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A randomized controlled trial of the impact of pharmacist-led patient-centered pharmaceutical care on patients' medicine therapy-related quality of life

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ABSTRACT

Background: Due to a lack of pharmaceutical care (PC)-specific measures for health-related quality of life, a novel generic questionnaire "Patient-Reported Outcomes Measure of Pharmaceutical Therapy for Quality of Life (PROMPT-QoL) was developed. Little was also known about an impact of pharmaceutical care on medicine therapy-related quality of life.
Objective: First, evaluate the impact of PC on medicine therapy-related QoL using the PROMPT-QoL in Thai patients. Second, compare the outcomes of drug-related problems (DRPs) between usual care (UC) and PC groups. Third, assess the responsiveness of the PROMPT-QoL.
Methods: A randomized controlled trial was conducted at a tertiary public hospital in Bangkok, Thailand from March to October 2016. A total of 514 patients were randomly allocated into the UC (N = 255) and pharmacist-led patient-centered PC (N = 259) groups. The follow-up period was three months.
Results: A split-plot ANOVA showed that the PC group significantly improved four domain scores and total score of the PROMPT-QoL than the UC group (all $p < 0.01$). For improved patients in the PC group (N = 164), the responsiveness of these four domains and the total score was moderate-to-high with standardized effect sizes between 0.23 and 3.01. The PC group also significantly yielded higher proportion of patients with better DRP outcomes than the UC group ($p < 0.01$).
Conclusions: Pharmacist-led patient-centered PC could improve patients' medicine therapy-related QoL and DRP outcomes. Four out of eight domains and the total score of the PROMPT-QoL were responsive to assess a humanistic impact of PC. More research can be conducted in longer follow-up periods.
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1. Introduction

The concept of pharmaceutical care (PC) was first defined by Mikeal et al., in 1975 as "the care that a given patient requires and receives which assures safe and rational drug usage".[1] In 1990, Hepler and Strand provided a more comprehensive definition of PC as "responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life".[2] Over a decade later, PC was been defined more extensively by Cipolle et al. as "patient-centered practice in which the practitioner assumes responsibility for a patient's drug-related needs and is held accountable for this commitment".[3] Clearly, the latter definitions by Hepler and Strand[2] and Cipolle et al.[3] have identified the roles of a PC provider in the assessment of a patient's drug-related needs (DRNs) that include indication (understanding), effectiveness (expectation), safety (concern), and convenience (medication non-adherence behavior) to prevent or solve drug-related problems (DRPs) to improve a patient's health-related quality of life (HRQoL).

To provide a comprehensive picture of the impact of medicine or healthcare interventions, in addition to clinical and economic outcomes, humanistic outcomes in the form of HRQoL should be measured.[4] HRQoL is a multidimensional concept defined as the patient's subjective perception of the impact of their disease and treatment on physical, psychological and social functioning.[5] HRQoL can be measured using either generic or disease-specific instruments. In a systematic review and meta-analysis by

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Mohammed et al.,[6] original articles that were published in English on the impact of pharmacist-led PC interventions on HRQoL outcomes were summarized. The authors found that PC interventions had significantly improved one domain, and three or more domains of HRQoL measures in 66.7% and 27.1% of the 48 included studies, respectively. The social functioning, general health, and physical functioning of the 36-Item Short Form Health Survey (SF-36), which is the most widely used generic measure, yielded a moderate sensitivity to PC interventions (standardized mean difference [SMD]: 0.30–0.59). The pooled data on heart failure-specific, asthma-specific, and chronic obstructive pulmonary disease-specific measures showed no significant impact of PC on HRQoL (SMD: 0.09–0.17). Mohammed et al. eventually concluded that the development of a sensitive HRQoL measure for PC interventions may generate better evidence of the impact of pharmacist-led PC on HRQoL.

Hence, due to the lack of PC-specific measures for HRQoL, the present research team began developing a new generic questionnaire called the Patient-Reported Outcomes Measure of Pharmaceutical Therapy for Quality of Life (PROMPT-QoL).[7] This measure was originally designed in the Thai language based on the concept of patient-centered PC as defined by Cipolle et al.[3] This instrument can be suggested to be used as a screening tool for identifying DRNs, and may provide a means to measure the humanistic outcome of PC interventions. The PROMPT-QoL has 42 items within eight domains and one item about general attitude toward medication use. All items and domains of the instrument yielded item and scale levels of content validity indexes above the acceptable values of 0.80 and 0.90, respectively.[7]

The PROMPT-QoL was also psychometrically tested in a large sample of 1156 Thai patients with chronic diseases.[8] It took an average administration time of 13.4 ± 5.8 min. All domains provided good-to-excellent test-retest reliability with intraclass correlation coefficients between 0.67 and 0.83. All domains also yielded high Cronbach's alpha values between 0.77 and 0.89 greater than an acceptable level of 0.70, except for Availability and Accessibility domain (0.58). The PROMPT-QoL also provided good known-groups validity with patients' characteristics.

Because a main application of the PROMPT-QoL is to measure humanistic outcomes of PC interventions, the first objective of this present study was to apply the PROMPT-QoL to compare drug therapy-related QoL between PC and usual care (UC) groups. A portion of this objective was previously reported in Thai language in a local journal.[9] Nevertheless, there is a main difference between this present and previous studies about the method of SMD calculation. This present study applied the difference in means at posttest between two groups divided by the pooled standard deviation like that of the study of Mohammed et al.[6] However, the previous study calculated the SMD as the difference in mean changes between two groups divided by the pooled standard deviation of mean changes.[9] The second objective of the present study was to compare DRP outcomes between PC and UC groups. Since the evidence of the responsiveness of the PROMPT-QoL was still lacking. the third objective of this study was to evaluate its responsiveness.

2. Methods

2.1. Patients and eligibility criteria

A randomized controlled trial was conducted at a tertiary public hospital in Bangkok, Thailand from March to October 2016. Ethical approval was obtained from the hospital's Ethical Committee. A convenience sampling technique was employed to recruit the patients. Inclusion criteria were: (1) outpatients aged 18 or over; (2) willing to participate in the study; and (3) having at least the following criteria: (a) receiving medicine treatment from more than one physician, (b) changing dosage regimens, (c) taking at least five medicines, (d) having abnormal laboratory caused by a medicine, (e) not complying to treatment regimen, (f) having an adverse drug reaction (ADR), or (g) facing financial problems for medication.

The exclusion criteria included cognitive impairment or communicative problems. Information for the inclusion and exclusion criteria were assessed from the patients' medical records and or collected through interviews by the researchers. A block size of four was employed to randomize eligible patients into the intervention (PC) group and control (UC) group. Written informed consent was obtained from each of the eligible patients. Patient population eligibility, participation, and randomization diagram are shown in Fig. 1.

2.2. Sample size calculation

The G*Power program version 3.1.9.2 was employed to calculate the sample size required to measure the responsiveness of the PROMPT-QoL using the paired *t*-test.[10] A small effect size of 0.2, with a power of 80%, and a two-sided significant level of 0.05 were determined. The required total sample size was 199 patients, which also covered the other two objectives.

2.3. Pharmaceutical therapy related quality of life assessment by the PROMPT-QoL

The PROMPT-QoL measures the following domains and their respective items: General Attitude toward Medication Use (GAMU, 1 item), Medicine and Disease Information (MDI, 9 items), Satisfaction with Medicine Effectiveness (SME, 3 items), Impacts of Medicines and Side-effects (IMS, 8 items), Psychological Impacts of Medication Use (PIMU, 9 items), Convenience (CON, 3 items), Availability and Accessibility (AA, 4 items), Therapeutic Relationships with Healthcare Providers (TRHC, 3 items), and Overall QoL (OQoL, 3 items). The recall period is the current day of administration. Each item was measured using a 5-point Likert scale except the one item in the GAMU domain that had four choices which asked patients about their treatment preference (medicines, alternative medicines, both, and other).

Item scores ranged from 1 (not at all) to 5 (very much), with higher scores indicating better QoL. Domain scores ranged from 0 to 100. These scores were calculated using the following formula: Domain score = 100*(observed score - minimum domain score)/(maximum domain score - minimum domain score). For example, if a patient rated level 4 for all three items of Overall QoL domain, the score for this domain would be $100*(12-3)/(15-3)=75$. The total score would be the sum of 42 items, except for item 1, which range from 42 to 210.

2.4. Data collection and interventions

Prior to meeting physicians, the clinical pharmacist (TS) interviewed the patients about their medicine therapy and health behaviors. TS also performed medication therapy review and examined laboratory and physical examination results from the medical records. The patients were then asked to answer the PROMPT-QoL by themselves. In cases where assistance would be required (e.g., elderly with eyesight problems), TS would help by reading the questionnaire without any explanation of the meaning of the items to the patients.

After completing the interview, the administration of the PROMPT-QoL and the reviewing of the patients' medical records, TS

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