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INTERNET-BASED TREATMENT OF STRESS URINARY INCONTINENCE: A RANDOMISED CONTROLLED STUDY.

Hypothesis / aims of study

Stress urinary incontinence affects one in eight women and may cause distress.[1] Pelvic floor muscle training is the recommended first line of treatment.[1, 2] However, many women never seek medical attention, sometimes due to shame. Internet-delivered treatment is a growing field,[3] and women often use the Internet for information on health care issues, particularly for conditions perceived as embarrassing. The aim of this study was to compare the effectiveness of an Internet-based treatment programme with a treatment programme sent by post for stress urinary incontinence.

Study design, materials and methods

This randomised, controlled study included 250 community-dwelling women, aged 18–70 years, with stress urinary incontinence at least once weekly. Consecutive recruitment was achieved after online registration at the study's open access website. Clinical diagnosis was based on a validated questionnaire (ICIQ-UI SF), a 2-day bladder diary, and a telephone interview with an urotherapist. Women with symptoms that required physical examination were excluded. The study was conducted in Sweden in 2010-2011.

The study included two parallel treatment arms. Randomisation was computer-generated in blocks of eight, and allocation was performed by an independent administrator. The arms included three months of the following:

1. An Internet-based treatment programme (n=124).

2. A treatment programme sent by post (n=126).

Both programmes were based mainly on pelvic floor muscle training. The Internet-based programme was more extensive, and included support from an urotherapist, through asynchronous encrypted email contact. No face-to-face contact was made throughout the study. Study participants, caregivers and researchers were not blinded to the group allocations.

Patients were followed up at 4 months after treatment initiation, through self-assessed postal questionnaires. Primary outcomes were symptom-score (ICIQ-UI SF) and condition-specific quality of life (ICIQ-LUTSqol). Secondary outcomes were the Patient Global Impression of Improvement (PGI-I), use of incontinence aids, patient' satisfaction, health-specific quality of life (EQ5D), and incontinence episode frequency (IEF). An intention-to-treat analysis was performed.

Results

The mean age was 48.6 years (range 23-70). In all, 12.0% (n=30) of participants were lost to follow-up (Internet 13.7% (n=17), postal 10.3% (n=13), p=0.41).

Primary outcomes

Both groups improved significantly (p<0.001) in symptom-scoring and condition-specific quality of life, but the observed differences between the groups were not significant. (Table I)

However, a subgroup analysis showed that participants with more severe leakage at baseline achieved a significantly lower mean score in the ICIQ-UI SF, when treated with the Internet-based compared to the postal programme (mean score at follow-up: Internet 8.1 [95% CI: 6.8-9.4]; Postal 11.0 [9.6-12.4]).

Table I. Summary of primary outcome measures by treatment group							
Outcome	Treatment	Baseline	4 month	Difference	Within group	Between groups	Effect size
variable	group		follow-up		p-value	p-value	(95% CI)
ICIQ-UI SF							
	Internet	10.2 (3.0)	6.9 (3.1)	3.4 (3.4)	< 0.001	0.27	0.99 (0.76-1.22)
	Postal	10.2 (3.3)	7.3 (3.9)	2.9 (3.1)	<0.001		0.95 (0.72-1.17)
ICIQ-LUTSa	ol						
	Internet	32.6 (6.0)	27.8 (6.0)	4.8 (6.1)	<0.001	0.52	0.79 (0.57-1.01)
	Postal	33.3 (8.2)	28.8 (7.3)	4.6 (6.7)	<0.001		0.68 (0.47-0.89)
Numbers in brackets are standarddeviations.							
CI=Confiden	ce Interval; ICI	Q-UI SF=Inte	rnational Co	nsultation or	n Incontinence	Modular Questic	onnaire
Urinary Incor	ntinence Short	Form: ICIQ-L	.UTSgol=Inte	rnational Co	onsultation on	Incontinence Mod	dular

Questionnaire Lower Urinary Tract Symptoms Quality of Life

Secondary outcomes

After treatment, the leakage was perceived as much or very much improved, by 41% of the Internet-group and 27% of the postal-group. (Fig 2) Compared to the postal group, more participants in the Internet-group reduced the use of incontinence aids (41% vs. 60%, p=0.02), and indicated satisfaction with the treatment programme (62% vs. 85%, p<0.001).

Health-specific quality of life improved significantly in the Internet-group (mean change 3.7 [95% CI 1.6–5.8]), but not in the postal-group (mean change 1.9 [-0.5–4.3]). Both groups experienced significantly reduced (p<0.001) numbers of weekly leakage episodes (mean reduction: Internet 7.6 [95% CI 5.7-9.5]), postal 4.5 [3.0-6.0]). However, the groups were not significantly different in these latter two measures.

After treatment, 70% of participants in both groups had either ceased to leak, or reduced the number of weekly leakage episodes by over 50%.



Fig 1. Distribution of responses on the patient global impression of improvement rating scale by treatment group.

No important side effects were registered.

Interpretation of results

For primary outcomes, significant improvements with large effect sizes were observed in both groups. More improvements were recorded for the Internet-group, but no significant differences were found between the groups. However, the Internet-based treatment was more effective for most secondary outcomes.

Concluding message

Internet-based treatment of stress urinary incontinence is an effective treatment alternative.

References

- 1. National Institute for Health and Clinical Excellence. Urinary incontinence: the management of urinary incontinence in women. London: RCOG Press; 2006.
- 2. Dumoulin C, Hay-Smith J. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. Cochrane Database Syst Rev. 2010; Issue 1, Art. No: CD005654.
- 3. Andersson G, Ljotsson B, Weise C. Internet-delivered treatment to promote health. Curr Opin Psychiatry 2011; 24:168-72.

Disclosures

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