

## Managing Early Stress Incontinence Through Women's Health Clinics

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## **1. Executive Summary**

The project evaluates the effectiveness of offering a brief non-invasive intervention for prevention and early intervention with urinary incontinence. It targets mild urinary stress incontinence among middle-aged women, and recruits participants through FPA Health clinics and local general practices. Mild to moderate stress incontinence is reported by 30-40% of middle-aged women, but most do not seek treatment. The evidence suggests that non-surgical intervention, consisting of pelvic floor muscle training, bladder training, and education, may prevent severe incontinence in older age. However, there is little evidence on the acceptability or effectiveness of such a programme as a preventive or very early intervention strategy.

Participants completed a three-day bladder diary and a survey, before undergoing a clinical examination conducted by a qualified continence nurse. On the basis of this examination, they were given tailored instruction on bladder hygiene and taught how to perform pelvic floor muscle exercises effectively and to use "the Knack", a strategy for coping with transient increases in pressure on the pelvic floor muscles. A pelvic floor exercise programme, tailored to the individual woman's needs, was provided together with a booklet covering bladder training, pelvic floor exercises, and other relevant information. Urinary leakage, pelvic muscle strength, general physical and emotional health, strategies for coping with leakage, restrictions on physical and social activity, and satisfaction were assessed at pre-, post- and follow-up. A waitlist control design was used to assess the impact of screening on women's symptoms and help-seeking.

A total of 1200 brochures were distributed in a targeted fashion through FPA Health, general practices, and local fitness centres to women who expressed an interest in the intervention. A total of 97 women enrolled in the programme and 76 attended their first appointment. Sixty one completed their Week 9 follow-up and 54 their Week 16 follow-up, although not all completed all surveys and bladder diaries.

Analysis of data has shown significant improvements in self-reports of incontinence severity, as well as clinical and perineometer measures of pelvic floor muscle strength, and ability to perform pelvic floor muscle contractions. All but one of the women evaluated the programme positively, and all would recommend it to a friend. Improvements were well maintained at Week 16, and the programme was successful in producing measurable and maintained improvements in urinary control and pelvic floor strength.

The project demonstrates that women who attend the early intervention programme show measurable increases in pelvic floor strength and decreases in urinary leakage and reports of symptoms. Women who have participated have been positive about the experience. However, it also demonstrates that only a small minority of women with mild urinary leakage, or who are at risk, have the interest and motivation to participate. Our experience suggests that prevention and early intervention have the potential to be valuable tools in dealing with the problem of urinary incontinence, but that attention needs to be paid to raising middle-aged women's awareness of the problem and willingness to engage in preventive activities. Public education campaigns promoting early intervention may encourage more women to participate in relatively non-invasive and effective strategies, and these may prevent major problems in the longer term.

## 2. Recommendations

This demonstration project has shown that early intervention is effective in increasing pelvic muscle strength, reducing urinary leakage, and improving urinary hygiene. The demonstration project was positively evaluated by participants. We recommend that:

- 1. Early intervention programmes through women's health clinics are effective and should be promoted throughout Australia.
- 2. Further trials should focus on developing programmes targeting harder-to-reach groups, including indigenous women, women from non-English-speaking backgrounds, and those with social, educational or health-related disadvantages.
- 3. Public education campaigns should focus on educating the entire community that urinary leakage is a common problem among women of all ages, but that it is treatable, and that early intervention is effective in preventing major problems.
- 4. Public education campaigns should also seek to de-stigmatize the problem and encourage women to seek help.

## 3. Introduction and Rationale

#### 3.1. Urinary Incontinence

Although urinary incontinence does not have the high profile of other health problems, it is widespread among women of all ages and can have a major impact on women's quality of life and their work, social and sexual activity. It also has a major impact on health care costs; Doran, Chiarelli and Cockburn (2001) estimate that almost two million community-dwelling women in Australia experience some degree of urinary incontinence, and that the total annual cost is over \$700 million, roughly equally divided between treatment costs (diagnosis, investigations, procedures, medications) and personal costs (pads, protection, laundry).

Although its incidence increases with age and it is more common during and after pregnancy, urinary incontinence is not exclusively a condition of older women and those who have recently given birth. It is widespread, and does occur in younger women, and among those who have not had children (Burgio et al. 1991). The high rate among women – seven to eight times that among men – is largely explained by differing anatomical placement of the urinary meatus and the fact that women's pelvic floor muscles are often weakened or damaged by childbirth. Pelvic floor muscles are also affected by common problems which increase intra-abdominal pressure, including constipation, chronic coughing and sneezing, and obesity. Urogynaecological surgery and recurring urinary tract infections also exacerbate the problem.

Four types of urinary incontinence are generally defined: stress incontinence, urge incontinence, mixed incontinence and "other". Stress incontinence is the most frequent type among young to middle-aged women. It typically occurs when the intra-abdominal pressure is greater than the strength of the pelvic floor can withstand. Intra-abdominal pressure may be increased chronically by conditions that place additional load on the pelvic floor, including overweight, pregnancy and chronic constipation; it may also be raised acutely through conditions associated with coughing and sneezing, and activities such as jumping or running. Pelvic floor muscles may also be weakened as a result of stress or damage during childbirth or urogynaecological surgery (Miller, Brown, Russell & Chiarelli, in press).

The majority of women who experience urinary incontinence do not seek help, even though it may interfere significantly with work, social and sexual activity (Yarnell, Voyle & Richardson 1981). This is despite the fact that stress urinary incontinence is frequently associated with muscle weakness or dysfunction, which can be alleviated through pelvic floor muscle exercises and education in the correct use of the muscles. Many women think that some minor urinary leakage is normal, particularly after childbirth or as a normal part of ageing (Chiarelli & Cockburn 1999). Other women hope that the problem will simply go away by itself, are too embarrassed to discuss it with their doctor, or do not seek help for fear that the treatment could involve invasive surgery which might affect their sexuality or other aspects of their quality of life (Norton, MacDonald, Sedgwick & Stanton 1988). Studies of incontinence among older women have found that while many women develop adequate coping strategies and lead what they see as "normal lives", they frequently consider it an inevitable, irreversible and normal part of ageing and do not see treatment as practical or likely to be effective (Mitteness & Barker 1995).

In the long term, however, mild leakage of urine under physical stress (e.g. sneezing, lifting) can progress to total urinary incontinence, which has major effects on physical and emotional

health and on ability to live independently. Although many older women will have families who are able to cope with incontinence for a period of time, the financial burden of providing continence aids, the bother of applying and changing these aids, cleaning up after spills, broken sleep, and extra laundry eventually take their toll. This is particularly the case if the individual also suffers from dementia or impaired mobility. As a consequence, urinary incontinence is the most common reason given for admission to a nursing home (Harris, Brindley & Stevens 1996).

#### 3.2. Incontinence among Australian Women

The Australian Longitudinal Study on Women's Health, known as Women's Health Australia (Brown et al. 1998; Lee 2001), has provided an opportunity to obtain population data on incontinence among Australian women in three age groups, to assess its severity, and to examine its relationships with other factors. Women's Health Australia is a longitudinal cohort study which aims to examine the relationships between biological, psychological, social and lifestyle factors and women's physical and emotional health. The project involves three age cohorts of women (young 18-23 in 1996; mid-age 45-50 in 1996; older 7-75 in 1996) who were selected randomly from the Medicare database and are followed prospectively for twenty years.

Each age group completed Survey 1 in 1996. This included a list of common symptoms, including leaking urine. Women were asked to indicate whether, in the previous year, they had experienced each symptom never, rarely, sometimes or often. For those items they had experienced, women also indicated whether they had sought help for that symptom and, if so, whether they were satisfied with the help they had received.

Analysis of these data (Chiarelli & Brown, 1999; Chiarelli, Brown & McElduff, 1999) suggests that urinary leakage is a far greater problem among young and mid-age Australian women than is generally recognized. The overall prevalence of reporting leaking urine "ever" (i.e. rarely, sometimes or often) was 12.8% in the young cohort (aged 18-23), 36.1% in the mid-age cohort, and 35.0% in the older cohort. In each age group, the majority of women reporting leaking urine had not sought help. About half of those young women who had sought help were happy with the help they had received, compared with about two-thirds of the mid-age and older women.

Number of children was a strong predictor of prevalence of leaking urine: in the young and mid-age cohorts, a significant difference was found between those who had had any children and those who had had none, while among the older cohort, the difference was between those who had had two or more children, and those who had had one or none. The prevalence of leaking urine was significantly increased for women in all age groups who reported "urine that burned or stung" in the previous year (suggestive of urinary tract infections). It was also increased for those who experienced upper respiratory tract symptoms, probably because coughing and sneezing cause acute increases in intra-abdominal pressure which can place an excessive load on weakened pelvic floor muscles. It was also more common among those who reported other conditions which tend to increase the load on the pelvic floor, such as constipation, other bowel problems, and obesity (body mass index [BMI] greater than 30). In the mid-age and older groups, prevalence was also higher for women who had ever undergone gynaecological surgery, had been diagnosed with diabetes, or had a stroke.

Among the mid-age and older women, the use of hormone replacement therapy did not appear to be associated with higher or lower prevalence of urinary leakage. Leakage of urine was associated with reduced quality of life for women in all three age groups: women who reported "ever" leaking urine scored significantly lower than those reporting never having this problem on both the physical and the mental component scales of the SF-36, a widely used and well-validated measure of physical- and mental-related quality of life (Ware & Sherbourne, 1992).

This analysis was the first to provide such extensive information on urinary leakage among Australian women. A somewhat surprising finding was that urinary leakage was as common among mid-age as among older women, and that it was a problem among some younger women, particularly those with risk factors such as having given birth, being obese, and experiencing frequent chest and lung problems. These data suggested that there might be value in exploring the characteristics of women with mild levels of urinary leakage, and in particular in examining factors associated with help-seeking and with reluctance to seek help.

A targeted substudy of a random sample of the women who had reported leaking urine was therefore conducted (Miller, Brown, Russell & Chiarelli, in press). This examined in more detail the type of incontinence experienced, as well as collecting more information on gynaecological and obstetric history, and on treatment-seeking and reasons for not seeking treatment given by women in different age groups. The substudy showed that mid-age women tended to have symptoms that were at least as severe as those reported by the older age group, and likely to interfere significantly with social and role-related activities (Miller, Brown, Smith & Chiarelli, 2003). Over a quarter of the mid-age and older women reported avoiding sporting activities and choosing clothes that would avoiding showing "leaks", while smaller but significant numbers reported avoiding sexual activity, avoiding using public transport, refusing invitations to go out, and seeing less of their friends because of their incontinence. Habits that represent poor bladder hygiene, such as going to the toilet "just in case" and reducing fluid intake, were reported by over half the respondents.

Only 58% of the mid-age respondents had sought professional help or treatment. Most who had not believed that they could manage their symptoms without help, but a significant minority reported that they were too embarrassed to seek help (20%) or were afraid that they might be recommended surgery (21%). Of those who consulted a GP or medical specialist, approximately 20% were dissatisfied with the treatment or advice they had received, while of those who saw nurses (women's health or continence nurses), less than 5% were dissatisfied. In view of these data, there appears to be an unmet need for education, early detection, prevention and early intervention, and it appears that nurses may be the appropriate health professionals to provide this service.

#### 3.3. Interventions

There is considerable research on non-surgical interventions for stress urinary incontinence, and several systematic reviews of the literature have concluded that a combination of pelvic floor muscle exercises and bladder training leads to sustained improvements among women with mild to moderate levels of stress urinary incontinence (eg Berghmans et al. 1998; Bo 2000). Most of the research has been with women experiencing postnatal stress urinary incontinence (e.g. Morkved & Bo 2000, Glazener et al. 2001), although there is also evidence of the effectiveness of similar interventions among women aged over sixty (McDowell et al.

1999). The effects of non-invasive treatment appear to be reasonably persistent. Morkved and Bo (2000) found improvements to persist twelve months postnatally. Cammu et al. (2000) found that women who had undergone pelvic floor muscle training for stress urinary incontinence ten years earlier had maintained their improvements, particularly those who had continued to carry out pelvic floor muscle exercises.

While many studies have looked at the efficacy of treatment protocols which aim to improve clinical levels of urinary incontinence, there is little research examining the use of similar treatments with the aim of primary or secondary prevention of incontinence. Chiarelli and Cockburn (2002) report a successful trial with high-risk women after giving birth and showed reduced levels of incontinence, but there is little evidence on the use of preventive programs among other groups of women. The promotion of strategies to promote continence, or deal with mild urinary leakage, before clinical levels of incontinence are experienced, has the potential to prevent or delay the occurrence of the condition. A multidisciplinary approach to education, prevention and early intervention with women in middle age might thus result in fewer older women suffering the long-term effects of untreated incontinence.

Although many families can cope with a frail or disabled elderly relative at home, urinary incontinence is frequently the "last straw" which leads to admission to nursing home care (Harris et al. 1996). With more attention to the promotion of continence, and early detection and treatment of continence problems, it may be possible to reduce the morbidity associated with incontinence, the number of admissions to nursing homes, and the financial and social costs of caring for an ageing population.

#### 3.4. Rationale for the Women's Waterworks Demonstration Project

This project aims to evaluate the effectiveness of a brief non-invasive intervention designed to prevent stress urinary incontinence, or to provide early intervention to women with minimal or mild urinary leakage, targeting women in the 40 to 60 age group. The intervention is based on that developed by Chiarelli and Cockburn (1999, 2002) for new mothers, adapted for a middle-aged population. Practical aspects of using FPA Health clinics to recruit women and to provide a setting for the intervention are also explored.

The project evaluates a strategy that may help to prevent the development of stress urinary continence problems by intervening with middle-aged women who as yet have no symptoms, or whose symptoms are mild to moderate and have not yet led them to seek help for the problem. There is evidence to suggest that stress incontinence may begin or worsen in middle age, but that women often delay seeking treatment until their problems interfere markedly with their quality of life. Treatment at a relatively early age, and a relatively early stage in the progression of urinary stress incontinence, should play a role in reducing or delaying problems as women age. The majority of women with stress incontinence. Providing a programme administered by continence nurses challenges current practice by taking a proactive approach and focusing on middle-aged women with less well-established problems.

Thus, the aim of the project is to assess the effectiveness of a combination of physical and educational strategies in preventing and alleviating mild urinary incontinence among middleaged women. Women with severe incontinence or complicating medical conditions are excluded, in order to focus on prevention and early intervention.

## 4. Research Methods

#### 4.1. Staff

Ms Claire Johnson, a qualified and experienced Continence Nurse and Research Assistant, has been working between 2 and 3 days per week on this project. Her duties have included the design and production of project materials; preparation of data entry methods, forms and files; recruitment of participants; and conduct of clinical assessments and interventions. Ms Anne Hutchings, a qualified and experienced nurse who has worked for FPA Health in Newcastle for several years, has carried out a proportion of the clinical work.

#### 4.2. Intervention Materials

All materials were prepared and finalized by Claire Johnson, under guidance from Christina Lee and Pauline Chiarelli. All materials and procedures were approved by the University of Newcastle Human Research Ethics Committee and the FPA Research Ethics Committee. Copies of all these materials appear in Appendix A.

#### 4.2.1. Recruitment Materials

The main method of recruitment was the distribution of brochures through medical and nursing staff in the Newcastle FPA Health clinic, local medical practices, and local fitness centres (see Section 3.3 below). A three-colour brochure was developed by Claire Johnson, with the assistance of Mrs Joy Goldsworthy (Graduate Research Assistant, Research Centre for Gender and Health). A copy of this brochure appears as Appendix A.1.

#### 4.2.2. Consent and Information Forms

Informed consent is an essential aspect of ethical and effective research or treatment of any kind. Two versions of information and consent material were prepared, one for participants randomized to receive treatment immediately (see Appendix A.2), and a second with some modifications, for participants who were randomized to the wait-list control group (see Appendix A.3).

#### 3.2.3. Surveys and Bladder Diary

Surveys were completed by participants prior to commencement of treatment, prior to the Week 9 appointment and prior to the Week 16 appointment. These included items on incontinence-related symptoms, use of incontinence products, history of medical and other treatment for incontinence, general well-being (SF-36), impact of urinary symptoms on daily life, previous treatment of urinary incontinence, where participants heard about the program, and (at 9 and 16 weeks) treatment satisfaction.

Participants were also requested to maintain a bladder diary, recording fluid intake and urinary output for a three-day period prior to each assessment. The diary included details of urinary output (time and amount of each urination, any symptoms encountered and leakage that may have occurred).

Copies of surveys and bladder diaries appear in Appendix A.4.

#### 4.2.4. Protocol

A detailed intervention protocol was developed by Claire Johnson, so that all procedures were standardized. This document details procedures for recruitment and initial screening of proposed participants; obtaining fully informed consent; clinical assessment and intervention; research-related data collection and management; management of participant records, including their confidential storage; statistical analysis; and dissemination of findings to participants on completion of the project. This work was based on material previously developed by Dr Pauline Chiarelli for an intervention targeting women in the immediate postpartum period (Chiarelli & Cockburn 1999, 2002). The sections that involve participant contact were extensively modified in order to make the materials more appropriate for middle-aged women (see Appendix A.5).

#### 4.2.5. Clinical Notes

A standard form was designed for completion by the Continence Nurse at each clinical assessment. This provided a visual reminder of the tests and procedures to be conducted, as well as providing space for recording of physical data, recommendations to the participant, and any relevant clinical notes (see Appendix A.6).

#### 4.2.6. Women's Waterworks Booklet

An educational booklet was prepared by Claire Johnson to provide written reinforcement and extension of the verbal information provided during clinical visits. The booklet provided accurate and accessible information about the causes of urinary incontinence; who is likely to be affected; how the urinary system and the pelvic floor muscles work; what makes urinary incontinence worse; how to carry out pelvic floor exercises; and other relevant information. The booklet also included a section in which the participant or Continence Nurse could record an individually recommended exercise program. This booklet was based on an existing one, "One In Three Women Who Ever Had A Baby Wet Themselves," developed by Pauline Chiarelli for postnatal women, on the basis of clinical experience, research, literature review, and focus groups (Chiarelli & Cockburn 1999, 2002). This was re-written for women aged between 40 and 60, under Dr Chiarelli's expert supervision, by Claire Johnson. Mrs Joy Goldsworthy from the Research Centre for Gender and Health again provided extensive assistance with layout and design. See Appendix A.7.

#### 4.3 Recruitment and Participants

#### 4.3.1. Recruitment through FPA Health

The facilities of the FPA Health Clinic in Newcastle have been used without charge for all clinical assessment and intervention. It was initially proposed that all participants would be recruited through the Newcastle FPA Health Clinic. Staff from the Clinic indicated that approximately 150-200 women aged 40-60 attended clinics and groups each month, that about one in three would experience some stress urinary incontinence or be appropriate for preventive intervention, and that approximately half of those would participate. On that basis, we expected to be able to recruit 30 women per month through the FPA Health clinic.

Two meetings were held with FPA Health medical and nursing staff and management to finalise arrangements of the times, place and processes. FPA Health has a policy of encouraging staff to become increasingly involved in research, and have been extremely co-operative and supportive of the project. In order to enhance links between the project and FPA Health, a decision was made to employ an experienced reproductive-health-trained registered nurse, who worked on a sessional basis for FPA, as a second Project Assistant. Ms Anne Hutchings' role would be to conduct approximately half of the clinical assessments and interventions and to collect survey and clinical data. She undertook training with Dr Chiarelli on specific aspects of this intervention, worked through the intervention protocol to ensure practical and theoretical familiarity with the intervention, and conducted her first two clinical assessments under the direct supervision of Dr Chiarelli.

Initially, 600 Women's Waterworks brochures were supplied to FPA Health to be displayed in their waiting area and for clinicians to hand out to appropriate clients. Women interested in participating in the Women's Waterworks Program were asked to contact Claire Johnson at the Research Centre for Gender and Health for more information and to make an appointment. Recruitment commenced in late July 2001.

After eight weeks of recruiting through FPA Health (and the recruitment of several participants through personal contacts with RCGH staff), only 15 participants had been recruited, a quarter of the expected estimate of 60 in two months. On inquiry, staff at FPA Health assured the research team that they were handing out brochures where appropriate, but that the numbers of women presenting with mild urinary incontinence or risk factors seemed to be much lower at that time than had been estimated in February/March 2000, when the initial proposal had been prepared. Clinicians believed that some women who fitted the criteria, and would benefit from the program, were not responding to the invitation to participate. It became clear after two months of recruitment that it would not be possible to meet our participant numbers through the FPA Health Clinic alone and other methods of recruitment were explored.

#### 4.3.2. Recruitment through other general practices and fitness centres

It was decided that to increase the number of women participating in the program, access to a greater pool of women in the 40-60 year age group was required. To this end, thirteen general practices in the Newcastle area were approached and invited to provide information about the availability of the Women's Waterworks programme to suitable patients. Patients who were interested would receive a brochure and be invited to telephone Claire Johnson to make an appointment at the Newcastle FPA Health Clinic. This change was first approved by the University of Newcastle Human Research Ethics Officer.

Twelve group and individual general practices were selected on the basis that they were in the same geographical area as the FPA Health Clinic, or were in areas with good public transport, and that they had female doctors and/or saw a large number of middle-aged female patients. Each practice was initially contacted by telephone by Claire Johnson. The program was explained to practice managers, and a brochure and brief outline of the treatment program was faxed so that doctors could see the material involved. In the majority of Medical Practices this information was taken to a practice meeting before a decision was made to participate. One practice requested that Mrs Johnson attend a practice meeting to detail the program to the general practitioners.

In addition, one of the participants in the project mentioned the existence of the project to one of the medical practitioners at the University of Newcastle Medical Practice and suggested that she might like to provide brochures to her patients. Claire Johnson visited this medical practitioner, who took 30 brochures to distribute to participants.

In summary, thirteen practices in total considered the program. Seven practices agreed at a practice-based level to be involved with the program; in two practices, one of a number of medical practitioners agreed to be involved individually; three further practices already provided similar services through their practice nurses and therefore had no need of the programme; and one practice decided that the programme was not suitable for them and their patients. Overall, acceptance by general practices was high, suggesting that the program matches a need perceived by the majority of medical practitioners in this area. Between September 20 2001 and January 24 2002, a total of 542 brochures were delivered to private medical practices for display in waiting rooms and for distribution, where appropriate, by medical practitioners.

In order to further increase the number of potential participants, a total of 199 brochures were also distributed to five fitness centres. In each case Claire Johnson spoke with the gym manager, and in three cases with fitness instructors as well, to explain the purpose of the project and the target audience. Another seven brochures were provided to a chiropractor who expressed an interest in the project.

#### 4.4. Intervention

Each woman participated in the Women's Waterworks program over a 16 week period on the following basis, following the guidelines outlined in the Intervention Protocol (Appendix A.5).

#### 4.4.1. Initial Recruitment

Women who were interested in the project were invited to phone the Research Centre for Gender and Health and were initially interviewed by Claire Johnson. Participants were informed of the process as fully as possible: the three appointments, the survey and bladder diary that should be completed prior to each one, and what was involved in each consultation. Participants were informed that they would undergo a vaginal examination by a trained, experienced female nurse. A package was posted to each of 97 women who were interested and eligible, containing bladder diary, survey, informed-consent form and an information sheet that again described the program to participants. Of these 97 women, 90 made initial appointments.

#### 4.4.2. Week 1 Appointment

Of the 90 women who made appointments, 76 (84%) attended Week 1 and provided written consent to participate in the program. Two of the others withdrew when they realised that pre-existing medical conditions (one diabetes, one a chronic urinary tract infection) would make the preventive programme inappropriate for them; seven withdrew for other reasons; the others failed to attend appointments despite at least two follow-up telephone calls and rescheduled appointments. At the Week 1 appointment a pelvic floor assessment was performed by one or other of the two continence advisers (CJ and AH), both manually and

mechanically (using a perineometer). Maximum number of "squeezes," and maximal time a "squeeze" could be held, were recorded. The continence adviser performed a series of physical assessments. A visual assessment for visible prolapses, scarring, skin condition and any perineal abnormalities was performed. The participant was asked to cough to see whether leaking occurred and whether perineal contraction and elevation occurred. A digital per vaginum examination was then performed, testing for palpable prolapses, vaginal wall symmetry and pelvic floor muscle strength (using Laycock's PERFECT model, with a grading from 0 [nothing felt] to 5 [very strong squeeze with good upward movement of the perineum]).

Women were taught how to perform pelvic floor muscle exercises effectively, taught bladder training techniques, and advised of good bladder and general health care. The performance of pelvic floor muscle exercises was assessed visually, manually and by perineometer to ensure that the woman was performing the "squeeze" correctly. Women were taught "the Knack" (Miller et al. 1998), a strategy of deliberately contracting and elevating the pelvic floor muscles when coughing, sneezing, jumping or otherwise increasing intra-abdominal pressure. Miller et al. (1998) have demonstrated this technique to be effective in reducing urine loss when coughing, among older women with mild to moderate stress urinary incontinence. Participants were encouraged to use this technique in situations in which leakage of urine might occur. A pelvic floor muscle exercise programme was designed specifically to each woman's needs and participants were encouraged to practise over the following 9 weeks. Should a woman feel that she required further help prior to the week 9 appointment, she was encouraged to contact the research team and make a further short appointment. Three women, all of whom had difficulty in performing the pelvic floor muscle "squeeze" when it was taught to them, attended further appointments.

#### 4.4.3. Week 9 Appointment

A week prior to the Week 9 appointment, participants were sent a post-treatment survey and three-day bladder diary, which they were asked to complete and bring with them. At this appointment, the continence adviser repeated the assessments conducted at Week 1, provided feedback on changes, and offered follow-up treatment and advice as required. Of the 76 women who attended at Week 1, 62 attended the Week 9 appointment.

#### 4.4.4. Week 16 Appointment

This was a repeat of the Week 9 appointment, including the survey and bladder diary and the physical assessments. Participants were invited to review their goals for the programme and assess their satisfaction with progress. If necessary, they were referred back to their own medical practitioners for further management. A total of 56 women attended the 16-week appointment.

#### 4.4.5. Wait-List Control

Women were recruited on a sequential basis into immediate treatment or a four-week wait-list group. This was done on a 2:1 basis; that is, of every three participants, the first and second were recruited immediately, and the third invited to join a wait list. Those who were assigned to the waitlist control group were asked to complete a pretest survey, three day bladder diary and consent form, and to return them in a prepaid envelope. An appointment was made for

four weeks after the completion of the initial survey and bladder diary. Prior to this Week 1 appointment, participants were sent another bladder diary and survey to complete and bring to the appointment. A total of 27 women agreed to participate as waitlist controls; of these, 20 returned the initial package of materials and 19 kept their Week 1 appointment four weeks later (these 19 are included in the total sample size of 76 whose Week 1 data are used in the analysis).

## 5. Results

#### 5.1. Participant Demographics

A total of 76 women attended Week 1 appointments. Of these, 33 (43%) had heard about the programme through the FPA Health clinic, 14 (18%) from their GP, 19 (26%) through a friend, 7 (9%) through a gym or fitness centre, and one from her chiropractor.

Mean age was 50.5 years (range 27-72), with 53 (71%) aged between 40 and 60. Fifty-nine (78%) were Australian-born, none of indigenous origin. Of those born outside Australia, five were born in England, 6 in other European countries, 6 in New Zealand, 2 in Asian countries and one in the USA. Fifty-two (68%) were married and 3 (4%) in de facto relationships, 15 (20%) were divorced, one separated, one widowed, and four never married.

Most were in paid employment: 26 (34%) worked full-time and 21 (28%) part-time, while a further two worked without pay in family businesses. Of the 27 without formal employment, 10 were in home duties and 7 were retired, with the others medically unable to work (4), studying full-time (3), or doing volunteer work (3). Education levels were higher than Australian norms for middle-aged women, with 30 (39%) holding university degrees and 17 (22%) having other post-school qualifications. Of the others, 6 (8%) had finished 12 years of high school and 23 (30%) had 11 or fewer years of schooling.

When comparing those who completed the 16 week programme with those who did not, there was no significant difference in the proportion of participants in paid employment (61% of those who completed week 16 versus 63% of those who did not), in the proportion of participants who had completed post school qualifications (67% versus 50%), in the proportion of participants who were living in permanent relationships (74% versus 68%), and in the proportion of participants who were born in Australia (76% versus 81%).

#### 5.2. Initial Survey Data

Self-report survey data were used to classify the women according to the type of incontinence experienced. Women responded to fifteen standard items about the circumstances under which they had leaked urine in the past month, with the aim of identifying their condition as stress, urge, or "other" incontinence (see Question 2 of Pretest Survey, Appendix A.4). For each of fifteen items (e.g., "Coughed, laughed or sneezed"; "Were on your way to the toilet"), women indicated whether they had leaked urine never, rarely, sometimes or often in the previous month, and whether the leakage had been "just drops" or more than that.

Consistent with the findings of Miller et al. (in press- a) in the Women's Health Australia substudy, the traditional categories were found to be inappropriate for many of these women. Twenty-eight women (37%) reported levels of incontinence that were too mild to be classified, and were participating in the programme as a primary prevention measure. These women reported leaking urine "rarely", and no more than drops, in no more than two of the fifteen situations in the previous month ("never" in all other situations). Most of the others (31 women, 41%) were classified as experiencing "mixed" incontinence, endorsing a mixture of items indicating stress incontinence (e.g., leaking urine when they coughed, laughed or sneezed) and those indicating urge incontinence (e.g., leaking urine when they had to wait to use the toilet). Eight (11%) reported symptoms of stress incontinence only, and seven (9%)

urge incontinence only.

An overall incontinence severity score was calculated. This variable has a theoretical range from 0 to 90, with 0 indicating no problem and 90 indicating leaking a considerable amount "often" in every one of the fifteen situations. Week 1 scores ranged from 0 to 51, with a mean of 12.4 and median of 10.

About half the women used some form of sanitary protection for urinary leakage: thirty-nine (51%) used none, while 27 used panty liners, 9 used sanitary pads, and 6 used incontinence pads. None used a vaginal device.

Forty-two participants (55%) indicated that they were unable to stop the flow of urine midstream, and four reported having tripped, fallen or injured themselves on at least one occasion when rushing to the toilet.

Tables 5.1 and 5.2 summarize responses to the Urogenital Distress Inventory and the Incontinence Impact Questionnaire (Uebersax et al. 1995). Table 5.1 summarizes the extent to which the participants reported being "bothered" by leaking urine, while Table 5.2 summarizes the extent to which they reported urine leakage to have affected various aspects of their lifestyles and well-being. These data suggest that – despite generally scoring low on incontinence severity - most of the participants experienced considerable levels of symptoms and inconvenience. However, they coped effectively with these problems so that the overall effects on their day-to-day activities were generally mild to moderate.

#### Table 5.1. Week 1 survey responses (n=76): Urogenital Distress Inventory

Item	Not at all	Slightly	Moderately	Greatly
Frequent urination	25	22	22	6
Leakage related to urgency	22	20	21	11
Leakage related to activity, coughing,	17	26	13	19
or sneezing				
Small amounts of leakage (drops)	14	35	18	8
Difficulty emptying bladder	57	15	1	1
Pain or discomfort in lower	55	12	4	3
abdomen/genital area				

Responses to the item: How much are you bothered by aspects of urine leakage?

Note: Figures are frequencies

#### Table 5.2. Week 1 survey responses (n=76): Incontinence Impact Questionnaire

Responses to the item: To what extent has urine leakage affected aspects of lifestyle and wellbeing?

Item	Not at all	Slightly	Moderately	Greatly
Ability to do household chores	68	7	1	0
Physical recreation (eg walking)	40	17	12	5
Entertainment (eg movies)	61	8	3	1
Ability to travel by car or bus more	62	8	5	0
than 30 minutes from home				
Social activities outside home	59	14	3	0
Emotional health	59	11	5	0
Feelings of frustration	32	28	10	5

Note: Figures are frequencies

#### 5.3. Intervention and Waitlist Comparisons

The four-week waitlist control condition was used in order to assess the effects of repeated administration of the survey and the physical examination. In order to be confident that any self-reported changes observed between Weeks 1 and 9 reflected actual changes, it is necessary to demonstrate that completion of the assessment alone does not produce changes in target variables.

Table 5.3 shows self-report scores and bladder diary variables before and after waitlist for the 19 women who participated in the waitlist condition. Repeated-measures analysis of variance showed no significant differences between the two measurement occasions, while Pearson correlations indicated generally moderate to high levels of reliability over the four weeks. This suggests that any changes in women's self-reports of incontinence severity or general well-being, or in their bladder function, between Week 1 and Week 9, cannot be attributed to the effects of repeated use of the same survey items. This, in turn, strengthens the conclusion that changes are the result of real improvements in function.

Variable	Initial Week 1	Repeat Week 1	F	Pearson's r
	Assessment	Assessment		
	Mean	Mean		
	(standard devn)	(standard devn)		
Total incontinence	10.5	9.1	0.66	0.78
score	(11.5)	(7.6)		
SF-36 physical	46.8	48.5	0.25	0.86
component score	(10.4)	(11.5)		
SF-36 mental	47.6	46.6	0.27	0.70
component score	(8.5)	(11.2)		
Voids per day	8.72	8.95	0.37	0.89
	(3.34)	(3.74)		
Daytime mean void	224	217	0.67	0.93
volume (ml)	(108)	(96)		
Minimum time	0.49	0.63	1.32	0.27
between voids (hours)	(0.38)	(0.48)		
Voids overnight	0.77	0.64	1.46	0.61
	(0.57)	(0.55)		
Overnight void	378	388	0.22	0.74
volume (ml)	(130)	(135)		
(first void of morning)				
Daily fluid intake (ml)	2032	1999	0.18	0.80
	(580)	(559)		

Note: Analysis of variance shows no significant changes in these variables over four weeks.

#### 5.4. Clinical Observations and Main Outcomes, Week 1 and Week 9

Table 5.4 summarizes the main outcome variables assessed at Week 1 and at Week 9, and used in the statistical evaluation of the programme's effects. These data include the waitlist participants.

The Week 1 data indicate that the majority of the participants showed poor pelvic floor muscle strength as assessed by digital examination, and their perineometer readings averaged a pressure of 23.8 cm. Functional ability, as indicated by number of squeezes and maximum duration of contraction, was moderate to poor. Most women did not spontaneously demonstrate "the Knack," but 64% were able to demonstrate it immediately after training. Week 9 and Week 16 data show significant improvements in all measures of pelvic floor muscle strength. Digital examination indicated an overall increase in grading, with the majority of women now scoring 3 or higher. Perineometer readings, number of squeezes, and maximum contraction duration all showed significant improvements overall. The majority of participants spontaneously used "the Knack" when asked to cough, and 85% were able to demonstrate "the Knack" when asked.

Information from the three-day bladder diaries is also summarized in Table 5.4. It shows improvements on all measures of bladder activity: mean number of voids per day decreased from 7.8 to 6.7, while average daytime void volume increased significantly and the minimum time between voids also increased significantly. The "overnight void" mean of 0.75 at Week 1 indicates that on average they got up at night to visit the toilet on three of every four nights, while at Week 9 the mean of 0.44 means that they were getting up at night, on average, once every second night. The higher overnight void volume is another indication of healthier bladder function. These improvements were achieved without any change in daily fluid intake.

The SF-36 scores (see Table 5.4) indicate that the physical component scores were close to the population mean of 50 at both Week 1 and Week 9, while mental component scores rose significantly across the nine weeks, from a low Week 1 mean of 44.1 to a mean of 51.2, slightly higher than the population average, at Week 9. The Week 1 mean of 44.1 indicates levels of mental-related well-being that are markedly lower than those of the normal population, and are equivalent to those reported by women with diagnosed major illness. This suggests that the participants were experiencing significant levels of interference with their day-to-day quality of life, that were alleviated at Week 9.

# Table 5.4. Main outcome variables, at Week 1 and Week 9. These include survey data, clinical observations, and bladder diary data.

Variable		Week 1 (n=76)	Week 9 (n=61)	F
		Mean	Mean	
		(s.d.)	(s.d.)	
Survey Data				
Incontinence severity (ra	ange 0 – 90)	12.4	8.3	16.5
		(10.8)	(10.0)	(p<.001)
SF-36 Physical component	ent scale (population mean $= 50$ )	50.1	49.6	0.68
		(9.8)	(9.6)	ns
SF-36 Mental component	nt scale (population mean $= 50$ )	44.1	51.2	24.5
		(9.6)	(9.3)	(p<.001)
<b>Clinical Notes</b>				
Perineometer reading (c	m)	23.2	30.0	31.6
		(12.4)	(15.6)	(p<.001)
Endurance: Number	r of squeezes	3.8	4.3	56.7
		(1.2)	(1.4)	(p<.001)
Maximu	um contraction duration (sec)	3.3	4.4	18.7
		(1.2)	(1.1)	(p<.001)
		Freq (%)	Freq (%)	
Pelvic floor muscle	0 nothing	0	0	
strength (digital exam)	1 flicker	8 (11%)	2 (3%)	
Grade 0-5	2 weak squeeze	31 (41%)	16 (26%)	
	3 squeeze, some upward movement	32 (42%)	37 (61%)	
	4 good squeeze and lift	5 (7%)	5 (8%)	
	5 very strong squeeze and lift	0	1 (2%)	
"Knack" (contraction an	d elevation)			
Present on cough		12 (16%)	42 (69%)	
Present when requ	uested (after training)	49 (65%)	52 (85%)	
Bladder Diarv				
		Mean	Mean	
		(s.d.)	(s.d.)	
Voids per day (number)		7.8	6.7	12.1
· · · · · · · · · · · · · · · · · · ·		(2.4)	(2.0)	(p=.001)
Davtime mean void volu	ıme (ml)	237.5	291.2	32.3
5	× ,	(94.0)	(84.8)	(p<.001)
Minimum time between	voids (hours)	0.67	1.13	19.4
		(0.51)	(0.65)	(p<.001)
Voids overnight		0.75	0.44	6.86
		(0.84)	(0.52)	(p=.01)
Overnight void volume (ml)		404.3	449.2	8.01
(first void of morning)	• /	(125)	(157)	(p=.006)
Daily fluid intake (ml)		2047	2104	1.03
		(639)	(542)	ns

#### 5.5. Week 1, Week 9 and Week 16 analyses

Fifty six participants completed the 16 weeks of the Women's Waterworks program, however, complete data are available for only 51 participants.

Table 5.5 summarizes self-report and clinical data at Week 1, Week 9 and Week 16. The data were analyzed with repeated-measures analysis of variance; where this was significant, it was followed by Tukey's post hoc tests. Analysis showed that the significant reduction in reported incontinence severity observed between Weeks 1 and 9 was maintained at Week 16, and the significant increase in mental-related quality of life (SF-36 mental component scale) was similarly maintained. There were no changes in physical-related quality of life, which had been close to the population mean of 50.0 at Week 1.

Clinical observations for these women showed significant increases in perineometer readings, number of squeezes, and maximum duration of squeeze between Week 1 and Week 9. The perineometer reading maintained its improvement, but did not continue to improve significantly between Week 9 and Week 16. However, the number of squeezes and the maximum duration were significantly higher at Week 16 than at Week 9. The digital examination also suggested that improvements in pelvic floor muscle strength had continued; the number who achieved a grade of 3 or better increased across the three assessments from 52% at Week 1, to 73% at Week 9 and 88% at Week 16. This suggests that participants had continued to perform their pelvic floor muscle exercises over the entire four-month period, and that improvements were continuing.

Variable		Week 1	Week 9	Week 16	F
		Mean	Mean	Mean	
		(s.d.)	(s.d.)	(s.d.)	
Survey Data					
Incontinence sever	ity (range 0 – 90)	12.7	8.7	7.2	12.6
(n=51)		(11.4)	(10.4)	(7.0	(p<.001)
SF-36		48.6	48.6	50.0	1.5
Physical component	nt scale (population mean $= 50$ )	(10.3)	(9.7)	(9.0)	ns
(n=49)		44.1	10.5	<b>51</b> 0	1.5.5
SF-36 Montal component	$c_{abala}$ (nonvelotion mean $= 50$ )	44.1	49.5	51.0	15.5
(n=40)	scale (population mean – 50)	(0.0)	(9.5)	(8.0)	(p<.001)
Clinical Notes					
Perineometer readi	ng (cm)	23.8	30.5	31.2	16.0
(n=53)		(12.1)	(14.7)	(15.0)	(p < 0.01)
Endurance <sup>·</sup> Nu	imber of squeezes	38	4.5	52	36.4
(n=56)		(1.3)	(1.0)	(1.2)	(p<.001)
Ma	aximum contraction duration (sec)	3.3	4.3	4.7	45.1
(n=56)		(1.2)	(1.4)	(1.3)	(p<.001)
		Freq (%)	Freq (%)	Frea (%)	, v
		(n=56)	(n=56)	(n=56)	
Pelvic floor	0 nothing	0	0	0	
muscle strength	1 flicker	5 (9%)	1 (2%)	1 (2%)	
(digital exam)	2 weak squeeze	22 (39%)	14 (25%)	11 (20%)	
Grade 0-5	3 squeeze, some upward movement	27 (48%)	36 (64%)	35 (62%)	
	4 good squeeze and lift	2 (4%)	4 (7%)	9 (16%)	
	5 very strong squeeze and lift	~ /	1 (2%)	<b>``</b>	
"Knack" (contracti	on and elevation)				
Present on c	ough	11 (20%)	38 (68%)	42 (75%)	
Present when	n requested (after training)	38 (68%)	47 (84%)	48 (86%)	
Bladder Diary					
Diadact Diary		Maan	Maan	Maan	
		(a, d)	(a, d)	(a d)	
		(s.u.) (n=51)	(s.u.)	(s.u.)	
Voida por dou (nur	mh or)	(n 31) 80	(11-51)	(11-51)	8.0
voids per day (nur	nder)	8.0	(2.8)	(2,2)	$\delta.0$
Destine meen wei		(2.8)	(2.8)	(2.3)	(p<.001)
Daytime mean void	u volume (mi)	(02.2)	290.4	290.6	22.3
Minimum time hot	waan weide (hours)	(92.2)	(00.0)	(70.9)	(p < .001)
Minimum time bet	ween volds (nours)	(0.52)	1.10	1.13	11.4
Voids overnight		0.55	0.00	(0.08)	$\frac{(p < .001)}{6.07}$
volus overnight		(0.69)	(0.55)	.40	(n=0.03)
Overnight void vol	ume (ml)	388 /	440.5	444.8	<u>9</u> 6
(first void of morn	ing)	(127)	(161)	(157)	(n < 0.01)
Daily fluid intake (	(ml)	1998	2097	2030	13
	,	(618)	(516)	(547)	ns

## Table 5.5. Main outcome variables, at Week 1, Week 9 and Week 16, for those who participated in all three assessments (N=56).

#### 5.6. Evaluation and Qualitative Comments

Of the fifty six women who returned for assessment at Weeks 9 and 16, 51 completed the self-report surveys and provided open-ended comments on their impressions of the demonstration project. Responses were positive overall, with only one woman who considered that the programme had not been effective. Participants were asked to mark on an analogue scale the extent to which their incontinence had changed between Week 1, Week 9 and week16. The scale was centred at 0 and ran from "100% worse" to "100% improvement". The mean rating was a 34% improvement (standard deviation = 28.2) at week 9 and 50% (standard deviation = 32.5) reported at week 16, and scores ranged from 17% worse to 100% improved. The one woman who reported that her condition had deteriorated stated that she had found that her feeling of urgency to void had got stronger over the previous 12 months. This woman did show an increase in pelvic floor muscle strength as measured by the perineometer, and demonstrated the ability to perform "the Knack." She had been concerned about urinary leaking for five years, and had previously tried bladder training and medication, with which she had been "moderately" and "very" dissatisfied. She was referred to her GP for further advice.

Participants reported having completed a mean of 72% (standard deviation = 21.6, range = 20%-100%) of the pelvic floor exercises assigned at week 9 and 69% (standard deviation = 19.6, range = 20%-100%) at week 16. Participants' ratings of the extent to which the programme had met their expectations (on a scale from 0 to 100%) had a mean of 82% at week 9 (standard deviation = 20.9, range = 16 – 100) and again 82% at Week 16 (standard deviation = 20.3, range = 16 – 100). Forty-five participants (88%) said they would "definitely" recommend the programme to a friend, at both Weeks 9 and 16. At Week 9, six (12%) would "probably" do so, and at Week 16 two (4%) would "probably" do so. At Week 16, one (2%) would "possibly" recommend the programme and one (2%) would not recommend the program.

Forty-one of the participants (71%) had read the entire Women's Waterworks booklet that was provided at Week 1, while another 15 (29%) had read at least part. Only one (2%) had not looked at it at all. Table 5.6 summarizes responses to a series of questions about the content of the booklet and of the individualised programme: participants generally rated the content positively, although relevance of the booklet received somewhat less strongly positive endorsement than other aspects. Only two women felt that their individualised programme was "not really" appropriate and only one would not recommend the booklet to a friend. Two felt the booklet could have been improved upon, but one of these added, "The booklet needs more publicity. There are many women with this problem who are too self conscious to speak up." The other person did not comment on her view.

	Yes, definitely	Yes - okay	No, not really	Definitely not	Don't know/ don't remember
Booklet easy to read (n=57)	47	8	0	0	1
Booklet related to me (n=54)	27	25	0	0	2
Booklet instructions clear (n=55)	40	14	0	0	1
Individualised programme clear	39	14	0	0	1
(n=54)					
Individualised programme	38	12	2	0	1
appropriate (n=53)					
Would recommend booklet to a	41	11	0	1	1
friend (n=54)					

#### Table 5.6 Evaluation of the booklet and exercise programme at Week 9

Note: Figures are frequencies

#### 5.6.1. Comments at Week 9

Overall comments provided some additional insight into the women's evaluation of the programme. Several were entirely positive. One woman, who rated her improvement at 100%, said:

My condition was probably mild compared to others, but this program definitely nipped it in the bud. Consistently working on pelvic floor muscles needs constant reminders. Maybe gym class instructors could add it to their repertoire - for the small proportion of women who attend them.

Another, who rated her improvement at 95%, said:

I am very glad that I participated in this program (although 64 years old). Now much more aware of the bad habits I had formed, being at home a lot & free to 'go' whenever I chose. Anxiety played a part when I went out. Now I feel much more relaxed about needing a toilet - perhaps I don't! Grateful for the booklet for reference. Thank you for your efficiency - nurse counsellor 100% professional.

Some commented on specific aspects of the programme that had been most help. For example:

*My improvement is because of my efforts in bladder control. If I improve my exercises it should make a bigger difference again.* 

When stressed I practise the pelvic wall exercise - with pretty good results - in a quick response to try to stop the leaking. Just not quite confident enough yet to go out without a pad but feeling I am getting there.

I found that being told about Depend pads an absolute Godsend. It takes all the worry out of it and even helps control the problem as one feels quite comfortable.

Others commented on other changes to their health or daily life that had affected the extent of their leakage. For example:

Have been troubled by asthma since the beginning of the year therefore there has been a lot of coughing - hence leaking. However this last two weeks it has improved & coughing has decreased.

Cut out caffeine.

A number reported that they had learned things about their leakage which would be of use in continuing to tackle the problem. One woman, who rated herself 50% improved, said:

Since doing the program I have become aware that my problems are not simply about muscle control. There are other factors impacting on my bladder control

Two others commented that they had noticed that their leakage appears to vary with their menstrual cycle.

#### 5.6.2. Comments at Week 16

Week 16 comments were almost entirely positive. While it is of course possible that women who did not continue with the programme were less satisfied than those who attended Week 9 and Week 16, these comments do suggest that the programme is achieving its goals for those women who continue to participate.

For example, a woman who considered herself 95% improved wrote:

Changes have happened despite most of the answers being the same as previous answers. During the last month I have been able to survive unpredictable situations re toilets and if there was a leakage it was very, very small. The exercises have helped. At times I have worked hard with the exercises and family members have noticed the difference. I think this program has been at the right time for me because I had noticed changes in the 6 months prior to this study. I would like to completely resolve the leakage problem and will keep working on the exercise program. Thank you to all involved.

#### Another (100% improved) wrote:

Given that I have not been able to successfully exercise as regularly as I should, the improvement has been astonishing. I've gone from leaking almost every time I went to the gym or played strenuous sports to not at all. If I feel I'm at risk of leakage it is a reminder to continue my exercise program.

The following comment illustrates the extent to which some participants have learned about the process of managing their leakage, and the empowerment that is felt as women begin to learn to control the problem.

Between 2nd assessment and Friday just prior to 3rd assessment, I leaked urine 6 times. Apart from the fact that I have been very unwell during these last 7 weeks, I have also been holding on a lot longer prior to going to the toilet, and I usually leaked on most occasions just as I was getting ready to sit on the toilet. Despite all of this, during the last 7 weeks I haven't worn any pads while at home and amazingly enough the leaks have only occurred at home. However, I haven't been out enough to gauge my progress. I will still continue to wear pads when I go out. I do feel a lot

more free now, regarding my bladder, and no longer paranoid about toilets.

A number of women commented that as surveys were being completed during different times during their menstrual cycle, they were becoming more familiar with the ways in which their bodies changed during the cycle, and as a result had noticed their incontinence was worse at some times than at other times during their cycle. It is evident that further research and clarification of the hormonal influence on incontinence is necessary.

One woman summed up a successful experience and changed attitude to the problem in the following words:

Minor waterworks problems are part of getting old and will only get worse - I thought... This is not true. The Women's Waterworks program has provided me with information and an exercise program to enable me to take control. I feel confident and committed to keeping myself healthy and comfortable.

## 6. Discussion and Recommendations

This demonstration project has shown that women who participate in an early intervention programme, designed to develop pelvic floor muscle strength and good bladder habits, show significant increases in pelvic muscle strength and significant reductions in self-reports of urinary leakage. As well, their bladder diaries indicate improvements in urinary hygiene and self-reports show improvements in mental-related quality of life. The data suggest that these effects are maintained at least for several months. Evaluation of the programme by the participants was positive, suggesting that interventions such as these are well received by women who choose to participate.

The women who participated in the demonstration project were more highly educated than the norm for Australian women in this age group, although comparison with the characteristics of the mid-age cohort of Women's Health Australia (Brown et al., 1998) indicate that they were otherwise demographically representative. At Week 1 they generally showed mild levels of urinary incontinence, some so mild that they could not be classified. Thus, the participants were appropriate for the assessment of the programme as a strategy for prevention or early intervention. The women who chose to participate could be characterised as well-educated, well-motivated, and in good general health.

A major public health implication of this finding is that there may be a need to explore strategies for promoting prevention among women with lower levels of formal education, and among those who are traditionally less likely to access preventive services. These might include indigenous women, women from non-English-speaking backgrounds, and those with social or health-related disadvantages.

The low recruitment rate for the project – 1200 brochures were distributed in a targeted manner to obtain a total of 76 women attending their first appointment – is a second issue with major public health implications. While the project was effective for those women who attended, there appears to be a general lack of concern or motivation among the target group regarding this problem. Although brochures were made available to women who were already attending FPA Health or general medical practices, and were differentially targeted to women who were perceived by medical staff to be likely to benefit from the programme, uptake was still very low.

This finding is in line with survey findings (Miller et al., in press a and Miller et al, 2003) that the majority of women reporting mild urinary leakage have never sought professional help for their problem, with most of them believing they can mange on their own, that the problem does not warrant intervention, that it will go away spontaneously, or that it is natural and normal for women to experience some urinary leakage as they age.

Results indicate that there was significant improvement for all main outcomes (with the exception of the SF36 physical component scale, which was already at normal levels at Week 1). However, the majority of this improvement is demonstrated between Weeks 1 and 9.

This greater improvement within the first nine weeks of the program has implications for health planners. If a significant improvement can be demonstrated at a Week 9 appointment, a well motivated patient need not be seen again at Week 16 or later, unless further problems are encountered.

Urinary incontinence is highly stigmatized and is widely regarded as an "old lady's problem." Many of the women who participated in the programme appeared very embarrassed about seeking help for this condition. The necessity of making a phone call to initiate involvement appeared to be a major hurdle for many women. Many women refused to leave messages with other staff at the office of the Research Centre for Gender and Health if Claire Johnson was not available, despite the fact that all staff are female and are trained in an appropriate and confidential telephone manner. Others requested that staff should not call them back, or requested that staff who called them should not mention the purpose of their call to family or workmates. While normal professional ethics would preclude any such disclosure to third parties, it appears that the maintenance of secrecy was an important priority for many women and may serve as a barrier to seeking help. A related public health implication, then, is that public information campaigns are needed with the aim of de-stigmatizing the condition and emphasizing that it is common among young and middle-aged women, but is usually preventable through a simple, non-invasive and straightforward intervention.

Prevention and early intervention of urinary stress incontinence should ideally have the same level of recognition, acceptability and adoption as other major population-level prevention endeavours, such as screening for cervical abnormalities. If this can be achieved, there is the potential for major economic saving and for improved quality of life among Australian women and their families and caregivers.

## 7. Conclusion

This project has demonstrated that a non-invasive, nurse-administered intervention for prevention or early intervention of stress urinary incontinence is effective for those women who choose to participate. Directions for further research and evaluation include:

- 1. Strategies for recruiting women with average and low levels of education and others who are traditionally unlikely to access preventive services need exploration. These include indigenous women, women from non-English-speaking backgrounds, and those with social or health-related disadvantages.
- 2. Public information strategies aimed at education about, and destigmatization of, urinary stress incontinence are likely to increase women's willingness to participate in effective prevention and early intervention programmes. These strategies need to inform the public that urinary incontinence is common among women of all ages, that it is frequently preventable through non-invasive intervention, and that preventing urinary incontinence is likely to improve their ability to maintain independence and quality of life as they age. These strategies also need to address the sense of embarrassment and secrecy that many women seem to associate with the condition.

## 8. References

Berghmans LC, Hendriks HJ, Bo K, Hay-Smith EJ, de Bie RA, van Waalwijk van Doorn ES. Conservative treatment of stress urinary incontinence in women: a systematic review of randomized clinical trials. *British Journal of Urology* 1998; 82: 181-191.

Bo K. Pelvic floor muscle exercise and urinary incontinence - train yourself continent! *Tidsskrift for Den Norske Laegeforening* 2000; 120: 3583-3589.

Brown WJ, Bryson L, Byles JE, Dobson AJ, Lee C, Mishra G, Schofield M. Women's Health Australia: recruitment for a national longitudinal cohort study. *Women and Health* 1998; 28: 23-40.

Burgio KL, Matthews KA, Engel BT. Prevalence, incidence and correlates of urinary incontinence in healthy mid-age women. *Journal of Urology* 1991; 146: 1255-1259.

Cammu H, Van Nylen M, Amy JJ. A 10-year follow-up after Kegel pelvic floor muscle exercises for genuine stress incontinence. *British Journal of Urology* 2000; 85: 655-658.

Chiarelli P, Brown W. Leaking urine in Australian women: Prevalence and associated conditions. *Women and Health* 1999; 29: 1-13.

Chiarelli P, Brown WJ, McElduff, P. Leaking urine: Prevalence and associated factors in Australian women. *Neurourology and Urodynamics*, 1999; 18: 567-577.

Chiarelli P, Cockburn J. The development of a physiotherapy continence promotion program using a customer focus. *Australian Journal of Physiotherapy* 1999; 45: 111-119.

Chiarelli P, Cockburn J. Promoting urinary continence in women after delivery: Randomized controlled trial. *British Medical Journal* 2002; 324: 1241-1246.

Glazener CM, Herbison GP, Wilson PD, MacArthur C, Lang GD, Gee H, Grant AM. Conservative management of persistent postnatal urinary and faecal incontinence: randomised controlled trial. *British Medical Journal* 2000; 323(7313):593-596.

Harris F, Brindley J, Stevens J. *Incontinence – How long can carers cope?* Paper presented at the 5th National Conference on Incontinence, Melbourne, 1996.

Lee C (ed.) *Women's Health Australia: What do we know? What do we need to know?* Brisbane: Australian Academic Press, 2001.

McDowell BJ, Engberg S, Sereika S, Donovan N, Jubeck ME, Weber E, Engberg R. Effectiveness of behavioral therapy to treat incontinence in homebound older adults. *Journal of the American Geriatrics Society* 1999; 47:309-318.

Miller JM, Ashton-Miller JA, DeLancey JO. A pelvic muscle precontraction can reduce cough-related urine loss in selected women with mild SUI. *Journal of the American Geriatrics Society* 1998; 46: 870-874.

Miller YD, Brown WJ, Chiarelli P, Russell A. Urinary incontinence across the lifespan. *Neurourology and Urodynamics*, in press.

Miller YD, Brown WJ, Smith N, Chiarelli P. Managing urinary incontinence across the lifespan. *International Journal of Behavioral Medicine*, 2003; 10(2): 143-161.

Mitteness L, Barker J. Stigmatizing a "normal" condition: Incontinence in later life. *Medical Anthropology Quarterly* 1995; 9: 188-210.

Morkved S, Bo K. Effect of postpartum pelvic floor muscle training in prevention and treatment of urinary incontinence: a one-year follow up. *British Journal of Obstetrics & Gynaecology* 2000; 107:1022-1028.

Norton PA, MacDonald LD, Sedgwick PM, Stanton SL. Distress and delay associated with urinary incontinence, frequency and urgency in women. *British Medical Journal*, 1988; 297: 1187-1189.

Uebersax JS, Wyman JF, Shumaker SA, McClish DK, Fantl JA. Short forms to assess life quality and symptom distress for urinary incontinence in women: The Incontinence Impact Questionnaire and the Urogenital Distress Inventory. *Neurourology and Urodynamics* 1995; 14: 131-139.

Ware JE, Sherbourne CD.(1992). The MOS 36-Item Short-Form Health Survey (SF-36). Conceptual framework and item selection. *Medical Care* 1992; 30(6): 473-483.

Yarnell JWG, Voyle GJ, Richardson CJ. The prevalence and severity of urinary incontinence in women. *Journal of Epidemiology and Community Health* 1981; 35: 71-74.

## 9. Financial Statement

The financial situation at 15<sup>th</sup> March 2003 is summarized below.

		0004	••••		
Brief descriptor	Details	2001	2002		Total
General consumables	Examination gloves etc for	\$48	\$60		
and expenses	clinical assessments				\$108
Printing	Printing of booklets and materials	\$467	\$380		\$847
Services (categorized	Payment to FPA Health for Anne	\$784	\$1,956		
as "consultancy fees"	Hutchings' time (clinical				
and "outside	assessments)				
contractors")			\$5,000		
	Payment to Pauline Chiarelli for		ŗ		
	development of booklet and				
	training of continence nurses				
	č		\$10,000		
	Research Centre cost recoveries				
	(statistical assistance, office costs,				\$17,740
	computing, management fee)				,
University overheads	15% of grant to cover	\$4,500			
changes	infrastructure costs				\$4,500
Expenditure – Salary	Claire Johnson's salary (part time)	\$12,271	\$12,345	\$7,672	\$32,288
Expenditure – Salary	Salary on costs	\$1,973	\$2,020	\$1,228	
Related					\$5,221
Travel & expenses –	Christina Lee – airfare,		\$1,171		\$1,171
Health Outcomes	registration & accommodation to		ŕ		
Conference	present on project				
TOTAL		\$20,042	\$27,356		\$61,875

Table 9.1. Financial Summary as at 15<sup>th</sup> March 2003

## 10. Appendices

### 10.1. Appendix A

- A.1 Women's Waterworks Brochure
- A.2 Consent and Information Forms: Immediate Treatment Group
- A.3 Consent and Information Forms: Wait-List Participants
- A.4 Surveys and Bladder Diary
- A.5 Intervention Protocol
- A.6 Clinical Notes
- A.7 Women's Waterworks Booklet