Institution: University College London

Unit of Assessment: 1 – Clinical Medicine

Title of case study: Self-management intervention for men with lower urinary tract symptoms: development, phased evaluation and global adoption

1. Summary of the impact

Lower Urinary Tract Symptoms (LUTS) in men is a chronic disease of ageing that causes significant quality of life impairment in one third of men over the age of 60. Traditional management comprises a step-up regimen of drugs and surgical interventions aimed at relieving symptoms. At UCL we conceived, developed, evaluated and implemented a self-management intervention that results in greater symptom reduction than that achieved by medication, reduction in the use of medication and of referrals to secondary care, and reduced costs. The intervention is now a global standard of care.

2. Underpinning research

In about 2003 Emberton observed that many men were adopting informal strategies that would allow them to 'manage' their symptoms as an alternative to pharmacotherapy **[1]**. These were sometimes learnt by trial and error, and at other times they were acquired through the informal network of men with symptoms and, very occasionally, taught by a growing constituency of continence advisors and nurse specialists. These strategies included: fluid management, caffeine avoidance, timed toileting, urethral milking, double voiding and bladder re-training. We conducted a survey of urologists, nurse practitioners and continence advisors to determine the use of these strategies, and the results showed that these interventions are indeed advised by many in such circumstances **[2]**. However, there was a wide variation in their use, and no supporting evidence base, so we felt that it was necessary to test their effectiveness.

We began by assembling a multi-disciplinary research team (patients, urologists, continence advisors, specialist nurses, health services researchers and health psychologists) that was representative of the expertise necessary to address the research question. A systematic review of the literature confirmed that the evidence to support life-style modification was either weak or absent. A formal survey of UK practice indicated that the use of lifestyle interventions was infrequent but that professional groups would be receptive, if they were shown to be effective **[3]**. We conducted a needs assessment (qualitative methods comprising semi-structured interviews/surveys) that confirmed an unmet need from the patients' perspective and no barriers to adoption from the professions or pharmaceutical industry **[1]**. We defined the intervention prospectively using formal consensus methodology (RAND) through the process of item generation and item reduction in two rounds of scoring. **[4]**. The defined intervention was piloted in a single centre (UCLH). The pilot demonstrated good uptake by patients, adherence to the programme and provided a strong preliminary signal of efficacy. This pilot informed the design and conduct of an RCT that compared standard care to standard care plus the self-management intervention using a reduction in patient-reported symptom score as the primary outcome. This study demonstrated a reduction in symptoms equivalent to that achieved by surgery and a reduction in the need for medical and surgical treatment **[5,6]**.

3. References to the research

[1] Brown CT, Van Der Meulen J, Mundy AR, Emberton M. Lifestyle and behavioral interventions for men on watchful waiting with uncomplicated lower urinary tract symptoms: a national multidisciplinary survey. BJU Int. 2003 Jul;92(1):53-7. http://dx.doi.org/10.1046/j.1464-410X.2003.04268.x

[2] Lane T, Brown C, Emberton M. Behavioural approaches are helpful in overactive bladder. BMJ.

2003 Aug 2;327(7409):291. http://dx.doi.org/10.1136/bmj.327.7409.291

[3] Brown CT, Van Der Meulen J, Mundy AR, Emberton M. Lifestyle and behavioural interventions for men on watchful waiting with uncomplicated lower urinary tract symptoms: a national multidisciplinary survey. BJU Int. 2003 Jul;92(1):53-7. http://dx.doi.org/10.1046/j.1464-410X.2003.04268.x

[4] Brown CT, van der Meulen J, Mundy AR, O'Flynn E, Emberton M. Defining the components of a self-management programme for men with uncomplicated lower urinary tract symptoms: a consensus approach. Eur Urol. 2004 Aug;46(2):254-62; discussion 263. http://dx.doi.org/10.1016/j.eururo.2004.02.008

[5] Brown CT, Yap T, Cromwell DA, Rixon L, Steed L, Mulligan K, Mundy A, Newman SP, van der Meulen J, Emberton M. Self-management for men with lower urinary tract symptoms: randomised controlled trial. BMJ. 2007 Jan 6;334(7583):25. http://dx.doi.org/10.1136/bmj.39010.551319.AE

[6] Yap TL, Brown C, Cromwell DA, van der Meulen J, Emberton M. The impact of self-management of lower urinary tract symptoms on frequency-volume chart measures. BJU Int. 2009 Oct;104(8):1104-8. http://dx.doi.org/10.1111/j.1464-410X.2009.08497.x

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4. Details of the impact

As a result of our work, which provided an evidence base for the efficacy of self-management in LUTS, nearly all evidence-based practice guidelines recommend self-management as the initial form of therapy for all men presenting with LUTS. It has therefore become a global standard of care.

- NICE guideline CG97 (2010), on Lower urinary tract symptoms in men, recommends self-management in the text and in the therapeutic algorithms. The BMJ RCT is referenced **[a]**. Emberton acted as expert advisor to the group that produced the guidelines.

- 2011 guidelines issued by the European Association of Urology on treatment of non-neurogenic male LUTs (on which the majority of the national guidelines are based) cite our evidence that "*self-management as part of watchful waiting reduces both symptoms and progression*". Accordingly, they recommend that *"men with mild symptoms are suitable for watchful waiting…Men with LUTS should be offered lifestyle advice prior to or concurrent with treatment."* The table from Brown et al 2007 is cited directly and the recommendation is attributed a level of Evidence of 1b; Grade A **[b]**.

Self-management is now widely recommended to patients, for example on the patient.co.uk website **[c]** and on NHS Choices **[d]**. Private healthcare providers now recommend self-management according to the NICE guidelines (e.g. Benenden Healthcare **[e]**) and it is widely used in NHS Continence Services **[f]**. A survey of GPs in 2011 showed that 46% had implemented the guidance, and 80% of those had seen a reduction in referral costs **[g]**.

The impacts of our work on patients are as follows:

- **Fewer men require drug therapy:** our RCT demonstrated both a reduction in symptoms equivalent to that achieved by surgery and a reduction in the need for treatment whether it be medication or surgery

- **More effective therapy:** Our intervention arm was standard care plus self-management. Men receiving drug therapy who were randomised to the intervention arm had greater and

more sustained symptom improvement.

- **Fewer referrals:** Self-management is being applied in primary care and is being promoted through self-help groups. The resolution of symptoms without recourse to medication or surgery leads to fewer referrals to secondary care.

The impacts on patients also provide economic benefits to the healthcare system through a reduced cost of care. Our work has shown that once the self-management skills are taught the benefits are sustained. This has not been the case in other self-management programmes. A conservative estimate, abstracting from our data, is that men using self-management have a 3-fold reduction in risk of requiring therapy or progressing symptomatically. Estimates of the cost of treating LUTS in the UK are approximately £120m per year. Modelling of the effect size and uptake of self-management as an initial strategy produces an estimate of a £20m annual saving, largely derived as a result of fewer referrals to secondary care and to reduced drug costs.

Kaiser Permanente, the largest managed care organisation in the United States covering a population of 3.6 million, is in the process of adapting and implementing self-management as a standard intervention based on the work published by our team and the recommendations in international clinical practice guidelines. They state that it is *"exactly the type of innovative, impactful work that can help us break out of the traditional means of delivering health care, and help contain burgeoning costs while at the same time, improve the quality of care."* **[h]**.

5. Sources to corroborate the impact

[a] Lower urinary tract symptoms in men. National Institute of health and Clinical Excellence. NICE Clinical Guideline 97, 2010. http://www.nice.org.uk/nicemedia/live/12984/48557/48557.pdf

[b] Guidelines on the treatment of non-neurogenic male LUTs. European Association of Urology, 2011. These guidelines place self-management as an important intervention (Grade A) http://www.uroweb.org/gls/pdf/12_Male_LUTS.pdf

[c] Patient.co.uk recommendations on LUTS: http://www.patient.co.uk/doctor/lower-urinary-tract-symptoms-in-men

[d] NHS Choices guidelines on non-surgical treatment for urinary incontinence: http://www.nhs.uk/Conditions/Incontinence-urinary/Pages/Treatment.aspx

[e] Advice on continence provided by Beneden Health: https://www.benenden.co.uk/healthcare-membership/personal-healthcare/healthcare-services/continence-care/

[f] E.g. Brighton and Sussex University Hospitals – Department of Urology guidance on LUTS. Copy available on request.

NHS Evidence Update for lower urinary tract symptoms in men, 2012: http://arms.evidence.nhs.uk/resources/hub/691207/attachment

[g] http://www.medicalnewstoday.com/releases/228342.php

[h] Personal communication from Director of Research for Kaiser Permanente Southern California. Available on request.