Empowering hypertensive patients on chronic medicines at primary health care facilities in South Africa with knowledge to improve disease management

Enos M Rampamba, MPharm
School of Pharmacy, Sefako Makgatho Health Sciences University, Garankuwa, South Africa. Email: mrampamba@gmail.com
Johanna C Meyer, PhD (Pharmacy). School of Pharmacy, Sefako Makgatho Health Sciences University, Garankuwa, South Africa. Email: hannelie.meyer@smu.ac.za
Elvera A Helberg, MSc(Med) (Pharmacy), Department of Pharmacy, Sefako Makgatho Health Sciences University, Garankuwa, South Africa Email: elvera@mweb.co.za
Brian Godman, PhD, Strathclyde Institute of Pharmacy and Biomedical Sciences, Strathclyde University, Glasgow G4 ORE, UK. Email: brian.godman@strath.ac.uk; Health Economics Centre, Liverpool University Management School, Chatham Street, Liverpool, UK. Email: Brian.Godman@liverpool.ac.uk; Department of Laboratory Medicine, Division of Clinical Pharmacology, Karolinska Institute, Karolinska University Hospital Huddinge, SE-141 86, Stockholm, Sweden. Email: Brian.Godman@ki.se; Department of Public Health Pharmacy and Management, School of Pharmacy, Sefako Makgatho Health Sciences University, Garankuwa, South Africa

*Author for correspondence: Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde, Glasgow G4 0RE, United Kingdom. Email: Brian.godman@strath.ac.uk. Telephone: 0141 548 3825. Fax: 0141 552 2562 and Division of Clinical Pharmacology, Karolinska Institute, Karolinska University Hospital Huddinge, SE-141 86, Stockholm, Sweden. Email: Brian.Godman@ki.se. Telephone + 46 8 58581068. Fax + 46 8 59581070

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Abstract
Objectives: Uncontrolled hypertension negatively impacts on mortality. This study aimed to evaluate the impact of a pharmacist-driven patient counselling and education model to empower hypertensive patients on chronic medication. Methods: An operational research project with a quasi-experimental design including an intervention group (55 patients) and a control group (31 patients) of chronic hypertensive patients. Data were collected with interview-administered questionnaires and analysed using SAS® version 9.4. Pharmacist interventions included an educational diary on hypertension management and patient counselling. Findings: There was a 34.7% improvement in patients' understanding of what normal blood pressure (BP) is in the intervention group compared to the control group ($p< 0.001$). A 9.1% improvement was also observed in the intervention group in knowledge about the fact that systolic and diastolic BP are both important in controlling hypertension, with no change in the control group. After the intervention, 40.0% of patients versus 17.9% in the control group had adequate knowledge (≥75% correct answers) about hypertension and its management. Pharmacist interventions were well received by the majority of patients (>90%). Conclusions: A pharmacist driven patient counselling and education model can help improve patients' hypertension knowledge and BP control. These should increasingly become routine, aiming to improve chronic disease management.

1. Introduction

South Africa has one of the highest prevalence rates of hypertension worldwide reaching 77.9% in those above 50,[1] with high rates generally among African countries.[1.2] Hypertension is the fastest growing non-communicable disease (NCD) in South Africa, with hypertension the major cause of death among patients with NCDs.[3] Overall, hypertension accounts for most deaths due to stroke and heart attacks across Africa.[1,2,4]

Primary Healthcare (PHC) facilities are the foundation of the South African healthcare system and where the majority of hypertensive patients are managed; however, there are concerns with blood pressure (BP) control.[5,6] Hypertensive patients should receive counselling and education when visiting PHC facilities, as well as be satisfied with their treatment to reduce future morbidity and mortality.[3,7-9]

Written hypertension information leaflets or booklets are effective with improving knowledge about hypertension and subsequent medicine taking,[10,11] with written information serving as a continuous

reliable source about the disease and its treatment.[8,11] Patients should receive such information during counselling, which currently does not always happen in South Africa.[6] Such booklets provide a platform for both pharmacists and patients to develop hypertension care plans, empowering patients to become more personally involved with their treatment.[10,11] This is important in South Africa given concerns with BP control,[6,12] and following the implementation of the Central Chronic Medicines Dispensing and Distribution (CCMDD) programme to enhance access to medicines for patients in the public system in South Africa.[12] Within the CCMDD programme, medicines are packaged and distributed free of charge to patients' nearest pick-up point to aid adherence.[12]

Consequently, the main aim of this study was to evaluate the impact of a pharmacist-driven patient counselling and education model in South Africa in PHCs to empower hypertensive patients with knowledge. The specific objectives were to determine hypertensive patients' knowledge of their disease and its management, BP control, and self-reported adherence to treatment before and after the implementation of the pharmacist intervention. Subsequently, to determine hypertensive patients' satisfaction with pharmacist interventions to inform future initiatives.

2. Method

Operational reserach project with a quasi-experimental design among patients with hypertension attending PHC facilities in the Vhembe District of Limpopo Province.[13] The original design used stratified random sampling to allocate 60 out of 120 facilities to intervention and control groups. The intention was to initially approach 600 patients based on an estimated 50% drop out rate following statistical advice. Stratification was undertaken according to municipality, type and size to ensure each group was balanced and comparable. However, challenges such as community strikes and riots meant only 50 PHCs eventually took part, 25 in each group.

Data were collected on the scheduled clinic-return date over six months by trained pharmacists, with a 4-month interval for each patient between baseline and post-intervention visits. Randomisation was used to select up to 15 hypertensive patients per facility based on the availability and willingness of patients who met the inclusion criteria on the day of data collection, which was principally adults on chronic antihypertensive treatment for more than six months and without organ damage. The first random patient was approached, enrolled if willing, and when completed, the next available patient was approached. This process continued resulting in 253 patients being eventually enrolled in the study, 138 in the intervention group and 115 in the control group. These differences reflect that only patients with baseline- and post-intervention data were initially included in the analysis.

Patients in both groups received usual care and were requested to collect their medicines monthly. The intervention group was exposed to a pharmacist intervention at enrolment with the control group introduced to the intervention at the end. The pharmacist intervention included a hypertension information diary for daily use, with 15-30 minutes patient counselling and education about hypertension and its management, and the correct use of the diary. The diary also had space for patients to record their BP, lifestyle changes and any adverse effects. The counselling was performed on the first visit immediately after the questionnaire was administered.

A structured questionnaire was developed based on previously published studies,[14-16] translated into local languages and piloted amongst 22 hypertensive patients from another district in the Province with a similar socioeconomic status as the study PHCs. This assisted in simplifying the language used, helping to avoid different interpretations. Training of all data collectors and cross-checking of entered data took place to ensure the validity and reliability of the data.

The validity of the results was supported by the study design in which the control group was exposed to the same conditions as the intervention group except for the patient counselling and education model (intervention). Demographic data included educational status with patients with formal education (completed at least primary school and up to secondary school- and tertiary education) were classified as educated.[17]

Patients' knowledge on hypertension and its management, self-reported adherence and lifestyle habits, were assessed for both groups. Patients knowledge testing questions were classified into 4 groups including (1) understanding and knowledge of hypertension; (2) Knowledge on BP measurement and readings; (3) Knowledge about medication and lifestyle and (4) Knowledge of the

dangers of uncontrolled high BP. Adequate knowledge about hypertension was considered as 75% of answers provided correctly.[18] Patients rated their adherence to treatment using six pre-defined categorised responses, i.e. excellent, very good, good, fair, poor and very poor), previously used in adherence studies.[9,19] Previous studies had revealed that participants felt more comfortable and confident with words compared to numbers for rating adherence, and a 30-day recall performed better compared to a three-day or seven-day recall.[19,20]

Sensitivity analyses were performed using Chi-square tests. Patients' BP as taken by the nurse at the facility on the day of data collection was recorded on their clinic patient record card. BP recordings between enrolment and study end were collected retrospectively. At the study end, patients with uncontrolled BP were counseled on medication adherence and referred to the medical practitioner to assess their treatment regimen and discuss future care.

Data were captured electronically on Microsoft Excel™. Responses to open-ended questions were typed-up manually and grouped into categories. Data were analysed using SAS® version 9.4. Baseline characteristics between the intervention group and the control groups were compared using the Fisher's Exact Test. Positive changes in hypertension management knowledge from baseline to the final post-intervention visit in the intervention and control groups was determined using the same test. A two-sided p-value ≤ 0.05 indicated statistical significance.

The primary outcome was the proportion of patients with adequate knowledge of the management of hypertension after the pharmacist intervention. Secondary outcomes included (i) positive changes for individual variables from baseline to post-intervention; (ii) decrease in systolic and diastolic BP; (iii) proportion of patients with controlled BP; and (iv) the proportion of patients being satisfied with the pharmacist intervention. The pharmacist intervention was considered acceptable if there was at least 80% agreement or satisfaction amongst all respondents.

Ethical clearance for the study was obtained from the Medunsa Research Ethics Committee of the University of Limpopo, currently Sefako Makgatho Health Sciences University (MRECH 27/2014:PG). Permission to conduct the study was obtained from the Limpopo Department of Health and the Vhembe District Executive Manager. All patients provided written informed consent to participate.

3. Results

Losses to follow-up resulted in a final sample of 55 patients in the intervention group and 31 in the control group.

Table 1 shows that females predominated with no differences in baseline characteristics between the groups. Comorbidities were present in 33.3% of control group and 50.9% among intervention patients, of which diabetes was most common. Other co-morbidities included shortness of breath, ulcers, heart problems and arthritis.

Table 1: Comparison of baseline characteristics between the intervention group and the control group

Patient characteristics		Intervention group (n=55)	Control group (n=31)	*P**
Gender; n (%)	Female	49 (89.1)	25 (80.7)	
	Male	6 (10.9)	6 (19.4)	0.337
Age (years)	Mean ± SD	62.1 ± 11.2	65.9 ± 12.0	0.145
	Median (IQR)	63 (53 – 67)	65 (59 – 76)	-
Marital status; n (%)	Married	27 (49.1)	18 (58.1)	
	Divorced	3 (5.5)	0	
	Never married	9 (16.4)	4 (12.9)	
	Separated	1 (1.8)	0	
	Widowed	15 (27.2)	9 (29.0)	0.755
Education†; n (%)	Educated	23 (41.8)	13 (41.9)	
	Uneducated	32 (58.2)	18 (58.1)	1.000
Comorbidities; n (%)	Comorbidity	27 (49.1)	10 (33.3)	
	No comorbidity	28 (50.9)	20 (66.7)	0.178
	Diabetes as comorbidity	16 (29.6)	5 (16.7)	0.292
Duration on treatment; n (%)	1-5 years	14 (25.4)	9 (29.1)	
	>5 years	41 (74.6)	22 (70.9)	0.801
Blood pressure; mean ± SD	Systolic blood pressure	138.6 ± 21.8	138.7 ± 21.6	0.990
	Diastolic blood pressure	78.9 ± 9.6	82.6 ± 11.1	0.118
Weight and BMI; mean±SD	Weight (kg)	76.7 ± 14.5	76.6 ± 14.2	0.962
	BMI	30.9 ± 6.8 (n=32)	30 ± 4.8 (n=10)	0.673

*Fisher's Exact Test; †Completed at least primary education; SD=Standard deviation; IQR=Interquartile range; BMI=Body mass index

Before the intervention, approximately 90% of patients in both groups did not have adequate knowledge about hypertension management. This changed with 40.0% of patients in the intervention group and 17.9% in the control group having adequate knowledge, although not statistically significant.

Table 2 shows the positive changes for each knowledge question and self-reported adherence from baseline to post-intervention visits for both groups. However, although a number of positive changes were observed after the pharmacist intervention, the only statistically significant ($p<0.001$) improvement was in the understanding of normal BP.

Table 2: Positive changes in hypertension management knowledge from baseline to the final post-intervention visit in intervention and control groups

	Positive changes from baseline to post-intervention			
	Intervention group		Control group	
Statement	**Number/ sample size**	**%**	**Number/ sample size**	**%**
Understanding and knowledge of hypertension				
Definition of hypertension	20/49	40.8	14/29	48.3
Normal blood pressure	17/49	34.7	0/25	0.0
Causes of high blood pressure	13/53	24.5	6/28	21.4
Benefits of taking medicines for high BP correctly	9/45	20.0	4/27	14.8
Knowledge on BP measurement and readings				
Importance of BP numbers	5/55	9.1	0/29	0.0
Meaning of the reported BP numbers	6/55	10.9	1/28	3.57
BP readings written down on paper	13/55	23.6	3/29	10.3
Knowledge about medication and lifestyle				
Taking hypertension medicines as prescribed is necessary and important	0/55	0.0	0/31	0.0
Exercise is important to control high BP	1/49	2.0	0/27	0.0
Smoking is dangerous to hypertensive patients	2/49	4.1	1/29	3.5
Alcohol is dangerous to hypertensive patients	2/50	4.0	2/29	6.9
Can do something to lower high BP	16/53	30.2	9/30	30.0
Knowledge about hypertension complications and its dangers				
Dangers of uncontrolled high BP	6/55	10.9	2/28	7.1
Self-reported medication adherence	6/55	10.9	12/31	38.7[#]

NB: [#]Significant improvement in the control group; BP = Blood pressure

19.5% patients in the intervention group and 10.7% in the control group who had uncontrolled BP at baseline had controlled BP post-intervention (Table 3). However, this did not reach statistical significance.

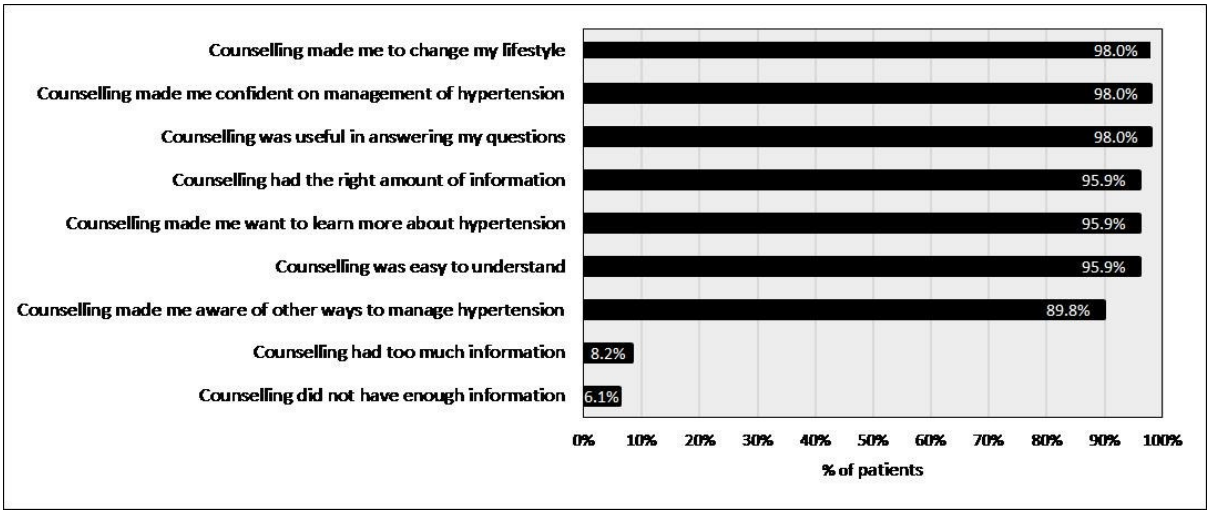
Table 3: Changes in mean systolic and diastolic blood pressure (BP) from baseline to post-intervention for the intervention and control groups

		Mean blood pressure; mmHg (SD)			
		N	**Intervention group**	**n**	**Control group**
Mean systolic BP	**Baseline**	52	138.6 (21.8)	31	138 (21.6)
	Post-intervention	55	135.7 (22.0)	28	138.4 (20.1)
	Change: Baseline to post-intervention*	40	-4.6	28	0.75
	p-value		0.122		0.869
Mean diastolic BP	**Baseline**	52	78.9 (9.6)	31	82.6 (11.1)
	Post-intervention	55	76.6 (11.3)	28	79.1 (12.9)
	Change: Baseline to post-intervention*	40	-2.5	28	-1.46
	p-value	40	0.272	28	0.496
Intervention group vs. control group*	**p-value**	40	0.584	28	0.379

NB: [*]Change was calculated only in patients with baseline and post-intervention data

The majority (≥89.8%) of patients in the intervention group expressed their satisfaction with various aspects of the counselling by pharmacists (Figure 1).

Figure 1: Patient satisfaction with pharmacist counselling and education (intervention group)



Most (97.7%) patients found the dairies easy to use, motivated them to change their lifestyle, and become more health wise. 90.9% stated the studies aided them to remember their medicines and clinic appointments. 90% of the patients who were exposed to the diary expressed their satisfaction with its content and use. Only a minority found them time consuming (43.2%). Family members also supported patients helping them to improve their BP control. This included reading from the diaries for those having difficulties, helped by trust in the information provided with this typically shared with family members and friends. Some patients though preferred face-to-face counselling sessions with the pharmacist instead of an information booklet, which needs to be factored into any future programme.

4. Discussion

It was encouraging to see pharmacist-driven interventions being well received, similar to Dawes et al in which a patient booklet was well received.[10] Some patients subsequently requested this pharmacist-driven intervention should be routinely implemented in PHCs throughout South Africa to assist with reducing BP. The strengthening of patient-pharmacist relationships could help improve satisfaction with healthcare services generally and treatment outcomes in the future.

There was also an indication that written information can improve patients' knowledge of hypertension with patients sharing their information with family and friends. In addition, those experiencing reading difficulties were assisted by family members. These factors should be considered as South Africa instigates a number of measures to improve adherence to medicines in patients with NCDs including the CCMDD programme.[12]

The greater change in patients' knowledge of what hypertension is in the control group may be due to patient curiosity after being asked what hypertension is during enrolment versus the knowledge provided to the intervention group. In addition, this knowledge was only provided once in the intervention group at the start, and forgetfulness could be an issue in the intervention group.[11]

However, to balance this, there was a significant improvement in patients' knowledge of what is normal BP in the intervention group (Table 2), similar to other studies.[10,11,21] A positive change in the intervention group in knowing that both systolic and diastolic BP readings are important for controlling hypertension is encouraging as this is likely to improve patients' involvement in the management of their disease.[22]

A positive change was also seen in BP control, with a greater reduction in the intervention group (Table 3); however, this did not reach significance. This may be due to high dropout rates as significant changes have been seen in BP control in patients with hypertension after pharmacist interventions in other studies.[21]

A negative finding was that self-reported medication adherence significantly improved in the control group compared to the intervention group (Table 2). This may be due to improved relationships between patients and pharmacists resulting in honest answers.[23] Consequently, low adherence in the intervention group may be a better representation of actual practice,[23,24] with previous studies showing that knowledge is the most significant factor in medicine adherence among hypertensive patients.[25]

With improved medicines accessibility through the CCMDD programme in South Africa,[12] it will be important to strengthen patients' involvement in their treatment. Such programmes should also include potential ways of addressing illiteracy among patients where this is a concern to help complete hypertension diaries.

The main limitation was the high dropout rate due to the inaccessibility of some of the PHCs. Cross-contamination between the intervention and control groups cannot be excluded. We have also not been able to compare our findings as we are unaware of studies that have jointly assessed the combination of patient diaries and counselling. Despite these limitations, we believe our findings give a basis for improving the future care of hypertensive patients in PHCs in South Africa.

In conclusion, encouragingly patients in PHC facilities in South Africa were highly satisfied with the pharmacist intervention, laying a strong foundation for improving collaboration in the future. Consequently, it is recommended that this intervention model be further developed and tested, with a greater focus on lifestyle changes and clinical outcomes. Pharmacists should also help routinely instigate and review patient diaries to help improve future control of blood pressure.

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Author contributions
EMR, JCM and EAH devised the concept for the study, developed the questionnaire and educated the pharmacists taking part. EMR and JCM undertook the initial analysis. EMR, JCM and BBG undertook the first draft of the paper, with all authors involved in the initial draft and subsequent revisions.

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References

1. Lloyd-Sherlock P, Beard J, Minicuci N et al. Hypertension among older adults in low- and middle-income countries: prevalence, awareness and control. IJE. 2014;43(1):116-28.
2. Irazola VE, Gutierrez L, Bloomfield G et al. Hypertension Prevalence, Awareness, Treatment, and Control in Selected LMIC Communities: Results From the NHLBI/UHG Network of Centers of Excellence for Chronic Diseases. Global heart. 2016;11(1):47-59.
3. Rampamba EM, Meyer JC, Godman B et al. Evaluation of antihypertensive adherence and its determinants at primary healthcare facilities in rural South Africa. JCER. 2018;7(7):661-72.
4. Mbui JM, Oluka MN, Guantai EM et al. Prescription patterns and adequacy of blood pressure control among adult hypertensive patients in Kenya; findings and implications. ERCP. 2017;10(11):1263-71.
5. Lalkhen H, Mash R. Multimorbidity in non-communicable diseases in South African primary healthcare. SAMJ. 2015;105(2):134-8.
6. Rampamba EM, Meyer JC, Helberg E, Godman B. Knowledge of hypertension and its management among hypertensive patients on chronic medicines at primary health care public sector facilities in South Africa; findings and implications. ERCT. 2017;15(8):639-47.

7. NDOH. National Department of Health. STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINES LIST FOR SOUTH AFRICA Available at URL: http://www.kznhealth.gov.za/pharmacy/edladult_2012.pdf
8. Patel S, Dowse R. Understanding the medicines information-seeking behaviour and information needs of South African long-term patients with limited literacy skills. Health Expectations. 2015;18(5):1494-507.
9. Nielsen JO, Shrestha AD, Neupane D, Kallestrup P. Non-adherence to anti-hypertensive medication in low- and middle-income countries: a systematic review and meta-analysis of 92443 subjects. Journal of human hypertension. 2017;31(1):14-21.
10. Dawes MG, Kaczorowski J, Swanson G et al. The effect of a patient education booklet and BP 'tracker' on knowledge about hypertension. A randomized controlled trial. Fam Pract. 2010;27(5):472-8.
11. Arul KSG et al. Development and Implementation of Patient Information Leaflet on Hypertension and to Assess its Effectiveness. International Journal of PharmTech Research.1 (3):712-9.
12. Meyer JC, Schellack N, Stokes J et al. Ongoing Initiatives to Improve the Quality and Efficiency of Medicine Use within the Public Healthcare System in South Africa; A Preliminary Study. Frontiers in pharmacology. 2017;8:751.
13. Zachariah R, Harries AD, Ishikawa N et al. Operational research in low-income countries: what, why, and how? The Lancet Infectious diseases. 2009;9(11):711-7.
14. Iyalomhe BS, Iyalomhe S. Hypertension-related knowledge, attitudes and life-style practices among hypertensive patients in a sub-urban Nigerian community. J Epidemiol Public Health. 2010;2(4):71-7.
15. Edo T. Factors affecting compliance with anti-hypertensive drug treatment and required lifestyle modifications among hypertensive patients on Praslin Island. Dissertation, University of Pretoria. Available at URL: http://uir.unisa.ac.za/bitstream/handle/10500/3249/dissertation_edo_t.pdf?sequence=1. .
16. Oliveria SA, Chen RS, McCarthy BD et al. Hypertension knowledge, awareness, and attitudes in a hypertensive population. JGIM. 2005;20(3):219-25.
17. Vagvolgyi R, Coldea A, Dresler T et al A Review about Functional Illiteracy: Definition, Cognitive, Linguistic, and Numerical Aspects. Frontiers in psychology. 2016;7:1617.
18. Han HR, Chan K, Song H et al. Development and evaluation of a hypertension knowledge test for Korean hypertensive patients. JCH. 2011;13(10):750-7.
19. Vagiri RV, Meyer J, Gous AGS. Health-related quality of life and adherence to antiretroviral treatment over a 12-month period for patients attending two public sector clinics in South Africa. African Journal for Physical, Health Education, Recreation and Dance. 2015;Supplement 2.2:228-40.
20. Wilson IB, Fowler FJ, Jr., Cosenza CA et al. Cognitive and field testing of a new set of medication adherence self-report items for HIV care. AIDS and behavior. 2014;18(12):2349-58.
21. Pawar S LK, Padma S, Diwan A. Effect of pharmacist mediated patient counselling in hypertensive patients in terms of knowledge, compliance and lifestyle modification. IJPPS 2014;6(4):277-81.
22. Yi-Bing W, De-Gui K, Long-Le M, Le-Xin W. Patient related factors for optimal blood pressure control in patients with hypertension. AHS. 2013;13(3):579-83.
23. Albrecht S. The pharmacist's role in medication adherence. US Pharm. 2011;36(5):45-8.
24. Shirindi ML MJ, Fraeyman J Barriers to Medication Adherence Among Women Living in Rural Areas Suffering from Hypertension: The Case of Dikgale-Communities. Ethno Med. 2016;10(1):76-86.
25. Jankowska-Polanska B, Uchmanowicz I, Dudek K, Mazur G. Relationship between patients' knowledge and medication adherence among patients with hypertension. Patient preference and adherence. 2016;10:2437-47.