Lower urinary tract symptoms in community-dwelling older men: natural history and associations with falls

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Statement of originality

I certify that the content of this thesis is my own work and that all the assistance received in preparing this thesis have been acknowledged.

Naomi Noguchi

Signature:
Synopsis

This thesis explores two major health themes in community-dwelling older men. The first theme is the natural history of common urological conditions (overactive bladder (OAB) and elevated post-void residual urine volume (PVR)). The second theme is the association between lower urinary tract symptoms (LUTS) and falls.

The first two research findings chapters (Chapters 3 and 4) describe the natural history of OAB and elevated PVR. Although previous studies suggest that OAB and elevated PVR often resolve naturally, understanding of their natural history is insufficient. If natural remission of these conditions can be expected, more men may be treated conservatively and avoid potential adverse effects of the treatments.

In a representative sample of community-dwelling men aged 70 and older in the Concord Health and Ageing in Men Project (CHAMP study) (n=1705), LUTS were assessed using the International Prostate Symptoms Score (IPSS) and the International Consultation of Incontinence Questionnaire (ICIQ) and urodynamic tests were conducted at baseline and two-year and five-year follow-up.

Chapter 3 describes the natural history of OAB in the absence of neurological disorders. Men with prostate cancer and those with history of urological treatment at baseline were also excluded. Of the 98 men with OAB at baseline, 28 (29%) received treatment for either benign prostatic enlargement (BPE) or OAB over five years. Of the 70 men who remained urologically intact during follow-up, 23 (33%) had natural and sustained remission at two-year and five-year follow-up.
Chapter 4 describes the natural history of elevated PVR in the absence of neurological disorders. Men with prostate cancer and those with history of urological treatment at baseline were also excluded and PVR was considered valid when the voided volume was 150mL and over. Of the 325 men with a baseline PVR of less than 400mL, 15 (5%) received surgery for BPE or indwelling catheterization over five years. In all 101 men with a baseline PVR of less than 400mL who remained urologically intact during follow-up and had valid follow-up PVR data, PVR did not exceed 400mL at either two-year or five-year follow-up.

Chapters 3 and 4 indicate that, in the absence of neurological disorders, OAB and elevated PVR often resolve naturally in older men living in the community. This may support initial conservative management in men with these conditions.

The next three chapters (Chapters 5 to 7) investigate the association between LUTS and falls in community-dwelling older men. A previous systematic review has identified falls as a potential adverse outcome of LUTS but showed that there is limited evidence for this association in men. Since the prevalence of both LUTS and falls are high, the associations between them may have significant implications for falls prevention.

Chapter 5 is a systematic review of the associations between LUTS and falls, injuries and fractures in community-dwelling older men. This review found that incontinence and storage symptoms have been associated with falls, and that the contribution by each of incontinence and storage symptoms that often coexist in men were unclear.

Chapter 6 then examines the contribution of each LUTS to falls risk using the CHAMP study data. One thousand three hundred and ninety men without neurological disorders, poor mobility and dementia were included in the analyses. Intermediate to high IPSS storage
subscores (IPSS-S) and high voiding subscores (IPSS-V) were associated with falls (adjusted IRR=1.73, 95% CI: 1.24-2.40 for intermediate IPSS-S, adjusted IRR=1.81, 95% CI: 1.13-2.90 for high IPSS-S, adjusted IRR=1.41, 95% CI: 0.97-2.04 for intermediate IPSS-V, and adjusted IRR=1.98, 95% CI: 1.09-3.60 for high IPSS-V). Urgency incontinence was associated with falls (adjusted IRR=2.57, 95% CI: 1.54-4.30) and intermediate to high IPSS storage subscores without urgency incontinence were also associated with falls (adjusted IRR=1.72, 95% CI: 1.24-2.38).

Lastly, since it is unclear whether LUTS directly cause falls or are merely markers of other fall risk factors, the urology clinic pilot study at Concord Hospital presented in Chapter 7 investigated the circumstances of falls in community-dwelling older patients with LUTS of both sexes to find out whether LUTS directly precipitate falls. Twelve patients who had had falls in the previous 12 months reported the circumstances of 26 falls in total. Although 23 out of these 26 falls were not directly related to voiding, three occurred in those with OAB on their way to the toilet both in daytime and night.

Chapters 5 and 6 show that urgency incontinence and storage and voiding symptoms are all associated with falls in community-dwelling older men. And Chapter 7 suggests that it is possible that urgency and nocturia directly precipitate a minority of falls in older people with LUTS although causality is still unclear. Circumstances of falls should be further investigated to generate more hypotheses about what types of intervention may be incorporated into falls prevention strategies and these need to be tested for efficacy. Also, trials to treat LUTS should consider including falls as an outcome.
Author’s contributions

The CHAMP study is an established cohort study that was set up to investigate a broad range of health issues in older men. I extended the focus of CHAMP study to include the natural history of common urological conditions and the association between LUTS and falls in community-dwelling older men. I planned the studies, conducted all analyses, presented at conferences, drafted and revised manuscripts for submission to peer-reviewed journals and wrote this thesis in consultation with my supervisors. Vasi Naganathan (VN), Robert Cumming (RC), Fiona Blyth (FB), Lewis Chan (LC), David Handelsman (DH), Louise Waite (LW), David Le Couteur (DL) and Marcus Seibel (MS) designed the CHAMP study, advised on the analyses and revised the manuscript.

For the systematic review, I planned the study, conducted the review, drafted and revised manuscript for submission to peer-reviewed journals and wrote this thesis in consultation with my supervisors. VN, RC, FB and LC advised on the analyses and revised the manuscript.

For the survey on circumstances of falls at urology clinics in Concord Hospital, I collected all the data from November 2015 to October 2016. I saw twelve people with LUTS aged 70 and over who have fallen in the previous 12 months. I planned the study, submitted ethics application, assembled, managed and analysed data and wrote this thesis in consultation with my supervisors. VN, BC, FB, LC, Karina So (KS), Vincent Tse (VT), Nichola Boyle (NB) advised on the design of the study and the analyses and revised the manuscript.
The percentage contribution of the author and co-authors are as follows.

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List of publications, presentations and awards

Publications


Noguchi N, Chan L, Cumming RG, Blyth FM, Handelsman DJ, Waite LM, Le Couteur DG, Naganathan V. Natural history of post-void residual urine volume over five years in community-dwelling older men: the Concord Health and Ageing in Men Project. Neurourol Urodyn (accepted for publication). (This paper is presented in Chapter 4.)

Noguchi N, Chan L, Cumming RG, Blyth FM, Naganathan V. A systematic review of the association between lower urinary tract symptoms and falls, injuries, and fractures in community-dwelling older men. Ageing Male 2016; 19(3): 168-174. (This paper is presented in Chapter 5.)

Related publications


Invited talk


Conference presentations


Noguchi N, Chan L, Cumming RG, Blyth FM, Handelsman DJ, Waite LM, Le Couteur DG, Naganathan V. Natural history of post-void residual urine volume over five years in community-dwelling older men: the Concord Health and Ageing in Men Project. Presented at the 46th annual meeting of the International Continence Society, Tokyo, Japan on September 14, 2016 (oral presentation)

Awards

International Continence Society Conference Travel Award, October 2015
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Ichiro, Toshiko, Masao, Kazue and Tomoko. I am glad that moving back home to save for my
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Abbreviations

BOO = Bladder outlet obstruction

CHAMP = Concord Health and Ageing in Men Project

CI = Confidence interval

DO = Detrusor overactivity

DU = Detrusor underactivity

ICIQ = International Consultation of Incontinence Questionnaire

IPSS = International Prostate Symptom Score

IRR = Incidence rate ratio

LUTS = Lower urinary tract symptom

MrOS = Osteoporotic Fractures in Men Study

OAB = Overactive bladder

PVR = Post-void residual urine volume

Qmax = Maximum urinary flow rate

SD = Standard deviation

UAB = Underactive bladder
1. Background
1.1 Overview of lower urinary tract symptoms (LUTS) in older men

LUTS refers to symptoms related to the lower urinary tract (bladder, prostate and urethra) and can be classified into storage symptoms, voiding symptoms and post-micturition symptoms (1). Storage symptoms are irritative symptoms that occur during the storage phase in the bladder such as urgency, daytime frequency and nocturia. Voiding symptoms are symptoms that indicate either obstruction or inadequate contraction of the bladder such as weak or intermittent stream and straining to void. Post-micturition symptoms are symptoms that occur immediately after micturition such as feeling of incomplete emptying and post-micturition dribble. These symptoms are common in older men and result in considerable morbidity as will be discussed in section 1.2.

Male LUTS were once called ‘prostatism’ because all LUTS were thought to arise from benign prostatic enlargement (BPE) (2). A better understanding of LUTS was developed by the use of pressure flow urodynamic studies which revealed that male LUTS actually have a wider variety of causes than BPE alone, such as detrusor overactivity (DO) or detrusor underactivity (DU) (3). It is difficult to differentiate the causes for LUTS from symptoms because the symptoms are not specific to underlying pathology and different types of voiding dysfunction often coexist in older men. Pressure flow urodynamic study is required to diagnose the causes but this test is invasive. As LUTS are common, men are often treated empirically, targeting symptoms that are the most bothersome, and invasive investigation is often spared unless the symptoms do not respond to empirical treatment. In keeping with this, most clinical practice guidelines provide guidance on the management of LUTS based on symptoms rather than the treatment of particular underlying pathology such as benign prostatic enlargement (BPE), DO and DU (4).
The International Prostate Symptom Score (IPSS) is a scoring system that is most often used to assess LUTS in clinical practice (5). IPSS consists of storage symptoms (urgency, frequency and nocturia) and voiding symptoms (incomplete emptying, intermittency, weak stream and straining to void) and IPSS subscores for each category of symptoms can be calculated separately (6). The US Osteoporotic Fractures in Men (MrOS) study reported the prevalence of LUTS in community-dwelling men aged 65 and over using the International Prostate Symptom Scores (IPSS) (7). LUTS were absent (IPSS of 0) in 2.3%, mild (IPSS of 1 to 7) in 51.6%, moderate (IPSS of 8 to 19) in 39.6% and severe (IPSS of 20 to 35) in 6.6% and the severity of LUTS increased with age.

Common types of voiding dysfunction among older men are discussed below. The choice of common conditions in older men and the course of treatment discussed below are based on our previous review article on older men’s voiding symptoms (8).

1.1.1 Overactive bladder (OAB) and urgency incontinence

OAB is defined by the International Continence Society (ICS) as “urgency, with or without urgency incontinence, usually with frequency and nocturia” where “there is no proven infection or other obvious pathology” (1). This definition is based on symptoms that are suggestive of DO in urodynamic studies. The severest form of OAB is urgency incontinence where urgency results in leakage of urine. A US telephone survey reported that the prevalence of OAB without urgency incontinence was 24 % and the prevalence of OAB with urgency incontinence was 10% in community-dwelling men aged 75 and over (9). A Finnish population-based mail survey in men and women between ages 18 and 79 reported that one in seven people with urgency has at least moderate bother (10).
Causes of OAB are classified into neurogenic and idiopathic (non-neurogenic). Neurological disorders that may be related to OAB includes multiple sclerosis, spinal cord injury, stroke and neurodegenerative diseases. Damage to the brain can decrease suprapontine inhibition of the micturition reflex and damage to the spinal cord leads to the emergence of abnormal micturition reflexes both resulting in DO (11). If no neurological disorder is present, OAB is assumed to be idiopathic.

Treatment should start with lifestyle modification such as reducing intake of caffeine and alcohol, which are mild diuretics, and avoiding fluids before going out or before bedtime (4). Absorbent products may also be used to achieve social continence (4). Behavioural modification such as bladder retaining to increase the bladder capacity, double voiding to empty the bladder and urethral milking to avoid post-void dribbling may also reduce the symptoms (12). If such conservative management fails, anticholinergic drugs may be used to relax the detrusor. The problem with anticholinergic medications is that they have a potential to cause significant adverse effects on cognitive and physical function especially in older people (13).

Population-based studies in older men have reported high remission rates of OAB and incontinence but these studies did not account for urological treatment (14, 15). It is, therefore, unclear if the remission occurred naturally or in response to treatment. Our hypothesis is that spontaneous remission of OAB occurs without treatment in some men. If so, it would be useful to know how likely spontaneous remission would be so that men will be spared from potential adverse effects of anticholinergic medications.
1.1.2 Bladder outlet obstruction (BOO) / underactive bladder (UAB)

BOO and UAB are discussed together here because the clinical presentation are similar. BOO refers to obstruction in any part of the lower urinary tract (bladder, prostate and urethra). BOO is most often caused by benign prostatic enlargement (BPE) in older men but other causes include urethral stricture and bladder neck obstruction. UAB is a condition where the bladder does not contract effectively to void urine and this can be of neurogenic and/or myogenic aetiology (16). Detrusor underactivity (DU) is a urodynamic finding that is consistent with UAB. Both conditions primarily cause voiding symptoms such as weak stream and straining that reflect failure to empty the bladder. Inadequate emptying at each void may also result in some storage symptoms such as frequency and nocturia. In severe cases, post-void residual urine volume (PVR) may also increase which can result in complications such as renal failure and urosepsis (16). As the symptoms and elevated PVR are not specific to each of BOO and UAB, these two conditions can only be differentiated by pressure flow urodynamic studies.

A Korean study of urological patients aged 65 and over who underwent urodynamic studies reported that 53% of the men had DU alone and an additional 18% had both DU and BOO (17). Although these patients presumably have undergone urodynamic studies because of persistent symptoms that did not respond to empirical treatment, DU and its coexistence with BOO is often encountered in clinical practice.

Although elevated PVR is often found incidentally in older people, its prevalence in the general population has not been studied. In community-dwelling men aged 70 and over in the Concord Health and Ageing in Men Project (CHAMP study), PVR was 0 to 49mL in 57%,
50 to 99mL in 18%, 100 to 199mL in 21%, 200 to 399mL in 4% and 400mL and over in 2% (unpublished data). Elevated PVR up to 200mL is common from our data.

In treating older men with predominantly voiding symptoms and/or elevated PVR, it is important to identify medications with anticholinergic effect that can reduce the contractility of the bladder especially in older people where polypharmacy is common. A Japanese study reported that medications with anticholinergic properties such as anti-Parkinson drugs, antidepressants and antipsychotics were commonly prescribed in patients who were receiving medications to treat LUTS (18) and the authors urged a medication review before pharmacologically treating LUTS. Epidemiological studies of LUTS also need to take the effect of these medications into account.

Lifestyle and behavioural modification as discussed above for OAB may also be given as needed to manage symptoms. If such conservative management fails, medications such as alpha-blockers and 5-alpha reductase inhibitors may be considered for BPE. Eligibility for cavitating prostate surgery, however, should be assessed with caution in older men because such surgery may not be very effective if severe DU coexists (3) and it has high complication rates in older men including stress incontinence. Ultimate treatment for DU is catheterization. Since intermittent catheterization is technically difficult in older people, indwelling catheterization is often the first choice but can result in in recurrent urinary tract infections (UTI) and also carries a risk of urethral trauma.

Moreover, DO and DU may coexist in older people. This condition is called detrusor hyperactivity with impaired contractility (DHIC) where patients have irritative symptoms but the detrusor contractility is inadequate to empty the bladder at the same time. In such patients, anticholinergics may further increase PVR. The above Korean study also revealed
that as many as 38% of the men aged 65 and over who underwent urodynamic studies had both DU and DO (DHIC) (17). Clinicians may often encounter this unresolved challenge where no guidelines for treatment exist.

With regards to the natural course, the US Olmsted County study of urinary symptoms and health status reported that extreme values of PVR tended to move closer to the mean over time (19). Although this may indicate that most cases of elevated PVR resolve without causing complications, it is unclear what level of elevated PVR is safe to be managed conservatively. Our hypothesis is that elevated PVR do not keep increasing in a majority of men. Knowing the natural history of different levels of elevated PVR may help guide the decisions as to whether men with elevated PVR need intervention or to be followed up closely.

1.1.3 Stress incontinence

Stress incontinence refers to leakage of urine caused by elevation of abdominal pressure and only occurs iatrogenically in men, such as after radical prostatectomy and radiotherapy for prostate cancer and cavitating prostate surgery for BPE. This is because the long urethra and the prostate protect men from leakage even when abdominal pressure is elevated. Details will not be discussed further because, in this thesis, the focus is on common conditions that occur naturally to older men.

1.2 Consequences of LUTS

Of all LUTS, OAB and incontinence, have been particularly associated with adverse outcomes such as impaired quality of life (QOL) (9, 20). Amongst symptoms of OAB, urgency
incontinence seems to affect QOL the most. Men with OAB with urgency incontinence have a higher prevalence of depression and are more likely to alter activities compared to men with OAB without urgency incontinence after adjusting for potential confounders (21). These associations were stronger in men than in women (21).

The consequences of LUTS may not be limited to impaired QOL, depression and social isolation. A Spanish study of patients admitted to a geriatric rehabilitation unit reported that patients with urinary incontinence had a higher risk of first-time nursing home admission compared with those without, after adjusting for potential confounders (22). Incontinence may add to carer burden and, therefore, may influence decisions whether or not to place a family member in a nursing home.

One adverse outcome of LUTS that has been looked at to a limited degree is falls. A systematic review identified nine studies that examined the associations between LUTS and falls (23). All studies were in older adults aged at least 65, the sample sizes ranged from 127 to 6049, but most studies were exclusively (n=4) or predominantly (n=3) of women. They found that urgency incontinence but not stress incontinence was associated with falls, and also identified studies that found positive associations of frequency and nocturia with falls. Our hypothesis is that some LUTS are also associated with falls in men. This association may have significant implications for falls prevention because both LUTS and falls are common in older people and falls can have serious impact on older people’s health and independence as will be discussed in section 1.4.
1.3 Incontinence and falls as components of the geriatric syndromes

Of all LUTS, incontinence has been most often examined in association with falls (23) and both incontinence and falls (instability) are components of the original set of the geriatric syndromes that Isaacs proposed as the ‘Giants of the Geriatrics’ in 1975, along with immobility and intellectual incapacity (24). Isaacs saw the Giants to be age-related conditions that can lead to further functional deterioration in older people.

In community-dwelling men aged 70 and over in the CHAMP study, we have found that incontinence and falls were the more common geriatric syndromes compared to poor mobility and dementia (25). The prevalence of recurrent falls in a year increased from 6% in men aged 70 to 74 to 13% in men aged 85 to 89, and the prevalence of incontinence that occurs more than once a week increased from 5% in men aged 70 to 74 to 15% in men aged 85 to 89.

Although only incontinence was a part of Isaac’s Giants of Geriatrics, other LUTS also become more common with age. The IPSS assesses storage and voiding symptoms but does not include incontinence. In community-dwelling men aged 70 to 74 in the CHAMP study, LUTS were absent or mild (IPSS of 0 to 7) in 67%, moderate (IPSS of 8 to 19) in 27% and severe (IPSS of 20 to 35) in 6% (unpublished data). Moderate to severe LUTS were more prevalent in men aged 85 to 89: absent or mild in 58%, moderate in 32% and severe in 10% (unpublished data).

The associations between LUTS and falls may be of interest to clinicians and the community, considering the prevalence of each of LUTS and falls. In addition, the potential association
does raise the question as to whether improving LUTS or behavioural modification around LUTS can reduce fall risk.

1.4 Consequences of falls

Falls result in significant morbidity and threaten the independence of older people. Five percent of falls in people older than 65 result in hospitalization (26). In addition, falls can lead to institutionalisation, with one study finding that 10% of patients aged 70 and over hospitalized for falls become first-time residents of residential care facilities (27). This could be a result of physical and mental decline following the fall, but having a major fall may also influence the decision to place family members to nursing homes.

Adverse effects of falls are not limited to injuries directly caused by falls. Older adults are known to restrict their activities due to fear of falling (28). This self-imposed restriction has a potential of leading to social isolation and further physical and mental deterioration.

1.5 Risk factors for falls

Falls are usually multi-factorial in older adults, who may have multiple predisposing factors that impair balance, gait and strength; when some precipitating factors such as acute illness or environmental hazard are added, the individual’s compensatory ability fails and he or she may fall (29).

Fall risk factors and interventions to prevent falls are usually discussed separately for institutionalized adults and non-institutionalized adults (30, 31). This is because the
The incidence of falls is three times higher in residential care facilities and factors contributing to falls are different between these populations. In one study, 41% of the falls in non-institutionalized adults were attributed to environmental hazards whereas, in institutionalized adults, only 16% of the falls were caused by environmental hazards. In the latter setting, a majority of the falls were due to intrinsic factors such as weakness, gait or balance disorder, dizziness or vertigo (32). This thesis will focus on falls in older adults living in the community.

Deandrea’s systematic review of falls risk factors identified a large number of factors that have been associated with falls in community-dwelling older people (33). Of these fall risk factors, only some may have direct causal relationships with falls, and furthermore, even fewer may be modifiable. Although modification of the other factors may not help prevent falls, they might serve as markers to efficiently identify at-risk individuals for falls who might benefit from multifactorial intervention.

Likewise, it is unclear if LUTS directly cause falls or treating LUTS reduces falls. Although multiple LUTS often coexist in one person, no previous study has looked at the association of a wide range of LUTS with falls in a single study sample to determine which LUTS are more strongly associated with falls (23). Moreover, none of the studies that have examined the association between LUTS and falls described the circumstances of falls (23). It is, therefore, unclear whether the association between LUTS and falls shown in previous studies is because LUTS cause falls or because people with LUTS tend to have other fall risk factors that could not be fully adjusted for in the analyses. The hypothesized mechanisms of how LUTS directly or indirectly cause falls include the following; people with incontinence may slip over leaked urine on the floor; people with urgency may fall when they rush to the
toilet; and nocturia may cause daytime sleepiness resulting in falls. Knowing which LUTS have strong associations with falls and how older people with LUTS fall would inform what types of intervention may decrease fall risk in older men with LUTS.
1.6 Background summary, aim and thesis outline

Figure 1.1 shows the structure of this thesis.

As mentioned above there is some data to suggest that common urological conditions in older men, OAB and elevated PVR, often resolve naturally. If natural remission of these conditions can be expected, more men may be treated conservatively and avoid potential adverse effects of the treatments. Evidence about the natural history of OAB and elevated PVR, however, is insufficient. The aim of Chapters 3 and 4 is to describe the natural history of OAB and elevated PVR in community-dwelling older men.
In Chapter 3, the natural history of non-neurogenic OAB and urgency incontinence is described in the community-dwelling men in the CHAMP study. The characteristics of the men who had continuous remission of OAB are also examined.

In Chapter 4, the natural history of elevated PVR including the incidence of related events is described in the community-dwelling men in the CHAMP study.

As mentioned previously the systematic review by Chiarelli identified falls as a potential adverse outcome of LUTS but showed that there is limited evidence for this association in men. Since the prevalence of both LUTS and falls are high, the associations between them may have significant implications for falls prevention. The aim of Chapters 5 and 6 is to explore further the association between LUTS and falls in community-dwelling older men.

Chapter 5 is a systematic review of the association between LUTS and falls in community-dwelling older men.

In Chapter 6, which builds on Chapter 5, the CHAMP study data is used to examine which LUTS are associated with incident falls in one year in community-dwelling older men.

It is also unclear whether LUTS directly cause falls or are merely markers of falls risk. The aim of Chapter 7 is to determine if LUTS precipitate falls in both men and women.

Chapter 7 describes the circumstances of falls in community-dwelling men and women using the data collected in the urology clinic survey.

The CHAMP cohort is described in detail in Chapter 2 and the specific methods to each study can be found in the research findings chapters.
2. Methods and sample characteristics
This chapter describes the recruitment and data collection methods for the Concord Health and Ageing in Men Project (CHAMP study) and provides some data on the characteristics of the study population. Three of the studies in this thesis were conducted with the CHAMP cohort. The specific analyses used for each study and the characteristics of the study sample for each of the studies appear within the relevant research findings chapters. Methods of the systematic review and the urology clinic survey, which did not involve the CHAMP cohort, are also described in the research findings chapters.

2.1 CHAMP study

The lead investigators of the CHAMP study are interested in a broad range of health issues in older men including the aetiologies and consequences of the geriatric syndromes such as falls, fractures, cognitive impairment, lower urinary tract symptoms (LUTS) and functional disabilities. To explore a number of hypotheses related to these outcomes, they obtained funding from the National Health and Medical Research Council (NHMRC) in Australia to conduct a large prospective study on a representative sample of community-dwelling older men. The CHAMP study was approved by the Concord Hospital Human Research Ethics Committee. All participants gave written informed consent.

2.1.1 Sample selection

The CHAMP study involves 1705 men aged 70 years and over living in the community in a defined geographical area of metropolitan Sydney. The only exclusion criterion was living in a residential aged care facility. Men aged 70 years and over living in the three Local Government Areas surrounding Concord Hospital (Burwood, Canada Bay and Strathfield)
were identified using the New South Wales Electoral Roll, on which registration is compulsory. Limiting participation to men who live around the hospital and using the electoral roll as a sampling frame were considered to be the optimal strategies to obtain and maintain a representative sample of older men living in the community. Men on the electoral roll were sent an invitation letter to take part in the study and were telephoned a week later if they had a listed telephone number. Men who did not respond to the first letter or did not have a listed telephone number were sent a second invitation letter. Recruitment occurred sequentially across the study area between January 2005 and June 2007.

Figure 2.1 shows the recruitment process of the CHAMP study. Of the 3627 men who were sent invitation letters, 3005 were contacted. Most of the 622 men who could not be contacted did not have a listed telephone number. Of the 3005 contacted men, 190 turned out to be ineligible because they had moved out of the study area, had moved into a residential aged care facility or had died. Of the 2815 eligible men, 1511 participated in the study. An additional 194 eligible men living in the study area volunteered to join the study before they received an invitation letter after hearing about the study from friends or reading articles about the study in local newspapers. Participation rate is, therefore, calculated as \( \frac{1511 \text{ from invitation letter system} + 194 \text{ volunteers}}{3627 \text{ invitations sent} + 194 \text{ volunteers} - 190 \text{ ineligibles}} = 47\% \).
Figure 2.1 Recruitment of the CHAMP study

3627 Letters sent

622 Could not be contacted

3005 Contacted

190 Ineligible

2815 Eligible

1304 Declined

1511 Agreed to participate

194 Volunteered before receiving invitation letters

1705 Participated
2.1.2 Measurement

2.1.2.1 Baseline measurement

Baseline data were collected between January 2005 and June 2007. The self-administered questionnaire and the clinic questionnaire used at baseline can be found in Appendix A. Men completed a questionnaire at home before coming to the study clinic at Concord Hospital. The questionnaire took about 45 minutes to complete and included questions on demographic characteristics, falls in the past year, the International Consultation on Incontinence Questionnaire (ICIQ) (34), the International Prostate Symptom Score (IPSS) (5), diagnosed medical conditions, the Older American Resource Scale (OARS) for instrumental activities of daily living (IADL) (35), history of surgery for benign prostatic enlargement (BPE) and dizziness. Medical conditions were assessed using a standardized questionnaire in which participants reported if a doctor had ever told them that they had diabetes, thyroid dysfunction, osteoporosis, Paget’s disease, stroke, Parkinson’s Disease, kidney stones, dementia, depression, epilepsy, hypertension, myocardial infarction, angina, congestive heart failure, intermittent claudication, chronic respiratory disease, liver disease, chronic kidney disease, arthritis or gout, and cancer.

Men were then seen in a study clinic at Concord Hospital during a study visit which lasted about three hours. Variables assessed by trained personnel included a modification of Katz index for basic activities of daily living (BADL) (36), the Mini-Mental State Examination (MMSE) (37), physical performance tests (timed chair stands, usual pace walk for six meters and narrow balance walk), and Logmar Visual Acuity Test (38). In addition, men brought
medications that they had been taking daily or almost daily for at least the past month to the clinic visit for medication inventory.

Urological assessments were conducted by trained nurses. Uroflowmetry was performed using Urodyn 1000 (Medtronic Functional Diagnostics A/S, Skovlunde, Denmark) and immediately afterwards, post-void residual urine volume (PVR) was measured using a BladderScan BVI 3000 portable scanner (Verathon Inc., Bothell, WA). The uroflow graphs were manually examined for artifacts. Maximum urinary flow rate and PVR were considered valid only when the voided volume was 150mL and over.

Shortly after the clinic visit, the Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) (39) was administered with a nominated informant, usually the participant’s wife, by telephone. The 535 men with an MMSE score of 26 or lower and/or an IQCODE score of 3.6 or higher were invited to have a detailed cognitive examination performed by a geriatrician and 395 were assessed. Diagnosis of dementia was made according to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) (40) criteria at a consensus meeting attended by two geriatricians, a neurologist and a neuropsychologist.

2.1.2.2 Follow-up measurement

Eight-year follow-up had only just been completed at the time of submission of this thesis. Data up to and including five-year follow-up were utilized in the studies in this thesis.

The above self-administered questionnaire and clinical assessment were repeated at two-year and five-year follow-up visits. In addition, men were telephoned every four months and were asked whether they had had any falls or hospitalizations since the previous follow-up
phone call. When falls were reported, number of falls was asked and study staff excluded ‘near-falls’ by asking if the man’s body landed on the ground, floor or other lower level (41). For hospitalizations, reason, date and place of admission were asked. Men who could not be contacted by telephone after several attempts were mailed a four-monthly questionnaire.

2.1.3 Sample characteristics

2.1.3.1 Demographic characteristics

Table 2.1 shows the baseline demographic characteristics of the CHAMP cohort. The age distribution in the CHAMP cohort is similar to that of men in the study area in the 2006 Australian Census (42). In the Census in the three Local Government Areas of Burwood, Canada Bay and Strathfield combined, 33% of men aged 70 and over were aged 70 to 74, 31% were aged 75 to 79, 21% were aged 80 to 84, 11% were aged 85 to 89 and 5% were aged 90 and over. Varied country of birth reflects the ethnic diversity of the study area. A majority of men were married at baseline.
Table 2.1 Baseline demographic characteristics of the CHAMP cohort (43)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n (%*)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age group</strong></td>
<td></td>
</tr>
<tr>
<td>70-74</td>
<td>673 (39.5)</td>
</tr>
<tr>
<td>75-79</td>
<td>536 (31.4)</td>
</tr>
<tr>
<td>80-84</td>
<td>315 (18.5)</td>
</tr>
<tr>
<td>85-89</td>
<td>135 (7.9)</td>
</tr>
<tr>
<td>90-97</td>
<td>46 (2.7)</td>
</tr>
<tr>
<td><strong>Country of birth</strong></td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>849 (49.8)</td>
</tr>
<tr>
<td>Italy</td>
<td>335 (19.6)</td>
</tr>
<tr>
<td>Great Britain</td>
<td>78 (4.6)</td>
</tr>
<tr>
<td>Greece</td>
<td>65 (3.8)</td>
</tr>
<tr>
<td>China</td>
<td>46 (2.7)</td>
</tr>
<tr>
<td>Other</td>
<td>332 (19.5)</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
</tr>
<tr>
<td>Married/de facto</td>
<td>1310 (76.8)</td>
</tr>
<tr>
<td>Widowed</td>
<td>220 (12.9)</td>
</tr>
<tr>
<td>Divorced/separated</td>
<td>90 (5.3)</td>
</tr>
<tr>
<td>Never married</td>
<td>85 (5.0)</td>
</tr>
</tbody>
</table>

*Denominators for calculating percentages varied due to missing data.

2.1.3.2 Overall health status

Table 2.2 shows the baseline prevalence of self-reported diagnosed health conditions. Cardiovascular disease (stroke, heart attack and angina) and its major risk factors (diabetes and hypertension) were common, half of the men had arthritis and 11% had a history of prostate cancer. Table 2.3 shows the baseline prevalence of the geriatric syndromes, frailty, multimorbidity, polypharmacy and IADL dependence. Each of the geriatric syndromes of poor mobility, falls, urinary incontinence and dementia and Fried’s phenotype frailty (44) were uncommon, but many men had two or more medical conditions (multimorbidity), were taking five or more medications (polypharmacy) and were dependent in at least one
IADL. Table 2.4 shows self-rated overall health at baseline. Seventy one percent of the men rated their health as either excellent or good compared with others their age.

Although the participation rate of the CHAMP study was 47%, the prevalence of major medical conditions and the proportion of men who reported excellent or good health were similar to the 915 men aged 70 and over in the nationally representative Men in Australia Telephone Survey (MATeS study) (45).

Table 2.2 Baseline prevalence of self-reported diagnosed health conditions in the CHAMP cohort (43)

<table>
<thead>
<tr>
<th>Condition</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arthritis</td>
<td>868 (51.7)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>780 (46.2)</td>
</tr>
<tr>
<td>Heart attack</td>
<td>311 (18.7)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>308 (18.3)</td>
</tr>
<tr>
<td>Angina</td>
<td>293 (17.7)</td>
</tr>
<tr>
<td>Chronic lung disease*</td>
<td>217 (12.9)</td>
</tr>
<tr>
<td>Prostate cancer</td>
<td>181 (10.7)</td>
</tr>
<tr>
<td>Depression</td>
<td>150 (8.9)</td>
</tr>
<tr>
<td>Stroke</td>
<td>143 (8.5)</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>86 (5.2)</td>
</tr>
<tr>
<td>Hypothyroidism</td>
<td>38 (2.3)</td>
</tr>
<tr>
<td>Parkinson's disease</td>
<td>32 (1.9)</td>
</tr>
</tbody>
</table>

Denominators for calculating prevalence varied due to missing data. *Chronic lung disease included chronic obstructive lung disease, chronic bronchitis, asthma, emphysema and COPD.
Table 2.3 Baseline prevalence of geriatric syndromes, frailty, multimorbidity, polypharmacy and IADL dependence in the CHAMP cohort (25)

<table>
<thead>
<tr>
<th>Conditions</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Geriatric syndromes</td>
<td></td>
</tr>
<tr>
<td>Poor mobility*</td>
<td>98 (5.8)</td>
</tr>
<tr>
<td>Recurrent falls in previous year</td>
<td>144 (8.5)</td>
</tr>
<tr>
<td>Urinary incontinence at least daily</td>
<td>121 (7.2)</td>
</tr>
<tr>
<td>Dementia</td>
<td>93 (6.0)</td>
</tr>
<tr>
<td>Fried’s frailty phenotype†</td>
<td></td>
</tr>
<tr>
<td>Frail (3-5 criteria)</td>
<td>158 (9.5)</td>
</tr>
<tr>
<td>Pre-frail (1-2 criteria)</td>
<td>679 (40.7)</td>
</tr>
<tr>
<td>Robust (0 criterion)</td>
<td>833 (49.9)</td>
</tr>
<tr>
<td>Multimorbidity (≥2 conditions)</td>
<td>1170 (69.3)</td>
</tr>
<tr>
<td>Polypharmacy (≥5 medications)</td>
<td>639 (37.7)</td>
</tr>
<tr>
<td>IADL dependence (≥1 IADL)‡</td>
<td>400 (23.7)</td>
</tr>
</tbody>
</table>

IADL, Instrumental activities of daily living. Denominators for calculating prevalence varied due to missing data. *Poor mobility was defined as needing help with walking across a small room and/or transferring from bed to a chair. †For Fried’s frailty phenotype, frail was defined as having 3 to 5 of weight loss, weak grip strength, exhaustion, slow walking speed and low activity level; pre-frail as having 1 or 2 of the criteria; and robust as having none. ‡IADL dependence was defined as needing help for at least one of the following tasks; telephoning, transport, shopping, meal preparation, housekeeping, management of medications and management of money.

Table 2.4 Self-rated overall health at baseline in the CHAMP cohort

<table>
<thead>
<tr>
<th>Self-rated health*</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
<td>268 (15.9)</td>
</tr>
<tr>
<td>Good</td>
<td>908 (54.0)</td>
</tr>
<tr>
<td>Fair</td>
<td>426 (25.3)</td>
</tr>
<tr>
<td>Poor</td>
<td>59 (3.5)</td>
</tr>
<tr>
<td>Very poor</td>
<td>21 (1.2)</td>
</tr>
</tbody>
</table>

Denominator was 1682 due to missing data. *Response to the question “Compared to other people your own age, how would you rate your overall health?” in the Short Form-12 (SF-12).
2.1.3.3 Urological Health

Table 2.5 shows the baseline prevalence of LUTS assessed using the IPSS. Thirty seven percent of the men had moderate to severe LUTS. Frequent urination, urgency and weak stream were most commonly reported, and 57% of the men woke up at least twice during the night to urinate. As shown in Table 2.3, 7% of the men had incontinence at least daily.

As shown in Table 2.2, 11% of the men had a history of prostate cancer at baseline. Table 2.6 shows the baseline prevalence of history of treatment for LUTS. Eighteen percent had a history of cavitating prostate surgery at baseline and 6% were taking medications for BPH at baseline (alpha blockers and/or five-alpha reductase inhibitors). Only 2% were taking urinary-specific antispasmodics for overactive bladder (OAB).
Table 2.5 Baseline prevalence of LUTS in the CHAMP cohort

<table>
<thead>
<tr>
<th>LUTS</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IPSS</strong></td>
<td></td>
</tr>
<tr>
<td>Low (0-7)</td>
<td>1008 (62.8)</td>
</tr>
<tr>
<td>Intermediate (8-19)</td>
<td>466 (29.1)</td>
</tr>
<tr>
<td>High (20-35)</td>
<td>130 (8.1)</td>
</tr>
<tr>
<td><strong>Incomplete emptying</strong></td>
<td></td>
</tr>
<tr>
<td>Not at all</td>
<td>1048 (63.5)</td>
</tr>
<tr>
<td>less than half the time</td>
<td>376 (22.8)</td>
</tr>
<tr>
<td>at least half the time</td>
<td>227 (13.7)</td>
</tr>
<tr>
<td><strong>Frequency</strong></td>
<td></td>
</tr>
<tr>
<td>Not at all</td>
<td>537 (36.2)</td>
</tr>
<tr>
<td>less than half the time</td>
<td>672 (42.5)</td>
</tr>
<tr>
<td>at least half the time</td>
<td>338 (21.4)</td>
</tr>
<tr>
<td><strong>Intermittency</strong></td>
<td></td>
</tr>
<tr>
<td>Not at all</td>
<td>1028 (62.4)</td>
</tr>
<tr>
<td>less than half the time</td>
<td>388 (23.5)</td>
</tr>
<tr>
<td>at least half the time</td>
<td>232 (14.1)</td>
</tr>
<tr>
<td><strong>Urgency</strong></td>
<td></td>
</tr>
<tr>
<td>Not at all</td>
<td>907 (55.0)</td>
</tr>
<tr>
<td>less than half the time</td>
<td>455 (27.6)</td>
</tr>
<tr>
<td>at least half the time</td>
<td>287 (17.4)</td>
</tr>
<tr>
<td><strong>Weak stream</strong></td>
<td></td>
</tr>
<tr>
<td>Not at all</td>
<td>903 (55.0)</td>
</tr>
<tr>
<td>less than half the time</td>
<td>428 (26.1)</td>
</tr>
<tr>
<td>at least half the time</td>
<td>310 (18.9)</td>
</tr>
<tr>
<td><strong>Straining</strong></td>
<td></td>
</tr>
<tr>
<td>Not at all</td>
<td>1328 (80.6)</td>
</tr>
<tr>
<td>less than half the time</td>
<td>226 (13.7)</td>
</tr>
<tr>
<td>at least half the time</td>
<td>93 (5.6)</td>
</tr>
<tr>
<td><strong>Nocturia</strong></td>
<td></td>
</tr>
<tr>
<td>0-1 times per night</td>
<td>723 (43.3)</td>
</tr>
<tr>
<td>2-3 times per night</td>
<td>759 (45.5)</td>
</tr>
<tr>
<td>4+ per night</td>
<td>187 (11.2)</td>
</tr>
</tbody>
</table>

IPSS, International Prostate Symptoms Scores. Denominators for calculating prevalence varied due to missing data.
Table 2.6 Baseline prevalence of history of treatment for LUTS in the CHAMP cohort

<table>
<thead>
<tr>
<th>Treatment</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery for BPE</td>
<td>302 (17.7)</td>
</tr>
<tr>
<td>Alpha blockers</td>
<td>91 (5.3)</td>
</tr>
<tr>
<td>Five-alpha reductase inhibitors</td>
<td>12 (0.7)</td>
</tr>
<tr>
<td>Urinary-specific antispasmodics</td>
<td>30 (1.8)</td>
</tr>
</tbody>
</table>

BPE, benign prostate enlargement. Denominators for calculating prevalence varied due to missing data.
2.1.4 Summary of the CHAMP cohort

The CHAMP cohort is a representative sample of community-dwelling older men and data about many aspects of men’s health were collected longitudinally. Although the participation rate was 47%, their baseline characteristics were similar to those in the nationally representative MATeS study cohort (45). Moreover, 22% (369/1705) declined follow-up in the first five years and there were further missing data for each item measured because the self-administered questionnaire and the clinic visit took a few hours each and some men found it difficult to complete these.

The CHAMP study included the data needed to answer questions about the natural history of LUTS and the association between LUTS and falls in older men living in the community. LUTS were assessed using validated questionnaires and the study also included objective urological measures of urinary flow rate and PVR from urodynamic studies. These measurements were repeated at two-year and five-year follow-up, which provides valuable information about the natural history of LUTS because LUTS are known to wax and wane over time. The CHAMP study also collected data about a wide range of fall risk factors including physical performance test, making extensive adjustment for confounders possible, and had prospective data about incident falls.
3. Natural history of non-neurogenic OAB and urgency incontinence in community-dwelling older men: the CHAMP study

Publication details:

ABSTRACT

Aims To describe the natural history of non-neurogenic overactive bladder (OAB) and urgency incontinence in community-dwelling older men.

Methods A representative sample of 1705 community-dwelling men aged 70 and older in a defined geographic area of Sydney, Australia, had their urinary symptoms assessed using the International Prostate Symptom Scores (IPSS) and the International Consultation of Incontinence Questionnaire (ICIQ) at baseline, 2-year follow-up and 5-year follow-up. Four hundred and eighty eight men without neurological diseases or prostate cancer during follow-up, or history of urological treatment at baseline were included in the analysis. Urgency incontinence was defined as leakage of urine occurring more than weekly in the above-defined population. OAB was defined as either urgency or urgency incontinence according to the 2002 International Continence Society consensus.

Results Of the men with OAB at baseline, 29% received treatment for OAB or benign prostatic enlargement over five years. Of the remaining men, 33% had sustained remission at both 2-year and 5-year follow-ups without treatment. Of the men with OAB at 2-year follow-up, remission rate at 5-year follow-up was 53% in men without OAB at baseline and 27% in men with OAB at baseline (p=0.23). No statistically significant difference was found in baseline characteristics between men with sustained remission and men with persistent symptoms.

Conclusions One in three older men with non-neurogenic OAB had sustained remission of symptoms without medical or surgical interventions. No significant predictor of sustained remission was identified.
INTRODUCTION

Overactive bladder (OAB) is defined as the presence of urinary urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence, in the absence of urinary tract infection (UTI) or other obvious pathology (1). It is a common clinical problem among patients presenting to general practitioners and other clinicians including urologists, gynaecologists, geriatricians, and neurologists. OAB may be related to neurological disorders such as multiple sclerosis, spinal cord injury, stroke, or neurodegenerative diseases (neurogenic OAB) or its exact aetiology may be unclear (idiopathic or non-neurogenic OAB).

High remission rates for OAB and incontinence have been reported in population-based studies of older men (14, 15, 46). These descriptive studies, however, did not have data about medical or surgical interventions, so it is unclear if the remissions occurred naturally or in response to treatment. Spontaneous remission of OAB symptoms is also suggested by the fact that improvement of OAB symptoms is often seen in placebo arms of randomized controlled trials of urinary-specific antispasmodics (47). It would, therefore, be useful to know how likely spontaneous remission of OAB symptoms is and which older men can expect remission so as not to expose them to potential adverse effects of anticholinergic medications (48). On the other hand, since OAB significantly impairs quality of life (21), it would be useful if we could identify men who have little chance of spontaneous remission in whom it might be better to institute treatment early.

The aim of this study was to describe the natural history of non-neurogenic OAB and urgency incontinence over five years in a representative sample of community-dwelling
older men. In addition, the study describes the characteristics of men who experienced sustained remission of OAB over five years.

MATERIALS AND METHODS

Study participants

The Concord Health and Ageing in Men Project (CHAMP) is a prospective cohort study of a wide range of health issues in older men. Baseline data were collected between January 2005 and June 2007. The study was approved by the Concord Hospital Human Research Ethics Committee. All participants gave written informed consent.

CHAMP involves 1705 men aged 70 years and over living in a defined region of metropolitan Sydney. The sampling frame was the New South Wales Electoral Roll, on which registration is compulsory. The only exclusion criterion was living in a residential aged care facility. The participation rate was 47%. The details of the sample selection process have been described previously (43).

Measurements

Men completed a questionnaire at home before coming to the study clinic. This included questions on demographic characteristics, history of diagnosed medical conditions including diabetes, stroke, Parkinson’s Disease, epilepsy, and prostate cancer, lower urinary tract symptoms (LUTS) (the International Prostate Symptom Score (IPSS) (5) and the International Consultation on Incontinence Questionnaire (ICIQ)) (34), and history of surgery for BPE.
For the purpose of this study, urgency was defined as three points or greater (at least half the time) in question four in the IPSS about urgency (‘Over the past month, how often have you found it difficult to postpone urination?’). Incontinence was defined as more than weekly leakage of urine over past four weeks. For the sake of simplicity, we assumed that all cases of incontinence in the final analytic cohorts were urgency incontinence after excluding men with a history of prostate cancer, surgery for BPE and neurological diseases from the analysis. OAB was defined according to the International Continence Society (ICS) consensus in 2002 (1): either urgency or urgency incontinence by above definitions. Since self-report is not always consistent or reliable, we assumed the presence of urgency if men had urgency incontinence. The storage subscore of the IPSS (IPSS-S) was calculated as the sum of questions number two, four, and seven (frequency, urgency and nocturia) (6). The voiding subscore of the IPSS (IPSS-V) was calculated as the sum of questions number one, three, five and six (incomplete emptying, intermittency, weak stream, and straining to void) (6).

Variables assessed at the interviews by trained personnel included the Mini-Mental State Examination (MMSE) (37) and functional disability using Katz activities of daily living (36). Also, participants brought medications that they had been taking daily or almost daily for at least the past month to the clinic visit. Poor mobility was defined as needing help with walking across a small room and/or transferring from bed to a chair (49). Use of urological medications (alpha blockers, five-alpha reductase inhibitors, and urinary-specific antispasmodics) and diuretics were determined from the medication inventory.

At the clinic visit, uroflowmetry was performed using Urodyn 1000 (Medtronic Functional Diagnostics A/S, Skovlunde, Denmark), and post-void residual urine volume (PVR) was measured using BladderScan BVI 3000 (Verathon Inc, Bothell, WA, USA). The uroflow graphs
were manually examined for artefacts. Peak flow rate and PVR were analysed only when the voided volume was 150mL and over.

The Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) (39) was administered by telephone shortly after the clinic visit. Men with an MMSE score of 26 or lower or an IQCODE score of 3.6 or higher had a detailed cognitive examination by a geriatrician. Diagnosis of dementia was reached using the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) (40) criteria at a consensus meeting attended by two geriatricians, a neurologist, and a neuropsychologist.

The self-administered questionnaire and clinical assessments were repeated at two- and five-year follow-up visits.

**Analysis**

Men who had neurological diseases (Parkinson’s Disease, stroke, and epilepsy) or prostate cancer at baseline or any follow-up points were excluded from the analyses because these conditions are likely to alter the course of OAB and incontinence. Men who had a history of surgery for BPE or were taking urological medications at baseline were excluded for the same reason. Having BPE surgery or starting urological medications during the five-year follow-up period were treated as an outcome that may indicate worsening of either OAB, BPE or impaired detrusor contractility.

Baseline characteristics of the analytic cohorts for OAB and incontinence are presented as either means (+standard deviations (SD)) or frequency distributions by OAB or continence status at baseline.
In the analytic cohorts, numbers of men who newly received treatment over five years were determined by baseline OAB and continence status. In men who did not receive surgery for BPE or urological medications over five years, the changes in OAB and continence status at baseline and two- and five-year follow-up are described. The men who had either OAB or urgency incontinence at baseline and did not have the conditions at both two- and five-year follow-up were deemed to have had sustained remission.

The characteristics of the men who experienced sustained remission of OAB without interventions for OAB or BPE were compared with those of the men who had persistent symptoms and had no interventions using Chi-square test. In addition, the characteristics of the men who received interventions over five years were described using proportions.

All analyses were performed using SAS version 9.3 (SAS Institute, Inc., Cary, NC, USA).

**RESULTS**

Of the 1705 participants at baseline, 382 (22%) deceased and 369 (22%) declined follow-up, leaving 954 men (56%) who were followed up for five years. Of the 954 men followed up for five years, 428 (45%) were excluded from the analyses because they had neurological diseases (n=96) or prostate cancer (n=137) at baseline or developed these conditions during five-year follow-up, or had a history of BPE surgery or were taking urological medications at baseline (n=226). After applying the above exclusion criteria, data on OAB were incomplete for 38 men (7%) and data on incontinence were incomplete for 27 (5%) men, leaving 488 men in the analytic cohort for OAB, and 499 men in the analytic cohort for incontinence. OAB and incontinence at baseline were more frequent by at least 5% in men who
subsequently died, in men who declined follow-up, and in men who were excluded because of medical conditions and treatment than in men included in the analyses (Table 3.1).

Table 3.1 Baseline prevalence of OAB and incontinence by inclusion/exclusion status to the analysis of OAB

<table>
<thead>
<tr>
<th></th>
<th>Analytical cohort</th>
<th>Incomplete data</th>
<th>Excluded&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Lost to follow-up</th>
<th>Deceased</th>
</tr>
</thead>
<tbody>
<tr>
<td>OAB</td>
<td>98</td>
<td>3</td>
<td>115</td>
<td>91</td>
<td>120</td>
</tr>
<tr>
<td>No OAB</td>
<td>390</td>
<td>21</td>
<td>305</td>
<td>264</td>
<td>249</td>
</tr>
<tr>
<td>Missing</td>
<td>0</td>
<td>14</td>
<td>8</td>
<td>14</td>
<td>13</td>
</tr>
<tr>
<td>Total&lt;sup&gt;a&lt;/sup&gt;</td>
<td>488</td>
<td>24</td>
<td>420</td>
<td>355</td>
<td>369</td>
</tr>
<tr>
<td>%OAB</td>
<td>20%</td>
<td>13%</td>
<td>27%</td>
<td>26%</td>
<td>33%</td>
</tr>
<tr>
<td>Incontinent</td>
<td>48</td>
<td>2</td>
<td>69</td>
<td>60</td>
<td>68</td>
</tr>
<tr>
<td>Continent</td>
<td>440</td>
<td>29</td>
<td>355</td>
<td>297</td>
<td>306</td>
</tr>
<tr>
<td>Missing</td>
<td>0</td>
<td>7</td>
<td>4</td>
<td>12</td>
<td>8</td>
</tr>
<tr>
<td>Total&lt;sup&gt;a&lt;/sup&gt;</td>
<td>488</td>
<td>31</td>
<td>424</td>
<td>357</td>
<td>374</td>
</tr>
<tr>
<td>%incontinent</td>
<td>10%</td>
<td>6%</td>
<td>16%</td>
<td>17%</td>
<td>18%</td>
</tr>
</tbody>
</table>

OAB, overactive bladder.

<sup>a</sup>Total does not include men with missing data. <sup>b</sup>‘Excluded’ includes men who were excluded from the analyses because of neurological diseases, prostate cancer, and urological treatment.

At baseline, 98 men (20%) had OAB and 48 (10%) had incontinence. Baseline characteristics of men included in the analyses for OAB and incontinence are presented in Table 3.2. Mean ages (<em>+SD</em>) were 74.5 (<em>+4.3</em>) years (range: 70 to 92 years) in men without OAB, and 76.3 (<em>+4.6</em>) years (range: 70 to 90) in men with OAB at baseline. Men with OAB had higher mean IPSS-V (<em>mean+SD</em>: 6.0±4.7) as well as IPSS-S (<em>mean+SD</em>: 7.5±3.1) than those without (means±SD: 1.7±2.5 and 2.9±2.0 respectively). There were no apparent differences in objective measures (peak flow rate and PVR) between men with and without OAB. None of the men with incontinence at baseline had either poor mobility or dementia, suggesting few if any had functional incontinence.
Table 3.2  Baseline characteristics of men included in analyses for OAB and incontinence

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th>Baseline status</th>
<th>Analytical cohort for OAB (n=488)</th>
<th>Analytical cohort for incontinence (n=499)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>no OAB (n=390)</td>
<td>OAB (n=98)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>mean±SD</td>
<td>74.5±4.3</td>
<td>76.3±4.6</td>
</tr>
<tr>
<td>Poor mobility</td>
<td></td>
<td>8 (2%)</td>
<td>2 (2%)</td>
</tr>
<tr>
<td>Dementia</td>
<td></td>
<td>3 (1%)</td>
<td>2 (2%)</td>
</tr>
<tr>
<td>Diuretic use</td>
<td></td>
<td>39 (10%)</td>
<td>16 (16%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td></td>
<td>57 (15%)</td>
<td>22 (22%)</td>
</tr>
<tr>
<td>IPSS</td>
<td>mean±SD</td>
<td>4.5±3.8</td>
<td>13.5±6.4</td>
</tr>
<tr>
<td>IPSS-S</td>
<td>mean±SD</td>
<td>2.9±2.0</td>
<td>7.5±3.1</td>
</tr>
<tr>
<td>IPSS-V</td>
<td>mean±SD</td>
<td>1.7±2.5</td>
<td>6.0±4.7</td>
</tr>
<tr>
<td>Peak flow (mL/s)</td>
<td>mean±SD</td>
<td>15.0±6.1</td>
<td>14.1±6.0</td>
</tr>
<tr>
<td>PVR (mL)</td>
<td>mean±SD</td>
<td>69.4±98.4</td>
<td>72.6±74.0</td>
</tr>
<tr>
<td>Daily incontinence</td>
<td>N.A.</td>
<td>19 (19%)</td>
<td>N.A.</td>
</tr>
</tbody>
</table>

OAB, overactive bladder; IPSS, International Prostate Symptom Score; IPSS-S, storage subscore of the IPSS; IPSS-V, voiding subscore of the IPSS; PVR, post-void residual urine volume.

Figure 3.1 shows the changes in OAB status over five years. Of men with OAB at baseline, 28 (29%) received interventions for OAB or BPE over five years, compared to 41 (11%) men without baseline OAB. The natural course of OAB could be observed for the 70 men with OAB at baseline who did not undergo any intervention over five years. Of these men, 23 (33%) no longer had OAB at both 2-year and 5-year follow-up (sustained remission, shown in bold letters in Figure 3.1). Of the men who had OAB at 2-year follow-up (shown in italics in Figure 3.1), remission rates at 5-year follow-up were 53% (n=20) in men without OAB at baseline, and 27% (n=9) in men with OAB at baseline (p=0.23).
Figure 3.1 Natural history of OAB in community-dwelling older men

OAB, overactive bladder.

a ‘Intervention’ refers to those for OAB or benign prostate enlargement.

b Bold letters indicate sustained remission, which is 23 men out of 70 men with OAB at baseline whose natural course over five years was observed (33%).

c Italics indicate the comparison of remission rates of OAB between 2- and 5-year follow-up by baseline OAB status.

Figure 3.2 shows the changes in continence status over five years. Of men with incontinence at baseline, 15 (31%) received treatment over five years compared to 54 (12%) of men without incontinence. Of the 33 men with incontinence at baseline who did not undergo any intervention for OAB or BPE over five years, 17 (52%) no longer had incontinence at both 2-year and 5-year follow-up (sustained remission, shown in bold letters in Figure 3.2). Of the men who had incontinence at 2-year follow-up (shown in italics in Figure 3.2), remission
rates at 5-year follow-up were 57% (n=16) in men without incontinence at baseline, and 45% (n=5) in men with incontinence at baseline (p=0.72).

Figure 3.2 Natural history of urgency incontinence in community-dwelling older men

‘Intervention’ refers to those for overactive bladder or benign prostate enlargement.

\(^a\) Bold letters indicate sustained remission, which is 17 men out of 33 men with incontinence at baseline whose natural course over 5 years was observed (52%).

\(^b\) Italic letters indicate the comparison of remission rates of incontinence between 2- and 5-year follow-up by baseline continence status.
Table 3.3 compares baseline characteristics of men with sustained remission of OAB to those who had persistent symptoms. In addition, baseline characteristics of men who were excluded from the analysis of natural course of OAB (those who received intervention for OAB or BPE during follow-up) are shown. A higher proportion of men with persistent symptoms of OAB had diabetes (n=13 (28%)) and were using diuretics (n=11 (23%)) at baseline compared with men who had sustained remission (diabetes: n=3 (13%), p=0.17, diuretics: n=3 (13%), p=0.31) although the differences were not statistically significant. Only one of 20 (5%) men with sustained remission had high baseline IPSS-V compared to six (13%) in men with persistent symptoms (p=0.33). No notable difference was seen in other variables between men who had sustained remission and those with persistent symptoms without intervention.
Table 3.3  Baseline characteristics of men with OAB at baseline by clinical course over five years

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th>Clinical course over five years</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No intervention for OAB or BPE</td>
<td>Sustained remission n=23</td>
<td>Persistent symptoms n=47</td>
<td>p-value $^a$</td>
</tr>
<tr>
<td>Age $\geq 80$</td>
<td>4/23 (17%)</td>
<td>10/47 (21%)</td>
<td>0.70</td>
<td>6/28 (21%)</td>
</tr>
<tr>
<td>Poor mobility</td>
<td>0/13 (0%)</td>
<td>2/47 (4%)</td>
<td>0.33</td>
<td>0/28 (0%)</td>
</tr>
<tr>
<td>Dementia</td>
<td>0/23 (0%)</td>
<td>2/44 (5%)</td>
<td>0.30</td>
<td>0/28 (0%)</td>
</tr>
<tr>
<td>Diuretics use</td>
<td>3/23 (13%)</td>
<td>11/47 (23%)</td>
<td>0.31</td>
<td>2/28 (7%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>3/23 (13%)</td>
<td>13/47 (28%)</td>
<td>0.17</td>
<td>6/28 (21%)</td>
</tr>
<tr>
<td>IPSS $&gt;20$</td>
<td>2/20 (10%)</td>
<td>9/46 (20%)</td>
<td>0.34</td>
<td>7/26 (27%)</td>
</tr>
<tr>
<td>IPSS-S $&gt;9$</td>
<td>6/20 (30%)</td>
<td>20/46 (43%)</td>
<td>0.30</td>
<td>12/26 (46%)</td>
</tr>
<tr>
<td>IPSS-V $&gt;12$</td>
<td>1/20 (5%)</td>
<td>6/46 (13%)</td>
<td>0.33</td>
<td>6/26 (23%)</td>
</tr>
<tr>
<td>Peak flow $&lt;15mL/s$</td>
<td>11/16 (69%)</td>
<td>19/35 (54%)</td>
<td>0.33</td>
<td>13/14 (93%)</td>
</tr>
<tr>
<td>PVR $&gt;50mL$</td>
<td>9/16 (56%)</td>
<td>13/31 (42%)</td>
<td>0.35</td>
<td>8/13 (62%)</td>
</tr>
<tr>
<td>$&gt;\text{Daily incontinence}$</td>
<td>3/23 (13%)</td>
<td>9/47 (19%)</td>
<td>0.52</td>
<td>7/28 (25%)</td>
</tr>
<tr>
<td>$&gt;\text{Weekly incontinence}$</td>
<td>13/23 (57%)</td>
<td>20/47 (43%)</td>
<td>0.27</td>
<td>15/28 (54%)</td>
</tr>
</tbody>
</table>

OAB, overactive bladder; BPE, benign prostatic enlargement; IPSS, International Prostate Symptom Score; IPSS-S, storage subscore of the IPSS; IPSS-V, voiding subscore of the IPSS; PVR, post-void residual urine volume.

Among men with OAB at baseline who had no intervention for OAB and BPE over 5-year follow-up period, sustained remission was defined as not having OAB at both 2-year and 5-year follow-up. Men who did not have sustained remission were categorized as having persistent symptoms.

$^a$Proportions were compared between men with sustained remission and those with persistent symptoms by Chi-square test.
DISCUSSION

To our knowledge, this is the first study to explore the natural history of non-neurogenic OAB and urgency incontinence in a representative sample of community-dwelling older men taking the potential effects of treatment into account. Of 70 men with OAB at baseline who had no surgical or medical intervention during five-year follow-up, a third no longer had OAB at both two- and five-year follow-up.

Previous population-based longitudinal studies that have examined progression and remission of OAB and incontinence in men (14, 15, 46) also found that OAB and incontinence status changed dynamically over time but did not account for medical treatment and conditions that can alter the clinical course. OAB and incontinence in men with neurological diseases may be more persistent, while incontinence caused by urological procedures such as TURP, radical prostatectomy, radiotherapy can be temporary. Our study focused on non-neurogenic idiopathic OAB and urgency incontinence.

All cases of incontinence in the analytic cohorts were assumed to be urgency incontinence. Men with common causes of other types of incontinence (such as neurological diseases, prostate cancer, and surgery for BPE) were excluded. Since we only included men who were followed up for five years, the analytic cohorts consisted of relatively healthy men with low baseline prevalence of poor mobility and dementia, suggesting few men had functional incontinence. Although overflow incontinence cannot be excluded, a study of nursing home residents suggests that this is a rare cause of incontinence even in an older and sedentary population (50).
Remission rates of OAB between 2- and 5-year follow-up was higher in men without OAB at baseline compared to men with OAB at baseline, but the difference was not significant. It is possible that OAB of recent onset may have a better chance of remission without treatment but a larger study would be warranted. Remission of incontinence between 2- and 5-year follow-up did not seem to depend on previous continence status. There was also a suggestion that taking diuretics, having diabetes and more severe voiding symptoms decreases the chances of spontaneous remission, but this also needs to be explored in a larger study as the findings were not statistically significant in this study.

This is a population-based study where urinary symptoms were measured using validated questionnaires. The primary strength of our study is that, unlike past studies, we had data on interventions for OAB and BPE so could separate out potential improvement of symptoms due to interventions. In addition, we determined the rates of sustained remission using data from three time points as opposed to only two time points. OAB is often a chronic condition that fluctuates over time: in our study, among the 38 men who had OAB both at baseline and at 5-year follow-up, 14 had a temporary remission at 2-year follow-up but developed OAB again at 5-year follow-up. Therefore, we judged that determining a rate of sustained remission would be more informative.

Our study has some limitations. Firstly, the results may only apply to non-neurogenic OAB in healthier older men. Men who died or declined follow-up were older and larger proportions of these men had poor mobility, dementia and more severe voiding symptoms. Since these factors seemed to predict persistent PVR in our study, although they lacked statistical significance, it is possible that remission rate was overestimated because of the attrition. Secondly, even after excluding men with neurological disorders and history of urological
procedures, our simplified definition of urgency incontinence may have included other types of incontinence such as overflow and stress incontinence and post-void dribble. Thirdly, although we aimed to look at non-neurogenic and idiopathic OAB, we did not have information on transient causes of OAB such as urinary tract infection, alcohol, caffeine, or fluid intake. We tried to exclude these transient causes by asking about the symptoms in the past month using the IPSS and the ICIQ. Lastly, the sample size was too small to analyse the predictors of sustained remission.

CONCLUSION

One in three older men with non-neurogenic OAB had sustained remission of symptoms for five years without medical or surgical interventions for either OAB or BPE. No significant predictor of sustained remission was identified.
4. Natural history of elevated PVR over five years in community-dwelling older men: the CHAMP study

Publication details:
ABSTRACT

Objectives To describe the natural history of post-void residual urine volume (PVR) in community-dwelling older men.

Design Prospective cohort study.

Setting Concord Health and Ageing in Men Project

Participants A representative sample of community-dwelling men aged 70 and older in a defined geographic area of Sydney, Australia. Three hundred twenty nine men who did not have neurological disorders or prostate cancer at any follow-up point or a history of urological treatment at baseline were included in the analyses.

Measurements The participants underwent uroflowmetry and PVR measurement at baseline and two-year and five-year follow-up. PVR was considered valid when the voided volume was 150mL and over.

Results Baseline PVR were 0-49mL in 183 men, 50-99mL in 59 men, 100-199mL in 72 men, 200-399mL in 11 men and 400mL and over in four men. Fifteen out of 325 (5%) men with a baseline PVR of less than 400mL had surgery for benign prostate enlargement (BPE) or indwelling catheterization over five years compared to three out of four men (75%) with a PVR of 400mL and over. In all 101 men with a baseline PVR of less than 400mL who did not receive urological treatment during follow-up and had valid PVR data for both two-year and five-year follow-up, PVR did not exceed 400mL at either follow-up time point.

Conclusion The majority of older men with incidentally found elevated PVR of up to 400mL may be managed conservatively for at least five years.
INTRODUCTION

Asymptomatic, elevated post-void residual urine volume (PVR) is often found incidentally in older men although the prevalence in the general population has not been studied (51).

Elevated PVR in older men is usually caused by a combination of bladder outlet obstruction (BOO) and underactive bladder (UAB), both of which may be multifactorial. BOO in older men is most often due to benign prostatic enlargement (BPE) but other causes include urethral stricture and bladder neck obstruction. UAB can be of neurogenic and/or myogenic aetiology. Elevated PVR may result in complications such as urinary retention, urinary tract infection (UTI) or renal impairment (16).

From a 12-year follow-up of a random sample of community-dwelling men, Rule et al showed that extreme values of PVR tended to move closer to the mean, reflecting regression to the mean (19). It is, therefore, speculated that most cases of elevated PVR may resolve without complications. It is, however, unclear at what level of PVR it is safe not to undertake extensive investigations or treatment such as surgery or indwelling catheterization.

The aim of this study was to describe the natural history of PVR in community-dwelling men without neurological diseases, prostate cancer, urological medications or surgery. Firstly, the five-year incidence of indwelling catheterization, surgical and medical treatment for benign prostate enlargement (BPE) and hospitalization for urinary retention and UTI was determined according to baseline PVR category. Secondly, the shift of PVR between volume categories at baseline and two- and five-year follow-up was determined in men who did not receive any urological treatment during follow-up.
METHODS

Study participants

The Concord Health and Ageing in Men Project (CHAMP) is a prospective cohort study of a wide range of health issues in older men. The study was approved by the Concord Hospital Human Research Ethics Committee. All participants gave written informed consent.

CHAMP involves 1705 men aged 70 years and over living in the community in a defined geographical region of metropolitan Sydney. The sampling frame was the New South Wales Electoral Roll, on which registration is compulsory. The participation rate was 47%. The details of the sample selection process have been described previously (43). Baseline data were collected between January 2005 and June 2007.

Measurements

Men completed a questionnaire at home before attending the study clinic. This included questions on demographic characteristics, history of diagnosed medical conditions including diabetes, stroke, Parkinson’s Disease, epilepsy and prostate cancer, lower urinary tract symptoms (LUTS) (the International Prostate Symptom Score (IPSS) (5) and the International Consultation on Incontinence Questionnaire (ICIQ) (34)) and history of surgery for BPE.

At the clinic visit, uroflowmetry was performed using Urodyn 1000 (Medtronic Functional Diagnostics A/S, Skovlunde, Denmark), and immediately afterwards, a trained nurse measured PVR using BladderScan BVI 3000 (Verathon Inc, Bothell, WA, USA). The uroflow graphs and ultrasonographic images to measure PVR were manually examined for artifacts. Maximum urinary flow rate (Qmax) and PVR were analysed only when the voided volume was 150mL and over. Indwelling catheterization was noted at the clinic visit as a reason for
inability to perform uroflowmetry and PVR measurement. Participants also brought to the clinic all prescription and over-the-counter medications that they had been taking daily or almost daily for at least the past month. Use of urological medications (alpha blockers, 5α reductase inhibitors and urinary-specific antispasmodics) and other medications with anticholinergic properties was determined from the medication inventory. The registered product information from the Medicare Information Management System was used to identify medications with clinically significant anticholinergic effects (52).

The self-administered questionnaire and clinical assessments were repeated at two- and five-year follow-up visits.

In addition, participants were interviewed by telephone every four months during which they were asked if they had been hospitalized in the previous four months, and if so, for what reason.

**Analysis**

Men who had neurological diseases (Parkinson’s Disease, stroke and epilepsy) or prostate cancer at any time point and men who had had surgery for BPE or were taking urological medications at baseline were excluded from the analyses because these are likely to alter PVR. Baseline characteristics of the analytic cohorts are presented as either means (+/- standard deviations (SD)) or frequency distributions. PVR was categorized by volume into 0-49mL, 50-99mL, 100-199mL, 200-399mL and 400mL and over. Since there is no consensus on cut-off values for PVR, we have set these arbitrary cut-off values. 200-299mL and 300-399mL were combined because they had small sample size and had similar results.
Two analyses were conducted. Firstly, the five-year incidence of indwelling catheterization, medical or surgical treatment for BPE and hospitalizations for urinary retention or UTI was determined by baseline PVR category in men with valid baseline PVR data who were followed up for five years (incidence of related events analysis). Changes in PVR between baseline and two- and five-year follow-up were described by volume category in men who had valid PVR data at all three time points and did not receive surgery for BPE nor urological medications during follow-up (changes in PVR analysis). All analyses were performed using SAS version 9.3 (SAS Institute, Inc., Cary, NC, USA).
RESULTS

Figure 4.1 shows the reasons for exclusions from the analyses. Of the 1705 participants at baseline, 382 (22%) died and 369 (22%) declined follow-up, leaving 954 (56%) who were followed up for five years. Of these 954 men, 428 (45%) were excluded because they had neurological diseases (n=153) or prostate cancer (n=137) at baseline or developed these conditions during the five-year follow-up, or had a prior history of BPE surgery (n=164) or were taking urological medications (n=69) at baseline. Of the 526 neurologically and urologically intact men, 196 (37%) did not have valid PVR data at baseline: 134 (25%) either voided less than 150mL or were unable to void at all (the median PVR for men who voided less than 150mL or were unable to void was 22mL); the portable scanner was unavailable for 33 (6%); and 29 (6%) either refused or reason was unclear. The remaining 329 men who had valid PVR data at baseline were included in the incidence of related events analysis. For the changes in PVR analysis, we further excluded 45 men (14%) who received either BPE surgery or urological medications during follow-up and 182 men (55%) who did not have valid PVR data at either two-year or five-year follow-up, leaving 102 men (31%) to be analysed.
Figure 4.1. Study participant exclusions from each analysis

1705 at baseline
- 382 (22%) died
- 369 (22%) declined follow-up

954 (56%) followed up for five years
- 428 (45%) ineligible
  - 153 (16%) neurological disorders at baseline or follow-up points
  - 137 (14%) prostate cancer at baseline or follow-up points
  - 164 (17%) BPE surgery at baseline
  - 69 (7%) urological medications at baseline

526 (55%) neurologically and urologically intact*
- 196 (37%) did not have valid PVR data at baseline
  - 134 (25%) voided less than 150mL or unable to void at all
  - 33 (6%) portable scanner was unavailable
  - 6 (1%) declined PVR measurement
  - 23 (4%) reasons unclear

329 (63%) had valid PVR data at baseline
  (included in the incidence of related events analysis)
- 45 (14%) received BPE surgery or urological medications during follow-up

284 (86%) remained urologically intact* during follow-up
- 182 (64%) did not have valid PVR data at either follow-up points

102 (36%) had valid PVR data at baseline and follow-up points
  (included in the changes in PVR analysis)

BPE = benign prostatic enlargement. PVR = post-void residual urine volume.

Participants could have more than one reason for ineligibility. *’Neurologically intact’ refers to having no neurological disorders. ‘Urologically intact’ refers to having no prostate cancer, no history of BPE surgery and taking no urological medications.
Table 4.1 shows the baseline characteristics of the analytic cohorts. In the analytic cohort for the incidence of related events, mean age (±SD) was 75.0 (±4.6) years (range: 70 to 92 years) and mean PVR (±SD) was 68.9 (±92.6) mL (range: 0 to 842mL). Eight percent were taking medications with anticholinergic properties such as tricyclic anti-depressants, beta-blockers and medications for gout. Men who died and those who declined follow-up were slightly older than the analytic cohort (mean (±SD) ages of 80.1±6.1 and 77.4±5.6 respectively). Men who did not have valid PVR data at either baseline and/or at follow-up points had similar baseline characteristics to men who were included in the analyses.

Table 4.1. Baseline characteristics of men included in the incidence of related events analysis and changes in PVR analysis

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th>Incidence of related interventions and hospitalizations analysis n=329</th>
<th>Changes in PVR analysis n=102</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years, mean±SD)</td>
<td>75.0±4.6</td>
<td>74.3±4.1</td>
</tr>
<tr>
<td>IPSS (mean±SD)</td>
<td>6.2±5.4</td>
<td>5.4±4.4</td>
</tr>
<tr>
<td>Weekly incontinence (n (%))</td>
<td>Yes 33 (10%)</td>
<td>No 294 (90%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 (6%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>95 (94%)</td>
</tr>
<tr>
<td>PVR (mL, mean±SD)</td>
<td>68.9±92.6</td>
<td>79.2±98.0</td>
</tr>
<tr>
<td>Qmax (mL/sec, mean±SD)</td>
<td>14.7±6.0</td>
<td>15.7±6.4</td>
</tr>
<tr>
<td>Diabetes (n (%))</td>
<td>Yes 50 (15%)</td>
<td>No 277 (85%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15 (15%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>87 (85%)</td>
</tr>
<tr>
<td>Use of medications with anticholinergic effect (n (%))</td>
<td>Yes 25 (8%)</td>
<td>No 302 (92%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5 (5%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>97 (95%)</td>
</tr>
</tbody>
</table>

SD = standard deviation. IPSS = International Prostate Symptom Score. PVR = post-void residual urine volume. Qmax = maximum urinary flow rate. The sum of numbers in each category may not add up to the total number because of missing data.
Table 4.2 shows the five-year incidence of indwelling catheterization, medical or surgical treatment for BPE and hospitalizations for urinary retention and UTI in the 329 men with valid baseline PVR data. Only 15 out of 325 (5%) with a baseline PVR of less than 400mL received surgery for BPE during the follow-up. Of the four men with a baseline PVR of 400mL and over, three had BPE surgery, one of whom also received indwelling catheterization. Only five men (2%) in this analytic cohort were hospitalized for UTI and only two men (0.6%) for urinary retention and there was no association with baseline PVR.

Table 4.2. Five-year incidence of medical or surgical treatment for benign prostate enlargement, indwelling catheterization and hospitalizations for urinary retention or urinary tract infection (n=329)

<table>
<thead>
<tr>
<th>Baseline PVR</th>
<th>Indwelling catheterization</th>
<th>BPE surgery</th>
<th>BPE medications only</th>
<th>Hospitalization for UTI</th>
<th>Hospitalization for retention</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>0-49mL</td>
<td>183 (0%)</td>
<td>6 (3%)</td>
<td>11 (6%)</td>
<td>1 (0.5%)</td>
<td>1 (0.5%)</td>
</tr>
<tr>
<td>50-99mL</td>
<td>59 (0%)</td>
<td>5 (7%)</td>
<td>5 (7%)</td>
<td>3 (5%)*</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>100-199mL</td>
<td>72 (0%)</td>
<td>2 (3%)</td>
<td>9 (13%)</td>
<td>1 (1%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>200-399mL</td>
<td>11 (0%)</td>
<td>2 (18%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>400mL+</td>
<td>4 (25%)*</td>
<td>3 (75%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1 (25%)‡</td>
</tr>
</tbody>
</table>

PVR = post-void residual urine volume. BPE = benign prostate enlargement. UTI = urinary tract infection.

*One man had two hospitalizations for UTI and had BPE surgery between these events. Another man received BPE surgery before the hospitalization for UTI. †One man received indwelling catheterization after receiving BPE surgery. ‡One man who was hospitalized for urinary retention later received BPE surgery.
Table 4.3 shows the changes in PVR over five years in the 102 men who had valid PVR data at all three time points and did not receive BPE surgery or urological medications during follow-up. Shifts towards lower PVR categories were commonly observed. None of the 101 men with a PVR of less than 400mL at baseline had a PVR of 400mL and over at either two- or five-year follow-up. One man with a PVR of 842mL had a PVR of 448mL at two-year follow-up and 853mL at five-year follow-up with voided volumes of 459mL, 641mL and 452mL respectively.
Table 4.3. Changes in PVR over five years by baseline PVR category (n=102)

<table>
<thead>
<tr>
<th>Baseline</th>
<th>n</th>
<th>2-year follow-up</th>
<th>n</th>
<th>5-year follow-up</th>
<th>n</th>
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<tbody>
<tr>
<td>0-49mL</td>
<td>44</td>
<td>0-49mL</td>
<td>23</td>
<td>0-49mL</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>50-99mL</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>100-199mL</td>
<td>3</td>
</tr>
<tr>
<td>50-99mL</td>
<td>12</td>
<td>0-49mL</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
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<tr>
<td></td>
<td></td>
<td>100-199mL</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>100-199mL</td>
<td>8</td>
<td>0-49mL</td>
<td>2</td>
<td></td>
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<td></td>
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<tr>
<td></td>
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<td>200-399mL</td>
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<td></td>
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<tr>
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<tr>
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<td>0-49mL</td>
<td>3</td>
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<td>100-199mL</td>
<td>1</td>
<td></td>
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<tr>
<td>50-99mL</td>
<td>15</td>
<td>0-49mL</td>
<td>3</td>
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</tr>
<tr>
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<td>0-49mL</td>
<td>2</td>
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<tr>
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<td>100-199mL</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
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<td>14</td>
<td>0-49mL</td>
<td>1</td>
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<td></td>
<td></td>
<td>50-99mL</td>
<td>3</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>100-199mL</td>
<td>7</td>
<td></td>
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<td></td>
<td>200-399mL</td>
<td>3</td>
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<td>1</td>
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</tr>
<tr>
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<td>100-199mL</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>400mL+</td>
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<td>400mL+</td>
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</tbody>
</table>

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DISCUSSION

This is the first study to report the natural course of different levels of elevated PVR including the need for treatment and adverse events requiring hospitalization. It extends the work of Rule et al, which involved 529 randomly selected community-dwelling men in the Olmsted (Mayo) cohort (19). Using a regression model, they found a negative correlation between baseline PVR and the mean annual change in PVR indicating that elevated PVR tend to decrease, but did not report the natural course of different levels of elevated PVR.

The natural course of PVR observed in our study is consistent with the negative correlation between baseline PVR and the following change found in the study by Rule et al. We also observed the phenomenon of regression to the mean (19): extreme measurements in either direction tended to move closer to the average at the next measurement. This phenomenon may be particularly notable for PVR because there are wide within-individual variations in PVR in men even within a short period of time (53) and, therefore, the first measurement may capture the highest or the lowest of the fluctuating PVRs.

Only a small minority of men in our study with a PVR of less than 400mL received surgery for BPE and, in men who did not receive urological treatment, PVR did not exceed 400mL over five years. We also found that older men with a PVR of less than 400mL rarely require hospitalization for urinary retention and UTI within 5 years.

On the other hand, most of the small number of men with a high PVR of 400mL and over received indwelling catheterization or surgery for BPE over five years. The only person in this group who did not receive catheterization or BPE surgery remained in the 400mL and over range over the next five years.
Baseline PVR did not seem to predict hospitalization for urinary retention and UTI in our study. This is consistent with a previous study that found that PVR did not predict bacteriuria in asymptomatic men who underwent transrectal ultrasonography of the prostate (54). Similarly, another study found that PVR in untreated men with BPE does not predict subsequent acute urinary retention (55).

In this study, men with conditions that are likely to alter PVR were excluded from the analyses. In fact, in men with prostate cancer and those with a history of BPH surgery, baseline PVR were lower in general and remained low during follow-up compared to the men included in the analyses. In contrast, in men with neurological disorders, there was no tendency of PVR regressing to the mean and, in a few men, PVR kept increasing and exceeded 400mL during follow-up. These observations support the decision we made to look at the natural history of PVR in men without neurological disorders, prostate cancer and a history of urological treatment.

A strength of our study is that it is a population-based study of community-dwelling older men whereas the findings from previous studies in urological patients may not be applicable to asymptomatic patients. The large sample size at baseline in our study allowed for reasonable numbers of men to study the natural history even after excluding underlying neurological and urological conditions. As the study participants were not specifically asked to drink water before the clinic assessment, a large number of men were excluded from the analysis because they were unable to void sufficient urine to record valid PVR data. The losses were likely to be random, however, because the baseline characteristics were similar between the men with missing PVR data and those included in the analyses. On the other hand, as the bladder was not artificially distended, our study reported on natural voiding.
Our study has other limitations beyond excluding men with invalid PVR data and the small sample size in higher volume categories. Men who died or declined follow-up were older and larger proportions of these men had diabetes or were taking anticholinergic medications which can impair detrusor contractility. It is, therefore, possible that elevated PVR in these men was more persistent. PVR was measured with a portable ultrasound scanner rather than by urinary catheterization which was too invasive for a population-based study of mostly asymptomatic participants. In any case, measurement of PVR using portable scanners has a good correlation with drainage by catheterization (r=0.93) (56).

With regards to the recording of adverse events during follow-up, urinary retention or UTI that did not require hospitalization or temporary catheterization would have been missed, and therefore the occurrence of adverse outcomes would have been underestimated. This underestimation would have reduced our statistical power to detect associations between baseline PVR and adverse events within five years of follow-up.

In conclusion, in men with incidentally found elevated PVRs of less than 400mL, a small minority required surgery for BPE or indwelling catheterization over the next five years and, in all the men who remained untreated, PVR did not exceed 400mL over five years. The present findings may suggest that a majority of these men may be managed conservatively for at least five years.
5. A systematic review of the association between LUTS and falls, injuries and fractures in community-dwelling older men

Publication details:

ABSTRACT

Background  Lower urinary tract symptoms (LUTS) have been associated with falls in studies either exclusively or predominantly of women. It is, therefore, less clear if LUTS are risk factors for falls in men.

Methods  We conducted a systematic review of the literature on the association between LUTS and falls, injuries and fractures in community-dwelling older men. Medline, Embase and Cinahl were searched for any type of observational study that has been published in a peer-reviewed journal in English language. Studies were excluded if they did not report male-specific data or targeted specific patient populations. Results were summarized qualitatively.

Results  Three prospective cohort studies and six cross-sectional studies were identified. Incontinence, urgency, nocturia, and frequency were consistently shown to have weak to moderate association with falls (the point estimates of odds ratio and relative risk ranged from 1.31 to 1.67) in studies with low risk of bias for confounding. Only frequency was shown to be associated with fractures.

Conclusions  Urinary incontinence and lower urinary tract storage symptoms are associated with falls in community-dwelling older men. The circumstances of falls in men with LUTS need to be investigated to generate hypotheses about what types of interventions may be effective in reducing falls.
INTRODUCTION

Falls are common among older people and often result in injuries (57). A systematic review by Chiarelli et al in 2009 (23) showed that lower urinary tract symptoms (LUTS) such as incontinence, urgency, and nocturia were associated with falls. Most studies included in the review, however, were exclusively or predominantly of women. The patterns of co-occurrence and severity of LUTS are different between men and women (58). In addition, there may be gender-related behavioural differences in strategies to manage LUTS which could also influence fall risk. There has not been a systematic review on the association between LUTS and falls that focuses on men and it is, therefore, less clear if LUTS are risk factors for falls in men.

We conducted a systematic review of the literature to determine if LUTS were associated with falls, injuries and fractures in community-dwelling older men. We also examined whether this association was influenced by type and severity of LUTS.

SEARCH STRATEGY AND SELECTION CRITERIA

The protocol was registered in the PROSPERO database (CRD42014009354).

Data sources and searches

One investigator (NN) carried out a systematic literature search in Medline (1966 to August 2015), Embase (1980 to August 2015) and Cinahl (1982 to August 2015). A search strategy was constructed with the assistance of a medical librarian. Terms for LUTS, such as urgency, frequency, nocturia, and incontinence, were used in combination with terms for falls,
injuries, and fractures. The full search strategy for Medline is presented in Figure 5.1. In each database, terms were searched as index terms where available or otherwise searched as key words within title and abstract. All the retrieved studies on the association between LUTS and falls regardless of study population were utilized to identify further eligible studies: reference lists were examined and publications that cited these studies were also identified using PubMed.

Figure 5.1 Search strategy for Medline

1 exp Lower Urinary Tract Symptoms/
2 exp Prostatism/
3 exp Urinary Bladder, Overactive/
4 urinary urgency.tw.
5 urinary frequency.tw.
6 frequent urination.tw.
7 exp Nocturia/
8 exp Urinary Incontinence/
9 incomplete emptying.tw.
10 impaired emptying.tw.
11 urinary intermittency.tw.
12 intermittent urination.tw.
13 weak stream.tw.
14 slow stream.tw.
15 strain* to void.tw.
16 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15
17 exp Accidental Falls/
18 exp Accidents/
19 exp Fractures, Bone/
20 exp “Wounds and Injuries”/
21 17 or 18 or 19 or 20
22 16 and 21
23 limit 22 to (english language and humans)
**Study selection**

One investigator (NN) scanned titles and abstracts, and evaluated full texts of potentially relevant studies referring to the prespecified inclusion and exclusion criteria as follows. Studies were considered for inclusion if they (1) included community-dwelling men with a mean age of 60 years and older, and (2) determined the associations of LUTS with falls, injuries and fractures. Studies were excluded if they (1) did not report male-specific data, or (2) targeted specific patient populations such as dementia or post-urological procedures. The search was limited to English language but no restriction was set for time of publication. Any type of observational study published in a peer-reviewed journal was included.

**Data extraction and quality assessment**

One investigator (NN) extracted data about the study characteristics and the estimates of associations. Another investigator (VN) checked the extracted data for accuracy. Results from multivariate analyses, if available, were selected. When estimates of associations were unavailable, unadjusted measures of association were calculated from raw data.

Methodological quality of included studies was assessed by one investigator (NN) using an adaptation of the study quality check list that Stalenhoef et al used in their systematic review of fall risk factors (59). Another investigator (VN) verified the quality assessment.

**Data synthesis and analysis**

Data were synthesized qualitatively structured around each LUTS. Types and severity of LUTS were taken into account where available. Because this is a review of observational studies, meta-analysis was not conducted and we focused on examining possible sources of heterogeneity between studies (60).
RESULTS

Selection of studies

Figure 5.2 shows the selection process for relevant studies. A search of the databases identified 2431 studies after removing duplicates. Two thousand four hundred and eight were excluded after reviewing titles and abstracts including 19 that were not community-based and 10 that were studies of women. After 23 full texts were retrieved, 14 studies were excluded because they did not meet the inclusion criteria: one included only younger men, nine did not report male-specific data, and four did not examine the association of interest. No additional study was identified from reference lists of retrieved articles. Nine studies that met all the inclusion and exclusion criteria were included in the review for qualitative synthesis (61-69).
Figure 5.2. Selection process of relevant studies

*Excluding duplicates within databases. †Reasons for exclusion after screening titles and abstracts include off topic (n=2362), case report (n=1), letters to editors or opinion papers (n=10), not community-based (n=19), study of women (n=10), and systematic review (n=6). ‡Reasons for exclusion after assessing full text include younger participants (n=1), male-specific data not available (n=9), did not examine the association (n=4).
**Appraisal of studies**

Table 5.1 summarizes the characteristics and the results of the included studies. The studies are listed chronologically. Studies by Parsons et al and Frost et al were large prospective studies exclusively of men (65, 68). Another study by Nakagawa et al was also prospective but had a small sample size (66). The cross-sectional studies by de Rekeneire et al, Asplund et al, and Foley et al also had large sample size of men (63, 64, 67). The study by Parsons et al looked at all the symptoms in the International Prostate Symptom Score (IPSS) (5) questionnaire individually (65). The other studies examined only one symptom each. Outcomes included one or more falls (any fall) (61-63, 65, 67, 69), two or more falls (recurrent falls) (65), any fracture (61, 66, 68), hip fractures (64), and osteoporotic fractures (68). Observation or recall periods were one year for falls and five years for fractures.
Table 5.1  Characteristics and results of the included studies

<table>
<thead>
<tr>
<th>Source</th>
<th>Country</th>
<th>Age</th>
<th>Sample size</th>
<th>Study design</th>
<th>Study factor</th>
<th>Outcome</th>
<th>Period</th>
<th>Association statistic</th>
</tr>
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<tbody>
<tr>
<td>Stewart 1992</td>
<td>USA</td>
<td>65+</td>
<td>520</td>
<td>Cross-sectional</td>
<td>Nocturia</td>
<td>Any fall</td>
<td>12mo</td>
<td>OR=1.93 (1.00-2.68)</td>
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<tr>
<td></td>
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<td></td>
<td>Any fracture</td>
<td>5y</td>
<td>OR=0.69 (0.35-1.34)</td>
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<td>Yasumura 1994</td>
<td>Japan</td>
<td>65-84</td>
<td>366</td>
<td>Cross-sectional</td>
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<td>12mo</td>
<td>OR=2.9 (0.8-10.4)</td>
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<tr>
<td>de Rekeneire 2003</td>
<td>USA</td>
<td>70-79</td>
<td>1447</td>
<td>Cross-sectional</td>
<td>Incontinence</td>
<td>Any fall</td>
<td>12mo</td>
<td>OR=1.5 (1.1-2.0)</td>
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<td>Asplund 2006</td>
<td>Sweden</td>
<td>73±6.0</td>
<td>2411</td>
<td>Cross-sectional</td>
<td>Nocturia</td>
<td>Hip fracture</td>
<td>5y</td>
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<td>Once - 3.2%*</td>
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<td></td>
<td></td>
<td></td>
<td>3 times - 6.8%*</td>
</tr>
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<td>Any fall</td>
<td>1y</td>
<td>RR=1.19 (1.06-1.33)</td>
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<tr>
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<td></td>
<td></td>
<td>Frequency</td>
<td>Any fall</td>
<td>1y</td>
<td>RR=1.39 (1.16-1.66)*</td>
</tr>
<tr>
<td></td>
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<td></td>
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<td>Recurrent falls</td>
<td>1y</td>
<td>RR=1.17 (1.04-1.33)†</td>
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<tr>
<td></td>
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<td>Intermitiency</td>
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<td>1y</td>
<td>RR=1.12 (1.02-1.53)†</td>
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<td></td>
<td></td>
<td>Recurrent falls</td>
<td>1y</td>
<td>RR=1.00 (0.98-1.23)†</td>
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<td>1y</td>
<td>RR=1.31 (1.17-1.47)†</td>
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<td>Recurrent falls</td>
<td>1y</td>
<td>RR=1.20 (1.09-1.42)†</td>
</tr>
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<td>RR=1.14 (1.06-1.46)†</td>
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<td></td>
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<td>Recurrent falls</td>
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<td>RR=1.60 (1.27-2.02)†</td>
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<td>RR=1.23 (1.08-1.41)†</td>
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<td>Recurrent falls</td>
<td>1y</td>
<td>RR=1.42 (1.16-1.74)†</td>
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<td>IPSS score</td>
<td>Any fall</td>
<td>1y</td>
<td>RR=1.13 (1.15-1.53)§</td>
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<td>Recurrent falls</td>
<td>1y</td>
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<td>2352</td>
<td>Cross-sectional</td>
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<td>1y</td>
<td>OR=1.36 (1.51-2.29)</td>
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<td>Denmark</td>
<td>60-74</td>
<td>4696</td>
<td>Cohort</td>
<td>Frequency</td>
<td>Any fracture</td>
<td>5y (mean)</td>
<td>HR=2.05 (1.25-3.36)</td>
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<td>Any fall</td>
<td>5y (mean)</td>
<td>HR=1.72 (0.81-3.64)</td>
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<td>471</td>
<td>Cross-sectional</td>
<td>Incontinence</td>
<td>Any fall</td>
<td>1y</td>
<td>OR=1.67 (1.13-2.47)</td>
</tr>
</tbody>
</table>

Note: IPSS = International Prostate Symptom Score, OR = odds ratio, RR = relative risk, HR = hazard ratio.

* 5-year incidence by number of nocturnal micturition. † 1/2 of the times relative to never. ‡ 4-5 times at night relative to 0-1 time. § Severe (20-35 points) relative to mild (0-7).
Methodological quality appraisal of included studies is presented in Table 5.2. Stewart et al, de Rekeneire et al, and Parsons et al limited participation to healthier or ambulatory community-dwelling men (61, 63, 65). Loss to follow-up was not a problem in any of the three prospective studies: Parsons et al excluded only one percent with incomplete data (65); and the other two were linkage studies in universal health care systems which capture nearly all fractures (66, 68). The time frame and frequency of occurrence of LUTS were specified only in the study by Parsons that employed the IPSS (65). Using this validated questionnaire, occurrence of LUTS was limited to the past month, frequency of the symptoms was taken into account, and also definitions of each LUTS were given. To determine LUTS, no study conducted objective tests such as pad weight test or bladder diary. Five studies collected data through self-administered questionnaires (64, 65, 67-69), and the other four used face-to-face interviews. The definitions of falls were not clearly stated in four studies (63, 65, 67, 69). All three prospective studies determined falls and fractures adequately either by close follow-up for falls (65) or by linkage to health care databases for fractures (65, 67). All the cross-sectional studies relied on recall over the past year for falls and past five years for fractures. All three prospective studies by Parsons et al, Nakagawa et al and Frost et al and the cross-sectional studies by Yasumura et al, de Rekeneire et al and Hedman et al made more extensive adjustments for potential confounders than for age alone (62, 63, 65, 66, 68, 69). We, therefore, considered these six studies to be more robust than the rest as confounding is the most important source of bias in observational studies (70).
<table>
<thead>
<tr>
<th>Source</th>
<th>Baseline sample size</th>
<th>Prospective study</th>
<th>Generalizable sampling frame</th>
<th>Random sample</th>
<th>&lt;20% loss to follow-up</th>
<th>Adequate definition of study factor*</th>
<th>Adequate assessment of study factor†</th>
<th>Adequate definition of outcome</th>
<th>Adequate assessment of outcome‡</th>
<th>Adjustment for potential confounders§</th>
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<td>Yes</td>
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<td>357</td>
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<tr>
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<td>4696</td>
<td>Yes</td>
<td>Not clear</td>
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<td>No</td>
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<td>Hedman</td>
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<td>471</td>
<td>No</td>
<td>Yes</td>
<td>N.A.</td>
<td>Yes</td>
<td>No</td>
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<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*Time frame and frequency of lower urinary tract symptoms should be considered.
†Subjective test and self-administered questionnaire are acceptable. ‡Data linkage, falls diary, and more than annual follow-up are acceptable. §Adjusted for other risk factors than age.
Study findings

(i) Nocturia

Nocturia was consistently shown to be associated with increased risk of any fall. In Parsons et al’s study, men who voided four to five times per night were at increased risk of falls relative to men who voided zero or one time (adjusted RR=1.23, 95% CI: 1.08-1.41) (65). A wide range of fall risk factors were accounted for in this large prospective study. Adjusted OR was 1.63 (95% CI: 1.00-2.68) in Stewart et al’s study in men who voided at least twice per night compared with men who voided zero or one time (61). This study only adjusted for age and determined falls retrospectively. Yasumura et al showed a positive association, but the confidence interval was wide as a majority of the small sample met the nocturia criteria of any night-time void (62).

Parsons et al also examined the association of nocturia with recurrent falls which was stronger (adjusted RR=1.42, 95% CI: 1.16-1.74) than with any fall (65).

The risk estimates for any fracture in five years were in opposite directions in the two studies that looked at fractures and not significant in either: adjusted HR was 2.61 (95% CI:0.76-8.95) in Nakagawa et al’s prospective study (66), and adjusted OR was 0.69 (95% CI:0.35-1.34) in Stewart et al’s cross-sectional study (61) with nocturia defined as two or more voids per night in both studies. The numbers of fractures over five years were limited in both studies (13 in Nakagawa et al’s and 38 in Stewart et al’s), resulting in wide confidence intervals.
Asplund et al reported that the recalled history of hip fractures in past five years increased as number of night-time voids increases, but adjustment was not made even for age and the information provided did not allow us to calculate OR (64).

(ii) Incontinence

In all three cross-sectional studies that examined the association between incontinence and any fall, incontinence was consistently shown to be associated with increased risk of any fall. The risk estimate was the largest in Foley et al’s study which did not adjust for any potential confounders and defined incontinence as any leakage of urine (unadjusted OR=1.86, 95% CI: 1.51-2.29) (67). The other two studies accounted for a wide range of fall risk factors but did not explicitly define urinary incontinence: adjusted ORs were 1.5 (95% CI: 1.1-2.0) in de Rekeneire et al’s study (63) and 1.67 (95% CI: 1.13-2.47) in Hedman et al’s (69).

None of the studies in men determined the association with falls by type or severity of incontinence.

(iii) Frequency

The large prospective study by Parsons et al found frequency, defined as having to void within two hours since the last void at least half of the times, to be weakly associated with any fall (adjusted RR=1.17, 95% CI: 1.04-1.33) relative to never having frequency (65). The association was slightly stronger for recurrent falls (adjusted RR=1.25, 95% CI: 1.02-1.53).

Another large prospective study, with extensive adjustment for potential confounders, by Frost et al found frequency (definition not given) to be moderately associated with any fracture (adjusted HR=2.05, 95% CI: 1.25-3.36) (68). Although results were also given for osteoporotic fractures, it was not clear how they were defined.
(iv) Other LUTS

The other symptoms on the IPSS (incomplete emptying, intermittency, urgency, weak stream, and straining) were examined for association with any fall and recurrent falls in the well-conducted study by Parsons et al (65). The strongest associations were found between urgency and any fall (adjusted RR=1.31, 95% CI: 1.17-1.47) and recurrent falls (adjusted RR=1.59, 95% CI: 1.33-1.89), and between straining to void and any fall (adjusted RR=1.24, 95% CI: 1.06-1.46) and recurrent falls (adjusted RR=1.60, 95% CI: 1.27-2.02). The risks above were shown for men who had the symptoms at least half the time relative to those who never did. Other symptoms had weaker associations with falls.

This study by Parsons et al also showed that high total IPSS (20-35 points) were associated with any fall (adjusted RR=1.33, 95% CI: 1.15-1.53) and recurrent falls (adjusted RR=1.63, 95% CI: 1.31-2.02) relative to men with low IPSS (0-7 points).

DISCUSSION

In our study, we systematically reviewed the association of LUTS with falls, injuries and fractures in community-dwelling older men. Although studies varied in methodology, incontinence and storage symptoms such as urgency, nocturia, and frequency were consistently shown to be associated with falls. The associations were weak to moderate when restricted to six studies with low risk of bias due to confounding. These findings are in line with the past studies predominantly or exclusively of women (23). Fewer studies examined fracture as an outcome of which only one study showed an association between frequency and all fractures. No study looked at injuries as an outcome.
As might be expected, the extent to which potential confounders were adjusted for had a substantial influence on observed effect sizes in included studies. The strongest evidence for an association between LUTS and falls comes from the study by Parsons et al (65): it had a large sample size, closely followed up participants for falls, assessed a wide range of LUTS using a validated questionnaire, and adjusted the risk estimates for an exhaustive list of fall risk factors that have previously been identified.

The time frame and frequency for the occurrence of LUTS was specified only in the study by Parsons et al using the IPSS (65). It is preferable to ask about the occurrence of LUTS during a specific period of time because LUTS status is known to change dynamically over time: a 30% annual remission rate and a 10% annual incidence of incontinence was reported in community-dwelling older men (15). As the majority of male incontinence includes a component of urgency (71), it is expected that there will be a change in storage symptoms such as urgency, frequency, and nocturia in keeping with the progression and remission of incontinence. Frequency of each symptom should also be asked because participants might regard symptoms that occur infrequently as insignificant. Although incontinence is not included in the IPSS, other validated questionnaires such as the International Consultation on Incontinence Questionnaire (ICIQ) may be utilized which incorporates the time frame and frequency of occurrence (34). The direction of bias that these ambiguities about time frame and frequency of symptoms may have introduced is uncertain. Administration of pad weight test or bladder diary may have provided better objective evidence of LUTS but may have been considered to be too resource intensive in large-scale studies. Thus we judged that the use of self-administered questionnaires which ensures privacy to be acceptable (72).
A fall is defined by World Health Organization to be ‘an event which results in a person coming to rest inadvertently on the ground or floor or other lower level’ (41). Most of the studies included in this review did not explicitly define falls. If falls were not well-defined, this may have inflated the number of falls because older people may regard merely losing balance without landing on lower level as falling (73). The impact of inclusion of ‘near-falls’ on the association with LUTS is uncertain. Only Parsons et al prospectively determined the occurrence of falls. Although the other studies that relied on recall of the past year may not be ideal, Mackenzie et al demonstrated that recalls of falls are fairly reliable in people aged 70 and older (74). As has been found in most studies on fall risk factors, stronger associations were consistently found with ‘recurrent falls’ than ‘any fall’ in the study by Parsons et al (65). Single falls may occur by chance to people with no tendency to fall whereas recurrent fallers may be more distinct as an at-risk group for falls.

Few studies examined fractures as an outcome. As discussed above, LUTS status changes dynamically over time. It, therefore, may not be appropriate to examine the association between LUTS at baseline and an outcome such as fractures in the following five years. Alternatively, it would require unfeasibly large sample size to observe sufficient number of fractures in a shorter period of time.

Our review showed that both urgency and incontinence were associated with falls in men. As the majority of incontinence in men is known to include an urgency component (71), the question arises as to whether actual leakage of urine makes any additional contribution to fall risk beyond the sense of urgency alone. To answer this question, data needs to be collected to differentiate between subjects with urgency without incontinence and those with urgency that results in incontinence.
High IPSS were associated with falls. Multiple symptoms within voiding or storage symptom subcategories tend to coexist in older men because the voiding symptoms may reflect different aspects of either bladder outlet obstruction (BOO) or impaired detrusor contractility, and storage symptoms reflect different aspects of overactive bladder (OAB). In addition, voiding and storage symptoms often coexist because some of OAB may be secondary to BOO, and OAB and impaired detrusor contractility may coexist in older people as detrusor hyperactivity with impaired contractility. Hence, the IPSS may have potential in assessing the overall fall risk related to LUTS. Although incontinence is not included in the IPSS, it is not yet certain whether it carries any additional risk of falls over the symptoms in the IPSS as discussed above.

There are a few limitations to our review. Firstly, the results of this review may not directly apply to frailer and less mobile men in the community who may be at greater risk for falls. Some studies limited participation to healthier men in clearly defined inclusion criteria while the other studies that did not limit participation in any way are still likely to have undersampled these men. Secondly, it is uncertain whether medical, surgical or behavioural interventions to LUTS alone may reduce falls in community-dwelling older people. A systematic review that investigated whether treating LUTS decreases falls identified two randomised controlled trials in nursing home residents: one that implemented a multidimensional intervention program including prompted toileting and physical exercise reported significant reduction in falls; and the other one that prescribed an anticholinergic agent failed to reduce falls (75). No study that reported the association between LUTS and falls in either men or women determined the events that precipitated the falls either. LUTS may directly precipitate falls or they may be merely a marker of other factors that cause
falls: for example, hypogonadism has been shown to often coexist with LUTS and some of the characteristic symptoms of hypogonadism such as depressed mood, cognitive impairment and decreased muscle mass and strength are risk factors of falls (76). The circumstances of falls should be explored to generate hypothesis about what types of interventions should be incorporated in multidimensional fall prevention strategies. Also, future trials to treat LUTS should consider including falls as an endpoint.

CONCLUSION

Urinary incontinence and lower urinary tract storage symptoms were consistently shown to have weak to moderate association with falls in community-dwelling older men in studies with low risk of bias for confounding.

Evidence is lacking on whether medical, surgical or behavioural interventions to LUTS decrease fall risk in community-dwelling men. The circumstances of falls in men with LUTS should be explored to improve fall prevention strategies.
6. The association between LUTS and incident falls in community-dwelling older men: the CHAMP study

Publication details:

ABSTRACT

Purpose To determine which lower urinary tract symptoms (LUTS) are associated with incident falls in community-dwelling older men.

Materials and Methods The Concord Health and Ageing in Men Project involves a representative sample of community-dwelling men aged 70 and older in a defined geographic region in Sydney, Australia. One thousand and ninety men without neurological diseases, poor mobility and dementia at baseline were included in the analyses in this paper. LUTS were assessed using the International Prostate Symptom Score (IPSS) and incontinence was assessed using the International Consultation on Incontinence Questionnaire (ICIQ) at baseline. The IPSS subscores were calculated for storage and voiding symptoms. Incident falls over one year were determined by four-monthly telephone follow-up.

Results Both IPSS storage and voiding subscores were associated with falls. Urgency incontinence was associated with falls (adjusted IRR=2.57, 95% CI: 1.54-4.30). In addition, intermediate to high IPSS storage subscores without urgency incontinence were associated with falls (adjusted IRR=1.72, 95% CI: 1.24-2.38). Other types of incontinence and urgency alone without urgency incontinence were not associated with falls.

Conclusions Both lower urinary tract storage and voiding symptoms were associated with falls in community-dwelling older men. Of symptoms of overactive bladder, urgency incontinence carries a high risk of falls. Storage symptoms also make a contribution to fall risk independently of urgency incontinence. Circumstances of falls among men with LUTS should be explored to understand how LUTS increase fall risk and to generate hypotheses.
regarding potential interventions. Furthermore, trials to treat LUTS in older men should include falls as an endpoint.

INTRODUCTION

Falls are common among older people and often result in injuries (57). Lower urinary tract symptoms (LUTS) such as incontinence, urgency, frequency and nocturia have been associated with falls, but the evidence on the association is less extensive in men than in women (23, 77). The patterns of co-occurrence and severity of LUTS are different between men and women (58). In addition, there may be gender-related behavioural differences in strategies to manage LUTS which could also influence fall risk.

Moreover, because multiple LUTS often coexist in one person, it is unclear which LUTS may potentially be targeted in strategies to reduce falls. Looking at all the important LUTS in one population would help identify which LUTS have stronger associations with falls. In particular, causally related symptoms such as urgency and urgency incontinence need to be examined for association with falls stratified by both of these symptoms to find out if urgency incontinence makes any additional contribution to fall risk over urgency alone.

The aim of our study was to determine which LUTS are associated with incident falls over one year in community-dwelling older men. To explore this, each LUTS by its frequency of occurrence, the International Prostate Symptom Score (IPSS) (5), incontinence by type and urgency by the presence or absence of urgency incontinence were examined for associations with incident falls.
MATERIALS AND METHODS

Study participants

The Concord Health and Ageing in Men Project (CHAMP) is a prospective cohort study of a wide range of health issues in older men. Baseline data were collected between January 2005 and June 2007. The study was approved by the Concord Hospital Human Research Ethics Committee. All participants gave written informed consent.

CHAMP involves 1705 men aged 70 years and over living in a defined region of metropolitan Sydney. The sampling frame was the New South Wales Electoral Roll, on which registration is compulsory. The only exclusion criterion was living in a residential aged care facility. The participation rate was 47%. The details of the sample selection process have been described previously (43).

LUTS

Information about LUTS was collected from a self-administered questionnaire using the IPSS (5) and the International Consultation of Incontinence Questionnaire (ICIQ) (34).

Nocturia was categorized into zero to one time, two to three times, and four times or more per night. Other symptoms in the IPSS were categorized into ‘not at all’, less than half the time, and at least half the time.

The total score of the IPSS was categorized into low (0 to 7 points), intermediate (8 to 19 points), and high (20 to 35 points) (5). The storage subscore of the IPSS (IPSS-S) was calculated as the sum of questions number two, four and seven (frequency, urgency, and nocturia) (6) and was categorized into low (0 to 3 points), intermediate (4 to 8 points) and
high (9 to 15 points). The voiding subscore of the IPSS (IPSS-V) was calculated as the sum of questions number one, three, five and six (incomplete emptying, intermittency, weak stream, and straining) (6), and was classified into low (0 to 4 points), intermediate (5 to 11 points) and high (12 to 20 points). For IPSS-S and IPSS-V, the above cut-off points between low, intermediate, and high scores were set at the same proportions as conventional cut-off values of total IPSS (5).

Incontinence was first categorized according to frequency: none or at most weekly, more than weekly but less than daily, and at least daily. Secondly, incontinence more frequent than weekly was categorized by type: incontinence without an urgency component (‘non-urgency incontinence’, including stress and other incontinence); incontinence with an urgency component (‘urgency incontinence’, including urgency and mixed incontinence); and incontinence that occurs at most once a week was classified as no incontinence. Type of incontinence was determined using question number four of the ICIQ (‘When does urine leak?’), with the response ‘(urine) leaks before you can get to the toilet’ indicating the presence of an urgency component.

To determine the individual contribution of each of urgency and urgency incontinence to fall risk, men were categorized into those with urgency incontinence, those with urgency without urgency incontinence and those with neither urgency nor urgency incontinence. For this analysis, urgency was defined as urgency occurring at least half the time, and urgency incontinence was defined as more than weekly incontinence with an urgency component.

Lastly, post-hoc analysis was conducted to determine the contribution of storage symptoms as a whole to fall risk accounting for urgency incontinence. This analysis was added because intermediate to high IPSS storage subscores, that incorporate all overactive bladder (OAB)
symptoms (1) were related to falls and urgency incontinence, which is the most severe form of OAB, was also associated with falls. For this analysis, having storage symptoms was defined as intermediate to high IPSS-S (4 to 15 points). Men were classified into those with urgency incontinence (regardless of IPSS-S), those with storage symptoms without urgency incontinence, and those with neither storage symptoms nor urgency incontinence.

**Falls ascertainment**

Participants were telephoned every four months. They were asked if they had fallen in the previous four months, and if so, how many times they had fallen. When falls were reported, study staff excluded ‘near-falls’ by asking if the participant’s body had hit the ground or an object. The first three telephone follow-ups representing the first year of follow-up were utilized in this study.

**Covariates**

Information on demographic characteristics, lifetime history of diagnosed medical conditions (including Parkinson’s Disease, stroke, epilepsy, and arthritis), history of falls in previous year, and dizziness was gathered using a self-administered questionnaire. Medical conditions and dizziness were dichotomised into absence and presence. Country of birth was categorized into Australia, Italy, Great Britain, Greece, China, and other.

Variables assessed at the clinic interviews by trained personnel included the Mini-Mental State Examination (MMSE) (37), functional disability using a modification of Katz activities of daily living (36), physical performance tests (repeated chair stands, usual pace walk and narrow balance walk) and visual impairment. Also, participants brought medications that they took daily or almost daily for at least a month prior to the clinic visit. Poor mobility was
defined as needing help with walking across a small room and/or transferring from bed to a chair (49). Time spent for each physical performance test was dichotomized into slow and normal/fast at the slowest quartile. Men who did not complete the tasks were categorized into the slowest quartile. Poor visual acuity was defined as below 20/63 on Logmar Visual Acuity Test (38). Drug burden index (DBI) was calculated by adding the burden from drugs with anticholinergic and sedative properties (78), and was categorized into DBI=0, 0<DBI<0.5 and 0.5<DBI (the median DBI among men who were exposed to these drugs was 0.5).

The Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) (39) is an informant screening questionnaire to assess cognitive decline and was administered by telephone shortly after the clinic visit. Men with an MMSE score of 26 or lower or an IQCODE score of 3.6 or higher had a detailed cognitive examination by a geriatrician. Diagnosis of dementia was reached using Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) (40) criteria at a consensus meeting attended by two geriatricians, a neurologist, and a neuropsychologist.

**Statistical analysis**

Participant characteristics were derived as means with SD or frequency distributions. Incidence rate ratios (IRR) for falls were estimated using negative binomial regression. Negative binomial regression is suitable for analysing recurrent events such as falls because it fully utilizes the count data in contrast to setting arbitrary cut-off values as occurs when logistic regression is used to analyse fall data. Negative binomial regression is a
generalization of Poison regression that can deal with overdispersed data and can also control for different follow-up lengths.

Men with neurological diseases (stroke, Parkinson’s disease, and epilepsy), poor mobility, and dementia at baseline were excluded from analyses because these conditions are known to affect fall risk and also to cause LUTS, including functional incontinence. Each of the symptoms, the IPSS, urgency/urgency incontinence status and composite storage symptoms/urgency incontinence status were entered into separate multivariate models as the main explanatory variable. The following risk factors for falls that have previously been identified were all forced into the multivariate models regardless of their statistical contribution to the model to ensure face validity: age, country of birth (79), dizziness, visual impairment, arthritis, DBI, repeated chair stands, usual pace walk and narrow balance walk.

All analyses were performed using SAS version 9.3 (SAS Institute, Inc., Cary, NC, USA).
RESULTS

Of the 1705 participants at baseline, 307 with neurological diseases, poor mobility, or dementia at baseline were excluded. After applying these exclusion criteria, an additional eight men (0.6%) who either withdrew from the study or died before the first telephone follow-up were excluded. The remaining 1390 men were included in analyses. Follow-up ranged from 4 to 12 months with a mean (±SD) of 11.8±1.0 months. Fall rates ranged from zero to 12 per year. One hundred and two men (10%) had a fall rate of one per year, and 97 (7%) had a fall rate of greater than one per year.

Table 6.1 shows the baseline characteristics of the included men. The mean (±SD) age was 76.3±5.2 years. About half the men (49%) were born in Australia and 20% were born in Italy. In the previous year, 10% had a single fall and 5% had two or more falls. Sixty four percent had a low IPSS, 29% had an intermediate IPSS and 7% had a high IPSS. Seven percent had more than weekly but less than daily incontinence and 7% had at least daily incontinence. A higher proportion of men in higher IPSS categories reported two or more falls in the past year (low IPSS: 4%, intermediate IPSS: 7% and high IPSS: 8%).
Table 6.1  Baseline characteristics of men included in the analysis from the Concord Health and Ageing in Men Project (n=1390)

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th>Total n=1390</th>
<th>IPSS at baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Low (0-7)</td>
</tr>
<tr>
<td>Age (mean±SD)</td>
<td>76.3±5.2</td>
<td>76.1±5.1</td>
</tr>
<tr>
<td>Country of birth* <em>(N(%))</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>686 (49)</td>
<td>426 (51)</td>
</tr>
<tr>
<td>Italy</td>
<td>273 (20)</td>
<td>156 (19)</td>
</tr>
<tr>
<td>Great Britain</td>
<td>62 (4)</td>
<td>39 (5)</td>
</tr>
<tr>
<td>Greece</td>
<td>59 (4)</td>
<td>33 (4)</td>
</tr>
<tr>
<td>China</td>
<td>43 (3)</td>
<td>27 (3)</td>
</tr>
<tr>
<td>Other</td>
<td>267 (19)</td>
<td>159 (19)</td>
</tr>
<tr>
<td>History of falls in previous year *(N(%))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>1162 (85)</td>
<td>738 (88)</td>
</tr>
<tr>
<td>Once</td>
<td>140 (10)</td>
<td>65 (8)</td>
</tr>
<tr>
<td>Twice or more</td>
<td>73 (5)</td>
<td>33 (4)</td>
</tr>
<tr>
<td>Incontinence *(N(%))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤Weekly</td>
<td>1181 (86)</td>
<td>787 (94)</td>
</tr>
<tr>
<td>&gt;Weekly, &lt;Daily</td>
<td>99 (7)</td>
<td>33 (4)</td>
</tr>
<tr>
<td>&gt;Daily</td>
<td>91 (7)</td>
<td>20 (2)</td>
</tr>
<tr>
<td>Dizziness *(N(%))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1035 (75)</td>
<td>672 (80)</td>
</tr>
<tr>
<td>Yes</td>
<td>339 (25)</td>
<td>165 (20)</td>
</tr>
<tr>
<td>Walking aid use *(N(%))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1351 (97)</td>
<td>817 (97)</td>
</tr>
<tr>
<td>Yes</td>
<td>39 (3)</td>
<td>23 (3)</td>
</tr>
<tr>
<td>Visual impairment *(N(%))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20/60 and over</td>
<td>1311 (97)</td>
<td>795 (97)</td>
</tr>
<tr>
<td>below 20/60</td>
<td>38 (3)</td>
<td>24 (3)</td>
</tr>
<tr>
<td>Psychotropic medication use *(N(%))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1234 (89)</td>
<td>758 (90)</td>
</tr>
<tr>
<td>Yes</td>
<td>156 (11)</td>
<td>82 (10)</td>
</tr>
<tr>
<td>Antihypertensive medication use *(N(%))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>622 (45)</td>
<td>380 (45)</td>
</tr>
<tr>
<td>Yes</td>
<td>768 (55)</td>
<td>460 (55)</td>
</tr>
</tbody>
</table>

IPSS, International Prostate Symptom Score. SD, standard deviation.

The sum of numbers in each category may not add up to the total number because of missing data.

*No other country contributed more than 3%.
Table 6.2 shows the associations between LUTS, the IPSS, urgency/urgency incontinence status and composite storage symptoms/urgency incontinence status and fall rates. Results from multivariate analyses are described below. Among individual symptoms on the IPSS, urgency and intermittency that occurred at least half the time were significantly associated with an increased fall rate and there seemed to be a dose-response relationship between frequency of these symptoms and fall rate. High total IPSS, intermediate to high IPSS storage subscores and high IPSS voiding subscores were associated with an increased fall rate. Urgency incontinence was significantly associated with an increased fall rate, but non-urgency incontinence was not. With regards to the combination of urgency incontinence and urgency, urgency incontinence was associated with an increased fall rate, but urgency without urgency incontinence was not. With regards to the combination of urgency incontinence and composite storage symptoms (urgency, frequency and nocturia), storage symptoms were significantly associated with an increased fall rate even in the absence of urgency incontinence.
Table 6.2 Incidence rate ratio of falls in community-dwelling older men from the Concord Health and Ageing in Men Project (n=1390)

<table>
<thead>
<tr>
<th></th>
<th>Men</th>
<th>Falls</th>
<th>Univariate IRR (95% CI)</th>
<th>Multivariate IRR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Storage symptoms</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not at all</td>
<td>467</td>
<td>122</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>&lt;1/2 the time</td>
<td>565</td>
<td>183</td>
<td>1.20 (0.85-1.70)</td>
<td>1.21 (0.85-1.73)</td>
</tr>
<tr>
<td>≥1/2 the time</td>
<td>261</td>
<td>79</td>
<td>1.23 (0.80-1.87)</td>
<td>1.10 (0.71-1.70)</td>
</tr>
<tr>
<td>Urgency</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not at all</td>
<td>749</td>
<td>171</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>&lt;1/2 the time</td>
<td>383</td>
<td>118</td>
<td>1.35 (0.95-1.90)</td>
<td>1.20 (0.84-1.71)</td>
</tr>
<tr>
<td>≥1/2 the time</td>
<td>220</td>
<td>102</td>
<td>2.08 (1.40-3.09)</td>
<td>1.62 (1.08-2.42)</td>
</tr>
<tr>
<td>Nocturia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-1 time</td>
<td>615</td>
<td>152</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>2-3 times</td>
<td>617</td>
<td>191</td>
<td>1.26 (0.92-1.74)</td>
<td>1.13 (0.82-1.55)</td>
</tr>
<tr>
<td>≥4 times</td>
<td>134</td>
<td>54</td>
<td>1.54 (0.93-2.57)</td>
<td>1.18 (0.71-1.97)</td>
</tr>
<tr>
<td><strong>Voiding symptoms</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Straining</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not at all</td>
<td>1097</td>
<td>296</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>&lt;1/2 the time</td>
<td>191</td>
<td>71</td>
<td>1.32 (0.87-2.02)</td>
<td>1.36 (0.89-2.07)</td>
</tr>
<tr>
<td>≥1/2 the time</td>
<td>62</td>
<td>20</td>
<td>1.23 (0.61-2.49)</td>
<td>1.22 (0.59-2.50)</td>
</tr>
<tr>
<td>Weak stream</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not at all</td>
<td>754</td>
<td>184</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>&lt;1/2 the time</td>
<td>344</td>
<td>113</td>
<td>1.31 (0.91-1.87)</td>
<td>1.37 (0.95-1.97)</td>
</tr>
<tr>
<td>≥1/2 the time</td>
<td>245</td>
<td>91</td>
<td>1.62 (1.10-2.40)</td>
<td>1.47 (0.99-2.19)</td>
</tr>
<tr>
<td>Intermittency</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not at all</td>
<td>858</td>
<td>207</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>&lt;1/2 the time</td>
<td>318</td>
<td>104</td>
<td>1.36 (0.95-1.94)</td>
<td>1.43 (0.99-2.06)</td>
</tr>
<tr>
<td>≥1/2 the time</td>
<td>174</td>
<td>75</td>
<td>1.93 (1.26-2.97)</td>
<td>1.87 (1.23-2.85)</td>
</tr>
<tr>
<td>Incomplete emptying</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not at all</td>
<td>863</td>
<td>235</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>&lt;1/2 the time</td>
<td>314</td>
<td>92</td>
<td>1.05 (0.73-1.52)</td>
<td>1.17 (0.80-1.69)</td>
</tr>
<tr>
<td>≥1/2 the time</td>
<td>175</td>
<td>57</td>
<td>1.35 (0.86-2.10)</td>
<td>1.29 (0.83-2.00)</td>
</tr>
<tr>
<td><strong>IPSS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total IPSS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low (0-7)</td>
<td>840</td>
<td>197</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Intermediate (8-19)</td>
<td>381</td>
<td>129</td>
<td>1.38 (0.98-1.93)</td>
<td>1.29 (0.91-1.82)</td>
</tr>
<tr>
<td>High (20-35)</td>
<td>90</td>
<td>45</td>
<td>2.44 (1.41-4.22)</td>
<td>2.06 (1.20-3.54)</td>
</tr>
<tr>
<td>IPSS storage subscore</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low (0-3)</td>
<td>702</td>
<td>132</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Intermediate (4-8)</td>
<td>461</td>
<td>177</td>
<td>1.99 (1.43-2.76)</td>
<td>1.73 (1.24-2.40)</td>
</tr>
<tr>
<td>High (9-15)</td>
<td>148</td>
<td>62</td>
<td>2.43 (1.53-3.86)</td>
<td>1.81 (1.13-2.90)</td>
</tr>
<tr>
<td>IPSS voiding subscore</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low (0-4)</td>
<td>973</td>
<td>247</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Intermediate (5-11)</td>
<td>264</td>
<td>97</td>
<td>1.41 (0.97-2.05)</td>
<td>1.41 (0.97-2.04)</td>
</tr>
<tr>
<td>High (12-20)</td>
<td>74</td>
<td>27</td>
<td>1.87 (1.02-3.46)</td>
<td>1.98 (1.09-3.60)</td>
</tr>
<tr>
<td><strong>Incontinence</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>by frequency</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤Weekly</td>
<td>1181</td>
<td>316</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>&gt;Weekly, &lt;Daily</td>
<td>99</td>
<td>42</td>
<td>1.60 (0.93-2.75)</td>
<td>1.34 (0.77-2.32)</td>
</tr>
<tr>
<td>≥Daily</td>
<td>91</td>
<td>37</td>
<td>1.72 (0.99-3.00)</td>
<td>1.13 (0.65-1.99)</td>
</tr>
<tr>
<td>by type</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No (≤Weekly)</td>
<td>1181</td>
<td>316</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Non-urgency</td>
<td>83</td>
<td>11</td>
<td>0.49 (0.23-1.04)</td>
<td>0.45 (0.21-0.94)</td>
</tr>
<tr>
<td>Urgency</td>
<td>107</td>
<td>68</td>
<td>2.56 (1.59-4.15)</td>
<td>1.87 (1.15-3.04)</td>
</tr>
<tr>
<td>Combinations of urgency incontinence and other OAB symptoms</td>
<td>Men n</td>
<td>Falls n</td>
<td>Univariate IRR (95% CI)</td>
<td>Multivariate IRR (95% CI)</td>
</tr>
<tr>
<td>-----------------------------------------------------------</td>
<td>------</td>
<td>--------</td>
<td>-------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>Urgency/ urgency incontinence</td>
<td>1083</td>
<td>265</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Urgency without urgency incontinence</td>
<td>161</td>
<td>57</td>
<td>1.60 (1.03-2.48)</td>
<td>1.33 (0.85-2.06)</td>
</tr>
<tr>
<td>Storage symptoms/ urgency incontinence</td>
<td>107</td>
<td>68</td>
<td>2.85 (1.76-4.63)</td>
<td>2.05 (1.25-3.36)</td>
</tr>
<tr>
<td>Storage symptoms without urgency incontinence</td>
<td>689</td>
<td>129</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Storage symptoms without urgency incontinence</td>
<td>521</td>
<td>186</td>
<td>2.01 (1.46-2.76)</td>
<td>1.72 (1.24-2.38)</td>
</tr>
<tr>
<td>Urgency incontinence</td>
<td>107</td>
<td>68</td>
<td>3.77 (2.29-6.22)</td>
<td>2.57 (1.54-4.30)</td>
</tr>
</tbody>
</table>

IRR, incidence rate ratio. IPSS, International Prostate Symptom Score. OAB, overactive bladder.

In multivariate models, the associations were adjusted for age, country of birth, dizziness, visual impairment, arthritis, psychotropic medication use, antihypertensive medication use, and walking aid use.

*For the analysis by storage symptoms and urgency incontinence, having storage symptoms was defined as intermediate to high IPSS-S (4-15 points).
DISCUSSION

This population-based prospective study showed that both lower urinary tract storage and voiding symptoms are associated with falls in community-dwelling older men. The strongest association was found for urgency incontinence occurring more than weekly. Also, storage symptoms (urgency, frequency and nocturia) as a whole, represented as intermediate to high IPSS storage subscores, were associated with falls independently of urgency incontinence.

A large, well-conducted prospective study of 5872 men by Parsons et al examined a wide range of LUTS for associations with falls, but unlike our study, it did not account for incontinence (65). This study found weak associations between individual symptoms on the IPSS and total IPSS and falls (80). In our study with a smaller sample size, only urgency, intermittency and total IPSS were associated with falls. In addition, we found that both storage and voiding subscores were associated with falls and neither had apparently stronger association than the other.

Urgency incontinence was associated with falls in our study, but other types of incontinence were not. This is consistent with studies in women (81, 82). Urgency has also been associated with falls in past studies in both men and women (23, 77), but these studies did not assess leakage of urine. In our study, urgency was further examined for association with falls by the presence of urgency incontinence to see if leakage of urine makes any additional contribution to fall risk beyond urgency alone. We defined urgency and incontinence as those occurring half the time and more than weekly respectively which we considered were clinically important. Urgency incontinence was moderately associated with falls, but urgency without urgency incontinence was not. As a post-hoc analysis, OAB symptoms as a whole,
represented as IPSS-S, was examined for association with falls by the presence of urgency incontinence, which is the most severe form of OAB. We found that intermediate to high IPSS storage subscores were associated with falls even in the absence of urgency incontinence. This indicates that storage symptoms collectively contribute to fall risk although urgency alone, without accounting for frequency and nocturia, does not make an independent contribution to fall risk.

Our study has a number of strengths. CHAMP involves a large, representative sample of community-dwelling older Australian men. While the response rate was relatively low (47%), the prevalence of major medical conditions and distributions of responses to a question on self-rated health are similar to those in 915 men aged 70 years and over in the nationally representative MATeS study (45). Validated questionnaires were used to assess a whole range of LUTS, falls were ascertained prospectively and the associations were adjusted for an extensive list of previously identified fall risk factors.

A limitation of our study is that, inherent in the study design, our results only apply to community-dwelling men without conditions that are related to both LUTS and falls (dementia, poor mobility and neurological diseases. These exclusions were made because in the presence of these conditions that can cause both LUTS and falls, the hypothesis of LUTS causing falls cannot be tested. Another limitation is that ascertainment of falls relied on recall of past four months without using fall diaries. Although this is not ideal, Mackenzie et al reported that recalls of falls in last 6 months were reliable in people aged 70 and over (74). Besides, the quality of responses are unlikely to have varied according to LUTS status. In determining LUTS, we did not discriminate between nocturnal micturition with and without urgency (83). This could have masked the possible association between nocturnal
urgency and falls. Lastly and most importantly, causality is unclear since we could not
determine the circumstances of the falls. It is, therefore, uncertain whether medical,
surgical or behavioural interventions for LUTS alone can reduce falls in community-dwelling
older people (74). Since falls are often multifactorial, other predisposing or precipitating
factors for falls that were not fully adjusted for may be playing a part in the increased fall
risk. The circumstances of falls in men with LUTS should be investigated to generate
hypotheses about what types of interventions may be incorporated into multidimensional
fall prevention strategies. Also, future trials to treat LUTS should consider including falls as
an endpoint.

CONCLUSIONS

Both lower urinary tract storage and voiding symptoms are associated with falls in
community-dwelling older men. In particular, urgency incontinence (incontinence with an
urgency component including mixed incontinence) carries a higher risk of falls. Also, storage
symptoms are collectively associated with falls even in the absence of urgency incontinence.
Other types of incontinence and urgency alone without urgency incontinence were not
associated with falls.

Evidence is lacking about whether treatment of LUTS decreases fall risk in community-
dwelling men. The circumstances of falls among men with LUTS should be explored to
generate hypotheses regarding potential interventions. Furthermore, trials to treat LUTS in
older men should consider including falls as an endpoint.
7. Circumstances of falls in community-dwelling older people with LUTS: a pilot study
ABSTRACT

**Background** Although lower urinary tract symptoms (LUTS) have been found to be associated with falls in community-dwelling older people, it is unclear whether LUTS directly cause falls or are merely markers of other falls risk factors.

**Methods** Outpatients aged 70 and over attending the urology clinics at Concord Hospital for LUTS who had had falls in the previous 12 months were interviewed between November 2015 and October 2016. Patients who live in residential aged care facilities and those with cognitive impairment or limited English language proficiency were excluded. Participants were asked the circumstances of their recent falls (up to three) in the previous 12 months either face-to-face or on the phone.

**Results** Eight men and four women between ages 70 and 94 were interviewed who reported the circumstances of 26 falls in total. Of these 26 falls, five falls occurred in the process of urination. These five falls occurred in four patients all of whom had overactive bladder (OAB) and were using walking aids. Three of these falls occurred in the patients’ own homes on their way to the toilet to urinate of whom two fell in daytime and the other when he woke up at night. The other two falls occurred when getting up from toilet seats after urinating in daytime. Sample size was limited because the frequency of falls was low and many patients did not speak sufficient English language to be interviewed.

**Conclusion** Of the 26 falls in older patients with LUTS, 23 were not directly related to voiding and only three occurred on their way to the toilet both in daytime and at night in patients with OAB. It is possible that urgency and nocturia directly precipitated a minority of
falls although causality is still unclear. It may be worth exploring if interventions to treat or manage these symptoms are effective in reducing falls.

**INTRODUCTION**

Lower urinary tract symptoms (LUTS) such as incontinence, urgency, frequency and nocturia have been associated with falls in community-dwelling older people (23, 77). Since none of the studies that examined the association, including our own (Chapter 7) (84), determined the circumstances of the falls, it is unclear how LUTS contribute to falls risk. LUTS may directly cause falls: for example, people with incontinence may slip over leaked urine on the floor; or people with urgency may fall when they rush to the toilet. It is also possible that LUTS indirectly cause falls: for example, noturia may cause daytime sleepiness resulting in falls. An alternative explanation for the association between LUTS and falls is that there are common risk factors for both LUTS and falls, such as neurological disorders and cognitive impairment, that could not be fully adjusted for in previous studies.

In this pilot study, we investigated the circumstances of the recent falls (up to three) in the previous 12 months in community-dwelling older people who were attending urology clinics for LUTS to determine if there were any instances of falls directly precipitated by LUTS. If this were the case, interventions to treat or manage LUTS should be incorporated into fall prevention strategies.
METHODS

This study was conducted at clinics in the Department of Urology at Concord Hospital, Sydney, Australia, between November 1, 2015 and October 31, 2016. The Concord Hospital Human Research Ethics Committee approved the study. Written informed consent was obtained from all participants.

All patients aged 70 and over attending the clinics for LUTS were screened if they had had at least one fall in the previous 12 months. If so, they were invited to take part in the study. Patients who live in residential aged care facilities and those who did not have capacity to give informed consent because of cognitive impairment or limited understanding of spoken and written English language were excluded from the study.

Recruitment was planned in three clinics that have about 15 patients per week in total. We estimated that six patients per week are seen for LUTS, are 70 and older, speak English and live in the community. Because one in three community-dwelling older people fall in a year (ref 56) and people with urinary symptoms may have twice as much fall risk without adjusting for confounders (ref 22), we estimated that four patients per week would have fallen in the previous year. In 40 weeks in a year, 160 patients may be eligible and 80% may agree to participate in the study. We, therefore, intended to interview 130 patients.

Participants were given a choice of telephone or face-to-face interview, either of which took approximately 10 minutes. Information on demographics, mobility and circumstances of up to three most recent falls in the previous 12 months was collected using a standardised data collection form (Figure 7.1, pp.114-121). For each fall, the interviewer confirmed that the patient landed on a lower level (41). Classification of the reason of the falls, activity at the
time and location were based on previous studies that investigated the circumstances of falls, and we added specific questions to investigate whether the falls were related to voiding or nocturia.

If the participants agreed for us to interview partners or family members that they live with, the nominated persons were asked the same questions about circumstances of falls as were asked to participants.

The participants’ medical files were reviewed to collect data on LUTS and medical history. Information on LUTS was also collected using the International Prostate Symptoms Score (IPSS) (5), and the International Consultation of Incontinence Questionnaire (ICIQ) (34) at the time of the interview. Information on medical history and medication use was collected from the medical files using the data collection form (Figure 7.2, p.122).

The characteristics of the patients and circumstances of the falls were summarized using frequency distribution.

RESULTS

During the study period, 640 patients visited the clinics of whom 14 were identified to be eligible. Of these 14 patients, two declined to be interviewed. We do not know the reasons why each patient was ineligible and/or was not able to be recruited. Table 1 shows the characteristics of the 12 participants who took part in the study. They were eight men and four women between ages 70 and 94. Seven were born in Australia, eight were using walking aid and nine had major cardiovascular or neurological comorbidities. Ten had overactive bladder (OAB) of whom six had incontinence with an urgency component and the
other two had stress incontinence post-transurethral resection of the prostate (TURP). In the previous 12 months, four had had a single fall and eight had recurrent falls. Three had more than three falls, but detail was only collected on the three most recent falls.

Table 7.1 Characteristics of the study participants (n=12)

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
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<tbody>
<tr>
<td>Age (years) Mean</td>
<td>80.3</td>
<td></td>
</tr>
<tr>
<td>Age (years) Range</td>
<td>70-94</td>
<td></td>
</tr>
<tr>
<td>Sex (n) Male</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Sex (n) Female</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Country of birth (n) Australia</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Country of birth (n) Overseas</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Walking aid use (n) Yes</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Walking aid use (n) No</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Comorbidities (n) Cardiovascular disease</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Comorbidities (n) Neurological disorder</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Number of medications (n) 5 or more</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Number of medications (n) 0 to 4</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>LUTS (n) OAB with incontinence</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>LUTS (n) OAB without incontinence</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>LUTS (n) Post-TURP incontinence</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Number of falls in previous year (n) 1</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Number of falls in previous year (n) 2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Number of falls in previous year (n) 3</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Number of falls in previous year (n) 4 or more</td>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

LUTS = lower urinary tract symptoms. OAB = overactive bladder. TURP = transurethral resection of the prostate.

These 12 participants reported the circumstances of 26 falls in total. Of these 26 falls, five falls occurred in the process of urination. These five falls occurred in four patients all of whom had OAB and were using walking aids.

Three of these participants fell on their way to the toilet. All of them were wearing absorbent pads at the time of the falls. Two of them were walking to the toilet in their own
homes in daytime, one of whom admitted both fear of leakage and being in a hurry. No particular environmental hazards were mentioned but one lost balance and legs gave way for the other. The other participant fell when he was getting out of bed to urinate at night. He was delirious due to urinary tract infection which required hospitalization on the following day but denied dizziness, fear of leakage and being in a hurry.

The other two falls that occurred in the process of urination took place when the participants stood up from toilet seats in daytime in their own homes. These falls appeared to be due to loss of balance and support failure but participants denied dizziness and environmental hazards.

Cohabiting partners and family members were interviewed for all five participants who lived with other people; there were no major discrepancies in the information provided.

DISCUSSION

We interviewed older patients with LUTS about the circumstances of their falls to determine whether LUTS directly cause falls. The interviewed patients who had LUTS and had fallen in the previous 12 months all appeared frail on the basis that they had gait instability requiring walking aids and/or had major comorbidities and the majority of the falls were not directly related to voiding. Gait instability and multiple comorbidities are falls risk factors (33) and this is in keeping with the hypothesis that older people with LUTS also have other falls risk factors. We did, however, identify a few instances of falls that might possibly have been directly precipitated by LUTS.
Three patients with OAB fell on their way to the toilet and one of them admitted hurrying.

These falls are consistent with the findings of a study that investigated the circumstances of falls in community-dwelling older people (85). They reported that 31% of the observed falls occurred when people were hurrying and 20% attributed their falls to not looking where they were going, although it was unclear what proportion were hurrying or lacked attention due to urgency to urinate. Urgency may also force abrupt movement which can result in falls.

The other two patients with OAB fell when getting up from toilet seats after urinating. In fact, the bathroom is a common location of falls in older people (86), but the contribution of LUTS to these falls over the normal activities of toileting and bathing has been unclear. It is possible that orthostatic or post-micturition hypotension precipitated these falls, but it is less likely that LUTS directly precipitated these falls given the fall occurred after urination.

Nocturia has been associated with falls (23, 77) and a number of hypotheses have been suggested to explain this association. It is possible that sleepiness and poor vision when going to the toilet at night, orthostatic hypotension when getting up from a lying position, and daytime sleepiness due to sleep deprivation increase falls risk. Also, there might be underlying comorbidities such as depression and pain that cause insomnia and also predispose individuals to falls (33). One patient in our study fell when he got up to urinate at night. Although delirium seemed to be the major precipitating factor of this fall, we cannot rule out the contribution of nocturia to this fall through the above mechanisms.

The major limitation of this paper is the small sample size since we enrolled far less patients into the study than we expected. We could not keep track of why each patient was excluded because this would have added significant workload for clinic staff who screened patients.
Our impression, however, is that the frequency of falls was very low and that many patients did not speak sufficient English language to be interviewed. Since many patients were accompanied by family and friends, shame or embarrassment may have affected their responses about falls. As for the language barrier, the study hospital is located in a multicultural area in Sydney and we would have been able to recruit more patients if we translated patient information sheet and had interpreters present. Since our sample size was very small, we may have missed other important circumstances of falls. For example, the above-mentioned study about the circumstances of falls also reported that 19% slipped on wet or slippery surface (85) and it is possible that people slip over leaked urine. It would be useful to further investigate the circumstances of falls to generate more hypotheses about what types of intervention may be effective. In future studies, ascertainment of falls may need to be done in privacy and reasonable efforts need to be made to overcome language barrier. We conducted this study in urology clinic patients to maximize efficiency but the issue could also be studied in a large population-based study of falls.

In conclusion, in this small study of older people with LUTS, those who reported falling had features of frailty such as gait instability and major comorbidities and the majority of falls were not directly related to voiding. This finding is consistent with the hypothesis that older people with LUTS are more likely to fall because of shared risk factors for LUTS and falls. However, three out of 26 falls in older patients with LUTS occurred in those with OAB on their way to the toilet both during the day and when they woke to urinate at night. It is possible that urgency and nocturia directly precipitated these falls. It may be worth exploring if the treatment and management of these symptoms are effective ways of reducing falls for some older people.
Figure 7.1 Data collection form for circumstances of falls

A study on circumstances of falls in older people with urinary symptoms living in the community

Data Collection Form (telephone/face-to-face interview)

Date:

Participant number:

CHARACTERISTICS OF PARTICIPANT

Q1 Who else lives with you at home?
1=lives alone, 2=spouse or partner, 3=children, 4=relatives, 5=friends, 6=others (give details)

Q2 Since leaving school, have you obtained a trade qualification, certificate, diploma or any other qualification?
1=no, 2=bachelor degree or higher, 3=trade/apprenticeship, 4=certificate/diploma, 5=other (give details)

Q3 In which country were you born?
1=Australia, 2=New Zealand, 3=United Kingdom, 4=Italy, 5=Greece, 6=Europe (other), 7=Middle East, 8=China/Hong Kong, 9=Vietnam, 10 other (give details)

Q4 What walking aid do you usually use to help you move about inside the house?
1=no walking aid, 2=walking stick, 3=pick-up frame, 4=rollator, 5=need help of others, 6=independent on wheel chair, 7=immobile

Q5 What walking aid do you usually use to help you move about outside the house?
1=no walking aid, 2=walking stick, 3=pick-up frame, 4=rollator, 5=need help of others, 6=independent on wheel chair, 7=immobile

FALLS
A fall is an event when you accidentally come to rest on the ground, floor or other lower level.

Q1 Have you fallen in the past 12 months?

1=Yes, 2=No >End of interview

Q1.1 If yes, how many times did you fall in the past 12 months?  ___ times
Tell us about the **most recent fall** over the past year.

Q2.1 When did you last fall?

_______________________________________________________________________

Q2.2 What time of the day was it when you last fell?

1=morning (after rising from bed to midday),
2=afternoon (before it gets dark), 3=evening (before bedtime) **>Skip next question**
4=night (bedtime to rising), 5=unsure

Q2.2.1 (If the fall occurred at night) Did you take sleeping pills before going to bed? 1=No, 2=Yes, 3=unsure

Q2.3 Did you have a poor vision when you fell? 1=No, 2=Yes, 3=unsure

Q2.4 What were you doing at that time?

1=getting out of bed, getting out of a chair/couch, 3=getting up from toilet/out of bath/shower,
4=walking indoors, walking outdoors, 6=outdoors activity (sports etc), 7=others (give details),
8=unsure

__________________________________________________________________________________

Q2.5 Describe why you fell?

1=slip, 2=trip, 3=loss of balance, 4=legs gave way, 4=dizziness/light-headedness, 5=support failure,
6=blackout/faint, 7=unclear/cannot remember, 8=other (give details), 9=unsure

___________________________________

Q2.6 Did this fall require medical attention?

1=no, 2=GP, 3=ED attendance, 4=hospital admission, 5=other (give details)

__________________________________

Q2.7 Did this fall occur in any of the following circumstances?

1=On your way to or inside of the toilet when you urinated

2=Other circumstances that you think was related to urination (give details)____________________

3=Nothing related to urination **>Go to next page if two or more falls**
If the fall happened on your way or inside of toilet, or in other circumstances that you think was related to urination,

Q2.7.1 Were you afraid of leaking urine? 1=No, 2=Yes, 3=unsure

Q2.7.2 Were you wearing absorbent pads/underwear/diapers? 1=No, 2=Yes, 3=unsure

Q2.7.3 Were you hurrying? 1=No, 2=Yes, 3=unsure

Q2.7.4 Were you dizzy? 1=No, 2=Yes, 3=unsure

Q2.7.5 Did you just rise up from chair or bed? 1=Within a minute, 2=After a minute, 3=unsure

Q2.7.6 Did you slip on leaked urine? 1=No, 2=Yes, 3=unsure >Continue to next page if two or more falls
Tell us about the second most recent fall over the past year.

Q3.1 When was your second last fall?

_______________________________________________________________

Q3.2 What time of the day was it when you had your second last fall?

1=morning (after rising from bed to midday),
2=afternoon (before it gets dark), 3=evening (before bedtime) »Skip next question
4=night (bedtime to rising) , 5=unsure

Q3.2.1 (If the fall occurred at night) Did you take sleeping pills before going to bed? 1=No, 2=Yes, 3=unsure

Q3.3 Did you have a poor vision when you fell? 1=No, 2=Yes, 3=unsure

Q3.4 What were you doing at that time?

1=getting out of bed, getting out of a chair/couch, 3=getting up from toilet/out of bath/shower,
4=walking indoors, walking outdoors, 6=outdoors activity (sports etc), 7=others (give details) , 8=unsure

_______________________________________________________________

Q3.5 Describe why you fell?

1=slip, 2=trip, 3=loss of balance, 4=legs gave way, 4=dizziness/light-headedness, 5=support failure, 6=blackout/faint, 7=unclear/cannot remember, 8=other (give details) , 9=unsure

_______________________________________________________________

Q3.6 Did this fall require medical attention?

1=no, 2=GP, 3=ED attendance, 4=hospital admission, 5=other (give details)

__________________________________________________________________________________

Q3.7 Did this fall occur in any of the following circumstances?

1=On your way to or inside of the toilet when you urinated
2=Other circumstances that you think was related to urination (give details) »Go to next page if three or more falls
3=Nothing related to urination
If the fall happened on your way or inside of toilet, or in other circumstances that you think was related to urination,

Q3.7.1 Were you afraid of leaking urine? 1=No, 2=Yes, 3=unsure

Q3.7.2 Were you wearing absorbent pads/underwear/diapers? 1=No, 2=Yes, 3=unsure

Q3.7.3 Were you hurrying? 1=No, 2=Yes, 3=unsure

Q3.7.4 Were you dizzy? 1=No, 2=Yes, 3=unsure

Q3.7.5 Did you just rise up from chair or bed? 1=Within a minute, 2=After a minute, 3=unsure

Q3.7.6 Did you slip on leaked urine? 1=No, 2=Yes, 3=unsure >Continue to next page if three or more falls
Tell us about the **third most recent fall** over the past year.

**Q4.1** When was your third last fall?

______________________________________________________________________________________________________________________________

**Q4.2** What time of the day was it when you had your third last fall?

1=morning (after rising from bed to midday),
2=afternoon (before it gets dark), 3=evening (before bedtime) **>Skip next question**
4=night (bedtime to rising) , 5=unsure

**Q4.2.1** (If the fall occurred at night) Did you take sleeping pills before going to bed? 1=No, 2=Yes, 3=unsure

**Q4.3** Did you have a poor vision when you fell? 1=No, 2=Yes , 3=unsure

**Q4.4** What were you doing at that time?

1=getting out of bed, getting out of a chair/couch, 3=getting up from toilet/out of bath/shower, 4=walking indoors, walking outdoors, 6=outdoors activity (sports etc), 7=others (give details) , 8=unsure

______________________________________________________________________________________________________________________________

**Q4.5** Describe why you fell?

1=slip, 2=trip, 3=loss of balance, 4=legs gave way, 4=dizziness/light-headedness, 5=support failure, 6=blackout/faint, 7=unclear/cannot remember, 8=other (give details) , 9=unsure

______________________________________________________________________________________________________________________________

**Q4.6** Did this fall require medical attention?

1=no, 2=GP, 3=ED attendance, 4=hospital admission, 5=other (give details)

______________________________________________________________________________________________________________________________

**Q4.7** Did this fall occur in any of the following circumstances?

1=On your way to or inside of the toilet when you urinated

2=Other circumstances that you think was related to urination (give details)________________________________________________________

3=Nothing related to urination
If the fall happened on your way or inside of toilet, or in other circumstances that you think was related to urination,

Q4.7.1  Were you afraid of leaking urine?  1=No, 2=Yes, 3=unsure

Q4.7.2  Were you wearing absorbent pads/underwear/diapers?  1=No, 2=Yes, 3=unsure

Q4.7.3  Were you hurrying?  1=No, 2=Yes, 3=unsure

Q4.7.4  Were you dizzy?  1=No, 2=Yes, 3=unsure

Q4.7.5  Did you just rise up from chair or bed?  1=Within a minute, 2=After a minute, 3=unsure

Q4.7.6  Did you slip on leaked urine?  1=No, 2=Yes, 3=unsure
A study on circumstances of falls in older people with urinary symptoms living in the community

Data Collection Form (medical records)

Date:
Participant number:

Medical history

Urological conditions
Urological procedures

[ ] Cognitive impairment
[ ] Neurological diseases
[ ] Poor vision
[ ] Depression
Other

Medications

[ ] Psychotropic medications
[ ] Antihypertensive medications
Other

Photocopy IPSS and ICIQ.
8. Thesis summary, discussion and conclusions
8.1 Natural history of common urological conditions in community-dwelling older men

The first aim of this thesis was to determine the natural history of two common urological conditions, non-neurogenic overactive bladder (OAB) and elevated post-void residual urine volume (PVR), in community-dwelling older men. The CHAMP study data were utilized to address these questions. The key conclusion from these studies was that, in the absence of neurological disorders, OAB often resolves spontaneously and most cases of elevated PVR remain stable. Each study is further discussed in the following sections.

8.1.1 Natural history of non-neurogenic OAB in community-dwelling older men

In the study presented in Chapter 3, we found that one in three men experienced natural and sustained remission of non-neurogenic OAB over five years. Our findings in untreated men sampled from the community support initial conservative management of OAB in primary care.

On the other hand, as many as two in three experienced either recurrent or persistent OAB, and we were not able to identify risk factors for persistent OAB because the sample size of men with OAB in the CHAMP study was small. Since OAB significantly diminishes quality of life (QOL), as discussed in section 1.2, it would be useful if we could identify patients who are not likely to experience continuous remission so that behavioural or pharmacological treatment can be implemented sooner. To obtain a sufficient sample size to analyse the predictors of persistent OAB would require a large cohort study of untreated patients with OAB rather than a population study.
8.1.2 Natural history of elevated PVR in community-dwelling older men

In the study presented in Chapter 4, we found that most men with PVR of less than 400mL did not require treatment for elevated PVR, and that PVR did not exceed 400mL in the next five years in the absence of neurological disorders. In addition, hospitalizations for UTI and urinary retention were rare. Elevated PVR is often detected incidentally and there is uncertainty about optimal management. This is because there has been insufficient evidence as to what level of elevated PVR results in complications and whether or how quickly elevated PVRs may progress. Our study indicates that most community-dwelling men with elevated PVR of up to 400mL, after excluding neurological disorders, may be safely managed without intervention for at least five years.

In contrast, three out of the four men with a baseline PVR of 400mL and over underwent surgery for BPE over five years, one of whom also received indwelling catheterization after a surgery. This would suggest that men with a PVR of 400mL and over need to be monitored closely, with the caveat that this recommendation is based on our finding in a small sample of men.

Renal failure is another potential adverse outcome of elevated PVR that we did not look at in this study. This is because elevated PVR rarely affect creatinine levels: a case series by George et al showed that normal creatinine levels can be maintained even in the presence of elevated PVR of 475mL and over and significant dilatation of the upper urinary tract (87). For interest, a post-hoc analysis in our study showed that, in the few men with very high PVR of 400mL and over, there was no clinically important elevation of serum creatinine.
As many as 25% of the otherwise eligible men for this study were excluded because they did not void at least 150mL and, therefore, their PVR data were regarded as invalid. Our data show that a great majority of these men simply did not have sufficient urine left in the bladder: their median PVR was 21mL. This occurred because men were not specifically asked to drink water before the urodynamic tests. We judged that it would be confusing if we ask men to fast for blood test but to drink plenty of water, and that men would worry about having to urinate on their way to the clinic. This is a weakness of our study that looked at many aspects of older men’s health compared to studies that focused specifically on urological outcomes. For example, in the Olmsted County study of urinary symptoms, instruction was given to drink water before urodynamic tests and the tests were rescheduled if men voided less than 150mL (88).

8.2 Associations between LUTS and falls in community-dwelling older men

The second aim of this thesis was to explore the associations between LUTS and falls in community-dwelling older men. This was achieved by taking a multi-method approach as summarized in Figure 8.1. In Chapter 5, we conducted a systematic review on the association between LUTS and falls, injuries and fractures in community-dwelling older men. We found that both incontinence and storage symptoms were associated with falls but, from this review, we could not determine which of these symptoms, that often coexist in men, contribute to fall risk. This was addressed in Chapter 6 where we examined the contribution of each LUTS to falls risk in community-dwelling older men in the CHAMP study. In this study, we found that urgency incontinence and both storage and voiding symptoms were associated with falls, and that storage symptoms collectively contribute to
falls risk even in the absence of urgency incontinence. Lastly, since it is unclear in both men and women whether LUTS directly cause falls or are merely markers of other fall risk factors, the urology clinic pilot study presented in Chapter 7 investigated the circumstances of falls in older patients of both sexes to find out whether LUTS directly precipitate falls. We observed that some people with OAB and poor mobility fell on their way to the toilet both during the day and when they woke up at night.

Figure 8.1 Summary of the findings (associations between LUTS and falls)
Our systematic review found that no study in community-dwelling men looked at injuries as an outcome and the few studies that examined the associations between LUTS and fractures lacked power because fractures are less frequent in men than women. After our systematic review was completed, Marshall et al published a prospective study about the association between LUTS and non-spine fractures from a maximum of eight-year follow-up of 5989 men in the MrOS cohort (80). Even in such a long follow-up of a large number of men, they did not find an association between LUTS and non-spine fractures after adjusting for potential confounders. This alone, however, does not negate the importance of LUTS as a risk factor for falls because adverse outcomes of falls are not limited to fractures or injuries directly caused by falls but also include fear of falling and self-imposed activity restriction as discussed in section 1.4.

In previous studies of the associations between LUTS and falls in both men and women, nocturia has been consistently associated with falls (23, 77). In the CHAMP study, however, no significant association was found between nocturia and falls. Since many older men have insomnia and may habitually go to the toilet when they wake up at night, simply counting episodes of urination during night time cannot differentiate between true nocturia and insomnia. Differentiating nocturnal micturition with and without urgency would allow us to isolate the effect of true nocturia on falls from that of poor sleep quality. One way this could be done is to record the presence or absence of urgency at each void: in a pharmacological trial to treat OAB, Weiss et al determined the degree of urgency at each void using the five-point Urgency Sensation Scale that the study participants recorded in a bladder diary (83).

In the urology clinic pilot study about the circumstances of falls, the only instances of falls that we identified that could possibly have been precipitated by LUTS were those in patients
with OAB that occurred on their way to the toilet. Since our sample size was small, it is possible that LUTS precipitate falls in other ways such as slips on leaked urine. It would be useful to identify more of the circumstances of LUTS-precipitated falls to generate hypotheses about what kind of interventions may be effective in preventing falls. Since Concord Hospital is located in a multicultural area in Sydney, many older patients in our clinics did not speak sufficient English language to be interviewed. Future studies may need to involve family and friends who accompany the patients and ask fewer and simpler questions.

To answer the question of whether treating LUTS reduces falls or not, ultimately, randomized controlled trials (RCTs) of medical or behavioural intervention for LUTS to prevent falls are necessary. There have been two RCTs to treat LUTS with falls prevention as the primary outcome in nursing home residents but none has been done in community-dwelling older people (75). One trial was a multidimensional intervention including prompted toileting and physical exercise which successfully reduced falls (89). But the other trial of a bladder-specific anticholinergic medication was unsuccessful (90). Since anticholinergic medications can cause adverse effects that are risk factors for falls such as blurred vision, tachycardia, confusion and cognitive impairment especially in older people, it is difficult to predict the direction of the effect of these medications on falls. Future studies of pharmacological treatment of LUTS in older patients should consider including falls as an outcome to answer this question. Furthermore, circumstances of falls should be further investigated among older people with LUTS, and then behavioural interventions based on these findings should be incorporated into multifactorial fall prevention strategies and be tested for efficacy.
References


Appendix A: CHAMP study questionnaires
Self-Completed Questionnaire

Chief Investigators
Professor Robert Cumming  Professor David Handelsman
Professor David Le Couteur  Professor Philip Sambrook  Professor Markus Seibel
Dr Helen Creasey  Dr Vasi Naganathan  Dr Louise Waite
CHAMP Self-Completed Questionnaire

Thank you for assisting us with our research and taking the time to complete this questionnaire. The information you provide will help us understand many important issues about older men’s health. We would like to assure you the answers you provide will remain strictly confidential.

Instructions
1. In general, we would like you to complete this questionnaire on your own. If you find that you need assistance please call Maggie Hayes or Melisa Litchfield on Freecall 1800 174 287 and they will assist you. If your spouse or partner assist you, please indicate this on the front cover of the questionnaire.
2. Please answer every question (unless you are asked to skip questions because they don’t apply to you). Please be as accurate as you can and choose the response that best describes your situation.
3. If you are unsure how to answer a question please give the best answer you can and make a comment in the left margin.
4. Answer every question by ticking the appropriate box ☣. Some questions also require a written response.

Statement of confidentiality
Information that would permit the identification of any person completing this questionnaire will be regarded as strictly confidential. All information provided will be used only for the CHAMP Study and will not be disclosed or released for any other purpose without your consent.

CHAMP Clinic
Suite 201
Concord Hospital Medical Centre
Concord Repatriation General Hospital
Hospital Road
Concord NSW 2139

Freecall: 1800 174 287
Phone: 9767 7269
Fax: 9767 5419
E-mail: CHAMP@anzac.edu.au
Section 1 – General Information

1. What is today’s date?  
   ______/______/______
   day   month   year

2. How old are you?  
   ______ years old

3. What is your date of birth?  
   ______/______/______
   day   month   year

4. What is your current marital status?  
   [ ] Married  
   [ ] Living with a partner/de facto  
   [ ] Widowed  
   [ ] Divorced  
   [ ] Separated  
   [ ] Never married  
   [ ] Other (please specify) ____________________________________________

5. For how many children are you the natural father?  ______ number

6. Who else lives in your home? (mark all that apply)  
   [ ] No one, I live alone  
   [ ] Wife/partner  
   [ ] Daughter(s)  
   [ ] Son(s)  
   [ ] Brother(s)  
   [ ] Sister(s)  
   [ ] Grandchildren  
   [ ] Other (please specify) ____________________________________________
7. What is your housing arrangement? Are you:
   ☐ The outright owner of your home
   ☐ Paying off your home
   ☐ Leasing, purchasing (or other financial plan) in a retirement village
   ☐ Paying rent or board to a private landlord
   ☐ Paying rent to the government for public housing
   ☐ Living rent or board free
   ☐ Other (please specify) ________________________________

8. In which country were you born?
   ☐ Australia → go to Question 9  ☐ Other (please specify) ________________________________

8a. If you were born in another country, how old were you when you first arrived in Australia?
   ________ years old

9. In which country was your natural mother born?
   ☐ Australia  ☐ Other (please specify) ________________________________

10. In which country was your natural father born?
    ☐ Australia  ☐ Other (please specify) ________________________________

11. When did you first learn to speak English?
    ☐ Before 12 years of age  ☐ After or equal to 12 years of age

12. What language do you usually speak at home?
    ☐ English  ☐ Other (please specify) ________________________________

13. How old were you when you left school?
    ________ years old  ☐ Didn’t go to school

CHAMP ID: ________________________
14. Since leaving school have you obtained a trade qualification, certificate, diploma or any other qualification?

☐ Yes  ☐ No ➔ Go to Question 15

14a. If yes, what is your highest qualification?

☐ Bachelor Degree or higher  ☐ Certificate/Diploma
☐ Trade/Apprenticeship  ☐ Other (please specify) __________________________

15. Are you currently in paid employment?

☐ Yes ➔ Go to Question 16  ☐ No

15a. If no, how old were you when you retired completely? ________ years old

16. Thinking of all the paid jobs that you ever had, what kind of work did you do the longest?
_________________________________________________________________________________________

17. Which of the following are sources of income for you? (mark all that apply)

☐ Age pension  ☐ Own business/farm/partnership
☐ Repatriation pension, Veteran’s pension  ☐ Wage or salary
☐ Superannuation or other private income  ☐ Other (please specify) __________________________

18. Are you currently driving at least once in a while?

☐ Yes ➔ Go to Section 2, Question 1  ☐ No

18a. If no, have you ever driven a car or have you given up driving?

☐ Never drove ➔ Go to Section 2, Question 1  ☐ Gave up driving

18b. If you gave up driving, how old were you when you stopped driving?

__________ years old
Section 2 - Medical History

1. Has a doctor or other health care provider ever told you that you had or have:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Yes</th>
<th>No</th>
<th>Yes</th>
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<tbody>
<tr>
<td>Diabetes?</td>
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<td>High thyroid, Grave's disease or an overactive thyroid gland?</td>
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<td>Low thyroid or an under active thyroid gland?</td>
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<td>Osteoporosis, sometimes called thin or brittle bone?</td>
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<td>Paget's disease?</td>
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<td>A stroke, blood clot in the brain or bleeding in the brain?</td>
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<td>Parkinson's disease?</td>
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<tr>
<td>Kidney stones?</td>
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<td>Dementia?</td>
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<tr>
<td>Depression?</td>
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<tr>
<td>Epilepsy or fits?</td>
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<td>Hypertension or high blood pressure?</td>
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<td>Heart attack, coronary or myocardial infarction?</td>
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<td>Angina (chest pain)?</td>
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<td>Congestive heart failure or enlarged heart?</td>
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<td>Intermittent claudication or pain in your legs from a blockage of the arteries?</td>
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<td>Chronic obstructive lung disease, chronic bronchitis, asthma, emphysema or COPD?</td>
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<tr>
<td>Liver disease?</td>
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<tr>
<td>Chronic kidney (renal) disease or kidney (renal) failure?</td>
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</table>
2. Have you ever had heart, or coronary, bypass surgery?
   □ Yes □ No ➔ Go to Question 3

2a. If yes, how old were you when you had this surgery? _______ years old

3. Have you ever had surgery to remove all or part of your stomach or intestines?
   □ Yes □ No ➔ Go to Question 4

3a. If yes, how old were you when you had this surgery? _______ years old

4. Has a doctor or other health care provider told you that you have arthritis or gout?
   □ Yes □ No ➔ Go to Question 5

4a. If yes, what type of arthritis did the health care provider say it was? (mark all that apply)
   □ Rheumatoid arthritis
   □ Osteoarthritis or degenerative arthritis
   □ Gout
   □ Some other type of arthritis (please specify) __________________________
   □ Don’t know

4b. Which of your joints have arthritis? (mark all that apply)
   □ Hip
   □ Hand/Fingers
   □ Back
   □ Shoulder
   □ Ankle
   □ Knee
   □ Wrist
   □ Other (please specify) ________________________
   □ Neck
   □ Elbow
   □ Foot/Toes
5. Have you ever had a serious head injury with loss of consciousness for more than 15 minutes?
   - Yes
   - No

6. Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill?
   - Yes
   - No → Go to Question 7

   6a. Do you get short of breath walking with other people of your own age on level ground?
       - Yes
       - No → Go to Question 7

   6b. Do you have to stop for breath when walking at your own pace on level ground?
       - Yes
       - No → Go to Question 7

   6c. Are you short of breath on washing or dressing?
       - Yes
       - No

7. Do you feel you have a hearing loss?
   - Yes
   - No

8. Compared to other people your age, how would you rate your memory?
   - Better than most
   - Average
   - A little below average
   - A lot below average
9. Do you sometimes have trouble with dizziness?
   [ ] Yes  [ ] No ➔ Go to Question 10

   9a. If yes, how long have you had trouble with dizziness?
       [ ] Less than 1 month  [ ] 1 month to 1 year  [ ] More than 1 year

   9b. Would you describe your dizziness as: (mark all that apply)
       [ ] Feeling like you are about to faint or pass out?
       [ ] Feeling that you or the room are spinning around?
       [ ] Feeling that you are losing your balance?
       [ ] Other (please specify) ________________________________

   9c. Is your dizziness troublesome enough to limit your activities, such as walking or other leisure activities?
       [ ] Yes  [ ] No

10. During the past 12 months, have you fallen and landed on the floor or ground, or fallen and hit an object like a table or chair?
    [ ] Yes  [ ] No ➔ Go to Question 11

    10a. If yes, how many times have you fallen in the past 12 months?
        [ ] Once  [ ] Twice  [ ] Three times
        [ ] Four times  [ ] Five times  [ ] Six or more times

    10b. Which of the following injuries did you have? (mark all that apply)
        [ ] I broke or fractured a bone
        [ ] I hit or injured my head
        [ ] I had a sprain or a strain
        [ ] I had a bruise or bleeding
        [ ] I had some other kind of injury
        [ ] I did not have any injuries from a fall in the past 12 months
11. **How tall were you without shoes when you were about 25 years old?**
   If you don’t remember exactly, give your best estimate.
   _______ feet _______ inches OR _______ centimetres

12. **What was your usual weight when you were about 25 years old?**
   If you don’t remember exactly, give your best estimate.
   _______ stone _______ pounds OR _______ kilograms

13. **What is the most you have ever weighed, and how old were you when you were at your heaviest weight?**
   _______ stone _______ pounds OR _______ kilograms
   at _______ years old
### Section 3 – Prostate Health

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<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Less than 1 time in 5</th>
<th>Less than half the time</th>
<th>About half the time</th>
<th>More than half the time</th>
<th>Almost always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Over the PAST MONTH, how often have you had a sensation of not emptying your bladder completely after you finish urinating?</td>
<td>☐</td>
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<td>2. Over the PAST MONTH, how often have you had to urinate again less than two hours after you finished urinating?</td>
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<td>3. Over the PAST MONTH, how often have you found you stopped and started again several times when you urinated?</td>
<td>☐</td>
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<td>4. Over the PAST MONTH, how often have you found it difficult to postpone urination?</td>
<td>☐</td>
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<td>5. Over the PAST MONTH, how often have you had a weak urinary stream?</td>
<td>☐</td>
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<tr>
<td>6. Over the PAST MONTH, how often have you had to push or strain to begin urination?</td>
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7. Over the PAST MONTH, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?

- None
- Once
- Twice
- Three times
- Four times
- Five or more times
8. If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?

☐ Delighted
☐ Pleased
☐ Mostly satisfied
☐ Mixed, about equally satisfied and dissatisfied
☐ Mostly unsatisfied
☐ Unhappy
☐ Terrible

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

9. How often do you leak urine?

☐ Never
☐ About once a week or less often
☐ Two or three times a week
☐ About once a day
☐ Several times a day
☐ All the time

We would like to know how much you think leaks.

10. How much urine do you usually leak (whether you wear protection or not)?

☐ None
☐ A small amount
☐ A moderate amount
☐ A large amount

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

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<th>0</th>
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<th>9</th>
<th>10</th>
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</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>A great deal</td>
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</table>
12. **When does urine leak? (mark all that apply)**
   - [ ] 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

13. **Over the PAST MONTH, how many pads or other incontinence aids, if any, did you usually use to help with leaking or dripping?**
   - [ ] No pads
   - [ ] 1 pad per day
   - [ ] 2 pads per day
   - [ ] 3 or more pads per day

14. **The Prostate Specific Antigen (PSA) test is a simple blood test that men are sometimes offered by their doctor, as a check for prostate disease. Have you ever had a PSA test?**
   - [ ] Yes
   - [ ] No ➔ Go to Question 15

14a. **If yes, in the past TWO YEARS, have you had a PSA test?**
   - [ ] Yes
   - [ ] No
15. A digital rectal exam is an exam in which a doctor, nurse, or other health professional places a gloved finger into the rectum to feel the size, shape, and hardness of the prostate gland. Have you ever had a digital rectal exam?

☐ Yes  ☐ No ➔ Go to Question 16

15a. If yes, in the past TWO YEARS, has a doctor or other health care provider checked your prostate by a digital rectal exam?

☐ Yes  ☐ No

16. Has a doctor or other health care provider told you that you have or had an enlarged prostate, also known as benign prostatic hyperplasia (BPH)? This means an enlarged prostate that is NOT due to cancer.

☐ Yes  ☐ No ➔ Go to Question 17

16a. Treatments for BPH usually are to improve urinary symptoms and flow. Have you ever had treatment for BPH?

☐ Yes  ☐ No ➔ Go to Question 17

16b. If yes, what type of treatment have you received? (mark all that apply)

☐ Surgery (laser surgery or transurethral resection of the prostate, sometimes called TURP or re-bore)

☐ Prescription medications

☐ Other (please specify) __________________________________________________________

17. Has a doctor or other health care provider told you that you had or have prostatitis (inflammation or infection of the prostate)?

☐ Yes  ☐ No ➔ Go to Question 18

17a. If yes, are you currently being treated for this condition by a doctor?

☐ Yes  ☐ No
18. Has a doctor or other health care provider ever told you that you have prostate cancer?

☐ Yes  ☐ No ➔ Go to Question 19

18a. If yes, how old were you at first diagnosis?

_______ years old

18b. What type of treatment did you receive? (mark all that apply)

☐ Radiation
☐ Surgery to remove prostate gland
☐ Surgery to remove testicles
☐ Hormone treatment
☐ No treatment or careful observation by a doctor
☐ Other (please specify) ________________________________

19. Has a doctor or other health care provider ever told you that you have any other cancer?

☐ Yes  ☐ No ➔ Go to Section 4, Question 1

19a. If yes, what cancer(s) were you diagnosed with?

List all the cancers you have had diagnosed. If you have been diagnosed with more than 3 cancers please list other cancers and the age at diagnosis in the blank space at the bottom of the page.

Cancer: ___________________________ Age at diagnosis: ________
Cancer: ___________________________ Age at diagnosis: ________
Cancer: ___________________________ Age at diagnosis: ________
Section 4 – Tobacco and Alcohol Use

1. Have you smoked at least 100 cigarettes (5 packs) in your entire life?

☐ Yes ☐ No ➔ Go to Question 2

1a. If yes, how old were you when you first started smoking regularly?

☐ Yes ☐ No ➔ Go to Question 2

1b. On the average of the entire time you smoked, how many cigarettes did you smoke per day?

☐ Yes ☐ No ➔ Go to Question 2

1c. Do you smoke cigarettes now?

☐ Yes ☐ No ➔ Go to Question 2

1d. About how many cigarettes do you smoke per day?

☐ Yes ☐ No ➔ Go to Question 2

1e. How old were you when you stopped smoking?

☐ Yes ☐ No ➔ Go to Question 2

2. Have you ever smoked a pipe or cigars regularly?

☐ Yes ☐ No ➔ Go to Question 3

2a. If yes, for how many years?

☐ Yes ☐ No ➔ Go to Question 3

2b. About how many do you smoke?

☐ Yes ☐ No ➔ Go to Question 3

2c. How many pipes or cigars per week.
3. Have you had at least 12 alcoholic drinks in your entire life?
   - Yes  
   - No ➔ Go to Section 5, Question 1

   3a. If yes, have you ever felt you should cut down on your drinking?
   - Yes  
   - No

   3b. Have people ever annoyed you by criticising your drinking?
   - Yes  
   - No

   3c. Have you ever felt bad or guilty about your drinking?
   - Yes  
   - No

   3d. Have you ever had a drink first thing in the morning to steady your nerves or to get rid of a hangover?
   - Yes  
   - No

Section 5 – Sun Exposure

1. How often do you go outside into the street or garden?
   - Never
   - A few times a month
   - Weekly
   - Most days

2. Do you avoid direct sunshine?
   - Always
   - Usually
   - Never

3. Have you had a suntan in the last 6 months?
   - No
   - Slight tan
   - Obvious tan
Section 6 – Physical Activity

1. Do you take walks for exercise, daily or almost everyday?
   □ Yes  □ No ➜ Go to Question 2

   1a. On the average, how many kilometres do you walk each day for exercise?
       ___________ kilometres

2. Over the PAST YEAR, have you spent more than one week confined to a bed or a chair as a result of any injury, illness or surgery?
   □ Yes  □ No ➜ Go to Question 3

   2a. How many weeks over this PAST YEAR were you confined to a bed or chair?
       ___________ weeks

The next few questions ask about your physical activity during the last 7 days. If the last 7 days have not been typical because of illness or bad weather, please estimate based on two or three weeks ago.

3. Over the PAST 7 DAYS, how often did you participate in sitting activities such as reading, watching TV, computing or doing handcrafts?
   □ Never ➜ Go to Question 4
   □ Seldom (1-2 days)  □ Sometimes (3-4 days)  □ Often (5-7 days)

   3a. What were these activities? ________________________________

   3b. On average, how many hours per day did you engage in these sitting activities?
       □ Less than 1 hour
       □ Between 1 and 2 hours
       □ 2-4 hours
       □ More than 4 hours
4. Over the PAST 7 DAYS, how often did you take a walk outside your home or yard for any reason? For example, for fun or exercise, walking to work, walking the dog, etc.

- Never ➔ Go to Question 5
- Seldom (1-2 days)
- Sometimes (3-4 days)
- Often (5-7 days)

4a. What were these activities? __________________________

4b. On average, how many hours per day did you spend walking?

- Less than 1 hour
- Between 1 and 2 hours
- 2-4 hours
- More than 4 hours

5. Over the PAST 7 DAYS, how often did you engage in light sport or recreational activities such as bowling, golf with a buggy, fishing from a boat or pier, or other similar activities?

- Never ➔ Go to Question 6
- Seldom (1-2 days)
- Sometimes (3-4 days)
- Often (5-7 days)

5a. What were these activities? __________________________

5b. On average, how many hours per day did you engage in these light sport or recreational activities?

- Less than 1 hour
- Between 1 and 2 hours
- 2-4 hours
- More than 4 hours
6. **Over the PAST 7 DAYS, how often did you engage in moderate sport and recreational activities such as doubles tennis, ballroom dancing, golf without a buggy, softball or other similar activities?**

   - [ ] Never ➜ Go to Question 7
   - [ ] Seldom (1-2 days)
   - [ ] Sometimes (3-4 days)
   - [ ] Often (5-7 days)

   **6a. What were these activities?** ________________________________

   **6b. On average, how many hours per day did you engage in these moderate sport or recreational activities?**

   - [ ] Less than 1 hour
   - [ ] Between 1 and 2 hours
   - [ ] 2-4 hours
   - [ ] More than 4 hours

7. **Over the PAST 7 DAYS, how often did you engage in strenuous sport and recreational activities such as jogging, swimming, cycling, singles tennis, aerobic exercise, skiing (downhill or cross country) or other similar activities?**

   - [ ] Never ➜ Go to Question 8
   - [ ] Seldom (1-2 days)
   - [ ] Sometimes (3-4 days)
   - [ ] Often (5-7 days)

   **7a. What were these activities?** ________________________________

   **7b. On average, how many hours per day did you engage in these strenuous sport or recreational activities?**

   - [ ] Less than 1 hour
   - [ ] Between 1 and 2 hours
   - [ ] 2-4 hours
   - [ ] More than 4 hours
8. Over the PAST 7 DAYS, how often did you do any exercise specifically to increase muscle strength and endurance, such as lifting weights or pushups, etc.?

☐ Never → Go to Question 9
☐ Seldom (1-2 days) ☐ Sometimes (3-4 days) ☐ Often (5-7 days)

8a. What were these activities? __________________________________________

8b. On average, how many hours per day did you engage in exercise to increase muscle strength and endurance?

☐ Less than 1 hour
☐ Between 1 and 2 hours
☐ 2-4 hours
☐ More than 4 hours

9. During the PAST 7 DAYS, have you done any light housework, such as dusting or washing dishes?

☐ Yes ☐ No

10. During the PAST 7 DAYS, have you done any heavy housework or duties, such as vacuuming, scrubbing floors, washing windows or carrying wood?

☐ Yes ☐ No

11. During the PAST 7 DAYS, did you engage in any of the following activities?

11a. Home repairs, like painting, wallpapering, electrical work, etc.?

☐ Yes ☐ No

11b. Lawn work or yard care, including leaf removal, wood chopping, etc.?

☐ Yes ☐ No

11c. Outdoor gardening?

☐ Yes ☐ No

11d. Caring for another person, such as children, dependent spouse, or another adult?

☐ Yes ☐ No
12. During the PAST 7 DAYS did you work, either for pay or as a volunteer?

☐ Yes  ☐ No  ➔ Go to Section 7, Question 1

12a. If yes, how many hours in the past week did you work for pay and/or as a volunteer?

__________ hours

12b. Which of the following categories best describes the amount of physical activity required on your job and/or volunteer work?

☐ Mainly sitting with slight arm movements
  Examples: office worker, watchmaker, seated assembly line worker, bus driver

☐ Sitting or standing with some walking
  Examples: cashier, general office worker, light tool and machinery worker

☐ Walking, with some handling of materials generally weighing less than 50 kgs
  Examples: postman, waiter/waitress, construction worker, heavy tool and machinery worker

☐ Walking and heavy manual work often requiring handling materials weighing more than 50 kgs
  Examples: stone mason, farmer or general labourer
Section 7 – Lifestyle (SF12)

1. Compared to other people your own age, how would you rate your overall health?
   - Excellent for my age
   - Good for my age
   - Fair for my age
   - Poor for my age
   - Very poor for my age

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf?
   - Yes, limited a lot
   - Yes, limited a little
   - No, not limited at all

3. Climbing several flights of stairs?
   - Yes, limited a lot
   - Yes, limited a little
   - No, not limited at all

During the PAST 4 WEEKS, have you had any of the following problems with your work or other regular daily activities because of your physical health?

4. Accomplished less than you would like
   - Yes
   - No

5. Were limited in the kind of work or other activities
   - Yes
   - No
During the PAST 4 WEEKS, have you had any of the following problems with your work or other regular daily activities because of any emotional problems (such as feeling depressed or anxious)?

6. Accomplished less than you would like  
☐ Yes  ☐ No

7. Didn't do work or other activities as carefully as usual  
☐ Yes  ☐ No

8. During the PAST 4 WEEKS, how much did pain interfere with your normal work (including both work outside the home and housework)?

☐ Not at all
☐ A little bit
☐ Moderately
☐ Quite a bit
☐ Extremely

These questions are about how you feel and how things have been with you during the PAST 4 WEEKS. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the PAST 4 WEEKS...

9. Have you felt calm and peaceful?

☐ All of the time
☐ Most of the time
☐ A good bit of the time
☐ Some of the time
☐ A little of the time
☐ None of the time

10. Did you have a lot of energy?

☐ All of the time
☐ Most of the time
☐ A good bit of the time
☐ Some of the time
☐ A little of the time
☐ None of the time
11. Have you felt downhearted and blue?
   - All of the time
   - Most of the time
   - A good bit of the time
   - Some of the time
   - A little of the time
   - None of the time

12. During the PAST 4 WEEKS, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?
   - All of the time
   - Most of the time
   - A good bit of the time
   - Some of the time
   - A little of the time
   - None of the time

The following questions are about your health and how you have been feeling in the LAST 4 WEEKS. In the LAST 4 WEEKS:

13. Have you felt keyed up or on edge?  
    - Yes  
    - No

14. Have you been worrying a lot?  
    - Yes  
    - No

15. Have you been irritable?  
    - Yes  
    - No

16. Have you had difficulty relaxing?  
    - Yes  
    - No

17. Have you been sleeping poorly?  
    - Yes  
    - No

18. Have you had headaches or neckaches?  
    - Yes  
    - No

19. Have you had any of the following: trembling, tingling, dizzy spells, sweating, diarrhoea or needing to pass water more often than usual?  
    - Yes  
    - No

20. Have you been worried about your health?  
    - Yes  
    - No

21. Have you had difficulty falling asleep?  
    - Yes  
    - No
Section 8 – Activities of Daily Living

We are interested to know about some of your activities of daily living, things that we all need to do as part of our daily lives. We would like to know if you can do these activities without any help at all, or if you need some help to do them, or if you can’t do them at all.

1. Can you use the telephone?
   - [ ] Without help, including looking up numbers and dialing
   - [ ] With some help (can answer phone or dial operator in an emergency, but need a special phone or help in getting the number or dialing)
   - [ ] Or are you completely unable to use the telephone?

2. Can you get to places out of walking distance?
   - [ ] Without help (can travel alone on buses, taxis, or drive your own car)
   - [ ] With some help (need someone to help you or go with you when traveling)
   - [ ] Or are you unable to travel unless emergency arrangements are made for a specialised vehicle like an ambulance?

3. Can you go shopping for groceries or clothes (if you have transportation)?
   - [ ] Without help (taking care of all shopping needs yourself, assuming you had transportation)
   - [ ] With some help (need someone to go with you on all shopping trips)
   - [ ] Or are you completely unable to do any shopping?

4. Can you prepare your own meals?
   - [ ] Without help (plan or cook full meals for yourself)
   - [ ] With some help (can prepare some things but unable to cook full meals yourself)
   - [ ] Or are you completely unable to prepare any meals?

5. Can you do your housework?
   - [ ] Without help (can scrub floors, etc.)
   - [ ] With some help (can do light housework but need help with heavy work)
   - [ ] Or are you completely unable to do any housework?
6. Can you take your own medications?
   [ ] Without help (in the right doses at the right time)
   [ ] With some help (are able to take medications if someone prepares it for you and/or reminds you to take it)
   [ ] Or are you completely unable to take your medication?

7. Can you handle your own money?
   [ ] Without help (write cheques, pay bills etc.)
   [ ] With some help (manage day-to-day purchases but need help with managing your cheque book and paying your bills)
   [ ] Or are you completely unable to handle money?

8. Are you able to do heavy work around the house, like washing windows, walls, or floors without help?
   [ ] Yes  [ ] No

9. Are you able to walk up and down stairs to the first floor without help?
   [ ] Yes  [ ] No

10. Are you able to walk half a mile (approximately one kilometre) without help?
    [ ] Yes  [ ] No
Section 9 – Caring

1. Do you have the main responsibility in caring for someone who has a long-term illness, disability, or other problem? (i.e. a problem that would prevent them from managing their household tasks or personal care independently.)
   - Yes
   - No ➔ Go to Section 10, Question 1

1a. If yes, who do you care for? (mark all that apply)
   - Wife/partner
   - Son
   - Daughter
   - Grandchild
   - Friend
   - Mother
   - Father
   - Other (please specify) ____________________________________________

Section 10 – Use of Health Services

1. In the LAST 12 MONTHS, have you consulted a GP or local doctor about your health?
   - Yes
   - No ➔ Go to Question 2

1a. If yes, in the LAST 2 WEEKS, have you consulted a GP or local doctor about your health?
   - Yes
   - No

2. In the LAST 12 MONTHS, have you visited or been visited by a community nurse or a private nursing service?
   - Yes
   - No
3. In the LAST 12 MONTHS, have you visited or been visited by a podiatrist or chiropodist? A podiatrist/chiropodist is a person who is specially trained to provide foot care.
   □ Yes  □ No

4. In the LAST 12 MONTHS, have you visited or been visited by a physiotherapist?
   □ Yes  □ No

5. In the LAST 12 MONTHS, have you spent at least one night in hospital?
   □ Yes  □ No

6. In the LAST 12 MONTHS, have you spent at least one night in a hostel/nursing home?
   □ Yes  □ No

7. In the LAST 12 MONTHS, have you spent at least one day in an Aged Care Day Centre?
   □ Yes  □ No

8. In the LAST 12 MONTHS, have you been visited by HomeCare to help with household or personal duties?
   □ Yes  □ No

9. In the LAST 12 MONTHS, have you used the services of the Community Aged Care Packages (CACPs) to help with any duties?
   □ Yes  □ No

10. In the LAST 12 MONTHS, did any service deliver or prepare your meals for you at home? For example, Meals-On-Wheels.
    □ Yes  □ No
Section 11 – Social Support

1. How many times during the PAST WEEK did you spend some time with someone who does not live with you? For example, you went to see them or they came to visit you, or you went out together:
   
   □ None  
   □ Once  
   □ Twice  
   □ Three times  
   □ Four times  
   □ Five times  
   □ Six times  
   □ Seven or more times

2. How many times did you talk to someone – friends, relatives or others – on the telephone in the PAST WEEK (either they called you, or you called them)?

   □ None  
   □ Once  
   □ Twice  
   □ Three times  
   □ Four times  
   □ Five times  
   □ Six times  
   □ Seven or more times
3. About how often did you go to meetings of social clubs, religious meetings, or other groups that you belong to in the PAST WEEK?
   - None
   - Once
   - Twice
   - Three times
   - Four times
   - Five times
   - Six times
   - Seven or more times

4. Does it seem that your family and friends (i.e. people who are important to you) understand you most of the time, some of the time, or hardly ever?
   - Hardly ever
   - Some of the time
   - Most of the time

5. Do you feel useful to your family and friends (i.e. people who are important to you) most of the time, some of the time, or hardly ever?
   - Hardly ever
   - Some of the time
   - Most of the time

6. Do you know what is going on with your family and friends most of the time, some of the time, or hardly ever?
   - Hardly ever
   - Some of the time
   - Most of the time
7. When you are talking with your family and friends, do you feel you are being listened to most of the time, some of the time, or hardly ever?
   - Hardly ever
   - Some of the time
   - Most of the time

8. Do you feel you have a definite role (place) in your family and among your friends most of the time, some of the time, or hardly ever?
   - Hardly ever
   - Some of the time
   - Most of the time

9. Can you talk about your deepest problems with at least some of your family and friends most of the time, some of the time, or hardly ever?
   - Hardly ever
   - Some of the time
   - Most of the time

10. How satisfied are you with the kinds of relationships you have with your family and friends very dissatisfied, somewhat dissatisfied, or satisfied.
    - Very dissatisfied
    - Somewhat dissatisfied
    - Satisfied

11. How many persons in this area (within one hours travel of your home) do you feel you can depend on or feel very close to?
    - _____ Number of family members
    - _____ Number of people who are NOT family members
    - None
Section 12 – Back and Joint Health

1. During the PAST 12 MONTHS, have you had any back pain?
   - Yes
   - No ➔ Go to Question 2

1a. If yes, how often were you bothered by back pain in the PAST 12 MONTHS?
   - All of the time
   - Most of the time
   - Some of the time
   - Rarely
   - Never

1b. When you have had back pain, how bad was it on average?
   - Mild
   - Moderate
   - Severe

1c. In what part or parts of your back is the pain usually located?
   (Mark all areas that apply with an X)
2. During the PAST 12 MONTHS, have you limited your activities because of back pain?
   □ Yes □ No ➔ Go to Question 3

   2a. If yes, how many days did you stay in bed (or lie down) at least half of the day because of your back?
       ________ days

   2b. How many days did you limit or cut down on your usual activities because of back pain? Do not include days in bed.
       ________ days

3. In the PAST 12 MONTHS, have you had pain in or around either hip joint, including the buttock, groin, or either side of the upper thigh, on most days for at least one month? Do not include pain from the lower back.
   □ Yes □ No ➔ Go to Question 4

   3a. If yes, was this pain in the left hip, right hip or both hips?
       □ Left hip □ Right hip □ Both hips

4. In the PAST 12 MONTHS, have you had pain, aching or stiffness in either knee on most days for at least one month? Include pain, aching and stiffness in or around your knee, including the front, back and side of knee.
   □ Yes □ No ➔ Go to Section 13, Question 1

   4a. If yes, was this pain in the left knee, right knee or both knees?
       □ Left knee □ Right knee □ Both knees
Section 13 – Geriatric Depression Scale

Choose the best answer for each of the following questions for how you felt over the LAST WEEK.

1. Are you basically satisfied with your life? □ Yes □ No
2. Have you dropped many of your activities and interests? □ Yes □ No
3. Do you feel that your life is empty? □ Yes □ No
4. Do you often get bored? □ Yes □ No
5. Are you in good spirits most of the time? □ Yes □ No
6. Are you afraid something bad is going to happen to you? □ Yes □ No
7. Do you feel happy most of the time? □ Yes □ No
8. Do you often feel helpless? □ Yes □ No
9. Do you prefer to stay at home, rather than going out and doing new things? □ Yes □ No
10. Do you feel you have more problems with memory than most? □ Yes □ No
11. Do you think it is wonderful to be alive now? □ Yes □ No
12. Do you feel pretty worthless the way you are now? □ Yes □ No
13. Do you feel full of energy? □ Yes □ No
14. Do you feel that your situation is hopeless? □ Yes □ No
15. Do you think that most people are better off than you are? □ Yes □ No
Section 14 – Family History

1. Is your natural mother still living?
   [ ] Yes  [ ] No  [ ] Don’t know → Go to Question 2
   1a. If yes, how old is your natural mother now?
       ________ years old
   1b. If no, how old was your natural mother when she died?
       ________ years old

2. Is your natural father still living?
   [ ] Yes  [ ] No  [ ] Don’t know → Go to Question 3
   2a. If yes, how old is your natural father now?
       ________ years old
   2b. If no, how old was your natural father when he died?
       ________ years old

3. Has anyone in your immediate family ever had dementia, Alzheimer’s disease, severe memory loss or mental confusion? Please include blood relatives only.
   [ ] Yes  [ ] No → Go to Question 4  [ ] Don’t know → Go to Question 4
   3a. If yes, please indicate their relationship to you? (mark all that apply)
       [ ] Natural father  [ ] Mother’s brother (maternal uncle)
       [ ] Natural mother  [ ] Mother’s sister (maternal aunt)
       [ ] Full brother  [ ] Father’s brother (paternal uncle)
       [ ] Full sister  [ ] Father’s sister (paternal aunt)
       [ ] Half brother  [ ] Son
       [ ] Half sister  [ ] Daughter
Fractures

4. Was your natural mother ever told by a doctor that she had osteoporosis, sometimes called thin or brittle bones? Please answer for your natural mother – the mother who gave birth to you.
   
   □ Yes □ No □ Don’t know

5. Did your natural mother ever break or fracture a bone? Please answer for your natural mother – the mother who gave birth to you.
   
   □ Yes □ No ➔ Go to Question 6 □ Don’t know ➔ Go to Question 6

5a. Did your natural mother ever break or fracture her HIP?
   
   □ Yes □ No □ Don’t know

5b. Did your natural mother ever break or fracture her WRIST OR FOREARM?
   
   □ Yes □ No □ Don’t know

5c. Did your natural mother ever break or fracture her SPINE?
   
   □ Yes □ No □ Don’t know

5d. Did you natural mother ever break a bone not listed above?
   
   □ Yes □ No □ Don’t know

If yes, please specify: ________________________________________

6. Was your natural father ever told by a doctor that he had osteoporosis, sometimes called thin or brittle bones?
   
   □ Yes □ No □ Don’t know
7. Did your natural father ever break or fracture a bone?
   - Yes
   - No ➔ Go to Question 8
   - Don’t know ➔ Go to Question 8

7a. Did your natural father ever break or fracture his HIP?
   - Yes
   - No
   - Don’t know

7b. Did your natural father ever break or fracture his WRIST OR FOREARM?
   - Yes
   - No
   - Don’t know

7c. Did your natural father ever break or fracture his SPINE?
   - Yes
   - No
   - Don’t know

7d. Did you natural father ever break a bone not listed above?
   - Yes
   - No
   - Don’t know

   If yes, please specify: ____________________________________________

Prostate Cancer

8. Has anyone in your immediate family ever had prostate cancer? Please include blood relatives only.
   - Yes
   - No
   - Don’t know

8a. If yes, please indicate their relationship to you: (mark all that apply)
   - Natural father
   - Son
   - Full brother
   - Mother’s brother (maternal uncle)
   - Half brother
   - Father’s brother (paternal uncle)

Thank you for completing this questionnaire.
Please bring this questionnaire with you to the CHAMP clinic.
Clinic Questionnaire

Chief Investigators
Professor Robert Cumming  Professor David Handelsman
Professor David Le Couteur  Professor Philip Sambrook  Professor Markus Seibel
Dr Helen Creasey  Dr Vasi Naganathan  Dr Louise Waite
Section 1 – Specimen Collection

1. Date of specimen collection
   _______ / _______ / _______
   day     month     year

2. Blood ID number ______________

3. “What is the date and time you last ate or drank anything except water?”
   3a. Date of last meal ______ / ______ / ______
       day        month        year
   3b. Time of last meal ______ : ______ (hours:minutes) ___ am ___ pm
   3c. How many hours has participant fasted? _______ hours

4. “Do you bleed or bruise easily?”
   □ Yes   □ No   □ Don't Know   □ Refused

5. “Have you ever been told you have a disorder relating to blood clotting or coagulation?”
   □ Yes   □ No   □ Don't Know   □ Refused

6. “Have you ever experienced fainting spells while having blood drawn?”
   □ Yes   □ No   □ Don't Know   □ Refused

7. “Have you ever had a shunt or port for kidney dialysis?”
   □ Yes   □ No   □ Don't Know   □ Refused

   7a. Which side?
    □ right (draw blood on left)
    □ left (draw blood on right)
    □ both (do NOT draw blood)
8. **Start time of venepuncture (butterfly or needle into vein):**
   _______ : _______ (hours:minutes) ___ am ___ pm

9. **Finish time of venepuncture:**
   _______ : _______ (hours:minutes) ___ am ___ pm

10. **Total tourniquet time:** (If tourniquet was reapplied, enter total time tourniquet was on)
    _______ minutes

11. **Was any blood drawn?**
    [ ] Yes    [ ] No

    11a. If no, why not?
    __________________________________________________________

12. **Which tubes were filled?**
   [ ] Hormones (9mL red tube)
   [ ] Bone assay (9mL red tube)
   [ ] Bone assay (9mL red tube)
   [ ] Future parameters – EDTA (9mL purple tube)
   [ ] Biochemistry and PSA (5mL yellow tube)
   [ ] Hematology – FBC (4mL small purple tube)
   [ ] Future parameters (9mL green tube)
   [ ] Future parameters (9mL red tube)
   [ ] Future parameters (9mL red tube)

13. **If any of the above blood tubes were not filled, why not?**
    ..........................................................................................................................
14. **Quality of venepuncture:**

☐ Clean  ☐ Traumatic

14a. If traumatic: (mark all that apply)

☐ Vein collapse

☐ Hematoma

☐ Vein hard to get

☐ Excessive duration of draw

☐ Leakage at venepuncture site

☐ Other (please specify) ____________________________________

15. **Comments on phlebotomy:**

__________________________________________________________________________
Section 2 – Alcohol Use

A show card that lists the measures of standard drinks should be shown while asking these questions.

1. “In the past 12 months, have you had at least 12 drinks of any kind of alcoholic beverage?”
   - [ ] Yes
   - [ ] No
   - [ ] Don’t know
   - [ ] Refused

   1a. In the past 12 months, on the average, how many days per week, month, or year did you drink any alcoholic beverage?
      - [ ] ______ days per [ ] Week  [ ] Month  [ ] Year

   1b. On the average, on the days that you drank alcohol, how many drinks did you have a day?
      - [ ] ______ drinks

   1c. In the past 12 months, how many days per week, month, or year did you have five or more drinks on a single day? Include all types.
      - [ ] ______ days per [ ] Week  [ ] Month  [ ] Year

      - [ ] Participant did not have at least five drinks on any day

2. “Was there ever a time in your life when you drank 5 or more drinks of any kind of alcoholic beverage almost every day?”
   - [ ] Yes
   - [ ] No
   - [ ] Don’t know
   - [ ] Refused
Section 3 – Functional Disability

“Do you need help from another person or special equipment or device to do any of the following things?”

<table>
<thead>
<tr>
<th>Activity</th>
<th>No, does not need help</th>
<th>Yes, needs help</th>
<th>Unable to do this</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking across a small room?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bathing, either a sponge bath, tub bath, or shower?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Personal grooming, like brushing hair, brushing teeth, or washing face?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dressing, like putting on a shirt, buttoning and zipping, or putting on shoes?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eating like holding a fork, cutting food, or drinking from a glass?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Getting from a bed to a chair?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Using the toilet?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Section 4 – Pain

1. “In the last 6 months, have you experienced pain in any part of your body which has lasted for 3 months or more, that is pain experienced every day for at least 3 months?”

   Yes  ☐  No  ☐

1a. In which part(s) of your body have you experienced this pain? (mark all that apply)

   - Hands  ☐  Shoulders  ☐  Neck  ☐  Ankles  ☐
   - Wrist  ☐  Face  ☐  Hips  ☐  Foot  ☐
   - Elbows  ☐  Jaw  ☐  Knees  ☐  Back  ☐
   - Other (please specify) ___________________________________________________________
Section 5 – Cognition

Say to participant: “In the next section we’re going to do some tasks which you may find challenging. That’s normal, because some of them are difficult. We’re doing these tasks to look at your memory and concentration...things like that. You won’t get them all right – that’s impossible. The important thing is that you try your best. Also, I will not tell you whether your answers are right or wrong during this session.”

LOGICAL MEMORY

Say to participant: “I am going to read a short story to you. Listen carefully and try to remember it just the way I say it, as close to the same words as you can remember. When I am finished, I want you to tell me everything I read to you. You should tell me as much as you can remember even if you are not sure. You will not be able to remember the whole story but just remember as much as you can. Are you ready?”

Read the following story in a steady, clear voice.

Robert / Miller / was driving / a ten-ton / truck / down a highway / at night / in the Hunter / Valley /, carrying eggs / to Newcastle /, when his axle / broke. His truck skidded / off the road /, into a ditch /. He was thrown / against the dashboard / and was badly shaken /. There was no traffic / and he doubted that help would come /. Just then his two-way radio / buzzed /. He quickly answered /, “This is Grasshopper /.”

1. Total for story Max = 26

After reading the story, say: “Tell me everything you can remember about the story. Start at the beginning.”

As the participant repeats the words to you, place a tick above the word. Score one point for each section of words (separated by a “/”). If the participant says anything that is not part of the story, record what they say on the right hand side of the story box.

When the participant has finished ask them: “Is there anything else you can think of?” as they often remember another couple of words.

Say to participant: “I want you to remember as much of this story as you can because I will ask you to tell me the story again later.”

2. Record the time this sentence was said to participant _____ : _____ (hours:minutes)
TRAIL MAKING TASK B

Hand the participant the “Sample Response Sheet” and a pencil.

Say to the participant:

*On this page there are some numbers and letters. When I tell you to,*

**please begin at number 1 (point to 1)**

**and draw a line from 1 to A (point to A),**

**then from A to 2 (point to 2),**

**from 2 to B (point to B),**

**B to 3 (point to 3),**

**3 to C (point to C)**

**and so on, in order, until you reach the end. (point to the circle marked end)***

Remember, first, you have a number (point to 1),

then a letter (point to A),

then a number (point to 2),

then a letter (point to B). Work as fast and accurately as you can. Try not to lift your pencil from the page. Ready? Begin.”

If the participant makes a mistake, point out the error and explain it. For example, say: "That’s not quite right. Let me show you how it should be done." If necessary, guide the participant’s hand through the trail without marking the page. Then say: "Now you try it,” and repeat the directions starting, “Begin at number 1.” The participant is allowed 3 attempts at the Sample Response Sheet. If they do not complete the sample successfully, do not administer the test.

If the participant completes the sample sheet correctly and shows that he understands the task, say: “Good! Let’s try the next one...” and continue on with the test.

1. **Was the participant able to complete the Sample Response Sheet?**

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

1a. **If no, why not?**

   | Unable due to physical problems (hand tremor, cast, etc.) |
   | Participant did not understand directions |
   | Other |
   | Participant refused |

---

8 CHAMP CLINIC QUESTIONNAIRE
Hand the participant the “Test Response Sheet.”

Say to the participant:

“Here is another page with numbers and letters. Do this page the same way.

Begin at number 1 (point to 1)
and draw a line from 1 to A (point to A).
A to 2 (point to 2).
2 to B (point to B).
and so on, in order, until you reach the end. (point to the circle marked end)

Work as fast and as accurately as you can. Try not to lift the pencil from the page. I will be watching you as you work so I can point out any problems as they occur. I’ll be drawing a line across any incorrect lines as we go along. You will have five minutes to do as much of this as you can. Ready? Begin.”

Start timing as soon as the instruction is given above. Allow a maximum of 300 seconds (5 minutes) for the task. WATCH CLOSELY IN ORDER TO CATCH ANY ERRORS AS SOON AS THEY ARE MADE. If the participant makes an error, identify it immediately by saying “Excuse me, that’s not quite right.” Draw a perpendicular line through the incorrect line and tell him to proceed from the number or letter where the mistake occurred. Do not show him which circle to go to next and DO NOT STOP TIMING.

If the participant is having trouble, say “Just do the best you can.”

Record time in minutes and seconds and list the number of errors made. If the participant makes more than 5 errors or goes over 300 seconds, stop, and go on to the next test.

2. Number of circles connected (max = 25) circles

3. Total time in minutes and seconds (max = 5 mins) ______ : ______

4. Number of errors ______
ADDENBROOKE'S COGNITIVE EXAMINATION (ACE)

Say to the participant: "Now we will move onto the next section." Write the participants answer in the space provided in the response column.

1= Correct  0= Incorrect  R=Refused  U=Unable due to physical or language reasons

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.  What is the year?</td>
<td>Year</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>2.  What is the season? (Current season OR within 1 week of upcoming season OR within 2 weeks of previous season)</td>
<td>Season</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>3.  What is the date? (± 2 days)</td>
<td>Date</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>4.  What is the day?</td>
<td>Day</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>5.  What is the month?</td>
<td>Month</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>6.  What is the country we are in?</td>
<td>Country</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>7.  What state are we in?</td>
<td>State</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>8.  What city are we in?</td>
<td>City</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>9.  What is the name (or address) of this place?</td>
<td>Name</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>10. What floor of the building are we on?</td>
<td>Floor</td>
<td>1 0 R U</td>
</tr>
</tbody>
</table>

11. Listen carefully. I am going to say three words. After I have said them, I want you to repeat them. Remember what they are because I am going to ask you to name them again in a few minutes. Please repeat the names for me: APPLE, TABLE, PENNY.

(Score first try 0.3, but keep saying all 3 until subject can repeat all 3, up to 6 trials. Record number of trials required.)

No of trials necessary for the participant to repeat the sequence
<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>12. Now I’d like you to subtract 7 from 100. Then keep subtracting 7 from each answer until I ask you to stop. (If subject cannot or will not perform this task, administer 12B, WORLD)</td>
<td>93</td>
<td>1 0 R U</td>
</tr>
<tr>
<td></td>
<td>86</td>
<td>1 0 R U</td>
</tr>
<tr>
<td></td>
<td>79</td>
<td>1 0 R U</td>
</tr>
<tr>
<td></td>
<td>72</td>
<td>1 0 R U</td>
</tr>
<tr>
<td></td>
<td>65</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>12b. Administer only if subject cannot do 12. Now I am going to give you a word and ask you to spell it forwards and backwards. The word is WORLD. First, can you spell it forwards? Now spell it backwards. (Repeat if necessary, and help subject spell word forward, if necessary. Score number of letters given in correct order.):</td>
<td>D</td>
<td>/</td>
</tr>
<tr>
<td></td>
<td>L</td>
<td>/</td>
</tr>
<tr>
<td></td>
<td>R</td>
<td>Refused</td>
</tr>
<tr>
<td></td>
<td>O</td>
<td>Unable</td>
</tr>
<tr>
<td></td>
<td>W</td>
<td>Unable</td>
</tr>
<tr>
<td>13. What are the three objects I asked you to remember?</td>
<td>Apple</td>
<td>1 0 R U</td>
</tr>
<tr>
<td></td>
<td>Table</td>
<td>1 0 R U</td>
</tr>
<tr>
<td></td>
<td>Penny</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>14. I am going to read a name and address – I want you to repeat it when I have finished. Wait until I finish telling you the complete address. (Now read aloud the following name and address.)</td>
<td>Peter Marshall</td>
<td>Refused</td>
</tr>
<tr>
<td></td>
<td>42 Station Street</td>
<td>Unable</td>
</tr>
<tr>
<td></td>
<td>Geelong</td>
<td>Victoria</td>
</tr>
<tr>
<td></td>
<td>Victoria</td>
<td>/</td>
</tr>
<tr>
<td>14a. Trial 1</td>
<td>Marshall</td>
<td>Refused</td>
</tr>
<tr>
<td></td>
<td>St</td>
<td>Unable</td>
</tr>
<tr>
<td></td>
<td>Geelong</td>
<td>Victoria</td>
</tr>
<tr>
<td>14b. Trial 2</td>
<td>Marshall</td>
<td>Refused</td>
</tr>
<tr>
<td></td>
<td>St</td>
<td>Unable</td>
</tr>
<tr>
<td></td>
<td>Geelong</td>
<td>Victoria</td>
</tr>
<tr>
<td>14c. Trial 3</td>
<td>Marshall</td>
<td>Refused</td>
</tr>
<tr>
<td></td>
<td>St</td>
<td>Unable</td>
</tr>
<tr>
<td></td>
<td>Geelong</td>
<td>Victoria</td>
</tr>
<tr>
<td>15. Tell me the name of:</td>
<td>PM</td>
<td>1 0 R U</td>
</tr>
<tr>
<td></td>
<td>the previous Prime Minister</td>
<td>Last PM</td>
</tr>
<tr>
<td></td>
<td>the Leader of the Opposition</td>
<td>Opposition</td>
</tr>
<tr>
<td></td>
<td>the President of the United States of America</td>
<td>USA President</td>
</tr>
<tr>
<td>Question</td>
<td>Response</td>
<td>Score</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>----------</td>
<td>-------</td>
</tr>
<tr>
<td>16. Tell me all the words you can think of beginning with the letter P, but don’t tell me names of people or places. Remember, no people or place names. (Time the patient for 60 seconds and list all the answers in the space provided. The score is the number of words they think of if the person mentions a person or a place you may remind them of the rules once.)</td>
<td>Number of words correct</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refused</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unable</td>
<td></td>
</tr>
<tr>
<td>17. Now tell me names of all the animals you can think of (it doesn’t matter what letter they start with). (Time the patient for 60 seconds and list all the answers in the space provided. The score is the number of words they think of,)</td>
<td>Number of words correct</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refused</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unable</td>
<td></td>
</tr>
<tr>
<td>18. (Show wrist watch) What is this called?</td>
<td>Watch</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 0 R U</td>
<td></td>
</tr>
<tr>
<td>19. (Show pencil) What is this called?</td>
<td>Pencil</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 0 R U</td>
<td></td>
</tr>
<tr>
<td>20. Show 10 pictures. Ask patient to name the pictures. Allow close synonyms. Ask the patient: What do you call this?</td>
<td>Giraffe</td>
<td>1 0 R U</td>
</tr>
<tr>
<td></td>
<td>Kite</td>
<td>1 0 R U</td>
</tr>
<tr>
<td></td>
<td>Helicopter</td>
<td>1 0 R U</td>
</tr>
<tr>
<td></td>
<td>Pig</td>
<td>1 0 R U</td>
</tr>
<tr>
<td></td>
<td>Kangaroo</td>
<td>1 0 R U</td>
</tr>
<tr>
<td></td>
<td>Crown</td>
<td>1 0 R U</td>
</tr>
<tr>
<td></td>
<td>Windmill</td>
<td>1 0 R U</td>
</tr>
<tr>
<td></td>
<td>Goat</td>
<td>1 0 R U</td>
</tr>
<tr>
<td></td>
<td>Barro</td>
<td>1 0 R U</td>
</tr>
<tr>
<td></td>
<td>Camol</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>Question</td>
<td>Response</td>
<td>Score</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>-------------------------------</td>
<td>-------</td>
</tr>
<tr>
<td><strong>21. Please obey the following simple commands:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Point to the door</td>
<td>Point to the door</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>• Point to the ceiling</td>
<td>Point to the ceiling</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>• Point to the ceiling then the door</td>
<td>Ceiling to door</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>• Point to the door after touching the desk</td>
<td>Desk to door</td>
<td>1 0 R U</td>
</tr>
<tr>
<td><strong>22. Read the words on this page, then do what it says.</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(The paper reads “CLOSE YOUR EYES.” Contact if subject closes eyes.)</td>
<td>Close your eyes</td>
<td>1 0 R U</td>
</tr>
<tr>
<td><strong>23. I’m going to give you a piece of paper. When I do, take the paper</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>in your right hand, fold the paper in half with both hands, and put</td>
<td>Right hand</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>the paper down on your lap.</td>
<td>Fold in half</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>(Read the full statement, THEN hand over paper. Do not repeat instructions or coach)</td>
<td>Put it on lap</td>
<td>1 0 R U</td>
</tr>
<tr>
<td><strong>24. Repeat each of these words after me.</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Brown</td>
<td>Brown</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>• Conversation</td>
<td>Conversation</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>• Articulate</td>
<td>Articulate</td>
<td>1 0 R U</td>
</tr>
<tr>
<td><strong>25. I would like you to repeat each of these phrases after me:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“No ifs, ands or buts.”</td>
<td>No ifs, ands</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>“The orchestra played and the audience applauded.”</td>
<td>Orchestra</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>(Allow only one trial.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>26. Please read these words aloud:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Shed</td>
<td>Shed</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>• Wipe</td>
<td>Wipe</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>• Board</td>
<td>Board</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>• Flame</td>
<td>Flame</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>• Bridge</td>
<td>Bridge</td>
<td>1 0 R U</td>
</tr>
<tr>
<td>Question</td>
<td>Response</td>
<td>Score</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>----------</td>
<td>-------</td>
</tr>
<tr>
<td>27. Please read these words aloud:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Sew</td>
<td>Sew</td>
<td>1 0</td>
</tr>
<tr>
<td>• Pint</td>
<td>Pint</td>
<td></td>
</tr>
<tr>
<td>• Soot</td>
<td>Soot</td>
<td></td>
</tr>
<tr>
<td>• Dough</td>
<td>Dough</td>
<td></td>
</tr>
<tr>
<td>• Height</td>
<td>Height</td>
<td></td>
</tr>
<tr>
<td>28. Write any complete sentence on that piece of paper for me.</td>
<td>Sentence</td>
<td>1 0</td>
</tr>
<tr>
<td>(If examinee needs a sentence ask them to write about the weather. Ask subject to write on the page they folded in half. Sentence must contain a subject and a verb and be sensible. Correct grammar and punctuation are not necessary.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>29. Can you tell me the name and address that I told you before (the one you practiced 3 times)?</td>
<td>5 minuto delay</td>
<td></td>
</tr>
<tr>
<td>Peter _____ Marshall _____</td>
<td>Refused</td>
<td></td>
</tr>
<tr>
<td>42 _____ Station _____</td>
<td></td>
<td></td>
</tr>
<tr>
<td>St _____ Geelong _____</td>
<td>Unable</td>
<td></td>
</tr>
<tr>
<td>Victoria ____</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30. Here are two drawings. Please copy the drawings on the same paper.</td>
<td>Pentagon</td>
<td>1 0</td>
</tr>
<tr>
<td>Wire cube</td>
<td>1 0</td>
<td></td>
</tr>
<tr>
<td>31. Can you please draw a clock-face with numbers and the hands at ten past five.</td>
<td>Correct circle</td>
<td>1 0</td>
</tr>
<tr>
<td>Numbering</td>
<td>1 0</td>
<td></td>
</tr>
<tr>
<td>Position of hands</td>
<td>1 0</td>
<td></td>
</tr>
<tr>
<td>32. Total score MMSE:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>33. Total score ACE:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

34. Does the participant have any physical/functional disabilities or other problems that caused the participant difficulty in completing any of the tasks.

☐ Yes  ☐ No

34a. If yes, what is the most significant reason?

________________________________________________________

________________________________________________________

________________________________________________________

14 CHAMP CLINIC QUESTIONNAIRE
COLOUR FORM SORT

Spread the colour form pieces on the table in no apparent order. Say to the participant: “Sort the pieces into separate groups, so that the ones that are alike go together.”
If the participant asks for any advice, say: “It’s completely up to you.”
Leave the pieces as they are and say to the participant: “Now sort the pieces into groups that go together in a different way.”
If they sort the pieces incorrectly say: “That’s not different enough, sort them in a completely different way.”

1. 
   - [] Unable to do first sort
   - [] Sorts one category spontaneously
   - [] Sorts two categories spontaneously

If the participant is unable to sort the pieces into colours, ask them to name the colours.

2. 
   - [ ] Was the participant able to name the colours? [ ] Yes [ ] No

LOGICAL MEMORY RECALL

3. Record the time ______ : ______ (hours:minutes)

Say to participant: “Do you remember the story I read you a little while ago? I want you to tell me the story again. Tell me everything that you can remember about the story. Start at the beginning.”

If the participant does not recall any story, say: “The story was about a man who had trouble on the highway.”

4. 
   - [ ] Was the reminder sentence given? [ ] Yes [ ] No

Do not give any further help other than general encouragement. When they have finished say: “Is there anything else you can think of?”

| Robert / Miller / was driving / a ten-ton / truck / | /5 |
| down a highway / at night / in the Hunter / Valley / | /4 |
| carrying eggs / to Newcastle / when his axle / broke. | /4 |
| His truck skidded / off the road / into a ditch / | /3 |
| He was thrown / against the dashboard / and was badly shaken / | /3 |
| There was no traffic / and he doubted that help would come / | /2 |
| Just then his two-way radio / buzzed / He quickly answered / | /3 |
| “This is Grasshopper /.” | /1 |

5. Total for story Max = 26
Section 6 – Fracture History

1. “Has a doctor EVER told you that you broke or fractured a bone?”
   - [ ] Yes
   - [ ] No

1a. If yes:
   - which bones were they?
   - how old were you?
   - how did you break or fracture the bone?

   *Allow multiple breakages for the same bone. Record details for each breakage.*

<table>
<thead>
<tr>
<th>Yes</th>
<th>Age</th>
<th>How did you break the bone?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Spine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wrist</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hip</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Arm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ankle</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Leg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Other</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Other (please specify)</td>
</tr>
</tbody>
</table>


Section 7 – Height, Weight and Pulse

1. Standing Height
   Say to the participant: “Please stand with your back against this board. Your legs should be together and your heels, your buttocks and your back should be touching the board. Look straight ahead and stand tall.”
   Bring the horizontal bar down firmly onto the top of the participant’s head. Place the bean bag on the headboard to make sure the horizontal bar makes contact with the top of the scalp.
   Ask the participant to: “Take a deep breath.” Record the reading on the stadiometer just before the participant exhales. Then say: “Breathe out.”
   Ask the participant to step away from the stadiometer, then step back into the measurement position. Take the second measurement as before.
   1a. Measurement 1: ______ mm  1b. Measurement 2: ______ mm
   1c. Does measurement 1 and measurement 2 differ by 4 or more mm?
      □ Yes  □ No
      If yes: complete Measurements 3 and 4
   1d. Measurement 3: ______ mm  1e. Measurement 4: ______ mm
   1f. Does the participant have kyphosis?
      □ Yes  □ No

2. Weight
   Say to the participant: “In order to measure your weight, please remove your shoes and heavy jewellery, and empty your pockets. Please step forward onto the centre of the scale.” If the participant needs support you can tell them they can use the bars of the scales to steady themselves.
   Weight ______ kg
   2a. If weight was not measured, explain why______________________________

3. Circumferences
   Neck
   3a. Measure 1: ______ mm  3b. Measure 2: ______ mm  3c. Measure 3: ______ mm
   Waist
   3d. Measure 1: ______ mm  3e. Measure 2: ______ mm  3f. Measure 3: ______ mm
   Hip
   3g. Measure 1: ______ mm  3h. Measure 2: ______ mm  3i. Measure 3: ______ mm
4. Measurement of foot size
   Right 4a. Measurement 1: _______ mm  Left 4c. Measurement 1: _______ mm
   4b. Measurement 2: _______ mm 4d. Measurement 2: _______ mm

5. Radial Pulse
   5a. Measurement 1:
       _______ beats per 30 seconds x 2 = Measurement 1: _______ beats per minute
   5b. Measurement 2:
       _______ beats per 30 seconds x 2 = Measurement 2: _______ beats per minute

Blood Pressure

6. Exclusion criteria ➔ If any of these are ticked, DO NOT TEST
   [ ] Open wounds, ulcerations [ ] Unable to lie at <45 degree angle
   [ ] Bilateral amputation [ ] Participant refused

7. Cuff size
   [ ] Small  [ ] Regular  [ ] Large  [ ] Thigh

8. Arm Used
   [ ] Right  [ ] Left ➔ 8a. Why wasn’t the right arm used?: ____________________

9. Blood pressure while participant LYING DOWN
   Blood Pressure 1  9a. Systolic Measurement 1: _______ mmHg
   9b. Diastolic Measurement 1: _______ mmHg
   Blood Pressure 2  9c. Systolic Measurement 2: _______ mmHg
   9d. Diastolic Measurement 2: _______ mmHg

10. Blood pressure while participant STANDING UPRIGHT
    Blood Pressure 3  10a. Systolic Measurement 3: _______ mmHg
    10b. Diastolic Measurement 3: _______ mmHg
    Blood Pressure 4  10c. Systolic Measurement 4: _______ mmHg
    10d. Diastolic Measurement 4: _______ mmHg

11. After standing blood pressure has been measured, ask the participant: “Did you feel dizzy, woozy or lightheaded during any of the procedure?”
    [ ] Yes  [ ] No

CHAMP CLINIC QUESTIONNAIRE
Section 8 – Functional Vision

1. "Have you ever been told by a doctor or health professional that you have macular degeneration?"
   □ Yes □ No
   
   1a. If yes, are you currently being treated for this condition by a doctor?
       □ Yes □ No

2. "Have you ever been told by a doctor or health professional that you have glaucoma?"
   □ Yes □ No
   
   2a. If yes, are you currently being treated for this condition by a doctor?
       □ Yes □ No

3. "Have you ever been told by a doctor or health professional that you have cataracts?"
   □ Yes □ No
   
   3a. If yes, have you had surgery for cataracts?
       □ Yes □ No

LETTER LITERACY TEST

Administer the letter literacy test. Show participant letter literacy card. Be sure they are wearing their reading glasses, if needed. Script: "Can you see these letters? (point to card). Read me the letters one by one across the line."

ABO SE       RT H U P        IV Z J Q

4. Letter literacy test score: ______ number of correct letters

   4a. Were 10 or more letters read correctly?
       □ Yes ➔ Administer all functional vision tests
       □ No ➔ Administer FRISBY STEREO test only

CHAMP CLINIC QUESTIONNAIRE 18
LOGMAR VISUAL ACUITY

5. “Do you usually wear glasses or contact lenses to see things at a distance, like for driving or watching TV?”
   - Yes
   - No ➔ Go to Question 6

5a. Is the participant wearing glasses or contact lenses for the acuity test?
   - Yes
   - No ➔ Go to Question 6

5b. What is the participant wearing – glasses and/or contact lenses?
   - Glasses
   - Contact lenses

5c. What type of glasses?
   - Distance
   - Bifocal
   - No-line bifocal
   - Multi-focal

5d. What type of contact lenses?
   - Distance
   - Bifocal
   - Monovision (one eye corrected for near; one for distance)

6. Which distance was used?
   - 8 feet
   - 4 feet
   - Participant unable to read chart at 4 feet

Say to participant: “I’m going to ask you to read me the letters on that chart. Can you read the highlighted top row using both eyes? Don’t squint and don’t lean forward.”

If they correctly read the top line, continue. If they can’t read the top line, move the participant to 4 feet and try again. If they still cannot read the top line, stop the test.

Then say: “Now keep reading down the chart. If you are not sure about a letter, please guess.” Don’t tell the participant when they have made a mistake. If they hesitate, say: “Go ahead and guess. We need you to go as far as you can, guessing when you are not sure.”

Mark any incorrect letters on the table on the next page. If the participant gets three or more letters wrong in the one row, tell them to stop after they have finished the entire row. Say: “Okay, that’s great. Now you can stop.”
(Examiner note: make an "X" through each letter incorrectly identified. If the participant misses 3 or more letters on one row, stop administering the test and go to Question 8.)

<table>
<thead>
<tr>
<th>Chart</th>
<th>Letter Count</th>
<th>SNELLEN 8 feet</th>
<th>Equivalent 4 feet</th>
</tr>
</thead>
<tbody>
<tr>
<td>H V Z D S</td>
<td>5</td>
<td>20/200</td>
<td>20/400</td>
</tr>
<tr>
<td>N C V K D</td>
<td>10</td>
<td>20/160</td>
<td>20/320</td>
</tr>
<tr>
<td>C Z S H N</td>
<td>15</td>
<td>20/125</td>
<td>20/250</td>
</tr>
<tr>
<td>O N V S R</td>
<td>20</td>
<td>20/100</td>
<td>20/200</td>
</tr>
<tr>
<td>K D N R O</td>
<td>25</td>
<td>20/80</td>
<td>20/160</td>
</tr>
<tr>
<td>Z K C S V</td>
<td>30</td>
<td>20/63</td>
<td>20/125</td>
</tr>
<tr>
<td>D V O H C</td>
<td>35</td>
<td>20/50</td>
<td>20/100</td>
</tr>
<tr>
<td>O H V C K</td>
<td>40</td>
<td>20/40</td>
<td>20/80</td>
</tr>
<tr>
<td>H Z C K O</td>
<td>45</td>
<td>20/32</td>
<td>20/63</td>
</tr>
<tr>
<td>N C K H D</td>
<td>50</td>
<td>20/25</td>
<td>20/50</td>
</tr>
<tr>
<td>Z H C S R</td>
<td>55</td>
<td>20/20</td>
<td>20/40</td>
</tr>
<tr>
<td>S Z R D N</td>
<td>60</td>
<td>20/16</td>
<td>20/32</td>
</tr>
<tr>
<td>H C D R O</td>
<td>65</td>
<td>20/12.5</td>
<td>20/25</td>
</tr>
<tr>
<td>R D O S N</td>
<td>70</td>
<td>20/10</td>
<td>20/20</td>
</tr>
</tbody>
</table>

7. **Number of letters read correctly:** ______ letters

   (Examiner note: starting with the Letter Count for the last line read without errors, add one for each additional letter correctly read on lines below it.)

8. **Was the acuity test administered?**
   - [ ] Yes
   - [ ] No

   8a. If no, why not?
   - [ ] Did not pass letter literacy exam
   - [ ] Did not understand
   - [ ] Participant fatigued
   - [ ] Refused
   - [ ] Unable to see chart

CHAMP CLINIC QUESTIONNAIRE 21
PELLI-ROBSON TEST FOR CONTRAST SENSITIVITY

9. Is the participant wearing glasses and/or contact lenses for the Pelli-Robson test?
   [ ] Yes  [ ] No ➔ Go to Question 10

9a. What is the participant wearing – glasses and/or contact lenses?
   [ ] Glasses  [ ] Contact lenses

9b. What type of glasses?
    [ ] Distance  [ ] Bifocal  [ ] No-line bifocal  [ ] Multi-focal

9c. What type of contact lenses?
    [ ] Distance  [ ] Bifocal  [ ] Monovision (one eye corrected for near, one for distance)

10. Which chart was used?
    [ ] Chart 1  [ ] Chart 2

11. Which distance was used?
    [ ] 8 feet  [ ] 4 feet

(Examiner note: use the same distance as for the acuity chart or if the participant cannot identify the darkest triplet correctly at 8 feet, move to 4 feet.)

Explain the task to the participant: “Now on this chart, the letters stay the same size, but get more faded as you read down the chart. Again, I want to encourage you to guess if you aren’t sure of a letter, and sometimes it helps just to stare at the letter for a moment. I’d like you to start with the top line. Can you read that line?”

If the participant can’t read the first three letters, move them or the chart to 4 feet.

Say to the participant: “Now keep reading down the chart. If you are not sure about a letter, please guess.”

If they hesitate, say: “Go ahead and guess. We need you to go as far as you can, guessing when you are not sure. Do not lean forward. Keep looking, sometimes the letter appears even though it is invisible when you first look at it.”

When the participant gets all three letters in a triplet wrong, say: “Okay, that’s great. Now you can stop.”
CHAMP ID: __________

(Examiner note: make an “X” through each letter incorrectly identified. When the participant misses all 3 letters in a triplet, stop administering the test and go to Question 13.)

<table>
<thead>
<tr>
<th>Chart 1</th>
<th>Letter Count</th>
<th>Chart 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>H S Z</td>
<td>D S N</td>
<td>06</td>
</tr>
<tr>
<td>C K R</td>
<td>Z V R</td>
<td>12</td>
</tr>
<tr>
<td>N D C</td>
<td>O S K</td>
<td>16</td>
</tr>
<tr>
<td>O Z K</td>
<td>V H Z</td>
<td>24</td>
</tr>
<tr>
<td>N H O</td>
<td>N R D</td>
<td>30</td>
</tr>
<tr>
<td>V R C</td>
<td>O V H</td>
<td>36</td>
</tr>
<tr>
<td>C D S</td>
<td>N D C</td>
<td>42</td>
</tr>
<tr>
<td>K V Z</td>
<td>O H R</td>
<td>48</td>
</tr>
<tr>
<td></td>
<td>V R S</td>
<td>K D R</td>
</tr>
<tr>
<td></td>
<td>N H C</td>
<td>S O K</td>
</tr>
<tr>
<td></td>
<td>S C N</td>
<td>O Z V</td>
</tr>
<tr>
<td></td>
<td>C N H</td>
<td>Z O K</td>
</tr>
<tr>
<td></td>
<td>N O D</td>
<td>V H R</td>
</tr>
<tr>
<td></td>
<td>C D N</td>
<td>Z S V</td>
</tr>
<tr>
<td></td>
<td>K C H</td>
<td>O D K</td>
</tr>
<tr>
<td></td>
<td>R S Z</td>
<td>H V R</td>
</tr>
</tbody>
</table>

12. Number of letters read correctly: _____ letters

(Examiner note: starting with the Letter Count for the last line read without errors, add one for each additional letter correctly read on lines below it.)

13. Was the Pelli-Robson test administered?

☐ Yes  ☐ No

13a. If no, why not?

☐ Did not pass letter literacy exam
☐ Participant fatigued
☐ Unable to see chart
☐ Did not understand
☐ Refused
FRISBY STEREO TEST – DEPTH PERCEPTION

14. Does the participant usually wear glasses and/or contact lenses for reading?
   - Yes
   - No

| 14a. Is the participant wearing glasses and/or contact lenses for the Frisby Stereo test? |
|---------------------------------|---------------------------------|
| □ Glasses                       | □ Contact lenses                |
| □ Not wearing either            |                                 |

14b. What type of glasses?
   - Distance
   - Bifocal
   - No-line bifocal
   - Multi-focal
   - Reading

14c. What type of contact lenses?
   - Distance
   - Bifocal
   - Monovision
     (one eye corrected for near, one for distance)

Show the participant the thickest plate. The circle should be sticking out towards the participant.

**Script:** "This is a test of depth perception. One of the squares has a circular area of pattern standing out in front of it. Can you see which one it is?"

If the participant correctly identifies the square with the circle in it, begin testing on the medium thickness plate.

If they guess incorrectly or cannot see the circle, ask them to guess. If they guess wrong, turn the plate onto a corner and twist the plate slightly back and forth. This should allow them to see the circle without affecting the test. If the participant still cannot identify the correct square, point to the square with the circle.

Once they can see the circle, remove the plate from their vision and rotate the plate so the circle is in a new position. Place the plate back on the table in the standard testing position and ask the participant to identify the circle again.

After the participant correctly identifies the first square, remove the plate under the table and rotate it one side and ask the question again. After they respond to the second plate position, remove the plate under the table again but this time do not rotate the plate. Present it in the same position.
15. **Was the participant able to point out the depth cue without hesitation?** (either before or after a demonstration using monocular clues)

- [ ] Yes
- [ ] No

**If yes, start here ↓**

<table>
<thead>
<tr>
<th>Plate 2 (medium thickness)</th>
<th>Plate 3 (thinnest)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>17. Trial</strong></td>
<td>18. Trial</td>
</tr>
<tr>
<td>1. Correct</td>
<td>Correct</td>
</tr>
<tr>
<td>2. Correct</td>
<td>Correct</td>
</tr>
<tr>
<td>3. Correct</td>
<td>Correct</td>
</tr>
<tr>
<td>If 3 correct, record as Pass. Go to Plate 3.</td>
<td>If 3 correct, record as Pass. Go to Question 19.</td>
</tr>
<tr>
<td>4. Correct</td>
<td>Correct</td>
</tr>
<tr>
<td>5. Correct</td>
<td>Correct</td>
</tr>
<tr>
<td>6. Correct</td>
<td>Correct</td>
</tr>
<tr>
<td>Pass if 3/3 or at least 5/6 correct.</td>
<td>Pass if 3/3 or at least 5/6 correct.</td>
</tr>
</tbody>
</table>

17a. **Plate 2**

- [ ] Pass  ➔ Go to Plate 3
- [ ] Fail  ➔ Go to Plate 1
- [ ] Did not test

**If no, start here ↓**

<table>
<thead>
<tr>
<th>Plate 1 (maximum thickness)</th>
<th>16a. <strong>Plate 1</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>16. Trial</strong></td>
<td></td>
</tr>
<tr>
<td>1. Correct</td>
<td></td>
</tr>
<tr>
<td>2. Correct</td>
<td></td>
</tr>
<tr>
<td>3. Correct</td>
<td></td>
</tr>
<tr>
<td>If 3 correct, record as Pass. Go to Plate 2.</td>
<td></td>
</tr>
<tr>
<td>4. Correct</td>
<td></td>
</tr>
<tr>
<td>5. Correct</td>
<td></td>
</tr>
<tr>
<td>6. Correct</td>
<td></td>
</tr>
<tr>
<td>Pass if 3/3 or at least 5/6 correct.</td>
<td></td>
</tr>
</tbody>
</table>

16a. **Plate 1**

- [ ] Pass  ➔ Go to Plate 2, unless already completed.
- [ ] Fail  ➔ STOP. Go to Question 19 on next page.
- [ ] Did not test
19. Was a non-standard distance (other than 40 cm) used?

☐ Yes  ☐ No

19a. If yes, specify distance used: ______ cm

20. Was the Frisby Stereo test administered?

☐ Yes  ☐ No

20a. If no, why not?

☐ Participant fatigued
☐ Unable to see chart
☐ Did not understand
☐ Other (please specify) ________________________________
☐ Refused
Section 9 – Muscle Strength

GRIP STRENGTH

Say to participant: “This device measures your arm and upper body strength.”

1. “Do you have any pain or arthritis in your hands?”

☐ Yes  ☐ No  ➔ Go to Question 2

1a. Has any of it become worse recently?

☐ Yes  ☐ No  ☐ Don’t Know  ☐ Refused

1b. If yes, which side?

☐ Left (do not test)  ☐ Right (do not test)  ☐ Both (do not test either side)

2. “Have you had any surgery on your hands or wrists in the past 3 months (12 weeks)?”

☐ Yes  ☐ No  ☐ Don’t Know  ☐ Refused

2a. If yes, which side?

☐ Left (do not test)  ☐ Right (do not test)  ☐ Both (do not test either side)

Script: “I’d like you to take your right/left arm, rest it on the table, and bend your elbow. Grip the bars in your hand, like this. Please slowly squeeze the bars as hard as you can.” Hand the dynamometer to the participant. “Does that feel like a comfortable grip?” Adjust if needed.

Script: “Now try it once just to get the feel of it. For this practice, just squeeze gently. It won’t feel like the bars are moving, but your strength will be recorded. Are the bars the right distance apart for a comfortable grip?” Show dial to participant. Test twice on the right side, then twice on the left side.

Script: “We’ll do this two times. This time counts, so when I say squeeze, squeeze as hard as you can. Ready? Squeeze! Squeeze! Squeeze! Now, Stop!”

Right side

3a. Trial 1 _______ kg  3c. Trial 1 _______ kg

☐ Refused  ☐ Unable (did not attempt)  ☐ Refused  ☐ Unable (did not attempt)

3b. Trial 2 _______ kg  3d. Trial 2 _______ kg

☐ Refused  ☐ Unable (did not attempt)  ☐ Refused  ☐ Unable (did not attempt)
LEG STRENGTH

Say to participant: "Now we are going to measure the strength in your quadriceps muscles."

4. "Do you have any pain or arthritis in your knees?"
   □ Yes □ No
   If yes, the test should not aggravate the pain but ask the participant to tell you if he is concerned, or excessively uncomfortable or in pain. Make sure they do not push too hard as it may aggravate the knee.

Script: "I need you to sit on this chair and move your bottom all the way back. I'm going to place a strap around your shin."

Hang the spring gauge off the back rung of the chair. The participant's leg should be at an 80 degree angle so when they extend their leg it goes to a right angle. Fasten the Velcro around their leg, about 10cm up from the ankle. You can do the test over clothing and you should use the shoulder pads so that the strap does not dig into the skin.

Say: "Does that feel comfortable? Now, when we do the test, please hold onto the side of the chair for support. When I say Go I want you to push against the strap at a moderate pace but as hard as you can. Ready? Go! Push! Push! Push! Push! Now stop! We will do this test twice on each leg."

If the participant is very strong, the 40kg spring gauge will be too easy so use the 100kg spring gauge instead. You may only find this out after the first trial, that's fine, just swap the spring gauges. If they are strong and push really hard they may have some muscle soreness over the next couple of days. You may want to warn some people about this after the test is complete.

5. Which spring gauge was used?
   □ 40kg □ 100kg

6. Right side
   6a. Best trial _____ kg
   6b. □ Test not completed 6c. Why not? ________________________________

7. Left side
   7a. Best trial _____ kg
   7b. □ Test not completed 7c. Why not? ________________________________
Section 10 – Neuromuscular Function

Script: “I’m going to ask you to try to do several different movements of your body. I will first describe and show each movement to you. Then I’d like you to try to do it. If you cannot do a particular movement or you feel it would be unsafe to try to do it, please tell me and we’ll move on to the next one. Let me emphasise that I would like you to try each exercise. But I don’t want you to try to do any exercise that you feel might be unsafe.”

1. Ask the participant: “Do you have any problems from recent surgery, injury or other health conditions that might prevent you from standing straight up from a chair or walking up steps?”
   - Yes
   - No
   If yes, tell the participant: “Before we do each test, I’ll describe it to you. Please tell me if you think that you shouldn’t attempt the test because of the problems you described.”

2. Ask the participant: “Do you use any walking aids, such as a cane?”
   - No aids
   - Cane or quad cane
   - Walker, wheelchair, leg brace, crutches

3. Does the participant have any of the following? (mark all that apply)
   - Orthosis
   - Missing limbs
   - Prosthesis
   - Paralysis of extremity or side of body

SINGLE CHAIR STAND

Have the participant sit in the chair, assuming the position from which he would normally stand up from a chair (but no more than half-way forward on the seat of the chair) with the feet resting on the floor and the arms folded across the chest. Place the back of the chair against the wall to avoid the chair being pushed backwards.

Script: “This is a test of strength in your legs in which you stand up from sitting without using your arms.”

Demonstrate the procedure. “Fold your arms across your chest, like this, and stand, keeping your arms in this position. Do you understand?” Ask the participant to stand. Script. “Can you stand and sit one time for practice?”

If the arms unfold, or the participant puts one or both hands down on the chair to push up, remind him to keep his arms folded snugly across his chest, and ask him to repeat the chair stand. It is OK for the participant to move part-way forward in the chair before standing, but knees and hips should be flexed to approximately 90 degrees before standing.
If the participant cannot rise without using arms, say: “OK. Try to stand up using your arms to push off.”

4. Could the participant stand up one time unassisted?

☐ Stands without using arms  ☐ Rises using arms
☐ Unable to stand  ☐ Did not attempt/refused

If cannot stand without using arms then do not test the repeated chair stands. Go on to SIX METER USUAL PACE, next page.

REPEATED CHAIR STAND

When the subject is properly seated after practicing, say, “This time, I want you to stand up 5 times as quickly as you can, keeping your arms folded across your chest.”

Demonstrate the test. Script: “First I will show you. When you stand up, come to a full standing position each time, and when you sit down, sit all the way down each time. I will demonstrate two chair stands to show you how it is done.” Rise two times quickly as you can, counting as you stand up each time.

Script: “When I say ‘Go,’ stand five times in a row, as quickly as you can, without stopping. Stand all the way up and sit all the way down each time. Ready? GO!” Count “1, 2, 3, 4, 5” as the participant stands up each time.

If the participant fatigues before completing 5 stand-ups, confirm that he can’t do more by asking: “Can you continue?” If he says yes, keep timing. If he says no, record that he could not complete five stand-ups and DO NOT record a time for him.

5. Did the participant complete all 5 stands?

☐ Yes  ☐ No

5a. Record time and arm use for chair stand.

☐ _______ : _______ seconds to complete 5 stands

5b. Arm use:

☐ 5 times without using arms
☐ 5 times, uses arms part of time
☐ 5 times, uses arms all of time

5c. How many stands were completed?

☐ _______ stands completed

5d. Why weren’t 5 chair stands completed?

☐ Attempted, unable to stand up once
☐ Attempted, unable to finish 5 stands
☐ Did not attempt/refused
6 METRE USUAL PACE

The video should be set up to record the walking. PRESS RECORD on the video before the first walk. Hold up the large CHAMP ID number (on the back of the clinic checklist) in front of the camera for identification of the participant.

The participant should be wearing comfortable walking shoes. He may use a walking aid, but should be encouraged to walk without one if he is comfortable doing so.

Script: “This is a walking test that will also test your balance. First I want you to walk to the end normally, at a comfortable pace, ignoring the red coloured lines. For the second walk, I will ask you to walk keeping your feet inside the red lines. Each test will be done at least twice.”

Ask the subject to stand behind the line at one end of the course. Script: “Place your feet with your toes behind, but touching the yellow starting line. Wait until I say ‘Go.’ Remember, I want you to walk at a comfortable pace ignoring the red coloured lines.” Demonstrate and return. “Walk past the yellow finish line each time. Any questions? Ready? Go.”

Start the stopwatch at the first foot fall, and stop timing when the first footfall (complete or partial) crosses the finish line. Count the number of steps taken to cover the course (NOT ALOUD). One step is counted when either foot is placed down on the floor, including the first step and the step which a participant’s foot crosses or touches the end line. Record time and number of steps below.

6. Trial 1 (6m usual pace)

6a. ______: _______ seconds
6b. _______ steps

6c. Trial 1 Aid used:

☐ No aid
☐ Straight cane
☐ Quad cane
☐ Walker
☐ Crutch

6d. ☐ Trial 1 not attempted
☐ Trial 1 attempted but unable

When the participant crosses the end line, ask him to turn around and stand at the end line as before. Script: “Now, do the same thing in the other direction. Walk at your usual pace and go all the way, past the finish line, to the other end. Ready? Go.” Record time and number of steps below.

7. Trial 2 (6m usual pace)

7a. ______: _______ seconds
7b. _______ steps

7c. Trial 2 Aid used:

☐ No aid
☐ Straight cane
☐ Quad cane
☐ Walker
☐ Crutch

7d. ☐ Trial 2 not attempted
☐ Trial 2 attempted but unable
20 CENTIMETRE NARROW WALK

Script: "Now for this walk, I want you to keep your feet inside the red lines. It is important that you do your best to keep your feet inside the lines"

Script: "I'll demonstrate. Keep your feet inside the lines. Be sure to walk past the yellow finish line. Any questions? We will do this test 3 times."

Note: Time walk as before, but do not count steps. Not staying within the lines is defined as stepping on, or going outside of the red coloured tape two or more times. Perform up to three trials to obtain 2 valid times.

8. Trial 1 (Narrow walk)
   8a. _______ : _______ seconds
   8b. Did the participant stay within the lines?
       [ ] Yes, 2 or fewer deviations [ ] Trial 1 Not Attempted
       [ ] No, 3 or more deviations [ ] Trial 1 Attempted but unable
         (unable to assess time)
   8c. Trial 1 Aid used
       [ ] No aid [ ] Straight cane [ ] Quad cane [ ] Walker [ ] Crutch

9. Trial 2 (Narrow walk)
   9a. _______ : _______ seconds
   9b. Did the participant stay within the lines?
       [ ] Yes, 2 or fewer deviations [ ] Trial 2 Not Attempted
       [ ] No, 3 or more deviations [ ] Trial 2 Attempted but unable
         (unable to assess time)
   9c. Trial 2 Aid used
       [ ] No aid [ ] Straight cane [ ] Quad cane [ ] Walker [ ] Crutch

*Perform trial 3 only if Trial 1 or Trial 2 were labelled 'No, 3 or more deviations (unable to assess time)'*

10. Trial 3 (Narrow walk)
    10a. _______ : _______ seconds
    10b. Did the participant stay within the lines?
        [ ] Yes, 2 or fewer deviations [ ] Trial 3 Not Attempted
        [ ] No, 3 or more deviations [ ] Trial 3 Attempted but unable
           (unable to assess time)
    10c. Trial 3 Aid used
        [ ] No aid [ ] Straight cane [ ] Quad cane [ ] Walker [ ] Crutch

32 CHAMP CLINIC QUESTIONNAIRE
60 SECOND NARROW WALK

Script: “For the next walk, I want you to walk back and forth at a comfortable pace, keeping your feet inside the red lines. When I say go, walk until you pass the yellow line, turn around and come back again. Keep going until I tell you to stop. Remember, don’t touch the red lines. Any questions? Go.”

Note: The participant needs to walk for 60 seconds. This is a baseline walk for neuropsychological testing. You need to tell the participant to stop after 60 seconds, the other assessments will be completed by reviewing the recorded images.

11. Trial 1 (60 second narrow walk)
   11a. ______ deviations
   11b. [ ] Trial 1 not attempted [ ] Trial 1 attempted but unable

DUAL TASK – WALKING AND TALKING

Script: “Now I would like you to walk at the same pace, keeping your feet inside the red lines, but this time also name as many words you can think of starting with the letter C. Do not tell me names of people or places. Again, don’t touch the red lines and walk back and forth between the yellow lines until I say stop. Any questions? Go.”

Note: The participant needs to walk for 60 seconds. This walk is for neuropsychological testing. You need to tell the participant to stop after 60 seconds, the other assessments will be completed by reviewing the recorded images.

12. Trial 1 (Talk and narrow walk)
   12a. ______ deviations 12b. ______ words
   12c. [ ] Trial 1 not attempted [ ] Trial 1 attempted but unable

REMEMBER TO STOP THE VIDEO
**BALANCE (SWAY METER)**

Say to the participant: "This is a balance test. I'm going to put a strap around your waist. OK, now put your feet shoulder-width apart." Do not tell the subject this is a sway test.

It is important that the subject's legs are the same distance apart for all three tests. Place the strap firmly around the waist (on the belt line of men). Adjust the table height so that the swaymeter rod is horizontal. Position the pen over the front half of the graph paper.

"Now I want you to stand as still as you can for 30 seconds with your eyes open. Look slightly down and do not talk."

13. Was the participant able to complete the floor sway test?

   ☐ Yes  ☐ No  ➔ 13a. Why not? ________________________________

   Place the foam at the participant's feet and say: "Now I want you to very carefully step onto the middle of this piece of foam." Make sure his feet are again shoulder-width apart.

   Reassure the participant that you will not let them fall whilst undertaking the test. "Now stand as still as possible for 30 seconds. Again, look slightly down and do not talk. I am standing right here beside you and can support you if you lose balance."

   Reposition table so that the pen is over the back half of the graph paper. Repeat the procedure as per the test done on the floor.

14. Was the participant able to complete the foam sway test?

   ☐ Yes  ☐ No  ➔ 14a. Why not? ________________________________

   Say: "Now we will do another test with this device. I'm going to put it on you the other way around -- with the rod to the front."

   Position swaymeter with the rod at the front of the person. Place table with the 'race track' sheet in front of them and the pen positioned in the start position in the centre of the sheet.

   Say: "Keeping your feet still, I'd like you to move your body anyway you need so that you move the pen around the track without going outside the track. Go as slowly as you need to keep steady. Try your best to stay within the lines."

   Conduct a practice and a test. If the trial shows they can't reach the top and bottom of the track, move the paper to make it easier for them.

   If a participant is having trouble you can say "slow down" or "take your time". You can also tell them to cut the corners if they need to rather than lifting their feet.

15. Was the participant able to complete the race track test?

   ☐ Yes  ☐ No  ➔ 13a. Why not? ________________________________
Section 11 – Spirometry

Say to the participant: “This is a test of your lung function. To start with I need to ask you a few questions.”

1. “In the past three months have you had any surgery on your chest or abdomen?”
   - Yes
   - No

2. “Have you had a heart attack within the past three months?”
   - Yes
   - No

3. “Do you have a detached retina or have you had eye surgery within the past three months?”
   - Yes
   - No

4. “Have you been hospitalised for any other heart problem within the past month?”
   - Yes
   - No

5. Does the participant have a resting pulse of greater than 120 beats per minute?
   - Yes
   - No

If the participant answers YES to any of the above questions, DO NOT proceed with the spirometry test. Answer Question 6 – No. Unable to attempt due to medical reasons.

6. “Have you had a respiratory infection (cold) in the last three weeks?”
   - Yes
   - No

7. “Have you used any medication for breathing in the last three hours?”
   - Yes
   - No

Hand the machine to the participant and say: “Take a big deep breath, then place your lips completely around the top of the mouthpiece. Then I want you to blow out as hard and fast as you can. Ready? Go, deep breath. Blow! Blow! Blow! Now, stop!” Repeat the test three times.

8. Was the spirometry test completed?
   - Yes
   - No
   
   8a. FEV1 Trial 1 ____________
   8b. FEV1 Trial 2 ____________
   8c. FEV1 Trial 3 ____________

- Unable to perform adequate test
- Did not understand instructions
- Unable to attempt due to medical reasons
- Did not attempt/refused
Section 12 - Urinary Function

UROFLOW
Say to the participant: “This machine will measure various things about the way you wee. All you need to do is wee into the bowl and the machine will do the rest. I will be waiting outside to ensure no one comes in, just come out when you are finished. We need to keep a sample of your urine so please do not empty the jug.” A 5mL sample of urine should be kept and the rest discarded in the toilet.

1. Was the test completed?
   □ Yes □ No⇒ 1a. If no, why not? ________________________________

1b. Did the participant have a natural urge to urinate? □ Yes □ No

2. Did the participant void at least 150 mls? □ Yes □ No

3. Was urine collected?
   □ Yes □ No
   3a. Time of urine collection _______ : _______ (hours:mins)

4. “Can you please tell me how many times you have urinated this morning?”
   ______ times

5. “Can you tell me the time that you urinated last (prior to the test)?”
   Time of last urination _______ : _______ (hours:mins)

BLADDER ULTRASOUND
The bladder ultrasound should be completed soon after the participant has urinated.
Say to the participant: “I now need to measure how much wee is left in your bladder. Can you please lie down on the bed and undo your trousers for me?”
If there is more than 200mls left in the bladder ask the participant: “There is still quite a bit of wee in your bladder. Do you need to wee again?”

6. Was the bladder scan completed? □ Yes □ No

   6a. If yes, what were the total millilitres remaining? ______ mL

   6b. If no, why not? ____________________________________________

7. Was a second scan required?
   □ Yes □ No⇒ Go to Section 13

   7a. If yes, what were the total millilitres remaining? ______ mL
Section 13 – Heel Ultrasound

Basic rules:
1. Right heel preferred (note: machine defaults to LEFT so make sure this is changed).
2. Never scan a heel that has been broken.
3. Never scan with an open sore on heel or ankle.

1. “Have you ever broken either heel or have hardware in either heel?”
   - No
   - Yes, left heel (Do not scan left heel)
   - Yes, right heel (Do not scan right heel)
   - Yes, both heels (Do not perform ultrasound)

2. Does the participant have an open sore on either ankle or heel?
   - No
   - Yes, right side (DO NOT scan right foot. If answered ‘Yes, left heel’ in Question 1, STOP. DO NOT PERFORM ULTRASOUND)
   - Yes, left side (DO NOT scan left foot. If answered ‘Yes, right heel’ in Question 1, STOP. DO NOT PERFORM ULTRASOUND)
   - Yes, both sides (STOP. DO NOT PERFORM ULTRASOUND)

3. “Have you ever broken any bone in either leg?” (Do not include isolated toe fractures)
   - Yes
   - No

   3a. If yes, which leg was most recently broken?
   - Right leg (Scan left foot, if eligible. Otherwise scan right. Go to Question 5.)
   - Left leg (Scan right foot, if eligible. Otherwise scan left. Go to Question 5.)
   - Both legs/don’t know (Go to Question 4)

4. “Do you have any permanent weakness in your legs, ankles or feet from an old injury or stroke?”
   - Yes
   - No

   4a. If yes, which side is weaker?
   - Right side (Scan left foot, if eligible. Otherwise scan right.)
   - Left side (Scan right foot, if eligible. Otherwise scan left.)
   - Right and left same (Scan right foot, if eligible. Otherwise scan left.)
5. **Measurement 1**
   - 5a. BUA _____ dB/MHz
   - 5b. VOS _____ m/s

6. **Measurement 2**
   - 6a. BUA _____ dB/MHz
   - 6b. VOS _____ m/s

7. What is the difference between BUA measurement 1 and measurement 2?
   - _____ units
   - 7a. Was the difference between BUA measure 1 and BUA measure 2 > 10 units?
     - Yes ➔ **Repeat scan and record results in Question 8**
     - No ➔ **Go to Question 9**

8. **Measurement for repeat scan**
   - 8a. BUA _____ dB/MHz
   - 8b. VOS _____ m/s

9. Which heel was scanned?
   - [ ] Right
   - [ ] Left
   - [ ] Scan not attempted ➔

   9a. Why was the left foot scanned?
      - [ ] Fracture/Hardware on right
      - [ ] Permanent weakness on right
      - [ ] Open sore on right
      - [ ] Other (please specify) ______________________

   9b. Why wasn’t the scan attempted?
      - [ ] Feet too big/edema
      - [ ] Equipment problem
      - [ ] Participant refused
      - [ ] Other (please specify) ______________________

   9c. Why wasn’t the scan completed?
      - [ ] Out of range reading
      - [ ] Invalid measurement
      - [ ] Other (please specify) ______________________
Section 14 – DEXA

1. “Have you ever had hip replacement surgery where all or part of your joint was replaced?”
   - Yes
   - No (scan right hip)
   - Don’t know
   - Refused

   1a. Which side did you have hip replacement surgery?
   - Right (scan left hip)
   - Left (scan right hip)

   1b. Year of hip replacement ________

2. “Do you have any metal objects in your body, such as a pacemaker, staples, screws, plates, etc.?”
   - Yes
   - No
   - Don’t know
   - Refused

   Indicate the location of the joint replacement, hardware or other artifacts.

<table>
<thead>
<tr>
<th>Hardware?</th>
<th>Other Artifacts?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head</td>
<td></td>
</tr>
<tr>
<td>Left arm</td>
<td></td>
</tr>
<tr>
<td>Right arm</td>
<td></td>
</tr>
<tr>
<td>Left ribs</td>
<td></td>
</tr>
<tr>
<td>Right ribs</td>
<td></td>
</tr>
<tr>
<td>Thoracic</td>
<td></td>
</tr>
<tr>
<td>Lumbar spine</td>
<td></td>
</tr>
<tr>
<td>Pelvis</td>
<td></td>
</tr>
<tr>
<td>Left Leg</td>
<td></td>
</tr>
<tr>
<td>Right leg</td>
<td></td>
</tr>
</tbody>
</table>

3. “Have you had any of the following in the past 10 days?”
   Note: If ‘Yes’ to any test below, reschedule DEXA to at least 10 days after test.

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barium enema</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper GI X-ray series</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower GI X-ray series</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nuclear medicine scan</td>
<td></td>
<td></td>
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<tr>
<td>Other tests using contrast (“dye”) or radioactive materials</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. Was a bone density measurement obtained for:

<table>
<thead>
<tr>
<th>Body Part</th>
<th>Yes</th>
<th>No</th>
<th>Last 2 characters of scan</th>
<th>Date of scan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lumbar spine</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hip</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whole body</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Lateral spine</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

5. Temperature of room during scan: ________ degrees Celsius
Section 15 – Medication Use

1. “Do you have testosterone injections or implants at least once a month?”
   [ ] Yes   [ ] No
   
   1a. How many times a month do you receive testosterone injections or implants? ______ times
   
   1b. For how many months have you received this treatment? ______ months
   
   1c. What was the date of your last testosterone injection or implant?
       _______ / _______ / _______
       day    month    year

2. “Have you ever taken medicine to treat osteoporosis, Paget’s disease or other bone diseases?”
   [ ] Yes   [ ] No

3. “Have you ever taken Bisphosphonates?”
   [ ] Yes   [ ] No  ➔ Go to Question 4
   
   If yes, when did you start and stop taking bisphosphonates?
   3a. Start date _______ / _______  3b. Stop date _______ / _______
       month    year        month    year
   
   3c. Which bisphosphonates have you ever taken? (mark all that apply)
   [ ] Alendronate (Fosamax)
   [ ] Clodronate (Bonefos)
   [ ] Etidronate (Didronel)
   [ ] Ibndronate (Bonderonat)
   [ ] Pamidronate (Aredia)
   [ ] Risedronate (Actonel)
   [ ] Tiludronate (Skelid)
   [ ] Other/don’t know
4. “Have you ever taken any of the following:”

<table>
<thead>
<tr>
<th>Medication</th>
<th>Start date</th>
<th>Stop date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluoride (or Sodium Fluoride)</td>
<td></td>
<td></td>
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<tr>
<td>Calcitonin (or miacalcin)</td>
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<td></td>
</tr>
<tr>
<td>Vitamin D (Ostelin or cod liver oil)</td>
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<td></td>
</tr>
<tr>
<td>Calcium supplements (Caltrate, Sandocal, Citrical, etc.)</td>
<td></td>
<td></td>
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<tr>
<td>Other medication for bone health</td>
<td></td>
<td></td>
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<tr>
<td>Other (please specify)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. “Have you ever taken steroids such as Cortisone or Prednisone for asthma, arthritis or other conditions for more than one month?”

- [ ] Yes
- [ ] No
- [ ] Don’t know

5a. If yes, were the steroids: (mark all that apply)

- [ ] Oral
- [ ] Inhaled
- [ ] Nasal
- [ ] Injected
- Other (please specify) ________________________________
MEDICATION INVENTORY

6. Does the participant take any medication, daily or almost daily, for at least the past month? This includes both prescription and non-prescription medication.

☐ Yes  ☐ No

Prescription

<table>
<thead>
<tr>
<th>Name</th>
<th>Strength (mg) per tablet</th>
<th>No of tablets per day</th>
<th>Duration (months)</th>
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</tbody>
</table>

Non-Prescription

<table>
<thead>
<tr>
<th>Name</th>
<th>Strength (mg) per tablet</th>
<th>No of tablets per day</th>
<th>Duration (months)</th>
</tr>
</thead>
<tbody>
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</table>
7. “Are there any other medications that you take that you have not brought with you?” (This question is a prompt in case they have forgotten anything. Enter medications in the appropriate table on previous page.)

   Do you regularly take any medicines prescribed by a doctor?
   Do you regularly take any medicines purchased over the counter?
   Do you take any sleeping tablets?
   Do you take any nerve tablets?
   Do you take any fluid tablets?
   Do you take any laxatives/bowel medicines?
   Do you take any headache tablets/painkillers?
   Do you take any antacid/indigestion medicines?
Appendix B: Publications
Natural History of Non-Neurogenic Overactive Bladder and Urinary Incontinence Over 5 Years in Community-Dwelling Older Men: The Concord Health and Aging in Men Project

Naomi Neguchi,1,2 Lewis Chan,2 Robert G. Cumming,3,4 Fiona M. Blyth,3 David J. Handelsman,4 Louise M. Waite,2 David G. le Couteur,3,4 and Yasi Naganathan3
1Centre for Education and Research on Ageing and the Ageing and Alzheimer's Institute, Concord Hospital, University of Sydney, New South Wales, Australia
2Department of Urology, Concord Hospital, University of Sydney, New South Wales, Australia
3School of Public Health, University of Sydney, New South Wales, Australia
4ANLAC Research Institute, Concord Hospital, University of Sydney, New South Wales, Australia

Abstract To describe the natural history of non-neurogenic overactive bladder (OAB) and urgency incontinence in community-dwelling older men. Methods: A representative sample of 1,705 community-dwelling men aged 70 and older in a defined geographic area of Sydney, Australia, had their urinary symptoms assessed using the International Prostate Symptom Score (IPSS) and the International Consultation on Incontinence Questionnaire (ICIQ) at baseline, 2-year follow-up, and 5-year follow-up. Four hundred and eighty-eight men without neurological diseases or prostate cancer during follow-up, or history of urological treatment at baseline were included in the analysis. Urgency incontinence was defined as leakage of urine occurring more than weekly in the above-defined population. OAB was defined as either urgency or urgency incontinence according to 2002 International Continence Society consensus. Results: Of the men with OAB at baseline, 59% received treatment for OAB or benign prostatic enlargement over 5 years. Of the remaining men, 33% had sustained remission at 2-year and 5-year follow-ups without treatment. Of the men with OAB at 5-year follow-up, remission rate at 5-year follow-up was 53% in men without OAB at baseline and 27% in men with OAB at baseline (P = 0.23). No statistically significant difference was found in baseline characteristics between men with sustained remission and men with persistent symptoms. Conclusions: One in three older men with non-neurogenic OAB had sustained remission of symptoms without medical or surgical interventions. No significant predictor of sustained remission was identified. Neurourl. Urodyn. © 2016 Wiley Periodicals, Inc.

Key words: elderly; incontinence; longitudinal; men; overactive bladder

INTRODUCTION

Overactive bladder (OAB) is defined as the presence of urinary urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence, in the absence of urinary tract infection (UTI) or other obvious pathology. It is a common clinical problem among patients presenting to general practitioners and other clinicians including urologists, gynaecologists, geriatricians, and neurologists. OAB may be related to neurological disorders such as multiple sclerosis, spinal cord injury, stroke, or neurodegenerative diseases (neurogenic OAB) or its exact etiology may be unclear (idiopathic or non-neurogenic OAB). High remission rates for OAB and incontinence have been reported in population-based studies of older men.3 However, these descriptive studies, however, did not have data about medical or surgical interventions, so it is unclear if the remissions occurred naturally or in response to treatment. Spontaneous remission of OAB symptoms is also suggested by the fact that improvement of OAB symptoms is often seen in placebo arms of randomized controlled trials of urinary-specific anticholinergics. It would therefore, be useful to know how likely spontaneous remission of OAB symptoms is and which other men can expect remission so as not to expose them to potential adverse effects of anticholinergic medications. On the other hand, since OAB significantly impair quality of life, it would be useful if we could identify men who have little chance of spontaneous remission in whom it might be better to institute treatment early.

The aim of this study was to describe the natural history of non-neurogenic OAB and urgency incontinence over 5 years in a representative sample of community-dwelling older men. In addition, the study describes the characteristics of men who experienced sustained remission of OAB over 5 years.

MATERIALS AND METHODS

Study Participants

The Concord Health and Aging in Men Project (CHAMP) is a prospective cohort study of a wide range of health issues in older men. Baseline data were collected between January 2005 and June 2007. The study was approved by the Concord

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The self-administered questionnaire and clinical assessments were repeated at 1- and 5-year follow-up visits.

**Analysis**

Men who had neurological diseases (Parkinson’s disease, stroke, and epilepsy) or prostate cancer at baseline or any follow-up points were excluded from the analyses because these conditions are likely to alter the course of OAB and incontinence. Men who had a history of surgery for BPE or were taking urological medications at baseline were excluded for the same reason. Having BPE surgery or starting urological medications during the 5-year follow-up period were treated as an outcome that may indicate worsening of either OAB, BPE, or impaired detrusor contractility.

Baseline characteristics of the analytic cohorts for OAB and incontinence are presented as either means (± standard deviations [SD]) or frequency distributions by OAB or continence status at baseline. In the analytic cohorts, numbers of men who newly received treatment over 5 years were determined by baseline OAB and continence status. In men, who did not receive surgery for BPE or urological medications over 5 years, the changes in OAB and continence status at baseline and 2- and 5-year follow-ups are described. The men who had either OAB or urgency incontinence at baseline and did not have the conditions at both 2- and 5-year follow-ups were deemed to have had sustained remission.

The characteristics of men who experienced sustained remission of OAB without interventions for OAB or BPE were compared with those of the men who had persistent symptoms and had no interventions using χ² test. In addition, the characteristics of the men who received interventions over 5 years were described using proportions.

All analyses were performed using SAS version 9.3 (SAS Institute, Cary, NC).

**RESULTS**

Of the 1,776 participants at baseline, 382 (22%) deceased and 349 (20%) declined follow-up, leaving 1,545 men (56%) who were followed up for 3 years. Of the 954 men followed up for 5 years, 418 (44%) were excluded from the analyses because they had neurological diseases (n = 66) or prostate cancer (n = 117) at baseline or developed these conditions during 5-year follow-up, or had a history of BPE surgery or were taking urological medications at baseline (n = 226). After applying the above exclusion criteria, data on OAB were incomplete for 27 (5%) men, leaving 488 men in the analytic cohort for OAB, and 491 men in the analytic cohort for incontinence. OAB and incontinence at baseline were more frequent by at least 5% in men who subsequently died, in men who declined follow-up, and in men who were excluded because of medical conditions and treatments than in men included in the analyses (Appendix 1).

At baseline, 98 men (20%) had OAB and 48 (19%) had incontinence. Baseline characteristics of men included in the analyses for OAB and incontinence are presented in Table 1. Mean ages (±SD) were 74.5 (±4.3) years (range: 70-92 years) in men without OAB, and 76.8 (±4.6) years (range: 70-94 years) in men with OAB at baseline. Men with OAB had higher mean IPSS-V (mean ± SD: 6.0 ± 4.7) as well as EPS-V (mean ± SD: 7.5 ± 3.3) than those without (mean ± SD: 1.7 ± 2.5 and 1.9 ± 2.6, respectively). There were no apparent differences in objective
TABLE 1. Baseline Characteristics of Men Included in Analysis for OAB and Incontinence

<table>
<thead>
<tr>
<th>Baseline characteristic</th>
<th>Baseline status</th>
<th>No OAB (n = 458)</th>
<th>OAB (n = 98)</th>
<th>Continent (n = 431)</th>
<th>Incontinent (n = 49)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>Mean ± SD</td>
<td>74 ± 43</td>
<td>70 ± 43</td>
<td>74 ± 43</td>
<td>77 ± 49</td>
</tr>
<tr>
<td>Foot mobility</td>
<td>%</td>
<td>8 (2%)</td>
<td>2 (2%)</td>
<td>10 (2%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Dementia</td>
<td>%</td>
<td>3 (0%)</td>
<td>2 (2%)</td>
<td>6 (1%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Diabetic use</td>
<td>%</td>
<td>59 (0%)</td>
<td>16 (16%)</td>
<td>50 (11%)</td>
<td>7 (15%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>%</td>
<td>57 (5%)</td>
<td>70 (7%)</td>
<td>70 (16%)</td>
<td>10 (21%)</td>
</tr>
<tr>
<td>IPSS</td>
<td>Mean ± SD</td>
<td>4.5 ± 3.3</td>
<td>7.5 ± 3.1</td>
<td>7.5 ± 3.1</td>
<td>6.0 ± 3.1</td>
</tr>
<tr>
<td>PSS</td>
<td>Mean ± SD</td>
<td>1.7 ± 2.2</td>
<td>6.0 ± 2.7</td>
<td>3.2 ± 2.2</td>
<td>3.8 ± 4.4</td>
</tr>
<tr>
<td>Peak flow (mL/s)</td>
<td>Mean ± SD</td>
<td>156 ± 61</td>
<td>141 ± 60</td>
<td>148 ± 61</td>
<td>13 ± 5.4</td>
</tr>
<tr>
<td>PFV (mg)</td>
<td>Mean ± SD</td>
<td>0.6 ± 0.4</td>
<td>0.3 ± 0.4</td>
<td>0.5 ± 0.4</td>
<td>0.4 ± 0.5</td>
</tr>
<tr>
<td>Daily Incontinence</td>
<td>%</td>
<td>39 (15%)</td>
<td>29 (15%)</td>
<td>29 (15%)</td>
<td>18 (40%)</td>
</tr>
</tbody>
</table>

OAB, overactive bladder; IPSS, International Prostate Symptom Score; PFV, Storage Subscale of the IPSS; PSS, Urinary Subscale of the IPSS, PFV, peak-voided residual urine volume.

Figure 1 shows the changes in OAB status over 5 years. Of men with OAB at baseline, 28 (29%) received interventions for OAB or BPH over 5 years, compared to 41 (13%) men without baseline OAB. The natural course of OAB could be observed for the 70 men with OAB at baseline who did not undergo any intervention over 5 years. Of these men, 39 (55%) no longer had OAB at both 2- and 5-year follow-ups (sustained remission, shown in bold letters in Fig. 1). Of the men who had OAB at 2-year follow-up (shown in italics in Fig. 1), remission rates at 5-year follow-up were 53% (n = 20) of men with OAB at baseline, and 27% (n = 9) of men with OAB at baseline P = 0.23.

Figure 2 shows the changes in continence status over 5 years. Of men with incontinence at baseline, 15 (31%) received treatment over 5 years compared to 54 (12%) of men without incontinence. Of the 39 men with incontinence at baseline who did not undergo any intervention for OAB or

Fig. 1. Natural history of OAB in community-dwelling older men. OAB, overactive bladder. "Intervention" refers to those for OAB or benign prostate enlargement. Bold letters indicate sustained remission, which was observed in 77 men out of 97 men with OAB at baseline; natural course over 5 years was observed in 70 men. Italic letters indicate the comparison of remission rates of OAB between 2- and 5-year follow-up by baseline OAB status.
Fig. 2. Natural history of urgency incontinence in community-dwelling older men. "Intervention" refers to those for overactive bladder or benign prostate enlargement. Bold letters indicate sustained remission, with 17 men out of 33 men with incontinence at baseline whose urinary symptoms was observed (52%). Tables indicate the comparison of remission rates of incontinence between 2- and 5-year follow-up by baseline characteristics.

BPE over 5 years 17 (52%) no longer had incontinence at both 2- and 5-year follow-ups (sustained remission, shown in bold letters in Fig 2). Of the men who had incontinence at 5-year follow-up (shown in italics in Fig 1), remission rates at 5-year follow-up were 37% (n = 16) in men without incontinence at baseline, and 46% (n = 5) in men with incontinence at baseline, and 46% (n = 5) in men with incontinence at baseline.

Table 1 compares baseline characteristics of men with sustained remission of OAB to those who had persistent symptoms. In addition, baseline characteristics of men who

| TABLE 1. Baseline Characteristics of Men With OAB at Baseline by Clinical Course Over 5 Years |

<table>
<thead>
<tr>
<th>Clinical course over 5 years</th>
<th>No Intervention for OAB or BPE</th>
<th>Mediated intervention for OAB or BPE, n = 18 (8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline characteristics</td>
<td>Sustained remission, n = 33 (6)</td>
<td>Persistent symptoms, n = 67 (6)</td>
</tr>
<tr>
<td>Age 60</td>
<td>4/33 (12)</td>
<td>1/67 (9)</td>
</tr>
<tr>
<td>Poor mobility</td>
<td>0/33 (0)</td>
<td>2/67 (3)</td>
</tr>
<tr>
<td>Dementia</td>
<td>0/33 (0)</td>
<td>3/67 (5)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>5/33 (15)</td>
<td>13/67 (20)</td>
</tr>
<tr>
<td>BPE &gt;30</td>
<td>2/30 (7)</td>
<td>9/67 (13)</td>
</tr>
<tr>
<td>BPH &gt;30</td>
<td>4/30 (13)</td>
<td>2/67 (3)</td>
</tr>
<tr>
<td>BPH-V a ≥15</td>
<td>1/30 (3)</td>
<td>4/67 (6)</td>
</tr>
<tr>
<td>Peak flow &lt; 15 cc/ml</td>
<td>11/36 (30)</td>
<td>18/67 (27)</td>
</tr>
<tr>
<td>FEV &lt; 30 ml</td>
<td>9/36 (25)</td>
<td>13/67 (20)</td>
</tr>
<tr>
<td>urgency incontinence</td>
<td>3/36 (9)</td>
<td>9/67 (13)</td>
</tr>
<tr>
<td>No change incontinence</td>
<td>12/36 (33)</td>
<td>48/67 (72)</td>
</tr>
</tbody>
</table>

OAB, overactive bladder; BPE, benign prostate enlargement; PISI, international prostate symptom score; BPH-V, storage subscore of the PISI; PISI-V, voiding subscore of the PISI; PIV, post-void residual volume.

Among men with OAB at baseline who had no intervention for OAB and BPE over 5-year follow-up period, those who did not have sustained remission were categorized as having persistent symptoms.

aProportions were compared between men with sustained remission and those with persistent symptoms by χ² test.

Neurology and Urodynamics DOI 10.1002/nau
were excluded from the analysis of natural course of OAB (those who received intervention for OAB or BPH during follow-up) are shown. A higher proportion of men with persistent symptoms of OAB had diabetes (n = 13 [28%]) and were using diuretics (n = 11 [23%]) at baseline compared with men who had sustained remission (diabetes: n = 3 [13%], P = .17; diuretics: n = 3 [13%], P = .03) although the differences were not statistically significant. Only one of 20 (5%) men with sustained remission had high baseline IPSS-V compared to six (13%) in men with persistent symptoms (P = .38). No notable difference was seen in other variables between men who had sustained remission and those with persistent symptoms without intervention.

**DISCUSSION**

To our knowledge, this is the first study to explore the natural history of non-neurogenic OAB and urgency incontinence in a representative sample of community-dwelling older men taking the potential effects of treatments into account. Of 70 men with OAB at baseline who had no surgical or medical intervention during 5-year follow-up, a third no longer had OAB at 2 and 5-year follow-ups. Previous population-based longitudinal studies that have examined progression and remission of OAB and incontinence in men also found that OAB and incontinence status changed dynamically over time, but did not account for medical treatment and conditions that can alter the clinical course. OAB and incontinence in men with neurological diseases may be more persistent whereas incontinence caused by urological procedures, such as TURP, radical prostatectomy, and radiotherapy can be temporary. Our study focused on non-neurogenic idiopathic OAB and urgency incontinence.

All cases of incontinence in the analytic cohorts were assumed to be urgency incontinence. Men with common causes of other types of incontinence (such as neurological diseases, prostate cancer, and surgery for BPH) were excluded. Since we only included men who were followed up for 5 years, the analytic cohorts consisted of relatively healthy men with low baseline prevalence of poor mobility and dementia, suggesting few men had functional incontinence. Although overflow incontinence cannot be excluded, a study of nursing home residents suggests that this is a rare cause of incontinence even in an older and sedentary population. 16 Remission rates of OAB between 2- and 5-year follow-ups were higher in men without OAB at baseline compared to men with OAB at baseline, but the difference was not significant. It is possible that OAB of recent onset may have a better chance of remission without treatment but a larger study would be warranted. Remission of incontinence between 2- and 5-year follow-ups did not seem to depend on previous continence status. There was also a suggestion that taking diuretics, having diabetes, and more severe voiding symptoms decreases the chances of spontaneous remission, but this also needs to be explored in a larger study as the findings were not statistically significant in this study.

This is a population-based study where urinary symptoms were measured using validated questionnaires. The primary strength of our study is that, unlike past studies, we had data on interventions for OAB and BPH so we could separate out potential improvement of symptoms due to interventions. In addition, we determined the rates of sustained remission using data from three time points as opposed to only two time points. OAB often a chronic condition that fluctuates over time in our study, among the 38 men who had OAB both at baseline and at 5-year follow-up, 14 had a temporary remission at 2-year follow-up but developed OAB again at 5-year follow-up. Therefore, we judged that determining a rate of sustained remission would be more informative.

Our study has some limitations. Firstly, the results may only apply to non-neurogenic OAB in healthier older men. Secondly, although we aimed to look at non-neurogenic and idiopathic OAB, we did not have information on transient causes of OAB such as urinary tract infection, alcohol, caffeine, or fluid intake. We tried to exclude these transient causes by asking about the symptoms in the past month using the IFS and the ICQ.

**CONCLUSIONS**

One in three older men with non-neurogenic OAB had sustained remission of symptoms for 5 years without medical or surgical interventions for either OAB or BPH. No significant predictor of sustained remission was identified.

**ACKNOWLEDGMENTS**

We would like to thank the participants of CHAMP study for generously helping us, and the study staff for their hard work.

**REFERENCES**

### Appendix I

#### Table A1: Baseline Prevalence of OAB and Incontinence by Inclusion/Exclusion Status to the Analysis of OAB

<table>
<thead>
<tr>
<th></th>
<th>Analytical cohort</th>
<th>Incomplete data</th>
<th>Excluded&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Lost to follow-up</th>
<th>Deseased</th>
</tr>
</thead>
<tbody>
<tr>
<td>OAB</td>
<td>98</td>
<td>3</td>
<td>115</td>
<td>91</td>
<td>220</td>
</tr>
<tr>
<td>No OAB</td>
<td>320</td>
<td>21</td>
<td>309</td>
<td>214</td>
<td>249</td>
</tr>
<tr>
<td>Missing</td>
<td>0</td>
<td>1.6</td>
<td>6</td>
<td>14</td>
<td>12</td>
</tr>
<tr>
<td>Total&lt;sup&gt;b&lt;/sup&gt;</td>
<td>488</td>
<td>24</td>
<td>429</td>
<td>355</td>
<td>569</td>
</tr>
<tr>
<td>NotOAB</td>
<td>20</td>
<td>18</td>
<td>27</td>
<td>16</td>
<td>18</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Incontinent</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>OAB</td>
<td>48</td>
<td>2</td>
<td>65</td>
<td>60</td>
<td>68</td>
</tr>
<tr>
<td>No OAB</td>
<td>446</td>
<td>78</td>
<td>955</td>
<td>990</td>
<td>986</td>
</tr>
<tr>
<td>Missing</td>
<td>0</td>
<td>7</td>
<td>4</td>
<td>12</td>
<td>8</td>
</tr>
<tr>
<td>Total&lt;sup&gt;b&lt;/sup&gt;</td>
<td>488</td>
<td>31</td>
<td>424</td>
<td>397</td>
<td>374</td>
</tr>
<tr>
<td>NotOAB</td>
<td>10</td>
<td>6</td>
<td>14</td>
<td>17</td>
<td>18</td>
</tr>
</tbody>
</table>

OAB, overactive bladder

<sup>a</sup> Total does not include men with missing data.

<sup>b</sup> "Excluded" includes men who were excluded from the analyses because of neurological disease, prostate cancer, and urological treatment.
A systematic review of the association between lower urinary tract symptoms and falls, injuries, and fractures in community-dwelling older men

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Abstract

Background: Lower urinary tract symptoms (LUTS) have been associated with falls in studies either exclusively or predominantly of women. It is, therefore, less clear if LUTS are risk factors for falls in men.

Methods: We conducted a systematic review of the literature on the association between LUTS and falls. Injuries and fractures in community-dwelling older men. Medline, Embase, and CINHAL were searched for any type of observational study that has been published in a peer-reviewed journal in English language. Studies were excluded if they did not report male-specific data or targeted specific patient populations. Results were summarized qualitatively.

Results: Three prospective cohort studies and six cross-sectional studies were identified. Incontinence, urgency, nocturia, and frequency were consistently shown to have weak to moderate associations with falls (the point estimates of odds ratio and relative risk ranged from 1.31 to 1.67) in studies with low risk of bias for confounding. Only frequency was shown to be associated with fractures.

Conclusions: Urinary incontinence and lower urinary tract symptoms are associated with falls in community-dwelling older men. The circumstances of falls in men with LUTS need to be investigated to generate hypotheses about what types of interventions may be effective in reducing falls.

Introduction

Falls are common among older people and often result in injuries [1]. A systematic review by Chiarelli et al. [2] showed that lower urinary tract symptoms (LUTS) such as incontinence, urgency, and nocturia were associated with falls. Most studies included in the review, however, were exclusively or predominantly of women. The patterns of co-occurrence and severity of LUTS are different between men and women [3]. In addition, there may be gender-related behavioral differences in strategies to manage LUTS which could also influence fall risk. There has not been a systematic review on the association between LUTS and falls that focuses on men and it is, therefore, less clear if LUTS are risk factors for falls in men.

We conducted a systematic review of the literature to determine if LUTS were associated with falls, injuries and fractures in community-dwelling older men. We also examined whether this association was influenced by type and severity of LUTS.

Search strategy and selection criteria

The protocol was registered in the PROSPERO database (CRD42014009354).

Data sources and searches

One investigator (NN) carried out a systematic literature search in Medline (1966 to August 2015), Embase (1980 to August 2015), and CINHAL (1982 to August 2015). A search strategy was constructed with the assistance of a medical librarian. Terms for LUTS, such as urgency, frequency, nocturia, and incontinence, were used in combination with terms for falls, injuries, and fractures. The full search strategy for Medline is presented in Figure 1. In each database, terms were searched as index terms where available or otherwise searched as key words within title and abstract. All 17 retrieval studies on the association between LUTS and falls regardless of study population were utilized to identify further eligible studies.
estimates of associations were unavailable, unadjusted measures of association were calculated from raw data.

Methodological quality of included studies was assessed by one investigator (N.N) using an adaptation of the study quality check list that Stalenhoef et al. used in their systematic review of fall risk factors [4]. Another investigator (Y.N) verified the quality assessment.

Data synthesis and analysis

Data were synthesized qualitatively structured around each LUTS. Types and severity of LUTS were taken into account where available. Because this is a review of observational studies, meta-analysis was not conducted and we focused on examining possible sources of heterogeneity between studies [5].

Results

Selection of studies

Figure 2 shows the selection process for relevant studies. A search of the databases identified 2431 studies after removing duplicates. Two thousand four hundred and eight were excluded after reviewing titles and abstracts including 19 that were not community-based and 10 that were studies of women. After 23 full texts were retrieved, 14 studies were excluded because they did not meet the inclusion criteria: one included only younger men, nine did not report male-specific data, and four did not examine the association of interest. No additional study was identified from reference lists of retrieved articles. Nine studies that met all the inclusion and exclusion criteria were included in the review for qualitative synthesis [6–14].

Appraisal of studies

Table 1 summarizes the characteristics and the results of the included studies. The studies are listed chronologically. Studies by Parson et al. and Frost et al. were large prospective studies exclusively of men [10,13]. Another study by Nakagawa et al. was also prospective but had a small sample size [11]. The cross-sectional studies by de Rekensoine et al., Aspland et al., and Fokk et al. also had large sample size of men [8,9,12]. The study by Parsons et al. looked at all the symptoms in the International Prostate Symptom Score (IPSS) [15] questionnaire individually [10]. The other studies examined only one symptom each. Outcomes included one or more falls (any fall) [6–8,10,12,14], two or more falls (recurrent falls) [10], any fracture [6,11,13], hip fractures [9], and osteoporotic fractures [13]. Observation or recall periods were one year for falls and five years for fractures.

Methodological quality appraisal of included studies is presented in Table 2. Stewart et al., de Rekensoine et al., and Parsons et al. limited participation to healthier or ambulatory community-dwelling men [6,8,10]. Loss to follow-up was not a problem in any of the three prospective studies. Parsons et al. excluded only 1% with incomplete data [10]; and the other two were linkage studies in universal health-care systems which capture nearly all fractures [11,13]. The time frame and frequency of occurrence of LUTS were specified.
LUTS and falls

voided four to five times per night were at increased risk of falls relative to men who voided zero or one time (adjusted RR 1.23, 95% CI 1.08–1.41) [10]. A wide range of fall risk factors were accounted for in this large prospective study. Adjusted OR was 1.63 (95% CI 1.00–2.68) in Stewart et al.’s study in men who voided at least twice per night compared with men who voided zero or one time [6]. This study only adjusted for age and determined falls retrospectively. Yasumura et al. showed a positive association, but the confidence interval was wide as a majority of the small sample met the nocturia criteria of any nighttime void [7].

Parsons et al. also examined the association of nocturia with recurrent falls which was stronger (adjusted RR = 1.42, 95% CI: 1.16–1.74) than with any fall [10].

The risk estimates for any fracture in five years were in opposite directions in the two studies that looked at fractures and not significant in either: adjusted HR was 2.61 (95% CI: 0.76–8.95) in Nakagawa et al.’s prospective study [11], and adjusted OR was 0.69 (95% CI: 0.35–1.34) in Stewart et al.’s cross-sectional study [6] with nocturia defined as two or more voids per night in both studies. The numbers of fractures over five years were limited in both studies (13 in Nakagawa et al.’s and 31 in Stewart et al.); resulting in wide confidence intervals.

Asplund et al. reported that the recalled history of hip fractures is past five years increased as number of nighttime voids increases, but adjustment was not made even for age and the information provided did not allow us to calculate OR [9].

Incontinence

In all three cross-sectional studies that examined the association between incontinence and any fall, incontinence was consistently shown to be associated with increased risk of any fall. The risk estimate was the largest in Foley et al.’s study which did not adjust for any potential confounders and defined incontinence as any leakage of urine (unadjusted OR = 1.86, 95% CI: 1.51–2.29) [12]. The other two studies accounted for a wide range of fall risk factors but did not explicitly define urinary incontinence: adjusted ORs were 1.5 (95% CI: 1.1–2.0) in de Reijke et al.’s study [8] and 1.67 (95% CI: 1.13–2.47) in Holman et al.’s [14].

None of the studies in men determined the association with falls by type or severity of incontinence.

Frequency

The large prospective study by Parsons et al. found frequency, defined as having to void within 2 h since the last void at least half of the times, to be weakly associated with any fall (adjusted RR — 1.17, 95% CI: 1.04–1.33) relative to never having frequency [10]. The association was slightly stronger for recurrent falls (adjusted RR 1.25, 95% CI: 1.02–1.53).

Another large prospective study, with extensive adjustment for potential confounders, by Frost et al. found frequency (definition not given) to be moderately associated with any fracture (adjusted RR = 2.03, 95% CI: 1.25–3.30) [13]. Although results were also given for osteoporotic fractures, it was not clear how they were defined.
Table 1. Characteristics and results of the included studies.

<table>
<thead>
<tr>
<th>Source</th>
<th>Country</th>
<th>Age</th>
<th>Sample size</th>
<th>Study design</th>
<th>Study factor</th>
<th>Outcome</th>
<th>Period</th>
<th>Association statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stewart, 1992</td>
<td>USA</td>
<td>55+</td>
<td>550</td>
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<td>Nocturia</td>
<td>Any fall</td>
<td>12 mo</td>
<td>OR = 1.63 (1.00-2.68)</td>
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<td>Yasumoto, 1994</td>
<td>Japan</td>
<td>55-64</td>
<td>366</td>
<td>Cross-sectional</td>
<td>Nocturia</td>
<td>Any fall</td>
<td>12 mo</td>
<td>OR = 0.69 (0.35-1.34)</td>
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<tr>
<td>de Balkenbroek, 2003</td>
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<td>70-79</td>
<td>1447</td>
<td>Cross-sectional</td>
<td>Incontinence</td>
<td>Any fall</td>
<td>12 mo</td>
<td>OR = 1.5 (1.4-2.8)</td>
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<td>Asplund, 2006</td>
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<td>73.9±6.0 (mean±SD)</td>
<td>241</td>
<td>Cross-sectional</td>
<td>Nocturia</td>
<td>Hip fracture</td>
<td>5 y</td>
<td>OR = 3.38*</td>
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<td>1 time = 3.38*</td>
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<td>RR = 1.19 (1.06-1.33)</td>
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<td>Recurrent falls</td>
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<td>RR = 1.39 (1.06-1.60)</td>
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<td>Any fall</td>
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<td>RR = 1.25 (1.02-1.53)</td>
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<td>Urgency</td>
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<td></td>
<td></td>
<td>Any fall</td>
<td>1 y</td>
<td>RR = 1.31 (1.17-1.47)</td>
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<td>Intermittency</td>
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<td>Any fall</td>
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<td>RR = 1.10 (0.98-1.23)</td>
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<td>Weak stream</td>
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<td></td>
<td>Straining</td>
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<td>RR = 1.34 (1.06-1.64)</td>
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<td></td>
<td>Any fall</td>
<td>1 y</td>
<td>RR = 1.34 (1.16-1.57)</td>
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<td></td>
<td></td>
<td>IPSS score</td>
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<td>RR = 1.42 (1.16-1.76)</td>
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<td></td>
<td></td>
<td></td>
<td>Recurrent falls</td>
<td>1 y</td>
<td>RR = 1.42 (1.16-1.67)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Nocturia</td>
<td>1 y</td>
<td>RR = 1.23 (1.08-1.41)</td>
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<td></td>
<td>Recurrent falls</td>
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<td>RR = 1.42 (1.16-1.67)</td>
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<td></td>
<td>Any fall</td>
<td>1 y</td>
<td>RR = 1.33 (1.15-1.55)</td>
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<td></td>
<td>Recurrent falls</td>
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<td>RR = 1.43 (1.31-1.57)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Any fracure</td>
<td>2 y</td>
<td>RR = 2.31 (0.76-8.95)</td>
</tr>
<tr>
<td>Nakagawa, 2010</td>
<td>Japan</td>
<td>70+</td>
<td>397</td>
<td>Cohort</td>
<td>Nocturia</td>
<td>Any fall</td>
<td>1 y</td>
<td>OR = 1.86 (1.51-2.28)</td>
</tr>
<tr>
<td>Foley, 2012</td>
<td>UK</td>
<td>70+</td>
<td>2352</td>
<td>Cross-sectional</td>
<td>Incontinence</td>
<td>Any fall</td>
<td>1 y</td>
<td>OR = 1.86 (1.51-2.28)</td>
</tr>
<tr>
<td>First, 2012</td>
<td>Denmark</td>
<td>60-74</td>
<td>4866</td>
<td>Cohort</td>
<td>Frequency</td>
<td>Any fall</td>
<td>5.4 y (mean)</td>
<td>OR = 2.25 (1.25-3.96)</td>
</tr>
<tr>
<td>Hoddman, 2013</td>
<td>Sweden</td>
<td>75+</td>
<td>471</td>
<td>Cross-sectional</td>
<td>Incontinence</td>
<td>Any fall</td>
<td>1 y</td>
<td>OR = 1.72 (0.81-3.68)</td>
</tr>
</tbody>
</table>

Note: IPSS, International Prostate Symptom Score; OR, odds ratio; RR, relative risk; HR, hazard ratio; mo, month; y, year.

*A 5-year incidence by number of nocturnal micturition. 1/2 ≤ the times relative to never. 3 (severe 20-35 points) relative to mild (0-7). 5-6 times at night relative to 0-1 time.
The other symptoms on the IPSS (incomplete emptying, intermittency, urgency, weak stream, and straining) were examined for association with any fall and recurrent falls in the well-conducted study by Parsons et al. [10]. The strongest associations were found between urgency and any fall (adjusted RR = 1.51, 95% CI: 1.17–1.97) and recurrent falls (adjusted RR = 1.59, 95% CI: 1.33–1.89), and between straining to void and any fall (adjusted RR = 1.24, 95% CI: 1.06–1.46) and recurrent falls (adjusted RR = 1.50, 95% CI: 1.27–2.02). The risks above were shown for men who had the symptoms at least half the time relative to those who never did. Other symptoms had weaker associations with falls.

This study by Parsons et al. also showed that high total IPSS (20–35 points) were associated with any fall (adjusted RR = 1.33, 95% CI: 1.15–1.53) and recurrent falls (adjusted RR = 1.63, 95% CI: 1.31–2.02) relative to men with low IPSS (0–7 points).

**Discussion**

In our study, we systematically reviewed the association of LUTS with falls, injuries, and fractures in community-dwelling older men. Although studies varied in methodology, incontinence and storage symptoms such as urgency, nocturia, and frequency were consistently shown to be associated with falls. The associations were weak to moderate when restricted to six studies with low risk of bias due to confounding. These findings are in line with the past studies predominately or exclusively of women [2]. Fewer studies examined fractures as an outcome of which only one study showed an association between frequency and all fractures. No study looked at injuries as an outcome.

As might be expected, the extent to which potential confounders were adjusted for had a substantial influence on observed effect sizes in included studies. The strongest evidence for an association between LUTS and falls comes from the study by Parsons et al. [10]: it had a large sample size, closely followed up participants for falls, assessed a wide range of LUTS using a validated questionnaire, and adjusted the risk estimates for an exhaustive list of fall risk factors that have previously been identified.

The time frame and frequency for the occurrence of LUTS was specified only in the study by Parsons et al. using the IPSS [10]. It is preferable to ask about the occurrence of LUTS during a specific period of time because LUTS status is known to change dynamically over time: a 30% annual remission rate and a 10% annual incidence of incontinence was reported in community-dwelling older men [17]. As the majority of male incontinence includes a component of urgency [18], it is expected that there will be a change in storage symptoms such as urgency, frequency, and nocturia in keeping with the progression and remission of incontinence. Frequency of each symptom should also be asked because participants might regard symptoms that occur infrequently as insignificant. Although incontinence is not included in the IPSS, other validated questionnaires such as the International Consultation on Incontinence questionnaire (ICIQ) may be utilized which incorporates the time frame and frequency of occurrence [19]. The direction of bias that these ambiguities
about time frame and frequency of symptoms may have introduced is uncertain. Administration of pad weight test or bladder diary may have provided better objective evidence of LUTS but may have been considered to be too resource intensive in large-scale studies. Thus we judged that the use of self-administered questionnaires which ensures privacy to be acceptable [20].

A fall is defined by World Health Organization to be “an event which results in a person coming to rest inadvertently on the ground or floor or other lower level” [21]. Most of the studies included in this review did not explicitly define falls. If falls were not well defined, this may have inflated the number of falls because older people may regard merely losing balance without landing on lower level as falling [22]. The impact of inclusion of “near-falls” on the association with LUTS is uncertain. Only Parsons et al. prospectively determined the occurrence of falls. Although the other studies that relied on recall of the past year may not be ideal, Mackenzie et al. demonstrated that recalls of falls are fairly reliable in people aged 70 and older [23]. As has been found in most studies on fall risk factors, stronger associations were consistently found with “recurrent falls” than “any fall” in the study by Parsons et al. [10] Single falls may occur by chance to people with no tendency to fall whereas recurrent falls may be more distinct as an A-risk group for falls.

Few studies examined fractures as an outcome. As discussed above, LUTS status changes dynamically over time. It, therefore, may not be appropriate to examine the association between LUTS at baseline and an outcome such as fractures in the following five years. Alternatively, it would require a large sample size to observe sufficient number of fractures in a shorter period of time.

Our review showed that both urgency and incontinence were associated with falls in men. As the majority of incontinence in men is known to include an urgency component [18], the question arises as to whether actual leakage of urine makes any additional contribution to fall risk beyond the sense of urgency alone. To answer this question, data need to be collected to differentiate between subjects with urgency without incontinence and those with urgency that results in incontinence.

High IPSS were associated with falls. Multiple symptoms within voiding or storage symptom subcategories tend to coexist in older men because the voiding symptoms may reflect different aspects of either bladder outlet obstruction (BOO) or impaired detrusor contractility, and storage symptoms reflect different aspects of overactive bladder (OAB). In addition, voiding and storage symptoms often coexist because some of OAB may be secondary to BOO, and OAB and impaired detrusor contractility may coexist in older people as detrusor hypersensitivity with impaired contractility. Hence, the IPSS may have potential in assessing the overall fall risk related to LUTS. Although incontinence is not included in the IPSS, it is not yet certain whether it carries any additional risk of falls over the symptoms in the IPSS as discussed above.

There are a few limitations to our review. First, the results of this review may not directly apply to frailter and less mobile men in the community who may be at greater risk of falls. Some studies limited participation to healthiest men in clearly defined inclusion criteria while the other studies that did not limit participation in any way are still likely to have undersampled these men. Second, it is uncertain whether medical, surgical, or behavioral interventions to LUTS alone may reduce falls in community-dwelling older people. A systematic review that investigated whether treating LUTS decreases falls identified two randomized controlled trials in nursing home residents: one that implemented a multidimensional intervention program including prompted toileting and physical exercise reported significant reduction in falls and the other one that prescribed an anticholinergic agent failed to reduce falls [24]. No study that reported the association between LUTS and falls in either men or women determined the events that precipitated the falls either. LUTS may directly precipitate falls or they may be merely a marker of other factors that cause falls. For example, hypogonadism has been shown to often coexist with LUTS and some of the characteristic symptoms of hypogonadism such as depressed mood, cognitive impairment and decreased muscle mass and strength are risk factors for falls [25]. The circumstances of falls should be explored to generate hypothesis about what types of interventions should be incorporated in multidimensional fall prevention strategies. Also, future trials to treat LUTS should consider including falls as an endpoint.

Conclusions
Uriney incontinence and lower urinary tract storage symptoms were consistently shown to have weak to moderate association with falls in community-dwelling older men in studies with low risk of bias for confounding.

Evidence is lacking on whether medical, surgical, or behavioral interventions to LUTS decrease fall risk in community-dwelling men. The circumstances of falls in men with LUTS should be explored to improve fall prevention strategies.

Declaration of interest
The authors report no declaration of interest.

References
Voiding Dysfunction

Lower Urinary Tract Symptoms and Incident Falls in Community Dwelling Older Men: The Concord Health and Ageing in Men Project


From the Centre for Education and Research in Ageing, and Ageing and Alzheimer's Institute (INR, HSC, FMR, LMV), DLIC, ViA, Department of Urology (JQ) and ANZAC Research Institute (GHH, MJS, DLIC), Concord Hospital and School of Public Health (RISQ), University of Sydney, New South Wales, Australia.

Abbreviations and Acronyms
CHAMP = Concord Health and Ageing in Men Project
DRB = Drug Burden Index
HPS3 = HPS Storage subscore
IR = incidence rate
LUTS = lower urinary tract symptoms
OSAB = overactive bladder

Purpose: We sought to determine which lower urinary tract symptoms are associated with incident falls in community dwelling older men.

Materials and Methods: The Concord Health and Ageing in Men Project involves a representative sample of community dwelling men 70 years old or older in a defined geographic region in Sydney, New South Wales, Australia. Included in analysis were 1,090 men without neurological diseases, poor mobility or dementia at baseline. Lower urinary tract symptoms were assessed using I-PSS (International Prostate Symptom Score) and incontinence was assessed using ICIQ (International Consultation on Incontinence Questionnaire) at baseline. I-PSS subscores were calculated for storage and voiding symptoms. Incident falls in 1 year were determined by telephone follow-up every 4 months.

Results: I-PSS storage and voiding subscores were associated with falls. Urgency incontinence was associated with falls (adjusted incidence rate ratio 2.57, 95% CI 1.54–4.43). In addition, intermediate to high I-PSS storage subscores without urgency incontinence were associated with falls (adjusted incidence rate ratio 1.72, 95% CI 1.24–2.38). Other types of incontinence and urgency alone without urgency incontinence were not associated with falls.

Conclusions: Lower urinary tract storage and voiding symptoms were associated with falls in community dwelling older men. Of the symptoms of overactive bladder urgency incontinence carried a high risk of falls. Storage symptoms also contributed to the fall risk independently of urgency incontinence. Circumstances of falls among men with lower urinary tract symptoms should be explored to understand how lower urinary tract symptoms increase the fall risk and generate hypotheses regarding potential interventions. Furthermore, trials to treat lower urinary tract symptoms in older men should include falls as an end point.

Key Words: urinary bladder, lower urinary tract symptoms, aged, male, accidental falls

Falls are common among older people and often result in injuries. LUTS such as incontinence, urgency, frequency and nocturia have been associated with falls but evidence of the association is less extensive in
men than in women. The patterns of co-occurrence and severity of LUTS are different between men and women. In addition, there may be gender-related behavioral differences in strategies to manage LUTS that could also influence fall risk.

Moreover, because multiple LUTS often coexist in 1 person, it is unclear which LUTS may potentially be targeted in strategies to decrease falls. Looking at all of the important LUTS in 1 population would help identify which LUTS have stronger associations with falls. In particular, usually related symptoms such as urgency and urgency incontinence must be examined for an association with falls, stratified by both of these symptoms to determine whether urgency incontinence makes any additional contribution to the fall risk over that of urgency alone.

The aim of our study was to determine which LUTS were associated with incident falls during 1 year in community dwelling older men. To explore this we examined each lower urinary tract symptom by frequency of occurrence, IPSS, incontinence type and urgency by the presence or absence of urgency incontinence for associations with incident falls.

MATERIALS AND METHODS

Study Participants

CHAMP is a prospective cohort study of a wide range of health issues in older men. Baseline data were collected between January 2005 and June 2007. The study was approved by the Concord Hospital human research ethics committee. All participants provided written informed consent.

CHAMP includes 1,705 men 70 years of age or older living in a defined region of metropolitan Sydney, New South Wales, Australia. The sampling frame was the New South Wales electoral roll, on which registration is compulsory. The only exclusion criterion was living in a residential aged care facility. The participation rate was 47%. The details of the sample selection process have been described previously.

Lower Urinary Tract Symptoms

Information about LUTS was collected from a self-administered questionnaire using I-PSS and ICIQ.

Nocturia was categorized into zero to 1 time, 2 to 3 times and 4 times or more per night. Other symptoms in I-PSS were categorized as not at all, less than half the time and at least half the time. IPSS total score was categorized into low—9 to 2, intermediate—8 to 19 and high—20 to 35 points.

The storage subcore of I-PSS was calculated as the sum of questions number 2, 4 and 7 (frequency, urgency and nocturia) and categorized as low—0 to 3, intermediate—4 to 8 and high—9 to 15 points. IPSS-S was calculated as the sum of questions number 1, 3, 5 and 6 (incomplete emptying, intermittency, weak stream and straining), and classified as low—9 to 4, intermediate—5 to 11 and high—12 to 20 points.

Incontinence was first categorized according to frequency, including none or at most weekly, more than weekly but less than daily and at least daily. Also, incontinence was categorized by type, including incontinence without an urgency component (nonurgency incontinence, including stress and other incontinence), incontinence with an urgency component (urgency incontinence, including urgency and mixed incontinence) and incontinence that occurred at most once per week, which was classified as no incontinence. Type of incontinence was determined using question 4 of ICIQ (“When does urine leak?”) with the response “urine leaks before you can get to the toilet” indicating an urgency component.

To determine the individual contribution of urgency and of urgency incontinence to fall risk the men were categorized as those with urgency incontinence, those with urgency without urgency incontinence and those with neither urgency nor urgency incontinence. For this analysis urgency was defined as urgency occurring at least half the time and urgency incontinence was defined as more than weekly incontinence with an urgency component.

Lastly, post hoc analysis was performed to determine the contribution of storage symptoms as a whole to fall risk, accounting for urgency incontinence. This analysis was added because intermediate to high I-PSS storage subscores incorporating all OAB symptoms were related to falls, and urgency incontinence, which is the most severe form of OAB, was also associated with falls. For this analysis having storage symptoms was defined as intermediate to high IPSS-S (4 to 15 points). Men were classified into those with urgency incontinence regardless of OAB-S, those with storage symptoms without urgency incontinence and those with neither storage symptoms nor urgency incontinence.

Fall Ascertainment

Participants were telephoned every 4 months. They were asked whether they had fallen in the previous 4 months and if so, how many times they had fallen. When falls were reported, study staff excluded near falls by asking whether the body of the participant had hit the ground or an object. The first 3 telephone followups representing the first year of followup were used in this study.

Covariates

Information on demographic characteristics, lifetime history of diagnosed medical conditions including Parkinson’s disease, stroke, epilepsy and arthritis, history of falls in the previous year and dizziness was gathered using a self-administered questionnaire. Medical conditions and dizziness were dichotomized into absence and presence. Country of birth was categorized
as Australia, Italy, Great Britain, Greece, China and other.

Variables assessed at the clinic interviews by trained personnel included MMSE (Mini-Mental State Examination),% functional disability (a modification of the Katz activities of daily living%5), physical performance tests (repeat chair stands, usual pace walk and narrow balance walk) and visual impairment. Also, participants brought medications that they had ingested daily or almost daily for at least a month before the clinic visit. Poor mobility was defined as needing help with walking across a small room and/or transferring from a bed to a chair. The time spent for each physical performance test was dichotomized into slow and normal/fast at the slowest quartile. Men who did not complete the tasks were categorized into the slowest quartile. Poor visual acuity was defined as less than 20/63 on the Logmar Visual Acuity Test. DIH was calculated by adding the burden of drugs with anticholinergic and sedative properties. DIH was categorized as 0, greater than 0 to 0.5 and greater than 0.5. The median DIH in men exposed to these drugs was 0.5.

IQCODE (Informant Questionnaire on Cognitive Decline in the Elderly), an informant screening questionnaire to assess cognitive decline, was administered by telephone shortly after the clinic visit. Men with a MMSE score of 26 or less, or an IQCODE score of 3.6 or higher underwent a detailed cognitive examination performed by a geriatrician. A diagnosis of dementia was reached using DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, fourth edition)%6 criteria at a consensus meeting attended by 2 geriatricians, a neurologist and a neuropsychologist.

**Statistical Analysis**

Participant characteristics were derived as the mean ± SD or as frequency distributions. Fall IRIs were estimated using negative binomial regression. Negative binomial regression is suitable for analyzing recurrent events such as falls because it fully uses the count data, in contrast to setting arbitrary cutoff values, which occurs when logistic regression is used to analyze fall data. Negative binomial regression is a generalization of Poisson regression that can deal with overdispersed data and also control for different followup durations.

Men with neurological diseases (stroke, Parkinson's disease and epilepsy), poor mobility and dementia at baseline were excluded from analyses. These conditions are known to affect the fall risk and also to cause LUTS, including functional incontinence. Each symptom, I-PSS, urgency/urgency incontinence status and composite storage symptoms/urgency incontinence

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<table>
<thead>
<tr>
<th>Table 1. Baseline characteristics of 1,380 men in CHAMP*</th>
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<tbody>
<tr>
<td><strong>Baseline I-PSS (compa)</strong></td>
</tr>
<tr>
<td>Low (0–2)</td>
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<tr>
<td>-----------</td>
</tr>
<tr>
<td><strong>Number</strong></td>
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<tr>
<td>Male ± SD age</td>
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<tr>
<td>No. of previous falls (binary)</td>
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<td>No. of previous falls (binary)</td>
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*Values may be unequal total because of missing data.

1 No other country contributed more than 3% of patients.
Table 2. Fall IRR in 1,390 community dwelling older men in CHAMP

<table>
<thead>
<tr>
<th>Storage symptoms</th>
<th>Univariate</th>
<th>Multivariate*</th>
</tr>
</thead>
<tbody>
<tr>
<td>No.</td>
<td>Frequency</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Not at all</td>
<td>407</td>
</tr>
<tr>
<td></td>
<td>Less than half time</td>
<td>565</td>
</tr>
<tr>
<td></td>
<td>Half time or greater</td>
<td>218</td>
</tr>
<tr>
<td>Urgency</td>
<td>Not at all</td>
<td>748</td>
</tr>
<tr>
<td></td>
<td>Less than half time</td>
<td>363</td>
</tr>
<tr>
<td></td>
<td>Half time or greater</td>
<td>220</td>
</tr>
</tbody>
</table>

| No. | Urosepsis | | |
| | 1-2 | 615 | 1.00 | 1.00 |
| | 3-5 | 617 | 1.26 (0.92-1.74) | 1.13 (0.92-1.35) |
| | 4 or Greater | 134 | 1.26 (0.83-2.07) | 1.18 (0.71-1.92) |

| Voiding symptoms | | |
| | Not at all | 1,059 | 1.00 | 1.00 |
| | Less than half time | 152 | 1.22 (0.87-1.72) | 1.26 (0.86-1.87) |
| | Half time or greater | 21 | 1.23 (0.61-2.46) | 1.22 (0.58-2.55) |

| Voiding symptoms | | |
| | Not at all | 754 | 1.00 | 1.00 |
| | Less than half time | 244 | 1.21 (0.81-1.87) | 1.27 (0.86-1.87) |
| | Half time or greater | 146 | 1.52 (1.00-2.34) | 1.47 (0.99-2.26) |

| Incontinence | | |
| | Not at all | 838 | 1.00 | 1.00 |
| | Less than half time | 318 | 1.21 (0.91-1.60) | 1.42 (0.99-2.06) |
| | Half time or greater | 174 | 1.90 (1.26-2.87) | 1.67 (1.23-2.65) |

| Urine retention | | |
| | Not at all | 861 | 1.00 | 1.00 |
| | Less than half time | 314 | 1.05 (0.71-1.58) | 1.17 (0.88-1.59) |
| | Half time or greater | 176 | 1.26 (0.87-1.84) | 1.26 (0.86-1.87) |

| Prior usage | | |
| | Not at all | 840 | 1.00 | 1.00 |
| | Less than half time | 202 | 1.20 (0.89-1.53) | 1.20 (0.91-1.62) |
| | Half time or greater | 40 | 1.44 (1.01-2.05) | 2.06 (1.05-2.04) |

| Storage sub-area (range) | | |
| | Low (0-3) | 702 | 1.00 | 1.00 |
| | Intermediate (4-6) | 48 | 1.96 (1.43-2.70) | 1.75 (1.24-2.40) |
| | High (7-11) | 148 | 1.40 (1.23-1.56) | 1.31 (1.23-2.58) |

| Voiding sub-area (range) | | |
| | Low (0-4) | 83 | 1.00 | 1.00 |
| | Intermediate (5-11) | 294 | 1.54 (0.92-2.58) | 1.41 (0.92-2.06) |
| | High (12-23) | 74 | 1.97 (1.02-2.46) | 1.98 (1.06-3.00) |

Table 2 (continued)

<table>
<thead>
<tr>
<th>Storage symptoms/urgency</th>
<th>Univariate</th>
<th>Multivariate*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incontinence</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Not at all</td>
<td>801</td>
</tr>
<tr>
<td></td>
<td>Storage symptoms without urgency incidence</td>
<td>527</td>
</tr>
<tr>
<td></td>
<td>Urgency incidence</td>
<td>10</td>
</tr>
</tbody>
</table>

*Adjusted for age, birth, country, disease, visual impairment, arthritis, psychiatric medication, antidepressant medication and walking aid.

status were entered into separate multivariate models as the main explanatory variable. Risk factors for falls that were previously identified were forced into the multivariate models regardless of a statistical contribution to the model to ensure face validity, including age, country of birth,17 dizziness, visual impairment, arthritis, DBH, repeat chair stands, usual pace walk and narrow balance walk. All analyses were performed using SAS® version 9.3.

RESULTS

Of the 1,705 participants at baseline 307 with neurological disease, poor mobility or dementia at baseline were excluded from analysis. After applying these exclusion criteria an additional 8 men (9.6%) who withdrew from study or died before the first telephone followup were excluded. The remaining 1,390 men were included in analysis. Mean ± SD followup was 11.8 ±1.0 months (range 4 to 12). The fall rate ranged from zeros to 12 per year. A total of 102 men (10%) had a fall rate of 1 per year and 97 (7%) had a fall rate of greater than 1 per year.

Table 1 shows the baseline characteristics of the included men. Mean age was 76.5 ± 5.3 years. Of the men 49% were born in Australia and 20% were born in Italy. In the previous year 10% of the men had experienced a single fall and 0% had experienced 2 or more falls. I-PSS was low in 84% of participants, 29% had intermediate I-PSS and 7% had high I-PSS. Incontinence was experienced more than weekly but less than daily in 7% of men and at least daily in 7%. A higher proportion of men in higher I-PSS categories reported 2 or more falls in the last year, including 4% with low, 7% with intermediate and 8% with high I-PSS.

Table 2 shows associations of LUTS, I-PSS, urgency urgency incontinence status and composite storage symptoms/urgency incontinence status with fall rates. Results of multivariate analyses are
described. Of individual symptoms on I-PSS urgency and intermittency that occurred at least half the time were significantly associated with an increased fall rate. High total I-PSS, intermediate to high I-PSS-S and high I-PSS voiding subscores were associated with an increased fall rate. Urgency incontinence was associated with an increased fall rate but nonurgency incontinence and urgency without urgency incontinence were not. With regard to the combination of urgency incontinence and composite storage symptoms (urgency, frequency and nocturia) storage symptoms were significantly associated with an increased fall rate even in the absence of urgency incontinence.

**DISCUSSION**

This population based prospective study shows that lower urinary tract storage and voiding symptoms are associated with falls in community dwelling older men. The strongest association was found for urgency incontinence that occurred more than weekly. Also, storage symptoms (urgency, frequency and nocturia) as a whole, represented as intermediate to high I-PSS-S, were associated with falls independently of urgency incontinence.

In a large, well performed, prospective study of 5,872 men Parsons et al examined a wide range of LUTS for associations with falls.14 Unlike in our study, they did not account for incontinence but found weak associations of I-PSS individual symptoms and total I-PSS with falls. In our study with a smaller sample size only urgency, intermittence and total I-PSS were associated with falls. In addition, we found that storage and voiding subscores were associated with falls and neither had an apparently stronger association than the other score.

Urgency incontinence was associated with falls in our study but other types of incontinence were not. This is consistent with studies in women.19,20 Urgency has also been associated with falls in past studies in men and women17,21,22 but these studies did not assess urine leakage. In our series urgency was further examined for an association with falls by the presence of urgency incontinence to determine whether urine leakage would make an additional contribution to fall risk beyond that of urgency alone. We defined urgency and incontinence as those occurring half the time and more than weekly, respectively, which we considered clinically important. Urgency incontinence was moderately associated with falls but urgency without urgency incontinence was not.

On post hoc analysis OAB symptoms as a whole, represented as I-PSS-S, were examined for an association with falls by the presence of urgency incontinence, which is the most severe form of OAB. We found that intermediate to high I-PSS-S was associated with falls even in the absence of urgency incontinence. This indicates that storage symptoms collectively contribute to fall risk, although urgency alone without accounting for frequency and nocturia did not make an independent contribution to fall risk.

Our study has a number of strengths. CHAMP includes a large representative sample of community dwelling, older Australian men. While the response rate was relatively low at 47%, the prevalence of major medical conditions and the distribution of responses to a question on self-rated health were similar to those in 915 men 70 years old or older in the nationally representative MATeS (Men in Australia Telephone Survey) study.23 Validated questionnaires were used to assess a wide range of LUTS; falls were ascertained prospectively and associations were adjusted for an extensive list of previously identified fall risk factors.

A limitation of our study is inherent in the study design. Our results only apply to community dwelling men without conditions related to LUTS and falls, such as dementia, poor mobility and neurological disease. Another limitation is that ascertainment of falls relied on recall of the last 4 months without using fall diaries. Although this was not ideal, Mackenzie et al reported that recalls of falls in the last 6 months were reliable in people 70 years old or older.24 Besides, the quality of responses are unlikely to have varied according to LUTS status.

To determine LUTS we did not discriminate between nocturnal micturition with and without urgency.25 This could have masked the possible association between nocturnal urgency and falls.

Lastly and most importantly, causality is unclear since we could not determine the circumstances of the falls. Therefore, it is uncertain whether medical, surgical or behavioral interventions for LUTS alone could decrease falls in community dwelling older people.26 Since falls are often multifactorial, other predisposing or precipitating factors for falls that were not fully adjusted for may have had a part in the increased fall risk. The circumstances of falls in men with LUTS should be investigated to generate hypotheses about what types of interventions may be incorporated into multidimensional fall prevention strategies. Also, future trials to treat LUTS should consider including falls as an end point.

**CONCLUSIONS**

Lower urinary tract storage and voiding symptoms are associated with falls in community dwelling
older men. In particular, urgency incontinence (incontinence with an urgency component, including mixed incontinence) carries a higher risk of falls. Also, storage symptoms are collectively associated with falls even in the absence of urgency incontinence. Other types of incontinence and urgency alone without urgency incontinence were not associated with falls. Evidence is lacking about whether treatment of LUTS decreases the fall risk in community-dwelling men. The circumstances of falls among men with LUTS should be explored to generate hypotheses regarding potential interventions. Furthermore, trials to treat LUTS in older men should consider including falls as an end point.

REFERENCES
Appendix C: Ethics approval letter for the circumstances of falls study
19 October 2015

A/Professor Vasi Naganathan
cl/- Ms Naomi Noguchi
CERA
CONCORD RGH

Dear Professor Naganathan,

Re: HREC/15/CRGH/204
CH52/5/2015-163
Circumstances of falls precipitated by lower urinary tract symptoms in community-dwelling older people attending urology clinics

Thank you for submitting the above project for single ethical and scientific review. This project was first considered by the Executive Ethical Review Panel of the Sydney Local Health District Human Research Ethics Committee – CRGH at its meeting held on 16 September 2015. This Human Research Ethics Committee (HREC) has been accredited by the NSW Ministry of Health as a lead HREC under the model for single ethical and scientific review.

This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council’s National Statement on Ethical Conduct in Human Research and the CPIMP/ICH Note for Guidance on Good Clinical Practice.

I am pleased to advise that the Committee has granted ethical approval of this research project.

The documents reviewed and approved include:

Low & Negligible Risk Research (LNR) Ethics Application Form – submission code AU/8/410127
Protocol Version 1.2 dated 16/10/2015
Participant Information Sheet & Consent Form - Version 1.2 dated 16/10/2015
Data collection form (Patient: telephone/faceto-face) – Version 1.2 dated 16/10/2015
Data collection form (Medical records) – Version 1.1 dated 26/08/2015
Data collection form (Partner or family) – Version 1.2 dated 16/10/2015
International Prostate Symptom Score (IPSS) questionnaire
International Consultation on Incontinence Questionnaire (ICIQ)

The HREC has provided ethical and scientific approval for the following site:
1. Concord Repatriation General Hospital

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at Concord Hospital until a Site Specific Application has been reviewed and approved and separate authorisation from the Chief Executive or delegate has been obtained.
Please note the following conditions of approval:

1. You will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project, (including Serious Adverse Events).

2. Proposed changes to the research protocol, conduct of the research, or length of HREC approval will be provided to the HREC for review in the specified format.

3. You will notify the HREC, giving reasons, if the project is discontinued at a site before the expected date of completion.

4. You will provide an annual report to the HREC, and at completion of the study in the specified format.

5. You will adhere to the study protocol at all times.

6. HREC approval is granted on the assumption that all students and early career researchers are adequately supervised by the principal and senior investigators on a project. This supervision would ensure that all privacy concerns are met (including the completion of confidentiality agreements by participating students) and that both students and participants are supported in the conduct of the study in line with the approved research protocol.

HREC approval is valid for five (5) years subject to the supply of an annual progress report. The first report should be sent to the Concord Hospital Research Office by 31/10/2016.

Should you have any queries about the HREC’s consideration of your project please contact the Executive Officer - (02) 9787-5622. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the website: www.sswahs.nsw.gov.au/concord/ethics.

We wish you every success in your research.

Please quote the above file number in all correspondence.

Yours sincerely,

[Signature]

Professor Andrew McLachlan
Chairman
Sydney Local Health District Human Research Ethics Committee – CRGH

Please complete the boxes below and return a copy of this page to the Concord Hospital Research Office:

☐ I acknowledge and accept the Conditions of Ethical Approval.

☐ I will not commence this project at any site until separate written authorisation from the Chief Executive or delegate of that site has been obtained

Printed Name
Chief Investigator

Signature
Date
Appendix D: Information sheet and consent form for the circumstances of falls study
A study on circumstances of falls in older people with urinary symptoms living in the community

INFORMATION FOR PARTICIPANTS

The Urology Department and the Centre for Education and Research on Ageing at Concord Hospital is conducting the above-named study. This study has been approved by the Concord Hospital Human Research Committee in October, 2015, and will be carried out at Concord Hospital from November 2015 to October 2016.

Urinary symptoms (such as incontinence or urgency to go to toilet) are thought to increase the risk of falls. It is not known, however, how people with urinary symptoms fall. Knowing more about this may improve prevention measures for falls.

For this study, information on falls that you may have had in the past year will be obtained from either a telephone or face-to-face interview. If possible, we would also like to contact your partner or family who lives with you for more information about your falls. Recall of events at the time of falls can be unclear even in people with good memory. Also we will review your medical file to obtain information on urinary symptoms, medical history and medication use.

All details obtained will remain confidential. A report of this study may be published, but individual participants will not be identifiable by any means in such a report. The original data in paper files will be stored in a locked cabinet. Electronic data will be stored at a password-protected computer system.

What does it mean for me?

Participation to this study is completely voluntary. You may choose to refuse or withdraw from this study at any time, and if you choose to do so, it will not in any way affect your medical care. You may also elect for us not to contact your partner or family but take part in the study yourself.

We will call you or arrange a face-to-face interview to gather the falls information. Either can be arranged at a suitable time for your convenience. The interview will take no more than 10 minutes either way. We will ask about details of any falls you might have had in the last 12 months. We also ask a few questions about your living arrangements (do you live alone or not?), country of birth, qualifications and mobility.

Your usual medical care will not be interrupted, and any information relevant to your medical care will be relayed to your treating doctors.

Your partner or family member whom you nominate will be contacted to arrange a telephone or face-to-face interview. S/he will be asked about details of any falls you might have had in the last 12 months. We will not be asking them about anything else to do with your health or about them.
Further information

If you would like to know more at any stage, please feel free to contact Ms Naomi Noguchi, PhD student, at Centre for Education and Research on Ageing on (02) 9767 9170. If you have any concerns or complaints about the conduct of the research study, you may contact the Secretary of the Concord Hospital Human Research Ethics Committee, on (02) 9767 5622. Alternatively, if you wish to speak with an independent person within the Hospital about any problems or queries about the way in which the study was conducted, you may contact the Patient Representative on (02) 9767 7488.
Concord Repatriation General Hospital

A study on circumstances of falls related to urinary symptoms in older people living in the community

PARTICIPANT CONSENT FORM

I, .................................................................[name] of .................................................................[address] have read and understood the Information for Participants for the above named research study and have discussed the study with .................................................................

• I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers.

• I understand that, during the course of this study, my medical records may be accessed by the researchers, by regulatory authorities or by the Ethics Committee approving the research in order to verify results and determine that the study is being carried out correctly.

• I freely choose to participate in this study and understand that I can withdraw at any time.

• I also understand that the research study is strictly confidential.

• I hereby agree to participate in this research study.

☐ Please tick the box if we can contact your partner or family who lives with you.

Who can we contact? Name:................................. Phone:.................................

Name (Please Print): ...........................................................................................................

Signature:............................................... Date: ....................................................

Name of Person who conducted informed consent discussion (Please Print):

.................................................................................................................................

Signature of Person who conducted informed consent discussion:

Signature:............................................... Date: .....................................................