



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

Sonja Klemm<sup>a,\*</sup>, Saskia van Broeckhuysen-Kloth<sup>a</sup>, Sanne van Vliet<sup>b</sup>, Lummy Oosterhuis<sup>a</sup>, Rinie Geenen<sup>a,b</sup>

<sup>a</sup> Altrecht Psychosomatic Medicine Eikenboom, Zeist, The Netherlands

<sup>b</sup> Department of Psychology, Utrecht University, Utrecht, The Netherlands

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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

\* Corresponding author at: Altrecht Psychosomatic Medicine Eikenboom, Vrijbaan 2, 3705WC Zeist, The Netherlands.  
E-mail address: [s.klemm@altrecht.nl](mailto:s.klemm@altrecht.nl) (S. Klemm).

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

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