

**The provision of self-management support to patients with type 2 diabetes mellitus in routine primary care: the development, validity and reliability of a screening instrument**

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## Introduction

Diabetes mellitus (DM) is one of the most prevalent chronic diseases worldwide [1]. The number of patients with DM is expected to grow to 592 million by 2035, compared to 385 million today [2]. Type 2 diabetes mellitus (DM2) is the most common type of DM, accounting for at least 90% of all cases of DM [1]. DM2 is particularly troubling because the disease is associated with poor health outcomes. Over time, the heart, blood vessels, eyes, kidneys and nerves of patients with DM2 can be damaged [1,2]. As the number of patients with DM2 grows worldwide, the disease imposes an ever-increasing economic burden on healthcare systems [1].

A promising approach to improve health outcomes and reduce healthcare costs associated with DM2 is self-management. 'Self-management 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 [3, p. 178].' This implies an active involvement of patients with DM2 in the day-to-day management of their disease. They are expected to make and maintain behavior changes, leading to better disease control [4]. Self-management support is the ongoing process of healthcare professionals supporting patients with DM2 to manage their disease on a daily basis [5,6]. Usually, the healthcare professional and patient jointly develop an individualized support plan, which is largely focused on the patient's behavior change [4-7]. Self-management support is recognized as the cornerstone of diabetes care [5].

Routine care for patients with DM2 has shifted away from hospitals to primary care [8,9]. More than 90% of diabetes care takes place in primary care [8]. Practice nurses (PNs) see patients with DM2 on a regular basis and are therefore ideally positioned to provide self-management support. However, there is no standardized self-management approach in primary care [10]. PNs are to a different extent trained in providing self-management support and differently integrate this into their consultations [10-12]. Routine care for patients with DM2 is based on the healthcare standard of the Dutch Diabetes Federation (Dutch abbreviation: NDF) [13]. In practice, this healthcare standard is susceptible to multiple interpretations [14]. This implies heterogeneity in the content, mode and dose of self-management support provided by PNs. As a result, there is a lack of insight into the provision of self-management support to patients with DM2 in routine primary care [14,15].

In previous studies recommendations were made for healthcare professionals and researchers to properly describe the provision of self-management support, so that others can benefit from their experience [3,12,15,16]. A screening instrument (SI) can be used to collect and record this information in a structured fashion [17]. To date, there is no valid and reliable SI which can be used for this purpose. This study was designed to develop and assess the validity and reliability of a disease-transcending (chronic obstructive pulmonary

disease (COPD), asthma and DM2) SI, to determine the heterogeneity in the content, mode and dose of self-management support provided by PNs. PNs are the intended users of the SI. This paper exclusively reports on the results obtained for patients with DM2, which constitute the largest patient population in routine primary care [18].

### *Problem statement*

Self-management support is recognized as the cornerstone of diabetes care. In primary care, there is no standardized self-management approach. PNs differently integrate this into their consultations. As a result, there is a lack of insight into the provision of self-management support to patients with DM2 in routine primary care. Although it was recommended for healthcare professionals and researchers to properly describe the provision of self-management support, up to now there is no valid and reliable SI which can be used to collect and record this information.

### *Aim*

The aim of this study was to develop and assess the validity and reliability of a disease-transcending SI, to determine the heterogeneity in the content, mode and dose of self-management support provided by PNs. This paper exclusively reports on the results obtained for patients with DM2. The SI is intended for use in practice and future research to obtain insight into the provision of self-management support to patients with DM2 in routine primary care.

### *Research questions*

The research questions were: 1) Which themes and items cover the construct self-management support in a disease-transcending SI, to determine the content, mode and dose of self-management support provided by PNs?; 2) What is the validity of the SI for patients with DM2 in routine primary care?; and 3) What is the reliability of the SI for patients with DM2 in routine primary care?

## **Method**

This mixed-method study was conducted in three phases: 1) instrument development; 2) validity assessment; and 3) reliability assessment. The first and second phase were partly simultaneous, rather than strictly linear. Quantitative and qualitative approaches were applied [17]. An overview of the approaches applied per phase is shown in Figure 1.

### *Instrument development*

This phase consisted of three steps: 1) definition of the construct; 2) generation of themes and items; and 3) formation [19]. In the first step, a literature review was performed to define the construct self-management support. Themes and items were generated in the second step. They had to cover all facets of the construct and were generated from the literature reviewed in the first step. Themes were mainly generated from the Dutch healthcare standard for COPD [20], the Dutch multidisciplinary guidelines for asthma [21] and the healthcare standard of the NDF [13]. The taxonomies of Michie et al. [22], Michie et al. [23] and Taylor et al. [24] were the key articles from which items were generated. These taxonomies provided a clear description of all facets of the construct and their interrelationships. The literature was independently reviewed by three researchers (EM, TK, HW). Discrepancies in the generation of themes and items were resolved through discussion. The themes and items were translated in Dutch and formulated with the educational and reading level of the intended users (i.e. PNs) in mind. Additionally, the readability was assessed by a Dutch language specialist. The themes and items were refined and arranged in a suitable sequence in the third step. The items were distributed among the themes and rating scales were added.

### *Validity assessment*

There is no golden standard and thus, only the face validity and content validity could be assessed [17].

Seven nursing researchers of the University Medical Center Utrecht (UMCU) were invited by email to assess the face validity. They were purposefully selected, based on their experience with research on self-management support. None of the researchers was involved in this study, so they were all independent. They were asked to what extent the themes and items appeared (at face value) to cover the construct, by giving an overall rating of their relevance on a 10-point rating scale (1=not relevant, 10=highly relevant). Additionally, they were asked for comments. The ratings were analyzed by computing the mean ratings for the themes and items, which gave an overall impression of the face validity. The comments were used to guide decisions about adding, removing or revising themes and items.

The content validity was assessed by two focus groups, one with patients with COPD, asthma and DM2 and one with PNs. The patients were recruited through a convenience sampling method, by promotion of this study on the Twitter account of the UMCU and through patient organizations (e.g. information on their websites and online discussion boards). The PNs were recruited through a convenience and snowball sampling method. They were randomly approached by telephone and asked to refer to other PNs. The recruitment stopped at a sufficient number of participants (5 to 12) [17]. The focus groups were conducted in a relatively informal and comfortable setting within the UMCU. The participants were seated in a circle to facilitate the discussions [17]. During the 2-hours focus groups, the relevance of the themes and items was discussed. Prior to the focus group, the PNs also independently rated the relevance on a 4-point rating scale (1=not relevant, 4=highly relevant). During the focus group they jointly composed a list of the, approximately, ten least relevant and ten most relevant items. Both focus groups were videotaped and field notes were made, which served as a starting point for the subsequent analysis. The focus groups were analyzed by creating a written record of the relevant and useful parts of the discussions.

The Content Validity Index (CVI) was used to quantify the content validity. An expert panel was purposefully selected, using the researchers networks. The most important criterion for selection was a high level of expertise with self-management support. A number of 15 experts were invited per email. They were asked to assess the content validity, by rating each item on a 4-point rating scale (1=not relevant, 4=highly relevant). The ratings were analyzed by computing an item-level CVI (I-CVI) and a scale-level CVI (S-CVI). The I-CVI was computed by dividing the number of experts who rated the relevance of an item with either 3 or 4, by the total number of experts. According to Lynn [25], when the total number of experts is ten an item must achieve the minimum agreement of eight experts. The S-CVI was computed by averaging the I-CVIs. According to Polit and Beck [26], the S-CVI should be 0.90 or higher.

### *Reliability assessment*

In the context of reliability, the inter-rater reliability was assessed. Comparisons were made between the ratings of four raters (PNs, patients and two observers). PNs were recruited through a convenience and snowball sampling method. They were randomly approached by telephone and asked to refer to other PNs. Eligible for participation were PNs who saw patients with DM2 on a regular basis and provided self-management support. The PNs approached patients with DM2. Each patient could only participate once. After each consultation, the PN and patient independently completed the SI. The consultations were audiotaped and the two observers listened to the audiotapes. To detect recall bias, they

completed the SI after (the first observer) and while (the second observer) listening to the audiotapes. The researchers alternately took the role of first observer (EM, TK, BV) or second observer (HW, EB). The ratings of the PN and patient, PN and first observer, PN and second observer and the two observers were compared, by computing the percent agreement and Cohen's kappa for the total number of themes and items and each theme and item separately [27]. According to Altman [28], a kappa of 0.41 to 0.60 can be interpreted as moderate and a kappa of 0.61 to 0.80 can be interpreted as good. Additionally, the participants' demographic characteristics were collected. Statistical analysis was performed using SPSS version 20.0 for Windows (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.). Missing values were assumed to be missing completely at random and were removed from the analysis (pairwise deletion) [27].

#### *Ethical considerations*

Ethical approval was obtained from the Research Ethics Committee of the UMCU. PNs and patients provided written informed consent to participate in this study. The handling of personal data complied with the Personal Protection Act (Dutch abbreviation: Wbp).

## Results

### *Instrument development*

After performing the literature review, 17 themes and 123 items were generated. Duplicates were removed and discussion between the researchers resulted in a decrease to 9 themes and 42 items. Themes and items were reformulated according to the recommendations of the Dutch language specialist. Where necessary, instructions on how to interpret a theme or item were added. The themes and items were worded in such a manner that every theme can be rated on a nominal rating scale (not discussed, discussed or extensively discussed) and every item on a dichotomous, yes or no, rating scale. Only when a theme is rated as extensively discussed the items distributed among that particular theme can be rated. The distribution of the items among the themes is shown in Table 1. The formulation, as well as the number of themes and items, was further revised during the second phase. The revisions in the number of themes and items are shown in Figure 2. Table 2 shows the themes and items added to and removed from the SI.

### *Validity assessment*

All researchers who were invited assessed the face validity. The mean rating of the themes was 8.7 and the mean rating of the items was 7.7. The comments showed that two themes could be merged into one theme. Two items were too specific and were removed. Five items were merged with another item. This resulted in 8 themes and 35 items.

Five patients and seven PNs participated in the focus groups. The focus group with the patients mainly focused on discussing the relevance of the themes. Two themes were similar and could be merged into one theme. Additionally, the patients indicated three themes that were important to them and not yet added. During the focus group with the PNs the relevance of the items was extensively discussed. This resulted in a list of the, approximately, ten least relevant en ten most relevant items, jointly composed by the PNs. The least relevant items were mainly items which do not occur in practice. By means of this list and the written record of the relevant and useful parts of the discussions, 15 items were removed. To enhance the content validity, the participants' actual language was used to reformulate themes and items [29].

Ten experts who were invited assessed the content validity. During the focus groups, consensus was reached about the relevance of the themes. Therefore, the experts only assessed the relevance of the items. The I-CVIs are shown in Table 1. Four items did not achieve the minimum agreement of the experts and were removed. The comments showed that two items were similar. These items were merged into one item. The S-CVI was 0.99, exceeding the 0.90 cut-off point. Minor revisions in the formulation of the items were made,

as recommended by the experts. The final SI consists of 10 themes and 15 items which are shown in Table 1.

### *Reliability assessment*

Ten PNs participated and a number of 46 consultations were audiotaped. On average, a number of five consultations per PN were audiotaped with a range of two to nine. The participants' demographic characteristics are shown in Table 3. On average, the PNs worked for 6.8 years as a PN and, except for one PN, they all followed an additional training related to self-management support. The patients' mean age was 66 years and 40 patients had a disease duration of more than six months. The percent agreement and Cohen's kappa for the total number of themes and items and each theme and item separately are shown in Table 4. The highest agreement was shown between the ratings of the two observers. The percent agreement for the total number of themes was 83.7 and the kappa was 0.72. For the total number of items they were 88.1 and 0.75. Between the PN and first observer the percent agreement and kappa for the total number of themes were 77.4 and 0.62. For the total number of items they were 85.1 and 0.66. Between the PN and second observer the percent agreement and kappa for the total number of themes were 70.7 and 0.50. For the total number of items they were 78.7 and 0.54. The lowest agreement was shown between the ratings of the PN and patient. The percent agreement for the total number of themes was 65.1 and the kappa was 0.42. For the total number of items they were 71.0 and 0.41. One patient did not complete the SI. Additionally, only when a theme was rated as extensively discussed the items distributed among that particular theme could be rated. This resulted in a decrease of the comparisons which could be made for the items. As pairwise deletion was used, the number of comparisons was not equal for all separate themes and items. For several items it was not possible to compute Cohen's kappa, as not all assumptions were met [27].



## Discussion

In this study, a disease-transcending (COPD, asthma and DM2) SI, to determine the heterogeneity in the content, mode and dose of self-management support provided by PNs was developed. Additionally, the validity and reliability were assessed for patients with DM2 in routine primary care. The final SI consists of 10 themes and 15 items. The results showed excellent validity and good reliability.

To our knowledge, this is the first SI which was developed for this purpose. Several disease-transcending and disease-specific instruments were developed to assess self-management support, such as the Diabetes Self-Management Questionnaire (DSMQ) [30] and the Diabetes Self-Management Instrument (DSMI) [31]. However, these instruments were developed for a different purpose. With these instruments valuable information can be obtained on how patients with DM2 take care of themselves, but the provision of self-management support remains unclear. This makes the SI one of a kind.

This paper exclusively reports on the results obtained for patients with DM2. However, in the first and second phase no differences were made between the results for patients with COPD, asthma and DM2. The quantitative and qualitative approaches applied in these phases did not allow the researchers to make these differences. For example, in the second phase a focus group was conducted with patients with COPD, asthma and DM2. The results were not distinguishable for these patient populations. Thus, it is important to note that the SI is not disease-specific. Previous studies showed that disease-specific instruments are more sensitive to what is important for patients with DM2 and do not contain themes and items that are not relevant to the disease [32]. However, disease-specific instruments are not superior to disease-transcending instruments [32,33]. Furthermore, there are broad similarities across the provision of self-management support to patients with chronic diseases in routine primary care [3].

Several methodological strengths and limitations of this study need consideration. For scientific purposes, the face validity should not be considered sufficient documentation of the validity, because there is no standard for judging it [34]. We tried to improve the quality of the assessment of the face validity, by making it more systematic. Besides, the ratings of the researchers were consistent and no major differences were found between them.

Quantitative and qualitative approaches were applied to assess the content validity. The focus groups can be considered as a strength of this study. This qualitative approach allowed the researchers to learn about the meaning of the construct from the participants' perspective [35]. The SI is based on firsthand knowledge of the population under study (i.e. patients with COPD, asthma and DM2 and PNs). Many researchers develop instruments without the benefit of consultation with the population under study [36]. However, this is recommended to enhance the content validity [35,36].

As convenience sampling methods were used, selection bias could occur. The demographic characteristics of the participants of the focus groups were not collected. Consequently, we could not assess and control their representativeness. If selection bias did occur, this could have influenced the results.

The inter-rater reliability is best assessed when all raters are able to rate independently and simultaneously. This eliminates true differences in ratings as a source of measurement error [34]. In this study, this was not possible as interaction between the PNs and patients was required. It is explicable that the highest agreement was shown between the two observers. A number of factors interferes with objective ratings and the PNs and patients were most vulnerable for potential inadvertent misrepresentations [34].

The percent agreement and kappa were both computed. Studies showed that the percent agreement tends to inflate the degree of perceived inter-rater agreement, making it potentially misleading [37]. This indicates that these results should be treated with caution. However, the more stringent kappa was also computed. The percent agreement and kappa showed several times contradictory results. On the separate themes and items negative kappa's were found. A negative kappa represents great disagreement [27]. Data collected under conditions of such disagreement are not meaningful and unlikely to represent the facts of the situation with any meaningful degree of accuracy [37]. In the view of the low number of comparisons on which these results were based, this is not entirely surprising.

### *Conclusion*

A novel and unique SI was developed. The results of this study showed excellent validity and good reliability. The SI can be used to determine the content, mode and dose of self-management support provided by PNs. With the SI, an important contribution to the insight into the provision of self-management support to patients with DM2 in routine primary care can be made.

### *Recommendations*

For a proper substantiation of the reliability, we recommend researchers to assess the inter-rater reliability on a larger number of consultations. This will allow them to make statistically sound comparisons between the ratings of the raters on the separate themes and items. Additionally, the validity and reliability of the SI should be assessed for patients with COPD and asthma in routine primary care. The SI is recommended for use in practice and future research to obtain insight into the provision of self-management support to patients with DM2 in routine primary care.

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## Tables and figures

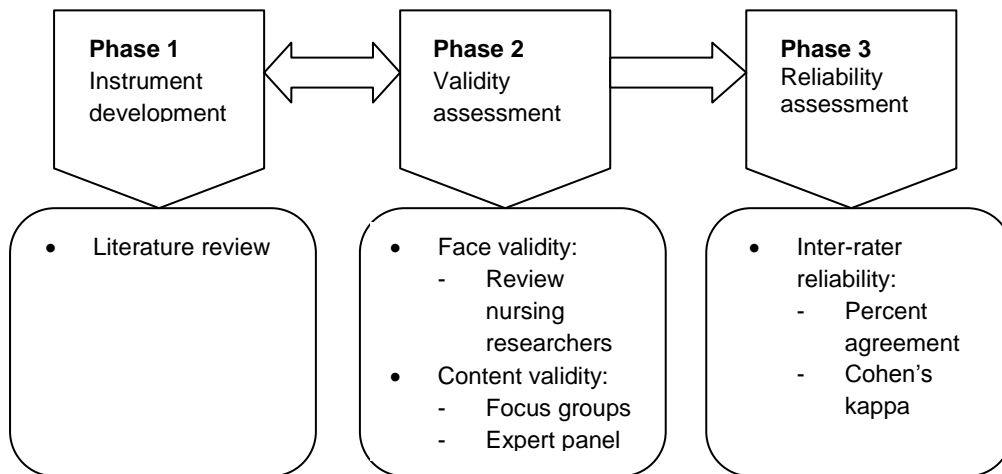


Figure 1. Overview of the approaches applied per phase

**Table 1. Themes and items of the final SI, distribution of the items among the themes and I-CVIs**

<b>Themes (rated as: not discussed, discussed or extensively discussed)</b>	<b>Distribution items</b>
1 General information about the disease	N.A.
2 Physical activity	1,2,3,4,5,6,10,11,12,13,14,15
3 Healthy eating	1,2,3,4,5,6,10,11,12,13,14,15
4 Quit smoking	1,2,3,4,5,6,10,11,12,13,14,15
5 Medication compliance	1,2,3,4,5,6,7,10,11,12,13,14,15
6 Alcohol use	1,2,3,4,5,6,10,11,12,13,14,15
7 Coping with stress	1,2,3,4,5,6,10,11,12,13,14,15
8 Management of symptoms and exacerbations	2,7,10,11,12,13,14,15
9 Coping with emotional and social consequences of the disease	3,6,10,11,12,13,14,15
10 Getting support from others	3,13,14,15
<b>Items (rated as: yes or no)</b>	<b>I-CVIs</b>
1 I gave information about healthy behavior tailored to the patient	1.0
2 I addressed the consequences of unhealthy behavior on the patient's health	1.0
3 We identified potential barriers to healthy behavior together	1.0
4 I assisted in setting feasible and practical goals to improve healthy behavior	1.0
5 I handed the goals on paper to the patient	1.0
6 I discussed that a relapse into old (undesirable) behavior can occur and how to deal with this	1.0
7 I trained practical self-management skills	1.0
8 I encouraged the patient to monitor his/her condition and health problems	1.0
9 We created an action plan which the patient can use in case of exacerbations	0.9
10 I assisted in improving problem solving skills	0.9
11 I assisted in decision making	0.89
12 I gave feedback and endorsed healthy behavior	0.89
13 We discussed how the patient can get support from others	0.78
14 I gave information on how to contact healthcare professionals with questions or health problems	0.8
15 I gave information about where to find practical support	0.8

**Note:** N.A.=not applicable.

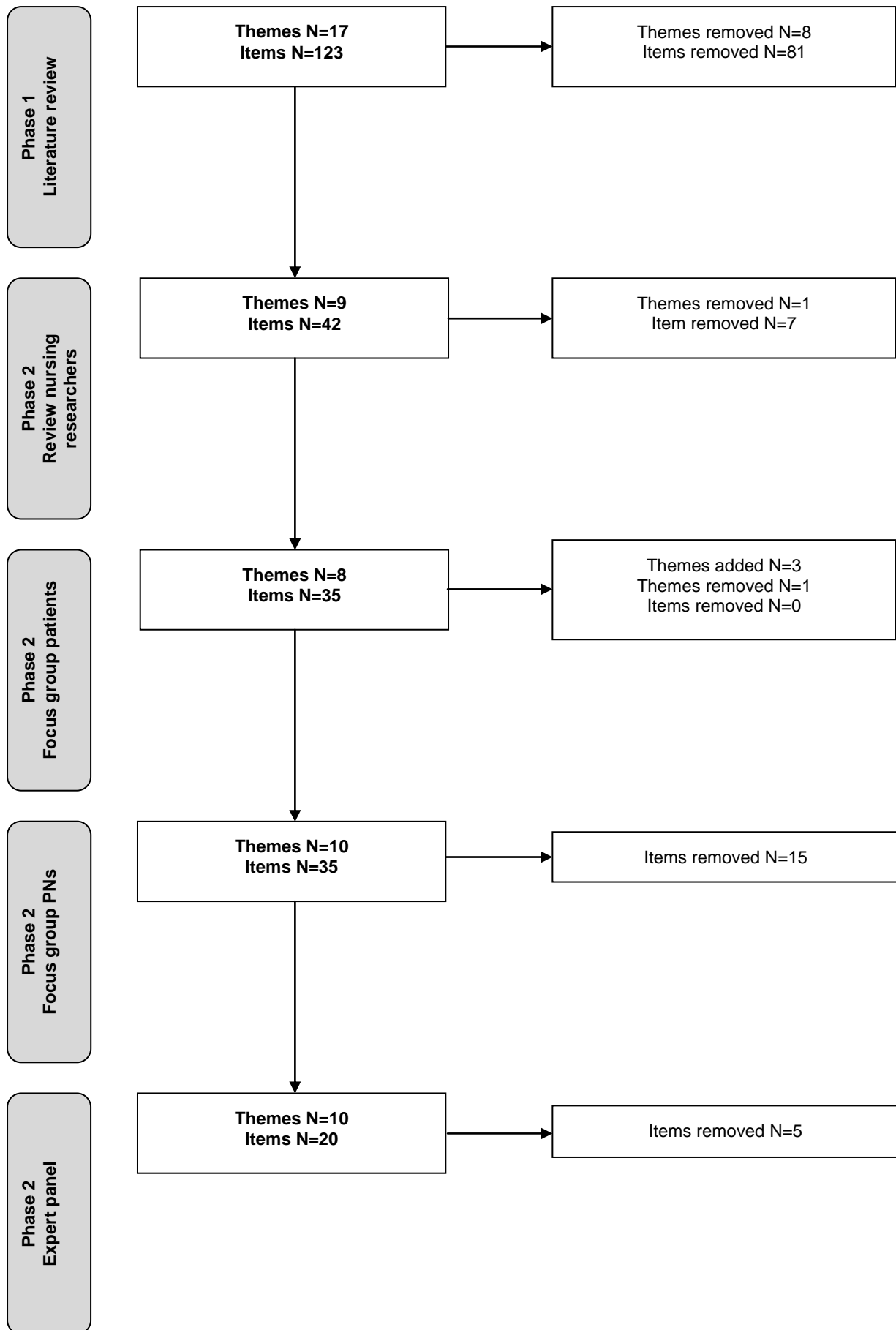


Figure 2. Revisions in the number of themes and items



**Table 2. Themes and items added to and removed from the SI**

Theme/item	Description	Added/removed	Reason
<b>Phase 1 – Literature review</b>			
8 themes/ 81 items	The themes and items were not specifically described yet	Removed	Duplicates and discussion between the researchers about the relevance of the theme/item
<b>Phase 2 – Review researchers</b>			
Theme	Preventive actions	Removed	Merged with another theme
Item	I discussed whether the patient sees himself/herself as a role model	Removed	Too specific (part of another item)
Item	I reflected on the words and behavior of the patient	Removed	Too specific (part of another item)
Item	I showed the instructions to the patient	Removed	Merged with another item
Item	I discussed how the patient can make time for healthy behavior	Removed	Merged with another item
Item	I encouraged the patient to monitor his/her symptoms	Removed	Merged with another item
Item	I emphasized the consequences of unhealthy behavior	Removed	Merged with another item
Item	We determined the discussed lifestyle aspect(s) together	Removed	Merged with another item
<b>Phase 2 – Focus group patients</b>			
Theme	Social position	Removed	Merged with another theme
Theme	General information about the disease	Added	Relevant from the patients' perspective
Theme	Alcohol use	Added	Relevant from the patients' perspective
Theme	Coping with stress	Added	Relevant from the patients' perspective
<b>Phase 2 – Focus group PNs</b>			
Item	I offered the possibility to discuss other topics	Removed	Rated as not relevant
Item	I showed respect for the patient's decision to change his/her behavior	Removed	Rated as not relevant
Item	I discussed how the patient can adapt his/her environment to a healthy lifestyle	Removed	Rated as not relevant
Item	I gave information about how the patient can cope with the emotional consequences of the disease	Removed	Rated as not relevant
Item	I discussed how the patient can deal with disappointments	Removed	Rated as not relevant
Item	I discussed the standard for a healthy lifestyle	Removed	Rated as not relevant
Item	I discussed how the patient can deal with negative reactions from others	Removed	Rated as not relevant
Item	I encouraged the patient to imagine himself/herself a situation in which he/she applied healthy behavior	Removed	Too specific (part of another item)
Item	I stimulated the patient to encourage himself/herself	Removed	Merged with another item
Item	Together with the patient a created a plan regarding healthy behavior	Removed	Merged with another item

Item	We reflected on previously set goals	Removed	Merged with another item
Item	I provided positive reinforcement	Removed	Merged with another item
Item	I assisted in setting long-term goals	Removed	Merged with another item
Item	I offered practical support	Removed	Merged with another item
Item	I encouraged the patient to reward his/her successes	Removed	Merged with another item
<b>Phase 2 – Expert panel</b>			
Item	I gave general information about the disease	Removed	Did not achieve the minimum agreement of the experts (I-CVI 0.5)
Item	I discussed that it is difficult to change behavior	Removed	Did not achieve the minimum agreement of the experts (I-CVI 0.5)
Item	I monitored the patient's condition and gave feedback	Removed	Did not achieve the minimum agreement of the experts (I-CVI 0.67)
Item	I asked about the patient's contact with other healthcare professionals	Removed	Did not achieve the minimum agreement of the experts (I-CVI 0.7)
Item	I gave feedback on the patient's performance	Removed	Merged with another item

**Table 3. Demographic characteristics of the participants**

<b>PNs (N=10)</b>	
Age, mean (range)	42 (22-55)
Female sex (N)	9
Education (N)	
Registered nurse	7
PN	3
Working experience as a PN in years, mean (range)	6.8 (0-16)
Additional training related to self-management support (N)	
No additional training	1
Self-management support	0
Motivational interviewing	4
Self-management support and motivational interviewing	4
Otherwise	1
<b>Patients (N=46)</b>	
Age, mean (range)	66 (44-91)
Female sex (N)	16
Education (N)	
Low	24
Middle	15
High	7
Ethnicity (N)	
Dutch	36
Moroccan	2
Surinamese	1
Southern-European	1
Eastern-European	1
Otherwise	5
Disease duration (N)	
< six months	6
> six months	40

**Note:** N=number of participants.

**Table 4. Percent agreement (% agreement) and Cohen's Kappa ( $\kappa$ )**

Themes/items	PN – patient			PN – observer 1			PN – observer 2			Observer 1 – observer 2		
	N	% agreement	$\kappa$	N	% agreement	$\kappa$	N	% agreement	$\kappa$	N	% agreement	$\kappa$
<b>Themes</b>												
1	45	42.2	0.04	46	52.2	0.17	46	43.5	0.01	46	69.6	0.44
2	45	55.6	0.14	46	80.4	0.63	46	78.3	0.57	46	84.8	0.72
3	45	48.9	0.12	46	60.9	0.36	46	52.2	0.28	46	73.9	0.61
4	45	84.4	0.64	46	91.3	0.81	46	80.4	0.60	46	89.1	0.78
5	45	55.6	0.29	46	67.4	0.47	46	60.9	0.29	46	67.4	0.41
6	45	80.0	0.63	46	91.3	0.84	46	87.0	0.75	46	95.7	0.92
7	45	75.6	0.43	46	84.8	0.63	46	76.1	0.41	46	87.0	0.62
8	45	57.8	0.31	46	67.4	0.48	46	63.0	0.38	46	82.6	0.71
9	45	75.6	0.15	46	84.8	-0.04	46	78.3	-0.11	46	93.5	0.38
10	45	75.6	0.14	46	93.5	0.54	46	87.0	0.18	46	93.5	0.37
Total	450	65.1	0.42	460	77.4	0.62	460	70.7	0.50	460	83.7	0.72
<b>Items</b>												
1	10	90.0	0.62	10	90.0	0.62	10	70.0	0.00	19	89.5	0.61
2	11	72.7	0.23	14	92.9	0.81	12	75.0	0.25	24	83.3	0.60
3	10	60.0	0.20	10	80.0	0.58	10	60.0	0.20	19	89.5	0.79
4	10	70.0	0.40	10	70.0	0.29	10	80.0	0.41	19	84.2	0.48
5	10	100.0	N.A.	10	90.0	N.A.	10	90.0	N.A.	19	100.0	N.A.
6	10	50.0	N.A.	10	90.0	N.A.	10	90.0	N.A.	19	73.7	-0.09
7	2	50.0	N.A.	5	100.0	1.00	3	66.7	N.A.	6	83.3	N.A.
8	1	100.0	N.A.	4	50.0	0.20	2	50.0	N.A.	5	80.0	N.A.
9	1	100.0	N.A.	4	50.0	N.A.	2	100.0	N.A.	5	100.0	N.A.
10	11	81.8	0.62	14	78.6	0.55	12	83.3	0.67	24	95.8	0.92
11	11	54.5	0.07	14	85.7	0.71	12	66.7	0.33	24	83.3	0.66
12	11	63.6	0.21	14	71.4	0.43	12	83.3	0.64	24	91.7	0.62
13	11	81.8	N.A.	14	100.0	N.A.	12	83.3	N.A.	24	79.2	0.23
14	11	54.5	0.04	14	85.7	-0.08	12	83.3	0.40	23	91.3	0.75
15	11	72.7	N.A.	14	100.0	N.A.	12	100.0	N.A.	23	95.7	N.A.
Total	131	71.0	0.41	161	85.1	0.66	141	78.7	0.54	277	88.1	0.75

**Notes:** N=number of comparisons; N.A.=not applicable.

## **Dutch summary**

**Titel:** Zelfmanagementondersteuning aan patiënten met type 2 diabetes mellitus in de routinematige eerstelijnszorg: de ontwikkeling, validiteit en betrouwbaarheid van een screeningsinstrument.

**Inleiding:** De manier waarop praktijkverpleegkundigen zelfmanagementondersteuning integreren in hun consulten verschilt. Hierdoor is er een gebrek aan inzicht in de zelfmanagementondersteuning aan patiënten met type 2 diabetes mellitus in de routinematige eerstelijnszorg. Hoewel het wordt aanbevolen om deze informatie te verzamelen en te registreren is er geen screeningsinstrument dat hiervoor kan worden gebruikt.

**Doel:** Het ontwikkelen en testen van de validiteit en betrouwbaarheid van een ziekteoverstijgend (chronische obstructief longlijden (COPD), astma en type 2 diabetes mellitus) screeningsinstrument. Dit artikel rapporteert uitsluitend over de resultaten voor patiënten met type 2 diabetes mellitus.

**Methode:** Het onderzoek werd uitgevoerd in drie fasen. In de eerste fase werd er een literatuuronderzoek uitgevoerd. In de tweede fase werd de indrukvaliditeit getest door verpleegkundig onderzoekers. De inhoudvaliditeit werd getest door twee focusgroepen (één met patiënten met COPD, astma en type 2 diabetes mellitus en één met praktijkverpleegkundigen) en een expert panel, waarbij gebruik werd gemaakt van de Content Validity Index (CVI). De interbeoordelaarsbetrouwbaarheid werd getest in de derde fase.

**Resultaten:** Het uiteindelijke screeningsinstrument bestaat uit 10 thema's en 15 items. De indrukvaliditeit werd beoordeeld met een 8.7 (thema's) en 7.7 (items). De focusgroepen voegden waardevolle informatie toe over de relevantie van de thema's en items vanuit het perspectief van de participanten. De CVI op schaal niveau was 0.99. Een percentage overeenstemming en kappa van 83.7 en 0.72 werden gevonden voor de thema's en van 88.1 en 0.75 voor de items.

**Conclusie:** Het screeningsinstrument heeft een excellente validiteit en een goede betrouwbaarheid.

**Aanbevelingen:** Het screeningsinstrument kan worden gebruikt in de praktijk en in wetenschappelijk onderzoek om inzicht te verkrijgen in de zelfmanagementondersteuning aan patiënten met type 2 diabetes in de routinematige eerstelijnszorg.

**Trefwoorden:** Zelfmanagement ondersteuning, diabetes mellitus type 2, screeningsinstrument, validiteit, betrouwbaarheid

## **English abstract**

**Title:** The provision of self-management support to patients with type 2 diabetes mellitus (DM2) in routine primary care: the development, validity and reliability of a screening instrument (SI).

**Background:** Practice nurses (PNs) differently integrate self-management support into their consultations. As a result, there is a lack of insight into the provision of self-management support to patients with DM2 in routine primary care. Although it is recommended to collect and record this information, there is no SI which can be used for this purpose.

**Aim:** To develop and assess the validity and reliability of a disease-transcending (chronic obstructive pulmonary disease (COPD), asthma and DM2) SI. This paper exclusively reports on the results obtained for patients with DM2.

**Method:** This study was conducted in three phases. In the first phase a literature review was performed. In the second phase the face validity was assessed by nursing researchers. The content validity was assessed by two focus groups (one with patients with COPD, asthma and DM2 and one with PNs) and one expert panel, using the Content Validity Index (CVI). The inter-rater reliability was assessed in the third phase.

**Results:** The final SI consists of 10 themes and 15 items. The face validity was rated with an 8.7 (themes) and 7.7 (items). The focus groups added valuable information about the relevance of the themes and items from the participants' perspectives. The scale-level CVI was 0.99. A percent agreement and kappa of 83.7 and 0.72 were found for the themes and of 88.1 and 0.75 for the items.

**Conclusion:** The SI has excellent validity and good of reliability.

**Recommendations:** The SI can be used in practice and future research to obtain insight into the provision of self-management support to patients with DM2 in routine primary care.

**Keywords:** Self-management support, type 2 diabetes mellitus, screening instrument, validity, reliability