The development, validity and reliability of a screening instrument to determine the perceived self-management support in routine primary care for patients with COPD, asthma and Diabetes Mellitus type 2.

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Introduction

The incidence of people living with one or more chronic conditions is rapidly increasing. Chronic diseases contribute for approximately 60% of the total reported deaths in the world and for approximately 46% of the global burden of disease [1]. This is expected to increase to 57% by 2020 [2] and will eventually lead to increasing costs and burden of health care systems [3]. One of the solutions is a shift from paternalistic driven models of health care, which sited the patient in the role of passive recipient, towards a more consumer driven model in which the patient is an active partner in health and disease management [4]. A promising approach is “self-management”, which refers to the individual’s ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent in living with a chronic condition. Effective self-management will lead to the ability of patients to monitor their own condition and to influence cognitive, behavioural and emotional responses regarding quality of life, achieving a continuous process of self-regulation and behavioral change. [4] p.187. Patients are informed and supported by healthcare professionals to increase their responsibility in healthcare decisions [5]. This implies an active involvement in the day-to-day disease management such as healthy eating, regular physical activity, and consistent use of medication [6].

Recently, several RCT’s have focused on the efficacy of self-management programs. Meta-analyses indicate that self-management can lead to improved disease-specific outcomes, higher quality of life, self-management behavior and reduced health care consumption [7-16]. Despite promising results, it is still unknown how self-management support can be successful in some chronic patients in contrast to others [17-22], suggesting that ‘one size does not fit all’ [23].

In The Netherlands, as in most western countries, routine care for patients with chronic conditions has shifted from hospitals to primary care [24-28]. Practice nurses (PN) play a key role in the care for these patients [24,26]. They are often specialized in chronic obstructive pulmonary diseases (COPD), asthma and Diabetes Mellitus type 2 (DM2), since these diseases are the most common in primary care [28]. PN’s are trained to different extent in self-management support and integrate this support differently into their consultations in combination with a large heterogeneity with regard to PN’s individual characteristics such as age and experience [29]. However, the actual perceived self-management support, including the content, mode and dose, for these patients in routine care is unknown. A screening instrument (SI) can be used to identify the perceived self-management support during a consultation with the PN. However, a valid and reliable SI is not available, and therefore no gold standard.

This study was designed to develop a valid and reliable SI which can be used by PN's in their consultations as self-assessment as well as for training purposes regarding support in self-management, as an integral part of routine care for these patients. Furthermore, this SI can be used in future research to understand the success or failure of self-management to eventually develop tailoring interventions to individual patients.

Problem statement

PN's integrate self-management support differently into their consultations of patients with COPD, asthma and DM2. Therefore, the actual perceived self-management support in consultations of PN's is still unknown. To date, there is no SI to gain insight in the perceived support of self-management in the care for patients with COPD, asthma and DM2.

Aim

The aim of this study is to develop a valid and reliable screening instrument which can be used by practice nurses to determine the perceived self-management support in their consultations as an integral part of routine primary care for patients with COPD, asthma en DM2.

Research questions

1. Which themes and items accurately reflect the construct self-management in a valid and reliable screening instrument to determine the perceived self-management support in routine primary care for patients with COPD, asthma and DM2?

2. What is the validity of the screening instrument to determine the perceived self-management support in routine primary care for patients with COPD, asthma and DM2?

3. What is the reliability of the screening instrument to determine the perceived self-management support in routine primary care for patients with COPD, asthma and DM2?

Methods

Design

A mixed methods clinimetric study was conducted to develop the SI and the assessment of the validity and reliability. The use of combined qualitative and quantitative approaches provides a better understanding of the problem than either approach alone [30]. In this study, data for assessing the validity was collected e.g. by an expert panel and focus groups, the qualitative data through the focus groups were used to explain and expand the quantitative results from the expert panel to assess the validity [30].

The development of the SI consisted of three phases: (1) instrument development; (2) validity assessment; (3) reliability assessment (Figure 1). When developing an SI of high quality, various measurement properties are of great importance. Validity and reliability are the most important to ensure the quality of the SI [31].

Ethical considerations

This study was conducted according to the principles of the Declaration of Helsinki. The Research Ethics Committee of the University Medical Center (UMC) of Utrecht provided ethical approval for this study. All participants received an information letter and gave informed consent. Personal data were coded, according to the Dutch Personal Data Protection Act.

(1) Instrument development

Domain identification

In order to obtain a valid instrument, the underlying concept of SM was defined [32]. After a thorough review of the literature, in the databases PubMed and Cochrane Central Register of Controlled Trails, the taxonomies of Michie et al. [33,34] and Taylor et al. [35] were considered as the conceptual basis. In addition, as guidance for classification and generation of subsequent formulated items, because they give the best and most comprehensive overview to identify dimensions and sub-dimensions of self-management.

Item generation

To generate items of all identified dimensions and sub-dimensions, the above mentioned taxonomies were used. A number of basic rules for the formulation of adequate items was applied; items were specific, comprehensive to the total population, contain only one question and negative wording in questions were avoided [36]. The first version of the SI contained as many items as possible, these items covered all domains which were identified,

and were phrased by extensive peer review of the research team. Three experts in the field of self-management were consulted once by e-mail to review whether these items covered the construct self-management sufficient. The items were divided under themes, which were drawn from self-management programs for COPD and DM patients [18,37] and Dutch guidelines of COPD, asthma and DM2 patients associations [38,39].

Step 3: instrument formation

The items were refined and arranged in a suitable sequence to establish the first draft of the instrument [36]. Readability is reviewed by a linguist affiliated to the UMC Utrecht.
During phase 2, proceedings were continued on the instrument development.

(2)Validity

To determine the validity of the instrument, the content validity is assessed, as one of the main types of validity [36]. Also the face validity is assessed, since it is the first aspect of content validity [36].

Face validity

Face validity is assessed by seven independent nursing scientists of the UMC Utrecht, using purposive sampling. They were approached by e-mail to assess the relevance of the themes and items of the SI by rates from 1 (not relevant at all) to 10 (very relevant) and to review the readability of the SI.
Data-analysis was carried out by calculating the mean and range of the scores. The feedback on readability was evaluated within the research team and when necessary, items were reformulated.

Content validity

The content validity assessment consisted of a qualitative part of research, by two focus groups, and a quantitative part by an expert panel.

The first part of the content validity was assessed by two focus groups; for patients and PN's. To recruit participants, convenience and snowball sampling were used. Patients were recruited by forums of patient societies and Twitter. Inclusion criteria were patients diagnosed with COPD, asthma or DM2, Dutch speaking and able to come to the UMC Utrecht. PN's were recruited by telephone, they were included if they were involved on a daily bases in the care of COPD, asthma or DM2 patients.

The purpose of the focus groups was to gain insight into which themes and items are discussed during a consultation, and which of them are most relevant according to patients and PNs.
In the patients focus group, important comments were noted on a flap-over and discussed by the group. The PN's were asked in advance to score the items at relevance by rates on a 4-point scale (1= Not relevant to 4=Very relevant). During the focus group the most and least relevant items were collectively selected, for the purpose of reducing items.
The focus groups were videotaped and transcribed. Comments and suggestions, based on the transcripts, were coded per theme and item and discussed, and if required modified, within the research team.

The second part of the content validity was assessed by an expert panel, experienced in self-management support. The expert panel determined the content validity according to the methods of Lynn [40]. The number of required experts is at least five and maximum ten experts [40].
Fourteen experts were approached by e-mail through purposive sampling, taking non-response into account. The experts were asked to evaluate the relevance of each item on the 4-point scale and to suggest possible improvements in phrasing. These suggestions were modified without interfering with the content validity judgment.
For purposes of data-analysis, the I-CVI (Content Validity Index) was calculated [40,41], based on the judged relevance per item. The I-CVI is the most widely used quantification of content validity [40]. The CVI is the proportion of experts that judges an item as content valid (score of 3 - 4) [42]. The I-CVI score needs to be at least 0.78 ($P > 0.05$), depending on the number of experts [40]. For the whole instrument the S-CVI was calculated (mean of I-CVI) and must be ≥ 0.90 [41]. At the end of this phase, the development of the screening instrument was completed.

(3)Reliability
To determine the reliability between two observers, the inter-rater reliability is assessed [36], by testing the SI in practice. After each consultation of a PN in a general practice, the SI was completed by four different persons; PN, patient, and two observers (researchers). Every consultation was audio taped. The PN, patient and observer 1 filled out the SI under similar conditions (afterwards), and observer 2 while listening to the consultation and therefore acts as the gold standard. In order to increase the reliability of the observations, the research team was trained in filling in the SI.

To recruit participants, purposive sampling was used. PN's, who are daily involved in the care of COPD, asthma or DM2 patients, were recruited by telephone. Patients were recruited by PN. In order to gain insight into the working routine of the PNs and achieve sufficient variation in PN's, at least five consultations, per PN were included, with the aim of including a minimum of 75 consultations (five consults per item). For PN's and observers the SI was digitalized and for patients a printed version was made, since there was no computer available. Demographic characteristics of the participants, and general information of the consultation were collected.

Data was analyzed per theme and per item by calculating the observed percent agreement and the inter-rater-reliability by the association measure Cohen's Kappa (K).
The percent agreement was measured between PN-patient, PN–observer1, PN–observer2 and observer1-observer2.
Cohen's Kappa was assessed between PN-observer1 to determine the inter-rater reliability, because they complied the SI under similar conditions. In the other groups the Kappa is measured to make comparisons in agreement. Cohen's Kappa measures the degree of agreement between two observers (which may occur by change) [43]. A Kappa between 0.4 and 0.75 is moderate and > 0.75 indicates a strong agreement [43]. A two sided *p* value of <0.05 was considered to be statistically significant. Missing values were very limited, therefore they were not included in the analyses to optimize reliability. IBM SPSS statistics, Version 20 [44] was used for the analyzes.
Items were only displayed when a theme was filled with 'extensively discussed' (Table 2&3), and could therefore only be analyzed in those consultations.

Results

(1) Instrument development

After the first phase, the first draft of the SI was developed (Figure 1) and consisted of 17 themes and 123 items. After extensive peer review of the research team and the reviewed readability, eight themes and 81 items were removed due to duplicates or were merged. Consequently, nine themes and 42 items were left for the validity assessment.

(2) Validity

Face validity

All seven researchers who were approached responded (100%). The mean relevance score of the themes was 8.7, (range 8-9) and of the items 7.7 (range 6-10). The comments of the participants to the specific themes and items and suggestions for reformulation were discussed within the research team, which led to a reduction of seven items. No changes were made in the themes.

Content validity

Focus groups

Two themes were merged and two new themes were added to a final number of ten themes. Finally, after removing nine items, merging six items and reformulating eight items, 20 items remained in the SI.

Expert panel

Nine out of fourteen experts responded (64%). Out of 20 items that were evaluated by the expert panel, four items had an I-CVI score lower than 0.78 (Table 1). The S-CVI was 0.86. The S-CVI, without the four items that had a score below 0.78, was 0.92. After thorough discussion with the research team, these four items were removed and two items were merged due to overlap. At the end of phase 1 and 2, the final SI consisted of 10 themes and 15 items, distributed over the themes (Table 2& 3).

(3)Reliability

The reliability assessment was conducted by 11 PNs, with a mean of 4.6 (range 2-9) consultations per PN, with a total of 51 consultations. Overall, 10 out of 11 PNs were women with a mean age of 42 (Sd 11.6) (Table 4). Of the patients, 18 out of 51 were women with a mean age of 66.1 (Sd10.9). In total, at least 46 out of 51 had DM (7 times in combination with COPD or asthma). One patient did not completed the education level, this missing value was

not included in the table (Table 5). The major part of the consultations, 43 out of 51, lasted 15-30 minutes (Table 6).

The percentage of agreement and Cohen's Kappa per theme and item between PN-patient, PN-observer1, PN-observer2 and observer1-observer2, were shown in table 7 and 8.The inter-rater reliability between PN-observer1 was sequentially for the overall themes and items; 78.3% (K=0.63) and 81.3 (0.53). Between observer 1 and 2, the highest percentages and K values were found; 84.7% (K= 0.74), and 89.4% (K= 0.78). Also the number of completed items in this group was significantly higher than in the other groups.
The results PN-patient were the lowest, 66% (K=0.43) and 75.6% (0.52). Thereafter between PN-observer2, the gold standard; 72.2% (k=0.53) for the themes and 78.3% (k=0.53) for the items.
In general, themes 1, 5, 9 and 10 and items 5, 6 and 13 had the lowest Kappa in all groups. The highest Kappa (K=1.00) was found for theme 6, between the observers (K=0.92). Regarding the items it was item 9, between observer1-observer2 and item 7 for PN-observer1.
Only one patient did not filled in the SI and was therefore not included in the analysis.

Discussion

This study has shown the development, validity and reliability assessment of an SI to determine the perceived self-management support in routine primary care in COPD, asthma and DM2 patients. The validity of the SI, for this target population, can be considered as very good, which means the instrument measures the constructs it purports to measure [31]. We have also shown a good assessed face validity and the S-CVI was found to be highly acceptable. The reliability assessment showed a moderate inter-rater reliability, between PN-observer1. The results of observer1-observer2 were the highest of all groups, considering that observer2 is the gold standard. Based on these findings, we assume PN's are not able to assess their own consultation accurately. Other studies have also shown a limited ability for nurses or other healthcare workers to assess their own performance or functioning [45-47]. This may be explained by several reasons; it is possible that individuals present themselves more positive than reality, there may be differences in interpretation, involvement of response bias and individuals may be in a poor position for recognizing their own personal characteristics [47]. In addition, accurate decision making on individual differences in personality and behavior by an observer has shown to advantageous [47]. According to Gordon (1991), training should be given to optimize the validity and accuracy of self-assessment [45]. Therefore, we suggest that the SI is not appropriate for assessing PN's own consultation, but can be used as an observational instrument or for training purposes. Generally, the results of the percent of agreement analyses are higher than the outcomes in the Kappa analyses. This may be explained by the fact that it has not been corrected for chance [43] or by the substantial imbalance in the table's marginal totals [48], as themes 9 and 10, related to support and emotional impact, had a very low Kappa but a high percentage of agreement. It appeared that these themes are in the majority of the cases not discussed during a consultation, although these themes belong to the construct of self-management, according to the taxonomies of Michie et al and Taylor et al. [34,35].
This is the first study which described the development of such an SI, which is a strength of this study. However, there is currently no gold standard that could be used as reference for our findings. We had a sufficient number of participants for testing the face and content validity, which positively influences the interpretation of the results. Every decision was taken after extensive peer review by the research team, and considerations were precisely described, which strengthens the reliability and reproducibility of the study [49]. Another strength is the use of a well described method to develop a new instrument, according to the methods of Lynn (1986) [40] and De Vet et al. [36]. Missing values were scarce, as it was not possible to skip themes or items.

A drawback of this study is that we measured the inter-rater reliability between PN and observer1 whom filled in the SI afterwards. Officially, the consultation had to be performed twice with the same patient by two different PN's. Since this is not ethical, and the content of the consultations can still be very divers, the chosen method was the most appropriate and responsible solution. The reliability of the SI has been tested for only 51 consultations, which could have influenced our results due to insufficient power. The planned sample size was not achieved due to time limitations, by difficulty in reaching the PN's because of a high work-load, and sometimes it seems to be a barrier to record the consultations. Each PN has another working routine relating to self-management and usually applies the same style in every consultation. Therefore, it may be possible that the assessment per nurse is consistent over time and may have affected filling out the screening instrument, as it was filled afterwards. As sufficient PNs were included, it was possible to analyze them as one group, assuming that the average work routine of these nurses will correspond, and multiple consultations per PN were included. Furthermore, the number of COPD and asthma patients was very limited and therefore it was not possible to specify the results per chronic condition. Patients in whom their illness is difficult to get under control, are referred to the hospital and this is probably a group of patients which may have benefit of self-management support. As only COPD, asthma and DM2 patients in primary care were included at this moment, the generalizability of the instrument is limited.

Conclusion

The SI showed a good face and content validity to determine the perceived self-management support in routine primary care for patients with COPD, asthma and DM2.
The reliability assessment showed a moderate inter-rater reliability between PN and observer1 which suggests that the instrument is insufficient to use as self-assessment instrument for PN's. However, it can properly be used as observation instrument, as the agreement between both observers was high.

Recommendations

Further research is needed to test the instrument in a larger population, at least in 75 consultations and with more COPD and asthma patients to specify the results per patient group. Additional studies are required to test the SI on feasibility, by testing the clinical usefulness of the instrument. To increase the generalizability, future studies need to be performed on assessing the SI in secondary care.

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Tables and Figures

Fig. 1: Flow-chart Phase 1, 2 and 3

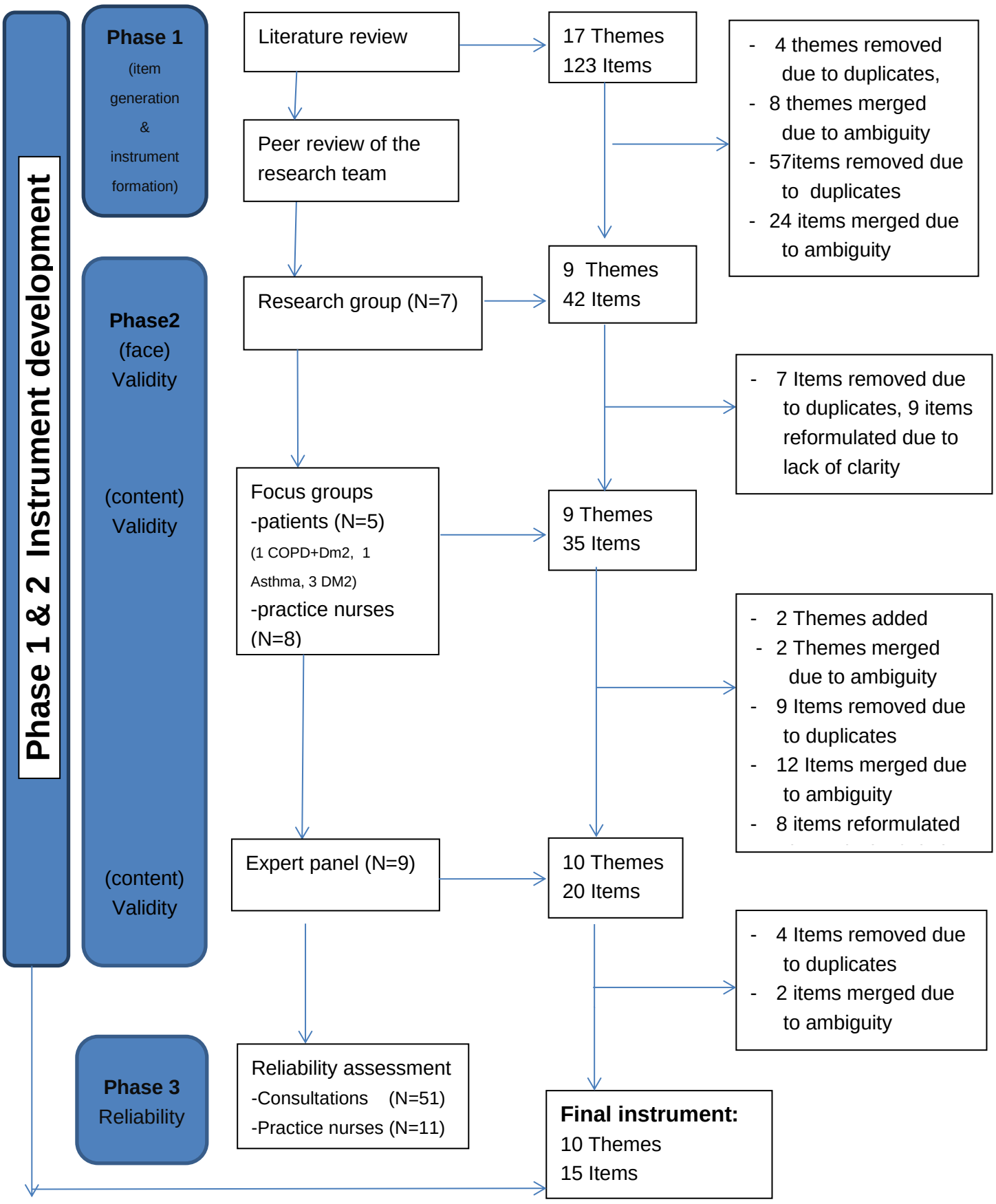

Table 1

Content Validity Index per item, inclusive removed items.

	Item –(Where is written 'him', 'her ' can also be read.) I have..	**I-CVI**
1.	given general information about healthy lifestyle	**0,5***
2.	given information about healthy behavior tailored to the individual situation of the patient	1.0
3.	given insight into the (possible) consequences of unhealthy behavior on the health of the patient	1.0
4.	looked at possible barriers to healthy behavior (e.g., behavioral, cognitive, emotional, environmental, social and / or physical barriers) together with the patient	1.0
5.	discussed that a relapse into old (undesirable) behavior can occur and how the patient can deal with this	1.0
6.	given insight into how an unhealthy lifestyle affects the health of the patient	1.0
7.	assisted with the drafting of feasible and practical (who, what, where, when, why) aims to improve patient behavior	1.0
8.	given the established goals in writing to the patient	1.0
9.	appointed that changing is often complicated	**0.5***
10.	encouraged the patient to come up with solutions to problems	0.9
11.	helped the patient taking his own considered decisions	0.89
12.	created an action plan that the patient can use to exacerbation of symptoms, together with the patient	0.9
13.	monitored the overall condition of the patient and have given them feedback	**0.67***
14.	encouraged the patient to self-monitor his overall condition and health	1.0
15.	given the patient feedback on what he has achieved	**0.9****
16.	supported the patient by positive reinforcement in step by step learning healthy behavior	**0.89****
17.	given information on how the patient can reach health care providers with questions or health problems	0.8
18.	given advice on how patients can communicate with caregivers	**0.7***
19.	given information on where the patient can find practical help (for example, patient organizations, representing interests, government services, activities in the area, purchase of tools)	0.8
20.	viewed how his relatives or other patients can support him together with the patient	0.78

*Item was removed due to a score < 0.78, ** Items were merged due to overlap.

Table 2

Final themes of the instrument and related items (see items table 3).

	Themes	Rating scale	Related items
1.	General information of the disease	☐ not appointed ☐ appointed ☐ extensively discussed	-
2.	Physical activity	☐ not appointed ☐ appointed ☐ extensively discussed*	1, 2, 3, 4, 5, 6, 10, 11, 12, 13, 14,15
3.	Healthy eating	☐ not appointed ☐ appointed ☐ extensively discussed*	1, 2, 3, 4, 5, 6, 10, 11, 12, 13, 14,15
4.	Quit smoking	☐ not appointed ☐ appointed ☐ extensively discussed*	1, 2, 3, 4, 5, 6, 10, 11, 12, 13, 14,15
5.	Adherence to medication	☐ not appointed ☐ appointed ☐ extensively discussed*	1, 2, 3, 4, 5, 6, 7, 10, 11, 12, 13, 14,15
6.	Alcohol	☐ not appointed ☐ appointed ☐ extensively discussed*	1, 2, 3, 4, 5, 6, 10, 11, 12, 13, 14,15
7.	Coping stress	☐ not appointed ☐ appointed ☐ extensively discussed*	1, 2, 3, 4, 5, 6, 10, 11, 12, 13, 14,15
8.	Management of symptoms and exacerbations	☐ not appointed ☐ appointed ☐ extensively discussed*	2, 7, 8, 9, 10, 11, 12, 14, 15
9.	Dealing with emotional and social impact of the disease	☐ not appointed ☐ appointed ☐ extensively discussed*	3, 6, 10, 11, 12, 13, 14, 15
10.	Support from others (emotional and / or practical support)	☐ not appointed ☐ appointed ☐ extensively discussed*	3, 13, 14, 15

*If the theme has been extensively discussed, than the related items will appear.

Table 3

Final items of the instrument.

	Items **(Where is written 'him', 'her ' can also be read.)**	Rating scale
	I have..	☐ yes ☐ no
1.	given information about healthy behavior tailored to the individual situation of the patient	☐ yes ☐ no
2.	given insight into the (possible) consequences of unhealthy behavior on the health of the patient	☐ yes ☐ no
3.	looked at possible barriers to healthy behavior (e.g., behavioral, cognitive, emotional, environmental, social and / or physical barriers) together with the patient	☐ yes ☐ no
4.	assisted with the drafting of feasible and practical (who, what, where, when, why) aims to improve patient behavior	☐ yes ☐ no
5.	given the established goals in writing to the patient	☐ yes ☐ no
6.	discussed that a relapse into old (undesirable) behavior can occur and how the patient can deal with this	☐ yes ☐ no
7.	trained the patient in practical self-management (injecting / e.g. self-insulin puffs / dispensing medications / diary .....)	☐ yes ☐ no
8.	encouraged the patient to self-monitor his overall condition and health	☐ yes ☐ no
9.	created an action plan that the patient can use to exacerbation of symptoms, together with the patient	☐ yes ☐ no
10.	encouraged the patient to come up with solutions to problems	☐ yes ☐ no
11.	helped the patient taking his own considered decisions	☐ yes ☐ no
12.	given the patient feedback and have healthy behavior positively energized	☐ yes ☐ no
13.	viewed how his relatives or other patients can support him together with the patient	☐ yes ☐ no
14.	given information on how the patient can reach health care providers with questions or health problems	☐ yes ☐ no
15.	given information on where the patient can find practical help (for example, patient organizations, representing interests, government services, activities in the area, purchase of tools)	☐ yes ☐ no

Table4
Demographic characteristics of the practice nurses (N=11).

Characteristics	Mean ± SD or N (%)
Female sex, N (%)	9 (91.0)
Age (years)	42.0 ± 11.6
Education, N(%)	
practice nurse	5 (45.5)
Registered nurse with bachelor of nursing degree	3 (27.3)
In-service nursing training	1 (9.1)
Practice nurse and Registered nurse with bachelor of nursing degree	2 (18.2)
Counseling of patients with, N (%)	
DM	7 (27.3)
Asthma+ COPD	1 (9.0)
DM + Asthma + COPD	3 (63.7)
Work experience (years)	6.45 ± 4.5
Received training, N (%)	
Motivational interviewing	4 (36.4)
Self-management + Motivational interviewing	4 (36.4)
Other	2 (18.2)
No training	1 (9.1)

Table 5

Demographic characteristics of patients (N=51).

Characteristics	Mean ± SD or N (%)
Female sex, N(%)	18 (35.3)
Age (years)	66.1 ± 10.9
Education, N (%)[a]	
Primary school	11 (21.6)
Lower vocational	13 (25.5)
Preparatory secondary education	1 (2.0)
Secondary school education	8 (15.7)
Secondary vocational education	9 (17.6)
Higher secondary level education	5 (9.8)
Higher professional	2 (3.9)
University	1 (2.0)
Ethnicity, N(%)	
Dutch	41 (80.4)
Moroccan	2 (3.9)
Surinamese	1 (2.0)
Eastern	1 (2.0)
South European	1 (2.0)
Other	5 (9.8)
Disease, N (%)	
COPD	2 (3.9)
Asthma	2 (3.9)
DM2	39 (76.5)
COPD + asthma	1 (2.0)
COPD + DM2	2 (3.9)
Asthma + DM2	4 (7.8)
COPD + Asthma + DM2	1 (2.0)
Treatment period, N (%)	
< 6 months	6 (11.8)
> 6 months	45 (82.4)

[a] Not adding up to 100 percent indicates a missing value.

Table 6

General information of the consultation (N=51).

General information	N (%)
Duration of the consultation (minutes)	
<15	4 (7.8)
15-30	43 (84.3)
31-45	1 (2.0)
>45	3 (5.9)
Number of consultations per half year	
< 1	1 (2.0)
1	4 (7.8)
2	42 (82.4)
3	2 (3.9)
>3	2 (3.9)
Patients expectations of the consult was asked (% yes)	
Answer patient	42 82.4
Answer practice nurse	28 (54.9)
Presence relatives (% Yes)	4 (7.8)
Sources recommended to the patient	
No sources recommended	44 (86.3)
Websites	4 (7.8)
Dairy	2 (3.9)
Other	1 (2.0)
Extra information given	
Nothing given	31 (62.7)
Leaflet/ brochure	4 (7.8)
Dairy	5 (9.8)
Leaflet/ brochure + dairy	9 (17.6)
Other	1 (2.0)

Table 7
Percent of agreement and Kappa; themes.

Theme	PN - patient % agreement- (k)	N	PN- OBS 1 % agreement - (k)	N	PN - OBS 2 % agreement - (k)	N	OBS 1 - OBS 2 % agreement - (k)	N
1	42.0 (0.03)	50	54.9 (0.21)	51	45.1 (0.05)	51	70.6 (0.45)	51
2	58.0 (0.17)	50	82.4 (0.66)	51	78.4 (0.59)	51	84.3 (0.72)	51
3	54.0 (0.20)	50	64.7 (0.41)	51	56.9 (0.34)	51	76.5 (0.65)	51
4	86.0 (0.69)	50	90.2 (0.80)	51	80.4 (0.61)	51	90.2 (0.81)	51
5	54.0 (0.26)	50	66.7 (0.46)	51	60.8 (0.30)	51	68.6 (0.46)	51
6	82.0 (0.66)	50	92.2 (0.85)	51	88.2 (0.77)	51	96.1 (0.92)	51
7	76.0 (0.44)	50	86.3 (0.66)	51	78.4 (0.46)	51	88.2 (0.66)	51
8	54.0 (0.26)	50	64.7 (0.46)	51	64.7 (0.43)	51	84.3 (0.75)	51
9	76.0 (0.14	50	86.3 (-0.03)	51	80.4 (-0.09)	51	94.1 (0.38)	51
10	78.0 (0.15)	50	94.1 (0.55)	51	88.2 (0.19)	51	94.1 (0.37)	51
Overall	**66.0 (0.43)**	**500**	**78.3 (0.63)**	**510**	**72.2 (0.53)**	**510**	**84.7 (0.74)**	**510**

N= number of consultations
PN= Practice Nurse
OBS= observer
(k)= Kappa

Table 8
Percent of agreement and Kappa; items.

Item	PN - patient % agreement – (K)	N	PN- OBS 1 % agreement - (k)	N	PN - OBS 2 % agreement - (k)	N	OBS 1 - OBS 2 % agreement - (k)	N
1.	88.9 (0.00)	9	84.6 (0.41)	13	69.2 (-0.13)	13	91.3 (0.62)	23
2.	90.0 (0.00)	10	83.3 (0.56)	18	70.6 (0.25)	17	87.5 (0.71)	32
3.	88.9 (0.77)	9	76.9 (0.54)	13	61.5 (0.22)	13	87.0 (0.74)	23
4.	77.8 (0.55)	9	69.2 (0.16)	13	84.6 (0.44)	13	82.6 (0.40)	23
5.	100.0 (N.A.)	9	92.3 (0.00)	13	92.3 (0.00)	13	100.0 (N.A.)	23
6.	55.6 (0.00)	9	92.3 (0.00)	13	92.3 (0.00)	13	78.3 (-0.08)	13
7.	50.0 (0.00)	2	100.0 (1.00)	7	83.3 (0.57)	6	92.3 (0.81)	23
8.	100.0 (N.A.)	1	40.0 (0.12)	5	50.0 (0.20)	4	88.9 (0.61)	9
9.	100.0 (N.A.)	1	40.0 (-0.36)	5	25.0 (-0.50)	4	100.0 (1.00)	9
10.	80.0 (0.58)	10	77.8 (0.56)	18	82.4 (0.65)	17	96.9 (0.94)	32
11.	54.5 (0.15)	11	73.7 (0.48)	19	66.7 (0.36)	18	81.3 (0.62)	33
12.	50.0 (0.00)	10	61.1 (0.28)	18	82.4 (0.65)	17	87.5 (0.53)	32
13.	80.0 (0.00)	10	100.0 (N.A.)	18	82.4 (0.00)	17	80.6 (0.21)	31
14.	66.7 (0.27)	9	82.4 (-0.85)	17	81.3 (0.29)	16	93.3 (0.81)	30
15.	70.0 (0.00)	10	94.4 (0.00)	18	94.1 (0.00)	17	96.8 (0.65)	31
Overall	**75.6 (0.52)**	**119**	**81.3 (0.59)**	**208**	**78.3 (0.53)**	**198**	**89.4 (0.78)**	**367**

N= number of consultations
PN= Practice Nurse
OBS= observer
(k)= Kappa
N.A.= Not Applicable, because it did not met the assumptions to run a Cohen's Kappa [43].

Dutch Summary/ Nederlandse Samenvatting

Titel De ontwikkeling van een valide en betrouwbaar screeningsinstrument om inzicht te krijgen in de zelfmanagementondersteuning bij patiënten met COPD, astma en Diabetes Mellitus Type 2 (DM2) in de eerstelijnszorg.

Inleiding Praktijkverpleegkundigen integreren zelfmanagementondersteuning op verschillende wijze in hun consulten met COPD-, astma- en DM2-patiënten. De exacte zelfmanagementondersteuning die patiënten ontvangen tijdens een consult met de praktijkverpleegkundige is daarom onbekend. Op dit moment is er geen screeningsinstrument die gebruikt kan worden om inzicht te krijgen in de zelfmanagement-ondersteuning door praktijkverpleegkundigen bij deze groep patiënten.

Doel Het ontwikkelen van een valide en betrouwbaar screeningsinstrument dat door praktijkverpleegkundigen kan worden gebruikt om inzicht te krijgen in de zelfmanagement-ondersteuning bij patiënten met COPD, astma en DM2 in de eerstelijnszorg.

Onderzoeksvragen Welke thema's en items geven het construct zelfmanagement accuraat weer in een screeningsinstrument om zelfmanagementondersteuning in kaart te brengen? Wat is de validiteit en betrouwbaarheid van het screeningsinstrument?

Methode Na de ontwikkeling van het screeningsinstrument zijn de volgende psychometrische eigenschappen van het screeningsinstrument beoordeeld; indruksvaliditeit, inhoudsvaliditeit en interbeoordelaarsbetrouwbaarheid. De validiteit is beoordeeld door een onderzoeksgroep, focusgroepen en een expertpanel. De interbeoordelaarsbetrouwbaarheid is beoordeeld door het screeninginstrument te testen in de praktijk.

Resultaten Het definitieve screeningsinstrument bestaat uit 10 thema's en 15 items. De inhoudsvaliditeit scoorde zeer hoog (S-CVI 0.92). De interbeoordelaarsbetrouwbaarheid werd beoordeeld met een Kappa (K) van (K=0.63) voor de thema's en (K=0.59) voor de items.

Conclusie Het screeningsinstrument is zeer valide. De interbeoordelaarsbetrouwbaarheid suggereert dat het instrument niet geschikt is voor zelfscreening door de praktijkverpleegkundigen, maar zou wel geschikt zijn als observatie-instrument.

Aanbevelingen Toekomstig onderzoek is nodig om het screeningsinstrument te testen in een grotere populatie. Daarnaast zal voor het verhogen van de generaliseerbaarheid vervolgonderzoek uitgevoerd moeten worden voor het gebruik van het screeningsinstrument in de tweedelijnszorg.

Trefwoorden; zelfmanagementondersteuning, screeninginstrument, chronische patiënten, eerstelijnszorg

English abstract

Title The development, validity and reliability of a screening instrument (SI) to determine the perceived self-management support in routine primary care for patients with chronic obstructive pulmonary diseases (COPD), asthma and Diabetes Mellitus type 2 (DM2).
Background Practice nurses (PN) integrate self-management support differently into their consultations of COPD, asthma and DM2 patients. Therefore, the actual perceived self-management support in consultations by PN's is still unknown. To date, there is no SI to gain insight in the perceived self-management support for these patients.
Aim To develop a valid and reliable SI which can be used by PN's to determine the perceived self-management support in their consultations in primary care for patients with COPD, asthma en DM2.
Research questions Which themes and items accurately reflect the construct self-management for an SI to determine the perceived self-management support? And what is the validity and reliability of the SI?
Method After the development , the following psychometric properties of this SI were established: face and content validity and inter-rater reliability. The validity is assessed by a research group, focus groups and an expert panel. The reliability is assessed by testing the SI in practice.
Results The final SI consists of 10 themes and 15 items. The resulting Content Validity Index was highly acceptable (S-CVI 0.92). The inter-rater reliability was assessed with a Kappa of (K=0.63) for the themes and (K=0.59) for the items.
Conclusion The SI can be considered as valid. The reliability assessment showed a moderate inter-rater reliability which suggests that the instrument is insufficient to use as a self-assessment instrument for PN's, but can properly be used as observation-instrument.
Recommendations Further research is needed to test the instrument in a larger population and to increase the generalizability. Future studies also need to be performed on assessing the SI in secondary care.

Keywords; Self-management, screening instrument, chronic patients, primary care