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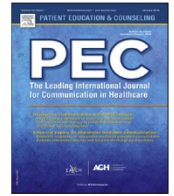
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Development, validation and evaluation of a patient information booklet for rectal cancer survivors with a stoma: A three-step approach

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ABSTRACT

Objective: Quantitatively measure the degree of patient satisfaction and perceived acquired knowledge through the development of a patient information booklet for rectal cancer survivors with a stoma, according to a novel three-step approach.

Methods: The study included a systematic literature review to identify relevant information for the booklet, which was validated by experts based on relevance, clarity and essentiality. It underwent testing on quality, readability, and layout and design and was quantitatively evaluated by rectal cancer survivors with a stoma.

Results: In total, 145 articles were used for the development of the booklet. It scored 91% for relevance according to 17 experts, 70% for readability, 75.63% for quality and 23 out of 32 for design. The mean score of patient satisfaction was 8.03 out of 10. All 20 patients found the booklet 'useful' and 95% felt better informed.

Conclusions: The booklet scored high for patient satisfaction and increased perceived acquired information. It ensured satisfactory levels of quality, readability, and layout and design.

Practice implications: This study offers a novel three-step approach for development of informational tools for cancer survivors, assuring that a variety of newly created written patient materials would be of increased quality and relevance to any target population.

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1. Introduction

Colorectal cancer is the third most common type of cancer worldwide, with an incidence of around 15,000 new cases per year in the Netherlands [1,2]. Approximately 25–30% of colorectal cancers occur in the rectum and most diagnoses are made in patients over the age of 65. Currently, the 5-year survival rate of rectal cancer is 67% (2017), which has drastically improved over recent decades [2]. In the Netherlands, radical resection of a primary rectal tumor leads to the creation of a temporary or permanent stoma in 60.6% of cases (2017) [3].

A stoma, or ostomy, is a purposeful anastomosis between a segment of the gastrointestinal tract and the skin of the anterior abdominal wall. It can serve as a method of fecal diversion for patients with rectal cancer. Having a stoma is especially associated

with a lower health-related quality of life (HRQoL) when compared to other surgical outcomes [4].

Due to the steadily growing population of rectal cancer survivors with a stoma, there is an increased demand for tailored cancer survivor care [5]. The European Organisation of Research and Treatment of Cancer Survivorship Task Force defines cancer survivors as patients whose primary tumors have been curatively resected [6]. Insufficient and incomplete information provided to cancer survivors can hamper the transition from curative surgical treatment to postoperative home care [7,8]. Such problems result in a lower HRQoL and can increase anxiety and depression occurrence [9]. Verbal instructions are less effective for patient education as patients recall only 14% of the information [10]. It is important to ensure that written information is provided at the healthcare facility, as this has been found to be associated with improved patient recall and increased satisfaction with follow-up information [11].

Currently, rectal cancer survivors with a stoma often do receive leaflets concerning surgery and daily stoma care, however, overlooking other important aspects such as possible psychological, sexual and physical implications and how to tackle them

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[12,13]. Lack of information and knowledge of what comes after operative care can lead to physical and mental impairments that further interfere with the patient’s quality of life [7]. Bigger adjustments are currently being made by several countries aiming at ameliorating cancer survivorship care overall, such as a special cancer survivorship training curriculum for healthcare professionals within cancer centers [14]. These adjustments are required due to the limited support cancer survivors are receiving, as opposed to other actively treated patients [15].

The study’s primary aim was to quantitatively measure the degree of patient satisfaction and perceived acquired knowledge through the development of a patient information booklet specifically tailored to the needs of rectal cancer survivors with a stoma. By these means, the study determined the usefulness and quality of the developed booklet for possible future implementation in clinical practice. The secondary aim was to develop a novel three-step approach for the creation of patient information materials.

2. Methods

This study was conducted according to a three-step approach, with each step being discussed in turn. The first step included a systematic literature review to gather relevant information. The second step involved the booklet’s validation through healthcare professionals using an international questionnaire. Additionally, the booklet’s quality, readability and design were assessed. The third step concerned the evaluation of the booklet by the targeted patient group to quantitatively measure the degree of patient satisfaction and perceived acquired knowledge after exposure to the booklet. These steps ensured the methodological validity and reproducibility of this study, depicted in Fig. 1.

2.1. 1st step: development

The comprehensive systematic literature review was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [16], the checklist of which is added in Appendix A. It identified relevant information concerning five domains: (1) stoma complications, (2) diet, (3) physical implications and exercise, (4) sexuality, and (5) psychological aspects. These domains were conceived following in-depth discussions with stoma and colorectal nurses, surgical and medical oncologists as well as dietitians. A search strategy was constructed with the assistance of two independent medical information specialists and was applied to the PubMed database for each of the five domains, presented in Appendix B.

Title, abstract and full text of publications were screened by four reviewers. Inclusion criteria were ileo- or colostomy, information on stoma complications, diet, physical implications and exercise, sexuality, and psychological aspects. Exclusion criteria were articles not available in English or Dutch, species other than humans, no data of interest, and surgical procedures not resulting in a (temporary) ileo- or colostomy.

Data from the systematic literature review were extracted to assess the relevance of the information. The most common complications were categorized according to the specific domain of interest. Information on diet and exercise was extracted from the included publications and The Netherlands Nutrition Centre’s website for better applicability to the Dutch population [17]. The booklet covering the five domains was then developed and assembled.

2.2. 2nd step: validation

2.2.1. Content validity index

Healthcare experts in colorectal cancer and stoma care from the University Medical Center Groningen (UMCG) were asked to review the booklet and validate it according to the Content Validity Index (CVI) [18]. The CVI was sent to the experts as an online validation questionnaire. Experts were invited to rate each subsection of the booklet according to its relevance, clarity and essentiality. Relevance of the specific subsection of the booklet was assessed using a 4-point Likert scale. Clarity and essentiality were based on 3-point scales. The relevance scale was therefore dichotomized into relevant (score of 3 or 4) and irrelevant (score of 1 or 2). The Content Validity of Individual Items (I-CVI) is defined as the proportion of validators rating an item as relevant (score 3 or 4) or essential. The Content Validity of the overall scale by Average (S-CVI/Ave) is established as the average of relevance I-CVIs for all items. The Content Validity of the overall scale by Universal Agreement (S-CVI/UA) is the proportion of items in the questionnaire for which all validators agree on their high relevance (score 3 or 4). The I-CVI threshold for a questionnaire validated by six to ten experts should be at least 0.78 [18]. For more than ten experts, the I-CVI threshold for essentiality and relevance was fixed at 0.70, due to absence of an internationally accepted threshold value. All items with a score higher or equal to 0.70 were considered essential and relevant for the booklet and remained in it. For this purpose, the individual I-CVI scores for relevance and essentiality were averaged and compared to the threshold value. All other subsections were removed. Additionally, whenever a subsection was marked as “not clear” = 1 or “needs revision” = 2 by more than 40% of validators, the text was adjusted according to their

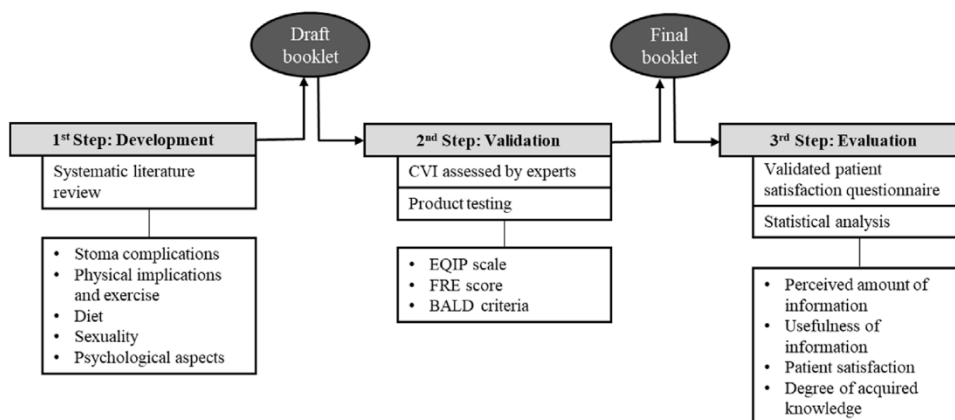


Fig. 1. The three-step approach.

CVI, Content Validity Index; EQIP, Ensuring Quality Information for Patients; FRE, Flesch Reading Ease; BALD, Baker Able Leaflet Design.

comments. This revision strategy was adopted from Rodrigues et al. and modified to ensure that more than half of the validators found the subsection to be clearly understandable [19].

2.2.2. Product testing

The final booklet underwent testing based on (1) quality, (2) readability, and (3) layout and design according to three internationally validated tools. Quality was tested using the Ensuring Quality Information for Patients (EQIP) scale [20]. The EQIP tool consists of 20 questions. Each reviewer determined a score using the formula $\frac{(Yes+1)+(Partly+0.5)+(No+0)}{20-Does\ not\ apply} * 100$ and the four scores were subsequently averaged. The Flesch Reading Ease (FRE) score was used to assess the readability of the written text [21]. Each subsection of the booklet was assessed using the Flesch-Douma formula $206.835 - 0.93 * \frac{total\ words}{total\ sentences} - 77 * \frac{total\ syllables}{total\ words}$, which is specific for the Dutch language [22]. A score of 70–80 is defined as fairly easy to read and can be understood by 11- to 12-year-old Dutch primary school students. A score of 60–70 is defined as plain Dutch and can be understood by 12- to 16-year-old Dutch lower secondary school students. The Baker Able Leaflet Design (BALD) criteria were used as a guide for layout and design characteristics of the patient information booklet [21].

2.3. 3rd step: evaluation

2.3.1. Patient recruitment

Patients were recruited at the outpatient clinic of the UMCG during April and May 2019. Additionally, patients identified via the Basic Registry Oncology outCome were contacted by telephone and invited to participate [23]. All patients were treated at the UMCG with a colostomy or ileostomy as part of primary rectal cancer treatment. Patients diagnosed with Lynch syndrome II were excluded as they need a different and more personalized type of psychological and medical care.

2.3.2. Patient questionnaire

Patients were asked to fill in an adapted version of an international questionnaire, shown in Appendix C, which was translated to Dutch to suit the patient population [24]. The questionnaire was used to determine patient satisfaction and perceived acquired knowledge. Data gathering occurred during an open interview or at home, in which case respondents were asked to return the questionnaire for analysis. All participants agreeing to take part in the study were sent the booklet by post together with the questionnaire. Participants received written information about the study and signed a consent form. Patients were asked to rate the amount of information, the usefulness and readability of the booklet. Furthermore, patients were invited to add comments and improvement points. The patients were given the possibility to indicate as many alternative display formats to the booklet as desired.

2.3.3. Statistical analysis

All results derived from the evaluation questionnaire were analyzed using the IBM SPSS Statistics for Windows, Version 23.0 (Armonk, NY; 2015). The sample size was calculated from the formula: $n = \frac{z^2 p(1-p)}{e^2}$, where “p” is the expected proportion of patients, indicating the adequacy of each item, and “e” represents the acceptable proportional difference compared to what would be expected. A confidence level of 95% was handled, thus resulting in $z = 1.96$, $p = 0.85$ and $e = 0.16$, eventually leading to a minimum of 19.133 or 20 patients being needed [25–27]. Therefore, we approached all suitable patients during a period of four weeks at the UMCG which resulted in 36 patients. During evaluation, the usefulness of information and the degree of perceived acquired knowledge were assessed on a 4-point Likert scale. The perceived amount of information was attributed a 3-point scale and the patient satisfaction was assessed on a 10-point scale. The results of each category were extracted and the mean satisfaction score was

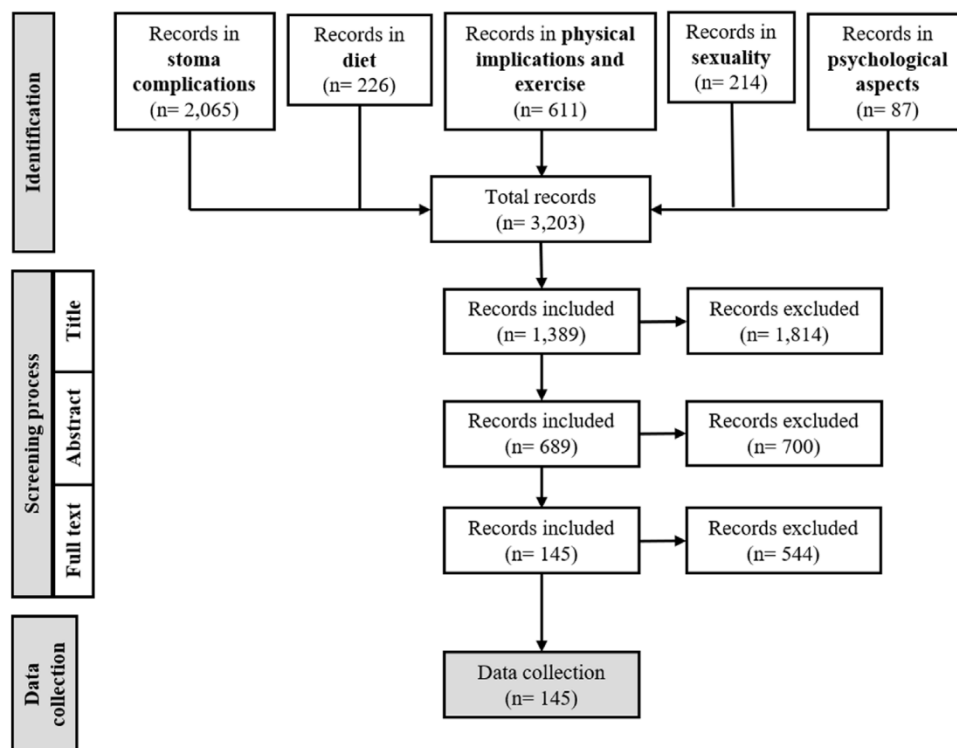


Fig. 2. Screening process of systematic literature review. Implementation of the search strategy in PubMed database on February 20th, 2019.

calculated. A high degree of patient satisfaction was determined as a score of 8 out of 10 and above, with > 9 being very high and a score between 6 and 8 considered moderate [28,29].

3. Results

3.1. 1st step: development

Through the systematic search of the PubMed database using the search strategy, depicted in Appendix B, a total of 3203 results were generated covering the following five domains of interest: stoma complications, diet, physical implications and exercise, sexuality and psychological aspects. Articles were screened based on title, abstract and full text, resulting in 145 included articles, illustrated in Fig. 2.

Information on the five domains of interest was collected, summarized and tailored to the needs of the targeted patient population. It was extracted based on frequency and relevance and was used for the creation of the patient information booklet. The included stoma complications amounted to ten (dehydration, dermatitis, parastomal hernia, stoma prolapse, stoma retraction, stoma stenosis, necrosis, stoma detachment, stoma bleeding, and peristomal fistulas and abscesses). The patient information booklet covered seven physical implications (tiredness, nausea, pain, obstipation, diarrhea, flatulence and urinary incontinence).

3.2. 2nd step: validation

3.2.1. Content validity index

The product was validated by 17 healthcare professionals in the field of rectal cancer and stoma care. Of the 17 experts, 6 were oncological surgeons, 3 medical oncologists, 3 oncological nurses, 3 stoma care nurses and 2 dietitians from the UMCG. In total, seven subsections of the booklet were removed based on averaged I-CVI scores below the set threshold (irrigation, necrosis, stoma detachment, peristomal fistulas and abscesses, feces color, nausea and less common physical implications). The mean scores of the remaining 29 subsections of the booklet were as follows: S-CVI/Ave = 0.91; S-CVI/UA = 0.41.

3.2.2. Product testing

The EQIP score was assessed by all four reviewers. The mean score was calculated by employing the mean numbers of each answer. In total, a mean of 13.50 questions were answered with a 'yes', 3.25 with a 'partly' and 3.25 with a 'no'. Thus, the final EQIP score of the product was 75.63%. The respective FRE score of each subsection and the attributed level of education needed to understand each part of the booklet was assessed. The subsection 'Acceptance' scored the lowest, graded with 61. The subsection 'How do I care for my stoma?' scored the highest, with 79. The mean FRE score of all subsections was 70. This represents a language level comparable to Dutch lower secondary education. The Baker Able Leaflet Design score was calculated for the final version of the product. The final booklet scored 23 out of the possible 32 points. This score corresponds to good layout and design characteristics.

3.3. 3rd step: evaluation

3.3.1. Descriptive statistics

The demographic characteristics of the recruited patients are depicted in Table 1. In total, 36 patients were contacted, 2 decided not to participate, and 22 answered the evaluation questionnaire on time. Two patients were later excluded from the study due to a diagnosis of Lynch syndrome II, resulting in a total of 20 patients included in the study. The mean age of respondents was 62.4 years

Table 1
Patient characteristics.

Number of patients, <i>n</i>	20
Age in years, <i>mean (range)</i>	62.4 (44–86)
Sex, <i>n (%)</i>	
Male	11 (55)
Female	9 (45)
Cancer stage*, <i>n (%)</i>	
Stage I	2 (10)
Stage II	7 (35)
Stage III	8 (40)
Stage IV	3 (15)
Type of stoma, <i>n (%)</i>	
Temporary ileostoma	4 (20)
Permanent ileostoma	2 (10)
Temporary colostoma	6 (30)
Permanent colostoma	8 (40)
Type of surgery, <i>n (%)</i>	
Lower anterior resection	11 (55)
Abdominoperineal resection	5 (25)
Total exenteration	3 (15)
Unknown†	1 (5)

* The 8th edition of the American Joint Committee on Cancer staging was used in this context.

† Data with regards to the type of surgery was not available in the medical records.

with a range extending over 42 years. The female to male ratio was roughly equal and 40% of patients had stage III rectal cancer. The most common stoma type was a permanent colostomy and more than half of the respondents had undergone a low anterior resection.

3.3.2. Patient questionnaire

The computed evaluations for information usefulness and perceived gained knowledge are presented in Fig. 3. All interviewed patients found the booklet's content useful or very useful, depicted in Fig. 3.1. Moreover, 95% of patients felt better informed after reading the booklet shown in Fig. 3.2.

Patients were also asked whether they wanted the content of the booklet to be presented in another format. Of the 20 patients that answered the questionnaire, 70% had suggestions for alternative displays. Most respondents (71%) would prefer to see the information online, whereas only one participant would have appreciated an Audio CD besides the booklet. The additional provision of a DVD was suggested by 21% of the respondents. The booklet contained enough information according to 90% of the patients. The results showed that all patients rated patient satisfaction with a 7 or more out of 10 points and the mean score for satisfaction amounted to 8.03, reflecting a high degree of patient satisfaction.

4. Discussion and conclusion

4.1. Discussion

Through the present study, we designed a novel three-step approach which we used to develop a booklet for rectal cancer survivors who have undergone a colostomy or ileostomy as a consequence of treatment with curative intent. This led to a high degree of patient satisfaction and perceived acquired knowledge.

This high satisfaction score and the fact that the vast majority of patients felt better informed is in line with the findings of MacFater et al. [11,28,29]. They concluded that written follow-up booklets for cancer survivors increased recall by at least 23% and only 5% of their study participants felt they had not received enough information. The high patient satisfaction can in turn be regarded

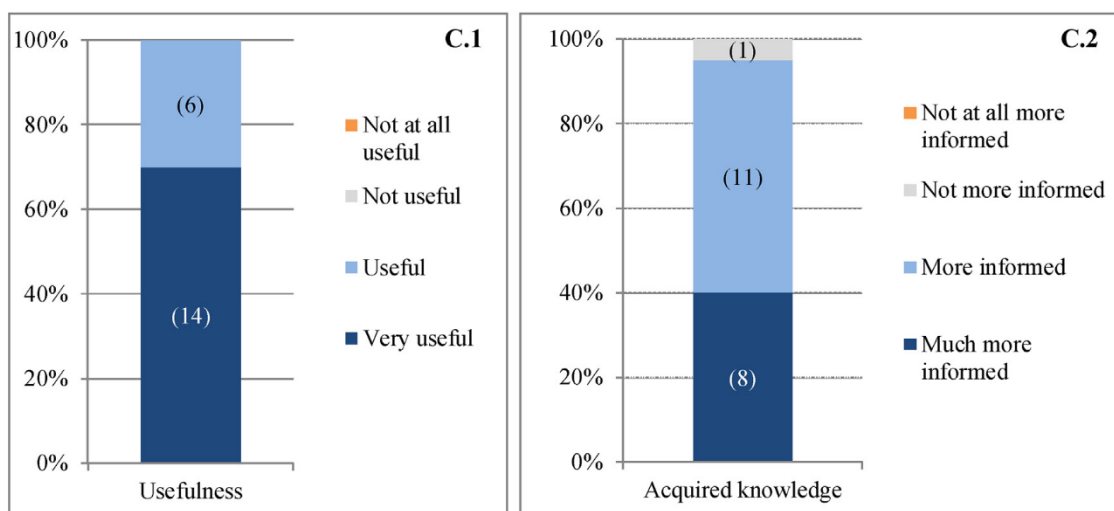


Fig. 3. Patient evaluation responses. C.1) Usefulness of information and C.2) degree of perceived acquired knowledge. Scale represents the percentage of patients with their respective response.

as affirmation that the booklet contains an appropriate amount of information without overcomplicating its content. Similarly, Kessels concluded in his article about patient memory that 'spoken information should be supported with written or visual material' [10]. Correspondingly, the surveyed patients appreciated the booklet in addition to the spoken information they usually receive from healthcare personnel. Moreover, the high S-CVI scores of the final booklet's sections demonstrate the high degree of content information validity. Rodrigues et al. found that overall S-CVI values comparable to the ones in this study represent high quality of information [19]. Although the number of validators in Rodrigues' study was more than double the amount in this study, Lynn stated that more than ten expert validators are probably unnecessary [30].

For evaluation of the booklet, we included patients with a stoma at time of recruitment as well as with a previous temporary stoma. This enabled recall bias, as patients with previous stomas might have forgotten about the information they had received earlier. Due to the limited timeline of the study and the very specific patient population, there was no possibility to evaluate the disease-specific knowledge of the patient population prior to exposure to the created booklet. In order to tackle that impediment, the evaluation questionnaire asked the respondents to compare their newly gained to their prior knowledge.

Moreover, there was a possibility of sample bias as patients who agree to take part in studies often take better care of their health [31]. In addition, such patients are already more informed about their health problems and they may therefore score lower with regards to the degree of perceived acquired knowledge after reading the booklet. This may have potentially influenced the results of the study. Furthermore, there was a methodological risk of inflated S-CVI/UA values among validators due to chance agreement. Therefore, one should further explore whether CVI results should be statistically confirmed using the Cohen's kappa coefficient in order to exclude interrater agreement. Wynd et al. suggest such an additional precautionary measure, but it remains unclear whether it will significantly influence the results when more than ten experts are consulted [32].

An important strength of this study was its novel three-step approach, which followed precise guidelines for each sub-step, ensuring its reliability and reproducibility. The systematic literature review served to filter all relevant information described in the literature, decreasing the risk of overlooking essential factors

associated with survivorship care. The literature search was only conducted in the PubMed database due to time constraint, so as to reserve sufficient time for the remaining parts of the three-step approach. In order to yield the best cost-effectiveness while maintaining the integrity of all three steps, we believe that more than one database would have no added value to the end result. By testing the booklet using validated tools we ensured its readability, quality, good layout and design. Good readability was of particular interest because it plays a fundamental role in patient empowerment, engagement and decision making [33]. The use of external validators and internationally accepted product testing methods in this study promoted the elimination of confirmation bias during booklet development. Evaluating the booklet through patients ensured the good readability of the booklet and suggested the added benefit of written information in patient satisfaction and perceived knowledge.

4.2. Conclusion

It can be concluded that the booklet developed using this novel three-step approach yielded a high degree of satisfaction and perceived acquired knowledge in the patient population. Additionally, the expert validation demonstrated high content validity. Thus, the created booklet could potentially smoothen the transition from hospital care to postoperative life at home. We propose this study's methodology to be used as a mainstay for medical information material development as it promotes satisfactory levels of quality, readability, layout and design.

4.3. Practice implications

This study showed that through patient involvement and product testing, a high degree of patient satisfaction and perceived acquired knowledge can be achieved. Therefore, we suggest the implementation of this novel three-step approach in the development of future patient information materials as a mainstay to provide an easier, user-friendlier and more direct access to information; while taking into account the specific emotional, psychological and physical needs of a patient population. The combination of EQIP scale, FRE score and BALD criteria could become the standard methodological tools to test information materials in healthcare settings. This would aid newly created written patient materials to be of increased quality and utility to the target population.

Rectal cancer survivors with permanent or temporary ileo- or colostomies may benefit from this booklet, as it covers areas such as physical implications, psychological aspects and sexuality, which are not commonly included in information brochures distributed by hospitals. Especially sexuality is often an area of many unanswered questions for stoma patients, since both healthcare professionals and patients themselves find it uncomfortable to initiate the topic [34].

This novel three-step approach can contribute to the bigger adjustments currently made by multiple countries aiming at ameliorating cancer survivorship care overall [14]. Future studies should also investigate the cost- and time-effectiveness of such a developmental framework for the creation of future patient information materials. As technology evolves and computer literacy among elderly patients continues to improve, the demand of online patient information materials will increase. In fact, half of the patients in this study would have appreciated seeing this information online as well as in printed form. In conclusion, the next step would be to make the patient material available online which would allow for unconstrained information provided inexpensively.

Compliance with ethical standards

Ethical approval was obtained by the Central Ethical Testing Committee of the UMCG. The study did not fall under the Dutch Law on Medical Scientific Research with Human subjects, as no iatrogenic intervention was used (Medical Ethical Committee number: 201,900,041).

Informed consent

Informed consent was obtained from all individual participants included in this study.

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CRedit authorship contribution statement

Panagiotis Giannopoulos: Conceptualization, Methodology, Validation, Formal analysis, Investigation, Visualization, Writing - original draft, Writing - review & editing. **Yannick J. Mertens:** Conceptualization, Methodology, Formal analysis, Investigation, Writing - original draft, Writing - review & editing. **Laura E. Secomandi:** Conceptualization, Methodology, Validation, Investigation, Writing - original draft. **Linde Olsder:** Conceptualization, Resources, Supervision. **Barbara L. van Leeuwen:** Methodology, Resources, Supervision, Project administration.

Declaration of Competing Interest

The authors declare that there is no conflict of interest that could be perceived as affecting the impartiality of this study.

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Appendix A.

Prisma Checklist			
Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	-
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3, 4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3, 4
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	1
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix B
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	4
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	4
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	4
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	-
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	4
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I ²) for each meta-analysis.	-
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	-
	16		-

Additional analyses		Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	6
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	6, 7
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	–
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	6
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	–
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	–
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	–
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	9
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	9
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	9, 10
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	1

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

Appendix B.

PubMed search strategy for systematic literature review and meta-analysis.

Stoma complications

“Rectal Neoplasms” [Mesh] OR rectal neoplasm* [tiab] OR rectal cancer* [tiab] OR rectal tumour* [tiab] OR rectal tumor* [tiab] OR rectal oncol* [tiab]) AND (“Surgical Stomas” [Mesh] OR “Rectum/surgery” [Mesh] OR “Colostomy” [Mesh] OR surgical stoma* [tiab] OR rectum surger* [tiab] OR colostom* [tiab] OR rectal stoma* [tiab] OR operative treatment* [tiab]) AND (“Postoperative Complications” [Mesh] OR “Reoperation/adverse effects” [Mesh] OR “Colostomy/adverse effects” [Mesh] OR “Surgical stomas/adverse effects” [Mesh] OR “Surgical Wound Infection” [Mesh] OR complication* [tiab] OR “Sickness Impact

Profile” [Mesh] OR Sickness Impact Profile [tiab] OR side effect* [tiab])

Number of hits: 2605

Diet

“Rectal Neoplasms” [Mesh] OR rectal neoplasm* [tiab] OR rectal cancer* [tiab] OR rectal tumour* [tiab] OR rectal tumor* [tiab] OR rectal oncol* [tiab]) AND (“Surgical Stomas” [Mesh] OR “Rectum/surgery” [Mesh] OR “Colostomy” [Mesh] OR surgical stoma* [tiab] OR rectum surger* [tiab] OR colostom* [tiab] OR rectal stoma* [tiab] OR operative treatment* [tiab]) AND (“Diet Therapy” [Mesh] OR “Diet” [Mesh] OR “Nutritional status” [Mesh] OR “Healthy Diet” [Mesh] OR “Constipation/diet therapy” [Mesh] OR “Dietary fiber/therapeutic use” [Mesh] OR “Colorectal Neoplasms/diet therapy*” [Mesh] OR “Diet Surveys” [Mesh] OR “Dietary Proteins/metabolism*” [Mesh] OR “Nutritional Sciences” [Mesh] OR diet* [tiab] OR nutrition [tiab] OR eat* [tiab] OR food [tiab] OR weight [tiab] OR consumpt* [tiab])

Number of hits: 226

Physical implications

“Rectal Neoplasms” [Mesh] OR rectal neoplasm* [tiab] OR rectal cancer* [tiab] OR rectal tumour* [tiab] OR rectal tumor* [tiab] OR rectal oncol* [tiab]) AND (“Surgical Stomas” [Mesh] OR “Rectum/surgery” [Mesh] OR “Colostomy” [Mesh] OR surgical stoma* [tiab] OR rectum surger* [tiab] OR colostom* [tiab] OR rectal stoma* [tiab] OR operative treatment* [tiab]) AND (“Recovery of Function” [Mesh] OR “Exercise” [Mesh] OR “Exercise Therapy” [Mesh] OR “Fecal Incontinence” [Mesh] OR “Urinary Incontinence” [Mesh] OR physical* [tiab] OR movement* [tiab] OR training [tiab] OR exercise* [tiab] OR Fecal Incontinence [tiab] OR Urinary Incontinence [tiab])

Number of hits: 611

Sexuality

“Rectal Neoplasms” [Mesh] OR rectal neoplasm* [tiab] OR rectal cancer* [tiab] OR rectal tumour* [tiab] OR rectal tumor* [tiab] OR rectal oncol* [tiab]) AND (“Surgical Stomas” [Mesh] OR “Rectum/surgery” [Mesh] OR “Colostomy” [Mesh] OR surgical stoma* [tiab] OR rectum surger* [tiab] OR colostom* [tiab] OR rectal stoma* [tiab] OR operative treatment* [tiab]) AND (“Sexual Dysfunction” [Mesh] OR “Sex Factors” [Mesh] OR “Sexual Behavior” [Mesh] OR “Sexual Partners” [Mesh] OR “Sexuality” [Mesh] OR “Spouses/psychology” [Mesh] OR “Sex Characteristics” [Mesh] OR “Libido/physiology” [Mesh] OR “Erectile Dysfunction” [Mesh])

Number of hits: 214

Psychological aspects

“Rectal Neoplasms” [Mesh] OR rectal neoplasm* [tiab] OR rectal cancer* [tiab] OR rectal tumour* [tiab] OR rectal tumor* [tiab] OR rectal oncol* [tiab]) AND (“Surgical Stomas” [Mesh] OR “Rectum/surgery” [Mesh] OR “Colostomy” [Mesh] OR surgical stoma* [tiab] OR rectum surger* [tiab] OR colostom* [tiab] OR rectal stoma* [tiab] OR operative treatment* [tiab]) AND (“Quality of Life” [Mesh] OR “Sick Role” [Mesh] OR “Disability evaluation” [Mesh] OR “Activities of Daily Living” [Mesh] OR “Adaptation, Psychological” [Mesh] OR “Mental Health” [Mesh] OR psychol* [tiab] OR mental* [tiab] OR emotion* [tiab] cognit* [tiab] OR qol [tiab])

Number of hits: 87

Appendix C.

Patient evaluation questionnaire



Information and support for people diagnosed with cancer and their families

This questionnaire is about the information booklet called “Omgaan met mijn stoma: Leven na endeldarmkanker”. We would like to know what you think of the booklet.

This questionnaire is for **everyone** who has distributed, read or used the information booklet.

We would like your views by completing this short questionnaire. This questionnaire does not require any information that will identify you. **Our deadline for responses is one week after the receiving of this booklet.**

**Please return to:
afd. Chirurgische Oncologie**

**t.a.v. P. Nijhuis
Huispostcode BA31
Antwoordnummer 332
9700 VB Groningen**

1. Where did you receive or pick up the booklet?

- At a hospital
- By post
- By e-mail
- Other (please state)

Please tick one box

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

2. Did you read the text of the booklet?

- Yes, all of it
- Yes, some of it
- No

Please tick one box

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

3. What do you think of the amount of information in the booklet?

Please tick one box

- Too much
- Too little
- Just about right

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

4. What do you think of the usefulness of the information?

Please tick one box

- Very useful
- Useful
- A lot did not apply to me
- Not at all useful

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

5. How satisfied are you with the information?

Please circle one number

- 0
- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10

6. Do you feel better informed?

Please tick one box

- Very informed
- Informed
- Not informed
- Not at all informed

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

7. Did you pass on the booklet to someone else?

Please tick one box

- Yes
- No

<input type="checkbox"/>
<input type="checkbox"/>

8. Do you think the information in the booklet could also be presented in different formats?

Yes No

9. If you answered yes, what formats do you consider useful?

Tick as many as apply

Displayed on television screens in hospitals and GP practices	<input type="checkbox"/>
Displayed on television screens in other public places	<input type="checkbox"/>
On a website	<input type="checkbox"/>
On a DVD for personal and family use	<input type="checkbox"/>
CD audio (sound only) for personal and family use	<input type="checkbox"/>
Other (please state)	<input type="checkbox"/> _____

10. Is there any additional information you would like included in the leaflet?

.....

.....

11. Any other comments about the leaflet?

.....

.....

Thank you for taking the time to complete this questionnaire and giving us your feedback. Please return within one week.

References

[1] Cancer, WHO Fact Sheets, WHO, 2018 <https://www.who.int/news-room/fact-sheets/detail/cancer>. Accessed 25 Mar 2020.

[2] The Netherlands Cancer Registry, Dutch Cancer Figures, Netherlands Comprehensive Cancer organization, IKNL, 2019 <https://www.cijfersoverkanker.nl/nkr/index>. Accessed 29 Apr 2019.

[3] D.C.R.A. Jaarrapportage, [DCRA annual report 2017], Dutch ColoRectal Audit, DICA, 2017, pp. 2018 <https://dica.nl/jaarrapportage-2017/dcra>. Accessed 29 Apr 2019.

[4] M. Bours, B. Linden, R. Winkels, F. Duijnhoven, F. Mols, E. Roekel, E. Kampman, S. Beijer, M.P. Weijenberg, Candidate predictors of health-related quality of life of colorectal Cancer survivors: a systematic review, *Oncologist* (2016), doi: <http://dx.doi.org/10.1634/theoncologist.2015-0258>.

[5] T. Gosselin, S. Beck, D. Abbott, S. Grambow, D. Provenzale, P. Berry, K.L. Kahn, J. L. Malin, The symptom experience in rectal Cancer survivors, *J. Pain Symptom Manage.* (2016), doi: <http://dx.doi.org/10.1016/j.jpainsymman.2016.05.027>.

[6] E. Moser, F. Meunier, Cancer survivorship: a positive side-effect of more successful cancer treatment, *Eur. J. Cancer Suppl.* (2014), doi: <http://dx.doi.org/10.1016/j.ejcsup.2014.03.001>.

[7] O. Husson, M. Thong, F. Mols, S. Oerlemans, A. Kaptein, L. van de Poll-Franse, Illness perceptions in cancer survivors: what is the role of information provision? *Psycho-Oncol.* (2012), doi: <http://dx.doi.org/10.1002/pon.3042>.

[8] J. Sisler, J. Taylor-Brown, Z. Nugent, D. Bell, M. Khawaja, P. Czaykowski, D. Wirtzfeld, J. Park, S. Ahmed, Continuity of care of colorectal cancer survivors at the end of treatment: the oncology–primary care interface, *J. Cancer Surviv.* (2012), doi: <http://dx.doi.org/10.1007/s11764-012-0235-9>.

[9] O. Husson, F. Mols, L. van de Poll-Franse, The relation between information provision and health-related quality of life, anxiety and depression among cancer survivors: a systematic review, *Ann. Oncol.* (2011), doi: <http://dx.doi.org/10.1093/annonc/mdq413>.

[10] R. Kessels, Patients' memory for medical information, *JRSM* (2003), doi: <http://dx.doi.org/10.1258/jrsm.96.5.219>.

[11] H. MacFater, W. MacFater, A. Hill, M. Lill, Individualised follow-up booklets improve recall and satisfaction for cancer patients, *N. Z. Med. J.* 130 (2017) 39–45.

[12] S. Hardcastle, C. Maxwell-Smith, M. Hagger, M. O'Connor, C. Platell, Exploration of information and support needs in relation to health concerns, diet and physical activity in colorectal cancer survivors, *Eur. J. Cancer Care* (2017), doi: <http://dx.doi.org/10.1111/ecc.12679>.

[13] M. Traa, J. De Vries, J. Roukema, H. Rutten, B. Den Oudsten, The sexual health care needs after colorectal cancer: the view of patients, partners, and health care professionals, *Support. Care Cancer* (2013), doi: <http://dx.doi.org/10.1007/s00520-013-2032-z>.

[14] M. Grant, D. Economou, B. Ferrell, G. Uman, Educating health care professionals to provide institutional changes in cancer survivorship care, *J. Cancer Educ.* (2012), doi: <http://dx.doi.org/10.1007/s13187-012-0314-7>.

[15] D. Blanch-Hartigan, L.P. Forsythe, C.M. Alfano, T. Smith, L. Nekhlyudov, P.A. Ganz, J.H. Rowland, Provision and discussion of survivorship care plans among cancer survivors: results of a nationally representative survey of oncologists and primary care physicians, *J. Clin. Oncol.* (2014), doi: <http://dx.doi.org/10.1200/JCO.2013.51.7540>.

[16] D. Moher, A. Liberati, J. Tetzlaff, D.G. Altman, Prisma Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement, *PLoS Med.* (2009), doi: <http://dx.doi.org/10.1371/journal.pmed.1000097>.

[17] Voedingscentrum, Stichting Voedingscentrum Nederland. Nutrition Center, Foundation Netherlands Nutrition center, 2018. <https://www.voedingscentrum.nl>.

- [18] D. Polit, C. Beck, The content validity index: are you sure you know what's being reported? Critique and recommendations, *Res. Nurs. Health* (2006), doi:<http://dx.doi.org/10.1002/nur.20147>.
- [19] I. Rodrigues, J. Adachi, K. Beattie, J. MacDermid, Development and validation of a new tool to measure the facilitators, barriers and preferences to exercise in people with osteoporosis, *BMC Musculoskelet. Disord.* (2017), doi:<http://dx.doi.org/10.1186/s12891-017-1914-5>.
- [20] B. Moul, L. Franck, H. Brady, Ensuring Quality Information for Patients: development and preliminary validation of a new instrument to improve the quality of written health care information, *Health Expect.* (2004), doi:<http://dx.doi.org/10.1111/j.1369-7625.2004.00273.x>.
- [21] R. Adep, M. Swamy, Development and evaluation of patient information leaflets (PIL) usefulness, *Indian J. Pharm. Sci.* (2012), doi:<http://dx.doi.org/10.4103/0250-474X.103857>.
- [22] W.H. Douma, De leesbaarheid van landbouwbladen: een onderzoek naar een toepassing van leesbaarheidsformules. [The readability of agricultural papers: a research into and an application of readability formulas], Landbouwhogeschool Wageningen, Afdeling Sociologie En Sociografie, Bulletin Nr. 17, Agricultural University Wageningen, Department of Sociology and Sociography, 1960.
- [23] H.E. Van der Veen, H.E. Middelveldt, Dashboard basic registry oncological OutCome (BROC), Nederlandse Federatie Van UMC's Consortium Kwaliteit Van Zorg (NFU), the Netherlands Federation of University Medical Centers Consortium Quality of Care, 2017 https://nfukwaliteit.nl/pdf/20171123_Eindrapportage_Oncologie_BROC_UMCG_SoK_NFU.PDF. Accessed 9 May 2019.
- [24] Information and Support for People Diagnosed With Cancer and Their Families, NHS Grampian, 2012 <http://www.nhsgrampian.org/files/Cancer%20Info%20Leaflet%20Evaluation%20Questionnaire.doc>. Accessed 29th April 2019.
- [25] M.V. Lopes, V.M. Silva, T.L. Araujo, Methods for establishing the accuracy of clinical indicators in predicting nursing diagnoses, *Int. J. Nurs. Knowl.* (2012), doi:<http://dx.doi.org/10.1111/j.2047-3095.2012.01213.x>.
- [26] E.J. Kuipers, W.M. Grady, D. Lieberman, T. Seufferlein, J.J. Sung, P.G. Boelens, C.J. H. van de Velde, T. Watanabe, Colorectal cancer, *Nat. Rev. Dis. Primers* (2015), doi:<http://dx.doi.org/10.1038/nrdp.2015.65>.
- [27] S.C. Oliveira, M.V. Lopes, A.F. Fernandes, Development and Validation of an Educational Booklet for Healthy Eating During Pregnancy, *Revista latino-americana de enfermagem*, 2014, doi:<http://dx.doi.org/10.1590/0104-1169.3313.2459>.
- [28] A. Neumayr, A. Gnirke, Jc Schaeuble, Mt Ganter, H. Sparr, A. Zoll, A. Schinnerl, M. Nuebling, T. Heidegger, M. Baubin, Patient satisfaction in out-of-hospital emergency care: a multicentre survey, *Eur. J. Emerg. Med.* (2016), doi:<http://dx.doi.org/10.1097/MEJ.0000000000000264>.
- [29] Sa. Smith, Magnet hospitals: higher rates of patient satisfaction, *Policy Polit. Nurs. Pract.* (2014), doi:<http://dx.doi.org/10.1177/1527154414538102>.
- [30] M. Lynn, Determination and quantification of content validity, *Nurs. Res.* 35 (1986) 382–386.
- [31] C. Pannucci, E. Wilkins, Identifying and avoiding Bias in research, *Plast. Reconstr. Surg.* (2010), doi:<http://dx.doi.org/10.1097/PRS.0b013e3181de24bc>.
- [32] C. Wynd, B. Schmidt, M. Schaefer, Two quantitative approaches for estimating content validity, *West. J. Nurs. Res.* (2003), doi:<http://dx.doi.org/10.1177/0193945903252998>.
- [33] A. Coulter, J. Ellins, Effectiveness of strategies for informing, educating, and involving patients, *BMJ.* (2007), doi:<http://dx.doi.org/10.1136/bmj.39246.581169.80>.
- [34] P. Weerakoon, Sexuality and the patient with a stoma, *Sex. Disabil.* (2001), doi:<http://dx.doi.org/10.1023/A:1010625806500>.