Development and validation of a generic questionnaire for the implementation of complex medical interventions

Entwicklung und Validierung eines generischen Fragebogens für die Implementierung komplexer medizinischer Interventionen

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Abstract

Introduction: The implementation of complex medical interventions in daily practice is often fraught with difficulties. According to the iterative phase model proposed by the British Medical Research Council (MRC), the development, implementation and evaluation of complex interventions should be theory-driven. A conceptual model that seems to be a promising framework is the Theory of planned behaviour (TPB). In our study we aimed to develop and validate a generic and multifaceted questionnaire based on the TPB to detect physicians' willingness to implement complex medical interventions and the factors influencing this willingness.

Methods: The questionnaire was developed according to the literature and was informed by previous qualitative research of our department. It was validated on the example of an electronic library of decision aids, arriba-lib. The sample consisted of 181 General Practitioners (GPs) who received a training regarding arriba-lib and subsequently filled in the questionnaire, assessing the TPB variables attitude, subjective norm, perceived behaviour control and intention. Follow-up assessments were conducted after two (assessing retest reliability) and eight weeks (assessing target behaviour). We performed a confirmatory factor analysis investigating the factorial structure of our questionnaire according to the TPB. Beside the calculation of the questionnaire's psychometric properties we conducted a structural equation model and an ordinal regression to predict actual behaviour regarding the installation and application of arriba-lib.

Results: The postulated three factorial model (attitude, subjective norm, perceived behaviour control) of our questionnaire based on the TPB was rejected. A two factorial model with a combined factor subjective norm/perceived behaviour control was accepted. The explained variance in the ordinal regression was low (Nagelkerke's R^2=.12). Neither attitude nor intention were able to predict the use or non-use of arriba-lib (attitude: p=.68, intention: p=.44). For the combined factor subjective norm/perceived behaviour control a significant, but small effect (p=.03) was shown.

Conclusions: The TPB is not an adequate theoretical framework to guide the development of a generic questionnaire in the context of the implementation of complex interventions. To enable the successful implementation of complex medical interventions evaluators have to go through the whole development and evaluation process according to the MRC-model, without short cuts. Further, it has to be discussed if a generic instrument can be valid and useful. Regarding the TPB a publication bias regarding the theory's applicability might have to be considered.

Keywords: implementation, questionnaires, primary health care, theory of planned behaviour

Zusammenfassung

Einführung: Die Implementierung komplexer medizinischer Interventionen in die tägliche Praxis ist oftmals mit Schwierigkeiten erfüllt. Gemäß dem schrittweisen Phasenmodell des British Medical Research Council (MRC) sollten die Entwicklung, Implementierung und Evaluation komplexer medizinischer Interventionen theoriegeleitet sein. Die Theorie des geplanten Verhaltens (TGV) könnte als konzeptuelles Modell einen entsprechenden Rahmen darstellen. In unserer Studie beabsichtigten wir die Entwicklung und Validierung eines generischen und facettenreichen Fragebogens basierend auf der TGV, um die Bereitschaft von Medizinern, komplexe medizinische Interventionen zu implementieren zu erheben sowie die Faktoren, die diese Bereitschaft beeinflussen.
Methoden: Unser Fragebogen wurde auf der Basis der Literatur und vorhergehender qualitativer Forschung unserer Abteilung entwickelt. Er wurde validiert am Beispiel einer elektronischen Bibliothek von Entscheidungshilfen, arriba-lib. Die Stichprobe bestand aus 181 Allgemeinmedizinern, die ein Training hinsichtlich arriba-lib erhielten und anschließend den Fragebogen ausfüllten, wobei sie die TGV-Variablen Einstellung, subjektive Norm, wahrgenommene Verhaltenskontrolle und Intention beurteilten. Follow-up Untersuchungen erfolgten nach zwei (Retestreliabilität) und acht Wochen (Erfassung des Zielverhaltens). Wir rechneten eine konfirmatorische Faktorenanalyse, um die faktorielle Struktur unseres Fragebogens hinsichtlich der TGV zu untersuchen. Neben der Berechnung der psychometrischen Eigenschaften des Fragebogens führten wir ein Strukturgleichungsmodell und eine ordinale Regression durch um das tatsächliche Verhalten der Installation und Anwendung von arriba-lib vorher zu sagen.
Ergebnisse: Die postulierte dreifaktorielle Struktur (Einstellung, subjektive Norm, wahrgenommene Verhaltenskontrolle) unseres Fragebogens basierend auf der TGV wurde abgelehnt. Ein zweifaktorielles Modell mit einem kombinierten Faktor subjektive Norm/wahrgenommene Verhaltenskontrolle wurde akzeptiert. Die erklärte Varianz im Rahmen der ordinalen Regression war gering (Nagelkerke's R^2=.12). Weder Einstellung noch Intention konnten die Verwendung oder Nichtverwendung von arriba-lib vorhersagen (attitude: p=.68, intention: p=.44). Für den kombinierten Faktor subjektive Norm/wahrgenommene Verhaltenskontrolle zeigte sich ein signifikanter, aber kleiner Effekt (p=.03).
Schlussfolgerung: Die TGV ist kein angemessener theoretischer Rahmen für die Entwicklung eines generischen Fragebogens im Kontext der Implementierung komplexer Interventionen. Um eine erfolgreiche Implementierung komplexer medizinischer Interventionen zu erreichen, muss der komplette Entwicklungs- und Evaluationsprozess des MRC-Modells bearbeitet werden. Des Weiteren sollte diskutiert werden, ob ein generisches Instrument valide und nützlich sein kann. Hinsichtlich der TGV könnte ein Publikationsbias bezüglich der praktischen Anwendung der Theorie vorliegen.

Schlüsselwörter: Implementierung, Fragebögen, Allgemeinmedizin, Theorie geplanten Verhaltens

Introduction

The implementation of complex medical interventions to improve the quality of care is fraught with difficulties as the intervention is often not taken up by the target group [1]. Thereby, complex interventions like guidelines, treatment pathways or decision aids are defined as interventions with several interrelated components [2]. As other research findings, the implementation of complex interventions face the gap between what is known to be best practice and the care patients actually receive [3], [4], [5]. For research results to be transferred into regular healthcare delivery it may take 10 to 20 years [6]. Multiple factors may influence physicians' professional behaviour change and thus the lasting implementation of complex medical interventions. These factors are situated

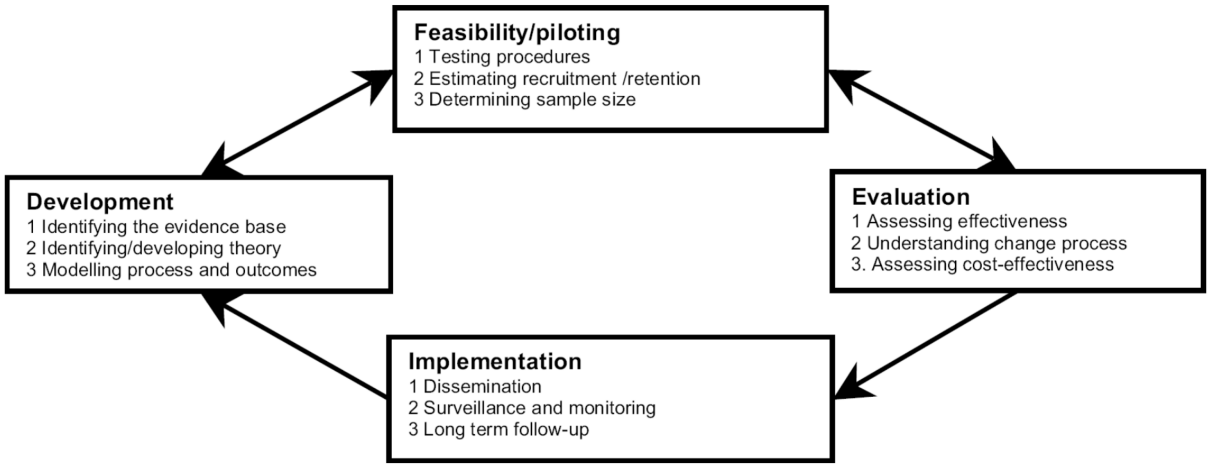

Figure 1: Key elements of the development and evaluation process, redrawn with permission according to [2]

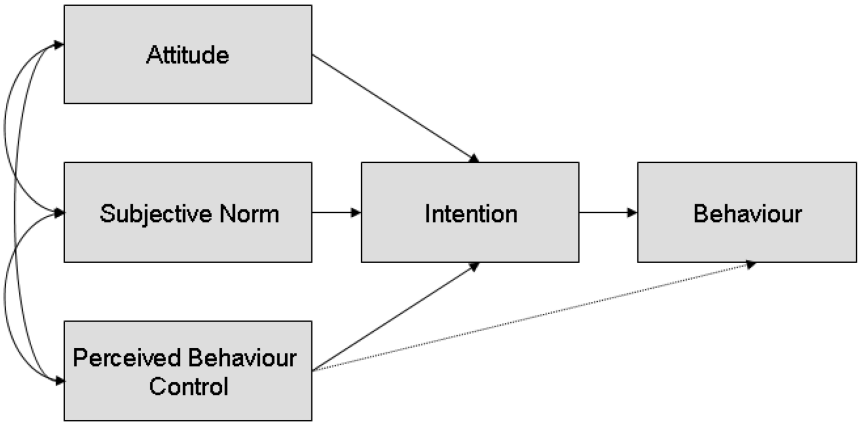

Figure 2: Theory of planned behaviour, based on [8]

at a number of levels (individual, colleagues, patients, system) [7]. As the implementation and evaluation of complex interventions requires time, financial and human resources it would be highly desirable to develop and provide a standardized instrument to measure health care professionals' willingness to implement an innovation. Thus by identifying physicians' willingness to implement complex medical interventions and the factors influencing this willingness possible conclusions (regarding the abortion or modification of the implementation process) could be drawn at an early stage. According to the iterative phase model (2) (see Figure 1) proposed by the British Medical Research Council (MRC) the development, implementation and evaluation of complex medical interventions should be theory-driven.

The use of conceptual models is considered to facilitate the choice for an adequate implementation strategy and thus make the implementation more likely. Theories explaining the changes that occur by implementation are numerous and focus on different levels (individual, interpersonal, and organizational). In this context, an established theory that offers a promising framework for studying the factors associated with physicians behaviour is the Theory of planned behaviour (TPB) [8], which is one of the best validated psychological models to predict individual behaviour [9], [10]. The theory, shown in Figure 2, assesses a persons' intention to perform a specific behaviour as a proximal predictor of behaviour.

According to the theory three kinds of considerations impact on a person's behaviour: behavioural (about the outcome of performing the behaviour), normative (about the expectations of other people to act) and control beliefs (about factors that facilitate or hinder the performance of the behaviour). Their respective cognitive aggregates (behavioural beliefs are associated with attitude, normative beliefs with subjective norm and control beliefs with perceived behaviour control) are assumed to influence intention to perform the behaviour, while the intention itself is considered as the main predictor for future behaviour. Attitude means a person's overall evaluation of the behaviour while subjective norm describes a person's own estimate of the social pressure to perform or not perform the behaviour under consideration. The third component perceived behaviour control is defined as the extent to which a person feels able to enact the behaviour. The perceived behaviour control consists of two subfactors: how much a person has control over the behaviour and how confident a person feels about being able to perform or not perform the behaviour. Ajzen considered the concept of perceived behaviour control as

being congruent to the dimension of self-efficacy, proposed by Bandura [11]. Beside its indirect impact on the behaviour, mediated by the intention, perceived behaviour control also has a direct effect on behaviour. While in previous health care studies the TPB was used to explain behavioural change on patients' side (i.e. condom use [12], physical activity [13]) in recent years the behavioural change of health care professionals came to the foreground [14], [15], [16] and has shown its suitability in a variety of medical consultations [17], [18], [19]. Despite its wide distribution and the fact, that the TPB explains almost one third of variance in the behaviour of health care professionals as suggested by a systematic review [20], the assumptions of the TPB regarding the predictive value of intention for actual behaviour are discussed controversially [17], [21].

As mentioned above, the lasting implementation of complex interventions is difficult to achieve and factors influencing physicians' willingness to take up the intervention are often identified late in the implementation process. Therefore, we aimed in our study to develop and validate a generic and multifaced questionnaire based on the TPB to detect physicians' willingness to implement complex medical interventions and the factors influencing this willingness.

Methods

Development of the questionnaire

The questionnaire's development and validation consisted of two phases: At first we aimed to design the questionnaire referring to a concrete complex medical intervention of potential interest for the participating General Practitioners (GPs). In a second step it was planned to transfer and cross-validate the research findings in further complex interventions to guarantee its generic character. In this article we describe the first development phase using the example of arriba-lib, a multimodular electronic library of decision aids [22], [23].

The questionnaire was developed in view of the literature on the construction of a TPB based questionnaire [24], [25]. As recommended [24], [26] we used qualitative interviews to elicit salient beliefs of GPs about facilitators and barriers of adhering to complex interventions. These were derived from previous qualitative research of our department on the implementation of different complex interventions [7], [27]. According to the principle of compatibility [28] the four TPB predictors referred to the use of arriba-lib in general and not to one specific module. We pretested the initial draft with 5 GPs of the department's GP network, which were not included in the final study. Minor revisions of wording were made to the questionnaire in the light of their comments. To enable the adaptation of the questionnaire to other complex interventions we only used items whose content and wording could be transferred to other contexts.

As we considered all areas elicited in the qualitative research the final version of the questionnaire (see Attachment 1) included 41 items and incorporated a different item number for each of the TPB variables, namely attitude (26 items), subjective norm (8 items) and perceived behaviour control (5 items). Thus, as recommended, each variable was assessed by multiple items to increase measurement reliability [26]. The amount of 26 items for attitude derives from the assumption that attitude is a more complex, multifaceted construct than subjective norm and perceived behaviour control. Intention was measured by two items ("In half a year arriba-lib will be routine in my practice."; "I intend to use arriba-lib in every consultation, if a corresponding problem exists."), which were summed up to predict the target behaviour, operationalized as the installation and application of arriba-lib. After transforming reversed items, higher values of scales indicated stronger/more positive influences, attitudes and intention to install and apply arriba-lib. Additionally, the questionnaire included questions about demographic details and the practices.

Due to practical considerations we deviated in some points from the recommendations [25]. In contrast to most TPB studies using a seven-point scale with verbal expressions of endpoints, we used a four-point Likert Scale with wording (1 = I do not agree, 2 = I rather do not agree, 3 = I rather agree, 4 = I fully agree) as response category. Further, as adding indirect measures is not considered to increase the level of prediction [29], we assessed the TPB variables directly by asking the participants to summarize their overall attitude, subjective norm, perceived behaviour control. In contrast to the indirect assessment of the TPB variables where specific beliefs and scores for the single variables are measured separately and then combined by the researcher, the direct assessment considers the respondents to combine both aspects themselves.

Study design and sample

Our survey study ran from July 2011 to March 2012. The target population included interested GPs in Germany, who were contacted via different GPs university networks. At baseline GPs received a standardized group training where arriba-lib was presented. Arriba-lib [30] presently contains evidence-based decision aids for the following topics: cardiovascular prevention, atrial fibrillation, coronary heart disease, dual platelet inhibition, oral antidiabetics, conventional and intensified insulin therapy, and unipolar depression. The modules are structured to assist physicians in counselling their patients according to the philosophy of shared decision making (SDM) [31]. An evaluation study showed that arriba-lib was accepted by a high number of patients and was also positively evaluated by GPs [22], [30]. Subsequent to the training a convenience sample of GPs filled in the questionnaire and gave their written informed consent to be contacted for the follow-up assessments. Confidentiality for the GPs was assured by a pseudonymous procedure. Ethic approv-

al for the study was obtained from the Ethics Committee of the Faculty of Medicine at the Phillips University of Marburg, Germany. In return for their study participation, the GPs received a free one year licence for the arriba-lib software (beta version). To assess retest reliability, GPs were two weeks later reminded by mail to fill in again the questionnaire and to indicate if they installed and/or used the arriba-lib software.
Further 6 weeks later GPs were contacted via phone to report on their (non-) use of the software and their evaluation of arriba-lib as a whole and its single modules.

Data analysis

We analyzed baseline characteristics of the GPs to identify possible selection bias between study dropouts and participants. Cross-tab analyses with χ^2-tests and standardized residuals were performed using Cramer-V as an effect size. A value of .40 or higher denotes a large effect [32], [33]. Mann-Whitney U tests were calculated to examine absolute differences in metric variables.
In order to examine the postulated three factorial structure (attitude, subjective norm, perceived behaviour control) of the questionnaire according to the TPB, we conducted a confirmatory factor analysis with unweighted least squares (ULS) as this estimation method makes no distributional assumptions [34] . Several fit indices were used to evaluate the factor analytic solution. The root mean square residual (RMR) measures the mean absolute value of the covariance residuals [35]. Values less than .05 indicate a good model fit [34], but other authors state that a value of less than .10 signals an acceptable model fit [36], [37]. The standardised root mean square residual (SRMR) eliminates scaling effects of the RMR. Values < .10 indicate a good model fit [37]. The Global Fit Index (GFI) can be considered as a measure of the proportion of variance and covariance that a given model is able to explain. A GFI equal or higher .90 can be considered as reflecting a good model fit [38]. The adjusted global fit index (AGFI) takes the number of parameters used in computing the GFI into account. An AGFI equal or higher .90 can be considered as showing a good model fit [37].
Internal consistencies of the factors were examined by Cronbach's α coefficients. Values >.7 are considered to be acceptable [39]. Spearman's correlation coefficients were used to examine retest reliability. Values >.7 are considered to be acceptable. Differences in absolute values between the two administrations of the questionnaire were tested by the Wilcoxon Matched Pairs Signed Rank Test with an alpha level ≤.05. We tested a structural equation model representing the TPB with unweighted least squares (ULS) and the above mentioned fit indices. Furthermore, due to the ordinal scale level of the outcome behaviour, an ordinal regression was used to predict actual behaviour regarding arriba-lib ("not installed, not applied", "installed, not applied", "installed, applied") assessed in the telephone interview by components of the theory of planned behaviour operationalized in our questionnaire at baseline [40].
Missing values were replaced using the expectation maximization (EM) algorithm [41]. All calculations were done using SPSS 19.0 and AMOS 19.0.

Results

Sample characteristics

At baseline a total of 181 GPs participated in the study. As seen in Table 1 the majority of the participating physicians were male (59%) and full-time working (90%). They were on average 51.9 years old (SD=7.6) The number of 181 GPs participating in our research can be considered as adequate for the performed analyses [37]. Additionally, our sample can be regarded as representative as demographic characteristics of primary care physicians in Germany are very similar to those assessed in our study [42].
To the first follow-up assessment measuring retest reliability 46.6% of the original sample (n=84) participated in the postal survey. At the second follow-up, where GPs were called by phone, the drop-out rate due to refusal accounted for 9.9% (n=18) compared to baseline. Figure 3 depicts the flow of the sample. There were no differences between the final sample and dropouts in sociodemographic characteristics at first follow-up, except for working hours in which the two groups differed significantly as the participants at the first follow-up were more often working part-time (p=.02), but the resulting effect size was low (Cramer-V: .17).

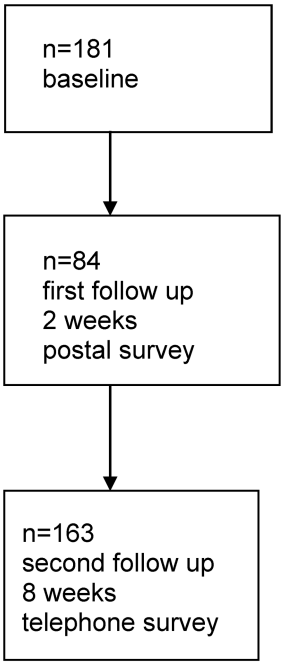

Figure 3: Flow of the sample

Table 1: Sociodemographic and baseline characteristics of the study population (n=181)

	t_0	
Demographics and professional characteristics	*n*	*(%)*[a]
Gender		
Male	107	(59)
Female	74	(41)
Age (years)		
<40	11	(6)
41 to 50	64	(35)
>51	106	(59)
Established since (years)		
<5	9	(10)
6 to 15	32	(33)
16 to 25	35	(37)
>26	19	(20)
Characteristic of the practice		
Single practice	80	(44)
Group practice	97	(54)
Patients per 3 months period		
<500	5	(3)
500–1,000	45	(25)
1,000–1,500	62	(34)
>1,500	65	(36)
Practice location (regarding inhabitants)		
<5,000	36	(20)
5,000 to 20,000	48	(27)
20,000 to 100,000	25	(14)
>100,000	69	(38)
Status		
Full time practice	162	(90)
Part time practice	18	(10)

[a] Numbers may not add up to 181 and percentages may not add up to 100% due to missing values and rounding

Confirmatory Factor Analysis (CFA)

Descriptive statistics (mean, standard deviation) for each item at baseline were shown in Table 2.

There was a maximum of 5% missing values on single variables (t0) which were missing completely at random (Little's MCAR-Test p=.19). These were imputed using the expectation maximization (EM) algorithm [41].

The three factorial model was rejected because of a not positive definite covariance matrix between the three postulated factors (see Attachment 2). Results suggested to combine subjective norm and perceived behaviour control in one factor. This two factorial model had an acceptable model fit (SRMR=.08, RMR=.04, GFI=.92, AGFI=.92) although the correlation between the combined factor and factor "attitudes" was .90. Table 3 depicts the factor loadings of the items on their respective factors.

Table 2: Descriptive statistics of the questionnaire's items at baseline

Item	Mean*	SD	Postulated factors
1. When I use arriba-lib, I have the impression to do something positive for my patients.	3.3	.62	Attitude
2. I am expected to use arriba-lib.	1.8	.80	Subjective Norm
3. It depends on myself if I use arriba-lib in the consultation.	3.6	.69	Perceived behaviour control
4. I can identify myself with the developer group of arriba-lib.	3.0	.74	Attitude
5. I think that arriba-lib will be accepted well by my patients.	3.1	.60	Subjective norm
6. arriba-lib helps me to structure the treatment of my patients.	3.1	.59	Attitude
7. In my opinion the design (layout, choice of colour, clarity) of arriba-lib is accurate.	3.1	.60	Attitude
8. I am confident to use arriba-lib in the consultation, if I like to.	3.3	.63	Perceived behaviour control
9. My patients would appreciate if I use arriba-lib.	3.1	.56	Subjective norm
10. arriba-lib fits in the current health care system.	2.9	.78	Attitude
11. In half a year arriba-lib will be routine in my practice.	2.6	.78	Intention
12. In my opinion arriba-lib is evidence-based.	3.4	.59	Attitude
13. I think that I can change in that way, that I can use arriba-lib in my daily practice.	3.0	.63	Perceived behaviour control
14. I worry that the use of arriba-lib can lead to drug regresses. (i)	3.5	.63	Attitude
15. I think that my GP colleagues will accept arriba-lib positively.	2.8	.61	Subjective norm
16. arriba-lib helps me to make decisions together with my patients.	3.4	.61	Attitude
17. I am open-minded towards medical innovations like decision aids or guidelines.	3.4	.61	Attitude
18. For me arriba-lib is well comprehensible.	3.3	.59	Attitude
19. Colleagues that are important to me think that I should use arriba-lib.	2.5	.84	Subjective norm
20. In the past I had already positive experiences with medical innovations like decision aids or guidelines.	3.0	.89	Attitude
21. By arriba-lib I feel restricted in my freedom of choice. (i)	1.5	.68	Attitude
22. My evaluation of arriba-lib depends on whether I was involved in the development of arriba-lib.	3.5	.68	Attitude
23. For me the use of arriba-lib is difficult. (i)	3.3	.78	Perceived behaviour control
24. I worry that the use of arriba-lib can have judicial consequences for me. (i)	3.7	.56	Attitude
25. For me arriba-lib is plausible.	3.3	.58	Attitude
26. The use of arriba-lib means a high temporal effort for me. (i)	2.3	.74	Attitude
27. By the use of arriba-lib I feel safer in my practice.	3.0	.75	Attitude
28. arriba-lib facilitates the work with my patients.	3.0	.64	Attitude
29. I like to test medical innovations like decision aids or guidelines.	3.2	.75	Attitude
30. I already treated my patients like arriba-lib recommends. (i)	2.1	.68	Attitude
31. arriba-lib should be embedded in other programs like DMP or GP contracts.	3.0	.86	Attitude
32. I feel under social pressure to use arriba-lib.	1.5	.63	Subjective norm
33. The use of arriba-lib reduces the uncertainty in treatment.	2.9	.74	Attitude
34. In the past I had already negative experiences with medical innovations like decision aids or guidelines. (i)	3.4	.75	Attitude
35. I intend to use arriba-lib in every consultation, if a corresponding problem exists.	2.4	.80	Intention
36. I find the implementation of arriba-lib in Germany desirable.	3.0	.68	Attitude
37. arriba-lib can be integrated well in daily practice.	2.8	.66	Attitude
38. The use of arriba-lib gives me the security to do the right.	2.9	.72	Attitude
39. arriba-lib means a significant change of my treatment routine. (i)	2.8	80	Attitude
40. I am often sceptic towards new innovations like decision aids or guidelines. (i)	3.0	.88	Attitude
41. A regular support for the use of arriba-lib in form of information material, trainings, phone hotline etc. is desirable.	2.7	.80	Attitude

i = inverted
* = Likert-scale from 1 = I do not agree to 4 = I fully agree

Table 3: Factor loadings in the two factorial model

	factor loading
attitudes	
item 1	.60
item 4	.66
item 6	.64
item 7	.52
item 10	.23
item 12	.58
item 16	.68
item 17	.51
item 18	.55
item 20	.56
item 22	–.04
item 25	.63
item 26	–.34
item 27	.56
item 28	.72
item 29	.56
item 30	.34
item 31	.57
item 33	.45
item 34	–.47
item 36	.76
item 37	.65
item 38	.58
item 39	–.29
item 40	–.44
item 41	.36
subjective norm/ perceived behaviour control	
item 2	.07
item 3	.18
item 5	.69
item 8	.71
item 9	.63
item 13	.67
item 14	–.18
item 15	.38
item 19	.47
item 21	–.52
item 23	–.55
item 24	–.32
item 32	–.29

Items 10, 22, 26, 30, and 39 have loadings <|.40| on factor "attitudes" and items 2, 3, 14, 15, 24, and 32 have loadings <|.40| on the combined factor "subjective norm and perceived behaviour control".

Psychometric properties of the questionnaire

Internal consistency coefficients and retest reliability for factor "attitude" were acceptable at both measuring points (internal consistency coefficients: t0: α=.87, t1: α=.90; retest reliability: .75), whereas the values for the combined factor subjective norm and perceived behaviour control were not satisfying (internal consistency coefficients: t0: α=.65, t1: α=.60; retest reliability: .41). The median differences of absolute values between baseline and retest did not differ significantly from 0 (attitude: p=.15, Z=–1.43; subjective norm and perceived behaviour control: p=.54, Z=–.61; Wilcoxon Matched Pairs Signed Rank Test)

Predicition of actual behaviour

Regarding the target behaviour 64 GPs (39.9%) indicated to have neither installed nor applied arriba-lib in the past eight weeks. 26 physicians (16%) installed arriba-lib but did not use the software. Most of the participants (n=73, 44.8%) installed and applied arriba-lib.

A structural equation model to predict actual behaviour regarding arriba-lib assessed in the telephone interview by components of our modified theory of planned behaviour operationalized in our questionnaire at baseline was rejected. We therefore calculated an ordinal regression with actual behaviour regarding arriba-lib ("not installed, not applied", "installed, not applied", "installed, applied") as dependent variable and sum scores of factors "attitudes" and "subjective norm/perceived behaviour control" and "intention", operationalized as sum score of items 11 and 35, as predictors. The explained variance of the model was low (Nagelkerke's R^2=.12). The test of parallel lines revealed that the estimators were the same across the three behaviour categories (p=.19). Attitude (regression weight = .007, p=.68) and intention (regression weight = .08, p=.44) did not have a predictive value regarding the target behaviour. A significant but small effect was observed for the combined factor subjective norm/perceived behaviour control (regression weight = .09, p=.03). The correct classification rate was therefore also low with 55.8%.

Discussion

Main results

The present study examined the supposed factorial structure and the predictive value of a generic questionnaire based on the TPB regarding GPs' willigness to install and use arriba-lib. In contrast to the findings of other research in health care [9], [43] we could neither demonstrate the TPB's postulated three factorial structure nor satisfactorily explain variation in behavioural intention by attitude toward the behaviour, subjective norm and perceived behaviour control. In our study a two factorial model structure combining subjective norm and perceived behaviour control had an acceptable model fit even though the correlation with attitude was high.

There might be different reasons for these negative results. On the one hand the wording or choice of items used in the questionnaire could have been inaccurate and therefore might have corrupted the factorial structure. Nevertheless, as the included items were based on sev-

eral qualitative studies [7], [27], we assumed them to be relevant for our research question. Another reason for the results might lie in the choice of the complex interventions. As arriba-lib included nine different modules, we can not exclude that the participating GPs referred to different modules when answering the questionnaire. Thus, the operationalization of the target behaviour as installing and applying arriba-lib might have been too general. However, we assume that all modules are of interest to GPs and can therefore be evaluated in combination. Additionally, the use of an electronic decision aid as an interactive tool in cooperation with the patient requires more considerations regarding the presentation and communication within the different modules than do more structured interventions like guidelines. It might also be possible that due to missing skills the use of a PC-software imposed retentions or problems to some GPs and thus might have influenced the GPs' behaviour in different ways.

Our findings indicate that none of the included predictors explain the actual installation and application of arriba-lib sufficiently. Neither do attitude and subjective norm/perceived behaviour control significantly predict intention, nor is intention significantly associated with the target behaviour. There was only a correlation of .20 between intention and behaviour.

Another reason for the lacking model fit might be the influence of external factors like structural pressures on the GPs by the health care system. As GPs in Germany are primarily paid for patient contacts of ten minutes this might have led to variations in behaviour not connected to the TPB.

The intention-behaviour gap found in our study is a phenomenon often discussed in matters of the TPB and the prediction of behaviour in general [9], [21], [44]. As we did not investigate further variables influencing the relation between intention and actual behaviour, we can not give definitive explanations for this finding.

Our results suggest that GPs with more positive attitudes, stronger subjective norms, and higher perceived behaviour control were more likely to have positive intentions to install and apply arriba-lib. Even though regression coefficients did not reach significance, attitude was associated most strongly with intention. In contrast to the combined factor subjective norm and perceived behaviour control, attitude might be regarded as a trait [45], characterized as a quite stable disposition and difficult to change. On the other hand, subjective norm and perceived behaviour control eventually depend more on situational aspects like patients' and colleagues' expectations or demands of the health care system and can thus be classified as state [46]. This assumption can be confirmed by the retest reliability, where attitude showed a much higher coefficient than the two other variables, although these results have to be considered with caution because of the relatively high drop-out rate. Further, possibly other processes like situation specific emotions become relevant for subjective norm and perceived behaviour control. The neglect of emotion in the TPB as cognitive attitude-behavioural theory was criticized by various researchers [47], [48] and might contribute to the missing amount of explained variance.

Strength and limitations

The strength of this study lies in the careful development of the questionnaire as a tool assessing physicians' willingness to change professional behaviour in the context of the implementation of complex interventions. The questionnaire's development followed the recommendations as it was theory guided and based on several qualitative studies.

However, in consideration of the negative results it has to be discussed how the questionnaire and the study design can be improved.

Although we followed the recommendations [24], [26] and based the questionnaire's items on previous qualitative research, these studies did not refer to a computerised tool like arriba-lib. Thus, the transferability to other complex interventions might be limited. Nevertheless, we assume our approach to be adequate as our aim was to develop a generic questionnaire, applicable to different types of complex interventions. Furthermore we used a neutral wording to allow the questionnaire's transfer to other interventions. Another limitation concerns the use of the 4-point Likert-scale as due to the small variances results might have been influenced. Also the operationalization of the intention might have been unfavourable as the two items had a different temporal reference point. Additionally, as we could not verify the postulated factorial structure of our data according to the TPB we had to combine subjective norm and perceived behaviour control in the ordinal regression. This limits comparison to other studies based on a three factorial model of the TPB. However, in the light of the large amount of studies supporting the assumptions of the TPB and scarcely published research not verifying the TPB, a publication bias might exist.

Conclusions

Based on the results of our study we can conclude that the TPB is not an adequate theoretical framework to guide the development of a generic questionnaire in the context of the implementation of complex interventions. Possibly, the actual implementation can not be predicted even by health care professionals themselves and their respective attitudes and evaluations. Thus, to enable the successful implementation of complex medical interventions evaluators have to go through the whole development and evaluation process according to the MRC-model, without short cuts. Further, it has to be discussed whether a generic instrument is likely to be valid and useful. Regarding the TPB a potential publication bias supporting the theory's assumptions might have to be considered.

Notes

Competing interests

The authors declare that they have no competing interests with respect to the research, authorship, and/or publication of this article.

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Attachments

Available from
http://www.egms.de/en/journals/gms/2014-12/000193.shtml

1. gms000193_Attachment1.pdf (1630 KB)
   Questionnaire for the implementation of complex medical interventions [in German]
2. gms000193_Attachment2.pdf (131 KB)
   Three factorial solution

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