



Impact of pharmaceutical care on mental well-being and perceived health among community-dwelling individuals with type 2 diabetes

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Abstract

Purpose Mental well-being among community-dwelling individuals with type 2 diabetes has not been well established. The primary objective was to evaluate the change in the mental well-being of individuals with diabetes. The secondary objective was to evaluate the association between changes in mental well-being and perceived health over 6 months, and any interacting factors in this association.

Methods This was a prospective, multicenter study. Community-dwelling individuals aged ≥ 21 years with type 2 diabetes were invited to meet with community pharmacists monthly for 6 months. Individuals who were unable to converse independently were excluded. A 12-item General Health Questionnaire (GHQ), measuring mental well-being was administered at baseline, and after 3 and 6 months. Perception of health was measured using the visual analog scale (VAS) of the EuroQoL 5-Dimension tool. Linear mixed model was used to analyze the change in mean GHQ and VAS scores. Association between the changes in GHQ and VAS scores was determined, and moderation analysis was conducted to elucidate the interacting variables of this association.

Results Ninety-six individuals (82.4%) were included for analysis. The mean age was 60.3 years with a baseline mean HbA1c of 7.6%. A mean GHQ score reduction of 1.36 ($p = 0.022$) was observed. This reduction of mean GHQ score was associated with the change in mean VAS score. Having a duration of diabetes diagnosis of < 3.2 years was identified as moderator of this association.

Conclusion Effective integrated pharmaceutical care with individualized counseling on lifestyle management appeared to improve the mental health of community-dwelling individuals with diabetes on top of glycemic control.

Keywords Community pharmacy · Mental well-being · Pharmaceutical care · Quality of life · Diabetes

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Introduction

The concept of “pharmaceutical care” was first introduced by Helper and Strand in 1990, pushing for the transformation of the Pharmacy profession from “product-focused” to “patient-centric” [1]. The importance of this conceptual distinction of patient-centered care was further emphasized by the advent of collaborative care models, which involves shared decision-making among multidisciplinary healthcare providers [2]. Today, “pharmaceutical care” is widely defined as “the care from anyone for patients in the field of drug-related needs in order to optimize the outcomes of disease management through a pharmaceutical care plan” [3, 4]. Efforts to implement pharmaceutical care services have seen significant promising outcomes across the globe in various healthcare settings [5–7]. In the Netherlands, collaboration between physicians and pharmacists in delivering pharmaceutical care was found to resolve almost half of all detected drug-related problems among individuals with cardiovascular disorders [7]. Delivery of pharmaceutical care to nursing home residents in Switzerland has led to resolution of greater number of drug-related problems and lowered the global medication costs by 14.6% [6]. However, these intensive pharmaceutical services were generally confined to nursing homes or among individuals with limited mobility [6, 8]. Studies to elucidate clinical and humanistic outcomes, such as measures of mental well-being, of integrating pharmaceutical care services in the community setting, especially for individuals with type 2 diabetes, are still lacking.

Individuals with type 2 diabetes often have multiple comorbidities and complications resulting from diabetes progression. Over the course of diabetes care, the use of pharmacological agents often becomes the mainstay for most people. Consequently, individuals with diabetes may be confronted with drug-related adverse events or drug–drug interactions. In a retrospective study, over 90% of individuals with diabetes had at least one drug-related problem [9]. Furthermore, pill burden and medication adherence also become problematic for many people over time [10]. As the majority of people with diabetes are discharged back into the community, many of these people were often left to look after themselves due to a lack of readily available access to pharmaceutical care advice and support especially in between their extended visits to the health institutions [11, 12]. Furthermore, even with therapy, glycated hemoglobin (HbA1c) tends to deteriorate by 1% every 2 years due to disease progression [13]. As such, the maintenance of good glycemic control needs to be closely monitored.

Integrating community pharmacists to provide pharmaceutical care services in a collaborative care team has

shown significant positive outcomes in the management of type 2 diabetes [14]. In addition, improvements in diabetes-related quality of life, diabetes knowledge, and beliefs about the need for medications were also observed [15]. These positive outcomes could be attributed to the unique roles played by the community pharmacists, including health education on disease state and medications, motivational counseling on lifestyle changes, and interpretation of laboratory tests [16]. Furthermore, community pharmacists also play vital roles in improving self-efficacy and self-management capabilities of people with diabetes [17]. Self-efficacy is a cognitive and psychological construct that describes the learning experiences that lead to development of belief that one can successfully perform a task [18]. This construct was associated with diabetes distress and quality of life, which in turn have an effect on optimal glycemic control [19, 20].

Psychological distress among individuals with diabetes encompasses emotions relating to the high demand of self management, worries about complications, fear of hypoglycemia and other lifestyle behavioral adjustments required [21]. According to a meta-analysis, diabetes distress is prominent but inadequately addressed and targeted [21]. Quality of life among individuals with diabetes was also adversely affected due to macrovascular complications and other comorbidities, adding further to the total disease burden [22]. Furthermore, the group of people with higher risk of worse quality of life was found to have psychological disorders [22]. A study conducted in the United States on community-dwelling individuals with diabetes also found significant association between psychological distress and quality of life, beyond the effects of depression [23]. The study further suggested that targeted interventions should be designed to address the psychological and mental well-being of this group of individuals [23]. These findings also corroborated with that from Australia, in which mental well-being was found to associate with diabetes-specific quality of life [24]. Coupling with the well-established association between mental well-being, quality of life, and glycemic control, the psychological and mental well-being of individuals with type 2 diabetes must be addressed urgently [19, 20].

The prevalence of diabetes is reaching epidemic state worldwide, and the demand for chronic care is rising at a pace that may soon exceed the capacity of healthcare systems [25]. It is therefore critical to tap onto the synergistic roles played by community pharmacists in provision of integrated pharmaceutical care to individuals with type 2 diabetes who often reside in the community. Community pharmacists serve as a convenient touch-point for these individuals who may require health-related advices such as medication knowledge, lifestyle modifications, and other self-care-related knowledge. While pharmaceutical care interventions have shown promising clinical outcomes [5, 7],

it is equally vital to investigate the psychological outcomes of pharmaceutical care interventions, especially those that involves community-dwelling patients with diabetes. The primary objective of this study thus aimed to evaluate the change in mental well-being of individuals with type 2 diabetes who received pharmaceutical care from community pharmacists. The secondary objective of this study was to evaluate the association between changes in mental well-being and perceived health over 6 months, as well as the interacting factors in this association.

Methods

Study design and setting

This multicenter, prospective study was conducted in retail community pharmacies located within residential areas in Singapore over 6 months. Singapore is a multiracial country resided by three main ethnic groups, Chinese, Malay, and Indian [26].

Eligibility criteria

The target population of this study was community-dwelling adults aged 21 years and above with type 2 diabetes. Community-dwelling adults in Singapore refer to individuals who are not institutionalized, with their medical conditions being managed by outpatient primary health care institutions. Individuals with acute or unstable medical conditions or cognitive impairment were excluded. This study was approved by the National University of Singapore Institutional Review Board.

Pharmaceutical care services

People who visited the community pharmacies were approached to determine eligibility for the study. After signing the informed consent form, eligible participants were scheduled to meet the community pharmacist monthly at one-on-one basis for 30 to 45 min. Using motivational interviewing techniques, the community pharmacist addressed identified drug-related problems, provided individualized counseling on the disease state, medications, lifestyle, and self-management techniques [27]. They also aimed to empower the participants through setting of personalized goals [28]. The intervention was delivered orally between the participants and the pharmacist, with relevant educational materials provided. HbA1c and lipid markers were obtained through point-of-care testing devices. Sphygmomanometer was used to confirm the blood pressure readings when the measurements from automated blood pressure meter were inconsistent or uncontrolled. All clinical

activities, recommendations, and counseling contents made at each visit were summarized and relayed to the participant's primary care team via phone or letter. The participants continued to visit their primary care team as scheduled.

Data collection

General mental well-being was assessed at baseline, at the 3rd month, and at the 6th month by trained interviewers using the 12-item Global Health Questionnaire (GHQ) [29]. The GHQ is an instrument used to screen for mental distress in people with chronic conditions [29]. The GHQ-12 includes items about feelings, emotional worries, enjoyment, confidence, and happiness. Each item has four responses from “better than usual” to “much less than usual”, with a score of 0 to 3 [29]. The individual score of each item was summed up, which ranged from 0 to 36, with higher scores indicating higher psychological distress level [29]. Perception of state of health was evaluated using the visual analog scale (VAS) component of the EQ-5D [30]. The VAS measures the individual perceived health state, with 0 as the worst imaginable health state and 100 as the best imaginable health state [30]. The authors have received consent to use both questionnaires.

Statistical analysis

Descriptive statistics for sociodemographic information and further inferential statistical analysis were conducted using the SPSS Statistical Package (SPSS 24.0, Chicago, USA). The GHQ score was analyzed over three time points using a linear mixed model. The analysis was followed by pairwise comparison with Bonferroni correction to adjust for multiple comparisons at the three time periods.

Association between change in GHQ and VAS scores over 6 months was analyzed. Interacting variables with change in GHQ scores on change in VAS scores was investigated through moderation analysis [31]. The analysis was conducted using the PROCESS macro for SPSS (version 3.1) Model 1 developed by Hayes [31]. PROCESS macro generates bias-corrected 95% confidence interval (CI) using bootstrapping of the sample distribution based on 10,000 draws with replacement [31]. Potential moderators (categorical and continuous variables) include sociodemographic parameters, medical, and medication histories. These potential moderators were determined a priori based on literature and advice of a board-certified clinical pharmacist [32, 33]. The Johnson–Neyman technique was used to probe an interaction for continuous variables [34]. The Johnson–Neyman plots were generated using Microsoft Excel 2016 (V16; Microsoft Corporation, Washington DC). The pick-a-point simple slope approach was adopted to probe interaction involving multicategorical interacting variables [34]. All

analyses adjusted for covariates. A two-tailed $p < 0.05$ was considered to be significant.

Results

A total of 136 people who visited the community pharmacies were determined to be eligible. After 22 individuals refused to participate, 114 of them were recruited for this study, of whom 18 were lost to follow-up due to work commitments. This left a total of 96 patients (84.2%) for analysis. The mean age of the participants was 60.3 ± 8.5 years, with approximately 60% being female. Most of the participants were Chinese female with high school education. The two most commonly reported comorbidities were hypertension and dyslipidemia. The mean baseline HbA1c was $7.6 \pm 1.3\%$. The mean baseline body mass index (BMI) was

Table 1 Baseline sociodemographic characteristics of participants

Characteristics	<i>N</i> = 96
Age (years)	60.3 ± 8.5
Gender	
Male	41 (42.7)
Female	55 (57.3)
Ethnicity	
Chinese	86 (89.6)
Malay	2 (2.1)
Indian	5 (5.2)
Others	3 (3.1)
Highest educational level	
No formal education	4 (4.2)
Primary	10 (10.4)
High school	44 (45.8)
College/University	38 (39.6)
Employment status	
Employed	45 (46.9)
Unemployed	51 (53.1)
Smoking status	
Non-smoker	78 (81.3)
Smoker	6 (6.3)
Ex-smoker	12 (12.5)
Body mass index (kg/m ²)	24.0 ± 3.6
Number of comorbidities	2.8 ± 1.1
Duration of diabetes	3.0 ± 1.4
Diabetes management	
Lifestyle control	5 (5.2)
Oral medications only	82 (85.4)
Oral and insulin-containing regimen	9 (9.4)

Data are reported in mean ± standard deviation or number (percentage)

HbA1c glycated hemoglobin

Table 2 Clinical characteristics of participants over 6 months

Characteristics (<i>N</i> = 96)	Baseline	6-Month	<i>P</i> value
HbA1c (%)	7.6 ± 1.3	7.1 ± 0.9	<0.001
Systolic blood pressure (mmHg)	130.2 ± 16.5	124.4 ± 16.3	<0.001
Diastolic blood pressure (mmHg)	77.7 ± 13.8	75.1 ± 10.2	0.042
Low-density lipoprotein cholesterol (mmol/L)	2.4 ± 1.0	2.3 ± 1.0	0.215
Triglyceride (mmol/L)	1.7 ± 0.9	1.8 ± 0.9	0.931

Data are reported in mean ± standard deviation or number (percentage)

HbA1c glycated hemoglobin

24.0 ± 3.6 kg/m² (Table 1). Overall, significant improvements were observed in the reduction of HbA1c and systolic and diastolic blood pressures (Table 2).

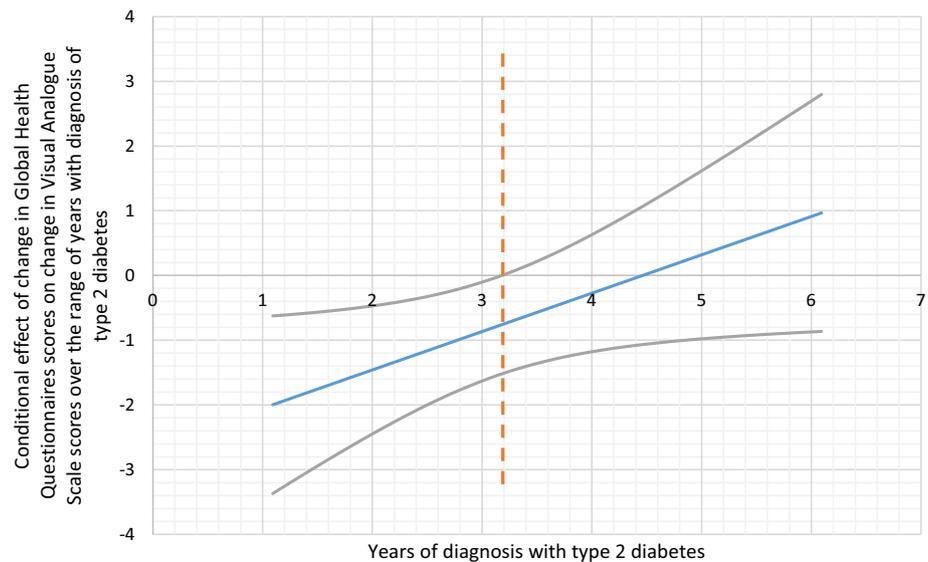
The mean baseline GHQ score was 21.8 ± 3.8 and the mean baseline VAS score was 72.4 ± 12.8 . An overall mean GHQ score reduction of 1.36 ($p = 0.022$) was observed from baseline to 6 months. The effect size of change in GHQ scores over 6 months was 0.33 (Cohen's *d*). Change in GHQ scores (measuring general mental well-being) was found to be associated with the change in VAS scores (measuring perceived health) over 6 months after adjusting for covariates ($p = 0.037$).

Duration of diabetes ($p = 0.039$) was found to moderate the change in GHQ scores on change in VAS scores (R^2 change = 0.055). Further probe using the Johnson–Neyman technique found that duration of diabetes for < 3.2 years moderated the change in GHQ scores on change in VAS scores (Fig. 1). This finding suggested that addressing the mental well-being of individuals who are at the early stages of diabetes may have influences on their overall perception of their state of health.

Discussion

This study was one of the first to highlight the mental well-being and perceived health of community-dwelling adults with type 2 diabetes, receiving care from retail community pharmacists who worked collaboratively with their health-care team. While pharmaceutical care services have shown to improve clinical outcomes [15], the psychological and humanistic outcomes of this type of services were not well established. Our study findings showed that pharmaceutical care delivered in the community appeared to not only add value to clinical improvement but also to the mental well-being of individuals especially in those with shorter duration of diabetes.

Fig. 1 Variation in moderating effects by years with diagnosis of type 2 diabetes mellitus. The point estimates (blue line) are bounded by the 95% confidence intervals (gray lines). Statistically significant moderation was observed at diabetes duration of <3.2 years (indicated by the orange dotted line). (Color figure online)



Studies have shown that psychological support by healthcare practitioners is vital for individuals with diabetes [33–35]. A diabetes management program in the United States reported that individuals who received mental support from pharmacists and life coaches had an average improvement of 0.16 points in their World Health Organization Quality of Life–Short Form (WHOQOL-BREF) scores ($p=0.01$), whereas those without such support did not show any significant improvement ($p>0.05$) [36]. Similarly, a diabetes education and management program in Australia achieved significant improvements in the mental well-being of individuals who received psychological support from community pharmacists (Well Being Questionnaire-12, WB-Q12: 21.9 ± 6.8 to 23.4 ± 6.8 ; $p=0.040$) but showed no changes in patients who did not receive such support (WB-Q12: 21.2 ± 7.3 to 21.2 ± 6.6 , $p=0.999$) [37]. Our community-based pharmaceutical care model emphasized on tailored care that extended beyond the usual 5–10 min of consultations. Moreover, the counseling session also equipped individuals to cope with the stress associated with diabetes management. Over time, individuals may become empowered to take charge of their own health and motivated to sustain self-management behavior.

As identified by numerous studies, our study further emphasized the association between general mental well-being and perceived health [24]. In addition, interactions between duration diagnosed with diabetes and change in general mental well-being were found to influence perception of health changes. The interaction between duration of diagnosed diabetes (specifically <3.2 years, i.e., early stages of diabetes) and mental well-being on perceived health was not surprising. In addition, perception of health was also found to be associated with emotional distress [38]. Individuals often faced mixed emotional reactions and

psychological burden during the initial phases of chronic disease diagnosis [39], thus affecting their quality of life and perception of health state [40]. Therefore, community pharmacists who aim to improve mental well-being level in people with diabetes may want to take into account duration of diabetes diagnosis.

International guidelines such as the American Diabetes Association Standards of Care have also placed great emphasis on the need to address quality of life and perception of health in individuals with diabetes through collaborative care approaches [41]. In addition, poor quality of life was associated with challenges in attaining treatment goals [41]. Furthermore, quality of life influenced self-efficacy, which was reported to be significantly correlated with glycemic control, medication adherence, and self-monitoring of blood glucose [19].

In this study, the perception of health remained unchanged over 6 months. Perceptions are often complicated by individual belief, experience, and exposure of cultural and societal environments, and hence, change in perception may require longer duration to achieve [18]. Healthcare professionals may consider adopting behavioral theories and frameworks to design culturally tailored approaches for individuals with diabetes based on needs assessment. It is also noteworthy that our participants had relatively well-controlled diabetes at baseline; as such, effective behavioral interventions targeted at this group of individuals to improve their mental well-being, perception of health, and ultimately quality of life can potentially play a significant role in minimizing the progression of their disease state and development of complications.

There were several limitations in this study. We did not have a control group for this study because there is no standard model in delivering pharmaceutical care in

the community in the retail setting. The single-group pre-test–posttest study design, however, allowed the participants to serve as their own control, thereby eliminating between-group variability [42]. Furthermore, this study could have attracted eligible patients who were more motivated to improve their medical conditions. This being said, the literature has demonstrated that willingness to participate in medical research did not differ significantly between individuals with diabetes and healthy subjects [43]. The reasons for unwillingness to participate in research were similar between individuals with diabetes and healthy subjects, such as risk and general aversion to research [43]. Lastly, the program duration was relatively short; hence long-term effects could not be ascertained. Future studies should address these limitations to confirm the findings of this feasibility study.

Conclusion

The community pharmacist-involved pharmaceutical care model was found to improve general mental well-being in individuals with type 2 diabetes in addition to improved glycemic control. This community model appeared to achieve the most benefit in individuals with short duration of diabetes.

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Compliance with ethical standards

Conflict of interest The authors have no conflict of interest to declare.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the National University of Singapore Institutional Review Board and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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