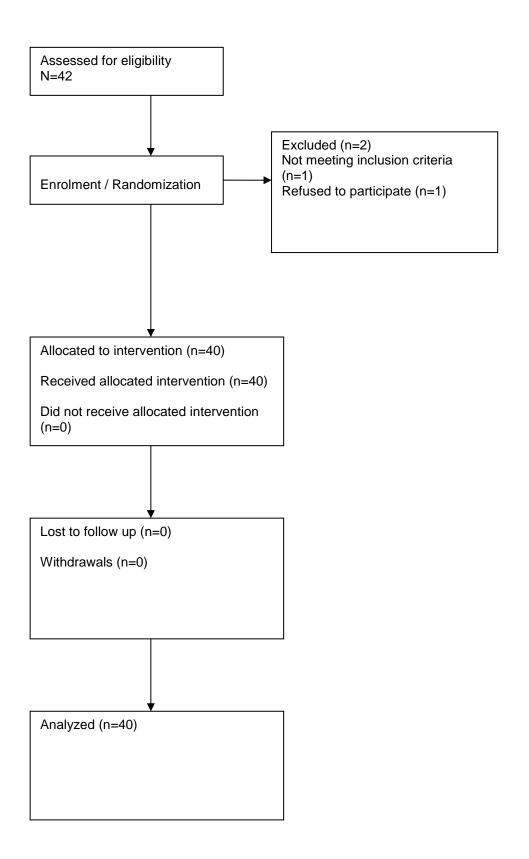
Participant flow



Baseline data

Table 1. Patient characteristics and urodynamic parameters – values presented as median [inter-quartile range (IQR)] or n (%)

	TVT (n=20)	TVTO (n=20)	Difference in means /difference in proportions (95% CI)	
Mean age (SD)	50.45 (12.22)	51.20 (11.95)	-0.75 (-8.49,6.99)	
BMI (SD)	26.19 (4.05)	28.66 (4.84)	-2.47 (-5.330,0.385)	
Parity (median)	3 [2-3]	2 [2-4]		
Menopausal status	7 (35)	7 (35)	0 (296,0.296)	
Hormone replacement	1(5)	1(5)	0 (-0.135,0.135)	
Previous surgery for prolapse	3 (15)	2(10)	0.05 (0.154,0.254)	
Duration of stress incontinence (months)(SD)	68.60 (72.42)	82.05 (89.08)	-13.45 (-65.417,38.517)	
Qave (Urine flow rate ml/s)	20.08 (4.996)	17.468 (4.364)	2.615 (-5.112,5.741)	

Intra & Post Operative Data

Table 2. Operative and post operative details.

Values are presented as mean [SD] or n (%)

	TVT n=20	TVTO n=20	Difference in means /difference in proportions (95% CI)
Procedure time (mins)	12.95 [3.14]	9.25 [1.45]	3.70 (2.14 – 5.26)
Theatre time (mins)	41.05[9.859]	33.40[8.18]	7.65(1.85,13.45)
Blood loss (ml) [IQR]	55 [32-150]	50 [30-90]	
Required post operative opiates	2 (10)	3 (15)	-0.05 (-0.25, 0.15)
Overnight stay due to voiding difficulty	8 (40)	5 (25)	0.15 (-0.14, 0.44)
Re-catheterization	7 (35)	3 (15)	0.20 (-0.06, 0.46)

Follow up - acceptability

Table 3. Two week follow up - acceptability

	TVT	TVTO	P value	Difference in proportions / mean difference (95% CI)
Totally / generally acceptable	19 (95)	19 (95)		0.00 (-0.14,0.14)
Recommend to a friend	18	20	0.487	01 (-0.23,0.03)

Table 4. Three month follow up - acceptability

	TVT	TVTO	P value	Difference in proportions / mean difference (95% CI)
Totally / generally acceptable	18	19		-0.05 (-0.21,0.12)
Recommend to a friend	20	19	1.00	0.05 (-0.05,0.15)

Follow up - Quality of life

.Table 5 - ICIQ scores

	TVT	TVTO	P value	Mean difference/ adjusted mean difference (95% CI)	
Baseline ICIQ score	13.5 (3.75)	12.80 (3.43)	0.541	0.700 (-1.60,2.99)	
2 week change ICIQ score	9.85 (5.87)	10.25 (4.92)	0.817	-0.40 (-3.87,3.067)	
2 week ICIQ ANCOVA			0.487	-1.07 (-3.8,1.65)	
3 month change ICIQ score	10.75 (4.77)	10.45 (4.21)	0.833	0.30 (-2.55,3.15)	
3 month ICIQ ANCOVA			0.815	26 (-2.49,1.97)	

Table 6. Change in KHQ scores

	Baseline TVT mean rank	Baseline TVTO mean rank	Change in score TVT mean rank	Change in score TVTO mean rank	P value
General health perceptions	25	25	20.53	20.48	0.987
Incontinence impact	83	66.67	19.93	21.08	0.749
Role limitations	50	66.67	19.93	21.08	0.752
Physical limitations	50	66.67	19.60	21.40	0.619
Social limitations	22.22	33.33	17.80	23.20	0.138
Personal relationships	16.70	0	20.05	20.95	0.805
Emotions	38.89	44.44	17.90	23.10	0.155
Sleep / energy	33.33	16.67	20.55	20.45	0.978
Severity measures	66.67	66.67	19.90	21.20	0.745

Adverse events

There were no significant adverse events in either group. The number requiring recatheterization was higher interval in the TVT group. The absolute difference was 20% (95% CI -6 to 46%). Although with the small sample size even this difference of 20% was not statistically significant. (Table2). Voiding difficulties were also more prevalent in the TVT group although again this does not reach significance with the small numbers included in this study (absolute difference 15% (95% CI -14 to 44%)). Patients were fully counselled about the potential risks of these complications prior to the procedure being performed, as is standard clinical practice.