



Safe and Effective Use of Medicines for Ethnic Minorities - A Pharmacist-Delivered Counseling Program That Improves Adherence

Pernille Dam*, Mira El-Souri, Hanne Herborg, Lotte Stig Nørgaard, Charlotte Rossing, Morten Sodemann and Linda Aagaard Thomsen

Danish College of Pharmacy Practice, Hillerød, Denmark

Abstract

Background: From studies, we know how ethnic minorities and people with reduced work ability often suffer from health problems, thus being socially disadvantaged. The municipal job centers are confronted with numerous problems related to medicine use and they lack relevant means of referral. Thus, there was a need to adapt a previously developed and validated medicine-based intervention “safe and effective use of medicines” to this vulnerable group of unemployed ethnic minority patients.

Methods: The objective of this before-after study was to improve medicines adherence, health status and work ability of the target group through an individualized pharmacist delivered intervention with focus on safe and effective implementation of medical treatments. The target group was ethnic minorities of non-western origin affiliated with a job center.

Results: At baseline, 35.7 % of the patients had a potential adherence behavior problem Powered by Editorial Manager® and ProduXion Manager® from Aries Systems Corporation (having an average adherence score of less than 5); at endpoint, this number had decreased to 27.3 %, meaning that 8.4 % no longer had potential adherence problems. Self-reported adherence was significantly improved on three out of four subscales (“Intentional, self-regulation” from 4.5 to 4.7, $p=0.016$); “Unintentional” from 3.9 to 4.2, $p=0.009$); “Intentional, effect-related” from 4.0 to 4.4, $p=0.025$; “General” 4.3 to 4.5, $p=0.173$.). On average, 47 % of the patients experienced improvements in concordance, due to the intervention.

Conclusion: The counseling program “Safe and effective use of medicines” was successfully adapted to unemployed ethnic minority patients, and tested in a new collaboration between job centers and community pharmacies. The counseling program resulted in statistically significant improvements in self-reported adherence as well as improved concordance for approximately half of the patients. Improvements in adherence removes one barrier for returning to the work force that exists in the complex interaction between adherence, health status and work ability.

Keywords: Ethnic minorities; Medication adherence; Pharmaceutical care; Community pharmacy; Unemployment; Concordance; Work ability

Introduction

Ethnic minorities and people with reduced work ability often suffer from health problems and a high unemployment rate, thus being socially disadvantaged [1]. Many unemployment beneficiaries have physical and mental illnesses [2,3]. In Denmark, the employment rate of ethnic minorities with a non-western background is significantly lower than in the background population [4]. Mental illness, musculoskeletal disorders and cardiovascular diseases are some of the most prevalent reasons for unemployment and disability income benefits. They experience physical, economical, temporal and mental barriers against being active in restoring or maintaining their health. The self-assessed health status is lower for the unemployed and ethnic minorities than in the average population [5]. Professionals working with unemployment groups point to the need for progressing slowly when promoting health among socially disadvantaged groups [6]. As patients, such groups need multidimensional interventions and tailored solutions taking into account the multifaceted causes of their medication-related problems [1].

The health-related problems and reduced work ability is enhanced for ethnic minorities due to language barriers, low health literacy, low self-efficacy, insufficient knowledge about disease and treatment as well as a culturally and an individually based incongruence between the view of the patient and health care provider [1,7-13].

The literature regarding prevalence, causes and connections between

medicines non-adherence and work ability among non-western ethnic minority groups is scarce. However, Danish studies among ethnic minorities have identified a high prevalence of medication-related problems in such patients, and also found that these problems could be identified, assessed and solved in collaboration between the patient, the community pharmacy and the general practitioner [14,15].

Employees at the Danish job centers taking part in this study have communicated to us, that they are often asked questions about medicines from ethnic minority citizens from non-western countries.

The ethnic minorities express difficulties coping with and assessing their medicines and often show signs of non-adherence. Insufficient implementation of a medical treatment can prevent or delay the process of assessing the ethnic minorities’ health and work ability. Danish job centers have a range of extended intervention programs to

***Corresponding author:** Pernille Dam, Msc Public Health Science, Pharmakon -Danish College of Pharmacy Practice, Hillerød, Denmark, Tel: +4528920938; E-mail: pd@pharmakon.dk

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assist unemployed and sickness beneficiaries in returning to the labor market, but until now, none of these programs has focused on the link between medicines use, health and work ability [16].

The previously developed and validated program “safe and effective use of medicines” delivered by community pharmacies has been shown to significantly improve adherence, health, well-being, knowledge, and satisfaction, in patients with chronic illnesses such as cardiovascular diseases or diabetes [17,18]. Adapting the program towards the needs of vulnerable, unemployed ethnic minority patients may have the potential to link medicines use, health and work ability.

The objective of the study was to improve medication adherence, health status and work ability of unemployed non-western ethnic minorities through an individualized community pharmacy delivered intervention focusing on safe and effective implementation of medical treatments. This article focuses on the effects of the intervention on medication adherence and concordance.

Materials and Methods

Study design

The study was conducted from October 2011 to December 2013. The study design was a formative before-after study with focus on adaptation of the program “Safe and effective use of medicines” to the target group of unemployed ethnic minority patients as well as implementation in four municipalities.

Setting

Four municipalities participated with one job center each, all situated in larger cities. Five local community pharmacies participated (two pharmacies participated in the municipality who included the highest number of patients).

Population

Ethnic minorities of non-western origin receiving unemployment or sickness benefits and affiliated with a participating job center were included. The social worker offered clients receiving at least three medicines for a chronic disease or showing signs of medication-related problems participation in the study. Patients agreeing to participate were referred to the participating local community pharmacy. All patients were offered interpretation in their native language. The counseling sessions took place at the pharmacy or the job center, as agreed locally.

The intervention - Safe and effective use of medicines for ethnic minorities

The intervention consisted of an individualized and multi-dimensional model for designing targeted solutions in collaboration with potential non-adherent patients. The model was based on a systems

approach suggested by World Health Organization (WHO), with five interacting dimensions influencing adherence: Social and economic factors; Health care team and system related factors; Condition-related factors; Patient-related factors; and therapy-related factors [19]. The WHO model was combined with Pharmaceutical Care models and theories focusing on therapy outcomes monitoring and patient empowerment leading to better self-management and adherence [20-22]. The model “Safe and effective use of medicines” was developed for implementation in primary care [16]. Various strategies were used: review of the patient’s medication profile and refill adherence; assessing goals for clinical parameters; assessing and distinguishing between types of non-adherence; use of patient narratives, motivational interviews, and coaching techniques; patient education, adherence-supporting technologies and collaboration with general practitioners. The model was validated for patients with hypertension and type 2-diabetes, based on the framework for complex interventions published by the British Medical Research Council (MRC) [23]. Hence, the model and the individual elements were evaluated and tested in more explorative and learning-oriented studies focusing on process and feasibility [24,25].

In this study, the program was adapted to suit the needs of the target population. The core content of the program was unchanged and only minor adjustments were made. The materials for patient education were altered so they became more visual and topics about the health care system were added. The theoretical and practical implications of counseling with an interpreter were added to the pharmacists’ training program. Theoretical aspects of working with minority citizens were added to the training as well. The time frame for the program was increased to 6 hours, as interpretation prolonged the counseling sessions. The time frame included time for delivery of the sessions, documentation and communication with general practitioners and social workers.

The focus of the four counseling sessions in the intervention is outlined Table 1.

Program delivery by community pharmacies

The participating pharmacists received a two-day educational course designed to prepare them for program delivery. A prerequisite for participation was previous experience with medication review. Materials to support the counseling program were developed by the research group and included: a pharmacist manual and interview guides for each session, supportive tools (questionnaire to detect potential adherence problems and individual goals, theoretical systems model for identifying problems and solutions, materials for patient education, list of relevant educational websites, adherence supporting tools, and instructions for motivational interviewing).

Session 1 Patient narrative on disease and treatment	Session 2 Medication review	Session 3 Patient education & adherence support	Session 4 Motivation & follow up
Narrative interview with patient on health, disease, treatment and daily living. Brown bag medication review (medicine brought by patient) Individual goal setting Questionnaire on health work ability and adherence	Data for medication review was: - Brown bag review from session 1 - Personal electronic medication profile Potential medication related problems were sought verified with the patient. Solutions were made in agreement. Patients GP was involved if changes to prescription was needed. Shared decision on topic for patient education. Follow up on individual goal.	Individually tailored patient education on topic relevant to the patient. Adherence support was initiated if needed – i.e. reminders, dosettes, social network support etc. Follow up on individual goal.	Follow up and adjustment of the previously made agreements and goals. Focus on the patient’s motivation for maintaining appropriate behavior in relation to medicine taking or life style changes.

Table 1: Outline of the intervention “Safe and effective use of medicines for unemployed ethnic minority patients”.

Data collection and analysis

Data from patients were collected via a questionnaire given at baseline and endpoint (given to the patient at the first and last counseling session). The patients filled in the questionnaire with assistance from the interpreter. The baseline questionnaire was a tool used by the pharmacist to tailor the following counseling sessions according to patient needs.

The questionnaire was previously validated as a quick screen instrument for potential non-adherence. The questionnaire was shortened to accommodate the low health literacy of the target group. Based on feedback from the pharmacists and the interpreters, pictograms were developed to increase understanding of numeric scales, which did not always make sense to the patients.

Self-reported adherence behavior was detected by a validated questionnaire [25], differentiating between intentional and unintentional non-adherence (Table 2). It consisted of three subscales related to behavior-related non-adherence: “unintentional”, “intentional self-regulation”, “intentional”, and “effect-related”. The questions were hypothetical and answers were given on a 5-point Likert scale with 1 = always and 5 = never. The scale was used to calculate an adherence-score at baseline and endpoint, in order to show progression in adherence behavior. An average adherence score across all questions of less than 5 meant that the patient had a potential adherence behavior problem.

At endpoint, patients were asked to assess the effects of the

counseling program on their health and medicines related knowledge, adherence, feeling of confidence with medicines use, and concordance. Social workers and pharmacists were asked about the same domains in an endpoint questionnaire (Tables 3-6). Data on self-assessed effects reported by patients, pharmacists and social workers were compared to extract valuable aspects and strengthen validity of the data. Data were reported as frequencies. Data on self-assessed improvement in adherence and motivation to adhere to treatment were collected from patients in the more detailed questionnaire reported in Table 2, and is therefore not in the comparison (Figure 1).

Statistical analysis was conducted with IBM SPSS Statistics Base 17.0 for Windows®. Only patients with complete adherence data at both baseline and endpoint were included in the analysis of changes in adherence behavior (n=43). A paired t-test was used for the comparison, and data reported with a significance level of 0.05.

Ethics

All participating patients gave informed consent. The form was translated into the seven most prevalent languages of the target population (Arabic, Somali, Turkish, Bosnian, Vietnamese, Farsi and Afghan). The patients gave written consent to the pharmacist having access to their medication profile and sharing information with their social worker and general practitioner. The study was registered with and applied to the guidelines of The Danish Data Protection Agency. According to guidelines from the Danish National Committee on

Subscale	Question	Adherence score (n=43)		
		Baseline Mean score (St.d.)	Endpoint Mean score (St.d.)	p-value (paired t-test)
General		4,3 (1,15)	4,5 (0,88)	0,173
	I take my medicines exactly as instructed	4,2 (1,15)	4,6 (0,88)	0,173
Intentional, self-regulation		4,5 (0,75)	4,7 (0,50)	0,016
	I stop taking my medicines for a while	4,4 (1,05)	4,8 (0,51)	0,023
	I take less of my medicines than instructed	4,4 (1,13)	4,6 (1,03)	0,317
	I take more of my medicines than instructed	4,5 (1,06)	4,7 (0,83)	0,202
	I decide to miss out a dose	4,5 (0,94)	4,7 (0,73)	0,107
	I stop taking my medicines, when I feel that my illness is under control	4,3 (1,19)	4,6 (0,95)	0,085
	I stop taking my medicines if I do something else to improve my health (e.g. stop smoking, exercise, weight loss)	4,7 (0,95)	4,7 (0,79)	1,000
Unintentional		3,9 (1,06)	4,2 (0,95)	0,009
	I generally forget to take my medicines	3,9 (1,07)	4,0 (1,08)	0,696
	I forget to take my medicines, when I am not at home	4,1 (1,17)	4,5 (1,05)	0,025
	I forget to take my medicines, when I am busy	3,8 (1,43)	4,2 (1,19)	0,028
	I have difficulties remembering to take my medicines	3,7 (1,47)	4,1 (1,18)	0,033
Intentional – effect-related		4,0 (1,51)	4,4 (1,14)	0,025
	I stop taking my medicines if I experience side effects of the medicines	3,8 (1,60)	4,4 (1,35)	0,005
	I stop taking my medicines if I believe they don't work	4,2 (1,52)	4,4 (1,16)	0,259

Table 2: Adherence score at baseline and endpoint.

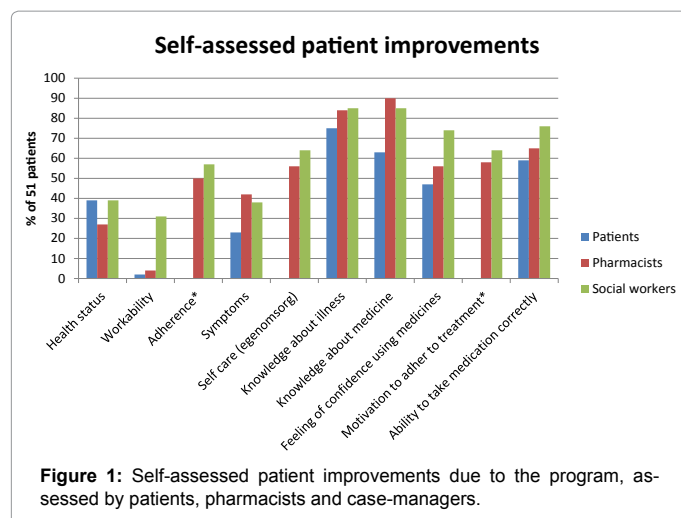


Figure 1: Self-assessed patient improvements due to the program, assessed by patients, pharmacists and case-managers.

Concordance N=51	Improved N (%)	Unchanged N (%)	Worsened N (%)
My satisfaction with the decisions made regarding my treatment	22 (43 %)	27 (53 %)	2 (4 %)
My influence on decisions regarding my treatment	23 (45 %)	28 (55 %)	0
My ability to carry out the agreements, that have been made regarding my treatment	23 (45 %)	26 (51%)	2 (4 %)
My knowledge in relation to taking part in decisions regarding my treatment	28 (55 %)	23 (45 %)	0
The way my point of view regarding the treatment of my illness(es) is being considered	24 (47 %)	25 (49 %)	2 (4 %)
Average	24 (47 %)	26 (51 %)	1 (2 %)

Table 3: Self-assessed improvement in concordance.

Self-assessed outcomes N =51 (%)	Improved N (%)	Unchanged N (%)	Worsened N (%)
My knowledge about the medicines' effect on my illness has...	38 (75 %)	13 (25 %)	0
My knowledge about my illness has...	32 (63 %)	19 (37 %)	0
My knowledge about the influence of my lifestyle on my illness has...	31 (61 %)	20 (39 %)	0
My ability to use my medicines correctly has...	30 (59 %)	21 (41 %)	0
My feeling of confidence using my medicines has...	24 (47 %)	27 (53 %)	0
My illness has...	20 (39 %)	23 (45 %)	8 (16 %)
My relationship with my doctor has...	13 (25 %)	35 (69 %)	3 (6 %)
My symptoms have...	12 (23 %)	31 (61 %)	8 (16 %)
My quality of life has...	8 (16 %)	38 (75 %)	5 (9 %)
My work ability has...	1 (2 %)	37 (76 %)	11 (22 %)

Table 4: Patients self-assessed outcomes due to the program.

Health Research Ethics, it is not possible to request approval for non-biomedical intervention studies [26].

Results

Eighty-two patients participated in the counseling program; 51 (62.2 %) completed both the baseline and the endpoint questionnaire. The remaining patients (38 %) either dropped out (mainly due to the patient feeling overwhelmed by the program) or were discontinued by the pharmacist who found no reasons to continue with the sessions.

The patients' age ranged from 25 years to 63 years (mean 47 years; s.d. 7.6); 64 (78 %) were female and 18 male (22 %). The patients

originated from 14 countries, Turkey, Iraq and Vietnam being the most prevalent. The medicines most prevalently used were for mental disorders (often depression) and pain.

Adherence and concordance

At baseline, 35.7 % of the patients had a potential adherence behavior problem (having an average adherence score of less than 5); at endpoint, this number had decreased to 27.3 %, meaning that 8.4 % no longer had potential adherence problems. Table 2 shows that the adherence scores on the subscale detecting unintentional non-adherence are lower than other subscales at baseline. One subscale did not significantly improve (general adherence), whereas the other three subscales significantly improved: "Intentional, self-regulation" from 4.5 to 4.7, $p=0.016$, "Unintentional" from 3.9 to 4.2, $p=0.009$, "Intentional, effect-related" from 4.0 to 4.4, $p=0.025$. Adherence data is missing for three patients, the cause of which is unknown.

On average, 47 % of the patients experienced improvements in concordance (Table 3). Between 43 % and 55 % of patients experienced an improvement in one of the five concordance-related domains as a result of the counseling program.

Comparison of data on assessed patient outcomes due to the program revealed that social workers estimated the improvements higher than pharmacists' and the patients did (Figure 1 and Tables 4-6). The largest difference in assessed improvement was in relation to work ability, where the case-managers assess improvement for 31 % of patients, pharmacists assess improvement for 3 %, and 2 % of the patients themselves assess improved work ability. Pharmacists were not formally trained to assess work ability, but were merely asked their opinion. The tendencies of assessed improvements were the same however, across categories, with improvement in knowledge and adherence categories being the most prevalent and health status, work ability and improvement in symptoms being the least prevalent across professionals and patients. The endpoint questionnaire showed that the majority of patients reported that the intervention improved their knowledge (between 61 % and 75 % of patients) and their ability to use medicines correctly (59 % of patients) (Table 4). For the remaining parameters, the majority of patients reported that the intervention had had no effect. Few patients reported improvements in quality of life (16 %) and work ability (2 %).

Data on social workers' assessments of outcomes exists for 42 of the 51 patients. The reason for not responding was that the patient no longer was assigned to the social worker who therefore was unable to do the follow up. Some social workers had limited contact with the patient and were therefore unable to assess all parameters, which limited the data collection.

Discussion

The counseling program "Safe and effective use of medicines" was successfully adapted to a vulnerable group of unemployed ethnic minority patients in a collaborative setting between municipal job centers and community pharmacies. The counseling program has previously shown significant improvements in outcomes for patients with hypertension and type 2-diabetes [17,24,25].

We found statistically significant improvements in adherence scores on the scales "unintentional non-adherence" and the two scales representing intentional non-adherence "self-regulation" and "effect related". The results show that knowledge about and attitudes towards medicines changed through counseling. Additionally, a statistically

Job center assessed outcomes N = 42 (%)	Improved N (%)	Unchanged N (%)	Worsened N (%)	Not able to assess N (%)	Missing N (%)
Knowledge about medicines	36 (85 %)	4 (10 %)	0	2 (5 %)	0
Knowledge about illness	36 (85 %)	4 (10 %)	0	2 (5 %)	0
Ability to take medicines correctly	32 (76 %)	6 (14 %)	0	4 (10 %)	0
Motivation to adhere to treatment	27 (64 %)	10 (24 %)	0	5 (12 %)	0
Feeling of confidence using medicines	31 (74 %)	8 (19 %)	0	3 (7 %)	0
Health status	16 (39 %)	24 (57 %)	1 (2 %)	1 (2 %)	0
Functional ability	16 (39 %)	22 (52 %)	1 (2 %)	3 (7 %)	0
Adherence	24 (57 %)	12 (29 %)	0	5 (12 %)	1 (2 %)
Symptoms	16 (38 %)	22 (52 %)	0	4 (10 %)	0
Self care	27 (64 %)	11 (26 %)	0	3 (7 %)	1 (2 %)
Work ability	13 (31 %)	26 (62 %)	1 (2 %)	2 (5 %)	0

Table 5: Job center assessed patient outcomes due to the program.

Pharmacist assessed outcomes N = 48 (%)	Improved N (%)	Unchanged N (%)	Worsened N (%)	Not able to assess N (%)	Missing N (%)
Knowledge about medicines	43 (90 %)	2 (4 %)	0	3 (6 %)	0
Knowledge about illness	40 (84 %)	5 (10 %)	0	3 (6 %)	0
Ability to take medicines correctly	31 (65 %)	13 (27 %)	1 (2 %)	3 (6 %)	0
Motivation to adhere to treatment	28 (58 %)	17 (36 %)	0	3 (6 %)	0
Feeling of confidence using medicines	27 (56 %)	18 (38 %)	0	3 (6 %)	0
Self care (egenomsorg)	27 (56 %)	15 (32 %)	1 (2 %)	4 (8 %)	1 (2 %)
Quality of medicinal treatment	24 (50 %)	19 (40 %)	2 (4 %)	3 (6 %)	0
Adherence	24 (50 %)	19 (40 %)	0	5 (10 %)	0
Symptoms	20 (42 %)	22 (46 %)	3 (6 %)	3 (6 %)	0
Health status	13 (27 %)	29 (61 %)	3 (6 %)	3 (6 %)	0
Work ability	2 (4 %)	40 (84 %)	3 (6 %)	3 (6 %)	0

Table 6: Pharmacist assessed patient outcomes due to the program.

significant improvement in unintentional non-adherence reflects the counseling program's focus on assisting patients in organizing medicines intake and adherence. An earlier study of "Safe and effective use of medicines" showed no significant improvement in the three adherence scales, but still showed significant and clinically relevant decrease in blood pressure [26]. It is difficult though to find comparable studies in terms of intervention intensity, duration and content, target group and adherence measurement. A recent Cochrane review of adherence enhancing interventions concluded that the studies with the highest quality interventions are generally complex and often include education, counseling, or daily treatment support [27]. Self-reported measurements of adherence have been known to overestimate adherence, and it is generally difficult to show significant improvement in self-reported adherence. We found that randomized clinical trials of pharmacist-delivered interventions targeting patients with different chronic conditions, with comparable content and adherence measurements, show varying results. Some found no significant improvement in adherence score from baseline to endpoint [28,29], whereas another randomized clinical trial of a pharmacist-delivered intervention targeting patients with chronic obstructive pulmonary disease (COPD), showed significant improvements in adherence in the intervention group [30]. However, in our study, focus was not on a specific chronic condition, and therefore specific clinical outcomes data were not collected for analysis.

The social workers, who expressed a need for this intervention, stated that unemployment beneficiaries with health problems risk being caught in the process of attaining permanent support benefits due to health reasons, if there is reason to believe that the medical treatment is not implemented correctly. Improved adherence may not suffice to lead to improved health or work ability for all patients, but the adherence program may support social workers in evaluating the patient's health

and possible future in the work force. Since this study is relatively small confirmation of results calls for a larger controlled study.

The patients' concordance (shared decision-making) improved during the study. Across categories of concordance, an average of 47 % of patients experienced improvement in concordance, reflecting a positive development in their ability to take an active part in decision making about their health and treatment. This improvement in concordance is higher than in a similar study conducted with patients with type 2 diabetes, where only 21 % of patients improved their self-reported concordance [25]. This may reflect a lower baseline concordance in the ethnic minority target group compared to patients with type 2 diabetes. Concordance is known to be a determinant of adherence, meaning that patient-provider communication has an effect on medication adherence, such that provider communication rated as more collaborative is associated with better medication adherence [31-33]. The improvements assessed by patients, pharmacists and social workers show the same tendencies for improvement in knowledge, adherence, confidence in medication taking and the ability to use the medicines correctly. These results reflect that this program has both targeted knowledge and capacity building of this highly vulnerable target group. Individualised patient education, patient narratives and interpretation in the patient's native language might have contributed to these effects.

In this study, the population of unemployed ethnic minority patients was highly selected. This can both be viewed as strength as well as a limitation. The strength is that patients were selected and referred to the program by social workers based on their assessment. This reflects a daily life situation with the program working in the context where it would later be implemented. The results therefore reflect what results can be expected as a result of the selection process occurring, and the

patients motivation to complete the program. The limitations are that little is known about who was/was not referred to the program, who accepted/did not accept to participate, and who completed/dropped out of the program. Some patients dropped out because they felt overwhelmed by the program, while some pharmacists discontinued the program for others when they did not detect further medication-related problems, and therefore did not see a need to continue the program. Therefore, the results implicate an effect on a portion of the patients who received the program, but the results give no answers on how to improve the program to accommodate a larger portion of the target group.

Study limitations

Data collection was based on previously validated questionnaires [34,35]. However, most of these had to be adapted to the target group, due to low health literacy, interpretation, and cultural differences. This compromised the validity of the tools. The key instrument for measuring self-reported adherence was not altered in order to avoid compromising validity.

The relatively low number of patients in the study limits the conclusions, although results are significant and supported by data from social workers and pharmacists.

Endpoint data were collected at the end of the fourth counseling session. This may have influenced the self-reported effects, as some effects take time to occur and perceive.

It may be that some patients were subject to other interventions held by the job centers in order to support a progression towards labor. Other confounding influences are progressing diseases and other health or work related issues that were not addressed and therefore not solved by this intervention. A larger study including a control group should be conducted in order to support the findings of this study.

Conclusion

The counseling program “Safe and effective use of medicines” was successfully adapted to unemployed ethnic minority patients, and tested in a new collaboration between job centers and community pharmacies. The counseling program resulted in statistically significant improvements in self-reported adherence as well as improved concordance for approximately half of the patients. The positive results need to be validated in larger studies. Improvements in adherence removes one barrier for returning to the work force that exists in the complex interaction between adherence, health status and work ability.

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