



Personalized treatment outcomes in patients with somatoform disorder: A concept mapping study

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ABSTRACT

Objective: From a patient-centered perspective, treatment outcome measures in somatoform disorder need to be (1) personalized to the patient, (2) fit core problems that are targeted in therapy, and (3) reflect one's ability to adapt and self-manage anticipated deterioration. The aim of this study was to identify an encompassing set of treatment outcome variables in patients with somatoform disorder.

Methods: In-depth interviews yielded a comprehensive overview of 60 treatment outcomes that were sorted in a card sorting task according to similarity of meaning by 30 patients. Hierarchical cluster analysis (squared Euclidean distances, Ward's method) was used to obtain a structured overview of treatment outcomes unbiased by subjective interpretations of researchers. Perceived importance and personal change were examined using descriptive statistics.

Results: The hierarchical structure of treatment outcomes showed seven clusters, classified in two broad categories: self-other relationships (comprising social support, health care use, and self-confidence) and self-management (comprising physical balance, psychological adjustment, symptom acceptance, and resilience). Ratings of the importance of the clusters showed large individual differences. Most participants retrospectively perceived positive personal change.

Conclusion: The wide variety of treatment outcomes and the observation that patients attach different importance to the outcome measures supports the value of developing new personalized outcome measures for effect studies. In clinical practice, the clusters of outcomes can be used in shared decision making during intake, to define treatment goals, and to map and evaluate change on a personalized set of outcome measures.

1. Introduction

Effectiveness of psychological treatment in patients with somatoform disorder, the precursor diagnostic category of somatic symptom disorder, has been shown, but the effect-sizes of treatment outcomes were generally small to moderate [1,15–17]. Although these modest outcomes may reflect that somatoform disorder is difficult to treat or that outcome measurements are not sufficiently sensitive to change and show large variability [22], an additional explanation is that the commonly used outcome measures do not validly reflect the changes that are pursued in treatment. Our starting-point in searching for new outcome measures was that these measures 1) should be customized to the patient with somatoform disorder, 2) should fit the core problems that are targeted in therapy, and 3) should not only reflect the outcome in terms of symptoms or function but also one's ability to adapt and self-

manage future deterioration in outcome.

With regard to this, we firstly strive for outcome measures that are customized to the individual patient with somatoform disorder. A basic assumption in initiating therapeutic change from a patient-centered perspective is that the patient will be more motivated, adhere better and benefit more and for a longer time when the intervention is customized to the individual needs, preferences, and values of the patient [6,9,11]. A theory consistent with this assumption is self-determination theory [24], which emphasizes the importance of keeping goals of behavior change close to the autonomous motivation of people. This patient-centered approach was the framework that guided our search for outcome measures that are valid for the individual patient with somatoform disorder.

Second, outcome measures should fit the core problems that are targeted in therapy. Effects of treatment are commonly measured with

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generic instruments [22], for instance, with the Brief Symptom Inventory (BSI; [10]) and EuroQol-5D (EQ-5D; [7]). However, while the obvious primary outcome measure is, for instance, the treatment of depression is depressive mood, in somatoform disorder there is no unequivocal, generic symptom (cf. [23]) or other generic outcome criterion. For instance, the symptom checklist-90 in a population of patients with severe somatoform disorder reflects healthier scores than a norm reference group of patients with psychiatric disorders, even on the somatization scale [13], which suggests that this is not an adequate outcome measure for at least part of the group. Moreover, many but not all patients with somatoform disorder have psychiatric and somatic comorbidities [28], which makes it even more difficult to pinpoint core outcomes that hold for the majority of the group. Thus, several considerations and findings indicate that common generic outcome measures do not apply to a large part of the heterogeneous group of patients with somatoform disorder.

Our third reason to search for personalized outcome measures is that the outcome measure should not only reflect the outcome in symptoms or functioning *per se* but also one's ability to adapt and to self-manage anticipated deterioration in outcomes. Most generic outcome measures reflect the World Health Organization (WHO) definition of health as 'a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity' [29]. This concept of 'health' is changing nowadays by including not only the physical, emotional and social health status of people, but also their ability to deal with these future problems [14]. These dynamic aspects of functioning should be part of outcome definitions.

Therefore, to get an overview of more personalized (idiosyncratic) outcomes beyond the commonly used generic (nomothetic) outcomes, this study focusses on outcomes in patients with somatoform disorder that not only reflect static results but also skills to achieve these results, and on outcomes an individual patient may have. The aim of our study was to identify an encompassing set of treatment outcome variables from the perspective of patients with somatoform disorder. The current study overlaps with and adds to previous (patient reported) qualitative, and narrative outcome studies in several groups that indicated outcome variables such as social support, (symptom) acceptance, commitment, relaxation skills, awareness, expression of emotions, personal experiences, self-confidence, and coping [12,18,19]. A core distinctive feature of our approach is that not interpretations of categories and themes by researchers but sorting by patients was used to structure the set of treatment outcomes. Patients that had finished therapy were considered to be the most experienced experts to offer an encompassing overview of treatment outcomes including skills to achieve these outcomes.

2. Method

2.1. Design and procedure

A concept mapping technique [26] was used to quantify qualitative information in a systematic way. In order to enhance the patients' perspective, a patient expert participated in the research group in every stage of the research process.

A four step procedure was used in people who had been treated for somatoform disorder. First, individual in-depth interviews were held, yielding a comprehensive set of treatment outcomes. Second, a representative set of statements from the interviews was derived by the research group comprising researchers, clinicians, a patient representative, and a master's student. Third, another group of participants who had been treated for somatoform disorder sorted the statements according to similarity of meaning in a card-sorting task. They also indicated the importance of these statements and retrospective rated their personal change to get preliminary insight into the variety and utility of these measures in effect studies. Fourth, a hierarchical cluster analyses was used to get a structured overview of outcomes unbiased by subjective interpretations of researchers.

The study was conducted according to the principles of the Declaration of Helsinki (revision, Fortaleza, Brazil, 2013 [30]). The study was approved by the institutional review board of Altrecht Psychosomatic Medicine, Zeist, The Netherlands (CWO, 1320). All participants provided written informed consent.

2.2. Participants

The participants were patients with somatoform disorder who were formerly treated at Altrecht Psychosomatic Medicine, a tertiary care center in Zeist, the Netherlands. Patients admitted to this institution on average have medically unexplained symptoms for 10 years, received about 5 previous treatments for somatoform disorder in primary or secondary care, and have comorbid mood, anxiety, or personality disorder in about half of the cases [28]. During the assessment phase before the start of therapy, somatoform disorder was diagnosed according to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV-TR; [2]) criteria by trained psychologists and confirmed by the resident medical doctor and psychiatrist.

The treatment was an intensive multidisciplinary treatment, focusing on body-related mentalization, acceptance and commitment, cognitive behavioral modulation, and the dynamic family environment [13]. Patients received either an outpatient or a (residential) inpatient program. Exclusion criteria for treatment at the institute were a) diagnoses of hypochondriasis or body dysmorphic disorder, b) diagnoses of addiction, bipolar disorder or psychoses, c) crisis situation requiring immediate attention (e.g. high suicidality), and d) current treatment by a specialized physician outside the center. Data collection consisted of interviews in 2013/2014 and a card-sorting task in 2014. Participants were eligible for this study when they ended their treatment 3 to 18 months before participation in the current study. This time frame was chosen, because we assumed that patients 3 months after therapy would be able to report about the outcomes of treatment with some distance, while they would not have forgotten the outcomes after 18 months.

To select patients for the interviews, data from a Routine Outcome Monitoring system were used. We wanted a heterogeneous group in terms of outcome at the somatization scale of the Brief Symptom Inventory (BSI; [8,10]). Eighty-nine eligible patients who had terminated treatment 3–18 month before, were selected and evenly distributed across the following four groups: patients, who showed deterioration (Cohen's effect size, d , smaller than -0.20), did not improve ($-0.20 < d < 0.20$), or showed a small to medium ($0.20 < d < 0.80$), or large ($d > 0.80$) improvement. Then, step by step, patients evenly divided across the four groups were informed and invited. In total, 56 former patients were invited. Data collection ended when no new information emerged from two successive interviews (data saturation).

For the card sorting task, we aimed for 30 participants. A sample size between 10 and 20 people has been suggested to be a workable number for a card sorting task [26] and 25–30 participants will likely yield results similar to those of several hundred, provided these participants are representative of actual users and are familiar with the domain being considered [31]. A group of 234 former patients received an information letter. The only selection criterion was to have ended treatment 3 to 18 months before participation in the study. Thirty-five patients responded to the invitation. Patients could choose to participate in both the interview and the card sorting task.

2.3. Instruments

Participants provided demographic data and completed the Dutch version of the Brief Symptom Inventory (BSI; [8,10]), a 53-item self-report questionnaire The 5-point Likert answering scales range from 0 ('not at all') to 4 ('extremely'). The items are assigned to nine subscales, which referred to different domains of psychopathology (during the

preceding 7-days). Cronbach's α of the total score was 0.96, indicating a very high internal consistency [8].

2.4. Data collection and analysis

2.4.1. Step 1: interviews

Interviews were held at the home of the participant or elsewhere, depending on the choice of the participant. Interviews lasted one to one-and-a-half hours. The interview was guided by the core open question 'what are the most important changes you noticed by the treatment?' Participants were asked to illustrate their answers by concrete examples and the interviewer asked additional open questions to encourage the participant to think of more answers (any other changes? Please, tell! Take your time to think of other changes, and so on...). Twelve interviews were audio-taped and transcribed afterwards. For one interview only notes were used, because it was stored incorrectly.

2.4.2. Step 2: selection of outcomes

All outcomes were independently screened and selected from the transcribed interviews by pairs of 2 members of the research group and again checked by another member of the research group, consisting of a researcher (RG), two clinicians (SvB and SK), a patient representative (LO), and a master's student (SvV). An outcome was selected using four criteria. First, it had to reflect a change by treatment. Second, it had to be applicable to the entire group (e.g., outcomes that only concerned women were deleted). Third, similar outcomes were combined and a single statement involving multiple outcomes was split into single outcomes. Fourth, the outcome should neither be ambiguous or abstract nor too specific and it should stick to the original verbalization by the interviewee as close as possible. Selected outcomes were discussed within the research group until consensus was reached about selected outcomes.

Each outcome was made to fit a format starting with the sentence 'Treatment can bring about change in...' (the selected outcomes are shown in a Supplementary Table 1). All outcomes were formulated in a neutral way, not implying positive or negative change after treatment. The selected outcomes were numbered randomly and written on separate cards for use in the card sorting task.

2.4.3. Step 3: sorting by content similarity, perceived importance and retrospective change

In a card sorting task, participants sorted the outcomes derived from the interviews. The task was sent by post to the homes of the patient. Participants were asked to group cards with treatment outcomes according to similarity of meaning on separate piles. The following rules applied: all outcomes had to be placed in a pile; each outcome could be placed in one pile only; each pile could contain 2–25 outcomes; and 4–12 piles could be formed. Occasional missing values or items sorted twice were put on separate 1-item "piles", which occurred with 6 participants concerning 9 items in total. The participants were asked to give the piles a label that could be used by the researchers to interpret the sorting. They wrote their sorting outcomes on sheets and returned their answers to the researchers by post.

In a second task, participants were asked to individually sort the selected outcomes into 5 categories of importance ranging from 'least important' (1) to 'most important' (5) outcome. Outcomes had to be equally allocated to the five categories of importance. This way of prioritizing was used to stimulate participants to think about differences in importance.

In a questionnaire, participants were asked to rate their personal change on the selected outcomes using a 5-point Likert-scale with the response format deteriorated, deteriorated a little, no change, improved a little, improved. The question was: "Please indicate your personal rate of change in...:"

2.4.4. Step 4: hierarchical cluster analysis

Hierarchical cluster analysis in SPSS statistical software version 21.0 (SPSS, Chicago, IL) was used to classify outcomes that were individually sorted by the participants during the card sorting task according to similarity of meaning in a hierarchy of clusters. In cluster analysis, the cells of the input matrix of outcomes comprised the number of times that two outcomes were not sorted in the same pile. Squared Euclidean distances were computed between each pair of outcomes and Ward's method was used to derive the hierarchical structure of outcomes. The final number of clusters was set by the members of the project group (SK, SvB, SvV, LO, RG) guided by the dendrogram and the agglomeration schedule produced by the statistical software program showing which statements were being combined at each stage of the hierarchical clustering process. The main criterion to decide on the number of clusters was that the clusters should reflect distinct components of outcomes.

In the first stage, a top-down interpretation was used starting with two clusters, then three and so on until additional clusters did not yield new content. In the second stage, the contents of both a lower and a higher number of clusters were compared to finally decide on the number of clusters, based on consensus of the project group. The research group gave names to the clusters.

The mean perceived importance was calculated for all outcomes and for the distinct clusters. The perceived change was expressed as the percentage of participants who deteriorated, remained equal, or improved on the clusters of outcomes. Both were examined using descriptive statistics.

3. Results

3.1. Participants

Thirteen participants agreed to be interviewed. Thirty-five participants agreed to participate in the card sorting task. Two were excluded because –as was observed afterwards– the participants did not receive treatment but were only included in the diagnostic phase, one participant was excluded because the sorting by similarity and importance was done incorrectly, and two participants were excluded because they did not do any card sorting. In the sorting of treatment outcomes according to content similarity, one additional participant was removed because only half of all outcomes were sorted, and in the sorting of perceived importance, two participants were removed because outcomes were not distributed equally across the five piles. Three participants participated in both the interview and the card sorting task.

Table 1 presents the characteristics of the participants. Many participants showed comorbid diagnoses. To get an impression of the representativeness, participants were compared to a larger group of patients treated at Altrecht Psychosomatic Medicine. Of 20 of the 30 participants who participated in the card sorting task, BSI scores before treatment could be derived from files. The BSI total score before treatment of these 20 participants (mean = 1.04; $SD = 0.51$) did not differ from a sample of 114 patients before the start of treatment at Altrecht Psychosomatic Medicine (mean = 1.24; $SD = 0.70$; internal publication [25]; $t = 1.22$, $p = .22$).

3.2. Card sorting task

A list of 278 treatment outcomes was derived from the interviews. After application of the four criteria and discussion in two consensus meetings, 60 outcomes remained for the card sorting task.

The number of sorted piles varied from 5 to 12 across the participants. A schematic representation of the dendrogram with the outcome of hierarchical cluster analyses is shown in Fig. 1. The items included in the clusters are shown in the Supplementary Table 1. The research group chose the solution with seven clusters. Decreasing the number of clusters from 7 to 6 or 5 clusters, would combine 'symptom acceptance'

Table 1
Demographic and clinical characteristics of participants with somatoform disorder (SFD) in the interviews and the card sorting task.

	Interview (n = 13)	Card sorting task (n = 30)
Sex, n (%)		
Male	4 (31%)	6 (20%)
Female	9 (69%)	24 (80%)
Mean age in years (min–max)	49 (30–68)	42 (23–68)
Civil status		
Married or living together	9	17
Single	2	10
Divorced	1	2
Widowed	1	–
Other, in divorce	–	1
Education		
Low	3	5
Middle	6	9
High	4	15
Unknown	–	1
Total duration of treatment (clinical, ambulatory or both)		
Up to 3 months	3	3
3 to 6 months	4	6
6 to 12 months	2	13
> 12 months	4	7
Unknown	–	1
DSM-IV diagnoses concerning SFD		
Undifferentiated SFD	10	13
Conversion disorder	2	9
Pain disorder	2	9
Unknown	–	1
DSM-IV comorbid diagnoses		
Major depressive disorder, single episode	2	6
Major depressive disorder, recurrent	1	1
Dysthymia	2	1
Panic disorder with agoraphobia	1	–
Generalized anxiety disorder	–	1
Posttraumatic stress disorder	2	2
Social anxiety disorder	–	1
Substance-related disorder	4	1
Dissociative disorder	–	1
Eating disorder	1	1
Adjustment disorder	–	2
Borderline personality disorder	–	1
Narcissistic personality disorder	–	1
Avoidant personality disorder	–	4
Dependent personality disorder	1	2
Obsessive-compulsive personality disorder	–	2
Personality disorder not otherwise specified	3	3
Diagnosis deferred on axis II	2	6
No as-II diagnosis	7	7
Unknown	–	4
Global assessment of functioning scale		
≤ 40	1	2
41–50	9	18
≥ 51	2	8
Unknown	1	2
Brief symptom inventory (BSI)	Mean (SD)	Mean (SD)
Somatization scale	1.34 (0.89)	0.90 (0.58)
Total	1.18 (0.75)	0.72 (0.49)

Note Education: Low = primary school or lower vocational secondary education, intermediate general secondary education; Middle = intermediate vocational education, higher general secondary education; High = university of applied sciences or university.

and ‘resilience’ (6 clusters) and ‘social support’ and ‘health care use’ (5 clusters), which are clearly distinct groups of outcomes. Increasing the number to 8 or more, showed coherent clusters of items until a 13 cluster solution. The research group decided that these clusters could be categorized as sub-clusters of 3 clusters (self-confidence, physical

balance, and psychological adjustment) in the more parsimonious 7 cluster solution. Increasing the number of clusters from 13 to 14, led to a split of Assertiveness in two constructs: social firmness skills (items 48, 58, 54, 4) and telling about oneself (items 6, 30, 47). We decided not to split this cluster, because both aspects came down to assertiveness.

The hierarchical cluster solution as shown in Fig. 1 shows a major distinction of two broad categories. The first category ‘self-other relationship’ comprises domains about how one relates to the immediate (social support) and health care environment as well as the way one interacts with and relates to other people (self-confidence). The second category ‘self-management’ comprises outcomes with respect to physical, psychological, and cognitive management.

3.3. Perceived importance

The score distributions of perceived importance at the seven clusters of treatment outcomes, is shown in Fig. 2; the Supplementary Table 1 shows the importance score at all clusters). The figure shows a wide range of individual differences. With exception of only two clusters (physical balance and psychological adjustment) the range of scores between the 10th and 90th percentile was more than two scores. All designated clusters are –on average– rated about equally important by the participants, showing one exception on health care use that was scored less important with 50% of the participants scoring these items least important (score 1) and 75% scoring lower than score 2.

3.4. Perceived change

Table 2 shows the percentage of participants that retrospectively reported to have deteriorated or improved on the outcomes. On all clusters, most participants perceived a positive personal change. Twenty-three patients perceived an improvement on self-confidence and symptom acceptance (77%). Three participants (10%) perceived deterioration on health care use and resilience.

4. Discussion

This study identified an encompassing set of treatment outcome variables from the perspective of patients with somatoform disorder. Seven clusters of outcomes were identified that were classified in two broad categories. The first category, self-other relationships, comprised the clusters of social support, health care use and self-confidence outcomes. The second category, self-management, comprised the clusters of physical balance, psychological adjustment, symptom acceptance, and resilience outcomes. The importance ratings of these clusters showed large individual differences. On all clusters, most participants retrospectively perceived a positive change.

In support of a patient-centered approach, participants in our study mentioned a wide variety of outcome measures and the importance attached to these outcome measures varied a lot between participants. Previous studies using semi-structured interviews [12,18,19], diary reports [20] and narrative reviews [21] also support a broader view on outcome measurement guided by the perspective of patients. These (partly) qualitative studies indicated some themes for therapeutic change comparable to our findings, such as the importance of the social context, functioning, managing emotional distress, self-confidence, physical balance, awareness, and acceptance. In terms of clinical applications, previously the PSYCHLOPS (psychological outcome profiles) instrument was developed to broadly assess all possible mental outcomes in primary care [5]. Our study adds to this instrument by offering a comprehensive overview of potential relevant clusters of outcomes for individual patients with somatoform disorder. In analogy to an ongoing study that was also guided by the results of a concept mapping study [3,4], the results of the current study provide a relevant set of individual treatment outcomes that can feed PSYCHLOPS [5] or goal-

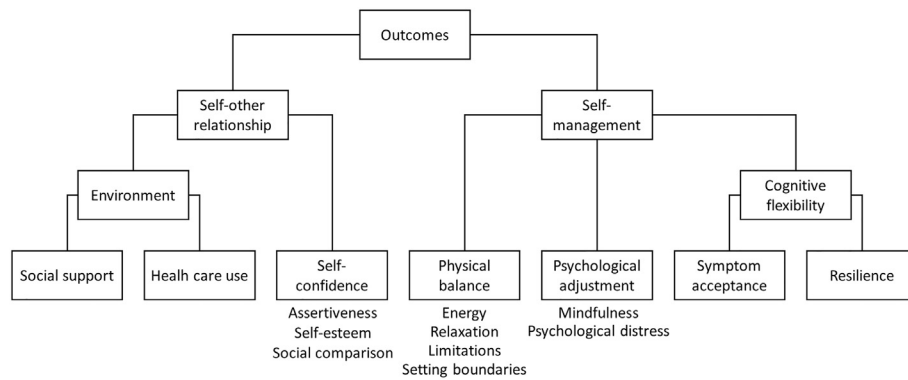


Fig. 1. Schematic representation of the hierarchical structure of treatment outcomes according to patients that had been treated for somatoform disorder.

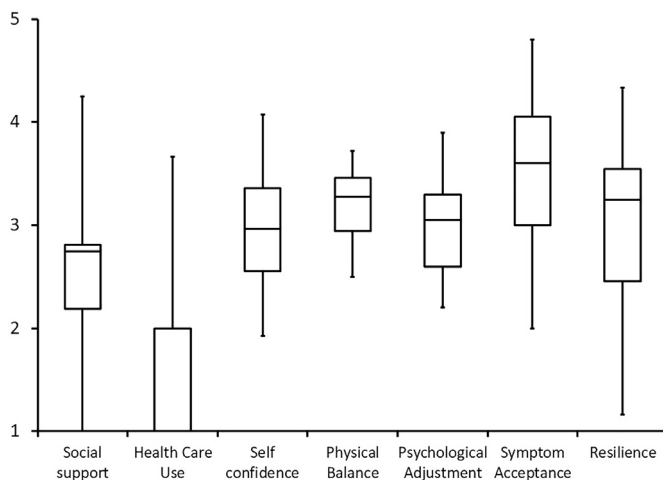


Fig. 2. Boxplot showing the importance of clusters of treatment outcomes as perceived by patients that had been treated for somatoform disorder. The lowest possible score is 1 (least important) and the highest possible score is 5 (most important). Each box represents the 25th percentile (bottom of the box) to 75th percentile (top of the box) with the median in the middle. Bars outside the boxes represent the 10th (bottom) to 90th (top) percentile.

attainment scaling [27] in shared decision making.

Common outcome measures in patients with somatoform disorder address somatic symptoms, psycho-behavioral features, and illness consequences [22]. The specific treatment outcomes as reported by patients in our study (Supplementary Table 1), are broader than the outcome measures that were mostly used in previous outcome evaluation studies [1,15–17]. All of our identified clusters reflected one's ability to adapt and to self-manage, which is in line with a modern view on health [14]. If symptoms do not change, but patients learn to deal with symptoms, then this is also a valuable outcome of therapy. In idiosyncratic evaluation of therapy, a set of outcomes customized to the individual patient can be used next to the commonly used nomothetic outcome assessments. Outcome measures that are more specific for

patients with somatoform disorder may show higher therapy effects than the commonly used generic set of measurements. This was tentatively indicated by the retrospective accounts of mostly positive change on these outcome measures by patients in the current study.

A strength of our study is that the perspective of patients was consistently applied. This design allowed a description beyond the subjective interpretation of researchers, because patients instead of researchers categorized the outcomes in meaningful constructs. The outcomes of our study were hierarchically structured according to the meaning of the outcome variables. This differs from correlational studies, e.g., factor-analysis, that structure outcome factors according to consistency of individual differences. This may explain why our set of outcomes is more encompassing than previous sets that were derived with factor-analytic procedures. In contrast to another study that differentiates between outcomes and mediators contributing to improved outcomes [18], a distinguishing feature of our study is also that not the outcome per se but also mediator variables that prevent anticipated deterioration of outcomes are conceived as an outcome of therapy.

Although our population was before the start of therapy diagnosed with somatoform disorder instead of somatic symptom disorder, the identified set of treatment outcomes does not appear to reflect DSM-IV diagnosis at the cost of DSM-V diagnosis, because it clearly includes a focus on psychological aspects of handling somatic symptoms. However, without replication the results of this study cannot be generalized beyond patients with somatoform disorder to other conditions causing persistent physical symptoms. Another limitation of this study was that many former patients did not respond to our invitation to participate in the study. In the interviews, we tried to prevent bias by acquiring an even amount of patients who showed improvement or deterioration on the BSI somatization scale and by offering the possibility to participate at home. Moreover, the BSI scores at the start of the therapy of subjects participating in card sorting did not differ from a common group at baseline. With respect to sample size, although 10 to 20 people are suggested to be a suitable number for card sorting [26], we noticed that the higher order structure of the hierarchical cluster solution slightly changed by reanalyzing the data while excluding few participants.

In conclusion, adopting the perspective of patients, our study

Table 2

Number of participants, who deteriorated, remained equal or improved on the seven clusters of outcomes after therapy.

Clusters	Deterioration	Little deterioration	Remained equal	Little improvement	Improvement
Social support	1	1	10	11	7
Health care use	0	3	16	9	2
Self-confidence	0	1	6	19	4
Physical balance	0	2	9	12	7
Psychological adjustment	0	2	9	10	9
Symptom acceptance	0	2	5	13	10
Resilience	1	2	9	15	3

yielded a well interpretable set of individual outcomes. This set appears to refer to core problems and targets of treatment of patients with somatoform disorder. The wide variety of outcome measures and the observation that individual patients attach different importance to the outcome measures motivates the development, testing and applying of new individual outcome measures for effect studies. In clinical practice, while taking account of needs, preferences, and expectations of patients, the clusters of outcomes can be used in shared decision making during intake, to define treatment goals, and to map and evaluate change on a personalized set of outcome measures.

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Conflicts of interest

The authors have no competing interests to report.

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