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ARTICLE

The development and initial validation of an observational tool for measuring patient participation in clinical consultations

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Abstract

Objective: The aim of this study was to further develop and test The Activity Barometer (TAB) as a tool for measuring patient participation in clinical consultations.
Methods: The tool was further developed and tested by double coding 18 audio recordings from consultations between nurses and patients and by qualitative discussions between 3 raters. The raters discussed the face and content validity of the tool and the inter-rater reliability was calculated. To assess the construct validity, it was hypothesised that the tool could be used to expose a difference in the patients' participation before and after the nurses had participated in communication skills training. This was assessed based on 31 audio recordings.
Results: All of the 3 raters found the items relevant for measuring patient participation. However, to get reliable ratings, an extended guide for coding was necessary. According to the content validity, we found that by taking a treatment-oriented perspective, core components of patient participation were not included in the tool. To capture the whole concept, the coding should be done from a holistic perspective, including the patients' everyday life. The inter-rater reliability for the total score (0.85), the questions (0.92) and the preferences/concerns (0.6) were all above acceptable thresholds. The construct validation showed that the tool could expose differences in the patients' participation before and after the nurses had participated in the communication skills training.
Conclusion: TAB is a promising tool for measuring patient participation. However, further validation of the tool in a larger sample is recommended prior to its use in research settings.

Keywords

Adherence to treatment, communication skills training, dyadic approaches, empathy, measurement tool, patient participation, person-centered healthcare, psychometrics, reliability, self-care, shared decision-making, validity

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Introduction

The majority of the existing tools for the assessment of communication in clinical consultations have been developed to measure the communication skills of healthcare professionals. However, patients' participation in clinical consultations is essential for successful communication in addition. Patients who actively participate in a consultation by expressing their concerns, asking questions and stating their expectations for care, are providing healthcare professionals with valuable information. These behaviours interject the patients' perspective into the interaction and can have a powerful influence on healthcare professionals' behaviour and decision-making processes [1]. Moreover, patients who take a more active role in their care are often more satisfied with care, receive more information and support, are more committed to treatment plans and have a better understanding of treatment options and experience greater improvement in health than passive patients [1]. Patient participation is thereby associated with improved patient outcomes, including shorter hospital stays, reduced re-admission, improved functional status and reduced mortality. Patient participation contributes to enhanced decision-making, reduced medical errors and adverse events, improved adherence, optimised self-management and increased staff-retention. Therefore, the facilitation of patient participation is essential for a patient-centred, high-quality healthcare delivery [2].

A review of the existing tools showed that there are few reliable and valid tools for measuring patient participation in healthcare. Most instruments are self-report scales that assess the patients' perspective regarding decision-making [2-6]. Thus, there remains a need for further study into valid, reliable and feasible strategies for measuring patient participation [2]. On the basis of the empirical literature, Philips *et al*. define the core requirements for patient participation as shared decision-making (SDM), promoting self-care and autonomy and acknowledging the patients as having critical knowledge regarding their own health and care needs [2]. Thus, SDM is a part of patient participation. SDM is a process in which patients are involved as active partners with the clinician in clarifying acceptable medical options and in choosing a preferred course of clinical care. The process offers a way of individualising recommendations, according to patients' special needs and preferences [7].

There seems to be a trend towards a dyadic approach in measuring SDM [4]. In the measurement of SDM, one has to distinguish between the tools that measure the perception of the patient or clinician (e.g., patient satisfaction or self-efficacy) and the observation measures of the competence and performance of the clinician or the patient. Further insight into SDM can be gained by triangulation of the different perspectives (i.e., patient, clinician and observer) and by the use of a dyadic data analysis focusing on both the clinician and the patient. However, observation tools focusing on the patients' behaviour in the medical encounter are missing [2-6].

A challenge in measuring patient participation seems to be a disparate evaluation among observers, clinicians and patients. In a systematic review, Philips *et al*. found a low correlation between many of the patient-completed tools and the other patient participation measurement tools. Further, when the observer-completed tools were compared with the other measures of patient participation, there was a pure correlation between them in addition [2].

The tool MAPPIN'SDM includes all 3 perspectives in measuring SDM. In testing the instrument, the correlation between the clinicians' and the patients' judgements was moderate. However, the observers' judgements were not interrelated with the subjective judgements of the clinicians and the patients [8]. Thus, there is a need to consider and combine all of the perspectives. Developing an observation instrument to assess patients' behaviour would be a further step towards a multi-faceted measurement of patient participation.

The Danish Knowledge Center of User Involvement in Healthcare (ViBIS) has developed an observation tool termed The Activity Barometer (TAB), which measures patient participation in clinical consultations. TAB was developed based on a literature review of existing validated tools, feedback from an expert and a patient panel and a pilot test [9,10]. Elements from the validated tools OPTION Patient [11] and MAPPIN'SDM [8] were used as inspiration. TAB is yet untested in clinical trials; therefore, there was a need to validate this tool. The aim of this study was to further develop and test TAB as a tool for measuring patient participation in clinical consultations.

Methods

Study design

The tool was tested by an assessment of its face and content validity and reliability, including qualitative data from discussions between 3 raters and quantitative data obtained from double coding of 18 audio-recorded consultations. Moreover, a construct validation was carried out to test if the tool could expose differences in patient participation according to the existing knowledge of the concept.

The Activity Barometer

TAB measures the extent to which patients actively seek to influence their treatment, measured by the extent to which patients ask questions and express preferences and concerns about their treatment. The tool consists of 3 categories used to describe the types of questions and statements that provide the patients with varying degrees of influence. Each question and statement is scored on a scale from 1 to 10 and assessments are finally calculated as a total score. It is assumed that the patients' ability to influence the treatment depends not only on the quantity but also the type of questions and statements. Unfinished questions or statements are awarded one point, while general questions and statements that are not related to the patients' own situation, but are completed, are awarded 3 points. Finally, specific questions and statements regarding the patients' own illness and treatment are awarded 10 points, as these were assumed to give the patient the best chance of influence [9,10].

Setting

The study took place at the Spine Centre of Southern Denmark. The center is a part of Lillebaelt Hospital and all clinical staff had participated in a 3-day communication course. As part of a separate study evaluating the training course, the clinical staff at the Spine Centre were asked to submit 5-8 audio recordings of their consultations with patients 1-2 weeks before and 4 weeks after training. The audio recordings were recorded between January 2014 and March 2015.

Study population

The study population included patients with back problems who consulted a nurse at the Spine Centre regarding pain management. In these consultations, the nurses make preference-sensitive decisions about pain medication. There is a genuine choice and the best course of action depends on how the patient feels about the different options in terms of efficacy and side effects of the medication. The nurse cannot make an appropriate treatment choice without eliciting the patients' preferences and concerns. Thus, there is a basis for SDM in these consultations [12]. In addition, motivational interviewing is often used to guide the patients on how to deal with their pain and change their behaviour by identifying new patterns. The patients were included consecutively and there were no inclusion or exclusion criteria for the admission of patients for the current study.

Data collection

The data included in this study are the nurses' audio recordings obtained from the consultations before and after the communication course. Different back pain patients participated in the before-training and after-training recordings. Due to limited time, the consultations, which lasted over 30 minutes, were excluded. The same applies to the consultations with both patients and their relatives. The pilot test of TAB has shown a correlation between active patients and less active relatives. Conversely, less active patients have more active relatives. This trend means that comparing patient participation in consultations with and without relatives could result in a misleading low score for the patients with relatives [9]. Eventually, the consultations concerning issues other than pain management were excluded.

Face and content validity

Prior to this study, ViBIS has heightened the face and content validity of TAB by reviewing the literature of existing validated tools; feedback from an expert and a patient panel, consisting of 5 experts in patient involvement and 4 patients with a different medical history and a pilot test where 38 video recordings of consultations were rated by 2 independent observers. The inter-rater reliability of the tool was calculated to 0.78. However, the tool was time-consuming and the scale was relatively complex. Based on this, the items with a low correlation were removed [9,10]. In this study, the face and content validity, the reliability and the construct validity of the new and reduced scale, were assessed. To assess the face and content validity, 3 raters, 2 nurses and one doctor double coded the first 18 audio recordings. Through this process, the raters discussed the relevance, coverage and understandability of the items.

Reliability

After the double coding process, the inter-rater reliability of the tool was measured by a Spearman's rank correlation coefficient (SCC). The next 13 audio recordings were coded by the first author and reviewed by the other 2 raters. The final scores were obtained by an inter-rater agreement. The coding was based on a guide prepared by ViBIS. To get a good basis for coding and more reliable ratings, all of the audio recordings were transcribed. The coding was carried out from the written material while listening to the audio recording to hear the patients' tone of voice. The audio recordings were coded randomly and data blinded so that the raters did not know if it was a before-training or after-training consultation. To minimise the risk of error, EpiData was used for data entry.

Construct validity

Construct validity was assessed by formulating a hypothesis based on previous findings. The nurses at the Spine Centre had participated in the communication course implemented at Lillebaelt Hospital. The course was founded on Albert Banduras' theory of social learning [13] and was based on the method described by Maguire *et al.* [14]. Role play and feedback were among the central pedagogical methods used during the course, which comprised 3 basic elements. First, there is a tight structure of the consultation with reference to The Calgary Cambridge guide [15]. Second, the communication techniques focus on how to listen, how to help the patient formulate the problems and how to ask the right questions. Finally, there is a patient-centred approach focusing on how to elicit and respond to patient concerns and needs and how to reach a mutual understanding of the problem and its treatment [16].

A systematic review [17] of the effect of patient-focused interventions has shown that communication skills training can improve the patients' knowledge and involvement in decision-making. This indicates that the communication skills training can improve patient participation. Moreover, a cross-sectional analysis [1] of 279 physician-patient interactions from 3 clinical sites has shown that patients who were more active participants received more facilitative communication from their physicians. When the physicians used partnership-building and supportive talk (e.g., praise, reassurance and empathy) in their consultations, the degree to which patients asked questions, were assertive and expressed concerns increased. On the basis of this knowledge, we formulated the following hypothesis:

> The patients become more active participants in the consultations after the nurses have participated in the communication skills training.

The final scores were analysed using a multiple linear regression in STATA Statistical Software, which was applied for the comparison between pre- and post-training scores. A p-value < 0.05 was considered significant. Cohen's D was used to estimate the effect size of the communication course.

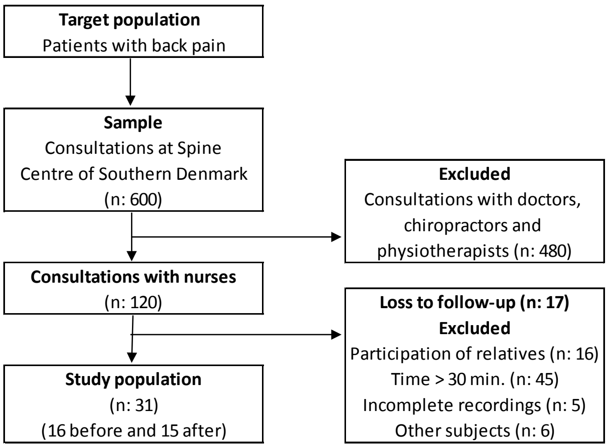
Ethics

Ethical approval was obtained from Danish Data Protection. Informed consent for the audio recordings was obtained from both the nurses and the patients. Written consent was obtained from the patients. Personal data were stored according to good clinical practice and confidentiality according to Danish recommendations.

Results

A total of 31 patients with audio records of their consultations were included in the study. The consultations were recorded by 4 different nurses. A flow chart of the in- and exclusion of the audio recordings are shown in Figure 1.

Figure 1 Inclusion and exclusion of the audio recordings



Face and content validity

During the process of double coding, the 3 raters had 6 qualitative discussions. All 3 raters found the items relevant for measuring patient participation. However, in the first 3 ratings, there was a pure correlation. This highlights the importance of a clear definition of the items and the proper training of the raters. Therefore, an extended guide for coding was developed. In particular, the distinction between the patients' concerns and other expressions such as information and descriptions of their symptoms was difficult. Herein lies a subjective assessment. However, by defining a concern as a statement in which the patient expresses an opinion about the information they provide, we raised the correlation on this item (e.g., I cannot stand the pain anymore. I cannot sleep at night. My stomach is ruined by drugs.).

According to the content validity, there was a variation in the raters' views of the concept. By taking a narrow treatment-oriented perspective, where only statements that are directly related to the specific treatment were rated, we found that the core components of patient participation were not included in the tool. On the basis of the definition of patient participation described by Philips *et al*., a part of patient participation is acknowledging that the patients have critical knowledge regarding their own health and care needs [2]. Therefore, the coding was conducted using a holistic perspective and the patients' expressions of how the treatment affects and fits into their everyday life was coded as general concerns, as these were seen as important statements and substantial knowledge in decision-making.

Reliability

During the process, the raters achieved a mutual understanding of the items. After the first 3 ratings with a pure correlation, the ratings were based on the extended guide. Measured by the next 15 double-coded audio recordings, we reached an acceptable SCC of 0.85 for the total score, with a mean difference of 26.6 points. For questions, the SCC was high, with a SCC of 0.92 and a mean difference of 8.73 points. Due to the higher degree of the subjective interpretation, the inter-rater correlation was lower for the preferences and concerns, with a SCC of 0.6 and a mean difference of 22.53 points.

Construct validity

Table 1 shows the distribution of age, gender and the duration of the consultation. It also shows whether it is the patients' first consultation with the nurse or if the two have met before. As there was a difference in the total score and, in some cases, an unequal distribution in the 2 groups, these parameters were seen as potential confounders and were adjusted for in the statistical analysis.

Table 1 Baseline characteristics (n=31)

Variables	Before Mean (SD)	After Mean (SD)	Total score Mean (CI)
Age (years)	46.88 (12.37)	48.2 (14.15)	
≤ 60			88.88 (70.1; 107.66)
> 60			83.83 (26.3; 141.36)
Time (mins)	18.97 (6.11)	16.86 (6.46)	
	Proportion (%)		
Gender			
Female	75	60	80.95 (59.56; 102.34)
Male	25	40	102.5 (70.93; 134.07)
No. cons.*			
First	37.5	33.33	77.45 (51.62; 103.29)
More	62.5	66.67	93.65 (70.08; 117.22)

* Number of consultations

The mean total activity score before the communication course was 79.88. After the course, the mean score rose to 96.47. For asking questions, the mean score before the course was 27.44, with a minimal increase to 30 after the course. For the preferences and concerns, the mean score rose from 52.44 to 66.47. The differences are shown in Figure 2.

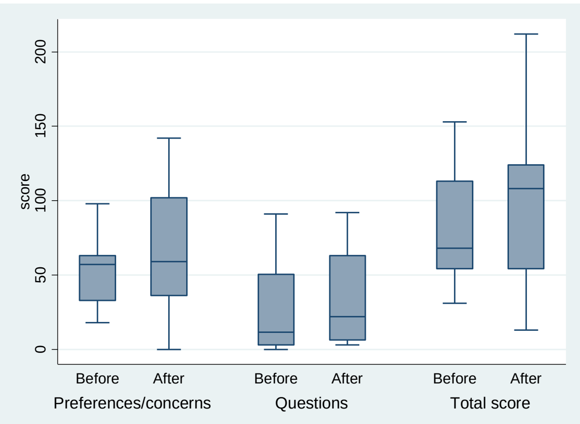
The boxes represent the interquartile range, with the lower and the upper edges of the boxes representing the 25th and the 75th quartiles, respectively. The whiskers show the lower and upper values. The lines within the boxes represent the median.

Table 2 The patients' activity scores before and after the nurses participated in the communication skills training (n= 31)

Nurse	Before Mean (CI)	After Mean (CI)	P-value	Adjusted P-vale	Cluster-analysis
All					
	Preferences/concerns				
	52.44 (40.34; 64.54)	66.47 (45.2; 87.73)	0.222	0.081	0.105
	Questions				
	27.44 (10.95; 43.93)	30 (13.71; 46.29)	0.815	0.808	0.79
	Total score				
	79.88 (58.91; 100.84)	96.47 (67.06; 125.88)	0.329	0.183	0.132
	Preferences/concerns				
1	62.6 (27.87; 97.33)	47.67 (-6.83; 102.17)	0.463	0.593	
2	45.25 (10.38; 80.12)	46.25 (-35.82; 128.32)	0.973	0.787	
3	41.2 (20.21; 62.19)	78.5 (55.92; 101.08)	0.012	0.057	
4	69.5 (-13.09; 152.09)	99 (-447.37; 645.37)	0.568	*	
	Questions				
1	27.4 (-2.41; 57.21)	39 (-13.58; 91.58)	0.517		
2	29 (-37.09; 95.09)	29.5 (-37.14; 96.14)	0.987	0.745	
3	15.2 (-18.36; 48.76)	33.67 (2.19; 65.14)	0.316	0.484	
4	55 (-313.48; 423.48)	6.5 (-37.97; 50.97)	0.239	0.733	
	Total score			*	
1	90 (33.43; 146.57)	86.67 (7.12; 166.21)	0.916	0.439	
2	74.25 (10.38; 138.12)	75.75 (-70.1; 221.6)	0.977	0.85	
3	56.4 (30.82; 81.98)	112.17 (81.52; 142.82)	0.006	0.085	
4	124.5 (-161.39; 410.39)	105.5 (-485.34; 696.34)	0.748	*	

* Insufficient data

Figure 2 Box plot showing the patients' activity scores before and after the nurses participated in the communication skills training (n=31)



The boxes represent the interquartile range, with the lower and the upper edges of the boxes representing the 25th and the 75th quartiles, respectively. The whiskers show the lower and upper values. The lines within the boxes represent the median.

Table 2 shows the patients' mean activity scores before and after the communication course. By using a multiple linear regression, we found no significant difference in the total activity score (p= 0.183), the score for preferences and concerns (p= 0.081) or the score for questions (p= 0.808) in the 2 groups. However, the number of preferences or concerns was close to being significant.

The assumptions of the normal distribution of the residuals underlie the multiple linear regression. This was checked by an inverse normal plot. The shape of the curve was almost similar to that of the normal distribution, but not perfect. In general, we are only interested in detecting marked departures from the normal distribution. The method is robust against the moderate departures, so that the estimate and hypothesis tests remain valid [18]. In the multiple linear regression, we also assumed that the residuals have equal variance. This was tested by a graphical representation of the variances of the 2 groups and was found to be acceptable.

Since the data are not independent when the same nurses have recorded several audio recordings before and after the intervention, this was taken into account by a cluster analysis. When clustering the data, a slight change in p-values was found (total score, p = 0.132; preferences/concerns, p = 0.105; questions, p = 0.79). By analysing the data for each nurse, we found that 3 of the nurses had actively participating patients with high mean scores before the communication course. These nurses did not raise the patients' activity scores after participating in the communication skills training. However, the nurse who had patients with a moderate activity score before the course managed to increase the patient participation for the preferences or concerns (p = 0.057) and the total score (p = 0.085), however not significantly.

The Cohen's D for the total score was 0.36, for the preferences/concerns 0.45 and for the questions 0.08. These estimates indicate a minimal effect of the intervention on the total number of the questions asked by the patients and a medium effect on the patients' expressions of preferences/concerns [19].

Discussion

The main findings of the study were that the face and content validity of TAB was good. However, an extended guide and some adjustments in the interpretation of the items were necessary to obtain reliable ratings. To embrace the concept of patient participation defined by Philips *et al.*, the coding should be conducted using a holistic perspective where expressions of how the treatment affects and fits into the patients' everyday life are included as general concerns. A comprehensive review [20] has shown that poor communication between the professional and the patient is often mentioned as a common cause of non-adherence. Other factors contributing to non-adherence include unresolved concerns of the patient. The professionals' attitude towards the patient and the ability to elicit and respect the patients' concerns, to provide appropriate information and to demonstrate empathy are of the utmost importance. Decisions about treatments should fit into the patients' beliefs and personal circumstances. The patients' own knowledge, ideas and experiences, as well as those of family members and friends, have been shown to correlate with adherence. Thus, the patients' own beliefs and the constraints of everyday life are important in determining adherence [20].

The low correlation between the first ratings elucidated that the raters had a different understanding and interpretation of the statements, probably due to their different educational background. Through continuous discussions, the raters achieved a common understanding of the concept and an acceptable SCC (lower for the preferences and concerns). These ratings depend on a subjective estimate and the results vary depending on the person who assesses the results. The qualitative discussions between the three raters have made the ratings more sharp and uniform, thereby increasing the reliability of the measurements. The variation was minimised by the consistency in the ratings. The first author rated all of the audio recording and the two other raters rated an equal amount of pre- and post-audio recordings. Since the raters were blinded, one must assume that any problems and errors were equally divided in the two groups. The variation in the final measurements was also minimised by an inter-rater agreement in the final scores.

According to the construct validity, the findings indicate that the tool could expose differences in the patient participation before and after the nurses participated in the communication skills training. Three of the nurses had high patient activity scores before the intervention, which could have provided a ceiling effect, thus making it difficult to improve the patients' scores after the communication course. The outcome was a secondary effect of the communication course and was dependent on the improved communication skills of the nurses. The study indicates that the communication skills training can improve patient participation in consultations regarding the expressions of preferences and concerns. However, we found no effect of the communication course regarding the number of questions expressed by the patients. Two reviews [21,22] have shown that multi-faceted interventions focusing on both the providers and the patients show promising results regarding patient participation. In future studies, TAB could be useful in measuring the effect of such interventions.

A limitation of this study was that the audio recordings did not give the raters an opportunity to read the patients' body language, which might affect the interpretation of the patients' statements. However, by blinding, double coding and transcribing the audio recordings, the measurements were as reliable and as valid as possible from the available material.

Another limitation was the small sample, which reduces the generalisability of the results. A disadvantage of TAB is that the scores do not tell whether or not the patients' participation is higher or lower than one might expect from the patients' individual situation. The scores provide a snapshot of the patients' participation in the concrete-observed consultation. The measurements cannot tell whether it is the ideal participation in the current situation, the ratings are consistent with the patients' experience or the patient actually does affect the treatment decision [9]. The tool should be seen as an observer perspective on patient participation, which can be used as part of a multi-faceted assessment.

Conclusion

Our study examined the face and content validity, reliability and construct validity of TAB. The results support TAB as a promising observation tool for measuring patient participation in clinical consultations. In future studies, the tool could be used advantageously as part of a multi-faceted assessment of the effect of patient-centred approaches, combining interventions that target the health professionals with patient-mediated interventions. However, further validation in a larger sample is recommended prior to the tools' use in research settings.

Acknowledgements and Conflicts of Interest

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