Patient satisfaction and psychological well-being after internet-based cognitive behavioral stress management (IB-CBSM) for women with preterm labor: A randomized controlled trial

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A B S T R A C T

Objective and methods: Despite its value for the management of psychological burden, little is known about the efficacy of and patient satisfaction with internet-based cognitive behavioral stress management (IB-CBSM) for women with preterm labor. The present study sets out to analyze stress/anxiety reduction, patient satisfaction and patient's working alliance in a group of 58 women with preterm labor participating in an online psychological stress management project. As part of the project, women were randomly assigned to online stress management or a control condition.
Results: Levels of stress and anxiety decreased significantly in both conditions from pre- to post-treatment measure. Participants in IB-CBSM reported significant higher working alliance inventory (WAI) scores in the task and goal subscale ($p < .001$; $p < .05$) than women in the control condition. In Addition the IB-CBSM group showed significant correlations of the WAI subscale task and goal and the stress/anxiety outcome. Regarding patient satisfaction, women in the IB-CBSM reported significantly higher satisfaction scores ($p < .001$) than women in the control condition. WAI explained nearly 40% of the variance in patient satisfaction. Furthermore, WAI mediates, at least in part, the relationship between group condition and patient satisfaction.
Conclusion: The current analysis indicated that participants in IB-CBSM had higher WAI scores and were more satisfied with the program. In addition only the IB-CBSM group showed significant correlations of the WAI with the stress/anxiety reduction outcome. Based on these findings, it can be presumed that measures of agreement with working alliance parameters, especially task and goal components, are substantially important for more effective and satisfactory therapeutic interventions.

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Introduction

Preterm birth (PTB), defined as delivery before week 37 of gestation, occurs at a rate ranging from 5% to 18% according to current worldwide data [1]. About 40–50% of PTBs are idiopathic and result from spontaneous preterm labor (PTL) [2]. Besides being linked to various medical risk conditions such as infections, inflammations and hemorrhages [3], PTL is also associated with physiological, psychological, and psychosocial factors of stress and anxiety [4,5]. An effective approach to reduce psychological burden and improve quality of life are psychological interventions based on cognitive behavioral stress management (CBSM) [6,7]. Also during pregnancy, indicated treatment interventions showed

positive effects in reducing maternal distress [8]. However, since women with PTL are often limited in their mobility, the delivery of these interventions is impeded by the underlying medical condition. In recent years, internet-based (IB) interventions have received more and more attention. Systematic reviews and meta-analyses support that IB treatments showed positive outcomes regarding psychological distress (symptoms of anxiety and depression, posttraumatic stress and medical-considered problems, e.g. chronic back pain and headache) [9–11]. Therefore, IB-CBSM has the potential to be an important component of the psychosocial management of PTL. Nevertheless, little is known about the feasibility of such interventions during pregnancy and about patient satisfaction with these interventions.

The concept of patient satisfaction is defined as the extent to which treatment meets the wishes and needs of patients [12]. If patient satisfaction ratings are recorded, an insight into the patient's perspective is gained that supplements the conventional outcome measures [13]. Previous studies regarding medical interventions have shown associations between patient satisfaction and compliance [14],

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adherence to treatment, health-related quality of life [15] and symptomatic improvement [16].

The patient–provider relationship, in particular, is often discussed as a possible factor that could partially affect the relation between patient satisfaction and symptom reduction [17]. Elements such as the patient's trust and confidence in the provider [18] and the extent of their agreement with the form of treatment [17] also seem to have a considerable impact on patient satisfaction. The concept of working alliance, which highlights the relationship between two individuals involved in a working process, is often used to observe these different aspects of alliance. Surprisingly, these elements often have an equal or even a higher impact on patient satisfaction than improvement of symptoms [17]. For example, it was found that the relationship between working alliance and patient satisfaction was more pronounced than the association of symptom reduction and patient satisfaction [19].

With regard to therapy outcome, working alliance seems to be particularly important. In face-to-face settings, positive and robust associations between the therapeutic alliance and treatment outcome for many different types of therapeutic interventions were recorded [20, 21]. Although body of research on working alliance is steadily growing also in online interventions, only few empirical studies exist that specifically focus on the therapeutic alliance and its relationship with therapy outcome in this specific setting [22]. Nevertheless, former results indicate that in IB treatments therapeutic alliance is also evaluated comparatively high [23] and that in some IB treatments positive associations between alliance and therapy outcome exist [24]. Based on these findings, we set out to examine stress/anxiety reduction, patient satisfaction and patient's working alliance with an internet-based stress management (IB-CBSM) for a group of pregnant women with PTL. The current paper focus on the associations between working alliance and the outcome parameters stress/anxiety reduction and patient satisfaction, further the predictive value of working alliance, symptom reduction and group for patient satisfaction will be examined.

Methods

The present study was part of the randomized controlled trial 'Stress and anxiety reduction in women with PTL to improve outcome: a randomized controlled intervention study' that set out to evaluate the efficacy of internet-based cognitive behavioral stress management (IB-CBSM) in comparison to an active control condition in women with preterm labor. The impact of the IB-CBSM on gestational and biological stress outcomes will be presented in a separate paper. For further information see Scherer et al. [25].

Participants and inclusion criteria

The sample consisted of 93 pregnant women between gestational ages of 18 to 32 weeks suffering from medically diagnosed PTL. Excluded were high-risk patients with severe medical complications (e.g., placenta previa, uterine and cervical anomalies, current vaginal bleeding, severe infections, premature rupture of membranes and fetal malformations) as well as women with a positive screening for psychosis, suicidal tendencies or substance abuse disorder (with the exception of nicotine). The medical situation was assessed together with the monitoring physician in charge of prenatal care.

Procedure

Information concerning the study was published in pregnancy-specific magazines and sent to gynecological professionals at specific organizations and institutes. Interested women could contact the research team through the website or by telephone. Participants were provided with detailed information and the terms of participation. The local ethics committee approved the study protocol and a written release from medical confidentiality as well as the written informed consent

form was collected from all participants. General information on demographics and mental health as well as pre-treatment distress level of stress and anxiety was gathered and assessed. After screening, participants were randomly assigned to the IB-CBSM or the control condition. A random assignment list was prepared within the website random.org. After module 2, 3, 4 and 5, participants were requested to evaluate the perceived working alliance. After the last module, participants completed the post-treatment measure regarding distress level of stress and anxiety as well as satisfaction with the program. After birth, detailed pregnancy and birth outcome data were collected together with the monitoring medical professional.

Intervention

The six core IB-CBSM modules are based on elements of stress management training by Kaluza [6]. The modules consisted of predetermined units (psychoeducational information, relaxation exercises) and interactive exercises (coping cards to reappraise stress-associated thoughts) as well as protocols (activity diary, stress and problem solving protocol; cf. (25)). The contents of the IB-CBSM training were illustrated with pregnancy specific issues and examples and have been adapted to the situation of women with PTL. The six modules were built on each other and were processed in the intended order (weekly entering a new module). The IB-CBSM also included guidance which consisted of a regular written exchange between the participant and her therapist (trained psychologist or a psychologist-to-be under supervision). Apart from answering questions, this concept contained a weekly feedback. Additionally, the participants had the opportunity to pose pregnancy-specific questions to the study team's midwife. The internet-based control condition was similar in format (also 6 modules) and involved exercises such as sudoku, riddles and writing stories. In the control condition the support provided was limited to instructions in these distraction strategies.

Measures

Two parameters served as the primary outcome. First, stress/anxiety reduction was measured using the Perceived Stress Scale and the Spielberger State-Trait Anxiety Inventory. The Perceived Stress Scale (PSS) [26] is a commonly used self-assessment scale measuring the perception of stress. The scale reveals adequate values regarding validity and reliability (Cronbach's $\alpha > 0.84$). Spielberger's State-Trait Anxiety Inventory (STAI) [27] assesses both current state and general trait anxiety. The questionnaire has been validated in German [28] showing high internal consistency (Cronbach's $\alpha = 0.90$–0.94 (state) and 0.88 (trait)).

Second, the overall satisfaction with the program was assessed by the German version of the Client Satisfaction Questionnaire CSQ-8 [29, 30]. The original questionnaire shows an acceptable internal consistency (Cronbach's $\alpha = .93$) [30]. Each item is scored on a 4-point Likert-scale and higher scores indicate higher satisfaction. The 8-item version used in the current study was adapted to the online program for women with PTL, asking specifically about satisfaction with the provided online program (Appendix A).

The secondary outcome for our analysis was working alliance. Working alliance was assessed via the short and revised form of the working alliance inventory WAI-SR [31]. The WAI-SR is a 12-item self-reporting questionnaire, based on Bordin's model of alliance [32]. Each item is scored on a 5-point Likert-scale ranging from 1 (never) to 5 (always). The questionnaire has been validated in German [33] with a good reliability (Cronbach $\alpha = .80$) [34]. The questionnaire was adapted to the provided online help for women with PTL [35]. Each question of the goal and task scale of the WAI-SR was adjusted by asking for the agreement with goal and task components of the online program. The items of the bond scale have been adapted in order that