

Qualitative research on the Belgian Cancer Rehabilitation Evaluation System (CARES): An evaluation of the content validity and feasibility

Peer-reviewed author version

SCHOUTEN, Bojoura; HELLINGS, Johan; Vankrunkelsven, Patrick; MEBIS, Jeroen; BULENS, Paul; Buntinx, Frank; VANDIJCK, Dominique & Van Hoof, Elke (2017) Qualitative research on the Belgian Cancer Rehabilitation Evaluation System (CARES): An evaluation of the content validity and feasibility. In: JOURNAL OF EVALUATION IN CLINICAL PRACTICE, 23(3), p. 599-607.

DOI: 10.1111/jep.12681

Handle: <http://hdl.handle.net/1942/24349>

TITLE PAGE

‘Qualitative research on the Belgian Cancer Rehabilitation Evaluation System (CARES): An evaluation of the content validity and feasibility.’

Schouten B., Hellings, J., Vankrunkelsven, P. , Mebis J., Bulens, P., Buntinx, F., Vandijck D., Van Hoof E.

Corresponding author:

Bojoura Schouten, MSc, PhD-student, Faculty of Medicine and Life Sciences, Hasselt University, Martelarenlaan 42, 3500 Hasselt, Belgium & Voluntary research assistant, Faculty of Psychological and Educational Sciences, Free University of Brussels, Pleinlaan 2, 1050, Elsene, Belgium, Contact information: Tel.: +32 11 26 85 06, Fax: /, Mail: bojoura.schouten@uhasselt.be

Other authors:

Johan Hellings, PhD, Professor, Faculty of Medicine and Life Sciences, Hasselt University, Martelarenlaan 42, 3500 Hasselt, Belgium & Managing director, AZ Delta Hospital, Rode-Kruisstraat 20, 8800 Roeselare, Belgium.

Patrick Vankrunkelsven, PhD, Professor, Department of Public health and Primary Care, Faculty of Medicine, KU Leuven, Kapucijnenvoer 33, PB 7001, 3000 Leuven, Belgium & Director, Belgian Center for Evidence-Based Medicine (CEBAM), Kapucijnenvoer 33- blok J, 3000 Leuven, Belgium.

Jeroen Mebis, PhD, Professor, Faculty of Medicine and Life Sciences, Hasselt University, Martelarenlaan 42, 3500 Hasselt, Belgium & Medical Oncologist, Jessa Hospital, Stadsomvaart 11, 3500 Hasselt, Belgium.

Paul Bulens, MD, Radiologist, Jessa Hospital, Stadsomvaart 11, 3500 Hasselt, Belgium.

Frank Buntinx, PhD, Professor, Department of Public health and Primary Care, Faculty of Medicine, KU Leuven, Kapucijnenvoer 33, PB 7001, 3000 Leuven, Belgium.

Dominique Vandijck, PhD, Professor, Faculty of Medicine and Life Sciences, Hasselt University, Martelarenlaan 42, 3500 Hasselt, Belgium & Professor, Faculty of Medicine and Health Sciences, Ghent University, De Pintelaan 185, 9000 Ghent, Belgium & Managing Director, ICURO, Brussel, Belgium.

Elke Van Hoof, PhD, Professor, Department of Experimental and Applied Psychology, Faculty of Psychological and Educational Sciences, Free University of Brussels, Pleinlaan 2, 1050 Elsene, Belgium.

Suggested running title: Evaluation content validity and feasibility CARES

KEYWORDS: cancer, quality of life, care needs, assessment, patient-centeredness

39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

ABSTRACT

RATIONALE, AIMS AND OBJECTIVES: The systematic assessment of cancer patients well-being and care needs is internationally recommended to optimize comprehensive cancer care. The Cancer Rehabilitation Evaluation System (CARES) is a psychometrically robust quality of life and needs assessment tool of US origin, developed in the early '90s. This article describes Belgian patients' view on the content validity and feasibility of the CARES for use in current cancer care.

METHOD: Participants were cancer patients recruited through media. Data were gathered in four focus groups (n=26). The focus group discussions were facilitated with key questions. A moderator and an observer conducted and followed the discussion. The audio file was transcribed verbatim and afterwards analyzed thematically.

RESULTS: Participants experience concerns and needs in a wide range of life domains: physical, emotional, cognitive, social, relational, sexual, financial, work-related and in the interaction with care professionals. According to participants, the items of the CARES are all relevant to capture the possible life disruption that cancer patients and survivors experience. One important theme is missing in the CARES, namely the well-being of loved ones. The completion time of the CARES was judged to be feasible, and according to participants only a few items need a reformulation .

CONCLUSION: In general, the results of this study support the content validity and feasibility of the CARES. However, little adjustments in formulation and a few extra items are needed. The instrument can be used to obtain a comprehensive assessment of cancer patients' overall well-being and care needs to take dedicated action in care.

61 INTRODUCTION

62 Cancer is a disease with a huge impact, going far beyond the threat of physical health. Patients and survivors
63 often struggle with multifactorial consequences of physical, psychological (cognitive, emotional), and social
64 nature (1-3). Since scientific evolutions increased survival in the cancer patient population, attention for quality
65 of life (QOL) in cancer care became more and more important. Along with other vital signs (temperature, blood
66 pressure, pulse, respiratory rate and pain), distress or psychosocial well-being is considered the ‘sixth vital sign’
67 that deserves follow-up in cancer care (4-6).

68 Most patients do not disclose their psychological problems spontaneously, they rather frequently wait on the
69 initiative of their doctor to discuss psychosocial topics (7). The majority of specialists working in medical
70 oncology acknowledge the need to detect psychosocial distress. Though, clinicians are not always accurate in
71 identifying patients who are significantly distressed and often underestimate emotional matters in patients (8). A
72 mutual expectation of doctors and patients that the other will introduce the topic often leaves psychosocial
73 concerns undiscussed (7). Care providers should ensure to minimize barriers for patients to disclose emotional
74 issues (8). The use of a screening or assessment instrument prevents doctors from having to ask questions that
75 they may feel are intrusive to the patient. Therefore, for example in Europe, Australia and the United States,
76 guidelines were developed to systematically screen for levels of psychosocial distress and care needs of cancer
77 patients (9-15). In Belgium there are no such guidelines, and psychosocial screening is not standardly applied in
78 cancer care. A limitation in Belgian research and practice is the absence of a validated comprehensive
79 assessment instrument to identify psychosocial concerns and care needs of cancer patients. However, multi-
80 domain screening can facilitate the dialogue between patients and clinicians and help detect distress (16, 17). A
81 subsequent in-depth assessment of distressed individuals could determine which unmet needs have contributed to
82 distress and give insights for triage and referral to different levels of intervention appropriate to each patient. In
83 this way, a stepped care approach supported by the use of screening or assessment results would contribute to the
84 organization of a more patient-centered and cost-efficient care.

85 In several systematic reviews (17-19), the psychometric qualities of needs assessment tools were compared,
86 mainly resulting in a positive evaluation of the Cancer Rehabilitation Evaluation System (CARES), and the
87 Supportive Care Needs Survey (SCNS). Since the researchers believe that the CARES assesses ‘health’ care
88 needs with the greatest depth in terms of biopsychosocial content, this instrument was chosen for further use.
89 The CARES is a QOL and needs assessment instrument, developed in the nineties to provide an efficient way of
90 gathering specific information about the day-to-day problems and rehabilitation needs of cancer patients. In the

91 past this instrument was successfully used for research and clinical purposes (20-24). Unfortunately, the
92 widespread use of the CARES was limited by a copyright and user fee imposed by the developers. Since the user
93 fee was abolished in November 2012 the instrument gained further visibility in research (25-28).
94 The time perspective, culture and language are important for the ecological dimension and validity of an
95 instrument. A correct adaptation for a different language and culture requires a broader design that takes into
96 account linguistic as well as technical and conceptual aspects in measuring health status (29). Since the CARES
97 was not frequently used in recent years, the validity in current patient populations is still uncertain. To resolve
98 this issue, new validation research had to be undertaken. Two studies were conducted to examine the validity of
99 the CARES for the Belgian population: a quantitative study on the translation and validation of the Belgian
100 CARES was conducted to examine the psychometric robustness of the instrument in terms of reliability,
101 construct validity and concurrent validity (30, 31), and the qualitative study that is described in this article.
102 The aim of this qualitative study is to involve the target population, namely Belgian cancer patients, in answering
103 the following questions: ‘Is the content of the CARES relevant and complete enough to have the potential to
104 capture the QOL and supportive care needs of Belgian patients?’ and ‘Is the CARES an acceptable and feasible
105 instrument for these patients?’
106

107 **METHODS AND MATERIALS**

108 The method of focus group (FG) discussions was used to deepen our understanding of participants’ experiences
109 and the meaning they attribute to such experiences. The diversity of participants in the group ensured that the
110 insights on the discussion topic were obtained from different angles and perspectives, and not merely based on
111 individual opinions. This is important for this study since it needed to explore the degree to which the content of
112 the CARES allowed to capture the QOL and supportive care needs of Belgian patients in general. Each
113 participant was encouraged to actively participate in the discussion.
114

115 **Participants and setting**

116 Participants were adult cancer patients recruited through a call in the local newspaper and on the radio in May
117 2014. There were no restrictions on type and time of cancer diagnosis, gender and age (‘adult’ was defined as 18
118 years and older). Patients were excluded when they lacked proficiency in Dutch as this would hamper their
119 participation in the focus group discussions. The FGs took place in the course of the summer of 2014 in ‘Huis

120 Erika Thijs', an open and well accessible house in Hasselt, Belgium, which offers various non-professional
121 support to cancer patients, survivors and their relatives.

122

123 **The QOL and needs assessment tool**

124 The original CARES contains 139 items (min. 93 and max. 132 applicable per person). Patients can rate each
125 item, formulated as problem statement, on a 5-point ordinal scale with zero representing "not at all" (no
126 problem) and four representing "very much" (severe problem). Additionally, patients are asked to indicate for
127 which problems they would want help, ticking 'yes' or 'no' to the question 'Do you want help?'. The items of
128 the CARES can be placed under 31 subscales, and subsequently taken together in six summary scales as shown
129 in Table 1.

130

131 **Procedure**

132 Interested patients were contacted and the date of their participation was registered. One week before FGs took
133 place, participants were sent an envelope containing an information letter, an informed consent form, and a short
134 questionnaire on socio-demographics, type of cancer and treatment. They were asked to fill in these documents
135 and bring them to the FG. All participants provided informed consent before taking part in this validation study,
136 which was approved by the local medical ethics committee. A copy of the CARES was also included in the
137 preparatory documentation for the participants, so that they could get acquainted with the assessment tool and
138 bring it to the FG.-The moderator (BS) and an observer (WE or EVH) conducted and followed the FG discussion
139 while it was audiotaped with prior consent. The group discussion was facilitated with several key questions
140 (Table 2). Each FG lasted about 120 minutes.

141

142 **Data analysis**

143 The digital audio files of the focus groups were transcribed verbatim (BS) and analyzed using thematic content
144 analysis (32-34). FGs were organized until data saturation was reached. Through repeated reading of
145 transcriptions, initial codes were noted by two independent readers (BS and EVH). Subsequently the codes were
146 organized into meaningful groups and combined in overarching themes. After reviewing the subdivision of
147 themes, categories and codes were given to two naïve readers (JH and PV) to revise for semantic correctness.
148 The resulting 'thematic map' was used to code all FG data.

149

150 **RESULTS**

151 **Participants**

152 Twenty-six cancer patients participated in four FG discussions (with seven, six, six and seven participants,
153 respectively). The mean age was 56.2 years (range 28-78). Counts and percentages of further socio-demographic
154 and medical characteristics are displayed in Table 3.

155

156 **Qualitative analysis results**

157 The FGs resulted in a large data corpus. All themes are shown in Supplementary file 1. However, only the data
158 set relevant to content validity and feasibility of the CARES will be described in this article.

159 Three themes divided in subthemes are discussed below. The first, 'Cancer and treatment related consequences',
160 contains the subthemes 'complaints and symptoms', 'financial impact', 'work-related impact' and 'well-being
161 loved ones'. The second theme is 'Interaction with care professionals'. The third theme, 'Assessment of
162 psychosocial well-being and care needs', is divided in the subthemes 'experiences with patient-reported outcome
163 measures in care', 'content CARES' and 'feasibility CARES'. For each theme a few example quotes are
164 presented in Table 4. More quotes can be found in Supplementary file 2.

165

166 **THEME: CANCER AND TREATMENT RELATED CONSEQUENCES**

167 *COMPLAINTS AND SYMPTOMS*

168 Cancer patients mentioned experiencing different kinds of *physical consequences* of cancer treatment. A
169 common complaint is the lack of energy making it difficult for people to regain their former level of activity.

170 Some patients experience limitations due to pain in the muscles or joints, loss of taste, or deterioration of the
171 skeleton. Temporary or permanent loss of fertility is a frequent concern for female patients since it can change
172 their future family perspectives.

173 Participants experience *psychological consequences* in terms of changes in cognitive functioning, emotions and
174 personality. Memory problems are often named, as well as feelings of fear, sorrow, loneliness, anger, shame,
175 guilt, insecurity, etc. Before they recognized these emotions patients were often overwhelmed and not aware of
176 their perception of the situation. For some, the experience was so heavy and hopeless that thoughts about the
177 desire to be dead came to their mind.

178 *Social life changes* occurred, either because the patient was pushing others away or because their context became
179 avoidant. Likewise, the opposite was experienced if the context of the patient responded supportively and
180 involved itself: relationships became closer and new friendships arose.

181 Patients *marital and sexual life is put to the test*. The patient and their partner sometimes cope with the situation
182 differently leading to relational tension. Damaged as well as strengthened relationships are experienced.

183 Likewise, physical and emotional aspects can induce a discrepancy in sexual needs. Amputations, scarves,
184 baldness and weight gain affect people's body image and sometimes influences their sense of masculinity or
185 femininity.

186 *FINANCIAL IMPACT*

187 The confrontation with cancer was also said to increase the health expenditure and induce huge financial burden
188 on those not properly insured. Even with good insurance, the loss of income requires adequate spending and
189 sometimes a change of life style. Even years after being cured from cancer, one can experience problems with
190 financial benefits like the application for a mortgage, insurances, scholarships, reimbursements, etc.

191 *WORK-RELATED IMPACT*

192 Patients working as independent entrepreneurs mentioned that they often have difficulties to stop working during
193 treatment because of the risk to lose clients and income, and they therefore cannot stay at home to focus on
194 treatment and recovery. For patients on sick leave, a part of their social context is missing because there is no
195 more daily contact with colleagues. Once returned to work there is sometimes little understanding for the altered
196 ability to work and the risk to be fired arises.

197 *WELL-BEING LOVED ONES*

198 Most participants talked about the impact their disease experience had on their loved ones. Partners, children and
199 parents had to change their lives to take care of the patient, manage the household on their own, deal with the
200 fact that their loved one was sick and possibly incurable. Some participants notice feelings of fear, anger or
201 sorrow in their partners or children, others don't know how their loved ones are coping with the situation
202 because the topic is avoided. According to participants, there is a lack of attention for the well-being of patients'
203 loved ones in cancer care.

204

205 *THEME: INTERACTION WITH CARE PROFESSIONALS*

206 Patients expect a comprehensive approach including medical care and psychosocial support. They report positive
207 and negative experiences with care mostly determined by aspects such as trust, personal approach,

208 multidisciplinary cooperation and referral, follow-up, holistic approach, availability/time, communication style,
209 clarity of information and familiarity with patients' medical or personal situation.

210

211 **THEME: ASSESSMENT OF PSYCHOSOCIAL WELL-BEING AND CARE NEEDS**

212 *EXPERIENCES WITH PATIENT-REPORTED OUTCOME MEASURES IN CARE*

213 Some participants had to complete questionnaires on their physical functioning for the insurance company or
214 other institutions. Their experiences with these questionnaires were negative. According to participants the
215 questions were too limited to properly assess aspects that matter for insurance companies. Only three participants
216 were familiar with the use of a patient-reported outcome tool in clinical care to assess and follow-up their
217 psychosocial well-being and care needs. They received the Distress Thermometer and Problem List in follow-up.
218 Their experiences on the use of this tool were positive.

219 *POTENTIAL ROLE OF PSYCHOSOCIAL SCREENING*

220 According to our participants, the use of a psychosocial screening tool could be of great value in practice. An
221 instrument with questions on the overall well-being could give help recognize patients' experiences and
222 normalize the taboo of psychosocial problems. Using psychosocial screening tools could also lower the threshold
223 to mention concerns and needs and stimulate the communication between patients and caregivers. In this way,
224 problems and care needs could be detected more easily by caregivers and allow them to provide input for
225 designated action in care.

226 *APPLICABILITY OF PSYCHOSOCIAL SCREENING*

227 The potential value and applicability of psychosocial screening depends on personal situation, personality,
228 preferences, and approachability.

229 According to cancer patients a screening instrument should be readily accessible and concise. When certain
230 concerns or problems are denoted, a more profound assessment can follow.

231 Repeated application of screening and assessment is seen as desirable by participants since well-being and
232 supportive care needs can change. The desired timing for psychosocial screening differs according to personal
233 experiences with the disease, treatment and recovery.

234 If screening and assessment were applied in practice, the majority of our FG participants would prefer to
235 complete this in a paper version. Some reasons often mentioned include better concentration, limited burden on
236 the eyes, ability to fill in anywhere, and lack of familiarity with the computer. Environmental concerns, the speed

237 of filling in a screening and processing of results nonetheless made other participants prefer screening in a
238 digital format.

239 Participants emphasize that the use of psychosocial screening can only be valuable if the obtained insights yield
240 to action and if revealed needs are monitored in follow-up and matched to the appropriate care.

241 *CARES*

242 *Content CARES*

243 The whole content of the CARES is seen as relevant and important for the wellbeing of someone confronted
244 with cancer, though this can vary according to the phase of the disease-trajectory one is going thorough or
245 according to one's personal situation. Topics mentioned as most important are mostly physical and daily
246 functioning, emotional well-being and relations with loved ones. Generally, the content of the CARES is judged
247 to be complete. According to several participants, one very important element is missing in the CARES as well
248 as in cancer care, namely the well-being of their relatives. Likewise, feelings of uncertainty and loneliness
249 associated with cancer are experienced by several participants and insufficiently discussed in the CARES.

250 *Feasibility CARES*

251 The CARES is experienced as a long questionnaire, yet participants find this acceptable considering the
252 importance of capturing people's overall wellbeing rigorously for utility in cancer care. The formulation of the
253 CARES in general is positively evaluated, and everything was clear for the participants. The only comment that
254 was raised is that the questionnaire might be difficult for non-native Dutch speakers because of the vocabulary
255 used. Some suggestions were raised to reformulate a few items to clarify or to make the formulation less
256 confronting. The 'yes'/'no' response categories linked to the question 'Do you want help?' were also seen as an
257 issue as sometimes neither 'yes' nor 'no' would fully allow patients to express themselves. One participant
258 suggested that some people might get anxious when they are confronted with some of the items, such as 'my
259 clothes do not fit anymore', 'relapse', and 'the emotional experience'.

260

261 After the qualitative analysis process, all data was reviewed again and CARES items were ticked if the topic was
262 discussed. Most items of the CARES (103/139) were covered spontaneously by participants in the FG discussion
263 (Supplementary file 3). A great percentage of the non-discussed items are the items that do not apply to all
264 patients (e.g. 'Difficulties to help the children cope').

265

266 **DISCUSSION**

267 The findings of this study, along with the quantitative research on the psychometric robustness of the instrument
268 (31), show a positive evaluation of the validity of the CARES.

269 As in other research populations participants in this study experience concerns and needs in a wide range of life
270 domains (1-3, 35). Physical problems, limitations in daily functioning as well as memory problems are often
271 named. The confrontation with cancer, related treatment and consequences may cause feelings of fear, sorrow,
272 loneliness, anger, shame, guilt and insecurity. Social life changes took place for some, and both marital and
273 sexual life are challenged. Work related and financial consequences are experienced not only in the active phase
274 of disease and treatment, but also later on.

275 The interaction with professional care givers plays an important role in the extent to which concerns are
276 addressed and care needs are met. Similar to other studies our data suggest that patients frequently want their
277 doctor to initiate discussion of psychosocial topics (7), or at least to minimize barriers to disclose emotional
278 issues (8). For participants, an important concern – and sometimes even a real burden – was the well-being of
279 loved ones. Patients partners and children sometimes struggled with the situation, but this was not noticed nor
280 discussed in the care system. The use of screening and assessment tools could initiate and facilitate the dialogue
281 between patients and clinicians regarding psychosocial topics and promote early identification of patients’
282 distress and related needs (16, 17).

283 The findings of our qualitative data collection are congruent with past study results on the content of the original
284 CARES (36, 37), namely that the content of the instrument is very relevant. In the literature on the original
285 CARES, no substantive shortcomings were mentioned. In our sample however, the absence of items on the
286 experience of loneliness and well-being of loved ones were explicitly stated as lacking. Participants noticed a
287 considerable impact of their disease and treatment regime on the lives and the well-being of their spouses,
288 parents and children. Patients often perceived the concern for their loved ones as burdensome, but this difficulty
289 was not recognized nor detected by health care professionals and might also be undetected by the CARES since
290 the questionnaire contained no item on this topic. In our future studies, we will explore the addition of the
291 missing topics in the Belgian CARES screening tool.

292 Our participants judged the CARES to be a feasible instrument. Completion of the instrument is experienced to
293 be time consuming, but acceptable. In our quantitative study which was conducted to test the psychometric
294 qualities of the CARES (31), data showed that all CARES item were indicated as being a problem for 0.6-88.1%
295 of the participants, and therefore relevant for a population of cancer patients. Nonetheless, the suggestion was
296 made to previously conduct a shorter screening version and to subsequently assess patients’ QOL and needs

297 more profoundly with the CARES if distress is detected. These preferences are in favor of a stepped-screening
298 approach. The CARES-Short Form, which includes 59 items of the full version, could potentially be used for
299 such initial screening purpose (38, 39). The original CARES items were constructed with involvement of
300 patients (36, 40). However, according to participants of this study, some items of the CARES could be adjusted
301 with simpler or less confronting vocabulary to optimize feasibility. Most participants favor completing a paper
302 version. Nevertheless, according to them both a paper and digital version should be available for the application
303 of the instrument in clinical practice. This would tailor psychosocial screening to individual convenience.

304 Several methodological considerations about this study should be mentioned. First, the representativeness of the
305 research population can be discussed. With a mean age of 56.2 years (range 28-78), our research population was
306 slightly younger than the average Belgian population of cancer patients, where respectively 66 percent of the
307 women and 77 percent of the men are 60 years or older at the time of diagnosis. The recruitment of participants
308 via media potentially gave opportunity for the emergence of a self-selection bias. Nevertheless, results on the
309 socio-demographic and medical characteristics show that the study sample is comparable to the general
310 populations of cancer patients in Belgium (41). Compared to the proportion found in the general Belgian
311 population of cancer patients, more women than men participated in our study. However, this is often seen in
312 psycho-oncology research, presumably because men are less prone to talk about psychosocial concerns (42, 43).

313 Participants were recruited without specification of cancer type, which led to a strong representation of breast
314 cancer patients in the research population. However, this is in accordance with the prevalence of this type of
315 cancer in our female population. In all likelihood, findings can be applicable for the broader population of cancer
316 patients in Belgium. Secondly, no participants with a low proficiency in Dutch and few people with a low level
317 of education participated in the FGs, yet these people represent a significant proportion of the Belgian society.

318 Thirdly, the neutrality of the study setting can be questioned. ‘Huis Erika Thijs’ was chosen for the FGs to take
319 place given that it is outside the hospital context, centrally located, and that the care offer of the initiative could
320 be discovered by participants visiting the center. Some FG participants had never heard of ‘Huis Erika Thijs’,
321 some had heard of it before, but the majority of the group did not visit the center before. If the location was of
322 influence for some participants, the effect probably was not uniform. Fourthly, in this study only the full version
323 of the CARES was discussed with participants, although, the CARES-Short Form was also validated in Flemish.

324 Letting patients compare both versions in content, completeness and feasibility would have been interesting.

325 We suggest that future research efforts should aim to enhance understanding of the feasibility of the CARES for
326 immigrants and patients with a low level of education. More future research could aim to compare between the

327 content and feasibility of the short and long CARES version, as well as on the key points for implementation of
328 effective QOL screening and needs assessment in clinical practice.

329

330 In conclusion, the results of this study suggest the CARES is a feasible QOL and needs assessment instrument
331 with acceptable content validity for use in a population of Belgian patients in current cancer care. The CARES
332 can be used to detect a wide range of problems and care needs and according to patients, its use can be of value
333 for the integration of psychosocial follow-up in supportive cancer care. In response to participants' input in this
334 qualitative study, minor adjustments to the CARES will be made before it is further used in research and clinical
335 practice: a few items regarding the well-being of loved ones will be added and the wording of some items will be
336 adjusted. This will increase the ecological fit and validity of the instrument with the Belgian patient population
337 in which we wish to use the CARES for further research and clinical application.

338

339 **ACKNOWLEDGEMENTS**

340 Our gratitude goes out to the team of Huis Erika Thijs for their hospitality and for the provision of facilities
341 during the focus groups. We would like to thank Willem van de Esschert for his practical support in conducting
342 the focus groups, Noémie Aubert Bonn for editing the manuscript for the English language, and Limburg Sterk
343 Merk (LSM) for funding the PhD-research project of Bojoura Schouten .

344

345

346

347 **REFERENCES**

- 348 1. Sanson-Fisher R, Girgis A, Boyes A, Bonevski B, Burton L, Cook P. The unmet supportive care
349 needs of patients with cancer. Supportive Care Review Group. *Cancer*. 2000 Jan 1;88(1):226-37.
350 PubMed PMID: 10618627. Epub 2000/01/05. eng.
- 351 2. Mikkelsen T, Sondergaard J, Sokolowski I, Jensen A, Olesen F. Cancer survivors' rehabilitation
352 needs in a primary health care context. *Family practice*. 2009 Jun;26(3):221-30. PubMed PMID:
353 19264838.
- 354 3. Harrison JD, Young JM, Price MA, Butow PN, Solomon MJ. What are the unmet supportive
355 care needs of people with cancer? A systematic review. *Supportive Care in Cancer*. 2009
356 Aug;17(8):1117-28. PubMed PMID: 19319577.
- 357 4. Holland JC, Bultz BD. The NCCN guideline for distress management: a case for making distress
358 the sixth vital sign. *Journal of the National Comprehensive Cancer Network : JNCCN*. 2007 Jan;5(1):3-
359 7. PubMed PMID: 17323529. Epub 2007/02/28. eng.
- 360 5. Bultz BD, Carlson LE. Emotional distress: the sixth vital sign--future directions in cancer
361 care. *Psycho-oncology*. 2006 Feb;15(2):93-5. PubMed PMID: 16444764. Epub 2006/01/31. eng.
- 362 6. Bultz BD, Johansen C. Screening for distress, the 6th vital sign: where are we, and where are
363 we going? *Psycho-oncology*. 2011 Jun;20(6):569-71. PubMed PMID: 21626609. Epub 2011/06/01.
364 eng.
- 365 7. Detmar SB, Aaronson NK, Wever LDV, Muller M, Schornagel JH. How are you feeling? Who
366 wants to know? Patients' and oncologists' preferences for discussing health-related quality-of-life
367 issues. *J Clin Oncol*. 2000 Sep 15;18(18):3295-301. PubMed PMID: WOS:000089433700013. English.
- 368 8. Mitchell AJ, Vahabzadeh A, Magruder K. Screening for distress and depression in cancer
369 settings: 10 lessons from 40 years of primary-care research. *Psycho-Oncology*. 2011 Jun;20(6):572-84.
370 PubMed PMID: WOS:000291113500002. English.
- 371 9. Medicine Io. *Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs*.
372 Washington, DC: The National Academies Press; 2008.
- 373 10. Accreditation C. *Omentum program 2009 standards: cancer care and oncology services (ver*
374 *2)*. Ottawa, ON. 2008.
- 375 11. Network NCC. *Distress management (v.1.2008): National Comprehensive Care Network, Inc.;*
376 *2007 [cited 2015 6 March]. Available from:*
377 https://www.nccn.org/professionals/physician_gls/f_guidelines.asp.
- 378 12. Centre NBC. *Clinical practice guidelines for the psychosocial care of adults with cancer*.
379 *Camperdown*2003.
- 380 13. Holland J, Watson M, Dunn J. The IPOS new International Standard of Quality Cancer Care:
381 *integrating the psychosocial domain into routine care*. *Psycho-oncology*. 2011 Jul;20(7):677-80.
382 PubMed PMID: 21710503. Epub 2011/06/29. eng.
- 383 14. UK National Institute of Clinical Excellence. *Improving supportive and palliative care for*
384 *adults with cancer*. 2004 1-84257-579-1.
- 385 15. Government A. *Australian clinical practice guidelines for the psychosocial care of adults with*
386 *cancer, 2003*. 2003.
- 387 16. Mitchell AJ. *Screening for cancer-related distress: when is implementation successful and*
388 *when is it unsuccessful?* *Acta oncologica (Stockholm, Sweden)*. 2013 Feb;52(2):216-24. PubMed
389 PMID: 23320770. Epub 2013/01/17. eng.
- 390 17. Carlson LE, Waller A, Mitchell AJ. *Screening for Distress and Unmet Needs in Patients With*
391 *Cancer: Review and Recommendations*. *J Clin Oncol*. 2012 Apr 10;30(11):1160-77. PubMed PMID:
392 WOS:000302995700003. English.
- 393 18. Wen KY, Gustafson DH. *Needs assessment for cancer patients and their families*. *Health and*
394 *quality of life outcomes*. 2004 Feb 26;2:11. PubMed PMID: 14987334. Pubmed Central PMCID:
395 PMC394345. Epub 2004/02/28. eng.

- 396 19. Richardson A, Medina J, Brown V, Sitzia J. Patients' needs assessment in cancer care: a review
 397 of assessment tools. *Support Care Cancer*. 2007 Oct;15(10):1125-44. PubMed PMID:
 398 WOS:000249632900002. English.
- 399 20. Ganz PA, Coscarelli A, Fred C, Kahn B, Polinsky ML, Petersen L. Breast cancer survivors:
 400 psychosocial concerns and quality of life. *Breast cancer research and treatment*. 1996;38(2):183-99.
 401 PubMed PMID: 8861837. Epub 1996/01/01. eng.
- 402 21. Ganz PA, Desmond KA, Leedham B, Rowland JH, Meyerowitz BE, Belin TR. Quality of life in
 403 long-term, disease-free survivors of breast cancer: a follow-up study. *Journal of the National Cancer*
 404 *Institute*. 2002 Jan 2;94(1):39-49. PubMed PMID: 11773281. Epub 2002/01/05. eng.
- 405 22. Ganz PA, Schag CA, Lee JJ, Sim MS. The CARES: a generic measure of health-related quality of
 406 life for patients with cancer. *Quality of life research : an international journal of quality of life aspects*
 407 *of treatment, care and rehabilitation*. 1992 Feb;1(1):19-29. PubMed PMID: 1301111. Epub
 408 1992/02/01. eng.
- 409 23. Schag CA, Heinrich RL. Development of a comprehensive quality of life measurement tool:
 410 CARES. *Oncology (Williston Park, NY)*. 1990 May;4(5):135-8;discussion 47. PubMed PMID: 2143399.
 411 Epub 1990/05/01. eng.
- 412 24. Schag CA, Ganz PA, Wing DS, Sim MS, Lee JJ. Quality of life in adult survivors of lung, colon
 413 and prostate cancer. *Quality of life research : an international journal of quality of life aspects of*
 414 *treatment, care and rehabilitation*. 1994 Apr;3(2):127-41. PubMed PMID: 8044158. Epub
 415 1994/04/01. eng.
- 416 25. Khan F, Amatya B. Factors associated with long-term functional outcomes, psychological
 417 sequelae and quality of life in persons after primary brain tumour. *Journal of neuro-oncology*. 2013
 418 Feb;111(3):355-66. PubMed PMID: 23292152. Epub 2013/01/08. eng.
- 419 26. Parker PA, Alba F, Fellman B, Urbauer DL, Li Y, Karam JA, et al. Illness uncertainty and quality
 420 of life of patients with small renal tumors undergoing watchful waiting: a 2-year prospective
 421 study. *European urology*. 2013 Jun;63(6):1122-7. PubMed PMID: 23419322. Pubmed Central PMCID:
 422 PMC3866912. Epub 2013/02/20. eng.
- 423 27. Zimmermann C, Swami N, Krzyzanowska M, Hannon B, Leighl N, Oza A, et al. Early palliative
 424 care for patients with advanced cancer: a cluster-randomised controlled trial. *Lancet (London,*
 425 *England)*. 2014 May 17;383(9930):1721-30. PubMed PMID: 24559581. Epub 2014/02/25. eng.
- 426 28. Borstelmann NA, Rosenberg SM, Ruddy KJ, Tamimi RM, Gelber S, Schapira L, et al. Partner
 427 support and anxiety in young women with breast cancer. *Psycho-oncology*. 2015 Mar 13. PubMed
 428 PMID: 25765893. Epub 2015/03/15. Eng.
- 429 29. Gjersing L, Caplehorn JR, Clausen T. Cross-cultural adaptation of research instruments:
 430 language, setting, time and statistical considerations. 2010;10(1):1-10.
- 431 30. Schouten B, Van Hoof E, Vankrunkelsven P, Schrooten W, Bulens P, Buntinx F, et al. Assessing
 432 cancer patients' quality of life and supportive care needs: Translation-revalidation of the CARES in
 433 Flemish and exhaustive evaluation of concurrent validity. *BMC health services research*.
 434 2016;16(1):86. PubMed PMID: 26969509. Pubmed Central PMCID: PMC4788884. Epub 2016/03/13.
 435 eng.
- 436 31. Schouten B, Hellings J, Van Hoof E, Vankrunkelsven P, Bulens P, Buntinx F, et al. Validation of
 437 the flemish CARES, a quality of life and needs assessment tool for cancer care. *BMC cancer*.
 438 2016;16:696. PubMed PMID: 27576341. Pubmed Central PMCID: PMC5006609. Epub 2016/09/01.
 439 eng.
- 440 32. Graneheim UH, Lundman B. Qualitative content analysis in nursing research: concepts,
 441 procedures and measures to achieve trustworthiness. *Nurse education today*. 2004 Feb;24(2):105-12.
 442 PubMed PMID: 14769454. Epub 2004/02/11. eng.
- 443 33. Braun V, Clarke V. Using thematic analysis in psychology. 2006 2006/01/01;3(2):77-101.
- 444 34. Kvale S. *InterViews: An Introduction to Qualitative Research Interviewing*. Thousand Oaks,
 445 CA: Sage; 1996.

- 446 35. Ganz PA, Schag CC, Heinrich RL. The psychosocial impact of cancer on the elderly: a
447 comparison with younger patients. *Journal of the American Geriatrics Society*. 1985 Jun;33(6):429-35.
448 PubMed PMID: 3998352. Epub 1985/06/01. eng.
- 449 36. Schag CC, Heinrich, R.L., & Ganz, P.A. . The Cancer Inventory of Problem Situations: An
450 instrument for assessing cancer patients' rehabilitation needs. 1983;1(11-24).
- 451 37. Heinrich RL, Schag CC, Ganz PA. Living with cancer: the Cancer Inventory of Problem
452 Situations. *Journal of clinical psychology*. 1984 Jul;40(4):972-80. PubMed PMID: 6480863. Epub
453 1984/07/01. eng.
- 454 38. Schag CA, Ganz PA, Heinrich RL. CAncer Rehabilitation Evaluation System--short form (CARES-
455 SF). A cancer specific rehabilitation and quality of life instrument. *Cancer*. 1991 Sep 15;68(6):1406-13.
456 PubMed PMID: 1873793. Epub 1991/09/15. eng.
- 457 39. te Velde A, Sprangers MA, Aaronson NK. Feasibility, psychometric performance, and stability
458 across modes of administration of the CARES-SF. *Annals of oncology : official journal of the European
459 Society for Medical Oncology / ESMO*. 1996 Apr;7(4):381-90. PubMed PMID: 8805930. Epub
460 1996/04/01. eng.
- 461 40. Schag CA, Heinrich RL, Aadland RL, Ganz PA. Assessing problems of cancer patients:
462 psychometric properties of the cancer inventory of problem situations. *Health psychology : official
463 journal of the Division of Health Psychology, American Psychological Association*. 1990;9(1):83-102.
464 PubMed PMID: 2323331. Epub 1990/01/01. eng.
- 465 41. BelgianCancerRegistry. Cancer Prevalence in Belgium 2010 Brussels: Belgian Cancer Registry,
466 2014.
- 467 42. Corney RH. Sex differences in general practice attendance and help seeking for minor
468 illness. *Journal of psychosomatic research*. 1990;34(5):525-34. PubMed PMID: 2231486. Epub
469 1990/01/01. Eng.
- 470 43. Galdas PM, Cheater F, Marshall P. Men and health help-seeking behaviour: literature
471 review. *Journal of advanced nursing*. 2005 Mar;49(6):616-23. PubMed PMID: 15737222. Epub
472 2005/03/02. Eng.
- 473
- 474

475 **TABLES**

476 **Table 1** Life domains covered by CARES summary scales and subscales

CARES Summary scales (n items)	CARES Subscales
Physical (26)	Ambulation Activities of daily living Recreational activities Weight loss Difficulty working Pain Clothing
Medical Interaction (11)	Problems obtaining info from medical team Difficulty communicating with medical team Control of medical team
Marital^a (18)	Communication with partner Affection with partner Interaction with partner Overprotection by partner Neglect of care by partner
Psychosocial (44)	Body image Psychological distress Cognitive problems Difficulty communicating with friends/relatives Friends/relatives difficulty interacting Anxiety in medical situations Worry Interaction with children ^a At work concerns ^a
Sexual (8)	Sex interest Sexual dysfunction ^a
Miscellaneous (32)	Compliance Economic barriers Dating ^a Chemotherapy-related problems ^a Radiation-related problems ^a Ostomy ^a Prosthesis ^a Miscellaneous items ^a

Preferred position: line 130

^a Items do not apply to all patients.

477

478

479 **Table 2** Interview guide for the focus group

Opening question	1. Can you please introduce yourself shortly and share with the group what your motivation was to participate in this study?
Introductory questions	2. Were you ever asked in care to fill in a questionnaire regarding your well-being? Which professional asked you this and with what purpose?
Transition and key questions	<p><i>The CARES is an assessment tool developed to explore the well-being and care needs of people confronted with cancer. There are several aspects of well-being discussed, that we have listed for you.</i></p> <p>3. If one wants to explore the well-being of cancer patients, which topics are according to you the most relevant/important? Are they included in the CARES? Which topics are less important?</p> <p>4. Are there topics not mentioned in the CARES that are important when one wants to explore cancer patients' well-being? Which?</p> <p>5. How did you experience the wording of the CARES-items?</p> <p>6. If such an assessment tool or questionnaire would be integrated as a standard part in care, what would be the value of this?*</p> <p>7. If you look back at the cancer care you have experienced until now, did a caregiver notice the concerns and care needs you experienced? *</p> <p>8. How did they detect these? / How could they have detected these? *</p> <p>9. What is the best way to introduce support in response to detected needs? *</p>
Ending question	<p><i>Our goal was to get a clear perspective on the topics cancer patients consider important to be followed up in care and the properties an instrument should meet in order to serve this goal. Specifically, we have asked you to evaluate the content and acceptability of the CARES as an assessment tool. (+ summary of what is been said during the focus group discussion)</i></p> <p>10. Is there something I have overlooked or something that still has to be discussed?</p>

* These questions go beyond the scope of the present paper and most data resulting from these are not discussed in depth in the present paper.

Preferred position: line 141

480

481

482

483 **Table 3** Participants' socio-demographic and medical characteristics

Participant Characteristics	N=26	
	n	%
Gender		
Men	4	15.4
Women	22	84.6
Relational status ^a		
Single	2	7.7
In a relationship: living with partner/married	22	80.8
In a relationship: not living with partner/married	-	-
Widowed	1	3.8
Children ^a		
No	3	11.5
Yes	22	80.8
Level of education ^a		
Elementary school	1	3.8
High school	9	24.6
Graduate school	13	50.0
University	1	3.8
Employment ^a		
Employed	7	26.9
Work interruption/on sick leave	2	7.7
Unemployed	1	3.8
Disabled	6	23.1
Housewife/houseman	-	-
Retired	8	30.8
Monthly household income ^a		
< € 1500	4	15.4
€ 1500- € 3000	15	57.7
> € 3000	4	15.4
Cancer diagnosis ^b		
Breast	11	42.3
Colorectal	4	15.4
Lung	1	3.8
Ovarian	1	3.8
Non-Hodgkin Lymphoma	2	7.7
Hodgkin Lymphoma	2	7.7
Brain	1	3.8
Prostate	1	3.8
Thyroid	1	3.8
Malignant melanoma	1	3.8
Pancreas	1	3.8
Liver	1	3.8
Uterine body	1	3.8
Other diagnosis	1	3.8
Treatment ^c		
Surgery	17	65.4
Chemotherapy	15	57.7
Radiotherapy	12	46.2
Hormonal therapy	7	26.9
Immune therapy	1	3.8
Bone marrow transplantation	1	3.8
Other treatment	-	-

^a Not all characteristics count up to 100% due to missing answers of some participants, ^b Cancer diagnosis in total counts up to more than 100%, because several participants got diagnosed with more than one type of cancer in the course of time, ^c Treatment types in total counts up to more than 100%, because most participants got treated with a combination of treatments.

484

485

486 **Table 4** Themes from thematic data analysis and example quotes**THEME: CANCER AND TREATMENT RELATED CONSEQUENCES****COMPLAINTS AND SYMPTOMS****Physical**

I have noticed that the problems are quite the same for everyone, in general I mean. Like being tired, the lack of energy...regardless whether you have breast cancer or any another type (FG-07).

Psychological

Sometimes I am so forgetful...at those moments, I think 'am I developing Alzheimer's or what?!' (FG-09)

I'm not easily scared, but in the waiting room, in the hospital department... there I get scared (FG-20)

I experience everything more intensely and view it positively. If I experience something with my children I always think, 'yesss that I have had already', not 'maybe I will not live to see that again' (FG-12).

Social

When I was sick, I could not breathe ... so many people came to visit me! This went on for weeks and weeks... and after that no one came any more (FG-05).

Marital/Sexual

... my husband was really struggling with the situation and yes ... his way of coping was actually quite annoying (FG-11)

I had a good sexual relationship with my wife, and from one day to the other it was done. I started with the treatment with Zoadex.... It suppresses the production of testosterone. And of course that effect on testosterone ... for a man ... that was chemical castration! (FG-15).

FINANCIAL IMPACT

We had bought our house on the basis of two full-time incomes, of which one failed because of my illness. But my loan will not decrease. It remains the same, the banks want their money (FG-06).

WORK RELATED IMPACT

I've heard ...as soon as my sick leave ends, I'm getting fired (FG-09).

I am independent, I cannot stop working, so I've just been working...but in in a limited way (FG-02).

WELLBEING LOVED ONES

My mom stayed at home to care for me. Their whole life changes and you already feel guilty and bad and then you also see them suffering from the situation (FG-10).

We get a lot of attention like 'how are you?', but the fear of the partner ...who possibly ends up alone... there is almost no one thinking about how they are doing (FG-14).

THEME: Interaction with care professionals

If they would have had attention for my deepest fear at the time I was sick to death of my chemo...the fear that said 'What if something goes wrong with me, what with my two sons?'...I think I would have been a lot more resilient to cope with the chemo (FG-26).

... the nursing staff were guardian angels for me. I had a lot of questions. They answered me and if there was something they didn't know, then the doctor came up with an answer. So I felt 'there is something happening here' (FG-13).

I have the experience that few doctors or specialists can identify with the psyche ... I think they are good technical people for surgery, but there are few who can empathize with the psyche of the patient (FG-17).

THEME: Assessment of psychosocial well-being and care needs**EXPERIENCES WITH PATIENT-REPORTED OUTCOME MEASURES IN CARE**

Not from the hospital, but from the health insurance...a questionnaire on self-reliance...really ridiculous questions they ask you, like 'do you have a handrail on the toilet? They use these to score...to decide if you are disabled or not (FG-13).

The hospital sent me a questionnaire like that (like the CARES)... I experienced it as something positive that they are interested in your well-being. That there is follow-up of your situation even if you're not in the hospital anymore... I did me well (FG-25).

POTENTIAL ROLE OF PSYCHOSOCIAL SCREENING

Then you know 'what I feel is completely normal'...sometimes you feel abnormal, but if you know that there are other people that are feeling that way...and it is a topic in follow-up...you would feel a lot better already (FG-11).

Aaaaah yes, I admit I answered some questions I would never talk about with my oncologist... or even with my general practitioner. And yet I'd like to get help for those things, but I don't dare to bring it up myself (FG-06).

APPLICABILITY OF PSYCHOSOCIAL SCREENING

When I started with chemo I wasn't sick and I thought "well I'm doing good, everything is going perfect"... but after that first week I felt completely different (FG-06).

CARES**Content CARES**

Everything is important, it depends on your own situation what is most. I can imagine that other aspects for some people are less important. I wouldn't let any topic out of the questionnaire (FG-21).

I think it certainly is important that there is attention for all those who are around you, how are they doing at that stage ... My partner, my children and so ... they also suffered a lot (FG-01).

Feasibility CARES

I think...if it would be possible to shorten it...everything must be addressed, but not too extensive (FG-12).

Preferred position: line 165, line 260 or somewhere in between