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ORIGINAL RESEARCH: EMPIRICAL RESEARCH – QUANTITATIVE

Evaluation of the outcomes of care of nurse-led continence care clinics for Chinese patients with lower urinary tract symptoms, a 2-year prospective longitudinal study

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Abstract

Aim. The aim of this study was to evaluate the 24-month outcomes of a nurse-led continence care service for Chinese primary care patients with lower urinary tract symptoms.

Background. Most studies evaluating the outcomes of continence care services have had short follow-up durations with limited knowledge on whether benefits are sustained beyond 12 months.

Design. Twenty-four month cohort study.

Methods. Two comparison groups were recruited: (1) Patients with lower urinary tract symptoms attending a nurse-led community-based continence care programme; (2) Primary care patients with lower urinary tract symptoms identified by screening, receiving usual medical care. Self-reported symptom severity, health-related quality of life, patient enablement and general health perception were measured at baseline and 24 months. Data collection occurred from March 2013–August 2015.

Results. Baseline and 24-month data were available for 170 continence care and 158 usual care subjects. After controlling for baseline characteristics, the continence care group was observed to have greater reductions in symptom severity and larger improvements in disease-specific health-related quality of life, patient enablement and general health perception than the usual care group. Deterioration in the mental components of generic health-related quality of life was observed in the usual care group, but not in the continence care group.

Conclusion. Over 24 months, when compared with usual medical care, nurse-led continence care services were effective in reducing symptom severity and improving health-related quality of life, patient enablement and general health perception and provided protection against deterioration in the mental

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components of health-related quality of life in patients with lower urinary tract symptoms. 15

Keywords: health services research, nurse practitioners urology, outpatient clinics, primary care, quality of care

Why is this research or review needed?

- Nurse-led continence care services are known to be effective in improving clinical outcomes in patients with lower urinary tract symptoms, however, most studies to date have had relatively short follow-up durations with limited evidence available on whether the effects are sustained beyond 12 months.
- As lower urinary tract symptoms are often chronic, data supporting the sustained effectiveness of nurse-led continence care interventions can help inform health service delivery planning and help to justify resource allocation for these services.
- Evidence supporting the effectiveness of nurse-led models of care is needed to help promote the development of primary care nursing, especially in Asia, where such delivery models are relatively new.

What are the key findings?

- Community-based nurse-led continence care services were more effective than usual medical care in improving lower urinary tract symptom severity, health-related quality of life, patient enablement and general health perception and the benefits were sustained for 24 months.
- Over 24 months, a naturalistic deterioration in the mental components of health-related quality of life was observed in patients receiving usual care but not in those who had received continence care services. Nurse-led continence care interventions therefore appears to be able to help protect patients with lower urinary tract symptoms against a naturalistic deterioration in the mental components of health-related quality of life.
- Physical components of health-related quality of life worsened equally in both intervention and control groups.

How should the findings be used to influence policy/practice/research/education?

- Community-based nurse-led continence care services appear to be an effective delivery model for managing lower urinary tract symptoms in Chinese primary care patients. This model of care has the potential to reduce the demand for specialist services and the burden on primary care medical services.
- With local evidence to show that nurse-led services provide quality care and are effective, educational programmes promoting nurse-led primary care should be incorporated into both undergraduate and post graduate nursing curricula to increase the nursing capacity in this field, especially in Asian settings where this model of care is still new.
- The findings from this study confirmed the effectiveness of nurse-led interventions for patients with lower urinary tract symptoms. With population ageing and a predicted increase in prevalence of continence care problems in the community, a cost-effectiveness analysis of these services should be conducted to evaluate whether these services should be expanded to help improve the health of more individuals.

Introduction

Lower urinary tract symptoms (LUTS) are a leading cause of burden to health-related quality of life (HRQOL) (Choi *et al.* 2014a, 2015c) and mental health (Choi *et al.* 2015d). The global prevalence of LUTS was reported to be 45·2% in both males and females in 2008 (Irwin *et al.* 2011) and it is estimated that by 2018, 2·3 billion people worldwide will have LUTS (Irwin *et al.* 2011). Conservative interventions such as pelvic floor muscle exercise (Hay-Smith *et al.* 2001) and diet modification (Emberton 2006) offered by trained nurses (Shaw *et al.* 2000) have been shown to be effective in alleviating LUTS symptom severity and improving HRQOL. A systematic review has shown that community-based continence care services are effective in improving clinical outcomes (Du Moulin *et al.* 2005), however, most studies performed to date have had relatively short follow-up durations with little evidence

available on longitudinal outcomes beyond 12 months. Given that LUTS are often chronic, it is important to know whether continence care interventions can have a sustained effect. Interventions which have sustained benefits can reduce the burden on resources of the healthcare system as well as on patients themselves.

Background

Numerous therapeutic interventions including behavioural, pharmacological and surgical interventions exist for LUTS. Behavioural treatments as known as conservative treatments, such as pelvic floor muscle exercise, lifestyle modification, bladder training are recommended as the first line treatment for LUTS because they are not invasive and carry low risk of side effects (Sampselle 2003). Ample evidence is available to support the effectiveness of behavioural interventions in patients with LUTS (Milne 2004). For example, a Cochrane review recommended that pelvic floor muscle exercise should be the first line treatment for women with continence problems (Dumoulin & Hay-Smith 2008). However, it is suggested that the effect of pelvic floor muscle exercise might not be sustained (Glazener *et al.* 2001, Milne 2004). A review article suggested that bladder training is effective (Roe *et al.* 2007). However, its long-term effect is uncertain (Roe *et al.* 2007). Although evidence for the effectiveness of LUTS interventions has been well documented in previous studies, most trials have only examined the effects of a specific intervention such as pelvic floor muscle exercise under well-controlled conditions. In clinical practice however it is unusual for only a single intervention to be offered in isolation. Instead, most patients are offered a management plan which usually incorporates a package of separate interventions such as pelvic floor muscle exercise, diet modification and bladder training. Currently, there is little translational evidence to support their effectiveness in routine clinical practice.

To evaluate the quality of care and to establish evidence for the effectiveness of the programme, a 12-month prospective longitudinal study was initially conducted to compare the outcomes of patients who received treatment in the NAHC-CC programme, to patients with LUTS who received usual care from their primary care doctor. The programme was found to be effective in alleviating LUTS severity, improving HRQOL, enhancing patient enablement and general health perception in males and females compared with usual care (Choi *et al.* 2015a).

As evidence for the sustainability of the benefits was needed to inform service and resource planning, the original cohorts were followed up again at 24 months for reassessment of the study outcomes. The objective of this present study was to evaluate the outcomes of care of the NAHC-CC programme over 24 months.

Nurse-led continence care services in Hong Kong

In 2008, the Hong Kong government introduced new primary care initiatives as part of a large healthcare reform. One of these new initiatives was the introduction of nurse and allied health-led primary care clinics into public sector primary care clinics to help ease the demand on medical services. The Nurse and Allied Health Clinic Continence Care services (NAHC-CC) of the Hospital Authority (HA) of Hong Kong were the first government-funded community-based nurse-led primary care services for the treatment of urinary problems in Hong Kong. Details of the programme have been reported previously (Choi *et al.* 2015a).

Programme description

NAHC-CC programme services are delivered by continence care nurses who conduct assessments and provide protocol-driven treatments according to the patient's main urinary problems. Patients are either referred to the programme by their primary care doctor, or can refer themselves by telephoning the clinic to book an appointment. The charge for each NAHC-CC session is HKD $45 (~US $5·75), with the bulk of the costs subsidized by the Hong Kong government. Patients who are identified to have more serious urinary problems or who fail to improve with conservative nurse-lead treatments are referred to hospital-based specialist clinics for further medical assessment and treatment in secondary care.

NAHC-CC programme nurse assessment

Patients in the programme receive an initial assessment by a nurse trained in urology and continence care. The initial assessment consists of: history taking, physical examination and baseline investigations (including uroflowmetry, measurement of the strength of pelvic floor muscle and estimation of the post-void residual urine volume).

NAHC-CC programme interventions

NAHC-CC treatment interventions are protocol-based and include conservative treatments tailored to the needs of each patient and according to the type of LUTS. Interventions may include conservative treatments such as pelvic floor muscle exercise, urethral massage (for males), bladder training and diet modification (Choi *et al.* 2015a).

The study

Aim

The aim of this study was to evaluate the 24-month outcomes of a nurse-led continence care service for Chinese primary care patients with lower urinary tract symptoms.

Design

A 24-month prospective, longitudinal cohort study was conducted. The intervention sites were independent of the researcher undertaking the evaluation research and have been previously described (Choi *et al.* 2015a).

Participants

Two comparison patient groups were recruited:

Subjects enrolled in the NAHC-CC program (Intervention/ 'NAHC-CC' group)
All new patients with LUTS were recruited by consecutive sampling from the NAHC-CC appointments list and received nurse-led continence care (Choi *et al.* 2015a).

Subjects under usual medical care (Control/ 'usual care' group)
Primary care patients with LUTS were identified by screening and recruited by consecutive sampling from the waiting rooms of primary care clinics where no NAHC-CC services were offered and received usual care from their primary care doctor.

Exclusion criteria: <18 years; non-Chinese; received continence care services within the past one year for his/her LUTS (Choi *et al.* 2015a).

Data collection

Baseline data collection occurred from March–July 2013. The 24-month data collection occurred from March–August 2015.

Eligible subjects were approached and invited to join the study by field workers. The aims, objectives and study procedures were explained prior to obtaining written informed consent. Subjects were asked to provide their telephone number as part of the consenting process. Trained survey interviewers subsequently contacted the subjects to conduct telephone interviews. The study questionnaire was administered by the trained interviewers via telephone within 2 weeks of recruitment (baseline) and again at 24 months (follow-up) (Choi *et al.* 2015a). Telephone interviews were used to help to enhance response and data completion rates: it helps to reduce the amount of time a patient needs to stay at the doctor's clinic; it also removes the need for subjects or interviewers to travel; and interviews can be conducted outside of business hours when respondents are more available (Chin *et al.* 2015). Interviews were conducted between 10:00 and 22:30 on weekdays. A maximum of five attempts were made for made to contact the subject participants (Choi *et al.* 2015a).

Instruments

Five instruments were used:

1 LUTS severity was assessed using the International Prostate Symptom Score (IPSS);
2 LUTS-specific HRQOL was assessed using the IPSS and modified Incontinence Impact Questionnaire-Short Form (IIQ-7);
3 Generic HRQOL was assessed using the Short From-12 Health Survey Version 2 (SF-12 v2);
4 Patient enablement was assessed using the Patient Enablement Instrument (PEI);
5 The change in general health condition was measured using the Global Rating of Change Scale (GRS).

All interviews were conducted in Chinese and a validated Chinese version of all instruments was used for data collection.

International Prostate Symptom Score (IPSS)
The IPSS comprises seven questions. These include: (1) incomplete bladder emptying; (2) frequency of urination; (3) intermittency; (4) urgency; (5) weak urine stream; (6) straining and (7) nocturia and one question about LUTS-specific HRQOL. Respondents were asked to rate the severity of each symptom on a 6-point Likert scale. The scores for each symptom are combined to give a total symptom score ranging from 0-35. The higher the total score the more severe the LUTS. The answers to the single item HRQOL question range from 0-6 (0 = delighted; 1 = pleased; 2 = mostly satisfied; 3 = mixed; 4 = mostly dissatisfied; 5 = unhappy; 6 = terrible) (Barry *et al.* 1992). The IPSS is a valid, reliable, sensitive and responsive measure to assess Chinese males and females with LUTS (Choi *et al.* 2014c, 2015b).

Modified Incontinence Impact Questionnaire-Short Form (IIQ-7)
The modified IIQ-7 has seven questions to assess LUTS-specific HRQOL. These questions evaluate the negative

impacts of LUTS on: (1) physical activities; (2) household chores; (3) recreation; (4) travelling; (5) social activities; (6) emotional health and (7) the feeling of frustration. Respondents rate the negative impacts of LUTS on each aspect on a 4-point Likert scale. The scores for each item are combined to give a total score ranging from 0-21. The higher the total score, the more severe the HRQOL (Choi *et al.* 2014b). The IIQ-7 is a valid, reliable, sensitive and responsive measure to evaluate the HRQOL of Chinese males and females with LUTS (Choi *et al.* 2014b, 2015b).

The Short From-12 Health Survey Version 2 (SF-12 v2)

The SF-12 v2, which has twelve questions to assess generic HRQOL, has two summary scores, namely the physical (PCS) and mental component summary (MCS) scores. The theoretical range of the score is from 0-100. The higher the SF-12v2 PCS and MCS score, the better the HRQOL. The SF-12 v2 is a valid and reliable measure to evaluate generic HRQOL in the general population in Hong Kong (Lam *et al.* 2005, 2010a). The SF-12 v2 has been used previously to evaluate the HRQOL of Chinese patients with LUTS in Hong Kong (Choi *et al.* 2014a).

Patient Enablement Instrument (PEI)

The PEI comprises six question items to assess patient enablement. It is designed to measure the change in patient's perception after consultations in the following ways: (1) ability to copy with life; (2) ability to understand one's illness; (3) ability to cope with one's illness; (4) ability to keep oneself healthy; (5) confidence about one's health and (6) ability to help oneself (Howie *et al.* 1998). Respondents were asked to rate each item on a 3-point Likert scale (0 = the same or less; 1 = slightly improved/increased; 3 = greatly improved/increased) (Howie *et al.* 1998). The scores for each item can be summed to give a total score. Subjects with a total score ≥1 were considered to have been enabled while those with a total score = 0 were considered not to have been enabled. The psychometric properties of the instrument have been evaluated in the local setting and found to be valid (Lam *et al.* 2010b). This measure is commonly used to assess the quality of primary care consultations (Mercer *et al.* 2008, Lam *et al.* 2014).

Global Rating of Change Scale (GRS)

The GRS is a single retrospective item. Study subjects are asked to rate the change in their general health condition over a specified period. Respondents rate each item on a 5-point Likert scale (−2 worse, −1 a little bit worse, 0 no change, +1 a little bit better, +2 better) (Kamper *et al.* 2009). The GRS has good sensitivity in many studies in Hong Kong population (Wong *et al.* 2013, 2014). The GRS has been used to evaluate the quality of care in health services research (Lam *et al.* 2014).

In addition to the original GRS, an adapted GRS was used to assess the subject's perception of any change in his/her overall LUTS condition on a 5-point Likert scale (−2 worse, −1 a little bit worse, 0 no change, +1 a little bit better, +2 better). The IPSS and modified IIQ-7 and SF-12 v2 were administered at baseline and 24 months. The PEI, GRS was only administered at 24 months.

Sample size justification

In the 12-month study, a small effect size was found for the difference in mean change in the IPSS total symptom score. Based on this, a sample size of 170 subjects (nurse-led care) and 158 subjects (usual care) was calculated to be sufficient to detect a small effect size (0·2) difference with 80% power and 5% level of significance by independent *t*-test. The calculation was conducted by G*Power (Faul *et al.* 2007).

Ethical considerations

The study protocol was approved by the institutional review board of the University of Hong Kong and the Hospital Authority of Hong Kong. Written informed consent was received from all participants.

Data analysis

Descriptive statistics were used to analyse the baseline socio-demographics characteristics and differences in outcomes between baseline and 24 months. Paired *t*-tests were used to estimate the mean changes between baseline and 24 months. Independent *t*-tests were used to compare the mean changes between the NAHC-CC and usual care groups. Multiple linear mixed-effect regression models were used to obtain the adjusted estimations. The difference in PEI and GRS scores between the NAHC-CC and control groups were assessed using chi-square tests. Multiple logistic mixed-effect regression models were used to obtain the adjusted estimations. Subjects with missing data were excluded. All data were entered into STATA Version 13·0 (StataCorp LP, College Station, TX, USA) to conduct the statistical analyses.

Validity and reliability

To standardize the telephone interviews, all study instruments were read verbatim. All telephone interviews were

conducted by staff of the Social Sciences Research Centre of the University of Hong Kong, which are independent of the investigation team. The investigation team was an external party commissioned to evaluate the quality of care of the programme. Nurses who delivered the continence care services were not part of the investigation team. The statistician who performed the analyses was not involved in subject recruitment or in data collection. All data analyses were cross-checked by an independent statistician. All instruments used had been validated for use in the local setting (Lam *et al.* 2010b, Choi *et al.* 2014b,c, 2015b).

Results

Baseline subject characteristics

The subject recruitment flow chart is shown in Figure 1. At baseline, 720 subjects were recruited (360 in each group). Of these, 519 subjects (248 in the NAHC-CC group and 271 in the usual care group) completed telephone interviews at baseline and 328 subjects (170 in the NAHC-CC group and 158 in the usual care group) completed the 24-month interview. Baseline subject characteristics (socio-demographics, clinical and HRQOL characteristics), are shown in Table 1. Analysis by independent *t*-test found that subjects in the NAHC-CC group were slightly younger (intervention group: 60·54 years, SD 11·66; control group; 64·20 years, SD 9·97; $P < 0·01$). Analysis by chi-square test found that more subjects in the NAHC-CC group were in paid employment (intervention group: 43·15%; control group: 26·57%, $P < 0·01$). Analysis by chi-square testing found that there was no statistical significant difference in gender, marital status, household income, smoking status and drinking habit between the two groups. Analysis by independent *t*-test found that subjects in the NAHC-CC group had poorer LUTS-specific HRQOL as measured by the IPSS HRQOL question ($P < 0·01$) and the IIQ-7 ($P < 0·05$) at baseline than those in the usual care group. Analysis by independent *t*-test found no statistical significant difference in LUTS severity as measured by the IPSS total symptom score and generic HRQOL as measured by the SF-12 v2 PCS and MCS between the two groups at baseline.

LUTS severity and HRQOL

The results of the paired *t*-tests (between baseline and 24 months) and independent *t*-tests (between intervention and control groups) are shown in Table 2. In the NAHC-CC group, IPSS total symptom scores (mean difference between baseline and 24 months: 2·48, $P < 0·05$ by paired *t*-test), IPSS HRQOL scores (mean difference between baseline and 24 months: 1·05, $P < 0·05$ by paired *t*-test) and IIQ-7 scores (mean difference between baseline and 24 months: 1·58, $P < 0·05$ by paired *t*-test) were statistically significantly decreased between baseline and 24 months, suggesting that LUTS severity and LUTS-specific HRQOL improved over the 24-month period. In contrast, SF-12 PCS scores (mean difference between baseline and 24 months: 1·86, $P < 0·05$ by paired *t*-test) were statistically significantly decreased, suggesting a deterioration in the physical component of generic HRQOL over 24 months. Analysis by paired *t*-test found no statistically significant change in the SF-12 v2 MCS scores between baseline and 24 months.

In the usual care group, analysis by paired *t*-test found no statistically significant difference in IPSS total symptom scores between baseline and 24 months. A statistically significant decrease was observed in the IPSS HRQOL score (mean difference between baseline and 24 months: 0·33, $P < 0·05$ by paired *t*-test), suggesting that LUTS-specific HRQOL as measured by the IPSS improved over the 24-month period in the usual care group. Analysis by paired *t*-test found no statistically significant difference in IIQ-7 scores between baseline and 24 months. Both the SF-12 PCS (mean difference between baseline and 24 months: 1·75, $P < 0·05$ by paired *t*-test) and SF-12 MCS (mean difference between baseline and 24 months: 2·96, $P < 0·05$ by paired *t*-test) scores decreased statistically significantly in the control group, suggesting a deterioration in the physical and mental components of generic HRQOL had occurred over 24 months in the control group (usual care).

Results of the independent *t*-test found statistically significant differences in the mean change (between baseline and 24 months) between groups for IPSS total symptom (difference in mean change: 2·04, $P < 0·05$ by independent *t*-test), IPSS HRQOL (difference in mean change: 0·72, $P < 0·05$ by independent *t*-test), IIQ-7 (difference in mean change: 1·46, $P < 0·05$ by independent *t*-test) and SF-12 MCS (difference in mean change: 3·41, $P < 0·05$ by independent *t*-test) scores.

Results of the multiple linear mixed-effect regression models are shown in Table 3. The NAHC-CC group showed a greater reduction in LUTS severity as measured by the IPSS total symptom score ($\beta = -1·92$, $P < 0·01$ by multiple linear mixed-effect regression) and greater improvement in HRQOL as measured by the IIQ-7 ($\beta = -1·55$, $P < 0·01$ by multiple linear mixed-effect regression) and the IPSS HRQOL ($\beta = -0·67$, $P < 0·01$ by

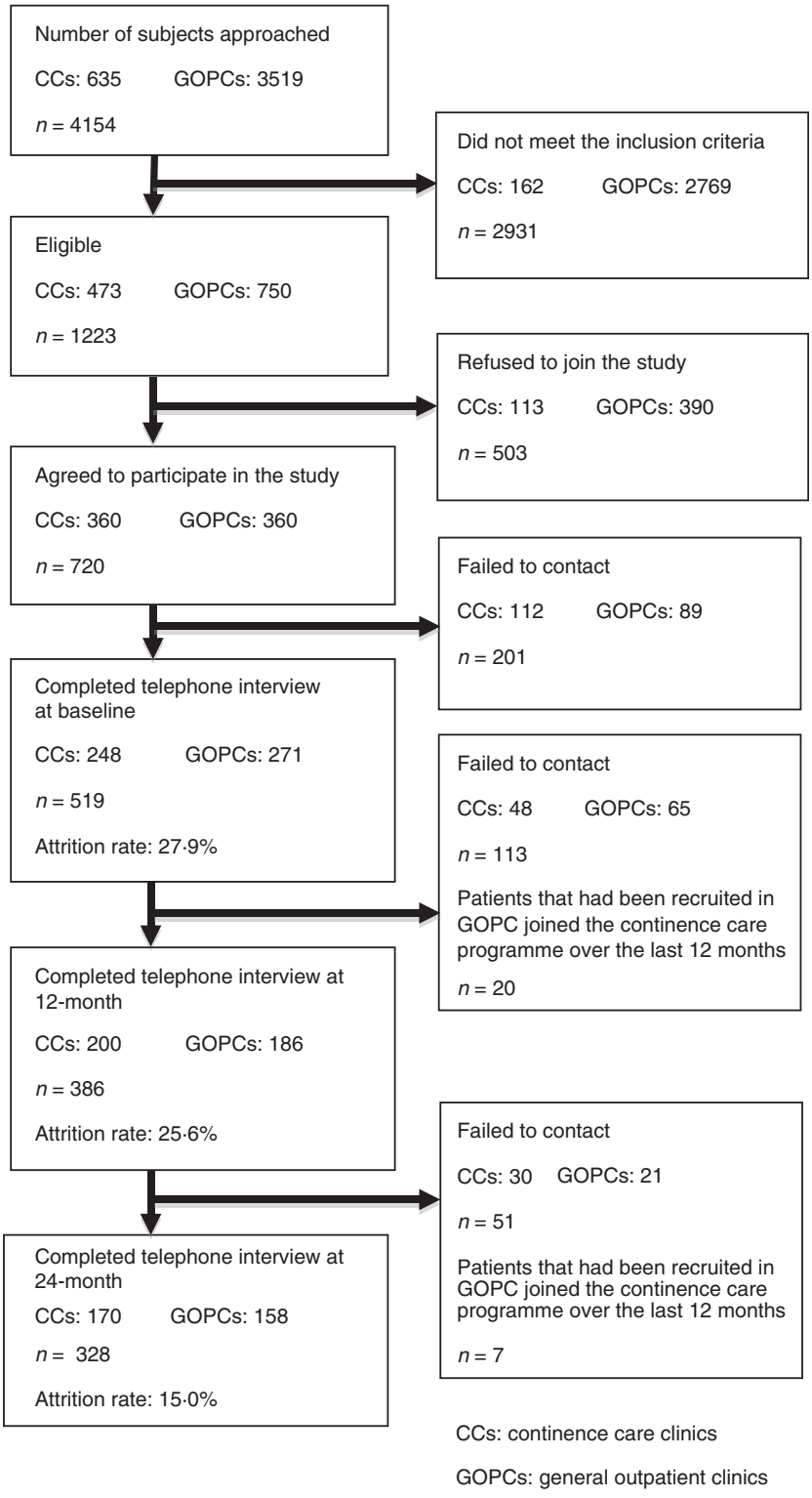

Figure 1 A total of 720 subjects (360 in each group) were recruited. Of these, 519 subjects (248 in intervention and 271 in control) completed telephone interviews at baseline and 328 subjects (170 in intervention and 158 in control) completed the 24-month interview.

Table 1 Baseline characteristics of the NAHC-CC participants and control subjects.

	Total (N = 519)	NAHC-CC participants (N = 248)	Control subjects (N = 271)	P value
Baseline socio-demographics				
Age mean (SD)	62·45 (10·95)	60·54 (11·66)	64·20 (9·97)	<0·001*
Age group, % (n)				
18-65 years	61·08% (317)	67·74% (168)	54·98% (149)	0·003†
>65 years	38·92% (202)	32·26% (80)	45·02% (122)	
Gender, % (n)				
Female	55·88% (290)	53·23% (132)	58·30% (158)	0·245
Male	44·12% (229)	46·77% (116)	41·70% (113)	
Marital status, % (n)				
Not married	23·51% (122)	22·98% (57)	23·99% (65)	0·788
Married	76·49% (397)	77·02% (191)	76·01% (206)	
Employment status, % (n)				
Not working	65·51% (340)	56·85% (141)	73·43% (199)	<0·001†
Working	34·49% (179)	43·15% (107)	26·57% (72)	
Household income, % (n)				
<$20,000	73·19% (333)	69·68% (154)	76·50% (179)	0·101
≥$20,000	26·81% (122)	30·32% (67)	23·50% (55)	
Smoking status, % (n)				
Non-smoker	96·96% (478)	97·89% (232)	96·09% (246)	0·246
Smoker	3·04% (15)	2·11% (5)	3·91% (10)	
Drinking status, % (n)				
Non-drinker	63·89% (315)	62·34% (149)	65·35% (166)	0·487
Drinker	36·11% (178)	37·66% (90)	34·65% (88)	
HRQOL and urinary symptoms mean (SD)				
SF-12 v2 PCS	45·97 (9·71)	46·17 (10·21)	45·79 (9·25)	0·656
SF-12 v2 MCS	51·76 (10·85)	51·47 (11·06)	52·03 (10·66)	0·556
IPSS Symptom Score (min 0-max 35)	11·12 (6·65)	11·62 (6·26)	10·67 (6·98)	0·105
IPSS Quality of Life Score (min 0-max 6)	3·30 (1·82)	3·78 (1·69)	2·86 (1·83)	<0·001*
IIQ-7 Score (min 0-max 21)	3·30 (4·08)	3·77 (4·24)	2·87 (3·89)	0·012*

*Significant at a level of 0·05 by independent t-test.
†Significant at a level of 0·05 by chi-square test.
NAHC-CC, nurse allied health clinic – continence care; PCS, physical component summary; MCS, mental component summary; IPSS, International Prostate Symptom Score; IIQ-7, Incontinence Impact Questionnaire – Short Form.

multiple linear mixed-effect regression) than the control group did. When compared with the usual care group, less deterioration was observed in the NAHC-CC group for the mental components of HRQOL as measured by the SF-12 v2 MCS (β = 3·85, $P < 0·05$ by multiple linear mixed-effect regression).

Patient enablement and global rating of change

Results of the PEI and GRS scores are shown in Table 2. Compared with the usual care group, more subjects in the NAHC-CC group were observed to have improved patient enablement (41·77% vs. 63·53%, $P < 0·05$ by chi-square test), improved general health condition (12·74% vs. 27·06%, $P < 0·05$ by chi-square test) and improved overall LUTS condition (42·60% vs. 14·65%, $P < 0·05$ by chi-square test).

The results of the multiple logistic mixed-effect regression models are shown in Table 3. The NAHC-CC group had a greater improvement in patient enablement (adjusted odds ratio (aOR): 2·05, $P < 0·01$ by multiple logistic mixed-effect regression), general health condition (aOR: 2·57, $P < 0·01$ by multiple logistic mixed-effect regression) and overall LUTS condition (aOR: 4·58, $P < 0·01$ by multiple logistic mixed-effect regression) respectively.

Discussion

We adopted Donabedian's taxonomy of 'structures', 'processes' and 'outcomes' (Kobayashi *et al.* 2011) which is one a commonly used framework in health services research to evaluate the quality of care of a healthcare programme (Fung *et al.* 2012, Chen *et al.* 2015) and to examine the outcomes of a community-based nurse-led continence care

Table 2 Comparison of outcomes between NAHC-CC participants and control subjects at baseline, 12 and 24 months.

	Baseline	12 months	24 months
SF-12v2 PCS Score			
NAHC-CC participants	46·17 (10·21) (*N* = 246)	NA	44·53 (10·59) (*N* = 169) Paired diff[§] = −1·86*
Control patients	45·79 (9·25) (*N* = 268)		43·62 (10·03) (*N* = 157) Paired diff[§] = −1·75*
Difference between groups	0·38		−0·11[¶]
SF-12v2 MCS Score			
NAHC-CC participants	51·47 (11·06) (*N* = 246)	NA	51·42 (11·67) (*N* = 169) Paired diff[§] = 0·46
Control patients	52·03 (10·66) (*N* = 268)		48·65 (11·71) (*N* = 157) Paired diff[§] = −2·96*
Difference between groups	−0·57		3·41[‡,¶]
IPSS Symptom Score			
NAHC-CC participants	11·62 (6·26) (*N* = 248)	8·66 (6·09) (*N* = 197) Paired diff[§] = −2·89*	9·32 (6·61) (*N* = 170) Paired diff[§] = −2·48*
Control patients	10·67 (6·98) (*N* = 271)	9·34 (7·44) (*N* = 186) Paired diff[§] = −1·15*	10·14 (7·30) (*N* = 152) Paired diff[§] = −0·44
Difference between groups	0·95	−1·74[‡,¶]	−2·04[‡,¶]
IPSS HRQOL Score			
NAHC-CC participants	3·78 (1·69) (*N* = 248)	2·71 (1·82) (*N* = 199) Paired diff[§] = −1·01*	2·84 (1·74) (*N* = 170) Paired diff[§] = −1·05*
Control patients	2·86 (1·83) (*N* = 271)	2·61 (1·75) (*N* = 186) Paired diff[§] = −0·33*	2·51 (1·67) (*N* = 158) Paired diff[§] = −0·33*
Difference between groups	0·93*	−0·68[‡,¶]	−0·72[‡,¶]
IIQ-7 Score			
NAHC-CC participants	3·77 (4·24) (*N* = 247)	2·45 (3·34) (*N* = 200) Paired diff[§] = −1·32*	2·29 (3·24) (*N* = 170) Paired diff[§] = −1·58*
Control patients	2·87 (3·89) (*N* = 271)	2·71 (3·69) (*N* = 186) Paired diff[§] = −0·29	2·87 (4·15) (*N* = 158) Paired diff[§] = −0·12
Difference between groups	0·90*	−1·03[‡,¶]	−1·46[‡,¶]
PEI Score >0			
NAHC-CC participants	NA	66·83% (*N* = 199)	63·53% (*N* = 170)
Control patients		43·48% (*N* = 184)	41·77% (*N* = 158)
Difference between groups		23·36%[†]	21·76%[†]
GRS (general health) >0			
NAHC-CC participants	NA	41·50% (*N* = 200)	27·06% (*N* = 170)
Control patients		17·74% (*N* = 186)	12·74% (*N* = 157)
Difference between groups		23·76%[†]	14·32%[†]
GRS (LUTS) >0			
NAHC-CC participants	NA	NA	42·60% (*N* = 169)
Control patients			14·65% (*N* = 157)
Difference between groups			27·95%[†]

SF-12 v2 and GRS (LUTS) were not available at 12 month.

*Significant at a level of 0·05 by paired *t*-test.

[†]Significant at a level of 0·05 by chi-square test.

[‡]Significant at a level of 0·05 by independent *t*-test.

[§]Paired difference between baseline and 12/24 months among subjects with paired data.

[¶]Difference in difference from baseline between groups.

NAHC-CC, nurse allied health clinic – continence care; PCS, physical component summary; MCS, mental component summary; IPSS, International Prostate Symptom Score; HRQOL, health-related quality of life; IIQ-7, Incontinence Impact Questionnaire – Short Form; PEI, patient enablement instrument; GRS, Global Rating Scale; LUTS, lower urinary tract symptoms; NA, not applicable.

Table 3 Changes in the clinical characteristics at 12 and 24 months by multivariable mixed effects regression analysis.

	NAHC-CC patients†					
	(1) At 12 months			(2) At 24 months		
Multivariable mixed effects regressions	Coef./OR	95% CI	*P* value	Coef./OR	95% CI	*P* value
Multiple linear mixed effects regressions						
Change‡ in PCS	NA			0·37	(−1·37, 2·11)	0·68
Change‡ in MCS	NA			3·84*	(1·87, 5·82)	<0·01
Change‡ in IPSS Symptom Score	−1·42*	(−2·51, −0·33)	<0·05	−1·92*	(−3·073, −0·76)	<0·01
Change‡ in IPSS HRQOL Score	−0·63*	(−0·97, −0·29)	<0·01	−0·67*	(−1·034, −0·32)	<0·01
Change‡ in IIQ-7 Score	−1·21*	(−1·87, −0·55)	<0·01	−1·55*	(−2·241, −0·86)	<0·01
Multiple logistic mixed effects regressions						
PEI >0	4·14	(0·049, 350·31)	0·53	2·05*	(1·23, 3·41)	<0·01
GRS (general) >0	3·52*	(2·02, 6·12)	<0·01	2·57*	(1·31, 5·05)	<0·01
GRS (LUTS) >0	NA			4·58*	(2·48, 8·45)	<0·01

SF-12 v2 and GRS (LUTS) were not available at 12 month.

†Control patients are the reference level for the comparison between groups.

‡Change in scores means (1) 12-month – baseline; or (2) 24-month – baseline.

NAHC-CC, nurse allied health clinic – continence care; PCS, physical component summary; MCS, mental component summary; IPSS, International Prostate Symptom Score; HRQOL, health-related quality of life; IIQ-7, Incontinence Impact Questionnaire – Short Form; PEI, patient enablement instrument; GRS, Global Rating Scale; LUTS, lower urinary tract symptoms; NA, not applicable.

programme. From previous studies on nurse-led models of care, it is already known that nurses can provide primary care and achieve excellent outcomes of care, including patient satisfaction, health status and hospitalization rates (Roe *et al.* 2000, Donald & McCurdy 2002, Chin *et al.* 2011, Stanik-Hutt *et al.* 2013). However, most of these studies have been conducted in western healthcare settings where this model of care has already been well adopted. Nurse and allied health led primary care service delivery has only recently been adopted in Asia and there is currently little data to provide evidence for the effectiveness this model of care in Asian healthcare settings. This was the first study to evaluate the long-term effects of a community-based nurse-led continence care programme on Chinese male and female patients with LUTS in Hong Kong. The findings of the study supplements our earlier work which evaluated the effectiveness of the programme over 12 months (Choi *et al.* 2015a). Our findings helps to strengthen the evidence to support the effectiveness and sustainability of community-based nursed led care in improving LUTS severity, HRQOL, general health perception and patient enablement over two years.

Similar to the findings of our original 12-month study and other studies performed in the UK, (Roe *et al.* 2000, Choi *et al.* 2015a) recipients of nurse-led continence care services showed a greater reduction in LUTS severity as measured by the IPSS, greater improvements in HRQOL as measured by the IIQ-7, better patient enablement as measured by the PEI and better general health perception as measured by the GRS than the usual care group at 24 months, even after controlling for socio-demographics and baseline scores.

Similar to a previous study evaluating the effectiveness of self-management interventions for Chinese patients with benign prostate hyperplasia (Chen *et al.* 2012), we also found that the IPSS total symptom score improved in the intervention group. However, the effect size in this study (0·36) was smaller than that of the previous study (1·47) (Chen *et al.* 2012). The modest effect observed may have been due to the milder range of LUTS severity in our primary care sample (11·8 points out of 35 points) and relatively smaller scope for improvement as evidenced by the higher baseline IPSS total symptom scores in the study by Chen *et al.* (2012) (20·52 points of 35 point).

It was observed that subjects in the NAHC-CC (intervention) group had more improvement in the IIQ-7 than the usual care (control) group. The study by Chen *et al.* (2012) also found that compared with controls, people enrolled in the intervention group had better improvements in HRQOL as measured by a short-form benign prostatic hypertrophy HRQOL questionnaire. Another study by Castro *et al.* (2008) reported that women who underwent pelvic floor muscle exercise had more improvement in HRQOL as measure by Urinary Incontinence Quality of Life Scale (I-QOL) than the control group. Our subjects also completed the SF-12v2, a generic HRQOL measure, at the 24-month time point to assess for changes in generic HRQOL because earlier studies had found that LUTS patients have poorer

generic HRQOL than the general population (Choi *et al.* 2014a) and people without incontinence (Roe & Doll 2000). While no significant change was observed in the SF-12 MCS scores between baseline and 24 months in the NAHC-CC group, scores were observed to deteriorate significantly in the usual care group. This suggests that the NAHC-CC programme may have a protective effect which helps to prevent or delay a naturalistic deterioration in the mental components of HRQOL in individuals with LUTS. It was observed that the physical components scores of the SF-12v2 deteriorated in both groups although the effect sizes were small (0·16 in the intervention group and 0·22 in the control group). There were at least two possible explanations. First, this deterioration may have been a result of the normal ageing process (Spirduso *et al.* 1995). Second, the SF-12 v2 is a generic HRQOL measure (Wong *et al.* 2013). It might not be sensitive and responsive enough to capture the impacts of LUTS interventions on the physical aspects of HRQOL. In the literature, it appears that only a few trials have used a generic HRQOL instrument to measure outcomes and the results have been conflicting. A trial of pelvic floor muscle exercise among women reported no difference in HRQOL as measured by a generic HRQOL instrument between intervention group and control group (Dumoulin & Hay-Smith 2010). Conversely, a study on males who received transurethral prostate surgery found that compared with controls, males who received sessions on pelvic floor muscle exercises had better SF-36 HRQOL scores (Hou *et al.* 2013). It should be noted that sample sizes for both studies were very small with only 55 subjects in the study by Dumoulin and Hay-Smith (2010) and 61 subjects in the study by Hou *et al.* (2013).

The IPSS HRQOL scores improved statistically significantly in both groups but the effect sizes were larger in the NAHC-CC group than in the usual care group. There were some possible explanations. First, even without specific LUTS interventions, patients can naturalistically improve due to coping and adjustment. Second, subjects in the usual care group received their usual medical care from their primary care doctor. It is possible that their doctors may have provided advice or medical care for their LUTS problems, resulting in some improvement. Third, the positive change captured by the IPSS HRQOL in the control group might be due to 'noise'. A previous study found the IPSS HRQOL item was very internally and externally responsive (Choi *et al.* 2015b).

Subjects in the NAHC-CC group reported that they were more able to cope with their illness and more confident about their health. As the treatments provided by the NAHC-CC nurses are conservative and aimed at improving self-management, it appears that subjects receiving these interventions are able to gain a better sense of control, leading to improved enablement (Clarke & Bennett 2013). This better enablement may have been a reason for the sustained improvements in HRQOL observed in the intervention group.

More subjects in the NAHC-CC group reported an improvement in their overall LUTS than those in the usual care group with the adjusted odds ratio (4·66). Previous clinical trials examining the effectiveness of pelvic floor muscle exercises in women have reported similar findings, however, the estimated size of treatment effects have varied widely. One study found that women in the intervention group were about 2·5 times more likely to report improvement than those in the control group, while another study found that women in the intervention group were 17 times more likely to report improvement in their incontinence problems (Dumoulin & Hay-Smith 2010). It is difficult to directly compare our findings with previous studies due to differences in research methodology, population and interventions.

Study implications

This was the first study to provide evidence to support the beneficial effects of community based nurse-led continence service for Chinese males and females with LUTS over 24 months. This study helps to translate evidence from previous randomized controlled trails into real clinical practice. Based on the findings of this study, we recommend that nurse-led continence care services should be offered in primary care settings to enhance the health of individuals with LUTS. This is particularly important where access to secondary care services is limited or not available.

According to the Third Global Forum on Human Resources for Health Report of the World Health organization, nurses are still being under-used in many settings (World Health Organisation, 2013). Nurse-led models of care remain uncommon in many settings, especially outside the West. Given that the outcomes of nurse-led services have been shown to be comparable or better than usual care provided by primary care doctors, nurse-led services should be expanded to help alleviate the increasing burden on the healthcare system due to the increased need for healthcare services associated with the rising prevalence of chronic diseases, coupled with predicted future physician shortages.

Limitations

First, this was an observational study and not a randomised controlled trial which would be the gold standard for

evaluation of effectiveness. There may be unknown confounders which have biased our results and randomized control trials are needed to strengthen the external validity of our findings. One advantage of our design is that the study was conducted in a pragmatic primary care setting, which may be able to provide better translational evidence. Second, all outcome measures were patient-reported which is prone to recall bias. Since we were not able to conduct chart reviews, clinical parameters and aetiology of LUTS of each patient could not be retrieved. Third, our study was conducted in the public-sector primary care setting where the LUTS of patients may be less severe than those in secondary care. Our findings might not be applicable to Chinese patients with more severe LUTS. Fourth, this current study focussed specifically on patient-reported outcomes. Future studies are needed to explore other outcomes of nurse-lead continence care interventions such as health service use and medication use and to conduct a cost effectiveness analysis to help better inform service planning and resource allocation.

Conclusions

This 24-month longitudinal observational study found that a structured community-based nurse-led continence care programme was effective in alleviating symptoms and improving HRQOL, patient enablement and general health perception and helpful in protecting patients against a naturalistic deterioration in the mental components of health-related quality of life in Chinese primary care patients with LUTS. Unlike randomized control trials, this evaluation study was conducted in a pragmatic primary care setting, which may be able to provide better translational evidence. Our findings support the implementation of nurse-led care as a service delivery model for primary care patients with LUTS. Particularly in settings where the number of doctors or where access to secondary care services is limited, this model of care can help to improve the health of patients with LUTS, without excessively burdening the healthcare system. For future studies, cost-effectiveness analyses need to be conducted to examine the resource implications and to assess the feasibility of scaling up this service to facilitate a wider delivery of community-based nurse-led continence care services to all regions of Hong Kong.

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Conflict of interest

No conflict of interest has been declared by the authors.

Author contributions

All authors have agreed on the final version and meet at least one of the following criteria [recommended by the ICMJE (http://www.icmje.org/recommendations/)]:

- substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
- drafting the article or revising it critically for important intellectual content.

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