

Evidence-based patient information about treatment of multiple sclerosis—A phase one study on comprehension and emotional responses

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Abstract

Objective: This study analysis the comprehension and emotional responses of people suffering from multiple sclerosis when provided with an evidence-based information module. It is a core module of a comprehensive decision aid about immunotherapy. The core module is designed to enable patients to process scientific uncertainty without adverse effects. It considers existing standards for risk communication and presentation of data.

Methods: Using a mailing approach we investigated 169 patients with differing courses of disease in a before–after design. Items addressed the competence in processing relative and absolute risk information and patients' emotional response to the tool, comprising grade of familiarity with the information, understanding, relevance, emotional arousal, and certainty.

Results: Overall, numeracy improved ($p < 0.001$), although 99 of 169 patients did not complete the numeracy task correctly. Understanding depended on the relevance related to the course of disease. A moderate level of uncertainty was induced. No adverse emotional responses could be shown, neither in those who did comprehend the information, nor in those who did not develop numeracy skills.

Conclusion: In conclusion, the tool supports people suffering from multiple sclerosis to process evidence-based medical information and scientific uncertainty without burdening them emotionally.

Practice implications: This study is an example for the documentation of an important step in the development process of a complex intervention.

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1. Background

Multiple sclerosis (MS) is an inflammatory and neurodegenerative disorder affecting young adults in their most productive years. It is the most common reason for neurological disability in young people in developed countries. MS appears in different types of disease course of which the relapsing remitting course (RRMS) is most common at time of diagnosis (approx. 85%); 50% of those diagnosed with MS will develop a secondary progressive

course within 10 years from onset [1]; approximately 15% have a primary progressive (PPMS) course. Various kinds of immunotherapy are available aiming at reducing progress and frequency of relapses [2]. They differ in extent of benefits, side effects and route of administration. Not all of them are licensed for all disease courses, indeed for patients with PPMS effective treatment does not exist. Overall the evidence for the benefit of immunotherapy is not very strong, effects are modest, and side effects unpleasant and frequent [2]. The treatment decision about immunotherapy highly depends on individual appraisal of the uncertain consequences of each option. The condition predestines a participative decision process between

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patient and physician [3]. This challenges the patients to deal with difficult and complex information and scientific uncertainty.

The present paper outlines a part of the development process of a decision aid for MS patients about immunotherapy. The final version of the tool is currently evaluated in a randomised controlled trial [4]. The part tested in this study represents the core module which exemplarily explains benefits and harms of immunotherapy using a representative clinical study. The development of the decision aid considered standards for patient information materials [5–7], ethical standards [8] and evidence on the presentation of data in an unbiased and balanced fashion [7,9]. The evaluation steps follow the *continuum of increasing evidence* of the framework for design and evaluation of complex interventions [10]. Similar to the clinical testing of a drug the framework consists of a phased approach that defines a sequence of five steps for the evaluation of a complex intervention. A preclinical theory building is followed by phase 1: this includes the modelling in which the components of an intervention and its underlying mechanisms are evaluated. During phases 2 and 3 the intervention is tested in clinical trials. Long term implementation is evaluated during phase 4. It has been argued that all phases of evaluation are equally important and should be reported [10].

The present paper reports a phase 1 study. This evaluation step had to involve the target group of MS patients for the following reasons. There is no evidence to determine the amount and complexity of information which patients with MS need in order to make an informed choice. The degree of information may interfere with patients' tolerance towards complexity, particularly if there are various options available and the evidence is ambiguous. This is the case in MS-immunotherapy [11]. Furthermore, it is not clear how the information material can support patients to handle numerical information rather than just mediating knowledge. Limitations in information processing may arise from the phenomenon of 'public innumeracy' according to which people are lacking competences in dealing with numbers and proportions [12]. Also, patients' information processing could be blocked or distorted anticipating adverse emotions associated with the disclosure of scientific uncertainty. Considering the weak evidence for available treatments, this could apply to MS patients. Developers of patient information have to account for different needs. This implies a strategy accounting for patients preferring different levels of complexity. This is particularly relevant for patients with MS who may be hampered due to fatigue. The challenge is to offer complex evidence-based information understandably without inducing stress in those with fewer information needs.

The aim of this study was to analyse comprehension and emotional responses to the core module designed for the development of a decision aid about MS-immunotherapy. We assessed whether MS-patients are able to process the numerical information presented in the core module. We

expected that the presentation of evidence-based information would enhance numeracy competence. Furthermore, the study should reveal possible adverse effects of the tool. Patients who understand the material may be disturbed by the new knowledge. Patients who do not comprehend the material may be disturbed by a higher degree of uncertainty and confusion. Motivation to deal with the material might vary with the course of disease. We hypothesized that compared to patients with RRMS patients suffering from the PPMS-type of the disease would be less motivated to process the information since no immunotherapy has been approved for them. We studied control beliefs which are a central element in *action motivation* and which could influence the comprehension and the emotional perception of the information [13].

2. Methods

2.1. Development of the core module

The overall development process was guided by the *continuum of increasing evidence* [10]. As recommended by Coulter, patients were involved in all steps of the evaluation beginning with the selection of the contents and finishing in readability tests of the final version of the tool [14]. The protocol was approved by the ethics committee of the Hamburg chamber of physicians.

The panel of developers consisted of a neurologist, a psychologist, health scientists, an MS-study nurse and three patients with additional professions as nurse, journalist and linguist. An initial draft was discussed and revised several times. Furthermore, questionnaires for the postal investigation were composed and items developed (see below).

In the next step the core module was presented to 54 patients with MS in six focus groups using a Power Point Presentation. Participants were asked to complete items concerning numeracy and emotional responses to the presentation as well as items assessing self-efficacy. The face validity and understanding of the questionnaire was confirmed by observation of response behaviour, in individual conversation and in context of other components of the focus group session, e.g. group discussion. The items and the answering formats were comprehensible in the intended meaning. The feedback from the focus groups informed the final version of the core module.

The preferred complexity of the module was determined through interviews with 10 patients at the MS-outpatient clinic of the University Hospital Hamburg. By comparing three versions of the core module we found that people with MS seem to be very motivated to deal with detailed and extensive materials about their condition as they voted the longest manuscript the most valuable.

Additionally, readability of the module was tested by another 10 patients visiting the outpatient clinic leading to further revision.

2.2. The core module

The core module tested in this study represents the basic concept of the more comprehensive decision aid, briefly described in [Box 1](#). It uses the presentation form which appears in variations in all chapters of the decision aid.

It contains three pages (673 words) of information about the effects of interferon therapy for MS-patients with the remitting course of the disease. The information refers to an advertising slogan of a pharmaceutical company, promising a 37% reduction of disease progression. The numbers were taken from one pivotal study of interferon- β [15]. The core module explains the slogan by mentioning the control event rate, the experimental event rate and the absolute risk reduction. This is explained by using three pictograms with 100 differentially coloured human stick figures ([Fig. 1](#)). In contrast, common information often presents the effectiveness of a drug only in terms of relative risk which does not allow the patient to make a fully informed decision. Additionally, the core module provides information about the time frame and measuring concept of the interferon study, relevant aspects for the critical appraisal of clinical MS-studies.

2.3. Design and sample

The core module was tested in a mail investigation from October 2002 to April 2003. It was designed as a before–after study. Participants received an envelope containing a cover letter, the core module, a before- and after questionnaire assessing numeracy competence, a post-questionnaire assessing emotional responses, a self-efficacy questionnaire and a self-addressed return envelope. The cover letter delineated the background and funding of the study and clarified the anonymous data protection policy. Participants were instructed to work through the material by

Box 1. Evidence-based decision aid on decision-making about immunotherapy in MS.

MS patients are provided with the decision aid in preparation for a decision about immunotherapy. It is designed as a comprehensive (90 pages) patient information tool to be used in combination with a working sheet.

Following a needs analysis in the target group and the evidence of the impact of patients' risk knowledge on role preferences and on treatment or screening choices the decision aid focuses mainly on the users' understanding of risk knowledge. It contains information about diagnosis and course of MS as well as risk information about possible benefits, side-effects, critical appraisal of relevant studies, information about clinical pharmacology and routes of administration of all available disease-modifying therapies. Presentation of estimations follows standards published by Edwards [7].

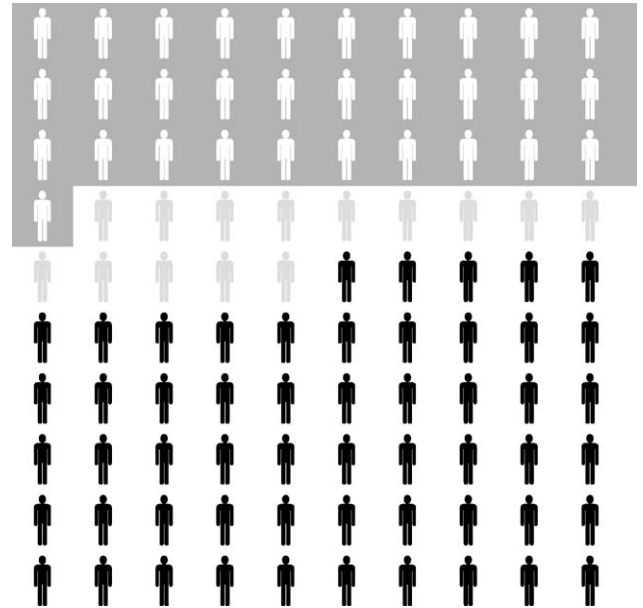


Fig. 1. Presentation form used in the example. The proportions of the different coloured human stick figures represent the effect of an interferon medication on disease impairment over 2 years. The 31 \square figures represent patients who would not impair even without medication, the black figures \blacksquare represent patients who would impair despite medication, the 14 grey \square figures represent patients who will benefit from therapy by not suffering an impairment in the study time window.

keeping the given order. By this, a before–after study including two measuring-points was conducted in one step and post-intervention data were likely to be immediately related to the core module. In addition, patients were sent the Control Preference Questionnaire [16] and a set of items assessing information needs. Results of this part of the study have been published elsewhere [11].

We included a random sample of 213 patients out of a pool of 1374 patients registered in the MS outpatient database of the University Hospital Hamburg. We contacted 100 patients each suffering the RR type and 100 with the PP type of the disease. Randomisation was provided by a priori creation of two groups out of the database and by random sampling out of the MS Clinic Outpatient database. In addition, all patients in the database with a disease duration of less than 1 year were included.

After 4 weeks non-responders were contacted by telephone and a second copy was mailed if requested; 31 patients declined to participate, most on grounds of ill health; 12 patients were randomly selected to replace those whose letters were not returned for other reasons.

2.4. Measurement of numeracy competencies

The core module implicitly highlights the difference between absolute and relative risk. Therefore, numeracy competencies were determined by using three items which differentiated patients' understanding of event rates ([Table 1](#)). Patients were asked to estimate the rates of

Table 1
Questionnaire items referring to treatment efficacy parameters

	Translated items assessing numeracy competence
Control event rate	Imagine you have a relapsing-remitting disease course. You have two relapses per year. In . . . out of 100 patients there is no worsening of impairment without treatment during 2 years of follow-up. (Please fill in) (Correct would be 65–85%)
Experimental event rate	Imagine you have a relapsing-remitting disease course. You have two relapses per year. A recently initiated interferon treatment should slow down the worsening of impairments. In . . . out of 100 patients there is no worsening of impairment with treatment during 2 years of follow-up. (Please fill in) (Correct would be 70–90%)
Absolute risk reduction	Asked differently: In the above task you calculated the patients remaining stable without therapy. How many patients additionally remain stable due to an interferon treatment? Answer: Out of 100 patients an additional . . . remain stable during 2 years of follow-up. (Please fill in) (Correct would be 10–30%)

impairment with interferon- β therapy (*experimental event rate*) and without therapy (*control event rate*) and then to determine the net benefit of this therapy (*absolute risk reduction*). The patients' determination of this net benefit demonstrates understanding of relative and absolute risks. Answers in a range of 10% to each side of the true relapse rate were valued as correct. The same questions were asked before and after the intervention. In the second questionnaire the patients were instructed to refer to interferons in general rather than the specific drug presented in the example. Thus, intended answers referred to different numbers than the numbers presented in the example of the core module. By this, we intended to measure competencies abstracted from the knowledge gained from the given example. Results were analysed based on the conservative assumption, that estimations identical to the presented example did not indicate the skill.

2.5. Measuring emotional response and control beliefs

Due to the limited amount of information provided, the core module did not have the potential to substantially change the general mood of the participants. Furthermore, due to the unselected study sample, we had no reason to assume any emotional priming e.g. decisional conflict or anxiety. Established instruments for state affect measurement were unlikely to show any emotional changes. To assess direct emotional responses we decided to use easily understandable visual analogue scales (VAS) which were presented only after the core module. This answering format is considered to allow more spontaneous responses compared to stepped answering formats. Furthermore, since VAS' provide continuous data, possible differences are more likely to be observed due to enhanced variance [17]. The development panel defined five dimensions as relevant for emotional appraisal of evidence-based medical-information: grade of familiarity with the information, subjective understanding, relevance, emotional arousal, and certainty. These dimensions were presented by labelling the extreme poles with pairs of adjectives, "unfamiliar" versus "already familiar with the information", "complete understanding" versus "no understanding", "highly relevant" versus "not relevant", "did make me curious" versus "did not make me

curious" and "wary" versus "encouraged". Responses were ascertained as percentage scores, which represented the proportion of the distance between the two poles. Scores were projected on a -50 to $+50$ scale.

To assess degrees of control beliefs the patients were also asked to complete a five item set out of the general self-efficacy scale [18]. The selection of five items out of 10 was advised by the author of the scale. To define high and low values a median split was conducted with the individual mean score values.

2.6. Statistical analyses

Change in the numeracy competencies were calculated using three paired *t*-tests each comparing before- and after-intervention values for the risk calculation items. Extend and direction of emotional responses were analysed descriptively. Differences in emotional responses in relation to high or low degree of self-efficacy and emotional responses in relation to the two types of disease course were analysed using *t*-tests. Differences in development of numeracy skills due to degrees of self-efficacy or due to types of disease course were calculated by use of *t*-tests of mean differences. To determine interactions between numeracy and emotional responses, three groups of numeracy responses were predefined: participants with correct answers before and after the intervention, without any correct answers and those who answered correctly after the intervention but not before. These groups built up three factor steps in an ANOVA on emotional responses. All procedures were calculated with SPSS 11.5 for WINDOWS.

3. Results

3.1. Description of the sample

The response rate to the mail investigation was 79% (169 out of 213): 75 patients with RRMS, 75 with PPMS disease and 19 patients with a disease course of less than 1 year (Table 2).

Non-responders ($n = 44$) showed similar demographic profiles compared to responders with exception of age and

Table 2
Demographic data

	Responders (n = 169)	Non-responders (n = 44)
Female/male (n)	106/63	25/19
Age in years (mean ± S.D.)	44 ± 11	50 ± 12
Relapsing remitting-MS (n)	75	21
Primary progressive-MS (n)	75	23
Early disease (n)	19	0
Disease duration in years (mean ± S.D.)	7.7 ± 6.9	12.4 ± 8.7
Higher education (n)	69	Not determined
MS immune therapy (n)	103	Not determined

disease duration. Non-responders tended to be older and to have a longer disease duration.

3.2. Numeracy competencies

Most of the study participants were apparently not familiar with relative risk statements as they are usually presented. At baseline assessment 134 of 169 (79%) did not complete item 3 (absolute risk reduction) in a range of 10% around the correct value. After reading the information, the number of correct answers for this item increased from 35 to 70 (21–41%). Still 99 participants were not able to answer this item correctly. The differences between the two measurements were significant for all three numeracy items (control event rate, 10–43%, $p < 0.001$; experimental event rate, 33–43%, $p = 0.043$, absolute risk reduction, 21–41%, $p < 0.001$, see Fig. 2). Results of four patients just repeating the earlier presented values were not counted as correct answers.

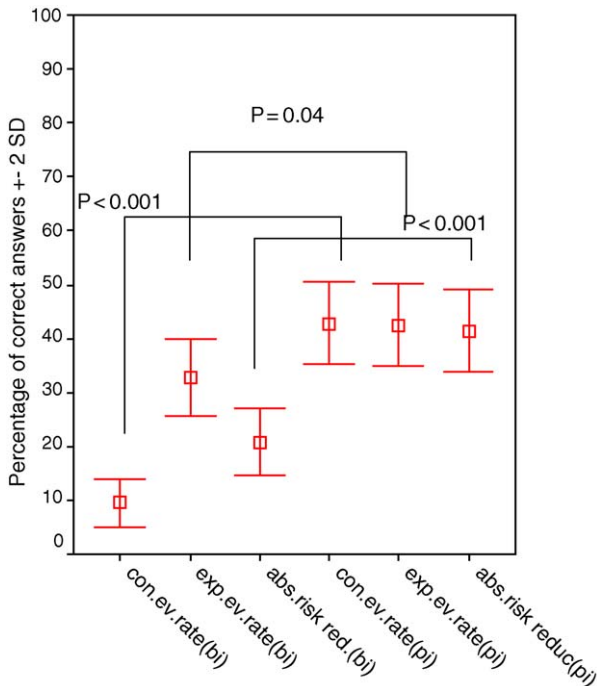


Fig. 2. Increase of calculation abilities (N = 169). Percentages of patients with correct answers to a set of three items (mean ± 2S.D.) presented before intervention (bi) and post-intervention (pi). They are: “control event rate”, “experimental event rate” and “absolute risk reduction”.

3.3. Emotional responses

Up to 42 of the 169 participants (25%) answered the VAS-items incompletely. Analyses of frequencies of the 127 remaining marks on each of the five dimensions showed no alarming mean value at all (Fig. 3). The most pronounced mean values were 18 for “understanding” and 9 for “emotional arousal” which are to be interpreted as desired responses to the information. The “certainty” scale showed a mean of –6 which can be interpreted as a minor degree of evoked uncertainty (Fig. 3).

3.4. Control beliefs

The self-efficacy items were completed by all participants. Cronbachs α values (0.71–0.75), item difficulty (2.6–3.0 on a scale ranging from 1 to 4) and variance (S.D. 0.75–0.90) were all comparable to the psychometric

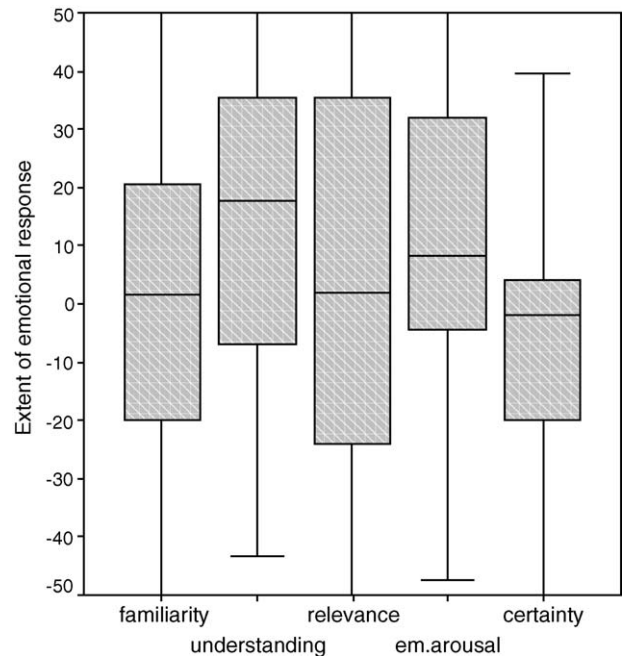


Fig. 3. Emotional response to the risk-information (n = 127). The figure shows the emotional responses on the five selected dimensions. Median, interquartile range and extreme values are presented, as they resulted from the assigned Visual Analogue Scales (VAS).

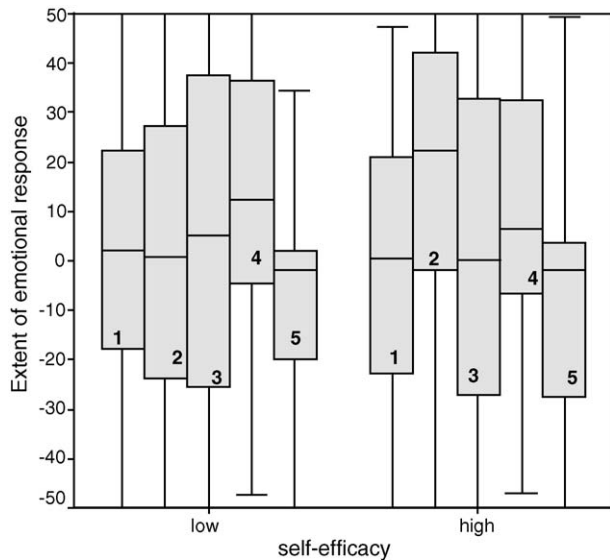


Fig. 4. Emotional response in relation to self-efficacy. Emotional responses to the information in participants with high versus low (median split) belief in their own self-efficacy. Median, interquartile range and extreme values are presented. Presentation of the bars: 1, familiarity; 2, understanding; 3, relevance; 4, emotional arousal; 5, certainty.

properties published by Schwarzer [18] for the complete version of his questionnaire.

The analyses of patients with high versus low self-efficacy related to emotional response showed a significant difference in the dimension “understanding” (Fig. 4). Patients feeling highly self-efficient reported greater understanding than patients with the belief of low self-efficacy ($p = 0.009$ /d.f. = 132). Other dimensions showed no differences. Furthermore, no associations were found between beliefs in self-efficacy and change of numeracy competencies. This was determined by independent *t*-tests of the mean differences. Thus, differences in subjective understanding could not be objectified as differences in mean knowledge increase.

3.5. Course of disease

We compared RR- and PPMS patients ($n = 75$ each), to test the hypothesis that information processing varies with the relevance of the information subject. There were no statistically significant differences comparing the emotional responses. However, while at baseline the groups did not differ in their numeracy skills in the post-intervention numeracy task, MS patients with the RR-course showed significantly higher numeracy compared to PPMS patients (independent *t*-test of mean differences control event rate: $p = 0.007$ /d.f. = 154, experimental event rate: $p = 0.06$ /d.f. = 153, absolute risk reduction $p = 0.24$ /d.f. = 155).

3.6. Adverse side effects of the information

We examined statistical interaction between emotional responses and the change of numeracy. We conducted

variance analyses of emotional responses between three factor groups of participants: patients who were already familiar with the information ($n = 27$), those acquiring the competence by reading the core module ($n = 43$), and patients not able to calculate absolute risk before intervention and without learning effect ($n = 99$). As anticipated by their results in the numeracy task, the groups showed distinctive differences concerning their subjective “understanding” ($p < 0.001$). Patients who were already familiar with the information and patients who benefited from the core module reported more “understanding” than patients, who did not comprehend the underlying message and did not develop the skill to deal with absolute and relative risk statements ($p < 0.001$). However, there were no differences regarding any of the four other response dimensions. Thus, we did not observe any adverse effects of the intervention even if it failed to impart the intended information.

4. Discussion and conclusions

4.1. Discussion

This study aimed to prove sustainable responses to evidence-based medical information on immunotherapy for patients with MS as part of a decision aid development process. It focused on the ability to recognise and understand risk information referred to as numeracy in the literature. This numeracy competence indicates a deeper understanding, which goes beyond “knowledge” usually taken as effect measure. Such skill is likely to exhibit meaningful support for medical decision making [12].

A part of the study group showed comprehension of the inherent message concerning numerical risk information. This can be interpreted as an indicator that the material mediates the skill to process absolute and relative risks. Still, a substantial part of the patients did not solve the risk calculation task. This may be due, at least in part, to the specific characteristics of the patient sample and setting. Participants were in different stages of their disease and not necessarily in a real decisional process about immunotherapy. Furthermore, the information given in the core module was limited. Therefore, the study most likely underestimates the potential effect of the comprehensive decision aid if presented to patients who are actually in a decision process about immunotherapy. This assumption is supported by higher rates of comprehension in the RRMS group compared to the PPMS group. Since immunotherapy is not proven effective for patients with PPMS and therefore of limited relevance, the findings might indicate motivational bias.

Patients’ decision making is not only a rational process. Process quality does not solely depend on patients’ degree of dealing with numbers. Our decision aid does not claim to cover all components of patients’ needs when deciding on treatment. Nevertheless, our results concerning numeracy

competencies show that this approach could contribute to a reflexive use of medical information by the patients [19].

The presented evidence-based medical information seems suitable for most of the patients as no extreme emotional statements were observed. This result confirms our previous observations with MS-patients using the focus group method. In the present study patients perceived the information as new, understandable and relevant. Also, it made participants feel curious. Even in the group of patients who did not understand the material, adverse emotional responses were not observed. This is an important result as it could convince physicians who are worried about confronting patients with complex medical information that could elicit uncertainty. The results are in accordance with other studies showing that decision aids do not provoke any adverse emotional effects [20,21]. Most studies report a decreased or unchanged state of anxiety, no differences in well being, psychological distress or worries after exposure to a decision aid [22,23].

However, the core module did induce uncertainty among participants to a moderate extent as assessed by the VAS. In most other studies, uncertainty as measured by the decisional conflict scale was decreased after an informed choice [24,20]. As we did not measure uncertainty in the context of a decision, but as response to information, these results are not comparable with studies using the decisional conflict scale. Reduction of a decisional conflict may not always be an appropriate criterion to evaluate an informed choice. Certainty could be illusive. Moderate exposure to uncertainty might even motivate patients to overtake autonomy and to participate in relevant decisions. Recently, McNutt argued that a main reason for involving patients in decision making should be the fact that the consequences of choice are unknown in the individual case in most clinical settings [25].

Patients with higher beliefs in self-efficacy estimated their understanding higher than patients with lower self-efficacy, while objective comprehension showed no difference. This can be explained by optimistic perception which corresponds to the construct of self-efficacy. No other emotional responses were affected by self-efficacy, indicating that the core module is suitable for users with different grades of belief in their own action control.

The present study has some limitations. Although we provided a clear instruction for test performance some participants may not have adhered to the order of handling the material. If so, they could have read the information before completing baseline items. This would have led to underestimation of the core module effect. In addition, results shown for the study population are not necessarily representative for other MS-populations. The demographic data indicate that young MS patients with comparably little disease progression were over-represented in this study. Emotional involvement or the workload of completing the questionnaire could be possible explanations for missing

data in the VAS. However, in our previous focus group study with MS-patients most VAS were filled in and no strong emotional reactions had appeared.

The decision about the complexity of an information tool to be developed has to consider target group and setting. To appraise this criterion we relied on the development process. This was performed stepwise by involving patients in the evaluation of the material to ensure its applicability as proposed by Coulter [14].

All results are shown for the particular tool and are not generalisable to other tools or target groups. Standards for the development of decision aids request a proof of effectiveness for every single tool [14].

The recently finished comprehensive decision aid [4] is currently being tested in a randomised controlled trial evaluating the tool under routine care conditions regarding target group, setting and decisional situation. The results of this study will allow further appraisal of benefit, risk and harm of evidence-based patient information in MS.

4.2. Conclusion

The presentation form tested as the core module of a more comprehensive decision aid supports people suffering from multiple sclerosis to process evidence-based medical information and scientific uncertainty without burdening them emotionally.

4.3. Practical implications

Details of the development process, the analysis of contextual conditions and the pilot testing of elements of a decision aid are important background information for the critical appraisal of a decision aid. This study is an example for the documentation of an important step in the development process of a complex intervention.

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