FACTORS RELATED TO QUALITY OF LIFE AMONG PERSONS WITH BENIGN PROSTATIC HYPERPLASIA IN WENZHOU, CHINA

CHUN MEI LI

A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF
THE REQUIREMENTS FOR MASTER DEGREE OF NURSING SCIENCE
(INTERNATIONAL PROGRAM)
IN ADULT NURSING PATHWAY
FACULTY OF NURSING
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2024

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วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรพยาบาลศาสตรมหาบัณฑิต (หลักสูตรนานาชาติ)

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ลิขสิทธิ์เป็นของมหาวิทยาลัยบูรพา

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CHUN MEI LI : FACTORS RELATED TO QUALITY OF LIFE AMONG PERSONS WITH BENIGN PROSTATIC HYPERPLASIA IN WENZHOU, CHINA. ADVISORY COMMITTEE: NIPHAWAN SAMARTKIT, Ph.D. CHUTIMA CHANTAMIT-O-PAS, Ph.D. 2024.

Benign Prostatic Hyperplasia (BPH) is a common chronic disease that affects the male quality of life. The aim of this research was to describe quality of life (QOL), and examine its relationship with severity of lower urinary tract symptoms (LUTS), sleep disturbance, depression, and social support, among the persons with BPH in Wenzhou, China. Simple random sampling technique was used to recruit 100 persons with BPH, who came to follow up their health at the Urological clinic outpatient department of the Second affiliated hospital of Wenzhou Medical University in Wenzhou, China. Research instruments included demographic data questionnaire, International Prostate Symptoms Score, Verran and Snyder–Halpern Sleep, Geriatric Depression Scale-15, Social Support Rating Scale, Revised version of Quality of Life Scale for Benign Prostatic Hyperplasia Patient, yielded Cronbach alpha of .89, .92, .79, .88, and .94. Data was analyzed by descriptive statistics and Pearson correlation.

The results of this study showed that the mean score of QOL BPH person was 102.2 (SD = 12.9) out of 160. There was significant positive relationship between social support and QOL among persons with BPH ($r = .485$, $p < .001$). There was negative relationship between severity of LUTS ($r = -. 736$, $p < .001$), sleep disturbance ($r = -.553$, $p < .001$), depression ($r = -.670$, $p < .001$) with QOL among persons with BPH.

The findings in this study could nurses and other health care providers have better understanding towards QOL of BPH persons in Wenzhou, China. Moreover, this research results are useful for development of effective interventions to reduce depression, sleep disturbances, LUTS, and increase social support, then improve QOL of BPH persons.

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Chun mei Li

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CHAPTER 1
INTRODUCTION

Background and significance of the study

Benign prostatic hyperplasia (BPH) is one of the most common diseases of the urinary system. It is a chronic disease mainly occurring in elderly men. According to the advent of an aging society, the number of older male with BPH is increasing year by year, and in the United States, over 15 million men have diagnosis of BPH (Egan, 2016). As reported by Chinese epidemiological statistics, the prevalence for BPH rate of men age <60 is 45%, age 61-70 is 70%, and that of men age 81-90 is 90% (Xiong et al, 2020). BPH has become one of the major chronic diseases that harm the health of older men. It seriously affects the QOL of the older male (Park et al, 2020).

The International Association of Urology has indicated that some patients with BPH have no serious complications, and the main purpose of these patients is to relieve the symptoms of the disease and further improve the QOL(Erkoc, Otunctemur, Besiroglu, & Altunrende, 2018) .The guidelines of the European Society of Urology also indicate that the treatment of patients with BPH should first consider whether the treatment improves the patient's QOL (Tanguay et al, 2009). Although BPH is not life-threatening, however it poses a serious threat to the QOL of patients. Long-term low QOL not only reduces the happiness of person with BPH and their family members, but also is not conducive to promoting the development of healthy aging of the elderly male in China (Alcaraz et al, 2016).

QOL is a term to comprehensively evaluate the quality of human life. The World Health Organization (WHO) defines the QOL as the living experience of people in different cultural value systems towards their goals, expectations, standards, and things they care about, including physical, psychological, social functions and material states. Domestic surveys have found that among the chronic diseases affecting the QOL of elderly male, the prevalence rate of BPH is ranked the first approximately 74.33%, which is more than high blood pressure (56.41%), diabetes (19.02%) and other diseases (Yang & Yongxue, 2015; Ma et al, 2015). Therefore,

BPH has become the primary chronic disease endangering the QOL of elderly male. Some literature has been reported that the QOL among BPH person is medium or low (Pan Yue, Sun Mengyuan, Ma Qinghan, & Kun., 2020; Fan, 2022).

BPH is a progressive disease, with the development of a bladder obstruction caused by hypertrophy of prostatic gland. These groups of patients with meaningful obstruction and moderate symptoms should be living with the clinical manifestations of BPH. About 60% of the patients with low-stage disease was affected by BPH symptoms (Wang & Foo, 2010). Although, transurethral resection of the prostate (TURP) and Holmium laser nucleation of the prostate operation method in the clinical treatment of prostate hyperplasia can quickly resolve urinary tract symptoms. However, these treatments will consider for BPH patients in stage 4, who had complications caused by BPH, such as urinary retention, bladder stone formation, and recurrent urinary tract infections. Thus, there are a large amount of BPH persons that waiting for the treatment process of TURP, moreover living and coping with lower urinary tract symptoms (LUTS). So, the main purpose of caring for BPH persons in stage 2-4, before receiving operation, are to relieve LUTS and further improve the QOL (Koh et al, 2015).

BPH is the most common cause of LUTS in elderly male, and about 25% of men with age over 50 years have moderate to severe LUTS, which increases with age. In addition, the prevalence of LUTS was high among those age 40-59 years (47.7%), 60-79 years (80.5%), and ≥ 80 years (91.2%) (Kim, Kim, Kim, Yoo, & Jeong, 2019). LUTS caused by BPH, showed a serious impact on patients' QOL (Calogero, Burgio, Condorelli, Cannarella, & La Vignera, 2019a). The prevalence of LUTS is expected to grow sharply in the coming decades, as Litman and McKinlay (2007) have predicted that 52 million adults will have LUTS by 2025. Approximately 50% of men with a histological diagnosis of BPH have moderate or severe LUTS (Erkoc et al, 2018).

LUTS refer to various abnormal manifestations in the urination cycle caused by changes in the structure and function of the lower urinary tract, including symptoms during storage, urination, after urination and other abnormal symptoms. According to the definition of LUTS from the International Continence Society (ICS), LUTS is a term that includes symptoms which are symptoms in the urine storage

phase include frequent urination, urgent urination, increased nocturia and urgent incontinence; urination include dysuria, urination dripping, urination waiting, urinary tract thinning and interruption of urination; and symptoms after urination refer to insufficient urination and post urination dripping (Wein, 2020).

****LUTS caused by BPH not only affect the urinary system function of the men, but also cause the irregular daily life of the men (Van Asseldonk, Barkin, & Elterman, 2015). Moreover, BPH with LUTS affects their sex life, their social behavior, and their physical and mental health (Koh et al, 2015). Frequent nocturnal urination also leads to decreased sleep quality in the elder and affects the sleep quality of their companions and increases the incidence of nocturnal falls in the BPH person. Because of frequent urination, some patients refuse to travel, or attend a meeting or watching a movie, etc. Difficulties in urinating lead to discomfort, pain and, more seriously urinary tract infections, etc., frequent toilet visits, urination pain, dysuria and other LUTS seriously affect the QOL of BPH persons (Kaplan, 2017).

Urination at night leads to the decline of sleep quality, and sleep disturbance can erode the QOL of BPH sufferers (Hanson & Huecker, 2020). Being not fully awake at night increase the incidence of falls during nighttime urination, resulting in trauma and fractures (Leslie, Sajjad, & Singh, 2022). Recurrence of lower urinary tract symptoms and related problems such as sleep disturbance, infection and sexual dysfunction can seriously affect the mental health of elderly men with BPH. Data show that the risk of falls increases to 10-21% for those who urinate more than twice at night (Leslie et al, 2020). More importantly, having more than three nocturnal urination episodes was associated with a significantly higher risk of death over 54 months of follow-up, which may be associated with heart disease or autonomic nervous dysfunction (Asplund, 2004). Thus, the quality of sleep probably has a strongly significant relationship to QOL.

Gao Tian et al (2014) investigated and analyzed the sleep efficiency and health status of 1,500 males age between 50 and 98 years and found that the worse sleep efficiency contributes to worse general health and decreased QOL ($P < .01$). Sleep studies show that sleep disturbance was closely related to poor QOL, and suggested that sleep disturbance was an independent risk factor affecting QOL (Lucena et al, 2020).

The survey found that the severity and incidence of anxiety and depression in BPH patients were higher than that in the general population (Kaplan, 2012). Moreover, the high severity of the lower urinary tract symptoms in BPH patients increases the degree of anxiety and depression (Rom, Schatzl, Swietek, Rücklinger, & Kratzik, 2017). The ability to perform daily tasks decreases with age, and the effect of negative depressive symptoms becomes more pronounced over time, leading to a decline in the QOL of a person with BPH. At the same time, high medical costs can also lead to anxiety, and the economic cost to society of BPH/LUTS has been estimated to be in the billions of dollars which, in turn, erodes a patient's QOL (Vuichoud & Loughlin, 2015). BPH person with depression have poor QOL (Sivertsen, Bjørkløf, Engedal, Selbæk, & Helvik, 2015).

Human beings are social, so the relationship of social support with individual well-being cannot be ignored. Among the factors related to the QOL, social support has a pronounced effect on QOL. A high level of social support is conductive to QOL (ZHENG Yan, 2015). A person with BPH with low social support tends to have worse QOL (Abdul Mutalip et al, 2020). Social support can provide a certain sense of security to cope with stress, reduce negative emotions, reduce the pain of disease in both spiritual and material aspects, and enhance confidence to face one's illness, which is a positive external protective factor. The lack of timely, accurate and long-term psychological support and nursing for patients with BPH and their families leads to strong stigma, poor compliance, and weakened treatment effects, resulting in delayed improvement of the patient's condition, poor social adaptability, and decreased QOL (Liu, 2020).

From the literature review, LUTS, sleep disturbance, depression, and social support are correlated with QOL among persons with BPH. However, there are few specific studies on the QOL of BPH patients and its related factors in China, especially in Wenzhou, where no relevant literature has been reported. Thus, health care providers in Wenzhou may lack basic understanding of QOL of the BPH sufferer and its related factors. Based on Symptom Management Theory, this study explored the relationship between LUTS, sleep disturbance, depression, and social support with QOL of persons with BPH. This research results should provide useful information for health care providers in Wenzhou to develop nursing interventions to care for

BPH patients, to support and guide them to effectively carry out disease management to improve health outcomes and their QOL.

Research objectives

1. To describe QOL among persons with BPH in Wenzhou, China.
2. To determine the relationship between severities of LUTS, sleep disturbance, depression and social support with QOL among persons with BPH in Wenzhou, China.

Research hypothesis

1. There is a negative correlation between severity of LUTS and QOL among persons with BPH in Wenzhou area
2. There is a negative correlation between sleep disturbance and QOL among persons with BPH in Wenzhou area
3. There is a negative correlation between depression and QOL among persons with BPH in Wenzhou area
4. There is a positive correlation between social support and QOL among persons with BPH in Wenzhou area

Scope of the study

The purpose of this study was to investigate QOL and to determine the relationships between the severity of lower urinary tract symptoms, sleep disturbance, depression, and social support with QOL in BPH persons. Data was collected from the Urology Clinic Department of the Second Affiliated Hospital of Wenzhou Medical University, from June to July 2022.

Research framework

Symptom Management Theory (SMT) describes symptom management as a multidimensional process. Symptom management consists of three factors that influence each other: symptom experience, symptom management strategy, and outcomes. In the 2019 revised version, the four elements covered by nursing were added to it, namely: person, environment, health, and disease (K. T. Hickey, 2019).

Dodd (2001) included possible influencing factors in the symptom management program, namely, the core concepts of nursing: person, environment, health, and disease. ‘Person’ is the inherent variable that affects the perception and response of the individual to symptom experience, including demographic characteristics, physiological, psychological, sociological, and developmental variables. Health/illness is the variable that contains three individual specific health or illness states, namely, risk factors, health state, disease, and injury. Environment is the physical, cultural, and social environment of symptom occurrence, and the physical variables include family, work or hospital environment, while social variables include interpersonal relationships or social support resources, and cultural variables include values, beliefs and other attributes related to race and belief. Person, environment, and health/illness will directly or indirectly affect symptom experience, symptom management strategies, and QOL outcomes (Dodd et al, 2001). When factors related to symptom management are identified, effective intervention can be taken to improve a patient’s QOL.

According to SMT and the related literature, lower urinary tract symptoms (LUTS), sleep disturbance, and depressive symptom are common symptoms perceived to be experienced by the BPH sufferer. Symptom experience consists of three dimensions: perception, evaluation, and response (Feng Fangming & Jianhua., 2012). Symptom perception refers to the patient's cognition of symptoms, symptom evaluation refers to the patient's evaluation of the cause and severity of symptoms, as well as the evaluation of symptoms on mood and life. Symptom response refers to the patient's physiological, psychological, social, and other behavioral reactions caused by symptoms. This can often lead to the enhancement of the body's perception of symptoms, such as the increased dependence on family and society. The patient's perception of LUTS, such as frequent urination, urgent urination, painful urination, increased nocturnal urination, etc., sleep disturbance, and depressive symptom are often reported by persons with LUTS. Social support is in the environment domain, and was selected to examine the relationship with QOL of the person with BPH. SMT has the advantage of being comprehensive, multidimensional, measurable, dynamic, and emphasizes that all objects, including patients themselves and their environment

need to be managed. The relationships between the variables in this study are described in Figure 1.

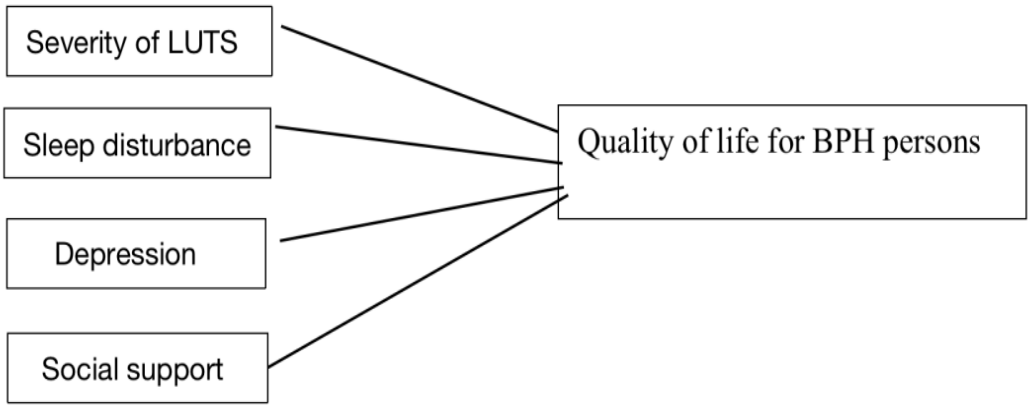

Figure 1 Conceptual Framework

Operation definition

In this study, 'BPH person' refers to a person with benign prostatic hyperplasia (BPH), who was treated and came for follow-up of their condition in the Urology Outpatient Department (OPD) of the Second Affiliated Hospital of Wenzhou Medical University in Wenzhou, China.

'Lower urinary tract symptoms' refer to the severity of various abnormal manifestations in the urination cycle caused by changes in the structure and function of the lower urinary tract, including symptoms during storage, urination, after urination, and other abnormal symptoms perceived by the BPH person. The Chinese version of the International Prostate Symptoms Score (IPSS) (Szeto, 2008) was used to quantify severity of lower urinary tract symptoms in BPH persons.

'Sleep disturbance' refers to disorders of initiating and maintaining sleep, disorders of excessive somnolence, disorders of sleep–wake schedule, and dysfunction associated with sleep or sleep stages as perceived by the person with BPH. The Chinese version of the Verran and Snyder – Halpern Sleep Scale (VSH) (Lin & Tsai, 2003) was used to measure sleep disturbance.

'Depression' refers to a mood disorder that causes a persistent feeling of sadness and loss of interest that affects how the BPH person feels, thinks, and behaves, and can lead to a variety of emotional and physical problems. The Chinese

version of the Geriatric Depression Scale-15 (GDS-15) (MeiJinRong, 1999) was used to measure depression of the BPH persons in this study.

'Social support' refers to the perception of the BPH person for receiving instrumental, informational, and/or emotional support from family, friends and significant others. In this study social support was measured by the Social Support Rating Scale (SSRS) compiled by Xiao (1994).

'Quality of life' (QOL) is defined as the BPH person's perception of their state of health, comfort, and ability to participate in, or enjoy life events in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns including physical, psychological, social functions, and material states. In this study, the revised version of the QOL Scale for Benign Prostatic Hyperplasia Patients (BPHQLS) (Guo et al, 2008) was used to measure the QOL of the BPH person.

CHAPTER 2
LITERATURE REVIEW

This chapter summarizes the literature on BPH, QOL of persons with BPH, SMT, and the factors related to QOL of the BPH person,

Benign prostatic hyperplasia

Benign prostatic hyperplasia (BPH) is one of the most common benign diseases causing dysuria in middle-aged and older men (Langan, 2019). BPH is a common condition in aging men that is frequently associated with troublesome LUTS (Langan, 2019). Compared with 1990, the incidence of BPH had increased 106% by 2019. BPH and subsequent LUTS are a very frequent pathology in Europe. Global predictions are that, by 2018, nearly 1.6 billion people will suffer from the symptoms of urine storage, and over 540 million people will suffer from symptoms of overactive bladder (Babic et al, 2015). In the USA, over 15 million men have received a diagnosis of BPH (Egan, 2016). As reported by Chinese epidemiological statistics, the prevalence of BPH of men age <60 is 45%, age 61-70 is 70%, and age 81-90 is 90% (Xiong et al, 2020). BPH contributed to the largest increase (110%) in disability-adjusted life-years in the past three decades (C. Zhu et al, 2021). China had the largest number of new BPH cases (2.8 million) in 2019 of any country in the world (Xu et al, 2021).

Definition of BPH

Clinical BPH can be defined as prostate adenoma causing a varying degree of bladder outlet obstruction (BOO), with or without symptoms. Clinical BPH can be diagnosed with non-invasive ultrasound in the clinic, grading it according to the shape intravesical prostatic protrusion (IPP) and size of the prostate (Foo, 2019). Studies have shown that obstruction depends more on the site than size of the adenoma (Luo, Foo, Kuo, & Tan, 2013). When the voiding function is affected, persistent post-void residual urine of more than 100 ml is observed, whereas when the storage function is affected, the maximum voided volume is low, i.e., less than 100 ml (Singapore

Urological Association Clinical Guidelines for Male Lower Urinary Tract Symptoms/Benign Prostatic Hyperplasia, 2017). Both parameters can be easily measured in the clinic. Obstruction is considered as significant when the above dysfunctions are present. The severity of the symptoms can be assessed with the International Prostate Symptoms Score (IPSS) and the QOL index (Foo, 2017).

The diagnosis of BPH should be based on clinical manifestations, physical signs, and laboratory examination. The diagnosis of typical BPH: progressive dysuria, initially with frequent urination, especially increased frequency at night, enlarged prostate on digital anal examination, increased residual urine, and maximum urinary flow rate decreased (Mobley, Feibus, & Baum, 2015).

Etiology

The development of BPH must be accompanied by the progression of aging and the functioning of testis. At the histological level, the incidence of BPH increases with age. Studies have found that the initial diagnosis of BPH usually occurs after the age of 40 years; the incidence of BPH rises to more than 50% once the age of 60 is reached. At the age of 80, the incidence of BPH increases to 83% (qun, 2014). With increasing age of BPH patients, symptoms such as dysuria will also appear and increase. However, the specific mechanism of BPH is still not clear. BPH may be caused by the disruption of the balance of epithelial and mesenchymal cell proliferation and apoptosis. The related factors of BPH include androgen and its interaction with estrogen, interstitial glandular epithelial cell interaction of prostate, growth factors, inflammatory cells, neurotransmitters, and genetic factors (Aaron, Franco, & Hayward, 2016).

Pathophysiology

Androgen receptors, 5 α -reductase enzyme, chronic inflammation, several age-related metabolic abnormalities (metabolic syndrome, obesity, dyslipidemia, diabetes) are important determinants of the development and progression of BPH/LUTS (Madersbacher, Sampson, & Culig, 2019). BPH leads to posterior urethral elongation, compression deformation, urethral strictures, and increase of urethral resistance, causing bladder hypertension and related urination symptoms. With the increase of bladder pressure, compensatory bladder detrusor hypertrophy, detrusor instability and related symptoms of urine storage stage appear. If the

obstruction remains unrelieved for a long time, the detrusor muscle loses its compensatory capacity. Secondary to BPH are changes in the upper urinary tract, such as hydro-nephrosis and renal function impairment. The main cause is increased pressure in the bladder (Foo, 2017).

Signs and symptoms

1.BPH symptoms

BPH symptoms are mainly characterized by LUTS such as dysuria, frequent urination and urgency, bladder outlet obstruction and other symptoms. In severe cases, renal failure, urinary tract infection, and cardiovascular/cerebrovascular diseases can occur (Xiong, 2019). Foods, fluid intake, caffeine, alcohol, and tobacco may influence LUTS. There is evidence of associations between increased fluid intake and urinary frequency/ urgency, and between modest alcohol intake and decreased BPH diagnosis and LUTS. (Bradley et al, 2017)

2. Bladder Outlet Obstruction (BOO) symptom

Difficulty in excretion of urine due to elevated resistance of urine outflow tract in bladder neck and/or urethra, e.g., dysuria, urine waiting, urine dribbling, urine line thinning, shorter range, and acute or chronic urinary retention in severe cases (Pyun et al, 2017).

Approximately 50% of male patients have moderate-to-severe LUTS (Egan, 2016).The main clinical manifestations were lower urinary tract symptoms such as urgency, frequency, nocturia, fine urine rheology, post urinate dribbling, and incomplete urine (Ng & Baradhi, 2022).

In clinical practice, clinicians assign a stage of BPH patients with LUTS based on the presence of meaningful obstruction and the presence of troublesome symptoms:

Stage 1: Patients who have no troubling symptoms and no meaningful obstruction can be observed and consulted

Stage 2: Patients with troubling symptoms but no meaningful obstruction may be treated with medication

Stage 3: Patients with meaningful obstruction, regardless of symptoms, require more aggressive treatment

Stage 4: Patients have complications caused by BPH, such as urinary retention, bladder stone formation, and recurrent urinary tract infections, which require surgical treatment

Investigation

BPH assessment must consider the following aspects of the disease separately: the presence and severity of LUTS, current nature and magnitude of the patient's symptoms, Prostate-Specific Antigen (PSA) level, Free Prostate-Specific Antigen (fPSA) and presence of comorbidities (Kobe, Donati, & Pfammatter, 2020). Digital rectal examination can be used to determine the size, shape, texture, and presence of nodules of the prostate. The correlation between serum PSA and prostate volume was 0.30 (ng/ml)/ml for BPH and 3.5 (ng/ml)/ml for prostate cancer (J. G. Robinson, Hodges, & Davison, 2014).

Prevention and treatment of BPH

Due to the different sites of obstruction and the size of hyperplasia, the severity of LUTS in clinical BPH patients is also different. Clinically, different treatment methods are adopted according to different symptoms of the lower urinary tract and the severity of BPH, the impact on patients' daily life behavior, and QOL.

Scholars generally use the International Prostate Symptoms Score (IPSS) to quantify LUTS in BPH patients and treatment management. The score ranges from 0-35 points. A score of 0-7 indicates mild symptoms, a score of 8-19 indicates moderate symptoms, and a score of 20-35 indicates severe symptoms (Y, 2001).

The treatment of BPH

Different stages of BPH, treatment methods are different. Clinically, depending on the patient's symptoms, patients in the first stage can wait for observation, patients in the second or third stage need medication, and patients in the fourth stage with complications need surgery.

1. Watchful waiting

Some patients with hyperplasia have no obvious clinical symptoms of the lower urinary tract for quite a long time in the early stage of the disease. According to the Chinese Guidelines for the Treatment of BPH, the criteria for severity is mild LUTSs (IPSS≤7) patients with or above moderate symptoms (IPSS≥8). Patients,

whose QOL has not been affected can choose watchful waiting and follow-up work should be done for such patients (huang jian, 2020)

2. Medication treatment

BPH drugs are now widely accepted by the physicians and patients because of their better efficacy and less pain. There is no absolute clinical indication for BPH drug therapy. Drug therapy can be considered when the patient feels that the QOL is adversely affected, but the clinical indications for surgery are not met, or when the IPSS scores are 1-8. Among the drugs used to treat BPH, A-blockers are the most commonly used drugs (Mahon & Welliver, 2020). Alpha blockers, such as tamsulosin (0.2 mg a day), 5-alpha-reductase inhibitors (I-5-AR) such as finasteride tablets (5 mg a day) are recommended as the drugs of choice for the treatment of patients with BPH (Kuzmenko, Kuzmenko, & Gyaurgiev, 2021) .

3. Surgical treatment

Studies have shown that the most effective radical cure for BPH is surgery, which has been the preferred treatment for a long time. Transurethral resection of the prostate (TURP) is characterized by small trauma and quick postoperative recovery, and TURP is still the "Gold Standard" for many doctors in the treatment of BPH patients. However, contemporary literature indicates that Holmium laser enucleation of the prostate (HOLEP) is replacing TURP, with open simple prostatectomy, as the size-independent surgical Gold Standard for BPH treatment (Das, Teplitsky, & Humphreys, 2019). The specific choice of surgical method should be based on the characteristics of the patient (Kuzmenko et al, 2021).

BPH is a progressive disease. With increased age, the duration of the disease is prolonged, the clinical symptoms are gradually more obvious, and the impact on the QOL is more serious. No matter which treatment method is used, the goal is to improve the QOL of patients.

QOL among persons with BPH

In the context of rapid social and economic development, the QOL of the general elderly male is generally not high to begin with BPH (Yang K & Fm, 2020). Poor QOL was reported in the literature for patients with prostate hyperplasia in 2012. The study of Gao Yang et al [7] showed that the QOL of elderly patients with BPH

was at a moderate level, i.e., mean score 104.77 (SD 20.04). That finding is consistent with the study by Zhang Daoxiu. However, Pan et al (2020) found that QOL of BPH persons was lower than found in those studies, indicating that the QOL of elderly BPH patients was at a low level. A study of 289 cases of senile patients with BPH had low-to-moderate QOL (Zhang DX, Li Min, SHENG JL, Li Can, & Pei, 2021).

Although BPH is not life-threatening, it poses a serious threat to the QOL of BPH persons (Calogero, Burgio, Condorelli, Cannarella, & La Vignera, 2019b). Age is an unavoidable factor for BPH patients, and the prevalence of BPH increases with age. According to the nature of this disease, increasing of age will be reflected in a decrease of QOL for people with BPH [1]. The older people get, the poorer their functioning level, and the higher the stage of BPH, the poorer QOL among BPH persons. The older the age, the more obvious the LUTS of BPH patients [2]. However, the QOL of persons with BPH has not been a major concern by society. Most people think that BPH is a normal physiological aging process, which does not need diagnosis and treatment. Thus, many sufferers miss the optimal time for treatment. At worst, serious complications may occur, which greatly erodes the QOL of elderly men (Tong, Xie, & Li, 2020).

A study found showed that 80% of BPH patients experienced a negative impact on QOL due to LUTSs (Abdelmoteleb, Jefferies, & Drake, 2016). Most patients with BPH are affected by LUTS symptoms, and their QOL is reduced. Prolonged duration of disease is associated with reduced QOL for BPH persons, as the disease progresses and the symptoms of LUTS get worse, the costs increases, and the QOL of the patient decreases significantly ($P < .05$). For patients with disease duration of less than 3 years, the impact on QOL is relatively small while, for patients with disease duration more than 5 years, the QOL is low or moderate (Meshkov, Kulchavenya, Shevchenko, & Neimark, 2018).

Moreover, the literature revealed that marital status can affect a BPH person's QOL, with research showing that married people with BPH have a higher QOL than those who are divorced or without a partner. As the daily companion and spiritual support for middle-aged and elderly patients with BPH, spouses not only play a role in supervision and care of patients, but also as a source of improved patient

confidence and sense of warmth, which can greatly enhance recovery from the disease.

The QOL of BPH varies according to the level of education. Studies show that the more educated, the better QOL among BPH persons. Persons with higher education are more likely to receive medical education and improve their self-care ability. The higher the education level, the stronger the awareness of self-health care, the more scientific the treatment of disease, enthusiasm, early recognition of disease and treatment, which enhances QOL.

The level of family income is positively correlated with the QOL. Many studies have found that elderly patients with high family income have a high QOL. The cost of BPH treatment has been at a high level for many years, which can impose great economic burden on patients, and seriously affects the QOL of the elderly. Low QOL has been reported in the literature for low-income patients (Robinson et al, 2021). There is evidence of a progressive increase in disease risk and a decline in QOL with lower income (LaRosa et al, 2020). The disease or the patient's health directly affects the patient's QOL. Low per capita monthly household income and the influence of disease are the adverse factors for relatively-low QOL in middle-aged and elderly patients with BPH (Liang, Luo, Lu, & Li, 2020).

Furthermore, BPH affects social activities of BPH persons. For example, sufferers may give up some hobbies, such as dancing and fishing. At the same time, some elderly people become estranged from friends or family because of this illness (Ellis-Jones, 2022), with corresponding decline in QOL.

The World Health Organization (WHO) defines health-related QOL as the experience of individuals in different cultures and value systems on their life condition related to their goals, expectations, standards, and concerns (Eraballi & Pradhan, 2017). QOL can be measured comprehensively across the dimensions of physiological, psychological, and social functional status of individuals and groups, and represents the ultimate goal of all health interventions.

The guidelines of the European Association of Urology (EAU) have proposed that the health-related QOL of patients with BPH should be considered first for the evaluation of symptoms and the choice of treatment methods (Eraballi & Pradhan, 2017) . In this study, QOL of patients with BPH include five dimensions:

disease dimension, physiological dimension, social dimension, psychological dimension, and satisfaction dimension, as follows:

1. Disease dimension: BPH symptoms and their impact on life; micturition interruption; urinary terminal drip

2. Physiological dimension: physical functioning; sleep; physical activity

3. Social dimension: Social role; disease affecting social activities

4. Psychological dimension: emotion; temper; worry about the disease

5. Satisfaction dimension: this is based on questions about whether BPH persons are satisfied with their economic and health situation

All symptoms of BPH, especially LUTS, can reduce the QOL of patients, and anything that reduces QOL requires symptom management (Luo et al, 2020).

Symptom Management Theory

The theoretical foundation for this study is Symptom Management Theory (SMT). SMT was developed from the Symptom Management Model of University of California, San Francisco, USA. It was first jointly established by members of the Symptom Management Teaching and Research Group of School of Nursing, University of California, San Francisco in 1994, and was updated twice in 2001 and 2008, and officially renamed as Symptom Management Theory (SMT) in 2008 (Linder, 2010).

SMT proposes that symptom management is a dynamic, multidimensional process that can change with the influence of three core concepts related to nursing and changes in outcomes. The basic components of the three-symptom management process include Symptom Experience, Symptom Management Strategies, and Outcomes.

Symptom experience

The symptom experience includes an individual's perception of a symptom, evaluation of the meaning of a symptom and response to a symptom. Perception of symptoms refers to whether an individual notice a change from the way he or she usually feels or behaves. People evaluate their symptoms by making judgements about the severity, cause, treatability, and the effect of symptoms on their lives. Responses to symptoms include physiological, psychological, sociocultural, and

behavioral components. Understanding the interaction of these components of the symptom experience is essential if symptoms are to be effectively managed.

Symptom management strategies

The goal of symptom management is to avert or delay a negative outcome through biomedical, professional and self-care strategies. Management begins with assessment of the symptom experience from the individual's perspective. Assessment is followed by identifying the focus for intervention strategies. The intervention strategies may be targeted at one or more components of the individual's symptom experience to achieve one or more desired outcomes. Symptom management is a dynamic process, often requiring changes in strategies over time or in response to acceptance or lack of acceptance of the strategies devised. The revised model includes the specifications of what (the nature of the strategy), when, where, why, how much (intervention dose), to whom (recipient of intervention) and how (delivered). Researchers and clinicians consider these questions as they design, develop, and prescribe symptom management strategies. The specifications should greatly aid in replications of intervention studies.

Outcomes

Outcomes emerge from symptom management strategies as well as from the symptom experience. In the revised model the outcomes dimension focuses on eight factors, functional status, emotional status, symptom status, self-care, morbidity & co-morbidity, mortality, and QOL. A new outcome - cost - includes financial status and health services utilization dimensions of the original model as well as receipt of workers compensation. Inappropriate symptom management can generate multiple symptoms problems which, in turn, result in person's health. All outcomes may be related to each other as well as to symptom management. The QOL of BPH people experiencing symptoms is often different. If a patient can deal with their symptoms well, or the symptom is of short duration, the QOL may be unaffected. However, when a symptom is extremely problematic, patients may get low QOL.

The domains of nursing science as they relate to the model

In the revised model, Dodd et al (2001) included possible influencing factors in the symptom management program, namely the core concepts of nursing: person,

health/illness and environment are contextual variables influencing all three dimensions of the model: symptom experience, management strategies and outcomes.

Person domain

Person variables include demographic, psychological, sociological, and physiological aspects. Which are intrinsic to the way an individual views and responds to the symptom experience. Developmental variables include the level of development or maturation of an individual. When the model is used, person variables may be expanded or contracted depending on the symptom(s) and the population of interest.

Health/illness domain

The domain of health and illness is comprised of variables unique to the health or illness state of an individual and includes risk factors, injuries, or disabilities. Individuals may be at risk for symptoms related to such environmental factors as occupational hazards, or from the side-effects of treatment for a disease or condition, or as a result of symptom sequelae that are associated with the persistent primary symptoms of disease. These symptoms can be anticipated, prevented, or diminished through intervention.

Environment domain

The environment refers to the aggregate of conditions or the context within which a symptom occurs; that is, it includes physical, social, and cultural variables. The physical environment may encompass home, work, and hospital. The social environment includes one's social support network and interpersonal relationships. Cultural aspects of the environment are those beliefs, values and practices that are unique to one's identified ethnic, racial, or religious group.

Therefore, guided by SMT, in this study, LUTS, depression, sleep disturbance (which is symptom experience), and social support (as an environment dimension), are treated as independent variables and may be associated with QOL among persons with BPH.

Factors related to QOL of person with BPH

Lower urinary tract symptoms (LUTS)

The LUTS of BPH person were taken as a controllable symptom. LUTS are the most direct clinical manifestations of elderly men with BPH. All kinds of LUTS will cause inconvenience to patients and affect their normal social activities. At night, LUTS will disrupt patients' sleep, resulting in a decrease in the quantity and quality of sleep, with adverse effects on QOL of patients (Kim SK, 2019). During the day, patients frequently urinate or have difficulty urinating, which leads to social difficulties and embarrassment. A variety of LUTS can have a serious impact on the patient's daily life, causing inconvenience to daily travel, which further leads to the patient's psychological disorders, causing insomnia, anxiety, depression, and other symptoms, ultimately leading to a low QOL (Martin, Tully, Kahokehr, Jay, & Wittert, 2022). Micturition interruption or urinary terminal drip can lead to pain and urinary tract infections that can reduce QOL (dang, 2018). At the same time, pain will cause depression and discomfort, which will seriously affect patients' daily behavior and QOL and affect their work. Both irritation symptoms and obstruction symptoms caused by BPH are quite serious, and obstruction symptoms are very prominent. No matter what form of LUTS is, it will pose a threat to the health and QOL of patients (Wen, 2013). It has been reported that a survey of 1,048 male patients with LUTS found that the more severe the LUTS symptoms were, the greater the impact on the QOL was (Kirby, Kirby, & Fitzpatrick, 2010).

The increase in LUTS or micturition interruption, and urinary terminal drip, the lower their QOL (Wang, Liao, Liu, Sumarsono, & Cong, 2018). That study confirmed that relieving LUTS symptoms among persons with BPH can significantly improve patients' QOL scores ($r = .67$, $p < .001$) (Hwancheol Son, Woo Suk Choi, Ja Hyeon Ku, Jae-Seung Paick, & Kim, 2016). This is consistent with the study by Liu C which found a significant negative correlation between LUTS and QOL score ($r = -.466$, $P < .001$) (Liu, 2021).

Sleep disturbance

BPH persons suffer from a series of changes such as sleep disturbance. Clinical data show that the sleep quality of patients with BPH is lower than that of ordinary people, and the longer the course of disease, the greater the impact on QOL

(P < .001) (Wang Chunxian, 2017). BPH sleep disturbance is mostly manifested as chronic insomnia, mainly night sleep disruption, and is related to the increase of nighttime urination times and decreased daytime energy, which also lead to the reduction of the QOL of patients (Yanli, 2017). Good physical function, good sleep quality, and good physical activity positively affect QOL (Krishnan et al, 2021).

Nocturia is the most frequent cause of sleep disturbance in the elderly, and one of the most bothersome complaints of men with LUTS attributed to BPH. Waking up during the night for voiding in less than three hours after bedtime is related to daytime tiredness, and is thought to have a strong impact on the QOL of men with BPH (Sountoulides et al, 2014). In elderly men with nocturia, sleep disturbance has a clear association with impaired QOL. Frequent nocturia is the main cause of sleep disruption in patients at night, and the decreased sleep quality will directly affect the QOL of patients, which is one of the reasons why patients with prostate hyperplasia elect to undergo surgery (Cuijpers & Smit, 2008; Guo Yanfang, 2008). Another study documented the relationship between sleep quality has an impact on the QOL (Zhao et al, 2019). Moreover, sleep disturbance was negatively correlated with QOL (r=-.55, P ＜ .01) (Luo, Huang, RR, Long, Wang, & Zhang, 2021). Another study also confirmed that sleep disturbances are negatively correlated with QOL (Baek, Jung, Kim, & Lee, 2020).

Moreover, in order to reduce nocturnal urination, many patients deliberately limit the amount of water they drink, and less water can damage renal function, or lead to kidney or ureteral stones, and corresponding decreased QOL (Bernard, Song, Henderson, & Tasian, 2020).

Depression

Depression is one of the most common mental disorders in the world, severely limiting people's social and psychological functioning, eroding QOL, and leading to an increase in functional disability and death (Cuijpers & Smit, 2008). Depression due to the presence of BPH accompanied by LUTS, and the related symptoms were evaluated. According to the survey, the prevalence of anxiety and depression in BPH patients was 10.3% and 21.6%, which are important psychological factors affecting the QOL of patients (Pinto JD, 2015). Patients with BPH were 1.9 times more likely to develop depressive symptoms during the one-year follow-up

period than those without BPH. That finding is generally consistent with the Clifford report that found the BPH patients were 2.1 times more likely to suffer from depression than those without BPH (Huang et al, 2011).

BPH is a slow, progressive disease. When the duration of the disease is prolonged, the clinical symptoms become more obvious, so that some elderly persons with BPH will worry about the cost of treatment and the consequences of the disease. Some may have adverse emotional changes, which will affect their QOL (Alcaraz et al, 2016). It has been reported that psychological changes, such as emotion, temper, and worry about the disease, will affect the QOL of patients (Harms et al, 2019).

Recurrent urinary tract infections and other chronic symptoms, as a long-term source of pressure, in addition to causing physical discomfort, LUTS will also cause psychological damage to patients. Sufferers may be prone to tension, anxiety, depression, and other adverse emotions. Treatment with antidepressants has been shown to improve symptoms and QOL in BPH persons. Depression negatively affects the QOL of patients. Reducing the depression of patients can improve the QOL among persons with BPH ($P<.05$) (Niu, Huang, Wang, & Liu, 2021).The literature shows that the QOL of patients without depression is significantly higher than that of patients with depression (Yang et al, 2014). The occurrence of depression reduces the QOL of patients (D. Zhu et al, 2021).

Social support

Social support is a very important protective factor for patients with BPH. Support from peers and family members can improve patients' confidence in the prognosis, ensure that the patient receives basic care, and improve patient QOL (Kever, Buyukturkoglu, Riley, De Jager, & Leavitt, 2021). Social support has an obvious beneficial effect on patients, and increasing social support can promote the QOL (Cao, Qi, Shen, & Han, 2017). Social support can improve patients' negative emotions and give them a positive psychological state (Dan, 2017). The literature highlights the importance of the quality of social relationships within the social support for long-term health QOL and well-being (McGarrigle & Layte, 2015).

Studies have found that older adults with higher levels of social support had better QOL. High social support can improve the QOL of BPH patients (Cao et al, 2017). Social support plays an extremely important role in the family and community

disease management of patients with BPH. One study found that the QOL of patients with BPH is affected by social support (Tang Zhiguo, 2015). High social support can effectively improve the physical, psychological, social and satisfaction of patients, so as to effectively improve the QOL of patients (Cao et al, 2017).

Some studies found that high social support is more effective in improving the QOL of patients with BPH than low social support ($P<.05$) (Cao et al, 2017). The social support of patients was positively correlated with QOL of BPH person ($r = .42, P < .01$) (Ao, 2020).

Summary

BPH has become a health problem that is of increased attention worldwide as populations continue to age rapidly, including in China. BPH is a common chronic disease in elderly men. The understanding of QOL among persons with BPH is an area of interest. BPH persons always suffer from LUTS. The more severe the LUTS, sleep disturbance, and depression, the lower the QOL (Wu, 2016). In contrast, high social support is more effective in improving the QOL of patients with BPH. But the situation about QOL among persons with BPH in China is not yet an area of focus. According to the literature review, studies on the factors related to QOL among persons with BPH are rare in China. Therefore, more investigation is needed to identify the factors associated with QOL among persons with BPH.

Accordingly, guided by the SMT, this study was conducted to explore the status of QOL among persons with BPH, and examine whether LUTS, depression, sleep disturbance, and social support are related to QOL among persons with BPH, in Wenzhou, China.

CHAPTER 3
RESEARCH METHODOLOGY

This chapter presents the research methodology including research design, population and sample, setting of the study, instruments, ethical consideration, data collection procedures, and data analysis procedures.

Research design

A descriptive correlational research design was used to investigate the relationship between LUTS, sleep disturbance, depression, and social support with QOL among persons with BPH in Wenzhou, China.

Population and sample

Population

The target population of this study is male with BPH, who were treated in the Urology OPD of the Second Affiliated Hospital of Wenzhou Medical University in Wenzhou, China. The information collected showed that approximately 30-40 BPH persons visit the OPD every day (Monday to Sunday).

Sample

The sample included persons with BPH who came to Urology OPD of the Second Affiliated Hospital of Wenzhou Medical University for follow-up of their condition. Simple random sampling was used to recruit the sample, using the following inclusion criteria:

1. Was diagnosed BPH in Stage 2-4
2. No history of surgery for transurethral resection of the prostate
3. ≥50 years of age
4. No history of cancer
5. Have a certain ability to write and speak Chinese
6. Have good orientation to place and time
6. No history of mental illness（from the medical history)
7. No history of physical disability which requires assistance for daily living

Sample size

The Thorndike formula (1978) was used to calculate sample size in this study. The formula is given by n = 10k+50 (where n is required sample size and k is number of independent variables). Since there are four independent variables in the current study, the sample size required is at least 90. Considering possible potential outlier data, the desired sample size was increased by 10% from the prescribed result (Martínez-Mesa et al, 2014). Thus, the final sample size was 99. In this study the researcher collected data from 100 cases.

Sampling technique

In this study, a simple random sampling method was used to recruit samples cases. Each individual had an equal chance to be selected. The researcher asked the attending OPD nurse to explain the basic information to the BPH person, and recorded the identification information for patients who met the inclusion criteria. Before collecting data, the researcher asked the patients for their informed, voluntary consent to participate in this study and asked them to sign an informed consent form. It was estimated that approximately 5~10 patients could be recruited every day. Data collection continued until the required sample size of 100 was obtained.

Research setting

The study was conducted at the Second Affiliated Hospital of Wenzhou Medical University, a Class A general hospital in Zhejiang Province and one of the affiliated hospitals of Wenzhou Medical University. The hospital is a general hospital with 3,121 beds. The OPD section for urological surgery has an average more than 500 new cases of prostatic hyperplasia annually (not included previous diagnosis of BPH). The Urology Clinic has five doctors and three registered nurses, which operates from Monday to Sunday to see BPH persons who need to be followed up. The doctor’s main job is to perform assessment of the patient's history, diagnose the nature of the condition, examine the patient, and give the appropriate medication, or write an admission order for the patient to be hospitalized. The nurses’ main job is to assess the patients' vital signs, collect the basic medical history, maintain the order of outpatient service queue, observe the patient's condition, etc.

Research instruments

The research instruments in this study consisted of six questionnaires, including a demographic questionnaire, the International Prostate Symptom Score (IPSS), the Verran and Snyder – Halpern Sleep Scale (VSH), the Geriatric Depression Scale (GDS-15), the Social Support Rating Scale (SSRS), and the revised version of the QOL Scale for BPH Patient (BPHQLS). Details of the research instruments are as follows:

1. Demographic questionnaire

The demographic questionnaire was designed by the researcher for this study. Part 1 contains information about the participants' characteristics, such as age, religion, education level, marital status, living condition, residential area, current occupation, household income, and method of payment for medical expenses.

Part 2 of the questionnaire contains health information of participants such as duration of BPH diagnosis, stage of BPH, co-morbidities, frequency of voiding the bladder at daytime and nighttime, medication used for BPH, how long received this BPH medication, medication used for other conditions, history and presence of alcohol consumption, reason for drinking, and ever been drunk.

The information in Part 1 was obtained by patient interview and self-report, while the information in Part 2 was obtained from the medical records.

2. The International Prostate Symptom Score

The International Prostate Symptom Score (IPSS) was used to measure the severity of LUTS among the participants. It was originally developed by the American Urological Association (AUA) (Barry et al, 1992). IPPSS was approved by the International Coordinating Committee in Paris, and IPSS was adopted as the official symptom scoring method for BPH patients worldwide. The Chinese version of IPSS was used in this study. The IPSS was translated into Chinese by the Hong Kong Urological Association (HKUA) in 1995 (Martínez-Mesa et al, 2014). The score was based on answering seven questions about urination symptoms. The severity of the patient's symptom was determined by asking the relevant questions in the IPSS scale. The scale consists of seven items, and each item had six response options: 0, 1, 2, 3, 4, 5: A score of 0 denotes no symptoms and a score of 5 denotes very serious symptoms. The total potential score ranges from 0 to 35. A score of 0-7 indicates mild

symptoms, 8-19 indicates moderate symptoms, and 20-35 indicates severe symptoms (Choi & Son, 2019).

IPSS has high reliability with the Cronbach's alpha was .90 (Wong et al, 2017).The Chinese version of IPSS also showed good reliability, Cronbach's alpha was .83-.86 (WN, 2019) .

3. The Verran and Snyder – Halpern sleep scale

The Verran and Snyder – Halpern sleep scale (VSH) was used to measure sleep disturbance among the BPH persons. The VSH was developed by Snyder-Halpern and Verran (1987), translated and validated to Chinese by Lin and Tsai (2003). The VSH was administered to measure a patient's magnitude and self-reported quality of sleep during the preceding night. VSH comprises 15 items: 8 items about sleep disturbance, 4 items about effectiveness of sleep, and 3 items about sleep compensation. The total score of this instrument was calculated by sum score of all items. Each item on the scale contains a visual analogue response on a 10 centimeters. In every item, there are words that explain the meaning of 0 to 10 scores. Items 2, 7, 12, and 14 are reversed scored. Thus, , the total potential score ranges from 0 to 150. Moreover, to describe the level of sleep disturbance, the score ranges from 0-50 = mild sleep disturbance, 51 - 100 = moderate sleep disturbance, and 101-150 = high sleep disturbance (Zhang et al, 2020).

VSH Cronbach' alpha coefficient, indicating reliability, was .82 in the original version (Snyder-Halpern & Verran, 1987) and .83 in the Chinese version (Lin, 2003).

4. The Geriatric Depression Scale

The Geriatric Depression Scale (GDS-15) was used to measure the depressive symptoms of the BPH person. The scale was developed by Brink et al, 30 items (Yesavage et al, 1982). Sheikh and Yesavage (1986) developed the GDS-15 based on the standard version of 30 items, considering the characteristics of the older adults (Shiekh JI, 1986). GDS-15 was translated to Chinese and validated by MeiJinRong (1999). GDS-15 was used to evaluate the depression status of the participants in the last week, thoughts of low mood, reduced activity, irritability, withdrawal from others, and pain, as well as their negative evaluation of the past, present and future. This scale asked for an answer "yes" or "no". The items 1, 5, 7 and

11 connote negative meaning: An answer 'No' was scored 1 point, while ‘Yes’ was scored 0 points; the items 2,3,4,6,8,9,10,12,13,14 and 15 connote positive meaning: An answer 'No' was scored 0 points; ‘Yes’ was scored 1 point. The highest potential score is 15 points; the higher the score, the more obvious the depressive symptoms; a score ⩾8 means having depressive symptoms.

The Chinese version of GDS-15 was tested for reliability among the older adults in Hong Kong, and the results showed that the Cronbach's α coefficient of the scale was .82 (MeiJinRong, 1999). Tang Dan tested the reliability the Chinese version in Chinese older adults, and the results showed that the Cronbach's α coefficient of the scale was .79, and the reliability of the one-week retest was 0.73 (Dan, 2013).

5. The Social Support Rating Scale

The Social Support Rating Scale (SSRS) was used to measure social support of the BPH person. The SSRS was published by Xiao Shuiyuan (Xiao, 1994), with a total of 10 items. The response to items 1-4 and 8-10 was 1-4 points; if the person chooses 1, the response is given 1 point; if 2, response is given 2 points; 3, 3 points; 4, 4 points. However, items 5 had five subitems of A, B, C, D and E, and the scores are also from 1 to 4 for each subitems which are represented as 1= no support and 4= full support. For Items 6 and 7, if the answer is "without any source" the response is given 0 points, and if the answer is "the following sources," then the person chooses several sources. If the person chooses three sources, the response is given 3 points; four sources are given 4 points. In items 6 and 7, the highest point score is 9 for each item. The total score of the scale is the sum of the ten items, with a maximum potential score of 66. The higher the mean score, the higher the level of perceived social support. Moreover, the level of social support among BPH persons is described as follows (Li et al, 2021)：

Total score ≤22 points = low level perceived social support

Total score 23-44 points = medium level perceived social support

Total score ≥45 points = high level perceived social support

This scale has been widely used in the Chinese population. The Cronbach's alpha coefficient of the total scale and sub-scale is .825-.896 (Liu, Fu-Ye, & Lian, 2008).

6. Revised BPH QOL Scale

In this study, the revised BPH QOL Scale (BPHQLS) was used to measure the QOL of BPH persons, including five dimensions: disease, physical, social, psychological, and satisfaction. The scale adopts a five-point equidistant scale, which includes "none at all", "a little", "medium", "serious" and "very serious". The score is 5, 4, 3, 2, and 1 point, respectively. The subject can choose the most suitable grade for himself. The original score is re-scored as 6 minus the original score for a total potential score ranging from 32 to 160. In 2003, Shi Jingzheng and other researchers developed a BPHQLS scale suitable for China's national conditions, consisting of five dimensions: disease, physiological, social, psychological, and satisfaction, with a total of 74 items (Shi, et al, 2005). Yanfang Guo et al revised the scale and modified it from 74 to 33 items (Guo et al, 2008), which was simpler and clearer. Of the 32 items, all are reverse items; Item 33 is a self-evaluation of the overall feeling, which is a subjective question, with a potential score of 0 - 100.The minimum total mean score is 32 and the maximum total mean is 160. The scoring index was calculated as follows: the true score of the scale/the highest possible score of the scale X 100%. For example: the QOL total score = the patient's measured score/160 points (total score of 160 points) x100%. Score : >66% =high QOL ; 66%-33%= medium QOL ;<33%=low level QOL (Li Shuxia, 2011) .

The score of the disease dimension is 75 points: physiological dimension 20 points, social dimension 25 points, psychological dimension 30 points and satisfaction dimension 10 points. The total score of each dimension is different, so it cannot be compared with the score of each dimension alone. Thus, the index of component number is converted for comparison.

The Cronbach's α of the revised BPHQLS is .86 (Guo, et al, 2008).

Quality of instruments

Since all the scales used in this study have already been validated and used in previous studies on BPH, the researcher used all these scales without modification.

For reliability, the IPSS, the VSH, the SSRS, the revised BPHQLS, and the GDS-15 were tested for internal consistency reliability. For this study, the reliability of the instruments was tested with 30 individuals who had characteristics similar to the sample population. The reliability of the BPHQOL was .94, the reliability of the VSH was .92, the reliability of the IPSS was .86, the reliability of the SSRS was .89, and the reliability of the GDS-15 was .78. Overall, all the scales used for the research were reliable. For this study with 100 participants. The reliability of the BPHQOL was .94, the reliability of the VSH was .92, the reliability of the IPSS was .89, the reliability of the SSRS was .88, and the reliability of the GDS-15 was .79.

Protection of human rights

This research was carried out after the research protocol was approved by the Institutional Review Board (IRB), Burapha University (Protocol code IRB3-090/2564) and the Second Affiliated Hospital of Wenzhou Medical University. Before the data collection process, all participants were carefully informed of the purpose of the study and the participating procedures. The researcher described this study's aims and procedures involved in the data collection process and emphasized individuals' right to participate or refuse to participate in the research. The data in this study was collected from individuals who are willing to participate and voluntarily signed the consent form. The consent form was filled out before data collection. Participants were told that they had the right not to answer any questions and had the right to change their mind and withdraw from the study at any time if they wished. Patients were informed that their denial to be a part of this study would not affect the quality of care they receive from the hospital. All the forms for collecting data were anonymous, and there was no harm for participants to participate in the study. Confidentiality was maintained, and names or other identifiable information were not disclosed in this study. All data on paper files were stored in a secure place for research only, and all electronic data was locked using a password that only the researcher could access. All data will be destroyed one year after the publication of the research. In addition, if any individual wants to know the study results, they can contact the researcher.

Data collection procedures

Data collection was conducted after the research proposal was approved by the Ethical Approval Committee, Burapha University, Thailand, and the Second Affiliated Hospital of Wenzhou Medical University. The researcher explained to the authorities, the purpose of the study, procedures, and methods of this study to each director. After receiving permission to proceed, the researcher began to recruit the samples. The data collection was carried out by the researcher as follows:

1. After getting permission from the head of the clinical agency, the researcher met the clinicians and nurses working in the Urology OPD section to apprise them of data collection.

2. The OPD nurse followed the registration record to find the participants who met the inclusion criteria. In addition, the researcher introduced herself to the potential research participants fulfilling the inclusion criteria. The researcher then recruited those subjects who were willing and volunteered to take part in the study.

3. In view of the Covid-19 situation, the researcher wore a sanitary mask at all the time and reminded patients to wear their mask all the time. At the OPD entrance, patients were required to go through temperature screening and show a health QR code (an official way to declare residents' health status). Patients who displayed a green code and temperature below 37.3℃ were allowed entry.

4. The researcher stayed in the Urology OPD from 8:30 to 11:30 a.m. and from 1:30 to 4:30 p.m. from Monday to Sunday.

5. The researcher was randomly selected BPH persons who met the inclusion criteria to participate in the data collection.

6. The researcher met and informed the participants and their families about the aim, ethical issues, and human protection of the study. Written consent was signed after the participants understood and were willing to participate. Every participant maintained one-meter social distancing from other participants and researchers.

7. The researcher used unified instructions to explain in detail the requirements for filling out the questionnaire so that the respondents can fill it out independently after fully understanding the procedures. The respondents completed the questionnaire as required. In the general questionnaire, participants' medication

history and co-morbidities were collected through inquiries and medical records, while other data were filled in by participants themselves.

8. The patients were invited to a separate interview room. The researcher interviewed each participant by using the demographic questionnaire, the IPSS, the VSH, the GDS-15, the SSRS, and the revised BPHQLS.

9. The average time for administrating the full questionnaire was 30-40 minutes. Finally, the researcher checked each filled-out questionnaire for completeness of information before allowing subjects to leave.

10. Because of Covid-19, the following guidelines for preventing Covid-19 were used:

10.1 The researcher and the participants had to a sanitary wear mask correctly throughout the data collection process

10.2 A safe distance of at least 1 meter were maintained between the researcher and the participant

10.3 Participants and the researcher needed to wash their hands with alcohol before and after data collection

10.4 Items touched by participants were cleaned and disinfected before being given to the next participant

10.5 Completed questionnaires were kept in a separate archive bag

11. This process was repeated until meeting the sample size

Data analysis

Data was analyzed by Statistical Package for the Social Sciences, version 17.0 (SPSS Inc., Chicago, IL, USA). The significance level was set at .05. The data analysis methods include the following:

1. Descriptive statistics was used to describe frequencies, percentages, means, and standard deviations of BPH persons the demographic data and their QOL.

2. All the data were assessed by the Kolmogorov-Smirnov test, and were deemed to be in accordance with normal distribution.

3. The Pearson's product moment correlation was used to examine the statistical relationship between LUTS, sleep disturbance, depression, and social support with QOL of persons with BPH.

CHAPTER 4
RESULTS

This chapter presents the results of the data analysis in three sections: Demographic characteristics and health information of the participants, description of QOL of the persons with BPH, and the factors related QOL among persons with BPH in Wenzhou, China.

Description of demographic characteristics and health information for among persons with BPH

Demographic characteristics

A total of 100 men with BPH participated in the study. The mean age of participants was 67.8 (SD = 7.5) years, range 55 – 87. Three out of five were between age 60 and 74 years. The majority of the participants were married (90%), and 85% lived with their spouse. Two-thirds of the participants (67%) lived in an urban area. One-third (34%) of the participants had completed junior high school and high school. Household monthly income was ¥8000-10,000 (1,190-1,488 US$) for 45%, and 28% had an average income of more than ¥10,000 (≥ 1,488US$). All participants (100.0%) had medical insurance. Of these participants, 33% were employed, while 60% were retired. Demographic characteristics of the participants are presented in Table 1.

Table 1 Frequency, percentage, mean, and standard deviation of demographic characteristics of the participants (n = 100)

Characteristics	Number *(n)*	Percentage *(%)*
Age (years)		
50-59	21	21
60-69	36	36
70-79	37	37
80-89	6	6
(M = 67.8, SD = 7.5, min = 55, max = 87)		
Religion		
Buddhism	67	67
Christianity	25	25
None	8	8
Educational level		
Illiterate	3	3
Primary school	18	18
Junior high school	34	34
High school	34	34
Technical secondary school	2	2
Junior college or above university	9	9
Marital status		
Married	90	90
Widowed	6	6
Divorced	4	4
Living condition		
Living alone	3	3
Living with spouse	85	85
Living with children (son/daughter)	12	12

Table 1 (Continued)

Characteristics	Number *(n)*	Percentage *(%)*
Residential area		
Urban	67	67
Rural	33	33
Current Occupation		
Employed		
labor	6	6
professional technician	14	14
administrative manager	13	13
Retired	60	60
Unemployed	7	7
Household income (Yuan per month; US$1 = ¥ 6.7)		
＜5000	1	1
5,000-8,000	26	26
8,000- 10,000	45	45
＞10,000	28	28
Payment method for medical expenses		
Rural insurance (60% reimbursed)	33	33
Healthcare insurance (80% reimbursed)	66	66
Fully reimbursed	1	1

Health information

Health information of the participants, duration since diagnosis of BPH, stage of BPH, co-morbidities, frequency of voiding the bladder at daytime and nighttime, medication used for BPH, duration on medication, and source of BPH information are illustrated in Table 2.

The BPH diagnosis duration of the participants ranged from 2 to 15 years (M=3.7, SD = 1.8). Most participants were in Stage 2 (53%) and 46% were in Stage 3.

All of the participants reported frequent urination, with 63% reporting 9-10 times and 28% reporting more than 10 times of urination per day. Most of the participants had increased nocturia frequency as 48% reported nocturia three times per night, while 33% reported nocturia four times per night. Three out of four participants had at least one co-morbidity, while hypertension (65%) was the most common. All participants were currently on BPH drug treatment, and 75% used two drugs (Tamsulosin hydrochloride and Finasteride) to control BPH every day. Fully 87% had a history of drinking alcohol, and 72% were currently drinking and had even been drunk. About two out of five (39%) said they drink to help them sleep.

Table 2 Frequency, percentage, mean, and standard deviation of health information of the participants (n =100)

Health Information	**Number (n)**	**Percentage (%)**
Duration of BPH diagnosis (years)		
2	18	18
3	44	44
4	16	16
5	17	17
8	3	3
≥10	2	2
(M = 3.7, SD =1.8, min = 2, max = 15)		
Stage of BPH		
Stage 2	53	53
Stage 3	46	46
Stage 4	1	1

Table 2 (Continued)

Health Information	Number (n)	Percentage (%)
Co-morbidities		
None	25	25
Yes * (n=96)	75	75
Hypertension	65	67.7
Diabetic	30	31.3
Heart disease	1	1
How frequency for your voiding at daytime		
7-8	9	9
9-10	63	63
11-14	28	28
(M = 9.9, SD =1.4, min = 7, max = 14)		
Frequency voiding bladder at nighttime (times)		
1	1	1
2	18	18
3	48	48
4	33	33
(M = 3.1, SD =0.7, min = 1, max = 4)		
Medication used for BPH		
Tamsulosin hydrochloride	5	5
Finasteride	20	20
Tamsulosin hydrochloride and Finasteride	75	75
Duration on BPH medication (years)		
1	10	10
2	40	40
3	33	33
4	12	12
≥5	5	5
(M = 2.6, SD =1.0, min = 1, max = 6)		

Table 2 (Continued)

Health Information	Number (n)	Percentage (%)
Medication used for other conditions		
None	26	26
Yes * (n=74)	74	74
Hypertension drugs	44	59.5
Hypoglycemic drugs	8	10.8
Heart disease drugs	1	1.4
Hypertension drugs and Hypoglycemic drugs	21	28.3
History of alcohol drinking		
No	13	13
Yes	87	87
How long have you drinking alcohol (n=87) **(year)**		
20-30	26	29.9
31-40	35	40.2
41-50	25	28.7
>51	1	1.2
Present of alcohol drinking		
No	28	28
Yes	72	72
Reason of alcohol drinking (n= 72)		
Help to sleep	39	54.2
Relieve worries	5	7.0
Only want to drink	19	26.4
No reason	9	12.5
Ever been drunk (n= 72)		
No	22	30.6
Yes	50	69.4

* multiple response allowed

Description of QOL in of the persons with BPH

The BPHQOL measure consists of five dimensions: disease, physiological, psychological, social, and satisfaction, as shown in Table 3.

In this study, the BPHQOL scores ranged from 79 to 132, and the mean score was 102.2 (SD = 12.9). The scoring index was 63.9%, which indicates a moderate level of QOL.

For subscales, the highest score index was for the physiological dimension (88.8%), indicating a high level. Moreover, the mean was 17.8 (SD=1.5). The item with the highest score was "*Can you take care of yourself?*" (M = 4.9, SD = 0.03). The lowest score was "*How is your sleep?*" (M = 3.4, SD = 0.07) (See details in Table 10, Appendix B.)

The mean score of the social dimension was 17.6 (SD = 2.4). The score index was 70.5%, and the item with the highest score being "*Has your illness lowered expectations of you?"* (M = 3.8, SD = 0.1). The lowest score was for the item "*Have you given up any hobbies you used to enjoy (such as dancing, card playing, fishing, etc.) due to illness?"* (M = 3.1, SD = 0.1), followed by "*Has your illness affected your family life?*" (M = 3.3, SD = 0.1) (Appendix B).

The mean score of the psychological dimensions was 18.4 (SD = 3.7). The score index was 61.5%, and the item with the highest score being "*Are you more irritable or angry than before?*" (M = 3.6, SD = 0.1). The lowest score was "*Are you worried about your health?*" (M = 2.8, SD = 0.07), followed by "*Are you worried about the consequences of your illness?*" (M = 2.8, SD = .07)(Appendix B).

The mean score of the satisfaction dimension was 6.0 (SD = 0.9). The score index was 60.4%, and the item with the highest score being "*Are you satisfied with your current financial situation?*" (M = 3.1, SD = 0.1). The lowest score was "*Generally speaking, are you satisfied with your health?*" (M = 3.0, SD = 0.05), (Appendix B).

The lowest score index was for the disease dimension (56.5%), indicating a low level. The mean score of disease dimension was 42.4 (SD = 6.8). The item with the highest score being "*After urinating, there are residual drops which wet one's pants.*" (M = 4.0, SD = 0.1). The lowest score was for the item "*The number of times you get up and urinate at night =?*" (M = 1.9, SD = 0.1), followed by "*How would*

you feel if your current urination symptoms were to last the rest of your life?" (M = 2.0, SD = 0.1) (Appendix B).

Table 3 Range, mean, standard deviation and score index of QOL among persons with BPH (n = 100)

Dimension	Range		*M*	*SD*	*Score index (%)*
	Possible score	Actual score			
Total score	**32-160**	**79-132**	**102.2**	**12.9**	**63.9**
Disease	15-75	29-58	42.4	6.8	56.5
Physiological	4-20	11-19	17.8	1.5	88.8
Social	5-25	12-24	17.6	2.4	70.5
Psychological	6-30	12-27	18.4	3.7	61.5
Satisfaction	2-10	4-8	6.0	0.9	60.4

Score index = (mean/ maximum possible total score) X100%

Factors related to QOL among persons with BPH in Wenzhou, China

The factors related to QOL among persons with BPH including severity of LUTS, sleep disturbance, depression, and social support. Table 4 presents the IPSS scores, which range from 5 to 29, with a mean of 19.3 (SD =5.0), indicating a moderate level of severity of symptoms. Just under half (48%) of the participants had moderate LUTS (M = 15.5, SD = 2.2), and half had severe LUTS (M = 23.6, SD = 2.3).

Table 4 Frequency, Range, mean and standard deviation of severity of IPSS among the participants (n = 100)

IPSS	**Range**		**Frequency**	***M***	***SD***
	Possible score	**Actual score**	***(n/%)***		
Mild symptoms	0-7	5-6	2	5.5	0.7
Moderate symptoms	8-19	11-19	48	15.5	2.2
Severe symptoms	20-35	20-29	50	23.6	2.3
IPSS sum score	0-35	5-29	100	19.3	5.0

Table 5 presents the scores for the VSH measure. The total score was 60.8 (SD = 11.0), indicating moderate sleep disturbance. The lowest score of depressive symptoms among persons with BPH was 0, and the highest score was 13. The mean score was 5.0 (SD=2.9), indicating lack of clinical depression. The results show that the participants had a moderate level of social support, with a total score of 39.0 (SD = 6.3).

Table 5 Range, mean and standard deviation of IPSS, sleep disturbance, depression, and social support among the participants (n = 100)

Variables	**Range**		*M*	*SD*	***Interpretation***
	Possible score	**Actual score**			
Severity of LUTS	0-35	5-29	19.3	5.0	Moderate
Sleep disturbance	0-150	37-92	60.8	11.0	Moderate
Depression	0-15	0-13	5.0	2.9	No depression
Social support	0-66	23-50	39.0	6.3	Moderate
BPHQOL	23-160	79-132	102.2	12.9	Moderate

The normal distribution of the variables was tested through skewness/standard error and the Kolmogorov-Smirnov test as well as a QQ-plot. All variables conform to a normal distribution.

The Pearson's product-moment correlation test was used to examine the statistical relationship between severity of LUTS, depression, sleep disturbance, social support, and BPHQOL.

Table 6 shows that the severity of LUTS ($r = -.736$, $p < .001$), social support ($r = .485$, $p < .001$), depression ($r = -.670$, $p < .001$) and sleep disturbance ($r = -.553$, $p < .001$) was significantly associated with QOL among persons with BPH. The relationships between QOL among persons with BPH and its selected factors are summarized in Table 6.

Table 6 Correlation coefficient between severity of LUTS, sleep disturbance, depression, social support and QOL among persons with BPH (n = 100)

	QOL among persons with BPH
Severity of LUTS	-.736***
Sleep disturbance	-.553***
Depression	-.670***
Social support	.485***

***p < .001

CHAPTER 5
DISCUSSION AND CONCLUSIONS

This chapter presents summary of the findings and discussion of the study results according to the research objectives and hypotheses. Implications of the study findings, limitations, and recommendations for future research are presented.

Summary of the study

The purposes of this research were to describe QOL among persons with BPH and to investigate the relationship among LUTS, sleep disturbance, depression, and social support with QOL among men with BPH in Wenzhou, China. The conceptual framework of this research was based on SMT. This study used simple random sampling to recruit 100 participants at the Urology Department of the Second Affiliated Hospital of Wenzhou Medical University in Wenzhou, China. Data were collected using self-reported questionnaires, which include a demographic questionnaire, IPSS (Barry et al, 1992), VSH (Snyder-Halpern & Verran, 1987), GDS-15 (Shiekh JI, 1986), SSRS (Xiao Shuiyuan,1994) and BPHQOLS (Guo et al, 2008). Cronbach's alpha for the IPSS, VSH, GDS-15, SSRS and BPHQOL were .89, .92, .79, .88, and .94, respectively.

The research found that participants' age ranged from 55 to 87 years, with a mean age of 67.8 (SD = 7.5). Fully 37% of participants' were between age 70 and 79 years, and 36% were age between 60 and 69 years. Most of the participants were married (90%) and 85% lived with their spouse. Two-thirds of the participants (67%) lived in an urban area. Fully 87% had a history of alcohol drinking, 72% still drink at present, and were ever drunk. About two out of five (39%) said they drink alcohol to help them sleep. One in three (34%) of the participants had completed junior high school and 34% had completed high school. Fully 45% of participants had household monthly income of ¥8,000-10,000 (1,190-1,488 US$), and 28% had an average income of more than ¥10,000 (≥ 1,488US$). All participants had medical insurance. Of the sample, 33% were employed, while 60% were retired.

Based on participants' health information, the study found that BPH duration ranged from 2 to 15 years, with a mean duration of BPH of 3.7 (SD = 1.8) years. Just over half the sample participants were in BPH Stage 2 (53%) and 46% were in Stage 3. All of the participants reported frequent urination, with 63% reporting 9-10 times, and 28% reporting more than 10 times of urination during the day. Most of the participants had increased nocturia frequency, with 48% reporting three times per night, and 33% reporting four times per night. Three-fourths of the sample had at least one co-morbidity, while hypertension (65%) was the most common. All participants were currently on daily BPH drug treatment, and 75% used two drugs (Tamsulosin hydrochloride and Finasteride) to control BPH.

The mean score of overall BPH QOL was 102.2 (SD = 12.9). The score index was 63.9%, indicating a moderate level of QOL. Of the five dimensions of QOL, the physiological dimension had the highest score index (88.8%), followed by the social dimensions (70.5%), psychological dimension (61.5%), satisfaction dimension (60.5%), and the lowest score was (56.5%) was for the disease dimension. The mean score of IPSS was 19.3 (SD =5.0), indicating a moderately severe level of symptoms. The mean VSH score was 60.8 (SD = 11.0), indicating a moderate level of sleep disturbance. The mean score of GDS-15 was 5.0 (SD=2.9), indicating lack of clinical depression. Participants reported a mean score for social support of 39.0 (SD = 6.3), indicating a moderate level of social support.

There was a statistically-significant positive relationship between social support and QOL among persons with BPH ($r = .485$, $p < .001$). There was negative relationship between severity of LUTS ($r = -.736$, $p < .001$), sleep disturbance ($r = -.553$, $p < .001$), and depression ($r = -.670$, $p < .001$) with QOL among persons with BPH.

Discussion

The findings of this study are discussed based on the research objectives and research hypothesis.

QOL among persons with BPH

In this study, the mean score of QOL among persons with BPH was 102.2 (SD = 12.9). The scoring index was 63.9%, indicating that persons with BPH in Wenzhou had a moderate level of QOL. This finding is consistent with studies by Daoxiu et al (2021) and Yang (2017). Yang (2017) reported that the mean score of BPHQOL of Chinese persons was 104.8 (SD = 20.0), and the scoring index was 65.5%.

The results of this study can be explained in the context of SMT, which posits that symptom experience (e.g., frequent, urgent, painful urination), physical and social environmental factors (e.g., residential area, work status), and individual and family factors (e.g., education and economic status) are related to QOL (Silva, Lopes, & Merces, 2021).

Age is one of the key factors affecting QOL among BPH persons. In this study, about 37% of participants were between 70 - 79 years old, and 36% of participants were age between 60 - 69 years old. Most of the participants are elderly which may lead to a moderate level of QOL in this group of persons. Kant et al found that, with advanced age, persons with BPH will experience significantly reduced QOL (Kant, Inbaraj, Franklyn, & Norman, 2021).

Educational level is considered a factor to be related to QOL among persons with BPH. This study found that two-thirds of participants had junior high school or high school education (68%), and 11% had post-secondary education. This study found that educational was a protective factor for QOL in older adults, as higher education was associated with better QOL (Gao Rui, 2022). A study in South Korea found that educational level might play an essential role in improving the QOL among BPH persons because it requires self-management skills and medical system navigation to improve the QOL and avoid life-threatening deterioration (Park, Ryu, & Lee, 2020). Similarly, research in China found that patients with higher levels of education were more able to actively use various advanced channels of information to

obtain BPH-related knowledge, and that is very important for improved QOL (Li Weitong, 2019).

The QOL scores of elderly BPH patients differed by marital status. BPH patients living with a marital partner had better QOL than widowed patients (Daely, Nuraini, Gayatri, & Pujasari, 2021). In this study, 90% of the participants were married. For elderly patients with illness, compassionately caring for a spouse can give imbue self-confidence and family warmth, and improve the sufferer's QOL (zhou., 2021).

Household income is also a factor affecting QOL. In this research, 45% of the participants' household income was ¥8,000-10,000 (1,190-1,488 US$), and 28% of the participants' household income was > ¥10,000 (1,488US$). The higher the household income, the higher the QOL of elderly BPH patients. The elderly with higher income have financial security and, when they fall ill, the can actively receive treatment and nursing without fear of going into debt. By contrast, lower-income elderly people tend to have lower QOL due to their limited economic conditions and poor health management (Tang Qi-qun, 2015). These differences may also be related to the overall living standards, education, culture, and economic level of Wenzhou (Zhang et al, 2022).

The duration of BPH diagnosis may affect QOL. This study found that most of the participants had a duration since BPH diagnosis of less than five years (18% participants had 2 years, 44 % participants had 3 years, 16% participants had 4 years). Gao's study showed that those with a disease duration of less than three years had higher QOL scores than those with a disease duration of more than five years (Gao Y, 2017). It may be that, with the prolongation of the disease, the clinical manifestations of BPH gradually worsen, and the complications (frequency and urgency of urination, nocturia, urinary retention) become a more painful experience for elderly patients.

Comorbidity may be an important factor leading to moderate QOL. BPH occurs mostly in the elderly, most of whom have one or more comorbidity. The study by Ao (2021) found that QOL in patients with BPH who had two or more chronic diseases was lower than that of those with no comorbidity. Comorbidities are often accompanied by high medical costs, imposing a relatively large economic burden to patients, resulting in a decline in the social dimension score of patients. Multiple

concurrent chronic disease will lead to overall decline of health satisfaction of patients, thereby adversely affecting their QOL (Huang, Yu, & Koplan, 2014).

This research found that the lowest score index was for the disease dimension (56.5%). This may be explained by the fact that one-third of the participants had nocturia ⩾4 times per night, and 46% were in Stage 3 of BPH. Thus, this group may face long-term urinary incontinence, frequency of urination, and other LUTS. Unfavorable treatment prognosis may have a deleterious impact on QOL in those cases (Wu Yanqin, 2014). These findings are consistent with those of Oelke, Adler, Marschall-Kehrel, Herrmann, & Berges, (2014) which found that the more times of nocturia, the lower the QOL of patients. Frequent nocturia will increase the risk of falls and even fractures in the elderly, as well as sleep disturbance, chronic fatigue, and other adverse consequences. Thus, nocturia is one of the risk factors leading to the decline of QOL in the elderly patients with BPH (Oelke, Weiss, et al, 2014).

Moreover, this research found that the highest score index was for the physiological dimension (88.8%). This can be explained by the fact that more than half of the participants were age less than 70 years, (21% were 50-59 and 36% were 60-69 years). Moreover, 44% of the participants had been living with BPH for three years and are in relatively good physical condition. In addition, the psychological dimension may be an important factor leading to QOL. In this survey, the score index of the psychological dimension of middle-aged and elderly BPH patients was 61.5%, which is at a moderate level. This could be explained by the fact that 85% of the participants were living with their spouse, and 12% were living with children. Having a spouse and other family members to provide emotional support is conducive to the improvement of self-care ability, which is basically consistent with other relevant research (Liu Jianchun, 2014).

The score of social dimensions in this survey is 70.5%, which is at a high level. Fully 85% of the participants lived with their spouse, and all had medical insurance. About three-fourths (73%) of the participants had a family income of more than ¥8,000. That said, BPH causes frequent and urgent urination, and that can disrupt social activities outside the home. The satisfaction of social interaction needs can

greatly enhance the sense of self-esteem of the elderly, moderate the negative emotions caused by disease, and improve QOL generally (Wang Meng, 2014).

Factors related to QOL among persons with BPH

This study found that sleep disturbance had a significant negative relationship at moderate level with QOL among persons with BPH (r= -.553, p < .001). Social support had a significant positive relationship at a moderate level with QOL among persons with BPH (r = .485, p < .001). There was a highly negative relationship between QOL among persons with BPH and severity of LUTS (r = -.736, p < .001) and depression (r = -.670, p < .001). The above results are in line with the hypothesis of this study.

Sleep disturbance

Sleep disturbance and QOL were negatively associated in BPH populations. That is consistent with the hypothesis of this study. In this study, 56% of participants reported insomnia. The participants in this study had a moderate level of sleep disturbance, with a mean score for sleep disturbance of 60.8 (SD = 11.0). This could be one reason why the participants' QOL was moderate. That finding is consistent with the studies of Zhang et al (2021) and Fan (2022) who found that BPH persons had moderate sleep disturbance, and that affected their QOL. This result is consistent with many studies which found that sleep disturbance was negatively associated with QOL (Baek et al, 2020).

The findings suggest that a higher level of sleep disturbance was associated with lower level of QOL. BPH sleep disturbance is mostly manifested as chronic insomnia and sleep disruption. Those are directly related to the increase of nighttime urination and decreased daytime energy, which also leads to the reduction of QOL (Lu Yanli, 2017).The QOL of BPH patients can be significantly improved by personalized intervention for reduced sleep disturbance (Ning, 2020).

Severity of LUTS

Severity of LUTS in patients with BPH seriously affects the QOL of the persons with BPH. Severity of LUTS and QOL were negatively associated in BPH populations (r = -.636, p < .001). That is consistent with the hypothesis of this study. According to SMT, severity of LUTS was a symptom that is acutely perceived by BPH persons. This study found that higher the severity of LUTS, the worse the QOL.

In this study, participants had moderate symptoms of LUTS (M=19.3, SD =5.0). Just under half (48%) of the participants had moderate LUTS (M = 15.5, SD = 2.2), and half had severe LUTS (M = 23.6, SD = 2.3). Similarly, 48% of participants in the survey reported three episodes of nocturia and 33% reported four or more episodes per night. Frequent nocturia was certain to affect QOL (Michel, Schumacher, Mehlburger, & de la Rosette, 2020). Studies have shown that there is a significant negative correlation between IPSS symptom scores and QOL, which is consistent with the stud by Choi, Heo, Lee, & Son, (2017).

Moreover, the effective management of LUTS can significantly improve the QOL of patients (Michel et al, 2020). In addition, effective symptom management strategies can better improve the health problems of patients and improve their QOL (Zuo L, 2020). As a result, nurses should pay more attention to LUTS symptoms, and focus on improving the patient's LUTS symptoms management to improve QOL.

Depression

This study found that depressive symptoms were negatively correlated with QOL among persons with BPH ($r = -.670$, $p < .001$), implying that depression is the main factor affecting the QOL among persons with BPH.

In this study, the participants did not indicate signs of clinical depression (M=5.0, SD=2.9). This may be related to the fact that the participants had higher social support, higher income, and all had health insurance. At the same time, more than half of the participants had been diagnosed with prostatic hyperplasia, which lasted two to three years, which is not that long a time period.

Previous research has pointed out that depression can have a great impact on the QOL of Chinese elderly (Bai & Cheng, 2022). Only 20% of participants reported depression in this study. It has been noted in the literature that BPH persons who have depression, the lower the QOL (Pei Li, Liu XX, Du HD, Li W, & CY, 2019). Thus, the attending nurse still needs to pay particular attention to the psychological condition of BPH patients, and arrange timely psychological interventions to maintain or improve QOL.

Social support

Social support and QOL were positively correlated in BPH populations ($r = .485$, $p < .001$). That finding is consistent with the hypothesis of this study. In the present study, the participants had a moderate level of social support ($M=39.0$, $SD = 6.3$). Social support has an obvious beneficial effect on patients, and increasing social support can promote QOL (Q. W. Cao Yi, Shen Kaizhong, Han Huihui, 2017). Social support can ameliorate a patient's negative emotions and help them achieve a positive psychological state (D, 2017). Social support plays an extremely important role in the family and community disease management of patients with BPH. Many studies have shown that the QOL of patients with BPH is affected by social support (Tang Zhiguo, 2015). High social support can effectively improve the physical, psychological, social and satisfaction of patients, so as to effectively improve the QOL of patients (Q. W. Cao Yi, SHEN Kaizhong, Han Huihui, 2017).

Studies have found that the level of social support is one of the main influencing factors of QOL among of BPH patients, that is, the higher the level of social support, the stronger the QOL, This is consistent with SMT(Zhu Sujuan, 2015).

Conclusions

The results of this study show that sleep disturbance ($r= -.553$, $p < .001$) and social support ($r = .485$, $p < .001$) had a statistically significant relationship at a moderate level with QOL among persons with BPH. There was a highly significant positive relationship between severity of LUTS ($r = -.736$, $p < .001$) and depression ($r = -.670$, $p < .001$) with QOL among persons with BPH. The results are in line with the hypothesis of this study. Therefore, increasing social support, reducing sleep disturbance, minimizing LUTS and depression can promote better QOL among persons with BPH in Wenzhou, China.

Implications of the findings

Finding of the current study might be useful in the following areas:

Nursing practice

This study provides helpful information about QOL and its related factors of persons with BPH in Wenzhou, China. This information provides a basis for the

development of targeted interventions to reduce depression, reduce sleep disturbances, reduce LUTS, and increase social support.

Nursing Administration

With the support of this study, nursing administrators can set up a system for evaluating depression, sleep disturbances, LUTS, and social support so that action can be taken to improve the QOL of BPH patients. The nursing administrator may also incorporate QOL profiles into their standard of care for patients with BPH.

Nursing Education

Findings from the present study provide evidence for nursing knowledge about the relationship between LUTS, depression, sleep disturbance, social support and QOL among persons with BPH. The results can be applied to health education as good instruction about BPH care. Results of the present study can also serve as a reminder for nurse educators to developing teaching-learning content of BPH care, focusing on how to manage LUTS, depression, and sleep disturbance, and encourage social support to improve QOL of BPH persons.

Recommendations for future nursing research

The study enrolled participants from only one hospital in Wenzhou. Thus, the findings may not be representative for other patient groups of the entire Wenzhou area of China. To generalize the results to BPH population in Wenzhou, we recommend that this study be replicated in multiple settings. Furthermore, the present study only analyzed correlations. Thus, a cause-effect relationship between LUTS, depression, sleep disturbance, social support and QOL among persons with BPH is inconclusive. Further intervention studies are needed to strengthen the understanding of this relationship and determine the exact methods that can be effective for improving social support, reduce LUTS, minimize sleep disturbances, and reducing depression to improve QOL.

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APPENDICES

APPENDIX A

Questionnaires in English version

Dear participant:

Please read all questionnaires carefully and give an honest answer. There are six parts which will take approximately 30 - 40 minutes of your time.

1. The Demographic Questionnaire

Direction: Please read the questions in Part 1 carefully and give an honest answer. Please choose the answer as follow by ticking ☑ or write down your answers in the space provided (____). Answers to the questions in Part 2 will be collected from the medical record by the researcher.

Part 1: General information (To be completed by the participant)

1. Your age : _____ (Year)
2. Your religious beliefs:

☐ none ☐ Buddhism ☐ Christian ☐ The other

3. Highest educational level：

☐ illiteracy ☐ primary school ☐ junior high school ☐ high school ☐technical secondary school ☐ junior college

.....

.....

15. Medical insurance

☐ No insurance ☐ Partially covered ☐ Fully covered

Part 2: Health information (To be collected by the researcher from the patient record)

16. Duration of BPH diagnosis (year): _____

.....

.....

23. Medication used for other conditions: _____

2. LUTS measurement tool

Direction: We would like to know how your LUTSs, that have been during the last month or so how often have you experienced the following symptom? Please read and think about it carefully and choose the suitable one on your condition. Please choose the answer as follow by ticking "√" in [ ] of each question.

	not at all	**Less than 1/5 of the times**	**Less than 1/2 of the times**	**About 1/2 of the times**	**More than1/2 of the times**	**Almost Always**
1) During the last month or so, how often have you had a sensation of not emptying your bladder completely after urinating?	0	1	2	3	4	5
.....	0	1	2	3	4	5
.....	0	1	2	3	4	5
.....	0	1	2	3	4	5
.....						
.....	0	1	2	3	4	5
.....						
.....	0	1	2	3	4	5
.....						
	None	1time	2times	3times	4times	5times
7) 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?	0	1	2	3	4	5
Total score of symptoms						

3. Geriatric depression scale

Directions: We would like to know your feelings during this week? Please read and think about it carefully and choose the suitable one on your condition. Please choose the answer that best describe how you feel by ticking "√" in [ ] "yes" or "no" after each question.

Verran and Snyder-Halpern sleep scale

		YES	NO
1	Are you basically satisfied with your life?		
2	.....		
3	.....		
4	.....		
5	.....		
6	.....		
7	.....		
8	.....		
9	.....		
10	.....		
11	.....		
12	.....		
13	.....		
14	.....		
15	Do you think that most people are better off than you are?		

4. The Verran and Snyder – Halpern sleep scale (VSH)

Directions: We would like to know the situation of your last night's sleep. Please read each question carefully and consider the night's sleep to begin from the time you first tried to go to sleep to the time you were finally "up" in the morning. Then choose the suitable one on your condition and pick the number between 0 and 10 that best describe about your last night's sleep by placing a circle mark across the number on the answer line.

1	Did not awaken	0 1 2 3 4 5 6 7 8 9 10	was awake ten hours
2	.....	0 1 2 3 4 5 6 7 8 9 10	.....
3	.....	0 1 2 3 4 5 6 7 8 9 10	.....
4	.....	0 1 2 3 4 5 6 7 8 9 10	.....
5	.....	0 1 2 3 4 5 6 7 8 9 10	.....
6	.....	0 1 2 3 4 5 6 7 8 9 10	.....
7	.....	0 1 2 3 4 5 6 7 8 9 10	.....
8	.....	0 1 2 3 4 5 6 7 8 9 10	.....
9	.....	0 1 2 3 4 5 6 7 8 9 10	.....
10	.....	0 1 2 3 4 5 6 7 8 9 10	.....
11	.....	0 1 2 3 4 5 6 7 8 9 10	.....
12	.....	0 1 2 3 4 5 6 7 8 9 10	.....
13	.....	0 1 2 3 4 5 6 7 8 9 10	.....
14	.....	0 1 2 3 4 5 6 7 8 9 10	.....
15	had enough sleep	0 1 2 3 4 5 6 7 8 9 10	did not have enough sleep

5. QOL Scale for Patients with BPH

Directions: In order to fully understand your current physical and mental health, whether your disease affects the following aspects of the question, each question has five possible answers on a scale of 1-5, please answer each question according to your actual situation in the last two weeks, and please tick the corresponding number.

A	.....	**No**	**a bit**	**medium**	**serious**	**very serious**
1	Urinate again within two hours of passing urine	1	2	3	4	5
2	.....	1	2	3	4	5
3	.....	1	2	3	4	5
4	.....	1	2	3	4	5
5	.....	1	2	3	4	5
6	.....	1	2	3	4	5
7	.....	1	2	3	4	5
8	.....	1	2	3	4	5
9	.....	1	2	3	4	5
10	.....	1	2	3	4	5
11	.....	1	2	3	4	5
12	.....	1	2	3	4	5
13	.....	1	2	3	4	5
14	.....	1	2	3	4	5
		0 time	1time	2times	3times	≥4times
15	Get out of bed at night urination number?	1	2	3	4	5

B. The following questions are related to your life. To what extent does your current health condition limit the following activities?

16.To carry loads of more than 20kg (Exclusive Choice)

☐ There is no limit

☐ Some restrictions

☐ Generally limited

☐ Very restrictive

☐ Can't do

C	.....	**NO**	**a bit**	**medium**	**serious**	**very serious**
20	Have you given up any hobbies you used to enjoy (such as dancing, card playing, fishing, etc.) due to illness?	1	2	3	4	5
21	.....	1	2	3	4	5
22	.....	1	2	3	4	5
23	.....	1	2	3	4	5
24	.....	1	2	3	4	5
D	.....	**NO**	**a bit**	**medium**	**serious**	**very serious**
25	.....	1	2	3	4	5
26	.....	1	2	3	4	5
27	.....	1	2	3	4	5
28	.....	1	2	3	4	5
29	.....	1	2	3	4	5
30	Are you more irritable or angry than before?	1	2	3	4	5

E.

.....

33. If you combine all the above (physical health, mental health, social relationships, and satisfaction). Give yourself an overall score of QOL, how much do you score?(100 points for satisfaction)

6. Social Support Rating Scale

Directions:: In order to understand the support you receive in society. Depending on the fact, please finish the rating scale in accordance with the specific requirements of each issue. Please choose the answer as follow by ticking "√" in [ ] of each question.

1. How many intimate friends do you have, from whom you can receive support and help? (Exclusive Choice)

☐ None

☐ 1~2

☐ 3~5

☐ no less than 6

.....

10. Organized activities for groups (such as, party and youth league organizations, religious organization, trade union, student union and etc.), you_____ (Exclusive Choice)

☐never attend

☐occasionally attend

☐often attend

☐take the initiative to attend and are active with

Thank you for your cooperation.

APPENDIX B

IRB Approval, letter for data collection, Participant's information sheet and consent form

สำเนา

ที่ IRB3-090/2564

เอกสารรับรองผลการพิจารณาจริยธรรมการวิจัยในมนุษย์
มหาวิทยาลัยบูรพา

คณะกรรมการพิจารณาจริยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยบูรพา ได้พิจารณาโครงการวิจัย

รหัสโครงการวิจัย : G-HS048/2564

โครงการวิจัยเรื่อง : Factors related to quality of life among persons with benign prostatic hyperplasia in Wenzhou, China

หัวหน้าโครงการวิจัย : MRS.CHUN MEI LI

หน่วยงานที่สังกัด : คณะพยาบาลศาสตร์

BUU Ethics Committee for Human Research has considered the following research protocol according to the ethical principles of human research in which the researchers respect human's right and honor, do not violate right and safety, and do no harms to the research participants.

Therefore, the research protocol is approved (See attached)

1. Form of Human Research Protocol Submission Version 3 : 22 July 2021
2. Research Protocol Version 1 : 20 May 2021
3. Participant Information Sheet Version 3 : 22 July 2021
4. Informed Consent Form Version 3 : 22 July 2021
5. Research Instruments Version 1 : 20 May 2021
6. Others (if any) Version - : -

วันที่รับรอง : วันที่ 29 เดือน กรกฎาคม พ.ศ. 2564

วันที่หมดอายุ : วันที่ 29 เดือน กรกฎาคม พ.ศ. 2565

ลงนาม *Assistant. Professor Ramom Yampratoom*

(*Assistant. Professor Ramorn Yampratoom*)

Chair of The Burapha University Institutional Review Board

Panel 3 (Clinic / Health Science / Science and Technology)

温州医科大学附属第二医院 温州医科大学附属育英儿童医院

伦理委员会审查批件

批件号：伦审（2021-K-53-02）

科室：泌尿外科	主要研究者：李春梅	职称：主管护师	
项目名称	温州地区前列腺增生人群生活质量的相关因素		
申办单位	温州医科大学附属第二医院、育英儿童医院		
审查类别	复审	审查方式	简易审查
审查日期	2021 年 7 月 1 日	审查地点	/
审查委员	王爱霞　陈勰		
审查材料	1. 临床课题研究复审申请 2. 临床课题研究初始审查申请 3. 试验方案（版本号：V2.0，版本日期：2021.6.23） 4. 知情同意书（版本号：V2.0，版本日期：2021.6.23） 5. 病例报告表（版本号：V2.0，版本日期：2021.6.23）		
审查意见	经过我院医学伦理委员会审查，审查结果为：同意		
年度/定期跟踪审查	审查频率为该研究批准之日起每 12 月一次，首次请于 2022 年 7 月 1 日前 1 个月递交“定期/年度研究进展报告”。 本伦理委员会有根据实际进展情况改变跟踪审查频率的权利。		
批件有效期	2021 年 7 月 2 日——2022 年 7 月 1 日（逾期未实施，自行废止）		
主任或副主任委员（签字） 日　期：2021 年 7 月 2 日 温州医科大学附属第二医院、温州医科大学附属育英儿童医院 医学伦理委员会（盖章）			

声明：

本伦理委员会的职责、人员组成和工作程序均遵循 ICH-GCP、NMPA-GCP、中国相关法律和法规。

地址：浙江省温州市龙湾区温州大道东段 1111 号　　电话：0577-85676879　　邮编：325000

温州医科大学附属第二医院 温州医科大学附属育英儿童医院

伦理委员会审查意见

意见号：伦审（2021-K-53-01）

科室：泌尿外科	主要研究者：李春梅		职称：主管护师
项目名称	温州地区前列腺增生人群生活质量的相关因素		
申办单位	温州医科大学附属第二医院、育英儿童医院		
审查类别	初始审查	审查方式	简易审查
审查日期	2021 年 6 月 16 日	审查地点	/
审查委员	王爱霞　陈勰		
审查材料	1. 临床课题研究初始审查申请 2. 研究者简历及 GCP 证书 3. 试验方案（版本号：V1.0，版本日期：2021.5.20） 4. 知情同意书（版本号：V1.0，版本日期：2021.5.20） 5. 病例报告表（版本号：V1.0，版本日期：2021.5.20）		
审查意见	经过我院医学伦理委员会审查，审查结果为：必要的修改后同意 具体意见见伦理审查意见通知函（YJ-2021-K-53-01）。		
主任或副主任委员签字： 日　期：2021 年 6 月 18 日 温州医科大学附属第二医院 温州医科大学附属育英儿童医院 医学伦理委员会（盖章）			

声明：

本伦理委员会的职责、人员组成和工作程序均遵循 ICH-GCP、NMPA-GCP、中国相关法律和法规。

注意事项：

1）修改试验方案、知情同意书、招募广告及其他提供给受试者的相关材料，请及时提交“修正案审查申请”。

2）本中心发生的医疗器械严重不良事件或药物可疑且非预期严重不良反应及研发期间安全性更新报告须按

照 NMPA/GCP 最新要求及时递交我院伦理委员会，国内外其他中心发生的严重不良事件或药物可疑且非预期严重不良反应需定期汇总后递交伦理委员会，伦理委员会有权对其评估做出新的决定。

3）研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验规定而未让受试者退出研究，给予错误治疗剂量，给予方案禁止的合并用药等没有遵从方案的情况；或可能对受试者的权益\健康以及研究的科学造成不良影响等偏离 GCP 原则的情况，请发现者及时提交“不依从或违背方案报告”。

4）自批件签发之日起，请研究者在规定的跟踪审查截止日期前 1 个月提交“定期/年度研究进展报告”，本伦理委员会有根据实际进展情况改变跟踪审查频率的权利。

5）暂停或提前终止临床研究，请及时提交书面申请。

6）完成试验请及时提交“结题报告”。

7）凡涉及中国人类遗传资源采集标本、收集数据等研究项目，必须获得中国人类遗传资源管理办公室批准后方可在本中心开展研究。

8）凡经我院伦理委员会批准的研究项目在实施前，申请人应按相关规定在国家卫健委、药审中心等的临床试验登记备案信息系统平台登记研究项目相关信息。

医学伦理委员会

地址：浙江省温州市龙湾区温州大道东段 1111 号　　电话：0577-85676879　　邮编：325000

MHESI 8137/1572

Graduate School, Burapha University
169 Longhaad Bangsaen Rd.
Saensuk, Muang, Chonburi
Thailand, 20131

August 9th, 2021

Dear President of The Second Affiliated Hospital of Wenzhou Medical University,

Enclosure: 1. Certificate ethics document of Burapha University
2. Research Instruments (Try out)

On behalf of the Graduate School, Burapha University, I would like to request permission for Mrs. CHUN MEI LI to collect data for for testing the reliability of the instruments.

Mrs. CHUN MEI LI ID 62910067, a graduate student of the Master of Nursing Science program, major in Adult Nursing Pathway, Faculty of Nursing, Thailand, was approved her thesis proposal entitled: "Factors Related to Quality of Life Among Persons with Benign Prostatic Hyperplasia in Wenzhou, China" under supervision of Assoc. Prof. Dr. Niphawan Samartkit as the principle advisor. She proposes to collect data from 30 prostatic hyperplasia persons who are aged ≥ 50 years old in Outpatient Department of Urology, The Second Affiliated Hospital of Wenzhou Medical University.

The data collection will be carried out from August 10th, 2021 - August 19th, 2021. In this regard, you can contact Mrs. CHUN MEI LI via mobile phone +86-1365-6777-035 or E-mail: 250120575@qq.com

Please do not hesitate to contact me if you need further relevant queries.

Sincerely yours,

(Assoc. Prof. Dr. Nujjaree Chaimongkol)
Dean of Graduate School, Burapha University

MHESI 8137/1573

Graduate School, Burapha University
169 Longhaad Bangsaen Rd.
Saensuk, Muang, Chonburi
Thailand, 20131

August 9th, 2021

Dear President of The Second Affiliated Hospital of Wenzhou Medical University,

Enclosure: 1. Certificate ethics document of Burapha University
2. Research Instruments

On behalf of the Graduate School, Burapha University, I would like to request permission for Mrs. CHUN MEI LI to collect data for conducting research.

Mrs. CHUN MEI LI ID 62910067, a graduate student of the Master of Nursing Science program, major in Adult Nursing Pathway, Faculty of Nursing, Thailand, was approved her thesis proposal entitled: "Factors Related to Quality of Life Among Persons with Benign Prostatic Hyperplasia in Wenzhou, China" under supervision of Assoc. Prof. Dr. Niphawan Samartkit as the principle advisor. She proposes to collect data from 100 prostatic hyperplasia persons who are aged ≥ 50 years old in Outpatient Department of Urology, The Second Affiliated Hospital of Wenzhou Medical University.

The data collection will be carried out from August 20th, 2021 - September 30th, 2021. In this regard, you can contact Mrs. CHUN MEI LI via mobile phone +86-1365-6777-035 or E-mail: 250120575@qq.com

Please do not hesitate to contact me if you need further relevant queries.

Sincerely yours,

(Assoc. Prof. Dr. Nujjaree Chaimongkol)
Dean of Graduate School, Burapha University

Graduate School Office
Tel: +66 3810 2700 ext. 701, 705, 707
E-mail: grd.buu@go.buu.ac.th
http://grd.buu.ac.th

AF 06-02

เอกสารชี้แจงผู้เข้าร่วมโครงการวิจัย
(Participant Information Sheet)

รหัสโครงการวิจัย : .....
(สำนักงานคณะกรรมการพิจารณาจริยธรรมในมนุษย์ มหาวิทยาลัยบูรพา เป็นผู้ออกรหัสโครงการวิจัย)
โครงการวิจัยเรื่อง : ...**Factors related to quality of life among person with benign prostatic hyperplasia in Wenzhou, China**.....

Dear participants

I am Mrs. Chun Mei Li, a student in Master of Nursing Science (International Program) Faculty of Nursing, Burapha University Thailand. My study is "Factors related to quality of life among person with benign prostatic hyperplasia in Wenzhou, China". The objectives are to describe quality of life and to determine whether severity of LUTS, sleep disturbance, depression and social support related to quality of life among person with BPH in Wenzhou.

This study will be a survey study. Participating in this study is voluntary. If you agree to participate in this study, you will fill out the following questionnaires, which will take approximately 30-40 minutes. During the data collection period, the researcher will clarify any questions posed by the participants for clarity regarding the language or content. Participating in this study will not bring you any direct benefits. However, the information collected from this study may be helpful for the subsequent improvement of nursing interventions, which can help the healthcare providers to provide more effective nursing services for improve the quality of life of persons with BPH, There will

be no identified physical and psychological risks to the individual participating in the study and no risk to the society..

You have the right to terminate your participation in this study at any time, without notifying the researcher, and it will not affect your medical rights and interests in this hospital, nor will it affect the quality of services you receive from. Any information collected from this study, including your identity, will be kept confidential. A coding number will be assigned to you and your name will not be used. Findings from the study will be presented as a group of participants and no specific information from any individual participant will be disclosed. All data will be accessible only to the researcher and research advisor which will be destroyed one year after publishing the findings. You will receive a further explanation of the nature of the study upon its completion, if you wish.

The research will be conducted by Ms. ChunMei Li under the supervision of my major-advisor, Associate Professor Dr. Niphawan Samartkit. If you have any questions, please contact me at mobile number: + 8613656777035 or by email 250120575@qq.com and/or my advisor's e-mail address nsamartkit@gmail.com Or you may contact Burapha University Institutional Review Board (BUU-IRB) telephone number 66-38-10-2620 or by email buuethics@buu.ac.th. Your cooperation is greatly appreciated. You will be given a copy of this consent form to keep.

ChunMei Li

尊敬的患者：

本研究将是一项调查研究，自愿参加这项研究。如果您同意参加本次研究，您将回答以下问卷，大约需要 30-40 分钟。在数据收集期间，研究者将澄清参与者提出的任何关于语言或内容的问题。参与本研究不会给您带来任何直接的好处。然而，您所提供的信息为目前关于具有下尿路症状的 BPH 患者生活质量相关因素的研究提供了信息和方法，对参与者没有生理或心理风险，也没有社会风险。不会有什么确定参与研究的人的身体和心理风险，对社会没有风险。

您有权在任何时候终止参与本次研究，不需要通知研究人员，也不会妨碍他们的职业生涯。从本次研究中收集的任何信息，包括您的身份，都将被保密。编码将被分配给你，你的名字将不会被使用。研究结果将以一组参与者的形式呈现，不会披露任何单个参与者的具体信息。所有的数据只有研究人员才能获得，这些数据将在发表研究结果一年后被销毁。如您愿意，我们会在研究完成后，进一步解释研究的性质。

该研究将由李春梅女士在我的专业导师 Niphawan Samartkit 教授的指导下进行。如果您有任何问题，请联系我:手机:+8613656777035，或通过电子邮件 250120575@qq.com 和/或我的导师的电子邮件地址 nsamartkit@gmail.com。或者您可以联系 Burapha University Institutional Review Board (BUU-IRB)，电话:66-38-10-2620，或通过电子邮件 buuethics@buu.ac.th。非常感谢您的合作。本同意书会发给你一份副本供你保存。

填表日期：2021 年__月__日

AF 06-03.1

เอกสารแสดงความยินยอม
ของผู้เข้าร่วมโครงการวิจัย (Consent Form)

รหัสโครงการวิจัย : .....
(สำนักงานคณะกรรมการพิจารณาจริยธรรมในมนุษย์ มหาวิทยาลัยบูรพา เป็นผู้ออกรหัสโครงการวิจัย)

โครงการวิจัยเรื่อง .....**Factors related to quality of life among person with benign prostatic hyperplasia in Wenzhou, China**

Date of data collection …….Month…..……Year …….

Before giving my signature below, I have been informed by researcher, Mrs. ChunMei Li, about the purposes, method, procedures, benefits and possible risks associated with participation in this study thoroughly, and I understood all of the explanations. I consent voluntarily to participate in this study. I understand that I have the right to leave the hospital and research at any time without worrying that it will interfere with my medical treatment.

The researcher Mrs. ChunMei Li **has explained to me that all data and information of the participants will be kept confidential and only be used for this study. I have read and understood the information related to participation in this study clearly and I am signing this consent form.**

Signature

……..…Participant

(……)

老年前列腺增生症患者生命质量状况调查

知情同意书

在我签字之前，研究人员李春梅女士已经向我详细说明了参与本次研究的目的、方法、程序、益处和可能存在的风险，我对这些解释都很了解。本人自愿参与本次研究。我明白我有权随时离开医院进行研究，而不必担心这会影响到我的治疗。

研究人员李春梅女士已经向我解释，所有参与者的数据和信息将被保密，只用于本研究。我已清楚阅读和理解参与本次研究的相关信息，并签署此同意书。

本人签名：_____

BIOGRAPHY

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