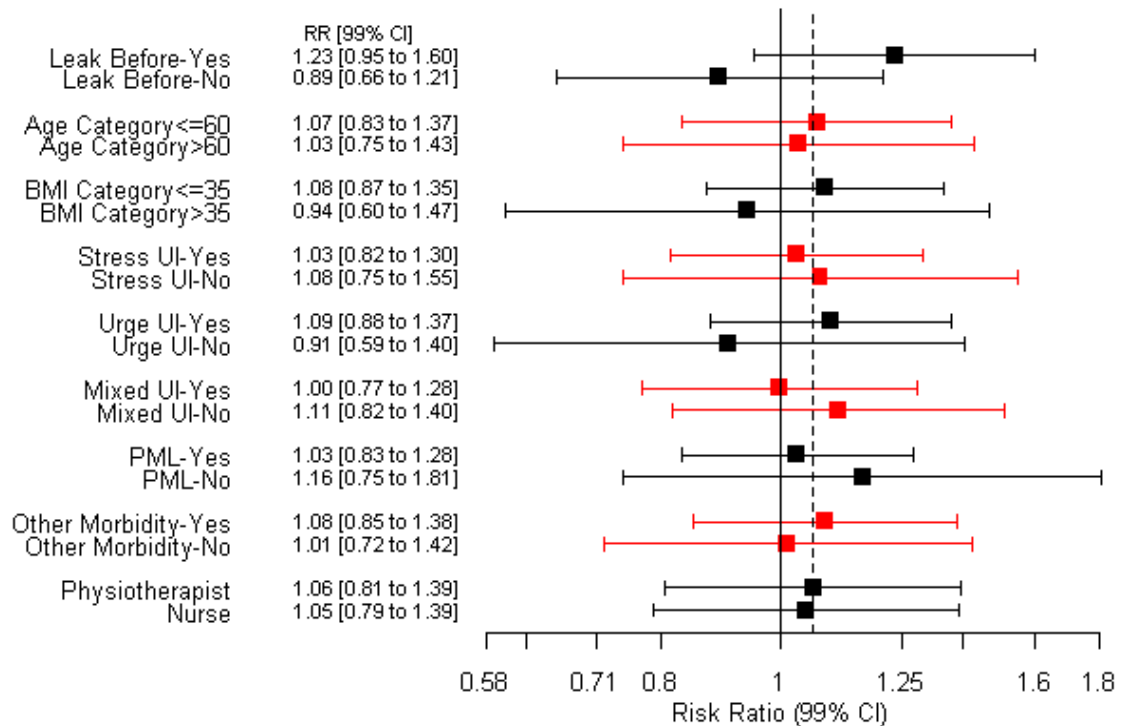
Figure 4 Forest plot of sub group analyses: Urinary Incontinence at 12 months

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

Reference List

- (1) Lourenco T, Armstrong N, Nabi G, Deverill M, Pickard R, Vale L, et al. Systematic review and economic modelling of effectiveness and cost utility of surgical treatments for men with benign prostatic enlargement (BPE). *Health Technology Assessment* 2008;12(35).
- (2) Lourenco T, Pickard R, Vale L, Grant A, Fraser C, MacLennan G, et al. Alternative approaches to endoscopic ablation for benign enlargement of the prostate: systematic review of randomised controlled trials. *BMJ* 2008;337.
- (3) Armstrong N, Vale L, Deverill M, Nabi G, McClinton S, N'Dow J, et al. Surgical treatments for men with benign prostatic enlargement: cost effectiveness study. *BMJ* 2009;338.
- (4) Sanda MG, Dunn RL, Michalski J, Sandler HM, Northouse L, Hembroff L, et al. Quality of life and satisfaction with outcome among prostate-cancer survivors. *New England Journal of Medicine* 2008 Mar 20;358(12):1250-61.
- (5) Smith DP, King MT, Egger S, Berry MP, Stricker PD, Cozzi P. Quality of life three years after diagnosis of localised prostate cancer: population based cohort study. *BMJ* 2009;339:4817.
- (6) Milsom I, Altman D, Lapitan MC, Nelson R, Sillen U, Thom D. Epidemiology of urinary (UI) and faecal (FI) incontinence and pelvic organ prolapse (POP). *Incontinence: 4th International Consultation on Incontinence*. 4th ed. Paris, France: Health Publication Ltd; 2009. p. 35-112.
- (7) DuMoulin C, Hay-Smith EJ. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. *Cochrane Database of Systematic Reviews* 2010;CD005645(1).
- (8) Imamura M, Abrams P, Bain C, Buckley B, Cardozo L, Cody J, et al. Systematic review and economic modelling of the effectiveness and cost-effectiveness of non-surgical treatments for women with stress urinary incontinence. *Health Technology Assessment* 2010;14(40).
- (9) Hunter KF, Moore KN, Glazener CMA. Conservative management for postprostatectomy urinary incontinence. *Cochrane Database of Systematic Reviews* 2007;(2).
- (10) Wallace SA, Roe B, Williams K, Palmer M. Bladder training for urinary incontinence in adults. *Cochrane Database of Systematic Reviews* 2009;(1).
- (11) Abrams P, Avery K, Gardener N, Donovan J, on behalf of the ICIQ Advisory Board. The International Consultation on Incontinence modular questionnaire: www.iciq.net. *J Urol* 2006;175:1063-6.
- (12) Dorey G, Glazener C, Buckley B, Cochran C, Moore K. Developing a pelvic floor muscle training regimen for use in a trial intervention. *Physiotherapy* 2009 Sep;95(3):199-209.
- (13) Kind P, Hardman G, Macran S. UK Population norms for EQ-5D. York, UK: University of York; 1999.

- (14) Zou G. A modified poisson regression approach to prospective studies with binary data. *American Journal of Epidemiology* 2004;159(7):702-6.
- (15) White IR. Uses and limitations of randomization-based efficacy estimators. *Statistical Methods in Medical Research* 2005;14(4):327-47.
- (16) Nagelkerke N, Fidler V, Bernsen R, Borgdorff M. Estimating treatment effects in randomized clinical trials in the presence of non-compliance. *Statistics in Medicine* 2000;19(14):1849-64.
- (17) Department of Health. NHS Reference Costs. <http://www.dh.gov.uk/en/publicationandstatistics/publication/publicationspolicyandguidance> 2009 [cited 2009 Nov];
- (18) National Health Service (NHS) in Scotland Information and Statistics Division (ISD). Scottish Health Services Costs. <http://www.isdscotland.org/isd> 2009 [cited 2009 Nov];
- (19) Department of Transport. COBA 9 Manual. London Department of Transport; 1989.
- (20) HM Revenue and Customs. EIM31240 - Employees using own vehicles for work: statutory mileage rates 2002/03 onwards: kinds of vehicle. <http://www.hmrc.gov.uk> 2009
- (21) The Bank of England. The Bank of England. www.thebankofengland.co.uk 2010 October 13 [cited 2010 Oct 13];
- (22) Staskin D, Kelleher C, Avery K, Bosch R, Cotterill N, Coyne K, et al. Patient-reported outcome assessment. Incontinence: 4th International Consultation on Incontinence. 4th ed. Paris, France: Health Publication Ltd; 2009. p. 363-412.
- (23) Frankel SJ, Donovan JL, Peters TI, Abrams P, Dabhoiwala NF, Osawa D, et al. Sexual dysfunction in men with lower urinary tract symptoms. *Journal of Clinical Epidemiology* 1998 Aug;51(8):677-85.
- (24) Floratos DL, Sonke GS, Rapidou CA, Alivizatos GJ, Constantinides CA, Deliboliotis C. Biofeedback versus verbal feedback as learning tools for pelvic muscle exercises in the early management of urinary incontinence after radical prostatectomy. *British Journal of Urology International* 2002;89(7):714-9.
- (25) Van Kampen M, De Weerd W, Van Poppel H, Feys H, Campesino AC, Stragier J, et al. Prediction of urinary continence following radical prostatectomy. *Urologia Internationalis* 1998;60(2):80-4.
- (26) Moore KN, Valiquette L, Chetner MP, Byrniak S, Herbison GP. Return to continence after radical retropubic prostatectomy: A randomized trial of verbal and written instructions versus therapist-directed pelvic floor muscle therapy. *Urology* 2008;72(6):1280-6.
- (27) Manassero F, Traversi C, Ales V, Pistolesi D, Panicucci E, Valent F, et al. Contribution of early intensive prolonged pelvic floor exercises on urinary continence recovery after bladder neck-sparing radical prostatectomy: Results of a prospective controlled randomized trial. *Neurourol Urodyn* 2007;26(7):985-9.

Appendix

MAPS Principal Investigators in Centres

Mr Muhammad Akhtar, Mr Prasad Bolina, Mr Sudhir Borgaonkar, Mr Gregory Boustead, Mr Derek Byrne, Mr Shiv Bhanot, Mr David Chadwick, Mr Noel Clarke, Mr Owen Cole, Mr Gerald Collins, Professor James N'Dow, Mr Peter Donaldson, Mr Roland Donat, Mr Ian Eardley, Mr David Gillatt , Mr Tahseen Hasan, Prof Howard Kynaston, Mr Pradip Javle, Ms Ling Lee, Mr Malcolm Lucas, Mr Ruairidh MacDonagh, Mr John MacFarlane, Mr Peter Malone, Mr Robert Meddings, Mr Geoffrey Orr, Mr Anup Patel, Mr Rajendra Persad, Mr Nigel Philp, Mr Alvan Pope, Mr Tim Porter, Dr Derek Rosario, Mr Naeem Shaikh, Mr Subramanian Kanagasundaram, Mr James Tweedle, Mr Mohammad Vandal and Mr Ralph Webb.

MAPS Recruitment Officers in Centres

Vanessa Adamson, Paul Allcoat, Margaret Austin, Irene Blythe, Aelens Brauckman, Vikram Bohra, Ruth Broom, Andrew Brown, Clare Buckley, Jo Butler, Jenny Butler-Barnes, Loveness Chikopela, J Connell, Helen Corderoy, Kirsty Crozier, Liz Dalgaty, M Davies, Debbie Delgado, Gill Driver, Lisa Egan, Charlotte Etheridge, Alison Finlay, Linda Fowler, Chris Garlick, Claire Gaskell, Debbie Gibbons, Louise Gray, Jane Griffiths, Andrew Harvey, Sam Genner, Louise Goodwin, Delyth Hague, Mary Hamilton, Lisa Hardstaff, Samantha Holliday, Gillian Hornzee, Joanne Howson, Peter Holding, Katrina Hurley, C Jones, Laura Jones, Louise Jones, Suriya Kirkpatrick, Gill Larsen, Lorraine Lamb, Angela Lee, Julie Longworth, Brenda McCallum, Patricia McClurey, Marilyn McCurrie, Sarah McKenna, Carolyn Mansfield, Barbara Mayne, Mariam Nasser, Neale O'Brien, Christine Oxnard, K Pearce, Linda Pennet, Valerie Powell, Kathryn Procter, Navin Ravindranath, Kez Richards, Kathleen Riddle, Paul Ridley, Stephanie Ridgway, Allison Robertson, Wendy Robson, Lisa Saville, Mary Simpson, Alison Steel, Andy Smallwood, Dorothy Sugden, Louise Taylor, Jill Taylor, Sarah Thompson, Nona Toothill, Barbara Townley, Karen Wilmott and Jill Youd.

Maps Therapists in Centres

Margaret Atherton, Annette Bell, Jill Branson, James Bolarin, Elaine Cathcart, Ada Cardiff, Alison Coughlan, Debbie Delgado, Ann Evans, Alison Finlay, Madeline Frank, Ann Gilchrist, Caroline Gill, Louise Goodwin, Sue Hallam, Linda Haworth, Kay Hildersley, Philip Howard, Fiona Jarvis, Fiona Key, Gill Larsen, Lorraine Lamb, Fiona Lennard, Maureen Lumber, Kath Moore, Kirsty Moore, Julia Muman, Mariam Nasser, Linda Pernet, Valerie Powell, Debbie Rigby, Allison Robertson, Karen Wilmott, Ann Yeats and Jill Youd.