

ENHANCING SELF-EFFICACY AND PELVIC FLOOR
MUSCLE EXERCISE ADHERENCE THROUGH
sEMG BIOFEEDBACK: A RANDOMISED STUDY

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sEMG BIOFEEDBACK: A RANDOMISED STUDY

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Abbreviations and Definitions

Explanations of these terms and abbreviations also appear in the main text

ICS	International Continence Society
UI	Urinary Incontinence
UUI/OAB	Urge urinary incontinence/overactive bladder
SUI	Stress urinary incontinence
MUI	Mixed urinary incontinence
PFME	Pelvic floor muscle exercises
NICE	National Institute for Health and Clinical Excellence
HAD	Hospital Anxiety and Depression scale
sEMG	Surface electromyography. The surface recordings of muscle activity through the monitoring of myoelectric signals (which can be used as a representation of muscle function for the purposes of biofeedback)
CMRR	Common Mode Rejection Ratio. This is a measure of how successfully the common mode signal (electrical noise from the environment) is filtered out. It is a term used to assess technical parameters of the sEMG equipment.
iCSP	Interactive CSP a web based discussion forum for Chartered Physiotherapists
The Knack	A conscious pre-emptive pelvic floor contraction used just prior to exertion activity, such as a cough, sneeze or lift

Biofeedback	The technique by which a normally unconscious physiological process is presented to the patient and/or therapist as a visual auditory or tactile signal (Peschers et al., 2001).
Self-efficacy	The belief in one's capabilities to organise and execute the sources of action required to manage prospective situations (Bandura, 1986).
Adherence	The extent to which the patient's behaviour matches agreed recommendations from the prescriber (Horne et al, 2006).
Health behaviour	Behaviour performed by an individual, regardless of his/her perceived health status, with the purpose of protecting, promoting or maintaining his/her health (Harris & Guten, 1979).
The (modified) Oxford (grading) Scale	A subjective measure of pelvic floor muscle strength and lift using vaginal palpation. Recorded on a six point scale from 0 to 5 (Messelink et al., 2005).
BMI (Body Mass Index)	A proxy calculation of body fat based on weight and height of an individual. It is defined as an individual's body mass divided by the square of his or her height.

Abstract

Background Pelvic floor muscle exercises are a recommended first-line treatment for stress urinary incontinence (SUI) in women (NICE, 2006). Poor adherence to pelvic floor muscle exercises (PFME) is a recognised problem which has the potential to compromise successful treatment (Bø, 1995; Alewijnse et al., 2001). Biofeedback is thought to help motivate PFME practice but so far this has not been evaluated in a randomised study.

Aim This study tests the hypothesis that use of clinic-based sEMG biofeedback improves women's motivation to exercise (PFME adherence) by increasing pelvic floor muscle exercise self-efficacy, an important construct in pelvic floor muscle exercise adherence behaviour.

Method After ensuring that they are able to make an informed decision to participate, a sample of sixty women referred for physiotherapy treatment of SUI between December 2008 and February 2010, gave consent to participate in the study. They were randomised into one of two groups. Thirty one women received clinic-based sEMG biofeedback in addition to the usual care, twenty nine received the usual care. Each participant attended clinic twice in a three month treatment period. Women were also asked to adhere to a daily home exercise programme (HEP). The primary outcome was pelvic floor muscle exercise self-efficacy. PFME self-efficacy and HEP adherence, were assessed by means of self-completed questionnaires.

Results Ten women dropped out of the study before completion. Both groups improved on all outcomes, but no significant difference was found between the groups in terms of self-efficacy levels or exercise adherence rates. PFME recall was more accurate in the intervention group receiving clinic-based sEMG biofeedback. A positive and significant relationship was confirmed between PFME self-efficacy and PFME adherence. These findings are discussed in respect to the concept of self-efficacy and behavioural change.

Conclusion In the short term, clinic-based sEMG biofeedback does not increase PFME self-efficacy or HEP practice beyond that achieved through instruction using vaginal palpation. These findings refute the belief that monitoring with sEMG biofeedback improves self-efficacy or women's motivation to adhere to a HEP, but does suggest that biofeedback may be a useful adjunct to teaching PFME.

Preface

Working in the area of bladder and bowel dysfunction has, for the past 10 years, allowed me to meet, work and learn alongside a variety of health professionals and patients. Through minor involvement in multi-centre trials, completing a post-graduate education course, visiting experienced clinicians and participation in conferences and study days, my interest in evidenced practice and research has developed. The doctorate programme has enabled me to maintain a clinical caseload alongside conducting research, the design of which I think is important in keeping research relevant. There is no better way of knowing what is current and relevant to patient care than to research while active in clinical practice. Having said this, maintaining these two strands of life has not been without difficulty and there have been frequent challenges in terms of balancing study, family and clinical obligations. Nevertheless it has been an enlightening journey which has helped to develop both my clinical and research skills, and working relationships. The rigour of academic study requires dedicated time and focussed attention. In addition, the relative newness of the course itself has necessitated repeated explanation as to the nature of the professional doctorate, a process which has helped to deepen my own understanding over time. What the DProf offers in terms of multi-disciplinary study and the mutual support offered by cohort learning has enriched both my studies and my clinical perspective. Similarly, joint clinical working and collaboration adds value to patient care, and, as in many other areas of health care, continence management functions best with an interdisciplinary approach.

Gynaecology, urology, nursing, physiotherapy and pharmacy all play a part in the overall management of the patient, with physiotherapy providing a particularly important role in the management of stress urinary incontinence (SUI). This focuses on improvement of pelvic floor function by use of pelvic floor muscle exercises (PFME), with the aim of reducing urinary leakage episodes. Teaching pelvic floor muscle exercises and working with my patients I became curious as to why some patients are keen to embrace pelvic floor muscle exercise treatment while others seem to struggle to remember to do it, or to commit to a regimen. I could see that high levels of motivation and self-confidence were evident in patients who were successful in adhering to treatment and wondered if these dimensions could be enhanced in sessions with my patients.

Self-efficacy is a psychological construct, levels of which are important in adopting and maintaining health behaviours, such as exercise adherence, motivation and self-management of treatment. Self-efficacy also seems to have the potential to be influenced through intervention and clinical contact, an issue of increasing importance in the ongoing scrutiny of treatment cost-effectiveness.

The existing research evidence for physiotherapy management of SUI is based on intensive rehabilitation programmes, which, while successfully demonstrating the *efficacy* of pelvic floor muscle exercises do not reflect the sometimes very limited level of support and supervision available to women who are accessing treatment. Economic restrictions are increasingly affecting all aspects of health delivery in both the private and public sectors, and continence services are under pressure to justify face-to-face clinical sessions in favour of encouraging self-

management in patients. More limited opportunity for clinician follow-up could have a negative impact on outcome with regards to PFME self-efficacy and PFME adherence, and the evidence would seem to support this.

The clinical guideline for urinary incontinence (CG 40), published by the National Institute for Health and Clinical Excellence (NICE) in 2006, is used by health services as the standard for urinary continence assessment and treatment. The NICE recommendations regarding treatment duration for exercise effectiveness and use of biofeedback in women with SUI initiated my interest in looking into conservative treatment effectiveness and whether some interventions may have benefit in improving self-efficacy and treatment adherence in a service where treatment supervision is more restricted.

Treatment of incontinence is delivered as packages of care, making appraisal of the effectiveness of a single modality challenging. Although PFME is advocated in treatment of SUI, the evidence relating to treatment *effectiveness* in the clinical reality of day-to-day practice is less abundant, highlighting the need for conducting pragmatic studies to explore this issue and interventions which may enhance exercise outcomes. Biofeedback is claimed to improve motivation and exercise adherence in women with incontinence, however this claim seems to be based on expert clinician opinion and speculation rather than specific studies.

CHAPTER ONE Background to the study

1.1 Introduction

This study investigates whether pelvic floor muscle exercise (PFME) self-efficacy and PFME adherence is enhanced by receiving clinic-based biofeedback treatment as part of a minimally supervised home PFME regimen for women with stress urinary incontinence (SUI).

PFME performed by women for a minimum of three months are demonstrated to be effective in the first-line treatment of SUI (Hay-Smith & Dumoulin, 2006), and are advocated in Department of Health clinical guidelines enshrining best practice for the treatment of urinary incontinence (NICE, 2006). Performing PFME consistently, several times a day over many weeks, gives a training effect to the muscles which is crucial for treatment success (Bø, 1995). However achieving the required adherence level can be a challenge for both therapist and patients embarking on a conservative treatment programme, and may be a reason why some women appear to succeed with PFME where others do not. Adherence to PFME should therefore be optimised, as not realising the full benefits of exercise as a treatment for SUI may lead to premature or even unnecessary surgery.

Confidence in the correct execution of PFME is important to levels of PFME self-efficacy (Whitford & Jones, 2011) which is an important predictor of PFME adherence (Messer et al., 2007). Behaviour-specific self-efficacy measures have allowed identification of important relationships, for example *exercise* self-efficacy

correlating positively with *exercise* adherence (Lyons, 1985) and assessment scales have been developed to assess PFME self-efficacy in the treatment of urinary incontinence (Broome, 1999; Chen, 2004). Research indicates that high PFME self-efficacy is associated with greater PFME adherence and improved clinical outcomes in women with SUI (Broome, 1999; Alewijnse et al., 2001; Demain et al., 2006; Hay-Smith, Ryan & Dean, 2007; Chen & Tzeng, 2009).

Self-efficacy as a psychological construct originated in Bandura's Self-efficacy Theory (Bandura, 1977), and is found in many conceptual models of health behaviour. This theory assumes that human motivation and action are based on three beliefs, situation-outcome, action-outcome and perceived self-efficacy. These beliefs are illustrated by the example of pelvic floor exercises used in the treatment of incontinence in Table 1 below.

Table 1 Self-efficacy theory translated to PFME in the treatment of SUI

<i>Situation-outcome</i>	If I do nothing my incontinence will worsen or I may require surgery.
<i>Action-outcome</i>	If I perform pelvic floor muscle exercises adequately my incontinence will improve.
<i>Perceived self-efficacy</i>	I am able to perform pelvic floor muscle exercises a) correctly and b) often enough, to be effective.

The link between levels of self-efficacy and behavioural change have been made in other areas of health promotion, for example smoking cessation (Rosal et al., 1998) and use of mammography services (Allen et al., 1998). However, although evidence establishes self-efficacy as an important determiner of such behaviour,

research to identify which treatment interventions can change self-efficacy is lacking (Ashford, Edmunds and French, 2010). Pelvic floor physiotherapy would be expected to improve PFME self-efficacy as it usually involves individual assessment, instruction, advice and clinician support, all of which promote patient self-management and improvement of UI. Some commentators propose that using machine-biofeedback, such as surface electromyography (sEMG), as part of pelvic floor physiotherapy treatment, may increase PFME motivation (Kegel, 1948; Burgio, Robinson & Engel, 1986; Glavind, Nohr, Walter, 1996; Berghmans et al., 1998; Morkved, Bø & Fjortoft, 2002). So far this claim has not been explicitly explored and recent review papers remain inconclusive as to the benefit of different methods of biofeedback (Herderschee et al., 2011).

sEMG involves monitoring pelvic floor muscle exercise performance, usually via an intra-vaginal probe, displaying patient effort in graph-form on a computer screen. This graphical display can be used as a teaching tool during the clinic exercise session (Haslam, 2008b), allowing discussion between physiotherapist and patient regarding exercise performance and ways to improve. Modification of effort is seen instantly on the screen. sEMG can serve to inform an appropriate home exercise regimen and may also be used as a training aid. The use of biofeedback would seem to fit well with the concept of enhancing perceived self-efficacy, as it imparts information to patients about the objective parameters involved in a muscle contraction, thought to be important in improving motivation and enhancing treatment adherence (Emmons & Rollnick, 2001). The use of interventions to increase self-efficacy has been shown to improve self-

management in diabetes management (Anderson et al., 1995), reduce risk factors relating to cardiovascular health (Edmundson et al., 1996) and increase adherence to PFME in pregnancy (Whitford & Jones, 2011). However there appears to be very few intervention studies aimed at increasing PFME self-efficacy in the treatment of urinary incontinence. The aim of this study was therefore to investigate whether the addition of an intervention (sEMG biofeedback) to an existing clinical physiotherapy programme would increase PFME self-efficacy and PFME adherence thereby optimising success of PFME in the conservative treatment of women with SUI. The diagram in figure 1 represents the proposed relationship.

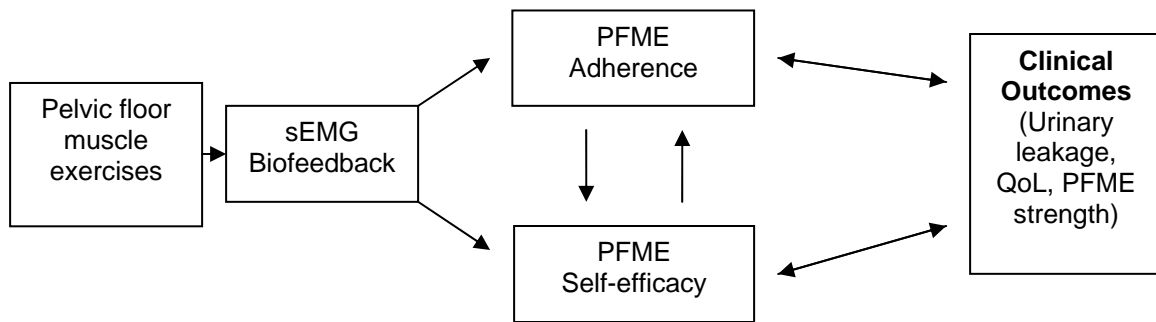


Figure 1 Diagram proposing the theoretical relationships between PFME, biofeedback, PFME self-efficacy, PFME adherence and clinical outcomes.

The diagram in figure 1 suggests that performing PFME with the assistance of sEMG biofeedback will affect PFME adherence and PFME self-efficacy. Changes in PFME adherence may also impact on PFME self-efficacy and vice versa. Each may influence clinical outcomes, which in turn could impact on PFME adherence and PFME self-efficacy.

1.2 Background to Urinary Incontinence

Urinary incontinence (UI) is defined as 'the complaint of any involuntary leakage of urine' (Abrams et al., 2002: p.1632). It can occur as a result of a variety of disease processes and as such should be viewed as a symptom rather than a disease in itself. Community prevalence of UI is thought to be high, however reports vary widely; from 50% of all people in residential care (Damian et al., 2004) to between 6% and 72% of community-dwelling women aged 17 to 79 (Hunnskaar et al., 2002). True prevalence estimates are complicated by probable under-reporting of symptoms, either due to embarrassment or because effective management of mild symptoms means it is not perceived to be a problem (Shaw et al., 2006). Nevertheless in general terms it can be said that UI is about twice as prevalent in women than men, increases with age and is estimated to affect about 30% of women over the age of 50 (Hannestad et al., 2000; Milsom et al., 2009). Urinary incontinence reduces quality of life, impinges on sexual life and causes social isolation (Temml et al., 2000). In addition, it leads to avoidance of physical exercise and activity, acknowledged as being important in maintaining general health and well-being and which increasingly forms a crucial part of many other disease-prevention strategies (Bouchard, Shephard & Stephens, 1994).

Treatment of UI involves conservative measures (PFME, behavioural and lifestyle advice), investigations and tests (such as urodynamics studies), drug therapy, surgery and provision of containment products (such as absorbent pads). These services carry a financial cost, requiring at least 2% of the annual health service budget (Ekelund, Grimby & Milsom, 1993). Given the high

community prevalence of UI, and the increasing longevity and lifestyle expectations of women wishing to remain active into older age, delivering effective treatment can be seen as being extremely important; both in terms of addressing improvements in quality of life as well as helping prevent health decline, for a significant proportion of the population.

1.3 Background to Stress Urinary Incontinence (SUI)

Sub-divisions of UI, as classified by the International Continence Society (ICS), include stress urinary incontinence (SUI), urge urinary incontinence (UUI)/overactive bladder (OAB) (see Table 2) and mixed urinary incontinence (MUI), which is a mixture of urge and stress symptoms.

Table 2 Types of urinary incontinence (ICS definitions, Abrams et al., 2002)

SUI	Involuntary leaking of urine on effort or exertion such as coughing, sneezing or with exercise.
UUI or OAB	Urinary incontinence related to feelings of an overwhelming desire to empty the bladder (urgency of urination). Leakage of urine is associated with, and immediately following, the feeling of needing to empty the bladder.

SUI is characterised by involuntary loss of urine at times of raised intra-abdominal pressure due, in part, to failure of the urethral sphincter closure mechanism and inadequately functioning pelvic floor muscles. An Italian study (Siracusano et al., 2003) reported that 83% of women with incontinence were suffering with SUI. SUI is thought to affect up to one in three women over 18

years of age in the UK (Hunskaar et al., 2004). These high figures are due to the main risk factor of pregnancy and vaginal delivery, with chronic coughing, smoking, constipation and obesity thought to be contributing factors (Bump et al., 1992; Spence-Jones et al., 1994). Worsening symptoms are associated with the menopause (MacLennan et al., 2000) both as a function of age and of hormonal fluctuation.

1.3.1 Treatments and use of PFME in SUI

Continence is maintained by the interplay of many mechanisms, and relies on well-functioning neurological, cognitive, physiological and musculoskeletal systems. Treatment of SUI includes surgery, such as colposuspension, which in recent years has been largely superseded by the Tension-free Vaginal Tape (TVT) and Trans-Obturator Tape (TOT). Alpha-agonist medication increases bladder neck tone and is a more recent treatment addition. The cure rates for Tape procedures are between 63% and 85% (Cody et al., 2003). Apart from the usual risks involved with any surgery, there are five main complications of artificial sling (TVT/TOT) procedures. These are failure to resolve symptoms of SUI (perhaps necessitating a repeat procedure), bladder injury, tape erosion, incomplete emptying of the bladder (requiring a period of intermittent catheterisation), and worsening or new symptoms of urinary urgency. However, as a first line treatment, there is capacity to improve overall pelvic floor function and symptoms of urinary incontinence by exercising the pelvic floor muscles (Bø & Sherburn, 2005). This approach has a long history of documented benefits

(Kegel, 1948) with high level research evidence supporting use of PFME in treatment of SUI. Pelvic floor muscle training currently forms the mainstay of conservative treatment for SUI in women, and this is supported by Cochrane reviews (Dumoulin & Hay-Smith, 2010) and national guidance (NICE, 2006). Therefore the NICE guideline advocates confirming (by muscle palpation) that a correct PFM contraction is being achieved, and a 12-week period of supervised PFME prior to considering surgery. For this to be successful, active patient participation is required. There are no contra-indications or precautions to PFME and they have no known side-effects. However, pelvic floor muscle exercise studies produce variable cure rates indicating that PFME may not work for every woman. Lack of success may be due to factors such as fascial weakness, nerve damage or anatomical anomalies, but another acknowledged issue is that of poor exercise adherence (Bø, 1995; Alewijnse et al., 2001; Chiarelli, Murphy & Cockburn, 2003).

Adherence behaviour is affected by many factors, and self-efficacy plays an important role (Bandura, 1977). Compliance with a PFME programme requires a high level of self-efficacy, with belief in the effectiveness of PFME and confidence in ability to perform the exercises thought to have the most influence on self-efficacy (Hay-Smith, Ryan & Dean, 2007; Whitford & Jones, 2011). Physiotherapists are aware of the need to teach correct contraction of the pelvic floor muscles (Bump et al., 1991) and also to motivate, support and guide their patients in home exercise programmes. Education regarding the benefits of PFME, individual exercise instruction and regular follow-up all seem to help with

this process (Lagro-Janssen et al., 1991; Kim, 2001; Konstantinidou et al., 2007). However, patient self-management of PFME seems to be associated with a decline in self-efficacy over time (Demain et al., 2006).

Anecdotal and expert opinion suggests that women appear to benefit from the use of biofeedback, the visual feeding back of individual performance and progress providing a feeling of accomplishment (Burns et al., 1993; Laycock et al., 2001a; 2001b). In addition, the confirmation that women are performing PFME correctly is thought to play a role in encouraging and increasing motivation to perform PFME and improving adherence to an exercise regimen (Taylor & Henderson, 1986; Glavind, Nohr & Walter, 1996; Wong et al., 2001; Laycock et al., 2001a; Aukee et al., 2002; Mørkved, Bø & Fjortoft, 2002; Schmidt et al., 2009). However, these suppositions are untested, as it appears that no biofeedback studies have specifically evaluated PFME adherence or self-efficacy alongside clinical outcomes as primary outcomes. Furthermore, studies assessing the clinical value of adding biofeedback seem to have produced contradictory evidence (de Kruif & van Wegen, 1996; Berghmans et al., 1998; Weatherall, 1999). Clinical guidance currently concludes that biofeedback confers no added benefit to performing PFME. Biofeedback is therefore not recommended for use routinely as part of pelvic floor muscle exercise training in women with SUI (NICE, 2006).

Success in the conservative treatment of SUI in women relies in part on women's ability to successfully follow a sufficiently intensive PFME training programme for a minimum period of 12 weeks (NICE, 2006). Adherence to a correctly executed

exercise regimen is therefore of the utmost importance and crucial to successful treatment; lack of adherence being recognised as a major barrier to symptom improvement (Bø & Talseth, 1996; Chen et al., 1999). Reasons for PFME non-adherence may be varied but could be due to women having low PFME self-efficacy. Self-efficacy is the belief in one's ability to make or pursue a specific action or change (Bandura, 1986) and is influenced by social, personal and situational factors. It is known to be an important construct in behaviour change and, in this context, is the belief that a woman can perform PFME correctly and often enough to be effective in improving her urinary incontinence. Clinician-supported conservative treatment would be expected to increase self-efficacy, and less clinician supervision appears to compromise self-efficacy in women with SUI (Kim, 2001; Demain et al., 2006). This is of concern, as continence service reviews increasingly scrutinise the cost-effectiveness of the contact time, and number of follow-up sessions, offered to patients. As biofeedback is thought to improve motivation, it is proposed that the addition of sEMG biofeedback may function by increasing self-efficacy to perform PFME, enhancing the value of clinical contact time available to women.

1.4 Conclusion

Self-efficacy appears to be an important factor in motivation and a high level is associated with improved exercise adherence. Self-efficacy acts to enable an individual; increasing perceived ability to deal with unforeseen situations and giving a sense of control, and, in this way becomes a worthy outcome in itself. Inclusion of sEMG biofeedback sessions for women with SUI is already

recommended for women who are unable to perceive a PFME contraction (NICE, 2006), and may improve PFME self-efficacy and PFME adherence in women with good PFME awareness, however this has not been studied before. PFME success correlates highly with PFM training levels because there is a dose response (Bø, 2007). Therefore poor exercise adherence compromises the PFME treatment effect. This is costly, not only economically due to wasted physiotherapy clinic time and continued use of containment products, but also in terms of human suffering through extending the misery for women suffering with urinary incontinence. Interventions to support patient exercise adherence in order to maintain treatment intensity, where access to clinic session support may be limited, would have clear clinical and cost-effective advantages. That said, machine-mediated biofeedback is an invasive intervention and has implications for resources. Equipment and probes can be expensive and expertise in using the equipment and knowledge of muscle training is needed. As sEMG is not available in all healthcare settings, it is also important to establish whether or not the current inequality of access to biofeedback services means that some patients are missing out on a potentially useful adjunct in their pelvic floor rehabilitation.

Chapter Two describes the anatomy and function of the pelvic floor and outlines the rationale for exercising the pelvic floor muscles as a treatment approach for women with SUI. Chapter Three explores adherence and the construct of self-efficacy in behavioural change. Chapter Four outlines the use of sEMG biofeedback in pelvic floor rehabilitation. Chapter Five concludes with a review of

the literature relating to interventions to enhance self-efficacy in the treatment of UI, and an in-depth review of the randomised study evidence for the efficacy of machine-mediated biofeedback (with pelvic floor muscle exercise instruction as a comparator). Against the backdrop of previous work conducted, justification is also presented for studying the role of clinic-based sEMG biofeedback in increasing PFME self-efficacy and adherence to PFME in women with SUI. Chapter Six outlines the methods of the study and Chapter Seven presents the results. Chapter Eight discusses the results and the clinical and further research implications of the study conducted.

CHAPTER TWO Pelvic floor muscle exercises in the treatment of SUI

The success of the physiotherapeutic treatment of SUI is based on improving the function of the pelvic floor muscles. To understand this more fully, it is important first to explain how pelvic floor muscle anatomy and physiology contribute to maintaining continence.

2.1 Muscle function

Anatomically, the pelvic floor muscles consist of 'superficial' and 'deep' layers forming the floor of the pelvic basin. In conjunction with the endopelvic fascia and ligaments, the deep layers, otherwise known as the levator ani, form the levator plate providing support to the pelvic organs and helping to control the urethral and bowel sphincter openings (Figure 2).

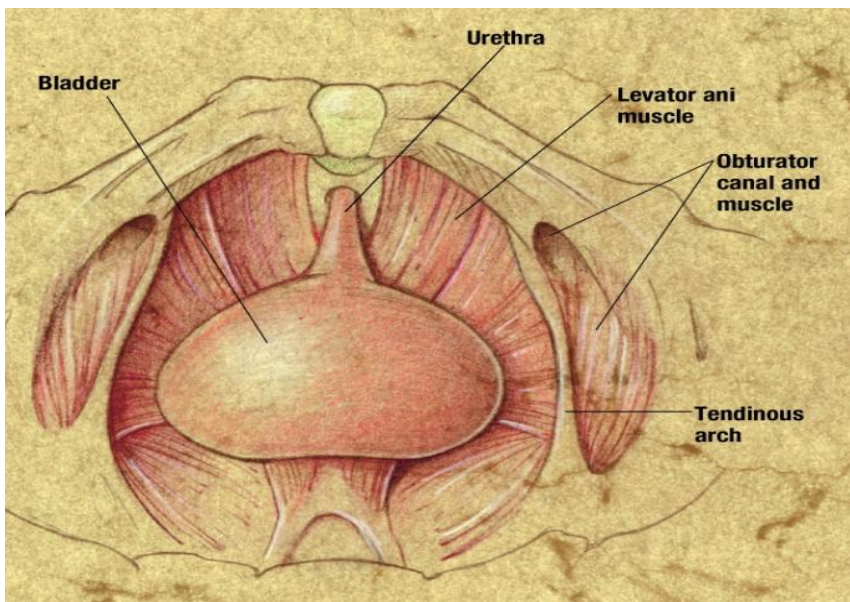


Figure 2 The female bladder viewed from above (taken from Gray's Anatomy)

Ligaments and fascia of the pelvic floor are subjected to gravitational and abdominal pressure forces, with tonic activity in the pelvic floor muscles functioning to relieving this pressure, reducing strain and damage to connective tissues (Ashton-Miller & DeLancey, 2007). Contraction of the pelvic floor muscles produces a forward (anterior) and upwards (cephaladic) movement, helping to close the pelvic openings (DeLancey, 1988), with a voluntary contraction of the pelvic floor muscles often described as a squeeze and inward lift.

2.2 Mechanism of muscle action

Pressure theory (Rud et al., 1980) posits that urethral closure pressure must be greater than bladder pressure to maintain continence. Urethral closure pressure is achieved by the configuration of the striated urogenital sphincter muscle (made up of a large proportion of type 1 muscle fibres responsible for maintaining constant tone and allowing voluntary increases in tone), a loop of smooth detrusor muscle and the vascular plexus present within the urethral sub-mucosa. In addition, longitudinal and circular smooth muscle layers assist urethral closure. Hypertrophy of the pelvic floor muscles, achieved through exercising, is proposed to increase the resistance of the striated muscle layer in the urethral sphincter (Ashton-Miller & DeLancey, 2007). In addition contraction of the pelvic floor muscles produces elevation and clamping of the urethra raising urethral pressure and maintaining continence. It is thought that this mechanism occurs automatically in *continent* women, milliseconds before a rise in bladder pressure (Constantinou & Govan, 1982). In incontinent women use of a well-timed pre-

emptive conscious PFM contraction ('the knack') is shown to be effective in preventing urinary leakage when coughing (Miller, Ashton-Miller & DeLancey 1998) and ultrasound imaging of the pelvic floor and urethral position supports the contribution of muscle contraction timing to good pelvic floor function (Thompson & O'Sullivan, 2003; Jones, Peng & Constantinou, 2006). The Hammock hypothesis (DeLancey, 1994) proposes that the anterior vaginal wall (plus connective tissue), the anterior portion of the levator ani, ligamentous attachments and the tendinous arch of the pelvic fascia act as a supporting 'hammock' under the bladder neck and urethra maintaining anatomical position (see Figure 2) and also functioning as a 'backstop' against which the urethra is compressed during raised intra-abdominal pressure to maintain continence. This rationale suggests that exercising the pelvic floor muscles increases the stiffness and rigidity in the levator ani, improving the function of the pelvic floor as a toned platform to squash the urethra against, keeping the urogenital hiatus closed and preventing descent during abdominal pressure and visceral inertial load (Bø, 2004; 2007). This theory is supported by studies demonstrating higher resting anatomical position of the pelvic floor in continent women (Peschers et al., 1997; Hoyte et al., 2001), smaller (MRI measured) surface area of the pelvic floor muscles (indicating increased tone) and greater resting urethral stability, both following a period of PFME training (Balmforth et al., 2004; Dumoulin et al., 2007).

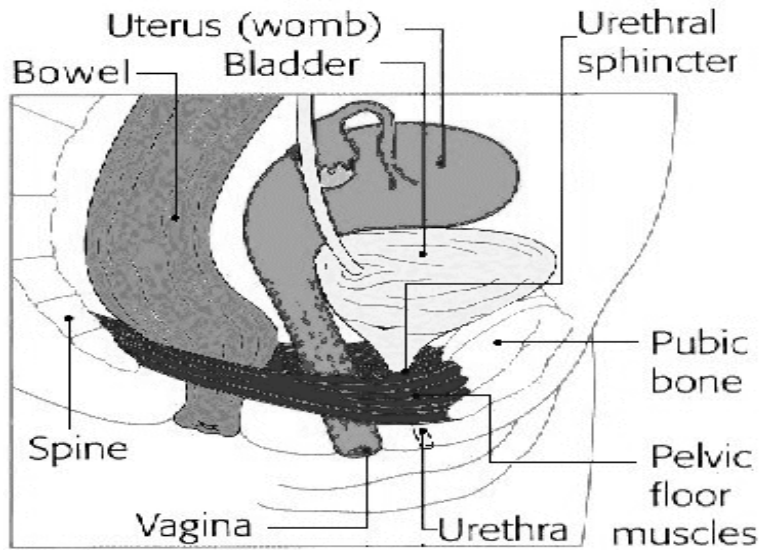


Figure 3 Diagram showing pelvic floor muscles in relation to bladder, vagina and bowel (courtesy of Julia Herbert).

Pelvic floor muscle training has been shown to improve women's overall continence status (Theofrastous et al., 2002), and positive correlation has been demonstrated between maximal pelvic floor strength and reduction in urinary leakage (Bø, 2003). Pelvic floor muscles in women with urinary incontinence are also shown to measure less maximal strength, responsiveness, endurance and tone than asymptomatic women (Morin & Bourbonnaise, 2004).

As a result of these findings, all mechanisms of PFM action are considered in the rationale for treatment.

2.3 Exercise regimens

PFME programmes aim to improve pelvic floor muscle strength and contraction timing in order to provide structural support, muscle tone or 'stiffness' and muscle responsiveness, thereby improving overall pelvic floor function (Bø, 2004). In

women with no (or little) discernable pelvic floor muscle contraction (graded on the Modified Oxford Scale as 0 or 1) neuromuscular electrical stimulation (NMES) is advised in the first instance (Laycock et al., 2001 b). If a muscle contraction is palpable, pelvic floor muscle exercises are encouraged using a regimen to facilitate muscle strengthening, responsiveness and endurance. The pelvic floor muscles are composed of 33% 'fast' phasic fibres and 67% 'slow' tonic fibres. Slow motor units are initially recruited, followed by fast motor units as greater load is placed on the muscle and improved muscular effort is required (Mendell, 2005). Therefore regimens to train both types of fibres are required to improve overall pelvic floor function.

Sports science evidence advocates exercises should aim for low repetitions and high loading of muscles to achieve strengthening, high repetitions and low load for endurance, and rapid muscle contractions to improve responsiveness and coordination (Bø, 1995). Indirect training of the pelvic floor muscles via recruitment of the deep abdominal muscles, in particular Transversus Abdominus (Sapsford et al., 2001) is an approach developed in response to the observation that the pelvic floor muscles contract as part of the 'abdominal capsule' in core stability work. However the evidence for this approach with regards to treatment for SUI is sparse and remains a contentious issue (Bø et al., 2009; Sapsford, Hodges & Smith, 2010). Low-level functional muscle work, that is low intensity contraction of PFM performed during everyday activity is also thought to improve continence (Carrierre, 2006), however evidence is lacking in support of this being used as the *only* method of treatment for SUI (Bø, 2007).

Regimens of exercises used in studies successfully demonstrating PFME effectiveness vary widely: Kegel (1951) suggested three exercise sessions a day aiming for 300 contractions, Bø et al. (1990) instruct 8-12 contractions performed three times a day, Choi, Palmer & Park (2007) advise at least 24 contractions per day, and others posit that pelvic floor strength can be maintained with as little as 8-12 contractions performed three to four times a week (Dougherty et al., 1993; Bø, 1995). As timing of contraction plays a role in reducing leakage, women are therefore encouraged to improve the responsiveness of pelvic floor muscle contractions as well as to perform *the knack* (Miller, Ashton-Miller & De Lancey, 1998). *The knack* is used just before moments of anticipated rise in intra-abdominal pressure (such as coughing or when lifting), in order to counterbrace and stabilise the pelvic floor, assist urethral closure (reduce leaking) and prevent stretching and further weakening of the pelvic floor musculature.

Current expert consensus from the evidence is that PFME should be performed daily and should address strengthening, co-ordination and endurance training principles, as depicted in Table 3, (Laycock et al., 2001b). More recent guidance (NICE, 2006), recommends three PFME sessions a day for a minimum of 12 weeks. The aim of treatment is to improve timing of contraction, strengthening and stiffness of the pelvic floor (Dumoulin & Hay-Smith, 2010).

Table 3 Principles of muscle training (McArdle, 1994)

Specificity	The correct group of muscles needs to be worked. These muscles need to be identified and a correct contraction confirmed by palpation.
Overload	Muscles need to be worked harder than usual for them to improve. This needs concentration and effort and is a continuous process. This is achieved by changing 'hold time', repetitions or reducing the rest periods between contractions.
Maintenance	Exercise needs to continue on a regular basis to maintain improvement. This may be at a lower level than the initial training intensity.
Reversibility	If training stops, muscle function declines in 4-6 weeks. However this is itself reversible with resumption of training.

2.4 Evidence for efficacy of PFME in SUI

Randomised controlled trials (RCTs) evaluated in Cochrane reviews, the most recent of which was conducted by Dumoulin & Hay-Smith in 2010, strongly support the use of PFME in treating women with SUI. This evidence not only shows PFME to be better than no treatment, but also reports a number of studies demonstrating cure rates of between 44% and 70% of participants (Henalla, Millar & Wallace, 1990; Wong et al., 1997; Bø, Talseth & Holme, 1999; Mørkved, Bø & Fjortoft, 2002; Dumoulin et al., 2004). When evaluating this evidence, it must be remembered that clinic support available to research participants is often generous: three to four sessions a day with the physiotherapist for four weeks (Glavind, Nohr & Walter, 1996), twice a week for four weeks (Wong et al., 1997),

clinic training once a week (Henalla et al., 1989; Bø, Talseth & Holme, 1999; Mørkved, Bø & Fjortoft, 2002; Aksac et al., 2003; Dumoulin et al., 2004). While delivering treatment intensively may ascertain efficacy of exercise treatment, frequent clinic sessions are becoming increasingly difficult to offer in day-to-day clinical practice, further emphasizing the importance of optimal patient adherence in ensuring that an effective level of muscle training is achieved. Therefore interventions are needed to improve exercise adherence and ensure treatment success.

2.5 Conclusion

Although the literature highlights a number of studies using a variety of different PFME protocols, there remains strong evidence for recommending PFME in treating SUI. The rationale is that contracting the muscles correctly, maximally and repeatedly, over a minimum period of 12 weeks, improves pelvic floor muscle strength and contraction timing, thereby improving overall pelvic floor function and reducing urinary leakage. However adherence is essential and poor adherence is a stumbling block to progress. Regular and correct PFME are important for successful treatment, and adoption of a daily exercise routine and self-management of exercises in the long term is crucial in maintaining improvement and preventing reversibility (see Table 3).

However, individuals who are prescribed an exercise routine will exhibit different health behaviour with varied levels of adherence. Therefore it is important to fully understand what influences a person's health behaviour, and to be aware of

negative adherence so as to develop strategies to improve adherence to prescribed exercise routines for them to be effective. This will be explored and expanded on in the next chapter.

CHAPTER THREE Adherence and self-efficacy

3.1 Introduction

Maintaining good health and successful health treatment often depends on adopting advice and following treatment programmes. Whether it is an exercise protocol, taking medication as prescribed, eating healthily or stopping smoking, healthy behaviour needs to carry on beyond the clinic and become a daily routine; a part of everyday life for the individual. Behaviour is therefore linked to health and vice versa. Health behaviour is defined by Harris & Guten (1979) as,

'behaviour performed by an individual, regardless of his/her perceived health status, with the purpose of protecting, promoting or maintaining his/her health'.

The terms *adherence* and *compliance* are often used interchangeably in the literature. Horne et al. (2006) usefully summarise the terminology found in the literature (see Table 4).

Table 4 Definitions of compliance, adherence, concordance and persistence (Horne et al. 2006).

<i>Compliance</i>	the extent to which the patient's behaviour matches the prescriber's recommendations
<i>Adherence</i>	the extent to which the patient's behaviour matches agreed recommendations from the prescriber
<i>Concordance</i>	A two-way relationship between patient and physician where treatment decisions are discussed and the treatment of choice is the one most acceptable to both parties
<i>Persistence</i>	the continued adherence over time to the prescribed medication

The word *adherence* is usually preferred by healthcare researchers as it implies patient autonomy, and a willingness to participate and co-operate rather than the traditional view of an expert doctor dictating to a naive patient. It is deemed to be a non-judgemental term, a descriptive statement of fact, with blame not apportioned to the patient, therapist or treatment (Haynes et al., 2002).

Successful adherence to treatment is a complicated issue to address. Adherence varies between patients and over time. It is also influenced by many factors, with over 200 variables shown to correlate with adherence to exercise alone (Sluijs & Knibbe, 1991) including previous experience with exercise, motivation, social support and time/economic considerations (Howard & Gosling, 2008). In pelvic floor muscle exercise treatment, reasons given for non-adherence with home exercise programmes include not achieving symptom relief, inability to remember the exercises, forgetting to do them, perceiving the leakage as not being a priority, concern that the exercises may control but not cure the symptoms and uncertainty about ability to execute PFME (Hayn et al., 2000; Chen, 2001; Dean, Hay-Smith & Elley, 2009). Other reasons expressed for being unable to adhere to treatment programmes include being unable to travel to clinic, lack of time, inconvenience, too long-lasting a treatment, or a poor relationship with the clinician (Paddison, 2002).

Urinary incontinence impacts on many aspects of life and a holistic view of adherence issues needs to be taken into account (Broome, 2003). Adherence may be described as relating to four main areas: *the patient, the condition, the treatment* and the *patient/clinician relationship* (Meichenbaum & Turk, 1987).

Other perspectives identify intentional and unintentional factors or practical and perceptual barriers, and disease-related factors and patient beliefs are thought to play a particularly important role (Horne et al., 2006). Although practical obstacles, such as time, access and cost can be relatively easy to ascertain, perceptual issues, such as beliefs, are harder to evaluate (Kane & Robinson, 2010). A deeper understanding of adherence is achieved by exploring the theoretical foundations of adherence behaviour, and concepts such as self-efficacy which seem important in mediating behaviour change (Sirur et al., 2009). The following section explores the theoretical foundations of adherence behaviour and subsequent sections focus specifically on self-efficacy.

3.2 Adherence

Leventhal & Cameron (1987) identified five theoretical perspectives from which to view adherence behaviour: Behavioural, Biomedical, Communication, Cognitive and Self-regulatory. Each of these perspectives may be mapped to several of the numerous theories of behavioural change described in the literature (Mitchie et al., 2005).

Behavioural approaches may include daily completion of a diary, posting of reminder stickers, and now, more commonly, electronic reminders to exercise which can be programmed into a mobile phone or set up to appear on a computer desktop. The rewards and cues used in this approach are useful and popular adjuncts to treatment, with reminder systems and diaries commonly used in PFME treatment. In one of the few studies testing the effect of these types of

interventions on PFME adherence, home audiotapes were shown to improve compliance with a home pelvic floor exercise programme (Gallo & Staskin, 1997).

The Biomedical perspective, perceives the clinician as the dispenser of objective advice and patients as (compliant) passive receivers, absorbing information and unquestioningly following instruction. Patients can respond well to the approach of the traditional authoritative health professional offering diagnosis and prescriptive treatment (Savage & Armstrong, 1990). Positive responses seen in patients may be attributed to the demonstration of referent or expert power (Stanton, 1987) or input from powerful others (Wallston & Smith, 1994). However, it seems unlikely that direct instruction alone will result in optimal adherence behaviour. The biomedical approach to adherence focuses on the *body* or *condition* and poor adherence is usually attributed to characteristics such as age, gender, socio-economic status or the severity of symptoms. Symptom severity certainly plays a role. Patients with less problematic symptoms and patients suffering with long-term chronic conditions are shown to be more likely to demonstrate reduced adherence levels (Damrosch, 1995). In incontinence, perhaps unsurprisingly, improved adherence to PFME is noted in those with more severe leakage (Alewijns et al., 2003; Shishani, 2003; Chen & Tzeng, 2009). Absence of symptoms in many asthma patients can result in a lack of recognition about the necessity to continue to take regular medication (Halm, Mora & Leventhal, 2006). Moreover, where no disease or symptoms are present at all, as is the case in health promoting strategies such as cervical smear screening, regular dental flossing, maintaining healthy dietary habits or attending

for mammograms (Luszczynska & Schwarzer, 2003), adherence behaviour seems especially difficult to achieve. This is also evident in incontinence prevention programmes where uptake of post-natal PFME instruction (Gillard & Shamley, 2010) and adherence to PFME programmes in asymptomatic undergraduate women (Tremback-Ball, 2006) is found to be poor.

Older studies indicate that one quarter of patients forget Information given to them about their condition, including instructions about 'how' and 'how long' to take medication (Bain, 1977; Crichton, Smith & Demanuele, 1978). Information-giving about bladder habit and PFM function forms a central component of continence health promotion with knowledge of risk factors shown to be important in self-management of UI (Holroyd-Leduc et al., 2011). Knowledge and education also features in guidelines and recommendations for the physiotherapy treatment of SUI (Laycock et al., 2001b; NICE, 2006). However studies examining adherence to PFME also demonstrate that knowledge alone is insufficient in improving adherence (Alewijnse et al., 2003; Tremback-Ball, 2006; Messer et al., 2007) and indicates that additional factors, other than merely knowing more about a condition or treatment, are important in adopting treatment advice.

How information is presented and delivered seems to make a difference (Ley, 1989), with *compliance* (the term used by Ley), directly predicted by the satisfaction with the clinical consultation, and the understanding and remembering of information given. Patient satisfaction with the consultation can be difficult to define. It is affected by information, for example whether this is

individualised or generic (Berry, Michas & Bersellini, 2003), how much information is given (Ley, 1989), how it is delivered, the perceived competence of the clinician giving it, as well as the emotional support and understanding shown by the clinician (Haynes, Sackett & Taylor, 1979; Ley, 1988; Sala, Krupat & Rother, 2002). In a meta-analysis of research looking at recall (Ley, 1981; 1989), age was found to have no bearing on accuracy of memory; but medical knowledge, intellect, information importance and quantity of information all seem to affect ability to remember information given during a consultation.

Clinicians treating incontinence make use of different types of information-giving in order to enhance remembering and understanding. Giving written instructions reinforces salient points and acts as a reminder. The patient can take the information sheet home and consult it again. Anatomical models, leaflets, analogy and imagery also help with this process. Locating the pelvic floor muscles on a model or diagram provides important visual information helping to achieve understanding which is not always possible through verbal or written explanation alone. Similarly, imagery and visualisation help the teaching of pelvic floor muscle exercises; for example, the muscle response may be likened to *a high speed lift going up to the top floor of a building* in order to visualise and establish a brisk, high intensity contraction. sEMG gives a visual representation of pelvic floor activity and can be used as a further way of giving information.

Illness cognition beliefs help patients understand and cope with their illness, as well as form implicit common-sense beliefs about their condition. Patient beliefs and perceptions of their illness impact on their motivation and adherence

(Leventhal, Meyer & Nerenz, 1980; Leventhal et al., 1997). For the clinician this underlines the importance of establishing coherence between a patient's illness beliefs and treatment beliefs. Beliefs around the success/prognosis of treatment and the health consequences of non-compliance have been shown to influence adherence (Friedman et al., 2008). Moreover, better adherence to medicine-taking is found if patients believe both that their condition is serious but that it can also be controlled (Brewer et al., 2002). Unsurprisingly, successful adherence is linked to a greater belief in the effectiveness of the medication (Senior & Marteau, 2007), with doubt about the necessity for treatment (and the effectiveness of the treatment) found in poor adherers (Horne & Weinman, 2002; Llewellyn et al., 2003). These findings further highlight the importance of evaluating patient perspective and attitude, as well as awareness of their condition, and the range and effectiveness of treatments available. Correction of misconceptions about incontinence, and accurate information about treatments, are crucial. Therefore clinician appraisal of patient perspective is vital to successful management. Exploring these beliefs with patients requires effective communication, which can be assisted by adopting an interactive, patient-centred consulting style (Byrne & Long, 1976; Emmons & Rollnick, 2001).

Reasons for poor PFME adherence have been studied before (Chiarelli, Murphy & Cockburn, 2003; Paddison, 2002; Alewijnse et al., 2001 and 2003) and theoretical underpinnings related to PFME adherence have also been discussed (Broome, 1999; Alewijnse et al., 2001; Chen, 2004; Chen & Tzeng, 2009).

Cognitive models encompass psychological theory and help understanding of the multiple levels of influence in adherence behaviour. These models share the assumption that the person is cognitively aware; that is, a person has foresight, planning, and decision-making capability and can also goal-orientate and self-regulate their responses (Brawley & Culos-Reed, 2000). Self-efficacy appears in different guises in many cognitive models of health behaviour, mainly because belief in personal efficacy not only affects health behaviour directly, but also indirectly by influencing goals, outcome expectations, and the individual factors which obstruct and assist change (Bandura, 2004). Incontinence impacts on the physiological, psychological and sociological aspects of women's lives, so it is important that any theory or model of adherence encompasses these dimensions. Self-efficacy is an important construct in adherence, and has been identified as important to optimal PFME adherence in UI (Chen, 2001; Alewijnse et al., 2003; Demain et al, 2006; Hay-Smith, Ryan & Dean, 2007).

3.3 Self-efficacy

Personal efficacy or self-efficacy first appeared in self-efficacy theory developed by Bandura in 1977, however it is also found in Protection Motivation Theory (Rogers, 1983), as *perceived behavioural control* in the Theory of Planned Behaviour (Ajzen, 1985) and forms the central concept of Social Cognitive Theory (SCT) (Bandura, 1986). Self-efficacy is also important in progression through 'stages' of behavioural change (Prochaska and DiClement, 1984; Schwarzer, 1992), in self-regulation (Morrison & Bennett, 2009), and goal-striving

(Locke & Latham, 2002). The presence of self-efficacy in so many health models indicates the overall significance of this construct in behavioural change and theories of adherence. This is because motivation to exercise is cognitively generated, and motivation is enhanced by self-efficacy (Bandura, 1997).

Self-efficacy is one of the main and most consistent factors predicting behavioural change (Morrison & Bennett, 2009, p.158) and a more powerful predictor of exercise adherence than either self-motivation or locus of control belief (Sallis et al., 1988; Dishman, 1994). The construct, sources and relevance of self-efficacy to this study is explored in the following sections.

3.3.1 Definition of self-efficacy

Self-efficacy is defined as ‘the belief in one’s capabilities to organise and execute the sources of action required to manage prospective situations’ (Bandura, 1986). It assumes that human motivation and action are based on three beliefs: *situation-outcome*, if I do nothing my situation will worsen; *action-outcome*, if I take action my situation will improve; and *perceived self-efficacy*, I am able to perform the required action correctly and for long enough to be effective. Apart from self-efficacy, other dimensions of SCT with regards to health include, *knowledge of lifestyle habits* and their influence on health, *health goals, costs and benefits of lifestyles*, the *value placed on outcomes* and *environmental facilitators and constraints*. Self-efficacy also affects these other SCT factors by influencing motivation through shaping goals and outcome expectancy (OE). Self-efficacy is largely influenced by self-referent thought, which in turn is affected by our concern of how others judge our capabilities (Bandura, 1977). It is

a belief in personal competence and capability, and as such affects the choices and courses of action pursued by the individual to:

“engage in tasks in which they feel competent and confident and avoid those in which they do not” (Pajares, 1996 p2).

Therefore the role of the pelvic floor physiotherapist should be aimed at promoting engagement in PFME, and helping patients to be competent and confident in their PFME performance.

3.3.2 Sources of self-efficacy

Self-efficacy is behaviour specific (Maibach & Murphy, 1995), and use of specific self-efficacy measures is recommended by Bandura and supported by studies such as Lyons (1985). This study studied aerobic exercise, and demonstrated poor correlation between general self-efficacy scores and exercise adherence, but positive and significant correlation between *exercise self-efficacy* and levels of *exercise* adherence. Cultural and wider political/social influences also play a role in self-efficacy appraisal.

There are four sources of self-efficacy:

1. Enactive attainment or performance accomplishment
2. Vicarious experience or social learning (modelling)
3. Verbal persuasion
4. Physiological state such as high anxiety or stress.

Performance accomplishment or *personal mastery* is thought to be the most important source of self-efficacy. In high level sport/skills those with low self-efficacy often devalue their own accomplishments, often because performance standards are high. In this situation personal mastery can be helped using *participant modelling*, that is, experience of skill success through initial demonstration followed by guided performance (Bandura, 1977). This involves breaking down a task into sections until success in the completed sequence is achieved. Participant modeling in gymnastics and other sport has been shown to increase self-efficacy measures (Felz, Landers & Raeder, 1979; McAuley, 1985). An additional source of performance accomplishment is achieved with *performance feedback*, which may be false (deception feedback) or true feedback. Feedback is shown to change self-efficacy and may be used to manipulate performance, for example by informing (falsely) that a competitor's time has not been achieved in order to raise performance, or by giving the performer a falsely inflated score to boost morale or self-confidence. It therefore seems that the key to building self-efficacy is perceived success. It is speculated by Burns et al (1993) that biofeedback used for feedback in pelvic floor muscle exercise may give this sense of accomplishment.

As well as one's own achievements, self-efficacy can be influenced to a lesser extent through viewing other's efforts on a task, that is, through vicarious experience (Bandura, 1986). This is the basis of the popularity of support groups such as exercise groups and slimming clubs and this principle is also used by physiotherapists in cardiac rehabilitation and post-surgery exercise groups. The

strength of influence is shown to be further increased if the person closely resembles the individual's own ability, experience and skill (George, Feltz & Chase, 1992). Verbal encouragement also raises self-efficacy and has the most influence when encouragement is delivered immediately after a performance accomplishment (Wise & Trunnell, 2001). Joint viewing of exercise performance by patient and clinician allows encouragement to be given to the patient during a biofeedback session. Physiological and emotional states affect self-efficacy with positive states such as happiness, associated with raised self-efficacy while negative states (depression) associate with low levels of self-efficacy (Maddux & Meier, 1995). Optimistic self-belief about ability or self-confidence creates positive affective states (Schwarzer & Fuchs, 1996), while pessimistic views of anticipated performance gives rise to anxiety or depression as perceived inefficacy results from trying to control prized outcomes. This may occur when outcomes are highly valued, outcome expectancy is high and performance expectation is low (Bandura, 1986). However Initial high levels of self-efficacy may also be associated with reduced performance if goals are controlled and not revised (Vancouver & Kendall, 2006). This is because high self-efficacy may give rise to complacency, causing decline in adherence and poor outcomes.

These sources and influences self-efficacy would seem to indicate that clinician contact, involving the support and guidance offered during usual physiotherapy treatment would present an ideal opportunity to enhance and support self-efficacy. In a review of studies aiming to target the four sources of self-efficacy (Ashford et al., 2010), feedback was given in less than one third and very few

looked at vicarious activity or affective states. General goal setting, verbal encouragement and identifying barriers were common. sEMG biofeedback involves the woman viewing a representation of her own muscle activity and receiving verbal feedback and endorsement of this physiological response. This experience, as well as using the biofeedback to highlight aspects of performance and concentrating on achievable components of the exercise, would be expected to further enhance pelvic floor muscle exercise self-efficacy through goal setting and affective response to the progress achieved. Biofeedback should also help address issues of complacency (Vancouver & Kendall, 2006) by allowing visualisation of performance and the re-setting of goals.

3.4 Conclusion

Understanding the theory of adherence behaviour helps identify factors associated with adherence and informs the development of interventions to improve adherence in patients. Nearly all more recently developed health behaviour models incorporate measures of personal efficacy, acknowledging self-efficacy as an important factor in adopting health behaviours. Self-efficacy is shown to be the most important predictor of adherence behaviour, and a valuable process indicator, especially important as actual adherence to home exercise is difficult to measure accurately.

Various factors impact on adherence. Some, for example condition or symptom severity, are not easy to directly influence. Others, such as the clinician-patient relationship, education, information-giving and goal-setting can be enhanced.

Approaches thought to improve adherence include using reminders to exercise, employing a patient-centred approach to consultation and having awareness about how information can be given. Clinical contact helps ascertain understanding (Ley, 1989) and written information plays a role in supporting oral advice (Ley & Morris, 1984). Self-efficacy theory would predict that high levels of self-efficacy enables good self-management and treatment adherence for women with urinary incontinence, with research confirming positive correlation between PFME self-efficacy and PFME adherence (Chen, 2001) as well as identifying self-efficacy as a major influence on exercise adherence (Chen & Tzeng, 2009). Therefore intervention studies aimed at improving self-efficacy have potential to augment adherence and treatment outcomes.

Authors to date acknowledge the difficulty of building and maintaining levels of self-efficacy in patients and intervention studies designed to improve self-efficacy in UI seem thin on the ground. Self-efficacy is thought to be influenced in four ways, through performance experience, vicarious experience, verbal encouragement and affective/emotional influences. Physiotherapists often adopt a problem-solving and skills-based approach in encouraging health promoting behaviour. This may include facilitating the learning of exercises and the adoption of exercise regimens, targeting health information and advice as well as teaching patients self-management strategies. Information (both oral and written) and education are important. Improving patient knowledge of pelvic floor muscle function, and education regarding the benefits of exercise, also play a role in improving self-efficacy (Hay-Smith, Ryan & Dean, 2007). However, information

and education alone seem insufficient in guaranteeing PFME adherence for long enough to give symptom relief. Regular contact and feedback on progress gives opportunity for reassurance and encouragement to continue with an exercise programme, as well as providing motivation to exercise independently at home. Confidence in ability to perform the exercises correctly (task self-efficacy) is also an essential component to pelvic floor muscle exercise adherence (Messer et al., 2007) and use of biofeedback in PFME clinic sessions has been suggested to improve motivation to exercise and help adherence. This thesis proposes that this is achieved by improving PFME self-efficacy, as sEMG biofeedback imparts information and enhances confidence in performance. This assistance with learning, is proposed to provide reassurance of correct performance during early contact with the patient, and the setting of exercise goals.

How biofeedback is used in pelvic floor muscle rehabilitation is outlined in the following chapter.

CHAPTER FOUR BIOFEEDBACK

4.1 Introduction

Biofeedback is 'the technique by which information about a normally unconscious physiological process is presented to the patient and/or therapist as a visual, auditory or tactile signal' (Peschers et al., 2001). As previously mentioned, in pelvic floor physiotherapy this is purported to assist pelvic floor muscle rehabilitation by helping the patient to learn the exercise and is also believed to help motivation to exercise in patients (Mørkved, Bø & Fjortoft, 2002). This definition of biofeedback may include muscle palpation, real-time ultrasound images and manometric pressure (Haslam, 2008b). Another common biofeedback tool is surface electromyography (or sEMG).

EMG can be defined in a wide sense as analysis of bioactivity of muscle through monitoring myoelectric signals. Electrical potentials, generated by the depolarisation of muscle, undergo amplification, rectification and 'smoothing' to produce a screen image. In this way, electrical activity of muscle can be monitored as a representation of muscle function (Haslam, 2008b). Traditionally in EMG, muscle response is measured after an artificial electrical stimulus is applied; this is called 'neurological EMG'. The term EMG may also be used to describe 'needle EMG' a more invasive technique where motor units are monitored by insertion of a needle electrode into the muscle. This is mainly used in research and has no practical application in day-to-day pelvic floor treatment and rehabilitation. In the context of pelvic floor physiotherapy (and this study), the

term EMG refers to *kinesiological* EMG, the surface recordings (sEMG) of muscle activity.

4.2 sEMG biofeedback: modalities and use

Neuromuscular activation is recorded through surface or skin placement of a sensor or probe. Surface EMG (sEMG) detects the overall pattern of concurrent activity of motor units (motor unit action potentials) through the skin, in the area of the sensor (Cram & Kasman, 1998). This is therefore less selective than needle EMG, meaning that ‘crosstalk’ (activity from other concurrent muscle activity) may be detected (Carrière, 2006, p.209). Electrical activity arising from muscle activity (during exercise and voluntary effort) is recorded in microvolts and displayed as a visual, and sometimes auditory, signal for both patient and therapist to view/hear (see figure 4)

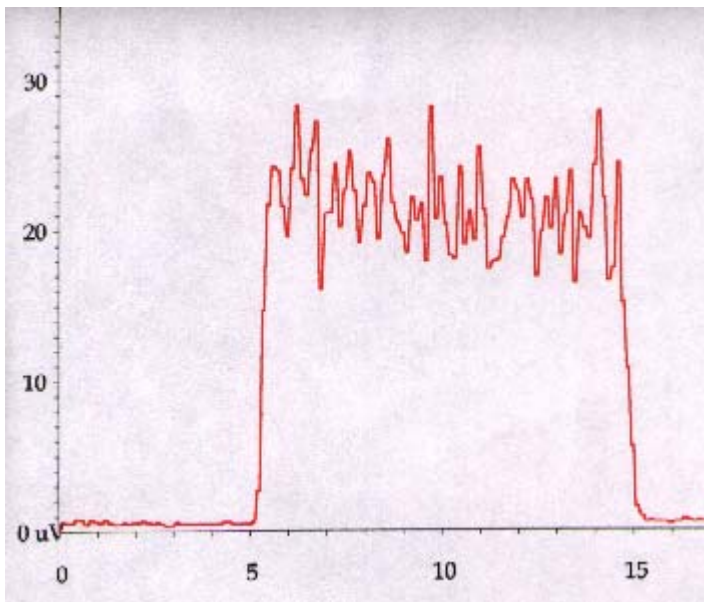


Figure 4 sEMG biofeedback output graph (demonstrating a 10 second muscle contraction)

This feedback of physiological or 'bio' information gives rise to the name 'biofeedback'. In general rehabilitation, this can be used solely as a research evaluation tool, but it is also commonly used by many physiotherapists to help patients to view their training effort and to assist in exercise goal setting. In pelvic floor training, sEMG biofeedback is used as part of the rehabilitation process aiming to improve pelvic floor muscle strength and function. In this way it is an adjunct to a home programme of pelvic floor muscle exercises.

4.3 sEMG biofeedback in pelvic floor rehabilitation

In this thesis the term 'biofeedback' will refer to surface EMG (sEMG) although the terms are used interchangeably throughout the text. Since the advent of well-designed and comfortable intra-vaginal probes, the popularity of using sEMG in pelvic floor rehabilitation has increased. The internal vaginal probe detects electrical information from pelvic floor muscle through surface recordings. The probe is connected by cables to a biofeedback unit (see diagram, figure 5). Three electrodes are necessary: two for recording and one for reference. With internal vaginal probes, the two recording points are conveniently integrated into the probe design. The reference electrode is usually a self-adhesive electrode applied to a local superficial bony point, for example the patient's pelvis or knee. Probe or electrode condition, conducting gel, skin condition and cables and connections can all affect the signal quality (Haslam, 2008b).

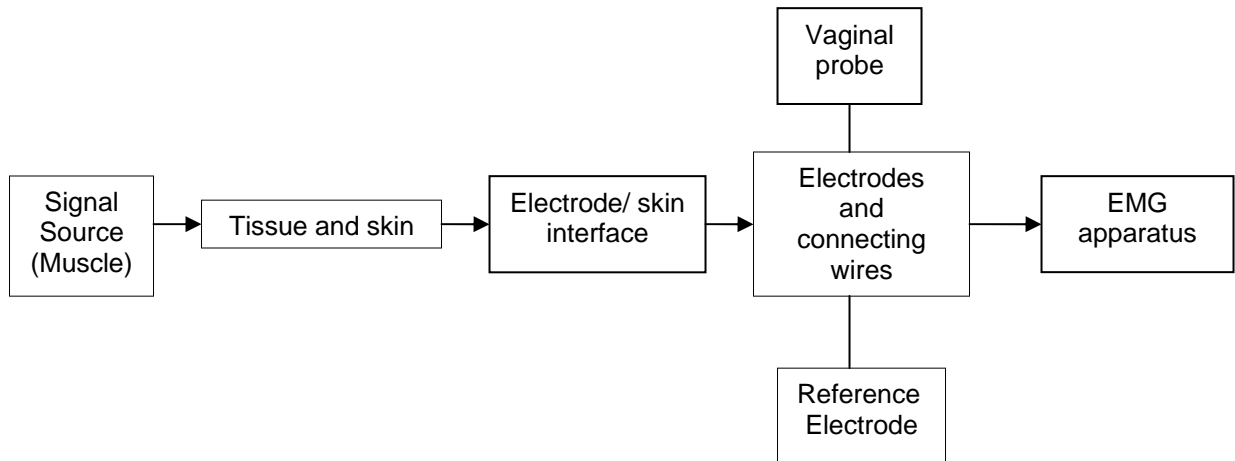


Figure 5 sEMG signal path to equipment

The sum of the motor unit action potentials is detected by the electrodes and amplified (by the differential amplifier) in the sEMG equipment (Figure 6). The equipment compares this recorded activity to the reference electrode activity and allows only unique signals from the recording electrodes to be processed further (Cram & Kasman, 1998). The common mode rejection ratio (CMRR) is a measure of how successfully the common mode signal (electrical ‘noise’ from environmental sources), is filtered out by the differential amplifier. Signal then passes through a *notch filter*, which is very narrow in width (49-51Hz in the UK, or 59-61 Hz in the United States) and works specifically to eliminate mains frequency (50hz in the UK, 60Hz in the United States) (Haslam, 2008b). The raw sEMG activity passes through a band-width filter, to enable only stable frequencies within a specified range to be processed further. Raw EMG signal is graphically displayed as an oscillation from positive to negative around a baseline and would be difficult to interpret. Therefore the signal is further amplified and displayed as a rectified signal which is uni-directional (appearing only above the

graph baseline) (see figure 4, p38). If necessary the clinician can further smooth the trace to reduce jumpiness and better facilitate interpretation of muscle activation by both the therapist and patient (Figure 6).

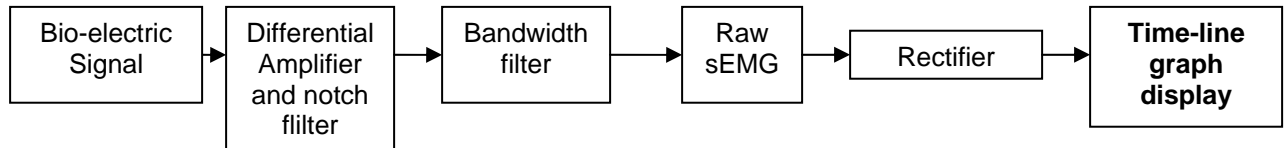


Figure 6 sEMG equipment processing of signal

4.4 The monitoring process

The vaginal probe is easily inserted by either the patient or clinician following a digital vaginal assessment. Biofeedback can be used in any position, however reproducibility of readings is helped by standardising patient position (Haslam, 2008b). Information, both graphic representation and numerical readings (in microvolts), regarding the resting state of the muscle, responsiveness during initiation of contraction, endurance, co-ordination, release of muscle activity (onset of relaxation), and the number of repetitions achievable in an exercise session can all be monitored during the treatment session (Carrière, 2006, p.214). As pelvic floor muscle activity increases (such as when the patient contracts the pelvic floor muscles) increasing levels of microvolt activity are displayed, represented by a rising graphical trace. Relaxation of the pelvic floor

muscles produces a fall in muscle activity and a fall of the graph trace (see figure 4, p.38).

4.5 sEMG equipment

'Cross-talk', electrical activity from other muscle groups, can occur when using sEMG (Mørkved, Bø & Fjortoft, 2002). For this reason clinic-based treatment (rather than use of home biofeedback units) allows the therapist to monitor extraneous muscle activity as well as to give individual correction and encouragement. Clinician monitoring also ensures consistent electrode placement and patient positioning thereby helping reproducibility of readings.

The surface EMG (sEMG) monitoring equipment used in clinic, and for this study, is a PRS 7300 EMG biofeedback (Neen Healthcare) (Figure 7), with an internal vaginal Periform® or Anuform® (small vaginal) surface electrode (Figure 8). The Neen PRS 7300 is a long-established piece of equipment designed specifically for use in pelvic floor muscle rehabilitation.

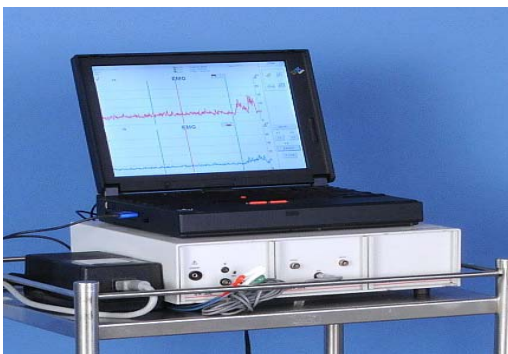


Figure 7 sEMG biofeedback equipment

The monitoring electrode, Periform® (or Anuform® a smaller vaginal or anal electrode) detects PFME activity vaginally. The probes are single patient, multi-use and are designed to be used for a six month period of treatment before needing to be replaced. The Periform® probe is made of high impact polystyrene and incorporates two medical grade stainless steel electrode plates. The surface area of each electrode plate is 4.9cm².



Figure 8 Periform® probe and Anuform® (small vaginal) probe (not pictured to scale)

The shape of the probes is designed to minimise displacement/movement within the vagina, and, as they record non-selectively, this helps to enable good test-retest reliability and content validity (Vodušek, 2007, p.61). Water-based gel (such as Aquagel) is the conducting medium used to coat the plates and assist vaginal insertion. Coupling gel also helps to create good contact between the electrode plates and muscle tissue surface also ensuring that a strong and valid signal is detected from the muscle. The probes are lightweight (19g), easy to insert, and can be used in a variety of functional positions (for example, standing

up, sitting down and lying down). This type of non-selective surface monitoring has two main advantages in the clinical rehabilitation setting. Firstly, it is less invasive, and therefore acceptable to patients, than placement of an intramuscular needle electrode. Secondly, it detects activity from all parts of the source muscles, that is, it monitors motor unit activity from the muscle in contact with the electrode plates and from the surrounding source muscle tissue not in direct contact with the probe, as muscle fibres from one motor unit may not be adjacent to each other (Vodušek, 2007). The Periform® probe has demonstrated good-to-high between-trial reliability (Auchincloss & McClean, 2009).

sEMG is thought to produce a valid and reliable signal (Glazer, Romanz & Polaneczky, 1999; Vodušek, 2007) and is sensitive to even small changes in muscle activation. Reliability and validity of the signal is improved by using the same equipment and clinic room, to minimise variation in electrical interference impacting on the sEMG signal. sEMG displays a good representation of patient exercise effort and has shown good retest reliability in non-symptomatic volunteers when ability to correctly contract the PFM is controlled for (Grape, Dederling & Jonasson, 2009). Reliable data display is needed for participants to accurately assess their performance so that the readings can be trusted and used to base self-efficacy judgements. Therefore the EMG equipment should be regularly serviced and the signal output checked. This occurs in the physiotherapy clinic every six months. In addition, and in order to ensure that sEMG provides a meaningful indication of source muscle activity, it is important

that interpretation of the trace is linked to actual muscle 'events' (Vodušek, 2007), in other words, output traces are interpreted in the light of patient effort and actual muscle activity occurring at the time. For this reason, clinic-based treatment with therapist involvement should be a key requirement in ensuring valid sEMG monitoring.

Chapter Five presents a review of the literature relating to self-efficacy used as an outcome measure and the efficacy of biofeedback, compared with PFME alone, in the treatment of UI.

CHAPTER FIVE Review of the Literature

5.1 Search strategy

The areas of literature searching relevant to the research presented in this thesis are sEMG biofeedback in augmenting physiotherapy treatment in SUI, PFME adherence and self-efficacy. The literature review specifically examines the efficacy of sEMG biofeedback in the treatment of SUI in women, the concept of self-efficacy, as well as appraising the evidence for linking self-efficacy and adherence behaviour. Studies looking at the impact of SUI treatment interventions on self-efficacy and PFME adherence are evaluated, and the theoretical role of sEMG biofeedback in increasing PFME self-efficacy and PFME adherence is explored.

This chapter gives an integrative review of the relevant literature critically evaluating current theory, practice and evidence relating to the key areas of this research. As the research conducted as part of this thesis is a randomised controlled trial (RCT) looking at intervention effectiveness, a detailed review of RCTs comparing biofeedback plus pelvic floor muscle exercises using 'pelvic floor muscle exercises alone' as a comparator was also conducted. A number of databases were searched and search terms or MesH headings that were used were formulated with help from the acronym 'PICO' (Participants, Intervention, Control, Outcome). See Table 5.

Table 5 Databases and search terms

Data bases	Search Terms
OVID Medline (R) In-Process & Other Non-Indexed Citations OVID Medline (R) 1950-present CINHAHL AHMED Cochrane PEDro	Self efficacy Patient compliance Treatment adherence Pelvic floor Biofeedback Urinary incontinence, Stress/

Limits used were English Language, Human studies, Adult and Clinical trials.

Additional research literature was obtained from the Cochrane database, PEDro, EBM reviews, NICE and also extracted from reference lists of known articles and clinical textbooks. A search of grey literature was performed using ProQuest, with dissertations and theses obtained as online abstracts located through GOOGLE scholar and conference presentations. Email correspondence with authors (Aleijwinse, Chen, Demain and Hay-Smith) was useful.

5.2 Adherence and self-efficacy for pelvic floor muscle exercises

The evidence for education and Information giving in PFME studies is mixed. While lack of knowledge about PFME has been identified as a barrier to PME adherence (Hayn et al., 2000; Chen, 2001; Chiarelli, Murphy & Cockburn, 2003), and is endorsed by Kim (2001) who demonstrated that giving educational information achieved greater PFME adherence (and improved levels of self-efficacy), Alewijinse et al. (2003) concluded that addition of a health education programme had no impact on UI treatment adherence. Similarly, Messer et al. (2007) found *knowledge self-efficacy* a poor predictor of PFME adherence.

PFME adherence seems to be enhanced by adopting a formalised routine for home PFME practice rather than an 'ad hoc' approach (Hines et al., 2007) and by using audiotapes (Gallo & Staskin, 1995). Confirming to the patient that they can contract their muscles effectively and establishing that a correct PFM contraction is being performed is recommended as best practice (Bø, 2007), and PFME task self-efficacy is associated with good adherence (Messer et al, 2007). Other work has highlighted the importance of an initial assessment incorporating individual exercise instruction (Konstantinidou et al., 2007; Felicissimo et al., 2010). Follow-up clinics and regular treatment sessions (more than once a week contact with the therapist), allow opportunity to reinforce the benefits of PFME compliance, as well as giving ongoing reassurance and individual feedback regarding correct exercise technique (Bø et al., 1990; Bø, 1995, Hayn et al., 2000; Alewijnse et al., 2001; Chiarelli, Murphy & Cockburn, 2003). Kim (2001) claims similar support is achieved through telephone contact. The importance of support is further evidenced by studies where no assessment of PFM contraction, or contact with the clinician occurs. Ramsey & Thou (1990) reports a poor adherence rate of 15% of the requested exercise level, and a Cochrane review concludes that control groups receiving reduced or no supervision with PFME are linked to poorer outcomes (Dumoulin & Hay-Smith, 2010).

In the longer term following a period of formal PFM training, a decline in PFME practice is observed, to the extent that only a third of participants were still exercising at 5 years, reducing further to 25% at 15 years (Bø & Talseth, 1996; Bø & Sherburn, 2005). Factors which enhance long-term PFME adherence

include positive intention to adhere, good levels of short term PFME adherence, high levels of self-efficacy and greater severity of leakage symptoms (Chen, 2001, Alewijnse et al., 2002; Alewijnse et al., 2003; Shishani, 2003; Chen & Tzeng, 2009). Evidence disagrees as to whether age is a significant influence on PFME adherence (Chen, 2001; Chiarelli, Murphy & Cockburn, 2003).

Self-efficacy appears to be vital to treatment success and several studies call for interventions to build and support levels of self-efficacy in a bid to improve pelvic floor muscle exercise adherence, self-management and treatment outcomes (Chen, 2001, Alewijnse et al., 2001, Demain et al, 2006, Dean, Hay-Smith & Elley, 2009). Chen & Tzeng (2009) further developed a three stage theoretical model to test which factors directly affected PFME adherence, and which indirectly affected adherence when mediated by PFME self-efficacy. Path analysis of this model suggests that PFME self-efficacy directly influences PFME adherence and that age, leakage severity also directly predict adherence (Chen & Tzeng, 2009). Attitudes, dyadic cohesion and perceived benefits of performing PFME were found to be associated with increase in self-efficacy which indirectly affects adherence, that is, these factors seem to be mediated by self-efficacy.

Pelvic floor muscle exercise self-efficacy is a behaviour specific construct, that is, it relates to the ability to perform pelvic floor muscle exercises correctly and regularly as advised and despite barriers. Self-efficacy is of particular importance in PFME because the action of contracting the muscles can only be *sensed*, as it takes place internally and is not directly visible. During vaginal examination by the clinician, women are usually reassured that they are indeed performing a

correct contraction. This is important as women may doubt that they are performing their exercises correctly, affecting confidence in performing PFME (Chen, 2004). High self-efficacy is important in short-term and long-term PFME adherence, but seems difficult to maintain (Alewijjnse et al., 2001; Kim, 2001; Alewijjnse et al., 2003; Demain et al., 2006; Gillard & Shamley, 2010; Dumoulin & Hay-Smith, 2010). This could have a detrimental impact on both adherence and motivation.

5.3 Appraising PFME self-efficacy

Developing and validating questionnaires and measurement scales have been crucial in the studying of pelvic floor muscle exercise self-efficacy. Validation studies for pelvic floor self-efficacy scales have been conducted in Japan (Kim & Kanagawa, 1998), in the United States (Broome, 1999; 2001), in Taiwan (Chen, 2004) and in Canada (Tannenbaum et al., 2008). One of the stated aims of scale development is to identify women with low self-efficacy levels in order to focus interventions to improve self-efficacy and achieve success with conservative treatment; however it appears very few studies have measured self-efficacy (as a mediating concept to adherence) in response to a physiotherapy intervention in urinary incontinence. The studies identified are reviewed in the following section.

5.4 UI intervention studies measuring self-efficacy (Table 6)

Studies researching UI treatment interventions measuring self-efficacy as an outcome are set out in Table 6. These studies have a variety of methodologies and aims. Studies to develop, test and validate self-efficacy measurement tools are not included in this summary.

Table 6 Summary of UI research studying interventions and their effect on self-efficacy

Author	Design	Intervention	Outcome measures	Results	Conclusions
Svengalis et al., 1995	Cohort study Women with UI, n=71 16 dropped out 55 completed 3 month PFME course	Evaluation of the relationship between perceived SE and treatment outcome after treatment with PFME	UI episodes per day measured at 3 months. SE measured at baseline and 3 weeks using a scale devised for the study.	Initial high SE associated with poor treatment outcome. Improved SE 'weakly' associated with reduction in leakage episodes $r = .31$ $p < 0.07$ (so not significant)	Initial unrealistic expectations reflected in high SE scores at baseline. Author concludes improved SE over 3 weeks is associated with good clinical outcomes at 3 months, but the result was not significant.
Kim, 2001	RCT: Women with SUI 3 groups n=48 5 dropped out 43 completed	3 visits in 3 months: 1. Continence Efficacy Intervention Programme 2. Info sheet and initial PFME teaching session 3. No treatment control. No confirmation of PFM contraction by the therapist, self-palpation advised.	SE measure (Continence Self-efficacy Scale developed for the study). 5 point ordinal symptom improvement scale	Significant difference in improvement for the CEIP group compared with the controls for SE, adherence and symptoms	Author concludes that encouragement and accurate information helped PFME adherence. Phone interviews helped this process. Lack of muscle assessment/palpation in all groups. Small sample number

Demain et al., 2006	Cohort study n=26 Women with UI Does self-efficacy change over a treatment period and is there an association between baseline self-efficacy and outcome?	One initial physiotherapy session followed by self-managed physiotherapy treatment for a 6 week period.	SE and outcome expectancy measure, Vaginal assessment and symptom severity, Kings health questionnaire Measures performed at baseline and at 6 weeks.	Significant reduction in SE over the treatment period.	Greatest improvement in symptoms in women with high initial SE and high outcome expectations. Significant and positive correlation found between outcomes and SE.
Messer et al., 2007	Cohort of post-menopausal women n=164 Prevention of UI	A 2 hour behavioural modification program session plus one follow-up session at 2-4 weeks. Aim to prevent onset of UI 12 month study	Adherence and SE measured at 2 weeks post-intervention and at 3 month intervals until 12 months. Regression analysis to see what types of self-efficacy predict PFME adherence.	Modest decline of S.E over time Establishes the link between SE and adherence over time	SE may be an index of motivation. Knowledge SE not a factor in PFME adherence but regulatory and task SE is important

Kim (2001) conducted the only RCT measuring self-efficacy as a response to a treatment intervention in UI. She tested an intervention programme called the Continence Efficacy Intervention Program (or CEIP) designed to address obstacles to exercise adherence, evaluated exercise continuity (adherence) and self-efficacy. The control groups received conventional care consisting of one assessment session where the women were trained to do pelvic floor exercises and given an information sheet. The CEIP intervention group received follow-up clinic sessions, telephone follow-up to ascertain understanding and encourage adherence, an instructional audio-visual tape, an adherence/exercise reminder diary and more detailed muscle training advice. It is difficult to deduce from the

published information whether PFM palpation was used to confirm a correct muscle contraction. The results at the end of the 12 week study period found significantly greater adherence and self-efficacy scores in the intervention group who had received the CEIP, however it was difficult to attribute this success to a specific aspect of the programme, such as support, contact sessions or exercise training. The sample number was small.

A small cohort study (26 women with SUI) conducted by Demain et al. (2006) measured levels of self-efficacy following initial assessment and instruction over a period of self-managed physiotherapy treatment. Initial high self-efficacy and improvement in pelvic floor muscle strengthening was found, but decline in both self-efficacy and outcome expectancy ratings occurred over the treatment course. This study demonstrates the difficulty of maintaining self-efficacy levels, and perhaps indicates the importance of supported treatment in maintaining self-efficacy and adherence. Similarly an earlier cohort study (a sample of 71 women) conducted by Svengalis (1995), demonstrated that supported rather than self-managed treatment is associated with improving levels of self-efficacy, agreeing with Demain et al (2006) that observed high initial self-efficacy scores were not associated with improved symptom outcome over the longer term. This contrasts with Broome (1999) who concluded that initial high PFM self-efficacy predicted positive clinical outcomes. A possible explanation for Svengalis et al.'s findings may be women's initial unrealistic expectations of the demands of treatment. Overall these findings should caution against drawing conclusions about likely successful outcomes based on very high pre-treatment self-efficacy scores.

Kassandra Messer et al. (2007) looked at self-efficacy in a group of asymptomatic women (n=164) on a UI prevention programme. Her study found good adherence to PFME, and although self-efficacy ratings revealed a modest decline over a 12 month period, 'task' and 'regulatory' self-efficacy rather than 'knowledge self-efficacy' contributed to the adherence levels seen.

Current guidance (NICE, 2006) recommends supervised exercises, and, as previously stated, return clinic visits (whether group or individual) seem to be associated with improved outcomes, and fewer clinician visits associated with a decline in self-efficacy scores. It is unclear what aspect of clinician contact may be responsible for improvement in self-efficacy. Clinical sessions enable the patient to report benefit in terms of symptom reduction and the clinician to give confirmation of progress in terms of muscle strengthening. Sessions also allow opportunity for problem-solving and allow discussion of set-backs, or perhaps function very simply to provide verbal encouragement to remain motivated and continue with the exercise programme. Both Messer et al (2007) and Whitfield and Jones (2011) advocate confidence in correct pelvic floor contraction as important to overall self-efficacy.

5.5 Measuring PFME adherence

Studies measuring PFME adherence generally show good exercising levels (Berghmans et al., 1996; Bø, Talseth & Holme, 1999; Hay-Smith et al., 2001; Alewijnse et al., 2002), which is often attributed to the intensive nature of the interventions and the enthusiasm of research trial participants, but is suspected

of bearing no relation to the realities of clinical practice. Given the belief that treatment adherence is believed to be difficult to achieve, these findings call into question the accuracy, and highlight the challenge, of measuring adherence. Self-reported adherence may overestimate to convey a socially acceptable impression, that is women report what they should be doing rather than what they actually did (Dumoulin & Hay-Smith, 2010), and clinicians may be equally guilty of over-estimating adherent behaviour in their patients (Gross, 2001). Objective measures are not always possible to implement in trials, especially when evaluating home exercise programmes. Self-completion of daily diaries can be onerous for the participant leading to the possibility of inaccurate recording or retrospective completion. Daily diaries also may, in the act of completing them, promote adherence (Myers & Midence, 1998), and remembering exercise behaviour after a period of time presents difficulty with accuracy of recall. Questionnaires completed while in the waiting area prior to each follow-up attendance reduces the likelihood of forgetting to bring the diaries to clinic. This method also addresses the possibility of associated inaccuracies through being too busy to complete a day-to-day diary, or the temptation for retrospective (and hurried) last minute completion (Hay-Smith 2007, correspondence). Although there remains the possibility of memory bias or inaccurate recall there is no evidence that this approach is less reliable than daily completion.

5.6 Measuring PFME self-efficacy

Although self-efficacy dimensions can be evaluated by interviewing participants, standardised scales and measures are desirable in an experimental study design. Generalised self-efficacy (GSE) is measured with a general self-efficacy scale, however behaviour specific scales are necessary to measure behaviour specific self-efficacy such as self-efficacy for performing pelvic floor muscle exercises. Appraising scales should include checking how the scale was developed. This includes the intended 'aim', definition of a priori considerations and methods for identification and selection of items (Frei et al., 2009). Scales may be constructed with different aims in mind and it is important to ensure that any instrument selected fulfils the needs of the study design; for the purpose of treatment/ intervention evaluation, the scale needs to detect changes over time and have longitudinal validity.

The three self-efficacy scales identified through literature searching were devised by Broome (1999), Chen (2004) and Demain et al. (2006). Tannenbaum et al.'s (2008) measure for use in elderly women was published after this study commenced and Kim's (2001) scale was published in Japanese so was unable to be used. The Demain scale (Demain et al., 2006) was not validated and the Broome scale (Broome, 1999) although validated, has an item relating to discouragement of abdominal muscle use, arguably thought to play a role in PFME (Neumann & Gill, 2002; Sapsford et al., 2001), and still in current debate (Bø et al., 2009). The Chen pelvic floor muscle exercise self-efficacy scale was validated in Taiwan in 2003 (Chen, 2004) and is shown to have solid

psychometric properties. Despite the cultural difference between Taiwan and the UK, the Chen scale specifically reflected the parameters studied in this intervention, that is, pelvic floor muscle exercise self-efficacy, with items relating to outcome expectancy and confidence in ability to perform the exercises. The potential for cultural difference causing difficulty with comprehension of the scale items was overcome by initially piloting the tool on a small sample of UK women with SUI. As an evaluation tool, Chen recommends using it at different stages in pelvic floor rehabilitation to see if self-efficacy is maintained, and as such it matched the aim of this research. It is considered in more detail in later sections.

5.7 Evidence for biofeedback efficacy

Glazer & Laine (2006) performed a single database search (Medline 1975 to 2005) for studies examining the evidence for using biofeedback in any type of urinary incontinence. At first glance, the evidence for the benefits seem encouraging, with no studies producing worse outcomes than exercises alone. Other studies confirm that biofeedback is effective when compared to 'no treatment' for SUI (Henella et al., 1989, Largo Janssen et al., 1991; Bø, Talseth & Holme, 1999), however the evidence for adding this treatment modality to pelvic floor exercises instruction needs to be examined more closely. The following section will explore the evidence for biofeedback use alongside PFME (in women with SUI) in more depth.

5.7.1 Rationale of the biofeedback literature review

The aim is to evaluate the evidence for the efficacy of machine biofeedback as an intervention in augmenting a PFME programme of treatment. For this reason, the comparison needs to be made with 'standard' conservative treatment for Stress Urinary Incontinence (SUI) which is unsupplemented PFME or 'PFME alone'.

A systematic review is considered to be the most reliable source of evidence to guide clinical practice (Clarke, 2011). It examines existing research and aims to give a detailed account of all the available primary research (in response to a research question) in order to establish the state of existing knowledge. Systematic reviews of RCTs are performed when investigating questions of effectiveness. According to the Cochrane Handbook, a systematic review should state clear aims and eligibility criteria, transparent methods, involve rigorous searching, assess the validity of studies findings, and synthesise and present the findings (Higgins & Green, 2011). Where possible, meta-analysis also helps in the synthesis process by pooling data from primary studies and producing a statistical summary to establish if an effect exists. Systematic reviews have appraised biofeedback in the treatment of urinary incontinence. Glazer & Laine (2006) and de Kruif & van Wegen (1996) did not specifically examine either SUI or women in their reviews. As part of a wider review of interventions for SUI in women, Berghmans et al. (1998) concluded that biofeedback did not offer added benefit to 'PFME alone', and although Weatherall's (1999) meta-analysis of three studies in the Berghmans' review supported the addition of biofeedback, the

confidence intervals were wide. These reviews do not therefore provide conclusive evidence. Studies have also been published since this last review. Therefore a review was conducted in order to examine randomised controlled studies and establish the current evidence for use of biofeedback.

5.7.2 Outcomes considered

The standardisation committee of the International Continence Society (ICS) (Lose et al., 1998) recommends that research investigating the effectiveness of treatments for urinary incontinence in women should incorporate outcome measurements in the following five areas:

1. the patient's observations (symptoms)
2. quantification of symptoms (leakage of urine)
3. the clinician's observations (anatomical or functional)
4. quality of life
5. socioeconomic measures.

Outcomes may be assessed through subjective reporting of symptom severity by the patient (patient perception of symptoms, for example bothersomeness, cure or improvement) and quantitatively by measuring of leakage, for example by using a pad test, counting the number of absorbent pads used in a 24 hour period or daily diary recording the number of incontinent episodes. Pelvic floor muscle strength and function is clinician-assessed by palpation of the muscle, recording of vaginal squeeze pressure or making surface EMG recordings of muscle electrical activity. Quality of life is deemed by incontinence sufferers to

be the most important outcome (Herbison et al., 2009). It is usually assessed through self-completed questionnaire and there is an array of validated tools available, some developed specifically for use in UI. Socioeconomic measurement is a relatively new area of assessment in health research and signifies the increasing importance now placed on the impact of incontinence in all areas of an individual's life.

For this review, treatment efficacy is assessed primarily in terms of a reduction in urinary leakage or symptom severity, for example improvement in incontinence episodes (either self-reported or demonstrated through objective testing). This is evaluated through patient perception of cure or improvement, patient recorded leakage episodes, symptom-specific patient completed questionnaires, pad test weight or an increase in pelvic floor muscle strengthening or function. Any monitoring of treatment compliance or adherence is also reported as this is of particular interest and relevance to the study being conducted. Additional outcomes, such as impact on social activity, economic measures and general quality of life were noted.

5.7.3 Type of study reviewed.

The purpose is to establish whether prior to conducting a randomised controlled trial, if any RCTs had been conducted on biofeedback effectiveness especially in terms of enhancing exercise adherence. A screening tool (Appendix 1) was used to help identify studies which fitted the inclusion criteria and this also helped to track the reasons for rejecting papers.

5.7.4 The search process

The bibliographic databases searched are listed in Section 5.1. A combination of search terms were used including 'biofeedback', 'pelvic floor muscle exercise' 'EMG biofeedback' 'myofeedback' 'pressure biofeedback' 'vaginal pressure biofeedback' 'perineal biofeedback' *combined with* 'stress incontinence' 'stress urinary incontinence' 'urinary incontinence' 'urodynamic stress incontinence' 'genuine stress incontinence'. Results were screened to exclude studies on men, children and dysfunctions other than SUI. Ultrasound studies were not included. Reference lists from relevant papers were hand-checked and grey literature and conference presentations searched electronically through the International Continence Society (ICS) online search facility. Electronic database searches were repeated every three months until no new papers were identified. The last search was conducted in May 2011.

5.7.5 Quality rating

Using likely sources of bias identified in the Cochrane Handbook (Higgins & Green, 2011) as a guide, a quality scoring tool was developed and each included study scored.

Quality rating took into account the randomisation method, whether concealment of allocation was achieved, the baseline equality of groups, the equal treatment of groups, blinding of outcome assessment, robust outcome measures, rigour of outcome reporting, participant 'drop-out' rate and how the data was analysed. As

research involving therapeutic complex packages of care does not usually allow for blinding of clinician/researcher or participant, these are not scored.

1. Randomisation: *not described*=0, *partial description*=1, *full description*=2
2. Concealment of allocation was achieved: *Yes* =1, *no*=0 ('unclear'=0)
3. Blinding of outcome assessors: *Yes*=1 *No*=0
4. Assessment made of baseline differences between groups: *Yes*=1, *No*=0
5. Equality of groups at the start: *Yes*=1, *No*=0, *Don't know*=0
6. Apart from the intervention all groups are treated equally; *Yes*=1, *No*=0, *don't know*=0
7. Main outcomes are robust: *Yes*=2, *Partially*=1, *No*=0
8. Main outcomes fully reported: *Yes*=2, *Partially*=1, *No*=0
9. Drop outs less than 10% or analysis of data by ITT: *Yes*=1, *No*=0

Total possible score is 12.

The quality of the studies were then further categorised as: High quality: scores 9 and over. Moderate: scores 5-8. Low quality: Scores of 4 and under.

5.8 Results of the review

The electronic healthcare database search identified 160 unique references of which 140 were excluded by screening the titles and abstracts. A further 10 were obtained through reference lists and conference abstracts. Full paper screening of 30 studies resulted in exclusion of a further 18. Studies were excluded if they were not randomised, were cohort or cross-over studies (Castleden, Duffin & Mitchell, 1984; Burgio, Robinson & Engel, 1986; Wilson et al., 1987; Burton et al., 1988; Dannecker et al., 2005; Capelini et al., 2006; Rett et al., 2007; Yoo, Kim & Kim, 2011), if they were not predominantly looking at biofeedback in the treatment of SUI in women ie were studying men or studying mainly urge urinary incontinence (Burgio et al., 2002) or if they combined biofeedback with other modalities such as electrical stimulation (Knight, Laycock & Naylor, 1998; Parkkinen et al., 2004). They were also excluded if they did not include 'PFME alone' as a comparison group (Wyman, 1998; Dougherty, 2002; Huebner et al., 2011), if they compared two types of biofeedback (Wilson et al., 1987; Wong et al., 2001; Aukee et al., 2002; 2004; Schmidt, 2009) or used an intra-vaginal resistance device (Ferguson et al., 1990; Klingler et al., 1995). Non-English-language papers were also excluded from this review.

The details of the 12 included studies are summarised in Table 7 (Appendix 2).

The 12 included studies (Table 7, Appendix 2) involve a total of 818 women and were conducted between 1983 and 2003. All appear to be single centre research except one, which was conducted across 4 countries in UK, New Zealand,

Ireland and Australia (Laycock et al., 2001a). One is limited in detail as it is a conference abstract.

5.8.1 Characteristics of the samples

Ages ranged from 18 to 79 with two studies specifically targeting post-menopausal women (Burns et al., 1993 and Taylor & Henderson, 1986). The symptoms of SUI were determined by assessment of symptoms reported by the women and/or by urodynamics testing. Exclusion criteria were given in most studies. Common exclusions were neurological conditions, (Taylor & Henderson, 1986; Pages et al., 2001), urinary infections (Taylor & Henderson, 1986; Burns et al., 1993; Mørkved, Bø & Fjortoft, 2002; Goode et al., 2003), previous surgery (Glavind, Nohr & Walter, 1996; Wong et al., 1997; Mørkved, Bø & Fjortoft, 2002), previous failed exercises (Wong et al., 1997), mainly symptoms of urgency or bladder overactivity (Glavind, Nohr & Walter, 1996; Sherman, Davis & Wong, 1997; Mørkved, Bø & Fjortoft, 2002), continuous leakage (Goode et al., 2003), high residual urine (Burns et al., 1993, Mørkved, Bø & Fjortoft, 2002, Goode et al., 2003), pregnancy (Mørkved, Bø & Fjortoft, 2002), medication affecting bladder function (Pages et al., 2001), specified medical conditions, faecal impaction and atrophic vaginitis (Goode et al., 2003). Interestingly, only one study stipulates a minimal strength of pelvic floor contraction as an inclusion criterion (Pages et al., 2001). Exclusion criteria were not reported in three studies (Shepherd, Montgomery & Anderson, 1983, Laycock et al., 2001a and Aksac et al., 2003).

5.8.2 Designs

Although most were 2 group RCT designs, some involved a third group (Burns et al., 1993, Laycock et al., 2001a, Goode et al., 2003, Aksac et al., 2003) and even a fourth (Taylor & Henderson, 1986) where additional interventions, a different treatment modality or a non-treatment control group were also included.

5.8.3 Interventions

Biofeedback monitoring was achieved either through recording vaginal or anal pressure (Shepherd, Montgomery & Anderson, 1983, Taylor & Henderson, 1986, Laycock et al., 2001a, Mørkved, Bø & Fjortoft, 2002, Goode et al., 2003) or surface EMG via an intra-vaginal electrode (Burns et al., 1993; Berghmans' et al., 1996; Sherman, Davis & Wong, 1997; Wong et al., 1997; Pages et al., 2001; Aksac et al., 2003). Four studies used home biofeedback units, five used biofeedback in clinic sessions only and four used both home and clinic biofeedback in their designs. Of note is that some studies also used the biofeedback equipment to obtain muscle contraction strength measurements for *all* the participants including the control group (Burns et al., 1993; Shepherd, Montgomery & Anderson, 1983), and while some state that the biofeedback was only used for clinician measurement ie the patient was unable to view the screen or be 'fed back' information, others do not. Sham biofeedback (using a probe not connected to the equipment or screen) was given to the control group in the Sherman, Davis & Wong (1997) study. Pelvic floor exercise programmes (the number of exercises performed in a 'set' and how many sets per day) were

diverse and it was not possible to compare regimens across studies. The control and intervention groups in each study did perform the same programme. Supervision or clinician contact also varied. Sherman, Davis & Wong (1997) Laycock et al. (2001a) and Goode et al. (2003) used one session per fortnight, however other regimens included one session per week (Shepherd, Montgomery & Anderson, 1983; Taylor & Henderson 1986; Burns et al., 1993; Mørkved, Bø & Fjortoft, 2002), twice a week (Wong et al., 1997), three sessions a week (Berghmans' et al., 1996) and even five times a week (Pages et al., 2001). Glavind, Nohr & Walter (1996), Goode et al. (2003) and Aksac et al. (2003) used different clinician contact frequency for each group, while Pages et al. (2001) saw participants at the same intervals but gave *individual* treatment sessions to the biofeedback group and *group* PFME classes to the control group.

5.8.4 Risk of bias (see Table 8, Appendix 3)

Areas of possible bias are described in Table 8 (found in Appendix 3). Sample sizes ranged from 200 to 13. Power calculations and even statistical analysis were missing from many studies. Power calculation was evident in three studies, Laycock et al. (2001a), Mørkved Bø & Fjortoft (2002) and Goode et al. (2003), with the remaining nine giving no indication of a desired sample size. As previously mentioned, equal clinician contact time was evident in all studies except four (Glavind, Nohr & Walter, 1996; Pages et al., 2001; Goode et al., 2003; Aksac et al., 2003). Not surprisingly, blinding of clinicians and participants is difficult in this type of study and does not usually occur, although one study

(Burns et al., 1993) was stated as single-blind as it had managed to blind the researcher to which group was the experimental treatment. Two studies used blinded outcome assessors (Berghmans' et al., 1996 and Mørkved, Bø & Fjortoft, 2002) with one also blinding the data analysis (Berghmans' et al., 1996).

Not all studies stated primary outcomes or data analysis *a priori*. A variety of outcome measures were used across the studies and although common measures were found, for example pad test weight, no standard pad test method was common to all studies, with some using a 48 hour test, 1 hour test, 24 hour test and one conducting a standard activity stress test measuring pad weight using a pre-defined bladder volume. All studies used the types of outcomes recommended by ICS such as subjective/patient reported outcomes and some measure of urine loss however none used outcomes from all five recommended domains. Broad and condition specific Quality of Life was measured in many studies, but was poorly reported. Use of measures, instruments and equipment was generally not reported in sufficient detail to allow evaluation of consistent use across groups in an individual study or to enable study replication. There was some use of validated questionnaires, such as Kings Health Questionnaire, Social Activity Index and Incontinence Impact questionnaire (IIQ) but most studies used measures such as self-rating ordinal scales or VAS type measures developed specifically for each study. Most studies reported the percentage of 'drop outs' but only three stated that data analysis 'Intention to Treat' (Berghmans' et al., 1996; Mørkved, Bø & Fjortoft, 2002; Goode et al., 2003), although Mørkved, Bø & Fjortoft (2002) stipulate that missing data were

substituted with baseline values, and Goode et al. (2003), used last value carried forward. Both of these practices for handling missing data are contentious (Lane, 2008).

Results are reported inconsistently and a general lack of detailed reporting (as per Consort guidelines) was noted across all studies. Some results were presented as percentage cure/improvement, others were mean/median scores 'before and after', some without measures of dispersal such as standard deviation or range; most included statistical analysis. Percentages as in 'percentage cure' or 'percentage still exercising' were also used but with no further analysis regarding statistical significance of the result. Many give *before* and *after* scores and the statistical significance of the change for each group (that is, they compare the 'p values'), however only Wong et al. (1997); Morkved, Bø & Fjortoft (2002) and Goode et al. (2003), compare the *change difference* of the groups and analyse this for significance. Most studies use 'p values' as an indication of statistical significance, but only Glavind, Nohr & Walter (1996) and Morkved, Bø & Fjortoft (2002) also give the confidence intervals. Berghmans' et al. (1996) calculates a 'combined measure of effect'.

Table 8 (Appendix 3) details the main sources of bias in each study.

5.8.5 Outcomes used in high and moderate quality studies

Quality scoring of the studies is shown in Table 9. Following further classification of scores, studies are categorised as high, moderate or low quality. Four studies (Burns et al., 1993; Berghmans' et al., 1996; Goode et al., 2003; Mørkved, Bø & Fjortoft, 2002) are scored as *high quality* with five studies rated as *moderate* and three studies rated as *poor*. No studies used PFME adherence as a stated outcome, but six studies report that encouragement and/or monitoring of adherence behaviour had occurred. In four of these (Glavind, Nohr & Walter, 1996; Sherman, Davis & Wong, 1997; Laycock et al., 2001a; Mørkved, Bø & Fjortoft, 2002) some compliance data was reported, for example 'percentage still exercising', however adherence data was not analysed further nor were adherence levels for each group compared. Meta analysis of data was not possible due to the variety of outcome measures used, how they were rated and the insufficient detail in the reporting. Evaluation of the high and moderate quality studies, nine studies, is given below. Biofeedback group size varied from 10 to 54 (median of 20, mean of 30).

1. Symptom severity

a) % subjective cure/improvement

Three studies used this outcome. Mørkved, Bø & Fjortoft, (2002) showed no difference in subjective cure overall, with Pages et al. (2001) reporting no difference between groups by three months. However Glavind, Nohr & Walter (1996) reported 26% cured, 42% improved in biofeedback group, versus none

cured and 29% improved in control group. The significance of this is not reported.

b) Rating scale

This outcome was used by four studies. Three authors (Berghmans' et al., 1996; Laycock et al., 2001a and Mørkved, Bø & Fjortoft, 2002) showed no difference between groups, however Wong et al. (1997) reported a significant difference ($p < 0.05$) in favour of the Control group.

2. Urinary loss

a) Pad test (weight change in grams over 48 hour/ 24 hour/1 hour

Six studies used pad tests. Although Berghmans' et al. (1996) found significant difference in favour of biofeedback at two weeks, at four weeks (the study end), there was no difference between groups reported. No difference between groups was also reported for Wong et al. (1997), Mørkved, Bø & Fjortoft (2002) and Aksac et al. (2003).

Glavind, Nohr & Walter (1996) reported significant improvement ($p < 0.02$) in favour of the biofeedback group. Cure rates (determined by pad test) were in favour of the biofeedback group, however they just failed to reach significance ($p < 0.057$).

b) Number of pads used

Only Laycock et al., (2001a) used this outcome and showed the control group used significantly less pads per day by the study end.

c) Number of leakage episodes (diary) in 24 hours/7 days

Five studies used this measure. Burns et al. (1993) showed no difference in urinary leakage episodes or in % *improvement* from the completed diary. Berghmans' et al. (1996), Wong et al. (1997) and Laycock et al. (2001a) also demonstrated no difference between groups. Using ITT, Goode et al. (2003) demonstrated a significant change difference between groups in percentage reduction of incontinence episodes over a 7-day diary, however there was a very high attrition rate in this study, and when just analysing 'completers', there was no difference shown between the groups.

Other measure: 4 point ordinal scale of incontinence frequency

Used by Aksac et al. (2003) and reported no difference between groups.

3. Muscle Strength

a) Perineometer/EMG (cm water/microvolts)

Five studies used this outcome. Burns et al. (1993) and Aksac et al. (2003) found significantly higher recordings in the biofeedback group compared with exercise group ($p < 0.001$) while Pages et al. (2001) reported significantly higher contraction strength in the biofeedback group at four weeks compared with the control but no difference was noted at three months. Laycock et al. (2001) and Mørkved, Bø & Fjortoft (2002) found no difference between groups.

b) Digital palpation, for example Oxford Grading

All studies which used this outcome (Pages et al., 2001; Mørkved, Bø & Fjortoft, 2002 and Aksac et al., 2003) showed no difference between groups.

4. Adherence scores

Exercise adherence was reported in three studies. Mørkved, Bø & Fjortoft, (2002) found 88.9% in the biofeedback group and 85.3% in the Control were exercising more than three times a week at six months. Laycock et al. (2001) reported 79% were compliant in biofeedback group compared with 81% in control group at 3 months. Glavind, Nohr & Walter (1996) showed 89% of the biofeedback group and 50% of the control group were still exercising at 2-3 years. None of these results were analysed for significance.

5. Quality of Life and other measures

The Kings Health Questionnaire was used by Laycock et al. (2001a) and showed no difference between groups. The Short Form 36 Health Survey, Incontinence Impact Questionnaire and Hopkins Symptom Checklist 90-R used by Goode et al. (2003) showed improvement for all participants but were not fully reported by group. The Social Activity Index was used by Mørkved, Bø & Fjortoft (2002) and Aksac et al. (2003) and showed no difference between groups.

5.8.6 Evaluation of high and moderate quality studies

A probable lack of power in most studies gives the possibility of a type 2 error in the results reported. Unfortunately three studies demonstrating biofeedback as beneficial in terms of Increase in sEMG values (Glavind, Nohr & Walter, 1996; Pages et al., 2001; Aksac et al., 2003), and two studies showing difference in exercise adherence and symptom improvement (Glavind, Nohr & Walter, 1996; Goode et al 2003) are flawed in terms of equality of treatment given to each

group, meaning that a difference in training or supervision levels may actually be responsible for the improvement seen. Among other studies, only Burns et al. (1993) showed significantly higher strengthening (demonstrated by higher sEMG values) in the biofeedback group with Berghmans et al. (1996) indicating early improvement in urinary leakage by pad test in the biofeedback group. All other outcome parameters in the studies indicate no difference between groups. The highest quality scoring study (Mørkved, Bø & Fjortoft, 2002) demonstrated no difference between groups for all outcomes measured.

Two high quality studies (Burns et al., 1993 and Berghmans et al., 1996) indicate some benefit in using biofeedback, however the highest rated study (Morkved, Bø & Fjortoft, 2002) found no support for use of biofeedback. The methodological issues found in many of the studies (Glavind, Nohr & Walter, 1996; Pages et al., 2001; Goode et al., 2003; Aksac et al., 2003) makes it impossible to conclude that the biofeedback intervention itself is responsible for the improvements seen. This is in contrast to the meta-analysis conducted by Weatherall (1999) and the reviews by de Kruif & van Wegen (1996) and Glazer & Laine (2006) which conclude that biofeedback is more effective than PFME alone, and recommends (with Berghmans' et al., 1998 and Neumann, Grimmer & Deenadayalan, 2006), that additional higher quality studies need to be conducted in order to clarify biofeedback effectiveness. The variety of biofeedback delivery and intensity of treatments offered in these studies highlights the different rehabilitation uses of biofeedback. Reasons for use include facilitation of teaching/learning of the exercises and use as a training aid in daily PFME home

practise. Although it is suspected that biofeedback may motivate patients and create enhanced adherence to a home exercise programme, this review shows this has not been specifically compared, reported or analysed in RCT studies to date.

Enhancing successful self-management is encouraged in wider policy, and should be enabled. If not, patients are left unmotivated and demoralised and conservative treatment will fail. Research has not examined use of biofeedback as a learning tool, or in terms of affecting exercise adherence and behavioural change in women with SUI. If biofeedback can add value to clinical contact, use of this asset could mean fewer clinic visits for patients. Apart from the convenience for patients, especially important if a specialist physiotherapist practises some distance away, this would also reduce overall treatment costs per patient and free more time for additional patients to be seen.

Limitations of this review include the possibility that not all papers and reviews may have been identified in the search process. Resources were also unavailable to involve independent assessors to review the papers. Other limitations are the exclusion of papers not written in English and the exclusion of studies other than RCTs. In addition, the use of a scoring method to assess quality is controversial; although in defence of this method, it assisted in the process of appraising the various aspects of study design, areas of bias and overall quality of the research conducted.

This review shows there is a lack of high quality research investigating the use of biofeedback to support individual pelvic floor exercise instruction in the treatment of women with SUI. Quality assessment of the studies in the review highlighted methodological flaws and also the use of intensive (and clinically unrealistic) clinic-training regimens. In addition, these studies have not specifically measured self-efficacy for PFME and have failed to analyse home PFME adherence levels. It therefore seems that despite suspecting that biofeedback helps motivation to perform PFME, no studies have analysed the impact of biofeedback on pelvic floor muscle exercise adherence or self-efficacy in women undergoing conservative treatment for SUI highlighting a gap in the current body of evidence.

5.9 Conclusion to the review of the literature

Pelvic floor muscle exercises have already been demonstrated as efficacious in the treatment of SUI in women (Dumoulin & Hay-Smith, 2010), however clinical effectiveness may be compromised by poor exercise adherence. As high levels of patient self-efficacy are required to maintain adherence to a pelvic floor exercise regimen (Hay-Smith, 2007), appraising interventions to raise self-efficacy would seem to be a way of promoting PFME adherence. Perception of self-efficacy is self-evaluation achieved through self-reflection. It is 'belief in one's own capabilities to organize and execute the courses of action required to manage prospective situations' (Bandura, 1997).

There are four main sources of self-efficacy and various components of the physiotherapy treatment of incontinence, such as exercise instruction, education, supervision and consultation style may all play a part in self-efficacy promotion. Separating and testing modalities from packages of care is not easy. Results of studies are difficult to interpret as many have compounding influences and the biofeedback has been used in different ways. sEMG biofeedback is an intervention used in treatment to augment PFME as it is thought to improve motivation and adherence to PFME however the literature shows this has not been specifically tested. sEMG biofeedback, used as part of clinic-based physiotherapy treatment sessions, may enhance pelvic floor muscle exercise self-efficacy and improve PFME adherence in women with urinary incontinence trying to adopt a conservative treatment approach in their day-to-day lives.

Although guidelines do not support sEMG biofeedback in offering increased benefit over pelvic floor exercises alone for patients who can already actively contract their pelvic floor muscles (NICE, 2006), and PFME treatment has been studied before in terms of the impact of self-managed treatment on self-efficacy (Demain et al., 2006), adding sEMG biofeedback to routine physiotherapy treatment to determine effects on PFME self-efficacy and PFME adherence levels has not previously been investigated. It is proposed that sEMG acts to raise self-efficacy through learning the correct contraction. This is achieved by means of feeding back the pelvic floor muscle response to the patient. Figure 9 shows how biofeedback may influence self-efficacy through the known sources of self-efficacy.

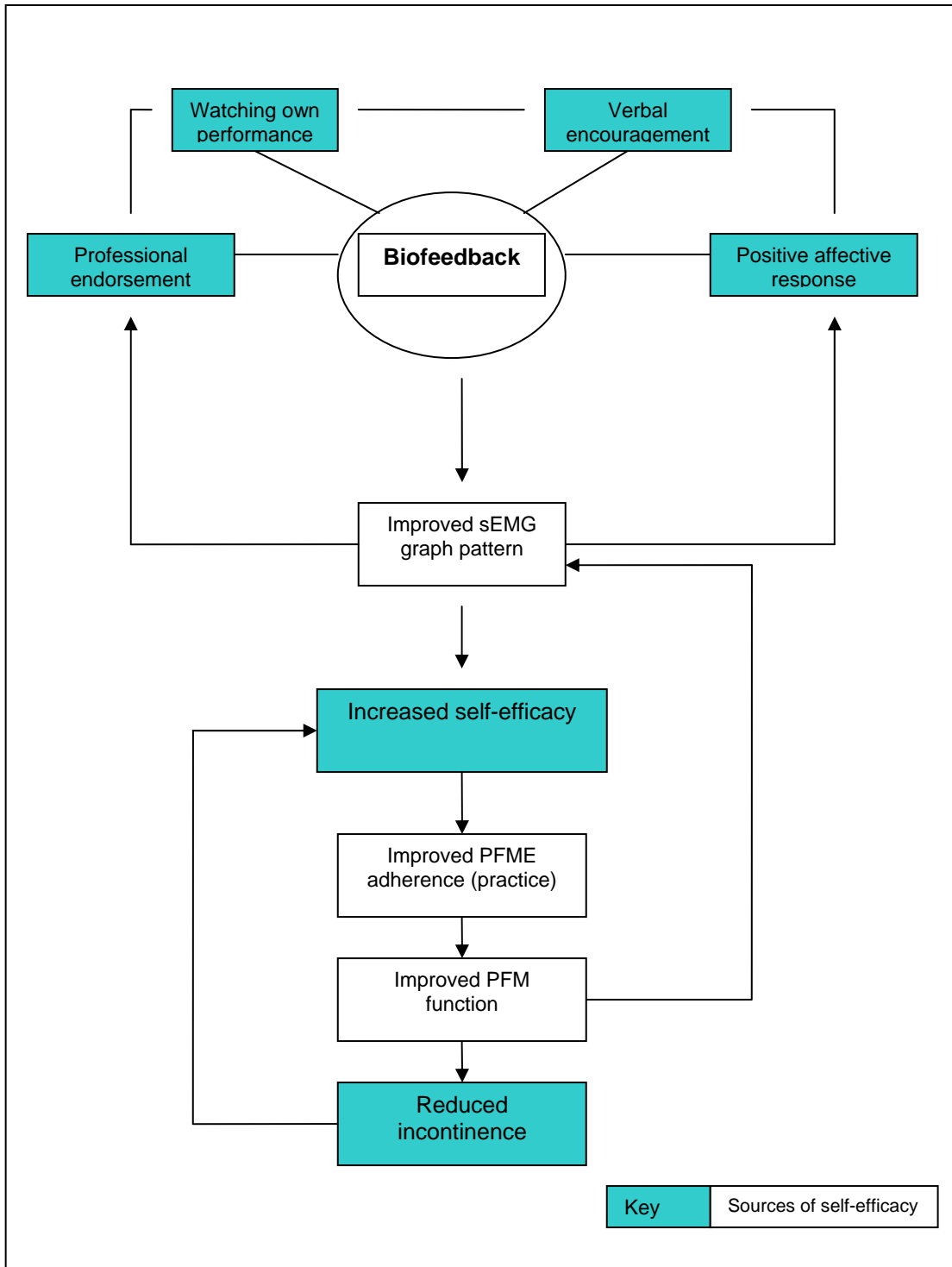


Figure 9 sEMG biofeedback and sources of self-efficacy

Self-efficacy sources are derived from observation of the muscle response (graph pattern) and the modification of patient effort to give instant feedback, verbal encouragement and physiotherapist feedback/endorsement. In turn this may serve to heighten effort (exercise practice), resulting in improvement in the sEMG traces and creating an affective response (women are pleased with their effort); a further source of self-efficacy. This study hypothesises that in allowing all patients to gain insight and knowledge regarding own pelvic floor function through use of sEMG in routine clinical practice, PFME self-efficacy and adherence will be improved. To date these outcomes have not been explicitly explored in a comparison trial.

The study design uses sEMG for periodic clinic-based biofeedback and monitoring of home exercise programme (HEP) progress in clinic rather than as a daily home training/strengthening aid. The aim of this pragmatic study is therefore to determine whether adding clinic-based sEMG biofeedback in this way, enhances PFME self-efficacy and PFME adherence in the conservative treatment of women with stress urinary incontinence. Secondary aims include evaluating symptom change and muscle strength as well as checking the reliability of using the Chen PFME self-efficacy scale in an intervention study in a sample of UK women with SUI.

Chapter Six details the methods of the study conducted.

CHAPTER SIX Methodology

6.1 The research question

Is the use of clinic-based biofeedback in women with stress urinary incontinence associated with improvement in pelvic floor muscle exercise self-efficacy and pelvic floor muscle exercise adherence?

6.2 Aims and Objectives

The aim of the study was to examine whether biofeedback could improve self-efficacy and exercise adherence to a pelvic floor exercise regime in women with urinary incontinence. The hypothesis was that giving clinic-based biofeedback on muscle activity while women performed pelvic floor muscle exercises in clinic would improve PFME self-efficacy and PFME adherence to a home exercise regimen. The objective was to test this hypothesis by conducting a randomised controlled trial to compare the effects of sEMG biofeedback plus standard treatment (pelvic floor muscle exercise instruction) with standard treatment alone on pelvic floor muscle exercise self-efficacy and PFME adherence in women with stress urinary incontinence. The dependent variables (DV) were PFME Self-Efficacy and PFME adherence. The Independent Variable (IV) was clinic-based sEMG biofeedback treatment.

6.3 Hypotheses

Null Hypothesis: There will be no difference in PFME self-efficacy or PFME adherence scores. Incontinence symptoms and other clinical outcome measures will be no different as a result of using clinic-based sEMG biofeedback.

Hypotheses

1. PFME self-efficacy levels, as measured by the Chen PFME self-efficacy scale, will increase over the treatment period for both groups, but the group using biofeedback will increase more than the control group. Internal consistency (as measured by Cronbachs alpha) for the Chen PFME self-efficacy scale will be demonstrated in this sample of women with SUI.
2. Daily and weekly self-rated home exercise practice scores as measured by a self-completed adherence questionnaire will increase over the treatment period in both groups, but the group using biofeedback will increase more than the control group. Exercise recall as measured on the self-completed adherence questionnaire will be more accurate in the group using biofeedback than the Control group.
3. A relationship between self-efficacy and PFME adherence will be demonstrated. Increase in PFME self-efficacy scores will be associated with increased levels of PFME adherence over the study period.
4. Muscle strength as measured by the Modified Oxford Scale will increase for both groups but the group using biofeedback will increase by more. Symptoms severity and *bothersomeness* of symptoms, as measured by the ICIQ-UI SF, will decrease in both groups over the treatment period, but there will be a greater decrease measured in the intervention group than the control.

6.4 Design

A randomised controlled trial (RCT) was chosen to test the effects of sEMG biofeedback on PFME self-efficacy and adherence. This was compared with usual treatment practice, in women with SUI who were able to contract their pelvic floor muscles. Participants were seen on a one-to-one basis in line with routine clinic practice. The study design comprised two treatment groups: *Group A, Control (standard treatment)* and *Group B, Intervention (standard treatment plus sEMG clinic-based biofeedback)*.

6.5 Participants

6.5.1 Inclusion and exclusion criteria.

Women with SUI symptoms (with or without additional urgency or urge incontinence symptoms), as established through clinical history taking, were recruited. This study seeks to establish whether routine use of biofeedback has benefit for women who can already contract their muscles. Therefore only women able to contract their pelvic floor muscles were eligible for recruitment. Women who were referred to the continence physiotherapy clinic at Tameside NHS Foundation Trust between December 2008 and February 2010 were recruited. The service accepts patients referred by a GP, gynaecologist, urologist, the Continence Advisory Service (CAS) or other health care professional.

The exclusion criteria ensured that results could be attributable to the treatments used and not to extraneous factors, and also to comply with the ethics of conducting research. They were kept to a minimum in order to maximise generalisability of the findings.

Exclusion criteria were:

- Women unable to give informed consent.
- Women with limited English language skills who were unable to complete the questionnaires, as no resources were available to enable translators or interpreters to be used.
- Women with insufficient cognitive or communication skills to complete the questionnaires, as assessed by the clinical team.
- Women with urgency or urge incontinence as their predominant complaint, as, although, women often present with mixed symptoms, the study primarily evaluated the intervention for women with SUI.
- Women with a fluctuating condition likely to affect their continence such as Multiple Sclerosis.
- Women who were unable to attend clinic, as the intervention was clinic-based.
- Women who could not tolerate use of an internal vaginal sensor probe as this was the method by which sEMG biofeedback was given.
- Women who, on vaginal examination, had no pelvic floor muscle contraction, as this study sought to establish whether biofeedback adds benefit for women who can already contract their pelvic floor muscles.

6.5.2 Ethical Considerations

All necessary ethical and R&D approvals including permissions from the University of Salford and Tameside NHS Trust R&D committee were obtained before the study started. Local chaperoning and infection control policies were adhered to. Ethical consideration was given to the information available to women about the study, the time needed for women to complete the

questionnaires used in the study, depriving the Control group of access to biofeedback treatment (for the study duration) and the acceptability and invasive nature of using an internal probe for biofeedback in the Intervention group. The study's focus was whether routine use of biofeedback added benefit for women who could already perceive a pelvic floor muscle contraction. sEMG biofeedback is already a recommended treatment option for women unable to perceive a pelvic floor muscle contraction. Including these women would risk them being allocated to the control group, resulting in a delay to treatment which was considered unethical by the researcher, as the biofeedback equipment was usually available for these women in this clinic. Neuromuscular electrical stimulation would be the treatment option of choice for women with no identifiable contraction on clinical examination (Laycock et al., 2001b).

Discussion with the women ensured they were fully informed of all aspects of the study, potential risks and benefits. They were given written information in the form of a patient information leaflet, and contact details of independent information sources should they needed further advice. The questionnaires were brief, requiring just a few minutes to complete. The principles of informed consent, data protection and anonymity were adhered to. Women were informed they could leave the study at any time and that their care would not be adversely affected by their decision. They were also made aware that the purpose of the research study was to generate new knowledge about the benefits of existing treatments, which are in common use. The researcher was trained in good practice in research and undergone research ethics training. At the final visit, women in the Control group were given the option to

receive sEMG biofeedback following discussion with the physiotherapist/researcher.

6.5.3 Power calculation and sample size

Normative data from the author of the primary outcome measure (personal communication, Chen 2007), and scores from the women who piloted the questionnaire prior to the main study, were used to calculate the effect size. This information estimated that a 10 point difference between groups on the pelvic floor muscle exercise self-efficacy scale (17 minimum and 85 maximum possible score) would be considered a clinically significant effect. Power and sample size were calculated using data from Chen (2004) and based on normality. This indicated that 25 patients per group would be needed to detect a clinically important difference of 10 points at the 5% significance level with 80% power, and assuming a control mean (standard deviation) of 64 (14). To allow for drop-out, a final sample of 60 was identified. It was expected that three new participants could be recruited each week, meaning recruitment would take 25 weeks and recruitment and delivery of the intervention would be completed within 12 months.

6.5.4 Recruitment process and randomisation

Women attending for their first physiotherapy appointment were seen by the researcher/physiotherapist. Those fulfilling the inclusion and exclusion criteria had the study explained to them and if they were interested in participating were given a written information leaflet and consent form (Appendices 5 and 6). A further appointment was given for two weeks time, along with a phone number and email address, allowing them to gain additional information if

needed. At the second visit there was further opportunity to ask questions and discuss any issues. If women agreed to participate, consent was obtained. A copy of the consent form was given to the participant and a copy was also attached to the patient record, after which baseline assessment questionnaires were completed and participants were randomised into either the intervention or control group.

To ensure adequate concealment of allocation, the participants were not randomised until after the baseline assessments had been completed. Randomisation was blinded. An independent statistician undertook this process and produced serially numbered, sealed opaque envelopes from the randomisation schedule, which was produced using a specially designed computer package (Stata version 8) incorporating randomly varying block sizes to prevent block size determination. After baseline tests were completed, the researcher opened the next numbered envelope to find out the allocated group for each participant. Due to the nature of the intervention it was not possible to blind the physiotherapist or the patient to the treatment received, however the data analysis was checked by staff blind to group identity.

6.6 Research Procedure

6.6.1 Pre-study screening assessment

Although this assessment occurs before consent and randomisation, this visit should be considered as forming part of the clinical intervention received by participants. Normal clinical assessment (a continence assessment) was performed. A symptom severity and 'bothersomeness' (ICIQ-UI SF)

questionnaire and 3-day frequency-volume chart was given to each woman to be completed and returned at the next visit in two weeks time. Inclusion/exclusion criteria for the study were checked and eligible women invited to participate in the research. They were then given the study information sheet and consent form. The participants' journey is depicted in Figure 10.

6.6.2 Second appointment: Baseline assessment (study week 0)

Consent was confirmed by the researcher. Two questionnaires, Chen PFME self-efficacy scale (Appendix 10) and Hospital Anxiety and Depression scale (Appendix 13) were completed by the participant. An internal vaginal examination was undertaken to evaluate muscle function and muscle tone. Participants were then randomised into either the control or the intervention group and the treatment session proceeded depending on group allocation. Although both groups received pelvic floor exercise instruction, the intervention group also received a session of sEMG biofeedback. All participants were given the written information sheet (see Appendix 5), an individually written prescription for exercise and an exercise diary (Appendix 8). Individualised information about bladder habit, fluid intake and bladder habit re-training advice was given as appropriate.

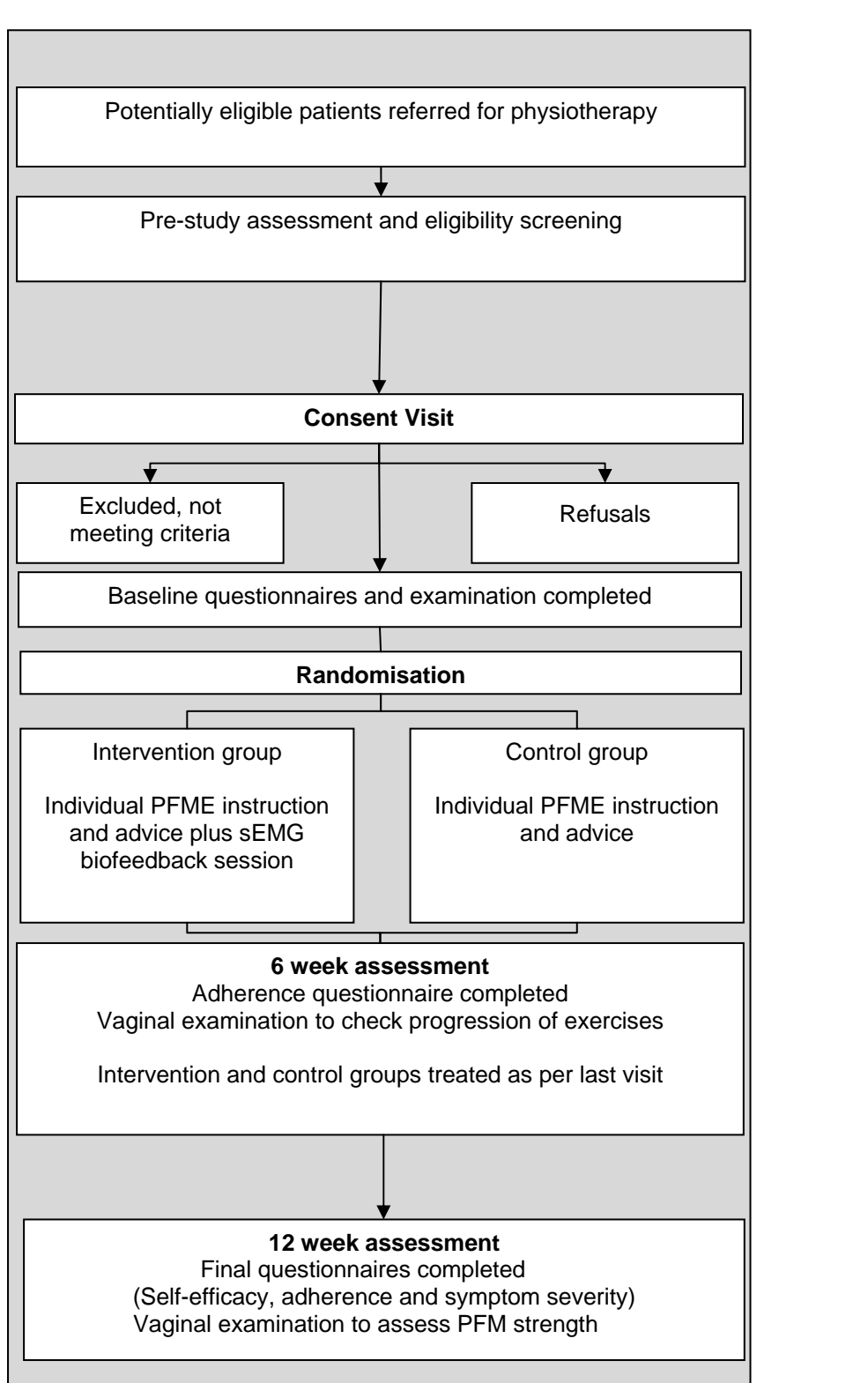


Figure 10 Participant Journey

6.6.3 Third appointment: week 6 (mid-point of the study)

An adherence questionnaire (Appendix 12) was completed by all participants on arrival to the clinic waiting area. During the treatment session, all participants were asked about their understanding of the treatment and any problems encountered and a vaginal examination was performed to decide whether the pelvic floor muscle exercises should be progressed (see treatment algorithm, Appendix 9) Any difficulties were discussed and all women were encouraged to adhere to the exercises and given bladder habit advice. In addition, the 'intervention' group performed pelvic floor muscle exercises with biofeedback monitoring as at Week 0.

6.6.4 Final attendance: week 12 (data collection only)

Adherence, PFME self-efficacy and symptom severity questionnaires (see Appendices) were completed in the clinic waiting area on arrival. In clinic, the physiotherapist ascertained patient understanding of the treatment and any difficulties encountered with each participant. A vaginal examination was performed and muscle strength assessed. Further advice was given and the exercise regimen progressed or changed as necessary. All women were encouraged to continue to adhere to exercise and bladder habit advice and thanked for their participation in the study.

6.7 Outcome measures

6.7.1 Self-efficacy

Measured using the PFME self-efficacy scale (Chen, 2004) detailed in Appendix 10.

The pelvic floor muscle exercise self-efficacy questionnaire is a 17 item scale, each with a 5-point Likert type scale. Each item is a statement about different aspects of pelvic floor muscle exercise self-efficacy, for example belief in ability to perform the exercises correctly, overcome barriers, belief that the exercises will provide benefit. Each statement starts 'I believe: and asks for a response category box 1-5 to be marked with a cross, for each statement. 1=not very confident to 5=extremely confident. The maximum score possible for the scale is 85 and the minimum is 17. High scores show high levels of pelvic floor muscle exercise self-efficacy.

The Chen PFME self-efficacy scale (Chen, 2004) was developed and validated in Taiwan on 106 women with urinary incontinence. Exploratory factor analysis identified two factors explaining 66.71% of the total variance. Construct validity was established through examining the concurrent validity against 3 other scales: the general self-efficacy scale (GSE) (Schwarzer, 1993), the incontinence impact questionnaire-7 (IIQ-7) (Shumaker et al., 1994) and a two item perceived PFME benefits scale (developed for the validation study). The scale shows high internal consistency (Cronbach's alpha of 0.95) and good test-retest reliability (over 6-30 days, $r=0.86$, $p<0.001$). This indicates good stability. Responsiveness was not evaluated in the validation study. To help establish whether the scale was able to be used by women in the UK (having been developed in Taiwan) the scale was tested

with patients who met the inclusion criteria during the preparation stage of the study and consultees were asked whether the items could be easily understood. As a result of patient feedback, an adjustment was made, without changing the meaning, to the wording of an item (see Appendix 11 for wording before and after this adjustment).

6.7.2 PFME Adherence

Adherence to PFME was measured using patient-reported recall of adherence behaviour from the previous day and the previous seven days (Alewijjnse et al., 2003 Appendix 12). One week was chosen as a period likely to reflect fluctuation in exercise behaviour, but not too long in order to ensure accurate recall. It is short and user-friendly and comprises six items which attempt succinctly to capture actual exercise behaviour and self-evaluated success (on a scale of 0 to 10). Whether the exercises had been remembered and understood was evaluated using a 7-point Likert scale (+3 to -3) as well as the number of days the exercises were performed, how many times a day and the reasons for non-adherence. Understanding and recall of the exercises was assessed by asking participants to provide a written description of the exercises they performed. Completion in the clinic waiting area prior to treatment reduced the likelihood of forgetting the diary, impact of social desirability, and ensured that participants had time to concentrate on completing them accurately (Hay-Smith 2007, personal correspondence).

6.7.3 Depression

The Hospital Anxiety and Depression Scale (HAD) (Zigmond & Snaith, 1983 Appendix 13) was used in this study to contribute to the descriptive

information presented for each group at baseline. This is because depression levels are thought to influence PFME self-efficacy (Broome, 2003). It is a commonly used 14-item ordinal scale used to detect anxiety and depression independent of somatic symptoms. It consists of 2 sub-scales (7 items in each) measuring anxiety and depression. A 4-point response scale from 0 (absence of symptoms) to 3 (maximum symptoms) is used. Possible scores for each sub-scale range from 0 to 21. Higher scores indicate greater levels of anxiety or depression.

6.7.4 Symptom Severity

The International Consultation on Incontinence questionnaire or ICIQ-UI SF (Avery et al, 2004) is a participant-completed questionnaire which provides a quick and simple measure of the severity and impact of urinary incontinence on the individual (see Appendix 14). It demonstrates high reliability, validity and responsiveness to change, and, has good correlation with other more cumbersome objective measures such as the pad test (Karantanis et al., 2004) and urodynamics findings (Seckiner et al., 2007). As a result, it is widely used internationally. It comprises 4 items, three of which (frequency of leakage, amount of leakage and interference with everyday life) are summated to give a single score. The fourth item diagnoses the participants' perceived causes of the incontinence. The score range is 0 to 21, high scores indicating greater severity of incontinence.

6.7.5 Pelvic floor muscle strength

The modified oxford scale (MOS) (Messelink et al., 2005) evaluates strength of the pelvic floor muscles assessed by vaginal examination at week 0 and week 12. The 6-point ordinal scale (0-5 described in Figure 11) is easy to perform and also establishes whether a correct muscle contraction and 'lift' is occurring (which is an important part of the treatment process). The MOS shows inter-rater reliability (Bø, 2001) but greater reliability if performed by a single assessor (Laycock et al., 2001b).

0	No contraction
1	Flicker of a contraction
2	Weak contraction
3	Moderate contraction (with lift)
4	Strong contraction (with lift)
5	Very strong contraction (with lift)

Messelink et al., 2005

Figure 11 Modified Oxford Scale to measure strength of the pelvic floor muscles

6.7.6 About data collection

All questionnaires were completed at clinic attendance to maximise return rates. They were self-completed in privacy in the waiting area, sealed into envelopes and returned to the clinic receptionist before having contact with the researcher and starting the treatment session. They were coded and anonymous to encourage the provision of accurate information. Completed questionnaires were stored unopened in a locked filing cabinet so the

physiotherapist/researcher had no knowledge of the questionnaire responses while the participant was undergoing treatment.

6.8 Interventions received: usual care

To standardise the interventions received in the study, one clinician (the researcher) provided the treatment for both groups. Guidelines for good practice in treatment of SUI, recommended by the Chartered Society of Physiotherapy clinical guidelines (Laycock et al., 2001b), and NICE (NICE, 2006), were adopted in order to standardise the assessment and exercise protocol and offer the most effective interventions. Usual care consisted of an individualized PFME regimen, education and advice delivered on a one-to-one basis. All participants received verbal information about the basic anatomy and physiology of bladder and pelvic floor muscle function. The purpose and aim of treatment, patient goals and expectations were also discussed.

Patients were taught how to perform PFME through vaginal palpation and verbal instruction incorporating individualised visualisation techniques. A regimen of home exercises to produce effective contraction and strengthening of the muscles was prescribed (see treatment algorithm Appendix 9). In line with current recommendations (Staskin et al., 2005), each woman completed a 3-day frequency volume chart (see Appendix 15) to record types, volumes and frequency of fluids consumed, frequency of bladder voiding and amounts of urine passed, which gives insight into bladder function/dysfunction and is used in discussion to illustrate, inform and educate about bladder habit and function. The results of the chart form the basis for talking about strategies

and treatment which can help in symptom management, such as bladder habit retraining, fluid intake advice and strategies to help control bladder urgency. Advice regarding managing constipation, exercise and general lifestyle advice such as diet and weight loss was also given as appropriate. Key messages were established (and repeated) and realistic goals set. Patients were also encouraged to talk about any ambivalence and discuss reasons (or not) for adopting advice (Mattick & Jarvis, 1993).

6.8.1 Components of usual care: pelvic floor muscle exercises

Women with SUI need to perform at least 24 daily contractions over a minimum of 6 weeks to reduce incontinence (Choi, Palmer and Park, 2007) however a 12-week period is the minimal training period recommended by NICE (2006) and was therefore chosen as the standard for this study. Participants were instructed how to produce an effective PFM contraction with elevation of the pelvic floor; to tighten the muscles as if trying to stop passing wind from the back passage or as if to stop the passage of urine. Pelvic floor muscle palpation through vaginal examination was also used for every participant at each treatment session to give feedback and reassurance about the effectiveness of the muscle contraction and improvement made. This enabled progress to be monitored and changes to the exercise regimen and revision of treatment goals to be instigated. Full informed and valid consent was obtained prior to examination.

Participants in both groups practiced the exercises in the following way:

- High intensity (maximal) contraction 'holds' at their individual maximum duration (to a maximum of 10 seconds) for an individually determined number of repetitions to improve strength and endurance.
- An individually determined number of 'fast' contractions (to a maximum of 10 repetitions) for muscle responsiveness
- Sub-maximal contractions during functional activities throughout the day to improve 'carry-over' into everyday activities.

In addition the participants were instructed to:

- Use PFM contraction to inhibit urinary urgency
- Contract PFM before and during coughing, lifting and any exerting activity. This is known as counterbracing, pre-contraction or 'the knack'.
- Relax muscles adequately in between PFM contractions, to prevent excessive muscle fatigue and ensure effective strengthening training can be achieved.

(Miller, Ashton-Miller & DeLancey, 1998; Bø, 2007; Haslam, 2008a; Carriere, 2006)

Each participant was also advised how and when to progress the exercises in between clinic attendances as depicted by the treatment algorithm (Appendix 9) by increasing the number of repetitions and shortening the relaxation period between contractions, aspiring to 10 repetitions holding each at maximum intensity for 10 seconds and 10 fast maximal contractions.

6.9 Biofeedback

The intervention group received the usual care (described in Section 6.8) plus sessions of biofeedback at week 0 and week 6. Each biofeedback session lasted 10-15 minutes using electromyography (EMG) equipment (described in Chapter 4) to produce a real-time display of PFM activity during maximal, sub-maximal and fast contractions according to the following procedure: Following vaginal examination, biofeedback monitoring was explained and the vaginal probe inserted and connected to the computer system. Participants were treated in crook supine lying which was modified as necessary to gain maximum comfort. Pelvic floor muscle activity was monitored at rest and this trace was discussed and relaxation encouraged. The participant then performed maximum contractions, and the onset time, release time, level and endurance of the contraction and relaxation of the muscles were monitored and discussed. Fast contractions were then performed to help improve speed, co-ordination and effective relaxation between contractions.

Effort was encouraged. Feedback and explanation was given regarding changes to the graph shape, however precise sEMG readings were not discussed or used to rate performance. Accessory movements and other muscle use were corrected as necessary throughout the session. The vaginal probe was removed and written exercise instruction and advice (based on the biofeedback session performance) was given. During the treatment session at week 6 the same procedure was followed. PFM relaxation was monitored and exercises were progressed or changed as indicated by individual assessment and performance.

6.10 Statistical Analysis

Questionnaire scores and other descriptive data were logged onto an SPSS (version 16) spreadsheet by the researcher after the final visit. Missing data was identified on the spreadsheet. Participants were analysed in their original allocated groups (Fergusson, 2002). First, all *completed cases* were analysed and then sensitivity analysis was performed for the main outcomes using substituted worse and best sample scores for those who dropped out. Comparison of groups for *exercise recall* was analysed using the chi-square test. *ICIQ-UI SF*, *bothersomeness* scores, Self-rating of adherence and *Modified Oxford Scale* ratings were analysed using the Mann-Whitney U test. As the PFME self-efficacy scale was validated using parametric measures (Chen, 2007 personal communication), and scores in the sample showed normal distribution, the unrelated t test was used to compare PFME self-efficacy total scores for each group at baseline (week 0) and again at the end of the study (week 12). PFME adherence scores for each group (at 6 weeks and 12 weeks) were also compared using the unrelated t. Within each group, changes in self-efficacy from baseline to week 12 and change in adherence levels from 6 weeks to 12 weeks were analysed using the related t test.

Chapter Seven details the results of the study.

CHAPTER SEVEN Results

7.1 Introduction

This chapter presents the results of the study. It was expected that clinic-based sEMG biofeedback would enhance self-efficacy, adherence and clinical outcomes which would be evidenced by the Intervention group scoring significantly better for these measures. Analysis was carried out by the researcher using the statistics computer package SPSS (version16).

Total PFME self-efficacy scores were checked for normality at baseline and then compared for each group at the end of the study (week 12). Change in PFME self-efficacy over the study period for each group was also compared. PFME adherence for each group is reported for week 6 and week 12 as well as change in exercise adherence levels for each group over the research study period. A description of the participants and baseline descriptive data is summarised for each group (see Section 7.2, 7.3 and Table 10a and b) and drop-outs described (Section 7.4 and Table 11). Inferential analysis of the main outcome measures (as described in Chapter 6 Methodology, Statistical analysis) are presented in Section 7.5, 7.6, 7.7, Tables 12 and 13. Clinical outcomes, that is 'bothersomeness' of urinary leakage, urinary incontinence symptom severity and pelvic floor muscle strength results are presented in Section 7.8 together with analysis of age, referral source and depression ratings. The Chen PFME self-efficacy scale is assessed for internal reliability in this study (Section 7.5.2).

7.2 Description of participants (see Consort flow chart, Appendix 16)

Out of over 400 referrals for UI over a two year period, one hundred and sixty potential participants (women with SUI) were identified. 85 did not meet the inclusion criteria, five did not want to participate in a study and ten declined for other reasons. Of the 60 consented, 29 were randomised to the Control group (Group A) and 31 to the Intervention group (Group B). All those randomised completed intervention according to their group allocation at week 0. Demographic characteristics of included participants are depicted in Table 10a.

Table 10a Demographics of participants (n=60)

Characteristic	Mean/Median (SD/IQR) n (%)
Age	43.8 (12.7)
Ethnicity: White British	60 (100%)
Parity	2 (1)
BMI	24.1 (3.2)
Smokers	2 (3%)
Work:	
Paid employment or maternity leave	48(80%)
Not in paid work	3 (5%)
Retired	9 (15%)

Over the twelve week study period, a total of 10 women dropped out. Three from the Control Group and four from the Intervention Group by week 6, and a further one from the control group and two from the Intervention Group by week 12. Therefore, 50 participants completed the study, 25 for the Control Group and 25 for the Intervention Group

7.3 Analysis of baseline data

There was no significant difference in measured characteristics between the control and intervention groups at baseline. This demonstrates group parity and successful randomisation. The Control Group contained 19 (65.5%) consultant and GP referrals and 10 (34.5%) continence nurse referrals. The Intervention group had 16 (51.6%) consultant and GP referrals and 15 (48.4%) continence nurse referrals. The mean age of participants was 41.76 (SD11.15) for the Control Group and 45.84 (SD14.06) for the Intervention Group. Analysis of PFME self-efficacy scores revealed normal and symmetrical distribution of scores in both groups. Other descriptive data is summarised in Table 10b. PFME adherence was not measured at baseline.

Table 10b Baseline measures for each group

Baseline Summary Measures	Control (Group A) (n=29)	Intervention (Group B) (n=31)
Incontinence Severity Median (IQR)	11 (5)	12 (4)
'Bothersomeness' Median (IQR)	7 (4)	6 (2)
Anxiety Scores Mean (SD)	9.85 (3.91)	9.44 (2.71)
Depression Scores Mean (SD)	7.15 (3.56)	6.85 (2.09)
PFM strength Median (IQR)	3 (0)	3 (1)
PFME Self-efficacy Mean (SD)	48.76 (15.44)	48.94 (14.29)

7.4 Participants who dropped out of the study

It is possible that those who dropped out may have been unrepresentative of the sample. In other words, they may have been less compliant, had more severe symptoms or poorer muscle function at baseline compared with the rest of the sample. Therefore it is important to compare the characteristics of completers and drop-outs at baseline. This data is displayed in Table 11. Reasons for drop-out by week six were: medical reasons (one in each group), personal reasons (one in each group), 'did not attend' (one in the control group and two in the intervention group). At week 12 one further participant 'did not attend' in the control group and two in the Intervention group. Of the ten who dropped out, two were referred by continence specialist nurses and eight were referred by consultant or GP. Of the 50 completing the study, 27 (54%) were referred by

continence specialist nurses and 23 (46%) by Consultants or GPs. Other baseline measures are compared in Table 11.

Table 11 Baseline measures of completers and non-completers

Baseline Characteristics	Failed to complete n=10 mean (SD)	Completed cases n=50 mean(SD)
Incontinence Severity	11.2 (2.4)	12.2 (3.5)
'Bothersomeness'	6.1 (1.6)	6.2 (2.3)
Anxiety Scores	10.2 (2.4)	9.6 (3.5)
Depression Scores	6.7 (2.3)	7.0 (2.9)
PFM strength	2.6 (0.7)	3.1 (0.7)
PFME Self-efficacy	46.6 (12.2)	49.3 (15.2)
Age	37.4 (8.8)	45.2 (13.1)

Data for those who dropped out was not statistically analysed as numbers lacked enough power to detect significance. Examining Table 11, all measures appeared to be broadly similar, except age. Those who dropped out seemed to have a lower mean age than those who completed the study. Participants were analysed in the groups to which they were randomly allocated and any missing values were identified on the SPSS datasheet. Only participants with available data were analysed (complete case analysis). However, as those who dropped-

out may have constituted a biased subset, additional sensitivity analysis was carried out for the primary outcomes for the sample randomised.

7.5 PFME self-efficacy analysis

***Hypothesis 1:** PFME self-efficacy levels, as measured by the Chen PFME self-efficacy scale, will increase over the treatment period for both groups, but the group using biofeedback will increase more than the control group. Internal consistency (as measured by Cronbachs alpha) for the Chen PFME self-efficacy scale will be demonstrated in this sample of women with SUI.*

Final self-efficacy scores (week 12) for the sample were checked to see if they formed a normal distribution (see Figure 12). The maximum score was 83 and minimum 24. The range was therefore 59 points. The range of values resembled a normal distribution, with a mean of 60.64 and a median of 60.50.

Table 12 details the complete case analysis of PFME self-efficacy scores recorded at baseline and week 12 with standard deviations, p values and confidence intervals.

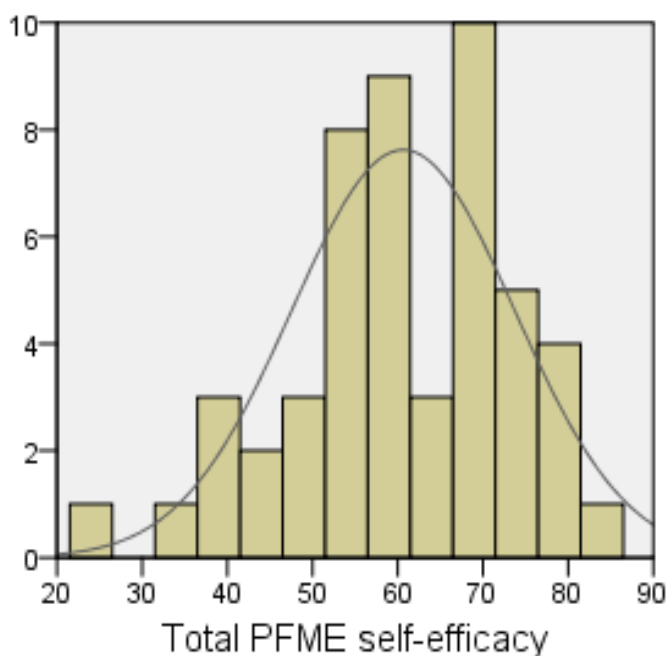


Figure 12 Distribution of total self-efficacy scores for the sample at week 12

The related t test was used for within-group analysis and group scores were compared using the unrelated t test. The Intervention group scored 61.68 and the Control Group scored 59.60 at the end of the study (week 12), a difference between the groups of -2.080, $p = 0.575$ (95% CI -9.49, 5.34). This result was not statistically significant. The relative effectiveness of the two interventions was then compared. The change in Control group PFME self-efficacy scores from baseline to week 12 was -9.96 points (16.48), $p=0.006$ (95% CI -16.76, -3.16) and -12.72 (11.29), $p=0.0001$ (95% CI -17.38, -8.06) for the Intervention group. The Intervention group changed by 2.76 points more than the Control, but this

difference between groups was not statistically significant $p=0.493$ (95% CI - 10.79, 5.27).

Table 12 PFME self-efficacy score results (Complete cases)

PFME Self-efficacy	Control Mean (SD)	Intervention Mean (SD)	Difference between groups (95% CI)	p value
At baseline	48.76 (15.44)	48.94 (14.29)	-0.177 (-7.86, 7.51)	0.963
At 12 weeks	59.60 (14.82)	61.68 (10.98)	-2.080 (-9.49, 5.34)	0.575
<i>Change in score from baseline to 12 weeks</i>	-9.96 (16.48)	-12.72 (11.29)	-2.76 (-10.79, 5.27)	0.493
<i>P value (95% CI)</i>	0.006 (-16.76, -3.15)	0.0001 (-17.38, -8.06)		

7.5.1 PFME self-efficacy sensitivity analysis

Using *best* and *worse* sample scores for total PFME self-efficacy at week 12, missing values for those who dropped out were substituted to allow analysis of all those randomised (total sample number of 60). This was done to assume a worse case/best case scenario for the participants who failed to complete the study and give an analysis forecast based on the original randomised sample.

Inputting Total PFME self-efficacy *worse sample score*, revealed a 6 point increase for the control group and a 5.5 point increase for the intervention group.

Neither of these changes in self-efficacy reached pre-set clinical significance of 10 points and the difference between these scores (0.5 points) remained statistically insignificant ($p=0.922$, CI -9.27, 10.22). Comparing the group scores at week 12 confirmed there was no significant difference between the groups ($p=0.949$, CI -9.15, 9.76). For *best sample score* substitution, the control group scores increased by 15 points and the intervention group increased by 17 points. The 2 points difference in effectiveness induced by the treatment remained non significant ($p=0.518$, CI -11.43, 5.82). Comparing the group total self-efficacy scores at week 12 confirmed there was no statistical difference between groups ($p=0.434$, CI -10.49, 4.53).

7.5.2 Reliability of the Chen PFME self-efficacy scale

Chen's 17 item PFME self-efficacy scale was tested for internal consistency in this study sample. It produced a Cronbach alpha of 0.929, indicating good internal consistency and comparing well with Chen (2004).

7.5.3 PFME self-efficacy results conclusion

For the participants completing the study, there was no significant difference in levels of PFME self-efficacy between the groups at week 12 (the study end). Both groups showed significant change in PFME self-efficacy, with the Intervention group also exceeding the clinical significance level set pre-study at a 10 point difference. Sensitivity analysis showed that even when substituting best

and worse sample scores, no significant difference in self-efficacy scores would be seen between the groups at 12 weeks.

7.6 PFME adherence results

***Hypothesis 2:** Daily, weekly and self-rated home exercise practice scores as measured by a self-completed adherence questionnaire, will increase over the treatment period in both groups, but the group using biofeedback will increase more than the control group. Exercise recall as measured on the self-completed adherence questionnaire will be more accurate in the group using biofeedback than the Control group.*

Adherence was high in both groups. Looking at the whole sample, nearly all participants (52 out of 53) had exercised 'in the last week' at the half-way point of the study (week 6), only falling to 92% (46/50) by the study end (week 12). At 6 weeks, 77% of participants in the control group and 82% in the intervention group stated that they had exercised 'yesterday', however analysis using the chi-square test showed the difference between the two groups was not significant ($p=0.682$). This level of exercise adherence was maintained over the course of the study for both groups, with 19/25 (76%) in the Control group and 21/25 (84%) in the Intervention group reporting 'exercising yesterday' at week 12 ($p=0.480$).

Exercise sessions *per day* and days exercised *per week* were compared for the groups at week 6 and week 12 using the unrelated t-test. These results are reported in Table 13.

7.6.1 How many *times a day* did participants exercise?

Women were instructed to exercise three times a day. The Control Group exercised 2.3 (SD1.6) times a day at week 6 (n=26) and 2.1 (SD1.8) times a day by week 12 (n=25), a change of 0.2 (SD 2.6) $p=0.695$, 95% CI -0.84, 1.24). The Intervention Group exercised 2.5 (SD 1.4) times a day at week 6 (n=27) and 2.6 (SD1.7) times a day by week 12 (n=25), a change of -0.16 (SD1.8) $p=0.668$, 95% CI -0.92, 0.60). The change in number of times exercised a day from week 6 to week 12 for each group was compared using the unrelated t test. As can be seen in Table 13, the difference in change induced was -0.36 exercise sessions per day ($p=0.566$, CI -1.61, 0.89), a non significant result.

7.6.2. How many *days a week* did participants exercise?

Women were asked to exercise every day (seven days a week). For the Control Group the mean number of days a week exercised at week 6 (n=26) was 5.0 (SD1.8) and 4.4 (SD2.1) at week 12 (n=25), a fall of 0.68 (2.2) days, the related t test shows this as insignificant, $p=0.137$ (CI -0.23, 1.59). For the Intervention Group, the number of days a week exercised at week 6 (n=27), was 5.0 (SD1.8) and 4.9 (SD1.8) at week 12 (n=25), a change of 0.12, an insignificant difference on related t testing, $p=0.749$ (95% CI -0.65, 0.89). The score change from week

6 to week 12 for each group was then compared using the unrelated t test. As can be seen in Table 13, the difference in change between the groups was -0.56, a non-significant difference $p= 0.486$ (95% CI -1.72, 0.60). Figure 13 illustrates adherence scores for each group at 6 and 12 weeks.

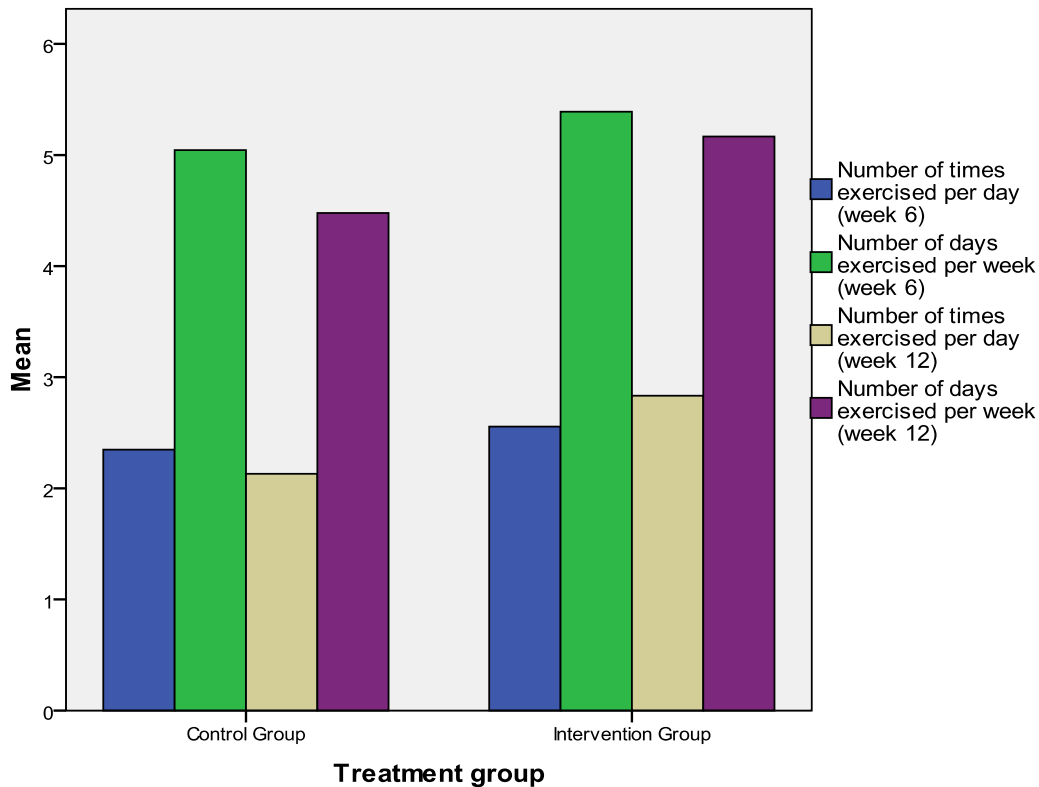


Figure 13 PFME adherence levels for each group at week 6 and 12

7.6.3 Sensitivity analysis of self-reported actual adherence

Calculations were repeated to include those who dropped out. Their missing *days per week* and *sessions per day* scores at 6 and 12 weeks were substituted with worse and best sample scores. Sensitivity analysis performed in this way did not change the significance of the results which remained statistically non-significant, demonstrating no difference between groups for actual adherence of

PFME, either in terms of sessions per day or numbers of days per week they were performed (see table 14).

Table 13 PFME adherence results for completed cases

PFME Adherence	Control Mean (SD)	Intervention Mean (SD)	Difference between groups (95% CI)	p-value
Sessions per day:				
At 6 weeks	2.3 (1.6)	2.5 (1.4)	-0.16 (-1.00, 0.68)	0.705
At 12 weeks	2.1 (1.8)	2.6 (1.7)	-0.52 (-1.5, 0.47)	0.298
Change in number of exercise sessions per day (from week 6 to week 12)	-0.2 (2.6)	0.16 (1.8)	0.36 (-1.61,0.89)	0.566
<i>(P value 95% CI)</i>	0.695 -0.84,1.24	0.668 -0.92, 0.60		
Days per week:				
At 6 weeks	5.0 (1.8)	5.0 (1.8)	-0.00 (-1.03, 1.03)	1.000
At 12 weeks	4.4 (2.1)	4.9 (1.8)	-0.56 (-1.67, 0.55)	0.316
Change in number of days exercised per week (from week 6 to week 12)	0.68 (2.2)	0.12 (1.8)	-0.56 (-1.72, 0.601)	0.337
<i>(P value 95% CI)</i>	0.137 -0.23, 1.59	0.749 -0.65, 0.88		

Table 14 Sensitivity analysis of PFME adherence (*sessions* per day and *days* per week).

PFME Adherence	Control Mean (SD)	Intervention Mean (SD)	Difference between groups (95% CI)	p-value
<i>Sessions per day:</i>				
At 6 weeks:				
Best	2.7 (1.9)	2.9 (1.8)	-0.2 (-1.19, 0.69)	0.599
Worse	2.0 (1.6)	2.1 (1.5)	-0.1 (-0.91, 0.72)	0.817
At 12 weeks:				
Best	2.9 (2.6)	3.6 (2.7)	-0.75 (-2.1, 0.62)	0.279
Worse	1.8 (1.8)	2.1 (1.9)	-0.30 (-1.25, 0.65)	0.528
<i>Days per week:</i>				
At 6 weeks:				
Best	5.2 (1.8)	5.2 (1.7)	0.08 (-1.0, 0.84)	0.856
Worse	4.7 (1.9)	4.6 (1.9)	0.05 (-0.95, 1.04)	0.929
At 12 weeks:				
Best	4.7 (2.2)	5.3 (1.8)	-0.56 (-1.62, 0.43)	0.248
Worse	3.8 (2.5)	4.0 (2.5)	-0.21 (-1.5, 1.09)	0.749

7.6.4 Self-rating exercise adherence

Participants were asked to circle a number on a scale of 1 to 10 (worse=1, best=10) to rate their own exercise efforts at week 6 and 12.

Control group self-rating score reduced from 5.88 (2.4) to 5.36 (2.3). Intervention reduced from 6.20 (2.3) to 6.16 (2.4). Comparing group scores at week 6 and

week 12 using the Mann-Whitney U test, no significant difference between groups was found ($p=0.602$ and $p=0.293$ respectively).

7.6.5 Remembering the exercises: accuracy of recall

Only 13 out of 24 in the Control Group could correctly remember the exercises while 17 out of 20 in the Intervention group could recall the exercise instructions accurately at week 12, the study end (see Table 15).

Table 15 Accuracy of remembering PFME at week 12

Remembering PFME	Control N=25	Intervention N=25
Unable to remember or inaccurate description	11	3
Accurate recall of PFME	13	17
Missing responses to this item	1	5

Comparing the groups using the Pearson Chi-square (asymptomatic 2 sided) reveals this difference as significant ($p=0.029$). However 6 participants did not complete this item.

7.6.6 PFME adherence conclusion

Throughout the study, PFME adherence was good for all participants and the groups showed no statistical difference in actual or self-rating of PFME adherence. However, recall of the exercises at week 12 was significantly better in the intervention group.

7.7 Relationship between PFME adherence and PFME self-efficacy

***Hypothesis 3** Increased levels of PFME self-efficacy will be associated with increased levels of PFME adherence over the treatment period.*

Pearson correlation analysis of sample data taken at 12 weeks revealed a positive and significant correlation between PFME adherence measures and total self-efficacy ($r = .373$, $p = 0.008$ 'exercise sessions per day' and $r = .448$, $p = 0.001$ for 'days exercised per week'). Group analysis at 12 weeks showed no significant relationship between these variables in the Control group, however, the Intervention Group demonstrated a positive and significant correlation between 'PFME self-efficacy measured at 12 weeks' and 'number of exercise sessions performed per day' $r = .434$, $p = 0.049$ and also with the 'number of days exercised per week', $r = .523$, $p = 0.007$.

7.8 Analysis of clinical outcomes

Hypothesis 4: *Muscle strength as measured by the Modified Oxford Scale will increase for both groups, but the group using biofeedback will increase by more. Symptoms of incontinence and bothersomeness of symptoms, as measured by the ICIQ-UI SF, will decrease in both groups over the treatment period, but there will be greater decrease seen in the intervention group compared with the control.*

Change in Modified Oxford Score (grading for pelvic floor muscle strength, ordinal 0-5) over the study period was calculated for each group using the Wilcoxon signed rank test. At week 0, median score (IQR) for Control group was 3 (0), range 2 to 4. Median score for the Intervention group was also 3 (1), range 2 to 5. Median score for the Control group at week 12 was 4 (0), range 3 to 5 and Intervention group recorded 4 (1), range 3 to 5. Although, both Control and Intervention groups showed significant change in muscle strength ($p < 0.001$) over the period, comparison of the groups at week 12 using Mann-Whitney U, revealed no significant difference in muscle strength between the groups at the study end ($p = 0.147$).

Symptom severity improved for both groups over the study period. Wilcoxon signed rank test showed ICIQ UI SF scores decreasing significantly from week 0 to week 12 for each group (Control from 12.36 (0.741) to 10.28 (0.840) $p = 0.004$, Intervention, from 12.00 (0.620) to 8.88 (0.759) $p = 0.002$). However, comparing scores at week 12, Mann-Whitney U showed no significant difference in symptom severity between the groups ($p = 0.192$). A positive and significant correlation

(Spearman rho) of HAD depression scores with baseline symptom severity as measured by ICIQ UI SF was evident for the sample, $r=.371$ $p=0.006$. *Bothersomeness* of symptoms improved in both groups. Control scores dropped from 6.28 (0.485) to 5.24 (0.623) $p=0.031$ and Intervention Group from 6.12 (0.424) to 4.62 (0.451) $p=0.013$. However there was no statistical difference in the improvement of bothersomeness scores between the groups at the study end $p=0.494$. *Bothersomeness* of symptoms at the end of the study correlated negatively and significantly with final self-efficacy scores for all women, $r=-0.360$ and $p=0.05$.

7.9 Results summary

The results answer the hypotheses laid out in the methodology. The sample had a mean clinical improvement of approximately 11 points on the Chen PFME self-efficacy scale, demonstrating both a statistically and clinically significant change as a result of physiotherapy intervention. However the difference between the groups at the end of the study period was not statistically significant. In terms of self-efficacy this indicates that the intervention group performed equally well as the control group. PFME adherence levels were good in both groups, and although a trend of increased adherence levels in the Intervention group was noted, there was no significant difference between actual or self-rated PFME adherence levels in groups either at the half-way point or at the end of the 12 week treatment period. This means that adding clinic-based sEMG biofeedback did not increase PFME self-efficacy (as recorded by the Chen scale) or exercise

adherence more than the levels measured in the group receiving standard taught exercises. The null hypothesis for the study is therefore retained. Clinical outcomes were as good in the Control as the Intervention group, meaning that biofeedback added no extra clinical benefit in terms of PFME adherence or self-efficacy. Accurate recall of the exercises was greater in the Intervention Group than the Control and a positive and significant correlation was also noted between final self-efficacy scores and levels of PFME adherence at week 12. This finding was absent in the Control group.

CHAPTER EIGHT Discussion and Clinical Implications

8.1 Summary of key findings

The results of this RCT indicate that there is no difference between the intervention group and control group in terms of mean PFME self-efficacy scores and self-reported PFME adherence levels. Participants in both groups showed significant increases in PFME self-efficacy over the course of the study and PFME adherence levels were high in both groups. In addition, the use of clinic-based biofeedback appears to be responsible for better recall of PFME and a positive and significant correlation between PFME self-efficacy and pelvic floor muscle exercise adherence.

Clinical outcomes improved significantly for all participants. Urinary leakage symptoms improved and *bothersomeness* of symptoms declined, with non-significant difference demonstrated between the groups. Muscle strength increased significantly but again no significant difference was demonstrated between the groups. *Bothersomeness* of urinary leakage positively and significantly correlated with both leakage severity and levels of depression. The Chen PFME self-efficacy scale demonstrated good internal reliability in this study, helping to standardise the tool for use in women with SUI in the UK. This study has demonstrated good outcomes for the control group, with high PFME self-efficacy and good levels of PFME adherence noted in both groups at the study end. Although a trend for higher self-efficacy ratings and adherence levels

was noticed in the group receiving sEMG biofeedback, the difference between groups was non-significant.

8.2 Explanation and Interpretation of results.

The results of this study suggest that in terms of PFME self-efficacy and PFME adherence, the addition of two sessions of clinic-based biofeedback to a physiotherapy treatment programme does not provide added benefit to the usual care offered to women who already have some ability to contract their pelvic floor muscles. Both groups received treatment which was equally effective in promoting PFME self-efficacy, PFME adherence and improving clinical outcomes for the participants. A revised theoretical mechanism is represented in Figure 14 below.

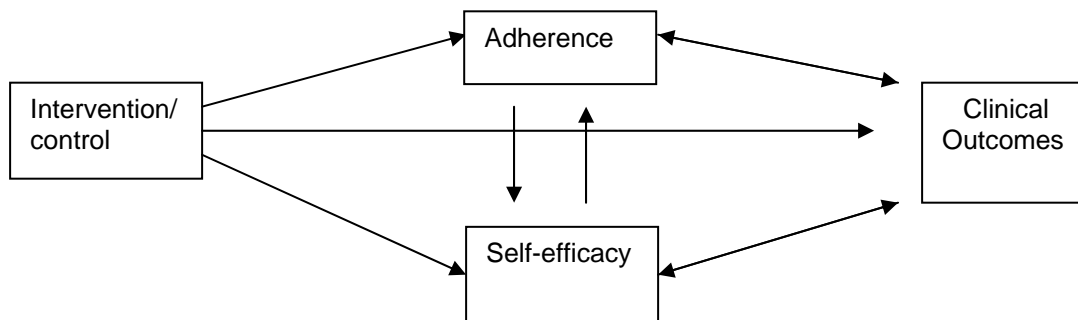


Figure 14 A diagram representing the possible relationship between the treatment offered by intervention and control groups, PFME self-efficacy, PFME adherence and clinical outcomes

As in the study conducted by Chen & Tzeng (2009), this study does not confirm the direction of influence with regard to self-efficacy, biofeedback, exercise adherence and clinical outcomes. The treatments received by both groups may have improved exercise adherence, directly influencing clinical outcome and self-efficacy which may in turn enhance exercise adherence levels still further. Alternatively the treatments may have increased PFME self-efficacy, which in turn influences adherence and also clinical outcomes. The diagram (figure 14) shows double headed arrows, acknowledging likely relationships between the variables. These interactions may not be linear because other human behaviour and influences play a part. In this way, outcomes are dependent on context (Shepperd et al., 2009).

Although theoretically the treatments may influence all outcomes directly and independently, the results from this study indicate relationships between some of the variables. A negative and significant correlation between self-efficacy and leakage severity is demonstrated and a relationship is also confirmed between PFME self-efficacy and PFME adherence, evidenced by the significant correlation noted between final self-efficacy scores and PFME adherence in the whole sample and also in the intervention group. This effect was absent in the Control group, so it would appear that the relationship between PFME self-efficacy and PFME adherence arises in those who receive the intervention. However, care must be taken in drawing conclusions. Multiple testing can give rise to spurious results, and relatively weak correlations ($r = < .50$) can be statistically significant but may not be clinically important. Numbers analysed are

important and the correlation for the whole sample (n=50) was strong and significant, confirming a likely relationship between PFME self-efficacy and PFME adherence (and agreeing with the findings of Chen & Tzeng, 2009). However, when analysing the groups separately, modelling a regression of adherence against self-efficacy should be performed to establish if there is interaction from the biofeedback treatment. Therefore the group analyses presented here should be considered exploratory, as a larger sample would be needed to confirm any hypothesis that the relationship between self-efficacy and adherence is different for each group.

The six-week intervals between study visits reflect the reality of pressures on treatment provision in current clinical practice. This design allowed appraisal of biofeedback as a learning tool and avoided the clinic exercise sessions themselves causing a strengthening or training effect. Therefore any improvement is attributed to improved self-efficacy and adherence to the home pelvic floor muscle exercise programme. Even with limited clinician supervision, the results show that good adherence levels and PFME self-efficacy levels were achieved, with or without biofeedback, demonstrating that care provided in this way is as effective as care supplemented with sEMG sessions. It is possible that sEMG biofeedback benefit has been diluted by the infrequent sessions and that more intensive delivery (for example, monthly or more frequent clinic attendance) would promote even greater PFME self-efficacy and PFME adherence than seen in these results.

The quality of consultation (palpation, verbal feedback and communication) given to all the participants, may mean that the results achieved by the Control group were actually too good to improve upon. However, the self-efficacy scores form a normal distribution, with a range of 24 to 83 (59 points). The maximum score possible for the Chen scale is 84 and the mean score at the end of this study was 61. These findings do not indicate a ceiling effect and suggests that even better self-efficacy could potentially be achieved in this sample. Although 12 weeks is the minimal recommended period for muscle training (NICE, 2006), this study period may not be long enough to see a difference between group outcomes. It is possible that biofeedback benefit with regards to maintaining self-efficacy and perseverance with PFME may actually be realised over a much longer time-frame, possibly functioning to ensure that participants continue the muscle strengthening programme and gain still further improvement in outcomes in the longer term.

High self-efficacy allows individuals to recover from set-backs and face up to challenges (Bandura, 1997), and it is often a struggle for individuals to juggle social, personal, behavioural and situational influences, which can impact on adherence commitment. It was hoped that the confidence in exercise performance given by biofeedback in the clinic environment would enhance commitment to a home exercise programme. Self-efficacy is known to have four main sources; sEMG biofeedback was expected to increase skill and confidence (mastery) in performing the exercises by feeding back muscle effort, give a vehicle for verbal encouragement from the clinician, show success in corrected

effort (seen on the biofeedback trace) and pleasure in achievement (affective influence). These self-efficacy source experiences were acquired through clinic visits, PFME self-efficacy relates to the exercises being performed correctly but also in the desired context; that is, when performed routinely at home and integrated into daily life. This relates to phase self-efficacy: *scheduling* and *coping* (remembering and managing to perform PFME daily) and *recovery* (resuming PFME following a period of poor adherence). These other phases of self-efficacy may be of greater relative importance than *task* self-efficacy in continued PFME adherence and need to be addressed alongside skill acquisition (Sallis et al., 1988). They would not necessarily be directly affected by biofeedback use in clinic but could be influenced by other components, for example communication style, encouragement and reinforcement of PFME benefits, all found in the usual care package which both treatment groups received.

The benefit derived from the biofeedback may not be fully captured by this self-efficacy scale. Enhancing confidence in effective execution of the exercises involves coaching women in contraction timing, pelvic floor relaxation and noting the change in shape and quality of the graphical line displayed on the biofeedback. This *quality* of contraction is not fully reflected in the questionnaire, as the four self-efficacy questionnaire 'task' items merely ask participants to express confidence in holding the contraction *strongly*, holding for *5 seconds*, holding for *10 seconds* and *sensation* of contraction. To fully assess improvement in overall muscle function, a questionnaire assessing additional

elements such as responsiveness, speed and relaxation would be desirable. Nevertheless the change in quality of contraction should have been assimilated into the way the exercises are performed, and, if important, would have made a difference either to muscle strength or to leakage symptoms. However, as there was no difference in clinical outcomes it is questionable as to how useful it would be to measure additional task indicators, unless clinical benefit due to enhanced exercise execution was yet to be realised in this sample.

Results of the secondary outcomes confirm what would be expected intuitively; that depression is associated with greater severity of urinary leakage, and higher levels of 'bothersomeness' of symptoms are associated with greater leakage. In addition, higher self-efficacy scores are associated with lower levels of depression and less urinary leakage. This finding supports those of Broome (2003).

The Chen scale was assessed for internal consistency in this group of women. The Cronbach alpha was high at .95, indicating good internal consistency across the scale, however may also suggest redundancy of items in the Chen scale. The scale could be changed to be more succinct however the balance must be made between shortening the scale while ensuring coverage of the dimensions of the self-efficacy construct. Further research could explore the potential for changes to the scale, perhaps even the usefulness of separate smaller subscales for phase specific PFME self-efficacy.

8.3 Contribution and clinical relevance

This study supports previous work examining PFME effectiveness and muscle strength improvement in the conservative treatment of SUI (Bø, 2007; Dumoulin & Hay-Smith, 2010). Although a *no treatment* control was not used in this study, the improvement in symptom severity and muscle strength scores from baseline concurs with studies finding biofeedback use to be as effective as pelvic floor muscle exercise instruction alone (Burns et al., 1993; Berghmans et al., 1996), and better than no treatment at all (Henalla et al., 1989; Bø et al., 1990; Largo-Janssen et al., 1991). The results also agree with a Cochrane review (Dumoulin & Hay-Smith, 2010) concluding that biofeedback offers no extra benefit over PFME alone. However hopefully it also addresses some of the criticism of methodology found in other studies. This study refutes the belief espoused by some authors that biofeedback assists adherence, motivation or effort (Kegel, 1956; Glavind, Nohr & Walter, 1996; Mørkved, Bø & Fjortoft, 2002) beyond that achieved with palpation and instruction alone.

Other studies investigating motivation and performance have observed decline in self-efficacy over time (Vancouver et al., 2002; Vancouver & Kendall, 2006). This is thought to be due to initial high self-confidence or 'miscalibration' giving rise to an unrealistically high self-appraisal of capability (or inflated sense of preparedness), which, when subsequently confronted with the actual demands of treatment causes a 'reality check'. Observations of decline in PFME self-efficacy by others (Svengalis et al., 1995; Demain et al., 2006) may endorse this effect. Similarly, control theory of self-regulation (Powers, 1973), predicts that highly

self-efficacious individuals (those with little self-doubt) see no need to dedicate the time to practising their exercises and use their self-efficacy to judge how much effort is required to achieve a set goal and tailor their practise accordingly. It is possible that biofeedback used in this context may serve to endorse confidence and self-belief. In this situation self-efficacy would be maintained, but adherence (exercise practice) would decline. This study was designed as a randomised controlled intervention study (comparing two groups), not a *within subject* design, so the intention was not to assess changes in individual subjects with high self-efficacy over time. However there was no decline in mean self-efficacy scores and neither was there demonstration of a negative relationship between self-efficacy and PFME adherence. This suggests that the needs of highly self-efficacious individuals in the sample were served in terms of goal revision. Adherence levels were high for all participants which seems to agree with some previous studies (Bo & Talseth, 1996; Alewijnse et al., 2003), although as previously discussed, self-rating of adherence is difficult to verify and likely to be over-estimated, especially by participants in research studies.

Since the completion of this research, a Cochrane review has been published (Herderschee et al., 2011) which advocates the studying of self-efficacy for PFME and the effect of biofeedback in three capacities: as a teaching or learning tool, a progress recorder and a training aid. All dimensions of biofeedback use have the capacity to improve self-efficacy. The research presented here satisfies this recommendation in that it examines sEMG biofeedback as a teaching/learning tool. Moreover, the improved recall demonstrated by the group

using biofeedback appears to confirm the benefit of sEMG in learning the correct execution of PFME. According to Ley (1989) enhanced recall of instruction is an essential prerequisite to adherence. It is perhaps the different method of information presentation made available through biofeedback monitoring which helps patients to remember the exercises accurately. Other capacity for sEMG biofeedback use, for example as a training aid or performance measurement tool, would need to be explored in future work.

In terms of overall symptom severity and muscle strengthening, the low supervision intervention used in this study produced surprising outcomes, given that clinician contact is thought to be a key factor in supporting adherence. However these results do agree with a study by Felicissimo (2010) which indicates good results can be achieved with low supervision intensity, providing comprehensive instruction is given at the outset. The present study shows increased PFME self-efficacy levels over the study period suggesting that even limited contact can support confident exercising in patients. Indeed, King et al. (1997) demonstrated that exercise persistence could be achieved unsupervised in patients with high exercise self-efficacy. Further follow-up would be needed in order to confirm similar findings in the present sample. Imamura et al.'s (2010) assertion that pelvic floor 'extra' can be defined as *either* extra clinical contact sessions *or* addition of biofeedback to PFME, is not endorsed by the results of the present study. In contrast, the current study demonstrates that adding biofeedback to limited supervision did not give 'extra' benefit in terms of actual clinical outcomes. Moreover the conclusions drawn by Imamura and colleagues

(2010) acknowledged the compounding influence of the extra supervision given to participants in biofeedback groups.

More recently published work (Holroyd-Leduc et al., 2011; Whitford & Jones, 2011) also warrants appraisal in light of the present study findings. Whitford & Jones (2011) found that PFME compliance was predicted by ability to confidently and correctly contract the pelvic floor muscles. This seems to advocate building of task self-efficacy in promoting adherence. The present study did not assess confidence in *correctness* of contraction but confidence in ability to exercise regularly in daily life despite barriers. It should therefore be assumed that correctness of contraction was achieved by both groups as there was no difference in adherence levels. Whitford & Jones (2011) also acknowledge that measures were needed to help maintain the PFME habit (in other words scheduling self-efficacy). Holroyd-Leduc and colleagues (2011) found significant improvement in self-efficacy and quality of life in a cohort of older incontinent women (n=103) as a result of using an incontinence risk-modification tool to promote self-management. These findings highlight the importance of self-initiated strategies based on condition knowledge and their effectiveness in condition management.

8.4 Strengths and weaknesses of the study

8.4.1 Study Design

The design used was an RCT. No design is perfect, however an RCT remains a powerful methodology to evaluate the effectiveness of a treatment as it controls

for threats to internal validity (Bø & Herbert, 2009). Confounding variables are dispersed through the groups by the randomisation process, to produce groups similar in characteristics, with the goal of producing results which are generalisable. The study presented here featured a design adequately powered and successful in creating two groups with equal characteristics. External validity of the results is believed to be high as women were recruited through the usual physiotherapy referral process from a wide range of referrers, and exclusion criteria were kept to a minimum. In this way the sample was representative of the population studied. However, women were not able to self-refer to physiotherapy and could only access treatment via a health care practitioner. As the women had all undergone some sort of initial screening appointment prior to a physiotherapy referral being initiated, these women may have had different experiences and expectations compared with women seeking out treatment through a self-referral mechanism.

The randomisation process aims to ensure that group allocation is free from selection bias. All patients referred through any source were considered eligible for the study and a log of patients fulfilling the inclusion criteria was kept. Reasons for not wanting to participate were documented. Employing an independent statistician to prepare the randomisation schedule and sealed envelopes, which were opened at the clinic attendance, assisted in ensuring allocation was concealed. However, other potential sources of bias must be acknowledged in this study. Blinding is not usually possible in a physiotherapy delivered intervention and in this case it was not possible to blind the researcher

or patient to receiving biofeedback. One person conducting the study raises the potential for researcher bias through recruitment, outcome assessment, data collection and inputting. This is difficult to mitigate in an educational study as usually there is no research team and not enough funding to employ independent assistance. Following CONSORT guidelines, attending good research practice (GCP) training, sharing data spreadsheets with supervisors, using an independent statistician, feedback from conferences and peer review sessions all aimed to help transparency in the process.

As pelvic floor muscle exercises are already an established and recommended treatment for SUI in women, a *no treatment* control was considered unethical as this would have meant withholding access to an established treatment service. However, as the physiotherapy waiting list at the time of this study was running at 16 weeks, baseline measures were actually made after a period of what was effectively a *no treatment* period. Study visits at 6 and 12 weeks reflected the number of contact sessions possible at this time due to waiting list pressures and restricted resources, and has relevance to the wider pressures experienced by clinicians in other fields. Twelve weeks is the minimum time recommended for muscle change due to training, and based on the expectation that PFME adherence at 12 weeks would be a predictor of longer lasting commitment to the regimen (Alewijjnse et al., 2003). Had time permitted, follow-up at 4 months, 6 months or even one year would have been desirable in order to ascertain any biofeedback benefits over a longer study period and to establish whether long-term adherence was maintained.

Although health interventions can be evaluated in other ways, such as observation and interview, RCTs still provide some of the most reliable evidence for therapeutic decision-making and a well-designed and appropriately used RCT is still widely recognised as producing one of the highest levels of research evidence (Moher et al., 2010). However, quantitative study design does not focus on the recording of individual experience of treatment and this study design did not set out to achieve this. Nevertheless, patient acceptability of sEMG biofeedback treatment is important and exploring women's experience of using this equipment may have provided insight into possible undisclosed reasons for study drop-out and benefits not fully captured in questionnaires. Moreover it may be interesting to explore through interview how biofeedback may have influenced insight into exercise performance, confidence in ability and desire/intention to adhere to the exercises.

8.4.2 Measures

Methods and measures were considered robust. Return of questionnaires and completion of items within the questionnaires was excellent. No questionnaires were not returned or not completed at all. Items not completed were related to 'recall of exercises' on the adherence questionnaire (six participants) and confidence in practising exercises during sexual activity on the Chen self-efficacy questionnaire (one participant).

PFME self-efficacy was measured with a self-completed questionnaire which was shown to be a valid and reliable behaviour-specific scale (Chen, 2004). It was

validated, however had not been used before in a UK population or as a *before and after* measurement in an intervention study. Although PFME self-efficacy scale stability is known (Chen, 2004), the responsiveness to change of the Chen scale had not been tested before. An effect size of 10 points was estimated by the researcher to be the minimal difference to be clinically important enough to change practice. This estimate was based on scores from a small sample of patients (pre-treatment) who tested the questionnaire for readability and comprehension prior to study commencement. Data from the initial validation study was shared by Chen and revealed good comparison with initial pre-study data collected from women receiving physiotherapy treatment. Piloting the PFME self-efficacy questionnaire in this way highlighted a problem with the wording of one of the Chen PFME self-efficacy questionnaire items, which was changed after seeking opinion and consent from the questionnaire author. This alteration did not affect the meaning of the item. The author of the scale did not think the change would influence scale validity (Personal communication, Chen 2007), however further testing was not undertaken to confirm this.

Adherence was measured with a self-completed questionnaire derived from another study and shared by the author (Alewijse et al., 2003). However it had not previously been validated and was not piloted prior to use in this present study. This is regrettable as it was noticed that giving a written description of the exercises to establish recall/remembering of the exercises requires the ability for to describe concisely and accurately using written description. Participants may have been put off completing this section (six women failed to complete this

item). Recall of the exercises could have been more accurately captured (and from more participants) if a voice recording of the participants' spoken description of the exercises had been used instead.

As previously stated, accuracy is a concern when using self-reported measures especially adherence questionnaires. Completing the questionnaires at clinic attendance, albeit in a waiting room and posting the questionnaires anonymously, may still have created a desire to please the therapist, causing inflation in the questionnaire responses. There is also the potential of memory bias associated with recalling behaviour from the last week. In addition there may be a *Hawthorne Effect*, a phrase coined by French (1953) and derived from initial results of experiments called the Hawthorne Studies. The term refers to the improvement seen in participants thought to occur as a result of being researched and measured as part of the study process. This is a problem recognised by researchers, however as each group received the same clinician contact, any effect should be lessened and dispersed across both groups. A postal questionnaire may have resolved some of these issues, but without help to chase up missing questionnaires, the method used seemed a compromise in ensuring an excellent questionnaire return, while giving the best chance of reliable data. These issues were discussed with an experienced researcher (Hay-Smith, 2008, personal communication), and the chosen format and questionnaire timing seemed to be the best that could be achieved given these concerns. There is also no evidence that retrospective use of a questionnaire to

evaluate exercise adherence is any less reliable than other methods (Herderschee et al., 2011).

Severity of leakage was measured using a validated tool (the ICIQ-UI SF questionnaire, Avery et al., 2004) both pre- and post-intervention. This is a brief, robust and easily completed questionnaire. Several studies have assessed the psychometric properties of the questionnaire, including content, construct and convergent validity, reliability and responsiveness to change. It has demonstrated good reliability, 'moderate' to 'very good' stability in test-retest analysis and a final Cronbach's alpha of 0.92 showing very good internal consistency (Avery et al., 2004). It is recommended for measuring outcomes both in research and clinical practice in assessing the effectiveness of interventions on severity and impact of incontinence.

Muscle strength assessment does not give a complete evaluation of total muscle function and does not indicate the quality of the contraction produced. The modified Oxford scale (Laycock, 1994; Messelink et al., 2005) is commonly used in clinical practice and assesses strength and lift. Vaginal palpation is used to assess muscle condition and function; the need for this only very rarely debated (Bardsley, 2007). However some studies have found that muscle strength is not differentiated by palpation scores using the Oxford grading Scale (Bo & Finckenhagen, 2001; Ferreira et al., 2010). Although intra-rater reliability in a scale is good for clinical evaluation and the modified Oxford scale has been appraised as showing good reliability when used by one assessor (Laycock & Jerwood, 2001; Frawley et al., 2006), this scale is probably not discriminating

enough to be used as an outcome measure in studies where muscle strength is being compared across groups in research studies (Ferreira et al., 2011). Other options include using sEMG (millivolts and seconds) to assess participants which may have helped evaluate other dimensions of muscle function such as muscle responsiveness (onset of contraction) and relaxation levels. However the intention of this study was to restrict use of sEMG to the Intervention group in order to prevent confounding influence. Use of other methods, such as ultrasound to measure muscle hypertrophy could have provided an additional outcome measure and is becoming more widely available. This may be a useful addition to the design of future studies.

8.4.3 Intervention delivery

In the present study the same person performed both the assessments and treatment for both groups. This had the advantage of minimising inter-rater error of measurement and maximising consistency in delivering the intervention. The disadvantage is that, in effect, it examines the effectiveness of a single person delivering the intervention. As the intervention delivered was highly standardised one could argue that similar results would be found if delivered by other suitably qualified professionals but it cannot be assumed that other people delivering the intervention (or the assessments) would do so with the same effect. This could be overcome by having a larger team of people delivering the intervention and undertaking the assessments possibly within a multi-centre trial. However this was not possible within the resources available. Assessment and advice about

exercise progression, fluids and bladder habit were all given in line with national clinical guidelines (Laycock et al., 2001a; Laycock et al., 2001b; NICE, 2006). Use of exercise reminder diaries with emphasis placed on planning scheduled time (three times a day) for exercise sessions rather than using an ad-hoc approach was also given (Hines et al., 2007).

Biofeedback may be employed in different ways to achieve various aims (Herderschee et al., 2011). Millivolts were not recorded in this study as measuring performance quantitatively was not the intention of this research. Instead the shape of the graph/trace and duration of contraction was used to teach and improve muscle contractions. Despite this, graph calibration was not hidden from the participants, which may have given the impression that 'higher' microvolt readings were desirable. In the context of improving self-efficacy, care must be taken to avoid the consequences of trying to aspire too soon to an ideal performance, as the setting of overambitious goals (by the therapist or the patient) may have a detrimental effect on self-efficacy. If possible, removing calibrations from the sEMG display may have helped focus attention on the graph shape, that is, correctness and quality of muscle response rather than the amplitude achieved. Each clinic session was performed in the same clinic room in order to provide the same clinic environment for all participants. This also minimised fluctuations in background noise from equipment in concurrent use and maximized reproducibility of the sEMG trace. Individuals kept their probes and brought them to each session. The same amounts of conducting gel and

positions for treatment/ monitoring were used, with each participant and in each session, in order to help ensure standardisation in treatment delivery.

8.4.4 Recruitment.

The source of referral could impact on patient management and expectations prior to attending for physiotherapy. Patients were referred from different sources; some had already been given exercise leaflets, had undergone a pelvic floor examination, been given advice and some had received no advice or instruction at all prior to referral. Broadly speaking, women referred by GPs do not usually receive bladder-specific advice and are less likely to have had started treatment for their incontinence. If referred via the uro-consultants patients may have received an exercise leaflet and will have discussed likely treatments. Women seen by continence or urology specialist nurses will almost certainly have received a baseline continence assessment, PFM examination, exercise instruction, initial treatment and advice. Referral sources were fairly evenly distributed between the groups, so these differences in experience prior to referral were not considered a potential confounder when interpreting the results.

8.4.5 Analysis

The drop-out rate of 16% compares well with other studies (Dumoulin & Hay-Smith, 2010) where drop-out of between 10% and 50% is reported. Participants who failed to complete the study were evenly split between the control and intervention groups. This suggests that participants did not drop-out because of not being randomised to the intervention group and that the intervention itself

was unlikely to be causing drop-out. Results for participants were analysed in the groups in which they were allocated (Fergusson et al., 2002) which is a quality standard of data handling for RCTs recommended by the CONSORT group (Moher et al., 2010). To further assist transparent reporting, missing data was identified and the drop-outs from the study were analysed to see if they differed significantly from the completers.

Analysis was undertaken on the completed cases and additional sensitivity analysis was performed for the main outcomes. Intention-to-Treat (ITT) analysis causes debate (Altman, 2009) as it includes various options for the handling of missing values (Hollis & Campbell, 1999; Gravel, Opatrny & Shapiro, 2007). Missing data reduces power, however the main concern is disruption of randomisation as incompleteness of data may not be random. No analysis option seems ideal. Imputation of missing values is complex and also requires assumptions to be made about the data, which in itself can cause bias (Lane, 2008). Proponents argue that ITT is a cautious approach which minimises Type 1 error, minimises the influence of those dropped-out as it accounts for all participants, preserves balance in the study arms and allows greater generalisability (Fergusson, 2002). CONSORT group recommend reporting all analysis so that data handling methods can be appraised (Moher et al, 2010). For this study, analysis of those who dropped out (n=10, 16%) is presented and revealed no obvious biases. The number of completed cases (n=50) met the recommendation for study power. A simple evaluation of a 'best' and 'worse' case scenario using substituted main outcome sample scores was decided upon

in order to allow a sensitivity analysis to be presented together with completed cases for comparison purposes. All these findings have been presented. An independent statistician, blinded to group allocation, provided additional checking of the analysis performed by the researcher.

The primary statistical analysis performed was direct comparison of the two groups at 12 weeks (two-sample method) and sample size was calculated to compare the two groups in this way. Actual data point differences, p values and confidence intervals are given. In addition, comparison of final scores against baseline is also given for each group (Bland & Altman, 2011). Mean score changes for each group are useful, especially as this scale has not previously been used pre and post intervention. However testing within-group changes for significance is controversial because of natural changes which may occur over time and the potential for regression towards the mean. There is also potential for erroneous conclusions to be drawn about treatment effectiveness by the direct comparison of p values (Bland & Altman, 2011).

8.5 External validity

As mentioned previously, there are often concerns regarding the external validity of RCTs. Despite this, the external validity of this study is thought to be high. The study setting is Secondary Care (an acute hospital), where specialist continence physiotherapists commonly reside and practice alongside urogynaecology and urology colleagues. Treatment delivery also reflects the way this service usually operates (whether in primary or secondary care) with

participants seen in a clinic environment rather than in their own homes, recruited to the study through the usual patient referral process and from the usual variety of referral sources for this service. The sample is therefore representative of the patient population being studied in that they are women with SUI presenting to a health care professional for help. The follow-up frequency and time allocated for assessment and treatment also highlights the reality of resource pressures in many services. The impact of budget constraints affects equipment purchase/replacement, training, as well as restriction on the number of clinic follow-up sessions and time spent per session with a patient. Restricted follow-up for patients is a clinical reality in many health facilities (private and NHS), reflecting the compromised service often offered to patients, a concern which helped prompt interest in conducting this study. Funding for services can be a struggle and justification to managers and commissioners needs to be made (naturally) on grounds of clinical and cost-effectiveness. Therefore this is a very relevant area for research in health services, and, in terms of setting and design, the results of this study can be generalised to other continence services as well and other physiotherapy settings where treatment adherence, self-efficacy and self-management are the focus.

8.6 Implications for practice and future research

8.6.1 implications for practice

The benefits of improving and maintaining pelvic floor muscle function through life from early adulthood, child-bearing and into later life means a lifetime of PFME self-management. Many find daily exercise adherence more challenging than attending clinic appointments or following other health advice (Evangelista, Berg and Dracup, 2001) and this can threaten patient self-management. Therefore, regard for concepts such as self-efficacy, which is related to the process of behaviour change, is needed in order to help us devise effective interventions.

This is the first RCT to explore the claim that machine-mediated biofeedback, such as sEMG, can help motivation and adherence to PFME in the treatment of women with SUI. This research shows that clinic-based sEMG biofeedback does not provide enhanced motivation to perform PFME in terms of improved self-efficacy and exercise adherence when used routinely by women with SUI who can already contract their muscles. Therefore sEMG should not be a substitute for individual coaching through palpation. Vaginal muscle palpation is a cost-effective and sensitive method for establishing correctness of muscle contraction and easily integrated into routine vaginal assessment. In addition these findings should reassure clinicians without access to biofeedback equipment that patients (who can already contract their pelvic floor) are not missing out. Nevertheless, this study demonstrates that using sEMG may help women learn and remember the PFME regimen. sEMG is also shown to be an equally effective modality

when used as part of a treatment programme. Although this research demonstrates that sEMG biofeedback does not promote *additional* PFME self-efficacy and exercise adherence, self-efficacy and adherence are positively influenced even by physiotherapy intervention for SUI. This means that patients should have opportunity to access physiotherapy treatment, even if it is a limited service, and regardless of their initial self-efficacy screening scores.

While sources of self-efficacy are known, there remains a gap in determining which interventions can change self-efficacy. A systematic review of self-efficacy for physical activity tried to identify which intervention approaches impact most on levels of self-efficacy (Ashford, Edmunds and French, 2010). Vicarious experience and feedback of past performance seemed to have the most impact on self-efficacy while graded mastery, persuasion and identifying barriers had the least or most negative effects. In the present study only women's current endeavour was displayed on the sEMG, therefore the full potential of biofeedback monitoring may not have been fully realised. Verbal encouragement from the clinician may have less effect on PFME self-efficacy than allowing participants own past performance to be viewed, or modelling a woman's own performance on the graph traces of others. As there is potential for biofeedback equipment to display a patient's past performance and that of others, further studies could explore the value of incorporating this into treatment sessions.

Belief in ability to perform the exercises correctly and the belief that effectiveness of PFME will control the symptoms of UI is the essential starting point in women

appraising whether they can adopt UI treatment strategies. Individual exercise instruction helps women experience the accomplishment and confidence in the execution of the exercise itself. Moreover, the regular monitoring of progress helps to establish the importance and usefulness of daily exercise performance so it is not forgotten. Although the benefits of seeing the sEMG trace (muscle effort) is not realised in terms of exercise practise, there may, however, still be benefit for women not able to understand the exercises, that is, those with low PFME task self-efficacy. This could be a subject of future study.

Exploring individual motivations, such as a desire to be rid of bothersome symptoms or avoid surgery, as well as identifying individual barriers to self-efficacy has potential to help tailor treatments for each and every patient. A means of identifying specific reasons affecting PFME adherence in individuals (rather than addressing more general factors associated with non-adherence across all women with SUI) is therefore important. In this way, limited time in individual clinic consultation is optimised. Motivational Interviewing (Emmons & Rollnick, 2001) and use of program-planning models such as *precede-proceed* (Green & Kreuter, 1991) help identify and explain possible barriers to self-efficacy or adherence prior to the evaluation of suitable interventions.

Although learning and teaching research indicates that greater confidence and ability in a task or skill can lead to complacency and reduced effort (Vancouver, 2002), this did not occur in this study. This is thought to be due, in part, to effective revision of exercise targets or goals. Therefore it is recommended that

treatment progression must be a key factor in PFM training sessions. It is also advisable to ensure that, from the outset, women with seemingly high initial self-efficacy for PFME do not hold mistaken self-efficacy beliefs. Clinicians need to be sure women have a realistic sense of what is required in effective treatment, to avoid decline in self-efficacy over the treatment period.

High exercise self-efficacy predicts good compliance with exercise programmes (Clark and Dodge, 1999). Specifically, *recovery* and *action-planning* self-efficacy allows the anticipation of demands and challenges, and the overcoming of setbacks. It is this aspect of self-efficacy which successfully predicts exercise adherence behaviour in the longer term (Schwarzer, 2008). These are therefore important considerations in developing and improving interventions. In this way, patients can maintain a life-long commitment to exercise programmes beyond mere mastery of the exercises achieved during clinic attendance.

8.6.2 Future research

1. Although clinic attendance and closer clinician supervision allows monitoring of factors affecting self-efficacy, the *proxy efficacy* provided by the clinician may have the potential to compromise patient independence and actually reduce self-confidence in the task (Bray, Brawley and Millen, 2006). Self-monitoring via home EMG units, and electronic reminder diaries or 'work-out' programmes through a smart phone applications ('apps') may help this process and provide the regular reinforcement

- needed to maintain longer term adherence. Exploring the use of these systems would seem to be worthwhile areas for future research.
2. Packages of care should be examined to see what aspects of treatment could assist with phases such as *coping* and *scheduling* self-efficacy.
 3. Conducting an RCT in a sample of women with poor perception of pelvic floor contraction and/or low confidence in ability to perform a pelvic floor muscle contraction would assess the usefulness of biofeedback in this population of women. Therefore further intervention studies looking at the impact of biofeedback on women with low task self-efficacy are recommended.
 4. Studying the effect of goal revision on PFME self-efficacy and PFME adherence in women with *high* PFME self-efficacy.
 5. Research into the effectiveness of tools and communication strategies to help identify barriers to self-efficacy in individuals in order to enable targeted interventions.

8.7 Conclusion

Increased life expectancy will mean people living longer with dysfunctions such as urinary incontinence. As these conditions become chronic, this ultimately affects quality of life. If effective health management through personal instigation of behavioural change can delay onset of chronic dysfunction, quality of life will be extended. Exercising personal control and making behavioural changes in managing health is achieved through self-efficacy: the exercising of personal

control itself reducing the likelihood of disease development and progression (Steptoe & Appels, 1989). Understanding the theoretical underpinnings of self-efficacy, can assist clinicians in deciding which interventions are most effective in helping individuals succeed with treatment. Adopting theoretical standpoints assists in evaluating previous research (both successes and failures) and helps devise subsequent studies (Sirur et al., 2009).

As the goal for a value-driven health service continues, clinician intervention needs to be timely and efficient, and patients are enabled (where possible) to manage their own treatment. Building self-efficacy is vital to this process. Indeed the necessity for long-term adherence to PFME therapy inevitably means that at some point, women will be discharged from clinician care to self-manage their own exercise programme. Opting for sEMG biofeedback should be a decision taken jointly with the patient and must occur against a background of good theoretical reasoning and appraisal as to the likely benefits for the individual. Routinely used, sEMG is unlikely to provide added benefit for women who can already perform PFME. However, if barriers to PFME adherence are identified which include lack of confidence or uncertainty about PFME execution, sEMG biofeedback may well assist exercise learning and may indeed be of use in the quest for confident self-management of urinary incontinence.

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Study Identifier:

1. Type of Study:

Randomised study YES UNCLEAR NO (exclude)

2. Participants:

Women with predominantly Stress Urinary Incontinence
YES UNCLEAR NO (exclude)

3. Interventions:

EMG or pressure biofeedback used as an intervention arm
YES UNCLEAR NO (exclude)

'Pelvic floor exercises alone' used as a control group
YES UNCLEAR NO (exclude)

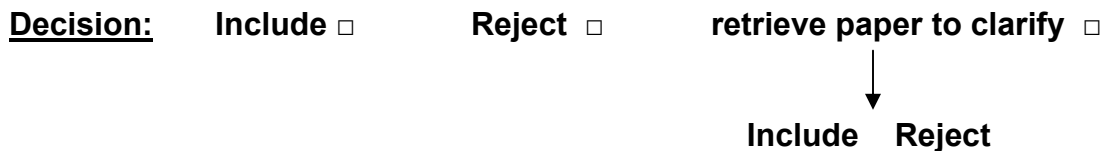
4. Outcomes:

Does study report one of the following: symptom improvement or cure, reduction in leakage or quality of life
YES UNCLEAR NO (exclude)

5. Other criteria:

Published in English YES UNCLEAR NO (exclude)

All 5 items must score 'Yes' for inclusion.
If 'unclear' on any of the items then retrieve paper to clarify.



Appendix 2 Table 7 Included studies comparing biofeedback with pelvic floor muscle exercises alone in women with SUI.

Study	Sample Inclusion and exclusion criteria	RCT Design	Biofeedback delivery and contact visits	Adherence measure	Treatment duration and assessment points	Outcomes used	Data, p-values, CI and Findings
Shepherd, Montgomery & Anderson, 1983	N=22 Women with SUI (confirmed by urodynamics) matched for age and parity. Exclusion: None mentioned	2 groups 11/11	Intervention: Biofeedback using a perineometer (pressure readings) at home plus HEP Control: PFME only. Each participant had one hour a week with physiotherapist.	Not reported	6 weeks Voiding chart completed in the week prior to the study, also perineometer readings at study start. Assessed again 'after 6 weeks'	Incontinence episodes (and urinary frequency) by self-completed voiding chart. Muscle contraction force (cm of water) using a perineometer	Range of actual and mean values for each group, but no analysis or p values given. <i>Intervention</i> = 8 out of 11 continent <i>Control</i> = 3 out of 11 continent. Episodes of incontinence per week, mean(range): <i>Intervention:</i> Pre 6.5 (1-18) Post 1.1(0-8) <i>Control:</i> Pre 5.5 (3-12) Post 4.1 (0-7) Muscle contraction (cm water) <i>Intervention:</i> Pre 6.4 (3-12) post 19.3 (10-30) <i>Control:</i> Pre 7.1 (3-15) Post 11.2 (5-20)

Taylor & Henderson, 1986	N=13, Symptoms of SUI. Excluded if neurogenic, neuromuscular disorder or urinary infection. Age range 55-79 (post-menopausal women)	4 groups. Not stated how many in each group	Intervention1; PFME programme and home visual biofeedback using a perineometer and clinic biofeedback once a week Intervention 2: PFME programme plus weekly clinic biofeedback. Intervention 3: PFME programme plus vaginal probe used as a IVRD at home without visual biofeedback and clinic biofeedback once a week Control: PFME alone. Attended clinic weekly.	Compliance diary	8 weeks X 8 (weekly clinic visits)	Subjective rating Urinary diary EMG measures	No useable data presented. 100% 'continence rate' in Intervention group1 (67% in the other groups)
Burns et al., 1993	N=135 Female volunteers over 55 years old and cognitively intact (as determined by	3 groups 40/43/40	Intervention: biofeedback session once a week for 8 weeks. 2nd Intervention Group: 30	Adherence not measured but adherence promoting activity was instigated, ie exercise	8 weeks Self-reported diaries completed 2 weeks prior to randomization, at 8 weeks	Muscle contraction force (assessed by EMG) Quick and sustained contractions. Urine loss	Data pre and post treatment, percentage improvement and p-values given (NB the 'no treatment' control results are

	<p>mini-mental state exam) with predominantly SUI a minimum of 3 times a week (and demonstrable on examination), a normal urinalysis and post-void residual urine measure of less than 50mls.</p>		<p>minute visits with ex instruction once a week for 8 weeks, Control: no treatment and no contact.</p> <p>Both intervention groups received exercise instruction and a home exercise program was encouraged daily</p> <p>1 session (30 minutes) per week Same contact visits for the 2 intervention groups.</p>	<p>reminder cards and encouragement at each visit.</p>	<p>and then 3 and 6 months. EMG and Urethral closure pressure assessed before randomisation and again 2 weeks after the 8 week intervention period</p>	<p>(number and severity by self-completed diary)</p> <p>Percentage improvement</p> <p>(Urethral closure pressure (by Urodynamic testing)</p>	<p>not given below)</p> <p>EMG(mv) Quick <i>Intervention:</i> pre 3.5 (3) and post 6.0(5.1) p<0.05 <i>2nd intervention:</i> pre 2.9(3.2) and post 3(3.4)</p> <p>Sustained <i>intervention:</i> pre 2(1.5) and post 4.0 (3.1) p<0.001 <i>2nd intervention:</i> pre 1.7(1.6) post 1.8 (2.0)</p> <p>Urine losses per week: mean (sd) <i>Intervention:</i> pre 13(12) to post 5(6) 61% improvement p<0.001 <i>2nd Intervention:</i> pre 18(15) post 8(10) 54% improvement p<0.001 No difference between groups.</p> <p>No difference between treatment groups but significantly higher EMG recordings in EMG group. Improvement was</p>
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							maintained at 3 and 6 months in women with moderate/severe leakage, but this was not broken down by group.
Berghmans' et al., 1996	N=40 Females between 18 and 70 years old, referred by Urologist or GP 'with mild or moderate SUI'. Excluded women taking medication known to affect lower urinary tract, with pudendal nerve lesions or neurological conditions affecting bladder function, with history of previous urological surgery, less than 6 weeks post-natal, with UTI, with severe SUI, with vaginal	2 groups 20/20	Intervention: sEMG 3 times a week for 4 weeks Control treatment sessions 3 times a week for 4 weeks Same contact sessions for each group ie 12 sessions over 4 weeks. Biofeedback equipment stated as reliable and valid.	Reports '100% compliance' however this refers to attendance at the study sessions not adherence to the home exercise program as this is not assessed.	4 weeks 48hr Pad test assessed before intervention started, after 2 weeks and at the end of 4 weeks. Symptom questionnaire and diary completed before each treatment. (12 times).	Urine loss by Pad test Self-reported symptom questionnaire and bladder diary.	Mean loss of urine (g) <i>Intervention:</i> pre 26.6 (24.5) after 2 weeks: 12.4(10) and post 12.2 (15.4) <i>Control :</i> pre 29(31.7), after 2 weeks 17.4(17.6) and post 12.5(12) 55% improvement for both groups (p<0.00) by end of treatment. Significant reduction in urine loss achieved by 2 weeks compared with control, but no significant difference between groups at 4 weeks (end of the study). Self-reported symptom improvement and daily incontinence frequency Mean

	irritation, with a pacemaker or hip prosthesis, unable to communicate in the language or fill out forms.						<p>data displayed graphically (no precise values or sd given) Improved in both groups but no significant difference shown between groups (symptoms, p=0.45, daily incontinence, p=0.18).</p> <p>Combined measure of effect showed slight trend towards the Intervention group but no significant difference in improvement between groups p=0.08</p>
Glavind, Nohr & Walter, 1996	N=40 Women demonstrating >2g leakage on 1 hour pad test. All women assessed by digital palpation but no distinction made between ability to contract with regards to	2 groups 20/20	<p>Intervention: Clinic biofeedback once a week for 4 weeks.</p> <p>Control: Individual instruction 'Physiotherapy' 2-3 times Unclear whether the control group were examined.</p>	Yes. Greater exercise adherence levels found in the intervention group 17/19 (89%) did their PFME regularly compared with 7/14 (50%) in the control group) at 2-3	4 weeks. Pad test assessed before the intervention, at 4 weeks (end of the intervention) and again 2 months later. Symptom severity and exercise	Urine loss by 'new standardised' Pad test ('cure' <1g) Symptom severity and PFME adherence questionnaire at 2-3 years.	Raw data, p-values and CI given. Pad weight g (CI) <i>Intervention:</i> Pre: 9 (5, 22), at one month: 2.5(1,10), Post: 0.8 (0,4). <i>Control:</i> Pre: 12.8 (9,44), at one month: 19 (0,51), Post: 10 (2, 27) p=0.02 found in favour of

	inclusion criteria. Excluded if had previous surgery for UI or had detrusor instability on Urodynamics testing.		Supervision and contact time is different for each group.	years.	adherence assessed (a median time of) 2.5 years later.		biofeedback group at 3 months. Relative reduction of pad weight in intervention group is 88.4% (78-94%) compared with 53.9% (2.1-78%) in the control group. Cure rates (<2g pad test) were: 11/19 in the intervention group and 3/15 in the control (P=0.057) Symptom severity at 2-3 years: <i>Intervention:</i> 5/19 (26%) subjectively cured and 8/19 (42%) improved. <i>Control:</i> none cured but 4/14 (29%) improved.
Sherman, Davis & Wong, 1997	N=46 Women soldiers with SUI and mixed UI demonstrated on urodynamics. Excluded if only	2 groups 23/23	Intervention: 'Urethral Biofeedback' EMG activity of the pelvic floor muscles Also biofeedback units for home use for the first 7 days.	Adherence was recorded by self-completed questionnaire, ie how many hours of exercises did they do a week. Control group practiced their	8 weeks Urodynamics and 'subjective patient report' before randomization and after 8 weeks.	Outcomes not stipulated. Data was gathered from Self-completed questionnaire, urodynamic assessment and clinical examination. No validity and reliability of	Actual data and p-values reported but no CI. Severity of the problem: Between group analysis of final values Mann Whitney U p=0.95

	urge incontinence		Control: sham biofeedback (the same equipment and timed exercise regimen, but not connected to the apparatus and did not view a screen). One session every 2 weeks (total 4 sessions)	exercises significantly more by the end of the study.		outcome measures was stated. 18 outcome 'items' reported including: self-rating severity of the problem 0=worst to 3= best Number of leaks (per day).	Number of leaks per day : mean(SD) <i>Intervention:</i> before 7.27 (7.44) after 2.90 (6.53) p=0.01 <i>Control:</i> before 15.72(10.71) after 5.25(7.24) p=0.03. Difference between groups p=0.06
Wong et al., 1997 (abstract only)	Numbers not stated. Data presented for 17 women. SUI proved on Urodynamics. Mean age=48.2 Excluded if previously failed PFME or had undergone incontinence surgery.	2 groups (10/7)	Intervention: PFME plus clinic EMG biofeedback twice a week for 4 weeks. Control: .PFME attending twice weekly for 4 weeks.	Not stated	4 weeks	Urinary 7-day Diary Urine loss on 1 hour pad test Incontinence impact questionnaire.	Not sure if drop outs occurred. Change scores reported for each group. Leakage episodes (per week) <i>Intervention:</i> 2.0 (3.5) <i>Control:</i> 9.1(12.3) p> 0.05. Pad test weight (g) <i>Intervention group:</i> 7.4(6.1) <i>Control:</i> 18.7 (24.8) p>0.05 IIQ score: <i>Intervention:</i> 8.5(19.9) and <i>Control:</i> 24.5(10.8) p<0.05.

Laycock et al., 2001a	N=101 women 'with symptoms of SUI'	3 groups 41/40/20	<p>Intervention 1: Cone therapy 10 minutes a day</p> <p>Intervention 2: Biofeedback using PFX home perineometer 10 minutes per day</p> <p>Control: PFME 10 minutes each day</p>	<p>Participants completed a daily exercise diary to record adherence to the trial protocol.</p> <p>Compliance scores presented as percentages for each group: Group 1: 77% compliant, Group 2; 79% compliant, Control; 81% compliant These were not analysed for significance</p>	<p>3 months All seen in clinic every 2 weeks (total 6 attendances).</p> <p>Assessment points were before randomization and after 3 months</p>	<p>Primary Outcomes: Urinary incontinence episodes (recorded by daily diary).</p> <p>Subjective assessment of symptom severity (by VAS)</p> <p>Secondary outcomes: Number of pads used per day (assessed by diary).</p> <p>Increase in contraction strength (by electronic perineometer)</p> <p>QoL (Kings Health Questionnaire)</p>	<p>No VAS score results given. No measure of dispersion, CI or change differences given. (<i>Intervention 1 results have been omitted here</i>).</p> <p>UI episodes per day: <i>Intervention 2</i> 2.04 before and 1.77 after (p=0.000) <i>Control:</i> 1.71 before and 0.47 after (p=0.003) ANOVA 0.465</p> <p>Muscle contraction force: <i>Intervention2:</i> 19.74 before and 32.10 after (p=0.001), <i>Control:</i> 20.11 before and 27.75 after (p=0.004) ANOVA 0.690</p> <p>QoL: <i>Intervention2:</i> 33.86 before and 41.13 after (p=0.002), <i>Control:</i> 28.75 before and 39.19 after (p=0.009) ANOVA 0.609</p>
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							<p>Number of Pads used per day: <i>Intervention</i>2: 3.21 before and 1.05 after (p=0.006) <i>Control</i>: 2.38 before and 0.05 after (p=0.002) ANOVA 0.043.</p> <p>Conclusion: All groups showed significant change but there was no significant difference demonstrated between groups.</p>
Pages et al., 2001	<p>N=51</p> <p>All participants had SUI confirmed with Urodynamics and could activate their pelvic floor recording at least a Grade 2. Exclusion: no significant coexisting medical illness especially neurological problems, and if</p>	<p>2 groups 13/27 (11 withdrew after randomisation)</p>	<p>Intervention: sEMG 5 times a week for 4 weeks (20 sessions) Control: Group PFME 5 times a week for 4 weeks (20 sessions)</p> <p>All participants then followed a home exercise programme for 2 months.</p>	Not reported	<p>4 weeks, Assessed at the start, 4 weeks and also reviewed 2 months after treatment finished. Subjective change was only recorded at 4 weeks and 2 months after treatment.</p>	<p>Muscle strength by digital grading assessment (and also 'speculum test')</p> <p>Urination frequency and pad dampness/leakage episodes by voiding diary</p> <p>Subjective improvement report by self-completed standardized questionnaire</p>	<p>Data and p values. No CI reported.</p> <p>Digital PFM strength(1-5) median(SD) <i>Intervention:</i> 2(0.9) before, 4(0.8) post and 4(0.8) 3 months after (p<0.0001). <i>Control:</i> 3(1.1)before, 3.5(1.0) post and 4(1.0) at 3 months after P<0.0001).</p>

	taking medication thought to interfere with bladder function.					Contraction strength measured with pressure biofeedback	<p>Pad dampness/leakage results not stated.</p> <p>Subjective improvement % <i>Intervention:</i> 28% had no leakage after with 62% at 3 month follow-up. 68% had improved symptoms declining to 38% at 3 months. 4% had no change post treatment with none reporting unchanged symptoms at 3 months(all had improved) <i>Control:</i> 22% had no symptoms post treatment improving to 69% at 3 months. 74% had improved symptoms post treatment declining to 31% at 3 months. 4% had no change at post treatment but these had improved by 3 months.</p>
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							<p>Contraction strength (cm2) median(SD) <i>Intervention:</i> 12(5)before, 50(14) after and 43(16) 3 months after (p=0.0005) <i>Control:</i> 11(7) before, 16(10) after and 17(14) at 3 months (p<0.0001)</p> <p>Initially a significant increase in contraction strength was noted in the intervention group at 4 weeks, but no difference between the 2 groups was noted at 3 months.</p>
Mørkved, Bø & Fjortoft, 2002	N=103 Urodynamically proven SUI>2g measured by pad test. Exclusion: Detrusor instability on Urodynamics, residual of more than 50mls, previous urological surgery,	2 groups 53/50	<p>Intervention: clinic vaginal pressure biofeedback and HEP using home biofeedback unit three times a day.</p> <p>Control: Seen in clinic for individual training</p>	'motivation' was given in the sessions. 88.9% in intervention and 85.3% in control group 'were training more than 3 x a week' (not significant) but it is not clear how this was assessed.	6 months Assessed at baseline and 6 months (end of treatment period), although vaginal squeeze pressure is additionally reported at 3 months	Leakage on Stress Pad test (<2g cure) (Also did 48 hour pad test as a secondary outcome) Symptom severity and Subjective cure. Leakage index.	<p>Statistical analysis performed with actual data, change difference, p values and CI reported.</p> <p>Change difference on standardised pad test (g) Mean(95%CI) <i>Intervention:</i> 19.6 (14.4,24.8) <i>Control:</i> 18.5(12.2, 24.7) p=0.73</p>

	neurological or psychiatric disease, urinary tract infection, use of concomitant treatments, pregnancy, not understanding instructions given in Norwegian or difficulties attending the trial sessions		<p>sessions (no biofeedback) and HEP 3 x a day</p> <p>Both groups seen once a week for 2 months and once a fortnight for a further 4 months</p>			<p>Social activity index.</p> <p>Muscle strength (assessed by vaginal palpation and by vaginal balloon catheter).</p> <p>Blinded outcome assessment.</p>	<p>Subjective Cure n(%) <i>Intervention: 19(40)</i> <i>Control: 14(30)</i></p> <p>Change difference Muscle strength. <i>Intervention:12.3</i> <i>(9.5, 15.1)</i> <i>Control: 11.1(8.1, 14.1) p=0.57</i></p> <p>Change difference Leakage index: <i>Intervention: 0.9</i> <i>(0.7, 1.0)</i> <i>Control: 0.9(0.7, 1.1) p=0.61</i></p> <p>No significant difference between the groups for all outcomes.</p>
Goode et al., 2003	<p>N=200</p> <p>Inclusion criteria: age >40 years, UI for at least 3 months, average 2 or more incontinence episodes/week, predominantly SUI.</p> <p>Exclusion</p>	<p>3 groups 66/67/67</p> <p>High attrition rate 54/59/42 completed</p>	<p>Intervention 1 PFMT + BF : Taught VPFMC with anorectal pressure biofeedback and received instruction for progressive PFMT regimen.</p> <p>Intervention 2 PFMT + BF + ES: This arm</p>	<p>High attrition rate (18.2%) from the Intervention 1 group and (37.3%) from the control group.</p> <p>Actual compliance with the exercises/ advice was not</p>	<p>8 weeks: Intervention groups were seen 4 times (every 2 weeks). Control group seen at the beginning and end (0 weeks and 8 weeks). Groups did not</p>	<p>Primary outcome: % reduction in number of incontinent episodes recorded by bladder diary.</p> <p>Secondary outcome: patient satisfaction and QoL (Incontinence Impact</p>	<p>Mean reduction in incontinent episodes: % (SD) <i>Intervention 1 68.6%(32.4)</i> <i>Control: 52.5%(42.7) p=0.02</i></p> <p>Pt complete satisfaction with progress: <i>Intervention 1: 31(66%) Control:</i></p>

	criteria: continual leakage, post-void residual volume >150 ml, severe uterine prolapse, decompensated congestive heart failure, haemoglobin A >= 9, impaired mental status. UTI, faecal impaction, severe atrophic vaginitis, uncontrolled diabetes.		not considered in this review. Control: PFMT written instructions: Received self-help booklet detailing isolation of PFM and progression of PFMT programme.	measured.	receive same contact.	Questionnaire, Hopkins Global Checklist and Short Form 36 Heath Survey)	20(50%) p=0.01 QoL: <i>Not reported for individual groups only for the whole sample.</i> IIQ Scores changed from mean 93.1 to 57.6 p<0.001 (Other questionnaires yielded significant changes for all groups but individual groups mean scores are not given)
Aksac et al., 2003	N=50 Urodynamically proven SUI. No exclusion criteria stated.	3 groups 20/20/10	Intervention: sEMG 3 times a week for 2 months Treatment 2: initial palpation and HEP instruction Control: a no treatment control group Groups did not receive the same contact time.	Not reported	8 weeks Assessed 'prior to and 8 weeks after the treatment'	1 hour Pad test cure (weight gain of 1g or less), pad test improvement (50% or greater reduction in pad weight). Vaginal squeeze pressure. Digital palpation score. Incontinence frequency (four	Statistically tests used, but specific tests used for each outcome not stated. %, Data and p-values reported but no confidence intervals given. 1 hour Pad test %cure/ %improvement: <i>Intervention: 80/20, Treatment2: 75/25</i> Vaginal squeeze

						<p>point ordinal scale): 1=once a day, 2=more than once a week, 3=less than once a week, 4= once a month.</p> <p>Social Activity Index (VAS)</p>	<p>pressure: median (SD) cm water <i>Intervention:</i> pre 19.1(4.8) post: 50.0(11.5) p<0.001 <i>Treatment2:</i>pre: 20.3(6.2) post 37.5(8.7) p<0.001</p> <p>Digital palpation score: 1-5 median (SD) <i>Intervention:</i> pre 3.3(0.4), post 4.9(0.2) p<0.001 <i>Treatment2:</i> pre 3.5(0.5), post 4.8(0.4) p<0.001</p> <p>Incontinence frequency: median(SD) <i>Intervention:</i> pre 2.3(0.6) post 3.6(0.4) p<0.001 <i>Treatment2:</i> pre 2.3(0.7) post 3.5(0.5) p<0.001 Intervention group had significantly higher perineometry readings than digital palpation group (p<0.001). Both treatment groups had significant</p>
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							improvement in all other parameters but there was no significant difference between the treatment groups.
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Appendix 3 Table 8 Likely sources of bias for included biofeedback studies

Study	Randomisation and Allocation Concealment	Adequate power/sample size	Blinding of participant, clinicians or assessors	Apart from the intervention, groups treated equally	Data Handling: missing data, drop outs and ITT	Outcome assessment and reporting
Shepherd, Montgomery & Anderson, 1983 UK	<p>Randomization procedure not fully reported: 'divided randomly'. Unclear if concealment of allocation was achieved.</p> <p>Assessment of baseline differences between groups measured but not compared or evaluated.</p>	No power calculation or determination of sample size	Not stated	Yes.	<p>3 dropped out (14%) but it appears that data for all participants (22, 11 in each group) is reported.</p> <p>ITT not stated</p>	<p>Validity and reliability of measures not stated. Extra outcomes (not stated in the methods) also appear in the results section: 'dry', 'improved', 'the same', but it is unclear how this data was gathered and if it is patient reported or clinician assessed. User acceptability of the perineometer was reported, but there is no evidence of how this is assessed and this was not an original stated aim of the study.</p> <p>The primary outcome data is presented as percentage cure for each group but not discussed and not statistically analysed. There is speculation that fewer intervention group 'drop-outs' meant that the intervention had created</p>

						'motivation in participants'.
Taylor & Henderson, 1986 USA	Method of random allocation not stated 'randomly assigned' Concealment of allocation unclear.	No power calculation or sample size estimate given	Not stated	Yes	1 drop out (1 out of 13= No useable data presented.	Subjective rating scale, urinary diary, compliance assessment, EMG measures all meet ICS guidelines.
Burns et al., 1993 USA	'Randomised in blocks of 12'. Concealment of allocation was likely. Initial measures made before randomization process. Baseline checks of each group showed no differences.	No power calculation or determination of sample size.	Not stated. Study described as 'single-blind' which appears to be the researcher who was blind to the 'treatment conditions' (deKruif, 1996)	Yes	10 dropped out (7%) A further 2 were excluded from analysis due to not completing diaries, so results were reported on only 123 out of 135 No mention of how missing values were handled. ITT not mentioned.	Reliability or validity of outcomes or measuring equipment not stated, but all measures were performed to a described protocol using the same equipment and comply with ICS recommendations. Additional sub-group analysis eg correlations are also presented, ie urethral length
Berghmans' et al., 1996 Netherlands	Randomised by 'sealed envelopes'. 'Observer was blinded to allocation', so low risk of bias.	No power calculation or determination of sample size	Effect measurement and data analysis was blinded.	Yes	No drop outs reported. Analysis was 'according to the ITT principle'.	Pad test stated as a reliable and valid test. Measures comply with ICS Speculation that initial improvement in urine loss

	Baseline differences were assessed and mean fluid intake difference was the only significant difference.				No mention of how missing values were dealt with.	assisted motivation in the intervention group, even though adherence or motivation to perform PFME is not assessed.
Glavind, Nohr & Walter, 1996 Denmark	Randomized by 'sealed envelopes'. Unclear if concealment of allocation was achieved. Groups were assessed for equality at the start. Greater severity of leakage was found in Control group at the start of the study.	No power calculation or determination of sample size	Not stated	No	6 dropped out (15%). This data is not analysed. No mention of ITT or how missing data is handled.	'New' standardized pad test used. Validity and reliability not stated. Questionnaire validity not stated. Measures comply with ICS All outcomes are reported and findings match the results.
Sherman, Davis & Wong, 1997 USA	Method of randomization not specified: 'subjects were stratified according to diagnosis and were then randomised'. Unclear if concealment of allocation was achieved.	No power calculation to determine sample size.	Not stated	Yes	7 dropped out (15%). These were excluded from the analysis, therefore analysis not ITT. Data for 39 was analysed (23 intervention group and 16 control group) (it is stated that 'all	Outcomes not stated at the outset but results were presented as 18 items, with ordinal categories such as 0=never 1= sometimes, 2=always. Some outcomes were self-reported ie degree of urgency, severity of the problem. Some rated by the clinician, such as size

	?how many were randomised (unclear in the text) Baseline similarity of groups was assessed, but not reported.				questionnaires were returned and filled out to a useable extent') No mention of how missing values were dealt with.	of 'paravaginal defect' and some were results from urodynamics, such as urethral closure pressure or bladder capacity. All comply with ICS Although designed as a treatment comparison trial, the findings did not report conclusions for this.
Wong et al., 1997 Conference presentation. Abstract only Hong Kong	Method of randomization and number randomized not stated. Baseline differences assessed and groups found to be 'comparable'.	No power calculation or determination of sample size.	Not stated	Yes	Study was incomplete Data presented for 17 Not sure if drop outs occurred as not stated.	Self-completed Urinary diary, 1-hour pad test, incontinence impact questionnaire (IIQ) are valid and reliable measures and comply with ICS guidance.
Laycock et al., 2001a Multi centre international (UK, Ireland, Australia, NZ)	Randomisation using prepared random numbers tables in the ratio 2:2:1 No significant difference found at baseline in any variable, supporting the randomisation	Sample size of 120 estimated by power calculation	Not stated	Yes	101 recruited but only 68 finished (33% drop out). ITT not mentioned.	All outcome measures were performed in a standard way. Incontinence episodes by bladder diary, Subjective symptom severity rating scale (VAS), Perineometer readings and Kings Health Questionnaire

	process.					(validated). All conformed with ICS guidelines.
Pages et al., 2001 Germany	Randomised using a 'randomization table' Baseline difference between groups was assessed using the Kolmogorov-Smirnov test	No power calculation to determine sample size.	Not stated	No. Possible difference in supervision intensity as Intervention group seen individually for treatment and control group received treatment as a group.	11 (22%) were excluded or decided to withdraw after randomization. This data was not analysed, so not ITT, and the paper says 'all participants completed the study'. Missing data for digital contraction strength as 7 participants declined a further examination. Data for this outcome is given for only 33 not 40 participants.	Digital palpation and speculum test (?) performed by same assessor. Neither measure has reliability or validity stated. Urination diary, subjective reporting and biofeedback procedure was standardized but not stated if validated. All comply with ICS Clear reporting of the 'change' for each group (and significance of change for each group) but unclear when reporting comparison of change for the groups.
Morkved, Bø & Fjortoft, 2002 Norway	Randomised after stratification (by participant drawing an 'opaque sealed envelope' from a larger one). Randomisation 'centralized but not computerised'.	Yes, power calculation and sample size calculation made based on estimated treatment effect.	Blinded assessors used.	Yes	9 dropped out (8.7%) Data 'analysed as ITT' 'Missing last values were considered as equal to baseline values'	Outcome measures were all referenced. Vaginal balloon recording of muscle strength was stated as 'a reliable and valid method' and referenced. The leakage index and

	Envelopes were not prepared by the staff involved in the research, so satisfactory allocation concealment and low risk. Baseline measures were compared to see if there was group parity.					Social activity Index had been tested for reproducibility. Main outcomes reported clearly comparing the change difference for groups and significance. Outcomes comply with ICS guidance.
Goode et al., 2003 USA	Patients were randomised by means of a computer-generated randomisation schedule. Stratification for UI type, severity and race. Unclear if concealment of allocation was achieved.	Sample size determined by power calculation	Not stated	No	High attrition rate (18.2%) from the Intervention 1 group and (37.3%) from the control group. Analysis is by 'intention to treat' but last value carried forward is used.	All outcomes were validated and reliable and in line with ICS guidelines. Main outcomes were reported but the QoL was not reported by group. Percentages, Mean/median with SD/range given but no Confidence Intervals given.
Aksac et al., 2003 Turkey	Participants 'allocated at random' by 'sealed envelopes'. Women were requested to choose an envelope.	No sample size estimate or power calculation performed	Not stated	No	No drop outs reported, although ITT not specifically stated. No mention of how missing values are	Some outcomes standardised eg pad test and digital grading of muscle strength. Unsure if VAS is self-reported/completed or clinician assessed.

	<p>Unclear if concealment of allocation was achieved. Groups compared at baseline in terms of severity of SUI and no difference was found. Other group characteristics were compared for parity at baseline and found to be not significantly different.</p>				<p>handled.</p>	<p>No mention of validity and reliability of measures used.</p> <p>All outcomes were reported and categories comply with ICS guidance</p>
--	--	--	--	--	-----------------	---

Appendix 4 Table 9 Quality rating of included studies

Quality category	Shepherd, Montgomery & Anderson, 1983	Taylor & Henderson, 1987	Burns, et al., 1993	Berghmans et al., 1996	Glavind, Nohr & Walter, 1996	Sherman, Davis & Wong 1997	Wong et al., 1997	Laycock, et al., 2001a	Pages et al., 2001	Morkved, Bø & Fjortoft, 2002	Goode et al., 2003	Aksac, et al., 2003
Randomisation	0	0	1	2	1	0	0	1	1	2	2	1
Concealed allocation	0	0	1	1	0	0	0	0	0	1	0	0
Blinded outcome assessors	0	0	0	1	0	0	0	0	0	1	0	0
Assessment of group equality at baseline	1	0	1	1	1	1	1	1	1	1	1	1
Equality of groups at baseline	0	0	1	1	0	0	1	1	1	1	1	1
Groups treated equally	1	1	1	1	0	1	1	1	0	1	0	0
Robust Outcome Measures (OM)	1	1	2	1	1	0	2	2	2	2	2	2
OM fully reported	1	0	1	2	2	0	2	2	1	2	2	2
Analysis by ITT or Drop-outs less than 10%	0	1	1	1	0	0	0	0	0	1	1	1
Total score (12)	4	3	9	11	5	2	7	8	6	12	9	8

Does physiotherapy treatment for the management of urinary incontinence improve pelvic floor muscle exercise self-efficacy and exercise adherence?

Introduction

You are invited to take part in a research study. Before you take part it is important you understand why the research is being done and what it involves. Please take time to read this information and discuss it with others if you wish. If after reading this leaflet, you would like more information or if anything is unclear, please discuss this with me at your first appointment or contact me on the telephone number at the bottom of the page.

If you want to participate, you will be asked to sign a consent form to show you have agreed to take part, however you would still be free to withdraw at any time during the study and this would not affect the standard of care you receive.

1. What is the purpose of the research?

Sometimes we don't know which way of treating patients is best. To find out, we need to compare different treatments. None of the treatments in this study are new, and all of them are thought to be effective in the treatment of urinary incontinence.

We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly).

The project will study women experiencing urinary incontinence, who have been referred for physiotherapy by their doctor. This research is to see if using different treatments as part of physiotherapy helps you to perform your pelvic floor exercises more effectively.

You have a 1 in 2 or 50/50 chance of being allocated into either one of the 2 groups.

2. What will I have to do?

You will be required to attend clinic for two 1 hour sessions plus two 40 minute treatment sessions over a period of 3 months. You may also receive biofeedback therapy, asked to follow advice about how to manage your leakage and asked to perform exercises at home.

You may also be examined at each treatment session. This will be no different to attending for Physiotherapy in the normal way.

In addition, you will be asked to fill in a short questionnaire at your first appointment, a questionnaire at each attendance and 4 short questionnaires after the last treatment session. It is an essential study requirement that you attend each clinic appointment and complete the questionnaires. Your answers are very important and will be used in the research. At the end of the 3 months you may be contacted for a short interview (held at the clinic) about your experiences of taking part in the study.

3. What will the treatments involve?

Pelvic floor muscle exercises are commonly used in the treatment of urinary incontinence. They need to be practised daily at home.

Biofeedback is the term given to therapy that more easily allows you to 'visualise' your muscle contractions. It involves using an internal vaginal sensor to record pelvic floor muscle contractions, displaying your efforts on a computer screen. It is not a new treatment and is commonly used in clinics throughout the country. There are no known dangers or side-effects associated with using it.

You may also be given information about your bladder function and tips to improve your symptoms, including charts and diaries to help record your progress.

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by Tameside Research Ethics Committee. We will follow ethical and legal practice and all information about you will be handled in confidence.

Your name will not appear on any of the questionnaires or transcripts of interviews, instead these will be coded.

Your name will only be known to the researcher and will not be passed on to anyone else.

4. Why have I been chosen?

All women with urinary incontinence referred by their doctor to this clinic for physiotherapy from October 2007 to October 2008 will be assessed and if eligible invited to participate in this research.

5. Do I have to take part?

Participation is voluntary and it is up to you whether you choose to take part. We cannot promise the study will help you but the information we get from this research will help improve the future treatment and services for people with incontinence.

If you do decide to take part, remember you can still withdraw at any time during the research without affecting your future treatment.

6. What will happen to the results?

Results will be used in a report and may be presented at conferences or published in scientific journals. Your name will not be used and any comments made during interview will not be traceable to you. All questionnaires and interview notes will be kept securely in a locked filing cabinet. A summary of the research findings will be made available to participants on request.

All completed questionnaires and interview transcripts and data will be kept for 10 years following completion of the study.

7. What happens next?

If you wish to take part, please keep this information sheet and bring the enclosed consent form to your next physiotherapy appointment. At this appointment you can ask any further questions about the project. If you want to participate in this research, you will need to sign the consent form.

You will then be allocated to one of two groups.

It is important for you to know that group allocation is a random process and you cannot choose to go into a particular group.

However, after the research has been completed, if you feel you would like further treatment, this can be discussed and arranged.

If you do not wish to participate in this study, then your treatment will continue as if you had been referred to physiotherapy in the usual way.

If you have a concern about any aspect of this study, you should ask to speak to the researcher who will do their best to answer your questions (contact number Sue Hallam Tel: 0161 331 6313)

If you are still unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

Sue Hallam, Continence Specialist Physiotherapist and Researcher
0161 331 6313

Does physiotherapy treatment for the management of urinary incontinence improve pelvic floor muscle exercise self-efficacy and exercise adherence?

Name of Researcher: Sue Hallam, Continence Specialist Physiotherapist

- | | |
|--|--|
| <p>1. I confirm that I have read and understand the box information sheet dated.....version 1 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.</p> | <p>Initial</p> <p><input type="checkbox"/></p> |
| <p>2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason, and without my medical care or legal rights being affected.</p> | <p><input type="checkbox"/></p> |
| <p>3. I understand that relevant sections of my medical notes and data collected during this study may be looked at by the Researcher and Clinical Audit Department from Tameside General Hospital, where it is relevant to me taking part in this research. I give permission for these individuals to access my records.</p> | <p><input type="checkbox"/></p> |
| <p>4. I agree to take part in the above study.</p> | |

Name of patient	Date	Signature
Person taking consent	Date	Signature

On completion: one copy for researcher, one for patient and one for medical notes

PromoCom
Disabled Living
Redbank House
St Chads Street
Cheetham
Manchester
M8 8QA
www.disabledliving.co.uk

Tel: 0161 834 2001

Tameside Hospital 
NHS Foundation Trust

Pelvic Floor Muscle Exercises

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An Information Leaflet

Exercises to Strengthen the Pelvic Floor Muscles

What are pelvic floor muscles?

The pelvic floor is a sheet of muscle extending between your legs from the 'tail bone' near your back passage to the pubic bone (below your bladder at the front). It makes up the 'floor' of our pelvis and helps support the bladder, womb and bowel.

Openings to the bladder, vagina and bowels pass through these muscles. Normally, we are unaware of these muscles working. They relax when we want to go to the toilet, and contract to help stabilise our lower body and stop us leaking when we are physically active. They also help us to 'hang on' when we need the toilet.

Why exercise them?

The muscles can become weak as a result of childbirth, straining when constipated, chronic coughing, being overweight, persistent heavy lifting and menopausal changes.

Improvement in pelvic floor muscle strength helps prevent leakage of urine from the bladder, improves bowel control and helps prevent prolapse. Stronger pelvic floor muscles will also help if you suffer heaviness or discomfort in your vagina or have piles.

Improving your pelvic floor muscle control may also improve your own, and your partner's enjoyment of sex.

Exercising your pelvic floor muscles after vaginal surgery or childbirth reduces discomfort and swelling and helps healing.

It is recommended that all women practise these exercises daily and throughout life!

References

1. Laycock, J., Standley, A., Crothers, E., Naylor, D., Frank, M., Garside, S., Kiely, E., Knight, S., Pearson, A. (2001) *Clinical Guidelines for the Physiotherapy Management of Females aged 16-65 with Stress Urinary Incontinence*.
2. NICE (2006) Guidelines for the Management of Urinary Incontinence (CG40).

For advice about all aspects of incontinence, please contact:

The Continence Advisory Service Tel: 0161 366 4132
Union Street Clinic
Hyde

Other useful information is available from:

The Bladder and Bowel Foundation (B&BF) Tel: 01536 533255
SATRA Innovation Park
Rockingham Rd
Kettering, Northants NN16 9JH

info@bladderandbowelfoundation.org

When you feel the urge to empty your bladder try the following delaying techniques:

- Tighten your pelvic floor muscles
- Sit on something hard, e.g. a chair arm
- Distract your mind

Bowel Urgency: If you have to rush to the toilet to open your bowels, you can try using the exercises to help you 'hang on'. Practising this should help you regain bowel control.

Additional Tips

- Trying to get down to your correct weight reduces the strain on the pelvic floor muscles and can make a considerable improvement.
- Straining when you open your bowels stretches and weakens your pelvic floor muscles. Make sure you are eating a healthy balanced diet and have an adequate fluid intake. If you still have problems seek help from your GP.
- Lifting puts strain on your pelvic floor. Remember to tighten your pelvic floor before you lift and hold it tight until you have lowered the load.
- If you attend fitness training or go to the gym, remember to take care with activities that increase abdominal pressure, e.g. sit ups, or any activity with 'high impact' such as trampolining. These type of activities may put your pelvic floor at risk of becoming weaker. Use pelvic floor contractions to 'brace' prior to such exercises, and seek specialist instruction. Failing this, avoid them altogether.

How to do the exercises

Get yourself into a comfortable position (sitting, standing or lying down).

Start by breathing out; then draw up the front and back passages as strongly and intensively as you can. Now relax and let go. It may help to imagine that you are trying to stop yourself from passing wind and at the same time trying to stop your flow of urine. The feeling is like a 'squeeze and lift' sensation. This is a pelvic floor contraction.

Remember to try **not** to hold your breath, or squeeze your legs or tighten your buttocks. Start gently and stop if it hurts.

The feeling of doing the exercise can also be described as "lift doors closing and the lift going up to the top floor" **or** tightening up as if you are trying to stop a tampon from slipping out.

You can examine yourself to check if you are doing the exercises correctly.

- Use a mirror to see your vagina 'squeeze and lift'
- Next time you are in the bath, put your right thumb inside your vagina and feel **downwards and to the left**. Try a contraction and see if you can feel the muscles tense. Now try a contraction with your left thumb feeling the muscles on the right hand side.

Now try these...

1. Briskly contract your muscles as strongly as you can and see how many seconds you can **hold** the contraction for. Aim for a maximum of 10 seconds. Try to lift higher with each second counted. Release and rest for the same number of seconds. How many times can you repeat this 'contract, hold and release pattern? ...times.
2. Next see if you can contract your pelvic floor briskly and strongly and then immediately let go. Aim for a maximum of 10. How many times can you repeat these? ...times. These are called 'quick' contractions and help your muscles respond quickly, especially useful to prevent leakage of urine when you cough or sneeze!

Both these types of exercises are important in training and improving pelvic floor muscle function. Try to perform these exercises 3-5 times a day every day. No-one can tell you are doing them! You can exercise in any position, standing up, lying down or sitting in a chair. Try them all out and see which position suits you best.

If you can exercise more often, so much the better ... see if you can do them 5 times day or every 2 hours. Make sure you rest for at least 4 seconds between each contraction to prevent tiring of the muscles.

The exercises are not difficult, but they do need practising regularly and they are often forgotten if you lead a busy life!

Think of ways to remind yourself to do your exercises...every time you wash your hands, listen to a news bulletin, feed the baby, stop at a red traffic light, queue for the checkout at the supermarket, after passing urine.

Eventually:

You will notice your pelvic floor awareness improve. You will also find that you can hold each contraction for longer and repeat more times. By increasing the exercises in this way, your muscles will become stronger.

Try to aim for 10 contractions holding each one for 10 seconds followed by 10 quick contractions, at least three times a day.

As with any muscle training, it takes time to build up strength and improve your muscle function. Don't expect to notice an instant improvement; it may take **3-6 months** of regular exercises to see a difference in symptoms.

If, however, you have been doing these exercises and your symptoms persist, **do** contact your doctor, continence advisor or physiotherapist, as other treatment options are available.

Other Advice

Liquid intake: You should aim for approximately 6-8 drinks a day (1-2 litres or 3-4 pints). Avoid caffeine e.g. Tea, Coffee or Cola, if you can. Restricting your fluid intake will not help and could make matters worse.

Sudden Movements: Try to tighten and hold the pelvic floor muscles prior to coughing, sneezing and lifting. This will improve your control and reduce leakage of urine or faeces.

Emptying your bladder: Although it is important to completely empty the bladder without straining each time you go to the toilet, try to avoid doing this too frequently, as this can reduce capacity. If you need to pass water frequently, try to train your bladder to wait longer.

Pelvic Floor Exercises

Try:

..... contractions

Holding each one for seconds

Rest for seconds in between each one

Followed by:

..... fast contractions

Do both types of exercises 3 times a day.

In addition:

3. Try a ‘first floor’ (less intensive) contraction and see if you can hold it for **twice as long** as the stronger ones. Do these while performing activities at home or at work e.g. As you climb the stairs, while shopping, when walking around.

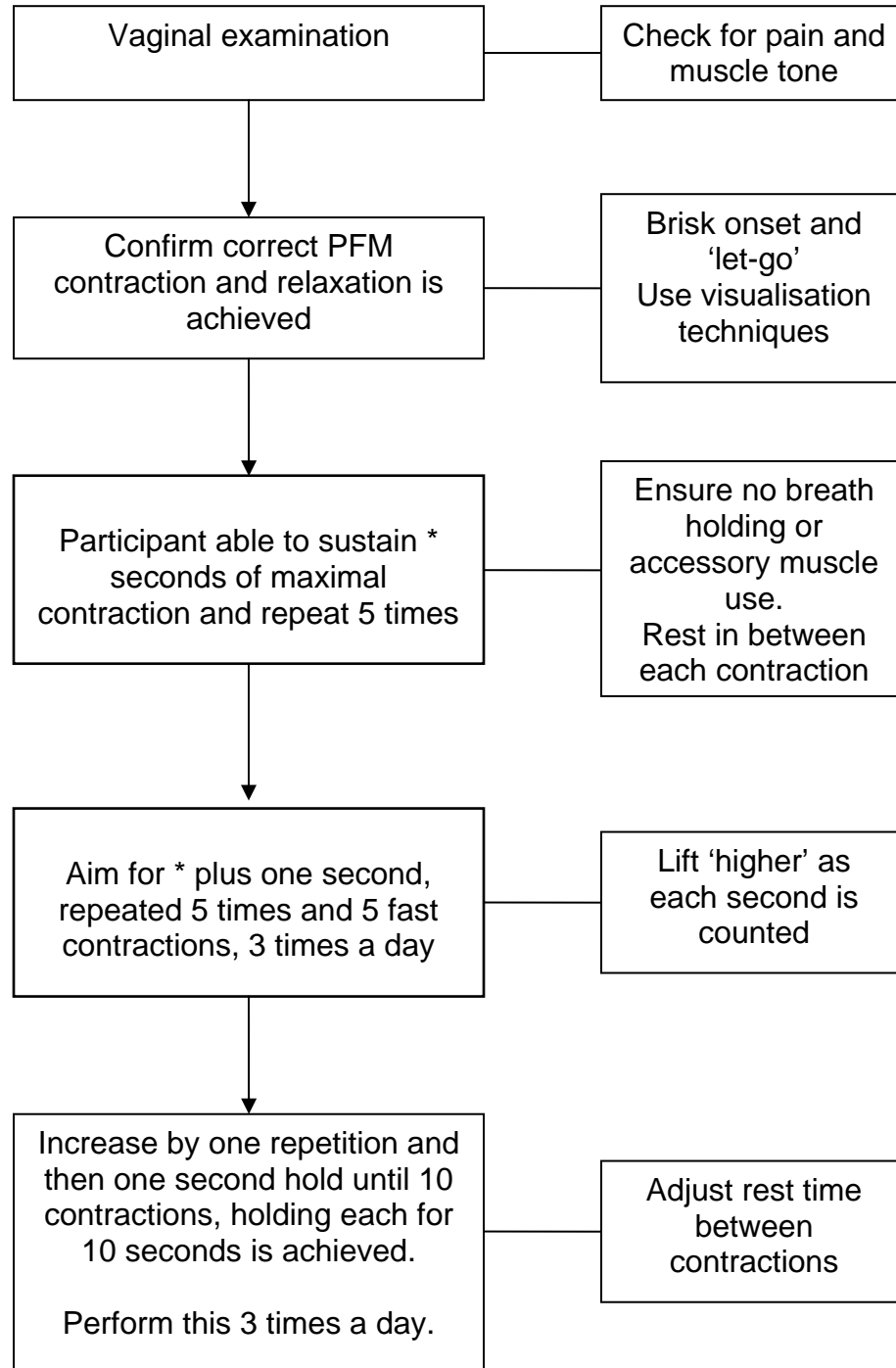
4. Remember to contract your pelvic floor muscles **strongly** before coughs and sneezes, and also before lifting, and other strenuous activities.

5. Contract your pelvic floor muscles to control any bladder urgency.

Diary

		1	2	3			1	2	3
		Tick	Tick	Tick			Tick	Tick	Tick
Week 1	Mon				Week 4	Mon			
	Tues					Tues			
	Weds					Weds			
	Thurs					Thurs			
	Fri					Fri			
	Sat					Sat			
	Sun					Sun			
Week 2	Mon				Week 5	Mon			
	Tues					Tues			
	Weds					Weds			
	Thurs					Thurs			
	Fri					Fri			
	Sat					Sat			
	Sun					Sun			
Week 3	Mon				Week 6	Mon			
	Tues					Tues			
	Weds					Weds			
	Thurs					Thurs			
	Fri					Fri			
	Sat					Sat			
	Sun					Sun			

Appendix 9 PFME treatment and progression algorithm



Pt Code : Week no:

Appendix 10 The Chen PFMSE scale

We would like to know how confident you are in performing pelvic floor muscle exercises. **Please answer as accurately as you can.**

For each of the following questions, please put an “X” in the response box which corresponds to your level of confidence in performing pelvic floor muscle exercises **at this time**. Response range is from (1) not very, to (5) extremely confident

- 1 = not very confident
- 2 = a little confident
- 3 = reasonably confident
- 4 = very confident
- 5 = extremely confident

- | | | | | | |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 1. I believe I can contract my pelvic floor muscles as strongly as I can | 1 | 2 | 3 | 4 | 5 |
| | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. I believe I can contract my pelvic floor muscles for a duration of 5 seconds | 1 | 2 | 3 | 4 | 5 |
| | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. I believe I can contract my pelvic floor muscles for a duration of 10 seconds | 1 | 2 | 3 | 4 | 5 |
| | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. I believe I can feel the contraction of the muscles while I am doing the exercises | 1 | 2 | 3 | 4 | 5 |
| | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. I believe I can do the pelvic floor muscle exercises daily | 1 | 2 | 3 | 4 | 5 |
| | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

1=not very confident, 5=extremely confident

6. I believe I can do pelvic floor muscle exercises regularly for 3 months
- | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 1 | 2 | 3 | 4 | 5 |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
7. I believe I can remind myself to do pelvic floor muscle exercises every day
- | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 1 | 2 | 3 | 4 | 5 |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
8. I believe I can do pelvic floor muscle exercises even when there is a lack of time
- | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 1 | 2 | 3 | 4 | 5 |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
9. I believe I can do pelvic floor muscle exercises even when I lack energy (too tired)
- | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 1 | 2 | 3 | 4 | 5 |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
10. I believe I can do pelvic floor muscle exercises while doing housework
- | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 1 | 2 | 3 | 4 | 5 |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
11. I believe I can do pelvic floor muscle exercises while watching TV
- | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 1 | 2 | 3 | 4 | 5 |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
12. I believe I can do pelvic floor muscle exercises any time I think of it, eg when waiting at the supermarket checkout, at red traffic lights, waiting for the kettle to boil, washing my hands
- | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 1 | 2 | 3 | 4 | 5 |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
13. I believe I can contract my pelvic floor muscles before physical exertion eg coughing, laughing, lifting, standing up
- | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 1 | 2 | 3 | 4 | 5 |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Pt code: week:

1= not very confident, 5= extremely confident

14.I believe that pelvic floor muscle exercise
can help reduce urinary leakage

1	2	3	4	5
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

15.I believe that pelvic floor muscle exercise
can help avoid (or delay) the need for
continence surgery

1	2	3	4	5
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

16.I believe I can contract my pelvic floor muscles
to increase pleasure during sexual intercourse

1	2	3	4	5
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

17.I believe I can do pelvic floor muscle exercises
even without additional guidance or intervention
from a therapist

1	2	3	4	5
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Appendix 11

Change in wording to item 17 of the Chen PFME SE questionnaire

Original wording:

I believe I can do pelvic floor muscle exercise even without the assistance of biofeedback and/or electrical stimulation

Changed to

I believe I can do pelvic floor muscle exercises even without additional guidance or intervention from a therapist

Appendix 12

Adherence Questionnaire

1. Did you do the pelvic floor muscle exercises yesterday?
(Please circle a letter)
 - A.** No, because I don't remember exactly how to do them
 - B.** No, because I forgot to do them
 - C.** No, because I didn't feel like doing them
 - D.** No, because my urinary leakage wasn't bothering me enough to do them
 - E.** No, because I was busy doing other things
 - F.** No, because I was too tired to exercise
 - G.** No, because the exercises give me an uncomfortable feeling
 - H.** Yes

2. How often did you do the exercises yesterday?
 - A.** I did not exercise yesterday
 - B.** I exercised a little,times
 - C.** I exercised now and then,times
 - D.** I exercised regularly,times

3. Did you do the exercises in the last 7 days?

- A. No, because I don't remember exactly how to do them
- B. No, because I forgot to do them
- C. No, because I didn't feel like doing them
- D. No, because my leakage wasn't bothering me enough to do them
- E. No, because I was too busy doing other things
- F. No, because I was too tired
- G. No, because the exercises give me an uncomfortable feeling
- H. Yes

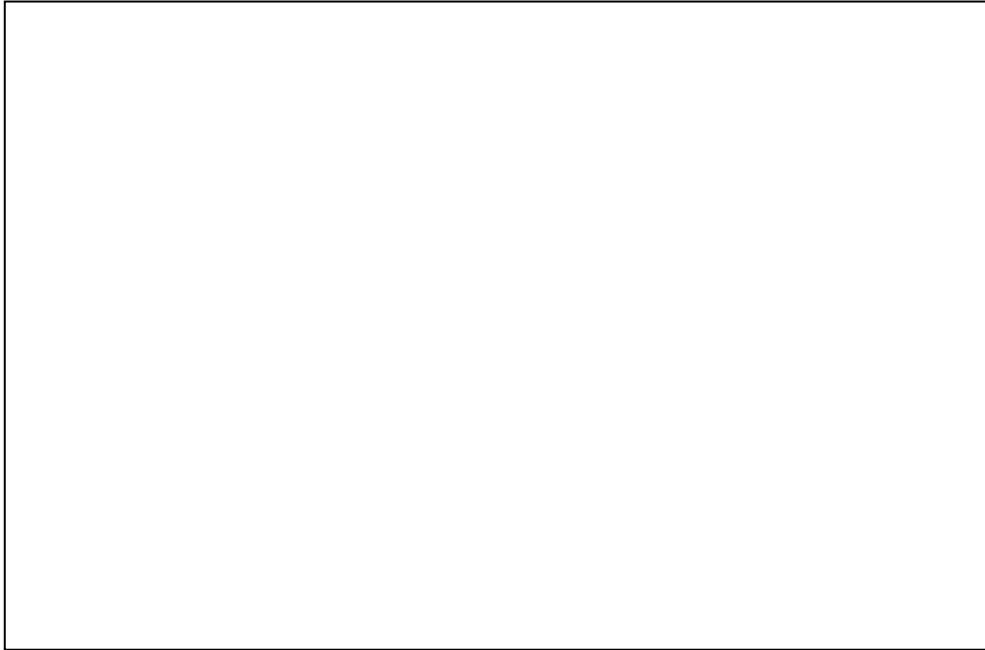
4. In the last 7 days, on how many days did you do the exercises?
Please circle.

0 days 1day 2 days 3 days 4 days 5 days 6 days 7 days

5. Give yourself a 'score out of ten' for how well you have exercised in this last week

1 2 3 4 5 6 7 8 9 10

6. Can you write down a **description of the exercises** that have been suggested by the physiotherapist?



Version 1, 27.08.07

Name _____

Date _____

Doctors are aware that emotions play an important part in most illnesses. If your doctor knows about these feelings he will be able to help you more.

This questionnaire is designed to help your doctor to know how you feel. Read each item and place a firm tick in the box opposite the reply which comes closest to how you have been feeling in the past week.

Do not take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought out process.

Tick one box only in each section

1 I feel tense or 'wound up' :

- Most of the time
- A lot of the time
- Time to time. Occasionally
- Not at all

2 I still enjoy the things I used to enjoy :

- Definitely as much
- Not quite so much
- Only a little
- Hardly at all

3 I get a sort of frightened feeling as if something awful is about to happen :

- Very definitely and quite badly
- Yes. But not too badly
- A little. But it does not worry me
- not at all

4 I can laugh and see the funny side of things :

- As much as I always could
- Not quite so much now
- Definitely not so much now
- No at all

5 Worrying thoughts go through my mind :

- A great deal of the time
- A lot of the time
- From time to time. But not too often
- Only occasionally

6 I feel cheerful :

- Most of the time
- Sometimes
- Not often
- Not at all

7 I can sit at ease and feel relaxed :

- definitely
- Usually
- Not often
- Not at all

8 I feel as if I am slowed down :

- Nearly all the time
- Very often
- Sometimes
- Not at all

9 I have lost interest in my appearance :

- Definitely
- I do not take so much care as I should
- I may not take quite as much care
- I take just as much care as ever

10 I get a sort of frightened feeling like butterflies ' in the stomach :

- Very often
- Quite often
- Occasionally
- not at all

11 I feel restless as if I have to be on the move :

- Very much indeed
- Quite a lot
- Not very much
- not at all

12 I look forward with enjoyment to things :

- As much as I ever did
- Rather less than I used to
- Definitely less than I used to
- hardly at all

13 I get sudden feelings of panic :

- Very often indeed
- Quite often
- Not very often
- Not at all

14 I can enjoy a good book, radio or TV programme :

- Often
- Sometimes
- Not often
- Very seldom

Appendix 14

ICIQ-SF
CONFIDENTIAL

Day Month Year
Today's date

Many people leak urine some of the time. We are trying to find out how many people leak urine, and how much this bothers them. We would be grateful if you could answer the following questions, thinking how you have been, on average, over the PAST FOUR WEEKS.

1. Please write in your date of birth:
2. Are you (tick one): Female Male

3. How often do you leak urine? (Tick one box)

never 0
about once a week or less often 1
two or three times a week 2
about once a day 3
several times a day 4
all the time 5

4. We would like to know how much urine you think leaks.
How much urine do you usually leak (whether you wear protection or not)?
(Tick one box).

None 0
a small amount 2
a moderate amount 4
a large amount 6

5. Overall, how much does leaking urine interfere with your everyday life?
(Please ring a number between 0 (not at all) and 10 (a great deal))

0 1 2 3 4 5 6 7 8 9 10
not at all a great deal

ICI-Q score: sum scores 3+4+5

6. When does the urine leak? (please tick all that apply to you)

never- urine does not leak
leaks before you can get to the toilet
leaks when you cough or sneeze
leaks when you are asleep
leaks when you are physically active/exercising
leaks when you have finished urinating and are dressed
leaks for no obvious reason
leaks all the time

Thank-you for answering these questions

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Appendix 16 Study flowchart

