




## Original Research

# A randomized control trial assessing the effect of a pharmaceutical care service on Syrian refugees' quality of life and anxiety

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### Abstract

**Background:** Syrian refugees residing in Jordan suffer from chronic illnesses, low quality of life (QoL) and anxiety. Pharmacists delivering the medication review service can have a role in improving this growing worldwide problem.

**Objectives:** To assess the effect of the medication review service on QoL and anxiety scores for Syrian refugees living with chronic medical conditions.

**Methods:** This randomized single-blinded intervention control study was conducted in Jordan. Syrian refugees were recruited and randomized into intervention and control groups. Two home visits were organized with each participant, at baseline and three months later. The medication review service was delivered to the participants and questionnaires regarding QoL and anxiety were completed by all participants. As a part of the medication review service, drug-related problems (DRPs) were identified by a clinical pharmacist for all patients, but recommendations to resolve these DRPs were delivered to intervention group refugees' physicians only (control group patients did not receive this part of the service till the end of the study); DRPs were corrected and pharmacist-delivered counseling and education were provided as well. At follow-up, DRPs assessment, QoL and anxiety scores were assessed for refugees in the intervention and control groups.

**Results:** Syrian refugees (n=106) were recruited and randomized into intervention (n=53) and control (n=53) groups with no significant difference between both groups at baseline. The number of medications and diagnosed chronic diseases per participant was 5.8 (SD 2.1) and 2.97 (SD 1.16), respectively. At follow-up, a significant decrease in the number of DRPs for refugees in the intervention group was found (from 600 to 182, p<0.001), but not for the control group (number stayed at 541 DRPs, p=0.116). Although no significant difference between the groups was found with regards to QoL at follow-up (p=0.266), a significant difference was found in the anxiety scores between the groups (p<0.001).

**Conclusion:** The medication review service delivered by clinical pharmacists can significantly improve refugees' DRPs and anxiety scores. As for QoL, significant improvements can be seen for all refugee patients, regardless of whether the DRPs identified were resolved or not.

### Keywords

Refugees; Quality of Life; Anxiety; Counseling; Pharmacists; Randomized Controlled Trials as Topic; Syria; Jordan

## INTRODUCTION

The stressful experiences that refugees are exposed to make them more susceptible to mental health conditions, including anxiety.<sup>1</sup> A study conducted in Germany indicated that a high prevalence of mental distresses among Arab refugees living there, as more than a quarter of the refugees were found to suffer from severe anxiety symptoms.<sup>2</sup> In Jordan, more than half of the refugees in the study sample were found to experience anxiety symptoms.<sup>3</sup> In addition, due to the displacement of refugees from their traditional environment, studies have shown that refugees are vulnerable to a number of problems that could affect their daily lives, leading to a decline in the quality of life (QoL).<sup>4</sup>

The civil war in Syria, which started in March 2011, has accounted for the world's largest forcibly displaced population.<sup>5</sup> Currently, Syria is first in the world as a source of refugees, as one out of four Syrians is a refugee. The United Nations declared the Syrian crisis "the worst humanitarian crisis of the twenty-first century"; and as of September 2017, according to statistics from the United Nations High Commissioner for Refugees (UNHCR), there were 661,859 registered refugees in Jordan, of which 80% have settled in urban and rural areas, while the remaining 20% lived in camps.<sup>6,7</sup> Refugees living outside the camps face numerous health-related challenges, and their healthcare needs are not sufficiently covered.<sup>8-11</sup>

Pharmaceutical care services have improved the use of medications, participants' adherence to their treatment, physicians' prescriptions and the overall participant's QoL.<sup>12,13</sup> Several studies have manifested the effect of pharmaceutical care and the pharmacist-led medication review service on improving participants' outcomes.<sup>14,15</sup> This service is defined as "a distinct service or group of services that optimize clinical outcomes for each participant to ensure the appropriateness, effectiveness and safety for each participant's medication(s); in addition to ensuring the ability of the participant to take his/her medication(s) as should be".<sup>16</sup> The medication review

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service has been established over the last decade in many countries, including Australia, the UK, the USA and Sweden.<sup>17</sup> It is promising to know that the medication review service has effectively led to excellent results in various countries and different populations, helping to optimize participants' therapy.<sup>10</sup> In Jordan, pharmaceutical care in general, specifically the medication review service, was shown to be highly necessary, and was being accepted well by both patients and healthcare professionals.<sup>18-23</sup> Drug-related problems have been defined as: "an event or circumstance involving participant treatment that actually or potentially interferes with an optimum outcome for a specific participant".<sup>24</sup> This is a serious problem that imposes a huge financial burden on the medical sector in all countries worldwide.<sup>25-27</sup> A previous randomized single-blinded intervention-control study that was conducted in Jordan assessed the effect of providing the medication review service on improving the frequency and type of identified drug-related problems for Syrian refugee patients who were diagnosed with chronic conditions.<sup>28</sup> This paper presents new outcomes with regard to the effect of this medication review service on Syrian refugees' QoL and anxiety levels.

The primary aim of this study was to assess the impact of the pharmacist-led medication review service on the QoL and the anxiety scores of Syrian refugees who had been diagnosed with chronic conditions and living in Jordan.

## METHODS

### Study design

A randomized single-blinded intervention control study was conducted over six months, from May to October, 2016, in three large Jordanian cities: Amman, Zarqa and Mafraq, where the majority of the refugees from Syria reside in these cities. Ethics approval was obtained from the Jordanian Ministry of Health. Refugees' specialized clinics were visited by the research team in order to recruit eligible participants and to arrange for their home visits. Participants were approached consequently, and were invited to join the study and were provided with the informed consent form. Patients who agreed to participate, and who met the inclusion criteria, were asked to sign the consent form.

The inclusion criteria for the Syrian refugees included living in Jordan for more than six months prior to the study recruitment, and intending to stay for the whole study period, being above the age of 18 years, having at least one chronic condition and taking five or more forms of medication or taking more than 12 doses of a medication per day.<sup>29</sup>

Following enrolment, study participants were randomized into intervention and control groups. Randomization was conducted using a predefined list previously generated by a computer randomization program ([www.randomizer.org](http://www.randomizer.org)). Participants were not aware of the group they were allocated to. However, they were informed that they would receive the pharmaceutical care service either at the beginning or the end (after three months) of the study.

Following the recruitment of participants at the physicians' clinic, participants' demographics, family history, past medical history, medications, acute and chronic current medical problems, vital signs, lifestyle, allergies, lab results and diagnostic test results were collected.

For each participant, the home visit was arranged, and the date and time of the visit were determined. Home visits were then conducted for all participants (intervention and control group participants) by the clinical pharmacist at the baseline (during the first two weeks from the study's initiation). It was planned that the home visits would not exceed 60 minutes in length, which is the usual time that is provided for in related studies.<sup>30</sup> During the home visits, patients were asked about the storage of their medications, their adherence to medications and the non-pharmacological physicians' advice (advice on lifestyle modifications), and knowledge of their medications.

From the information collected, the pharmacist was able to identify the s for each participant. In addition, during home visits, two questionnaires were completed by the participants themselves, thus self-evaluating their QoL and anxiety scores.

Pharmacist's recommendations to resolve each identified DRP were noted, using current therapeutic guidelines as a reference. For patients in the intervention group, these referenced recommendations were reported to the patients' physicians (the contact information of each physician was reported by each patient) via a formal letter.

The physicians studied the recommendations, and either approved or declined each recommendation, and informed the pharmacist of their decision during a preplanned pharmacist-doctor visit. Then, participants were called by the pharmacist to be informed and asked to visit the physician to have the approved recommendations applied. As for DRPs that could be resolved by the pharmacist, education regarding participants' health problems and medications was delivered to the participants in the intervention group. Control group participants did not receive the intervention, but if life-threatening problems were identified, they were excluded from the study and the problem was reported to the physician in order that it might be resolved.

Three months post-baseline, new appointments were arranged through a phone call by the clinical pharmacist and all participants were revisited at home. Data needed to assess the current DRPs for all participants were recollected (as was done at the baseline). The QoL and anxiety questionnaires were completed again by all of the participants.

### Data collection tools

For data collection and evaluation, the following self-completed questionnaires were used in this study. The European Quality of life - Five Domain (EQ-5D) questionnaire was used to assess the QoL for the Syrian refugees who were recruited for this study.<sup>31</sup> It is one of the most commonly used of the questionnaires that are applied to measure health-related quality of life. This questionnaire consists of five domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression domains. Each domain has five levels of severity; no

problem (level 1), mild problem (level 2), moderate problem (level 3), severe problem (level 4) and extreme problem (level 5). The answers provided for these domains were given a consequent number for each patient (for example 12232 or 22334). These numbers meet a utility score which has previously been published and validated for different populations in different countries. Due to the fact that this score is not yet validated in any of the developing countries, the score based on the UK population was used in this study. The scores represent a continuous QoL scale.

Refugees were also asked to write a number in the Health Status Box that mostly expressed their health status on the day of the interview (related to the status of their chronic condition/s, not the transient health condition/s). The numbers ranged from zero to 100, indicating worst to better health status respectively. The numbers reported here were categorized into groups (zero; 1 to 10; 11 to 20; 21 to 30; 31 to 40; 41 to 50; 51 to 60; 61 to 70; 71 to 80; 81 to 90; 91 to 99 and 100). The higher the category the better the patient's health status is.

The questionnaire used to assess refugees' anxiety was developed by Zigmond & Snaith and has well validated in primary care populations.<sup>32,33</sup> It is composed of seven questions that are relevant to generalized anxiety. The anxiety questionnaire was scored versus a scale of four, ranging from zero to three. Hence, the scores of participants ranged from zero to 21; the higher the score the higher the level of the anxiety suffered by the refugee.

#### Statistical analysis

SPSS Version 20 (IBM, Chicago, IL), was used for data entry through the coding system. Mean (SD) was used to express continuous variables. A paired sample t-test for continuous variables was used to detect any differences within the same group. Group differences (between the intervention and the control groups) were detected using the independent sample t-test, or the Mann Whitney U-test. The categorical data were expressed as proportions and were analyzed using the Chi-square test. For statistical significance, a value of  $< 0.05$  was considered for all of the analyzed tests.

#### Sample size

Based on the primary outcome variable of DRP improvement before and after the delivery of the medication review service, the study sample's size was calculated depending on previous findings.<sup>21</sup> In order to detect a significant improvement of one point difference in DRPs between the groups, using a power of 85%, a significance level of 5% and the standard deviation of the change of 1.7, the sample size was found to be 104 participants. Considering that there was a dropout rate of 15%, a sample size of 123 participants was determined for this study.<sup>21,34</sup>

## RESULTS

A total number of 123 Syrian refugee participants was approached and recruited into the study. After the participants' baseline interview by the pharmacist, 116 participants (94.3%) were found to be eligible for

participation. Some participants ( $n=10$ ) decided to leave the study for a variety of reasons, as reported in Figure 1. Following recruitment, participants were randomly distributed into two groups, intervention ( $n=55$ ) and control ( $n=54$ ). Following randomization, some patients (one patient from the control group and two from the intervention group) were lost to follow-up (Figure 1). The acceptance rate for home visits was 100%, all patients were actually visited at home, where the initial data were collected. No participants with life-threatening cases were identified in the control group. The rest of the participants ( $n=106$ , 53 in each group) completed the follow-up phase of the study.

The average age of the participants was 58.5 (SD 11.2), with 48.1% being females and 51.9% reporting that they had a primary or preparatory level of education. Many reported being smokers (41.5%), and the majority fell into the overweight (30.2%) and obese class 1 (33.9%) of the body mass index category; many were also categorized in the obese class 2 category (11.3%) and as being morbidly obese (5.7%). No statistical differences between the study groups at the baseline were detected.

The number (mean and standard deviation) of medications and chronic conditions per participant was 5.8 (SD 2.1) and 2.97 (SD 1.16), respectively. Diabetes and hypertension were the most common chronic conditions to be diagnosed among the participants (66.0%), followed by dyslipidemia (44.0%), cardiac illness (39.0%) and asthma (9.0%). The most frequent drug classes (mean  $\pm$  SD) included anti-diabetic agents 1.42 (1.3), anti-hypertensive agents 1.2 (1.0), cardiac-related agents 1.1 (1.1), anti-dyslipidemia agents 0.51 (0.54), and anti-asthmatic agents 0.16 (0.42).

For both groups, DRPs were identified (intervention,  $n=600$ ; control,  $n=541$ ), with a DRP average of 10.8 (SD 4.2) per patient. To resolve the DRPs, the most common action taken was to increase health monitoring via pathology testing (24.9%) and the delivering of patient education by the pharmacist (20.4%) regarding pharmacological and non-pharmacological therapies. None of the recommendations/ interventions was refused by the patients.

At the follow-up sessions, a significant decrease in the number of DRPs for refugees in the intervention group was found ( $n=182$ ,  $p<0.001$ ), but not for those in the control group ( $n=514$ ,  $p=0.116$ ). In addition, DRPs per patient were reduced significantly for patients in the intervention group (3.4; SD 1.5;  $p<0.001$ ) but not for patients in the control group ( $p=0.116$ ). Detailed results for the DRPs and for the improvements that were seen across the study are reported elsewhere.<sup>28</sup>

At the baseline, there was no significant difference between the study group with regard to the QoL mean scores ( $p=0.45$ ). Both groups' results improved significantly in the QoL scores across the study (Figure 2), and no significant difference was found between the two groups at the follow-up sessions ( $p=0.266$ ).

A closer look at the five domains that are included in the QoL questionnaire for both groups showed no significant differences between the two groups in any of the domains at the baseline. At the follow-up sessions, there was a

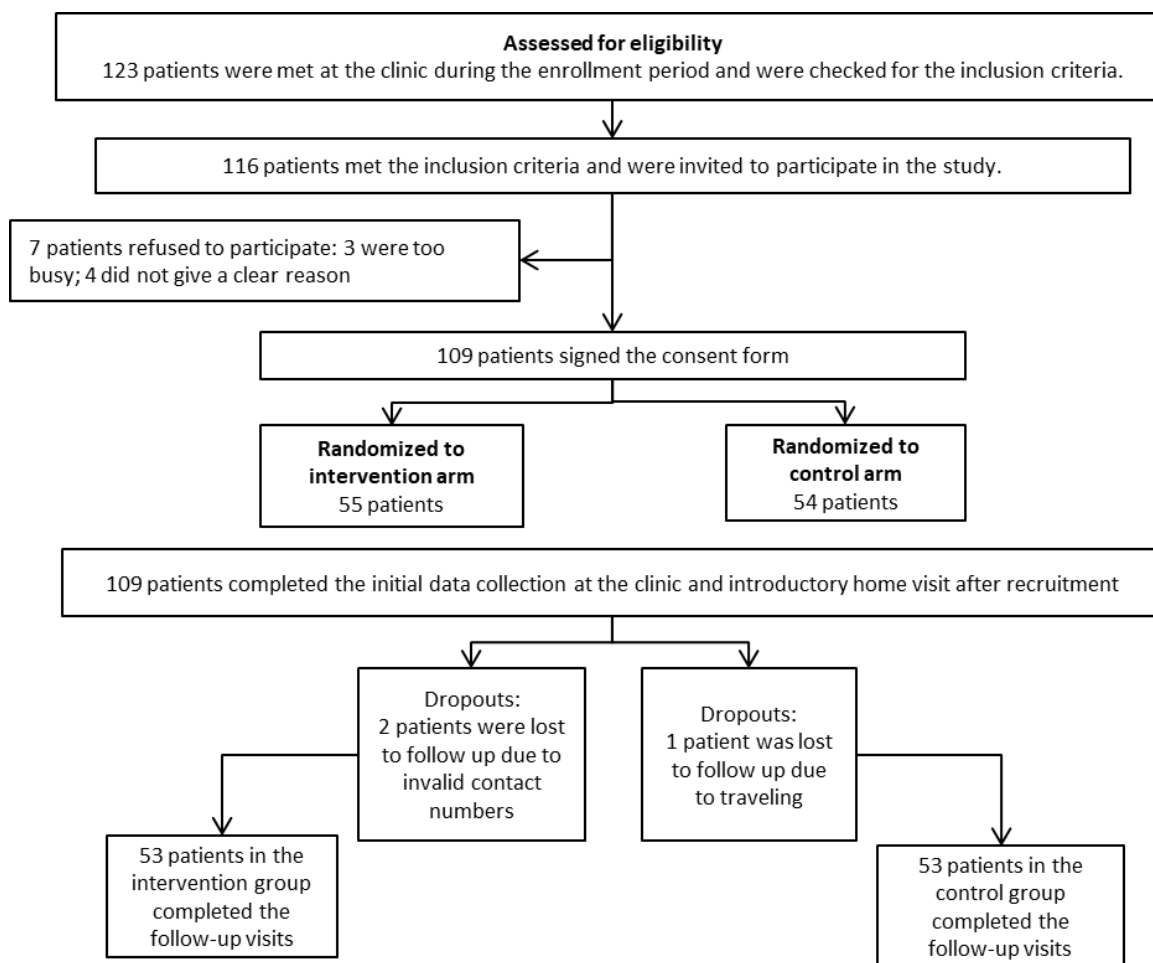


Figure 1. Consort diagram showing patients' recruitment and retention during the study period.

significant difference between the active and control groups in the fifth domain of the questionnaire, which is the anxiety/depression domain.

With regard to the 'Health Status' section of the QoL questionnaire, the intervention group participants' health

status score was significantly improved from its level at the baseline to that at the follow-up sessions (baseline: 50.0; SD 6.2, follow-up: 60.4; SD 5.1;  $p < 0.001$ ). For the control group, no significant improvement was found, while on the contrary, a significant decline in the health status score across the study was revealed (baseline: 68.7; SD 7.2; follow-up: 58.6 SD 5.4;  $p = 0.03$ ).

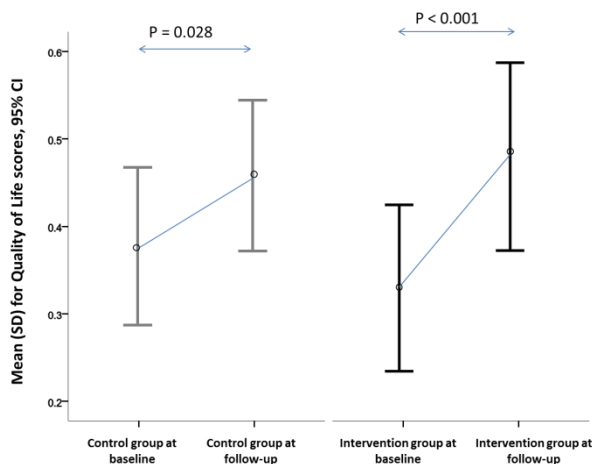


Figure 2. Comparing quality of life scores at baseline and at follow-up for patients in the intervention (n= 53) and control (n= 53) groups.

The higher the score, the better the quality of life of study participants. \*Independent sample t-test

Regarding participants' reported numbers in the Health Status Box, expressing their health status at the day of interview, results showed that the most frequent (20.8 %) health status category reported by participants in the intervention group at baseline was the '31 to 40' category, indicating low health status. At follow-up, the '81 to 90' category was mostly reported (18.9 %) indicating better health status. In the control group, the '51 to 60' category, which indicates intermediate health status, was the most frequently reported category by the patients, both at baseline and at follow-up, signifying no change in their health status (Figure 3).

At the baseline, no significant difference between the study groups with regard to anxiety scores was found ( $p = 0.202$ ), while at the follow-up sessions, a significant difference was revealed ( $p < 0.001$ ). Across the study, a significant difference in anxiety scores resulted from the reports from the intervention group ( $p < 0.001$ ), but not from those of the control group ( $p = 0.09$ ; Figure 4). Moreover, no significant differences between the two groups were found in all

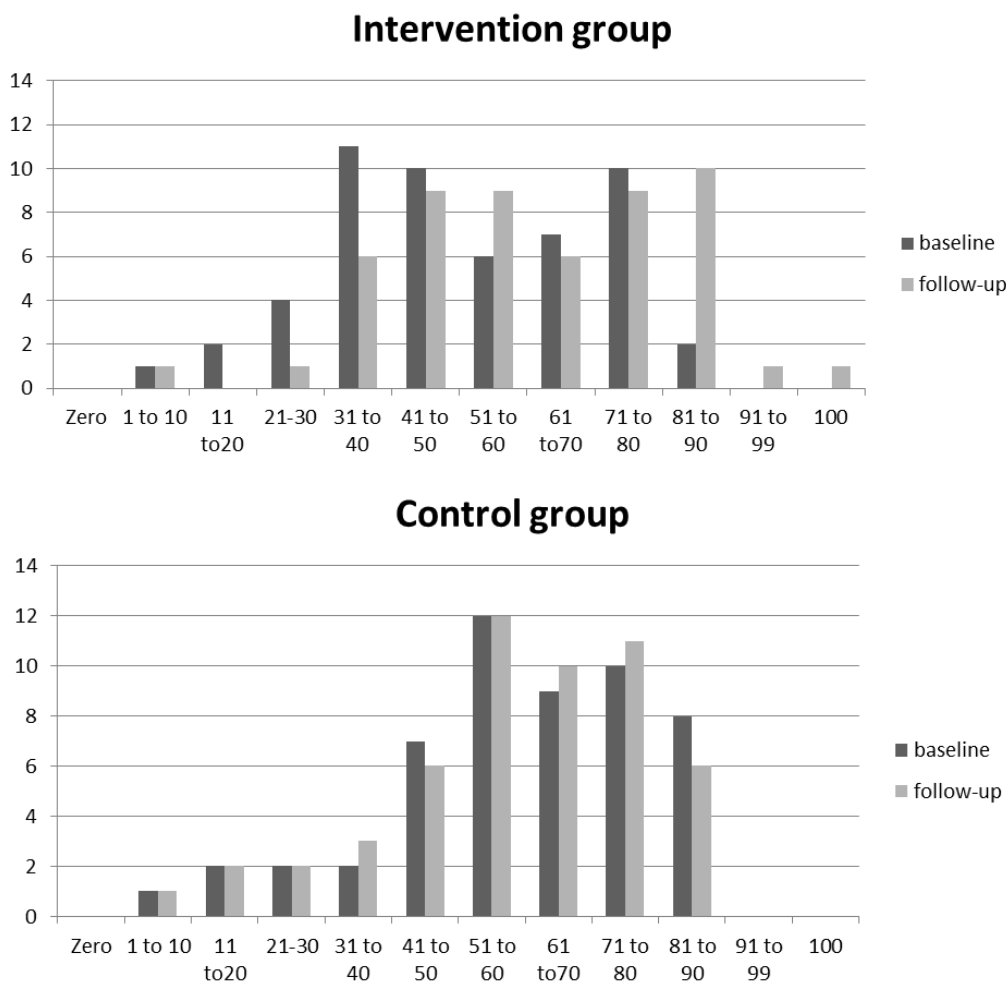


Figure 3. Health Status category as reported by the intervention (n= 53) and control group (n= 53) patients at baseline and follow-up.

seven of the domains that were included in the questionnaire at the baseline, while, at the follow-up sessions, significant differences were found in all of the seven domains (Table 1).

## DISCUSSION

This study highlights original and significant results in the area of pharmaceutical care delivery to refugee patients. The study emphasized a new role that clinical pharmacists can adopt worldwide in assessing and improving the health status and quality of the lives of refugees living with chronic health conditions. The results of this study showed that the provision of a pharmacist-lead medication review service can lead to significant improvements in the clinical and humanistic outcomes for those Syrian refugees living in Jordan. According to published literature, this randomized controlled trial is the first to be conducted for Syrian refugees around the world, assessing the impact of the well-known medication review service on their QoL and anxiety scores.<sup>20,21,28</sup>

The Syrian conflict has been declared as a humanitarian crisis leading to a health disaster for the country and the region.<sup>35</sup> Generally speaking, refugees are the weakest and most vulnerable group in the conflict setting, and therefore, their medical needs are expected to require urgent assistance.<sup>9</sup> Many studies conducted during the last years reported that pharmaceutical care interventions lead in most cases to significant improvement in clinical, humanistic and financial outcomes across many countries and populations.<sup>36</sup> Pharmacists were found to be capable

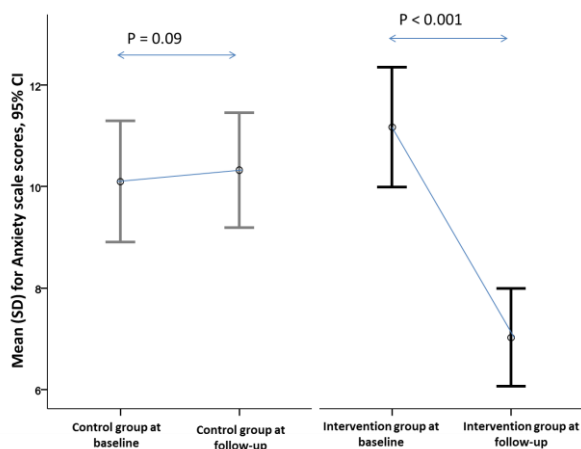


Figure 4. Comparing anxiety scores at baseline and at follow-up for patients in the intervention (n= 53) and control (n= 53) groups.

The lower the score, the better the anxiety level for study participants. \*Independent sample t-test



Table 1. Comparing the anxiety scale seven domains between the intervention and control groups

Parameter	Intervention group n=53		Control group. n=53		p-value		
	Baseline	Follow-up	Baseline	Follow-up	Baseline	Follow-up	
Feeling stressed, n (%)	Most of the times	7 (13.2)	0 (0.0)	9 (17)	9 (17)	0.085 <sup>1</sup>	0.012 <sup>1</sup>
	A lot of times	20 (37.7)	10 (18.9)	11 (20.8)	12 (22.6)		
	Sometimes	23 (43.4)	34 (64.1)	23 (43.4)	24 (45.3)		
	Never	3 (5.7)	9 (17)	10 (18.9)	8 (15.1)		
Enjoying things like before, n (%)	Very rare	14 (26.4)	4 (7.5)	10 (18.9)	11 (20.8)	0.741 <sup>1</sup>	0.001 <sup>1</sup>
	Little	18 (34)	6 (11.3)	17 (32.1)	17 (32.1)		
	Less than before	20 (37.7)	33 (62.3)	25 (47.2)	24 (45.3)		
	Exactly as before	1 (1.9)	10 (18.9)	1 (1.9)	1 (1.9)		
Fear from future, n (%)	Most of times	11 (20.8)	3 (5.7)	8 (15.1)	10 (18.9)	0.556 <sup>1</sup>	0.034 <sup>1</sup>
	Usually	9 (17)	4 (7.5)	8 (15.1)	10 (18.9)		
	Sometimes	16 (30.2)	26 (49.1)	23 (43.4)	17 (32.1)		
	Never	17 (32.1)	20 (37.7)	14 (26.4)	16 (30.2)		
Ability to see the positive sides of things, n (%)	Never	9 (17)	5 (9.4)	4 (7.5)	4 (7.5)	0.331 <sup>1</sup>	0.001 <sup>1</sup>
	Few times	23 (43.4)	6 (11.3)	22 (41.5)	24 (45.3)		
	Yes, but not like before	14 (26.4)	32 (60.4)	21 (39.6)	16 (30.2)		
	Always as I can	7 (13.2)	10 (18.9)	6 (11.3)	9 (17)		
Suspicious ideas, n (%)	Most of the time	6 (11.3)	3 (5.7)	3 (5.7)	4 (7.5)	0.410 <sup>1</sup>	0.001 <sup>1</sup>
	A lot of times	20 (37.7)	7 (13.2)	16 (30.2)	19 (35.8)		
	Not much	25 (47.2)	23 (43.4)	33 (62.3)	26 (49.1)		
	Very few times	2 (3.8)	20 (37.7)	1 (1.9)	4 (7.5)		
Feeling happy, n (%)	Never	6 (11.3)	1 (1.9)	7 (13.2)	8 (15.1)	0.210 <sup>1</sup>	0.037 <sup>1</sup>
	Rare	19 (35.8)	11 (20.8)	10 (18.9)	11 (20.8)		
	Sometimes	26 (49.1)	32 (60.4)	35 (66)	31 (58.5)		
	A lot	2 (3.8)	9 (17)	1 (1.9)	3 (5.7)		
Feeling relaxed and peaceful, n (%)	Never	10 (18.9)	1 (1.9)	9 (17)	9 (17)	0.339 <sup>1</sup>	0.004 <sup>1</sup>
	Rare	19 (35.8)	10 (18.9)	13 (24.5)	16 (30.2)		
	Usually	23 (43.4)	33 (62.3)	31 (58.5)	26 (49.1)		
	Always	1 (1.9)	9 (17)	0 (0.0)	2 (3.8)		

<sup>1</sup>Analyzed by Chi-square test; n: number of patients

of helping to improve patients' health by reducing medication-related side effects and encouraging medication adherence, by decreasing physician visits, hospital admissions, and amending the whole primary care delivery.<sup>37</sup> This study confirms these findings and adds a new perspective on the roles played by pharmacists in helping refugee patients.

Anxiety assessment showed significant differences between the two groups three months from receiving the medication review service. Although previous studies have shown a positive impact of a pharmaceutical intervention on anxiety, this study supports this finding for refugee patients.<sup>19,22,38</sup>

The European Quality of Life - Five Domain questionnaire (EQ-5D) that was used in this study has been validated well in assessing the QoL for patients. An analysis that included 1977 participants has shown that this questionnaire has a higher construct validity and responsiveness among the participants, if compared to other QoL questionnaires.<sup>39</sup> The QoL results in the current study have shown that both intervention and control groups improved their QoL scores significantly across the study period. However, although not statistically significant, the improvement seen in the intervention group was higher than that seen in the control group. The same pattern of results was found in a previous study by Bashedi *et al.*, in which a significant improvement

within the intervention and the control group with regard to QoL was reported.<sup>21</sup> The significant improvement seen in the control group's QoL scores may have been due to the effect of the home visit that was delivered by the clinical pharmacist at the start of the study, which involved an hour of interaction between the refugee and the clinical pharmacist. Being a refugee results in the need for support and having the opportunity to talk with a trusted healthcare professional can be of benefit. However, QoL for refugees can be very sensitive to local policies and processes that enable their settlement, as well as changes in their country of origin (impacting friends and relatives, for instance).<sup>11</sup> It is possible that the improved QoL may not have been related to the intervention provided in this study at all, but simply the fact that over time, some refugees learn to manage better in their new environment. The process of settlement can take many years. Hence, the QoL score may have been measuring many complex factors, not simply the intervention related to this study.<sup>40</sup> It can be argued that a longer follow-up period could have revealed a statistically significant difference in the QoL between the groups. Yet, the longer the follow up, the more difficult it would be to link changes to the QoL score directly to the intervention.

The results of this study support new roles for pharmacists around the world and not just in Jordan. Pharmacists have shown through this intervention, that they have an

important role in caring for refugee patients, through the medication review service. This result agrees with the WHO recommendations relating to the published report by the High-Level Commission on Health Employment and Economic Growth, which calls for "ambitious solutions to ensure that the world has the right number of jobs for health workers with the right skills and in the right places to deliver universal health coverage".<sup>41,42</sup> A focus on a trained universal health-workforce that has the ability to deliver different healthcare services in humanitarian settings was highlighted.<sup>42</sup>

Study limitations include the length of follow-up. A longer follow up could have revealed different results. Future studies could also measure the health literacy around the current medications used by patients, as this may have been a key factor in the reduction in anxiety, with improved self-efficacy around personal health care. Future studies could also measure whether there was a significant change in the number of current medications, as this also can impact positively on anxiety levels, due to associated reduced cost and easier management of health care. Recommendations rejected by the physicians or not applied by the patients were not studied, which can be useful considering the value of physician-patient involvement in decision making.<sup>43</sup>

## CONCLUSIONS

This study has revealed that many refugees are living with numerous chronic health condition, numerous DRPs, low QoL and high anxiety levels. The medication review service provided by a clinical pharmacist led to significant improvements three months following the service provision in all measured outcomes, including reduction in DRPs, improved anxiety and improved QoL scores. Medication review is an essential aspect of patient care and communication between health providers can help optimize this care with significantly improved outcomes for the individual refugee patient. While this understanding is intuitively correct, few studies have captured the findings to document these benefits. Therefore, this study provides an important contribution to this understanding of medication review for displaced refugee communities. The positive outcomes of this study emphasizes the significant role pharmacists can play in delivering a vital and needed service in a vast humanitarian setting worldwide.

## CONFLICT OF INTEREST

None.

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