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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ABSTRACT

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.

KEYWORDS

Internet-based stress management, patient satisfaction, preterm labor, stress/anxiety reduction,

working alliance, psychological well-being

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), 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 allianceand 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,positiveandrobustassociationsbetweenthe therapeutic allianceandtreatmentoutcomeformanydifferenttypesoftherapeuticinterventionswere 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 outcomein this specific setting (22). Nevertheless,former resultsindicate that in IBtreatments therapeutic alliance is also evaluated comparatively high(23)and thatin some IB treatmentspositive associations between alliance and therapy outcome exist(24).Based on these findings, we set out toexaminestress/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 reductionand patient satisfaction, further the predictive value of working alliance, symptom reduction and group for patient satisfactionwill 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 praevia, 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 they relate to the perceived alliance between the participant and the therapist, providing the program contact (appendix B).

Analysis

93 women were eligible for participation and started intervention. 35 of these women dropped out before post assessment, and had to be excluded (c.f. Figure 1). To investigate whether there are differences between women who completed the post assessment and women who did not drop-out analyses were performed. Residual gain scores were calculated for PSS, STAI-S and STAI-T (difference of pre- vs. post-treatment PSS and STAI-S/T scores). Additionally, an overall variable that indicated stress and anxiety symptom reduction was constructed (sum of all residual gain scores) and a mean-score of overall satisfaction was calculated. A total WAI score and a total score for each subscale of the WAI was computed by determining an overall

variable of the mean WAI scores of all four assessments. Group differences in baseline characteristics were tested with independent samples T-tests, Mann Whitney U tests and Chi square tests. Difference in stress and anxiety was measured with a two-way repeated analysis of variance. Group differences in patient satisfaction and WAI were calculated using independent samples T-tests and Mann Whitney U tests. To examine the associations between working alliance and the outcome parameters stress/anxiety reduction and patient satisfaction bivariate correlations (Pearson and Spearman) were calculated. Hierarchical linear regression (method enter) was used to test whether the variables WAI, group and symptom reduction have an influence on patient satisfaction. Mediation analyses were examined using the bootstrapping method with bias-corrected confidence estimates (95% confidence interval, 5000 bootstraps resamples (36)). To investigate how patient satisfaction might be expressed as a function of working alliance over time and group, a two-way analysis of variance was applied. Therefore, WAI ratings after module 2-5 were further split over the median into two groups (low vs. high WAI). Statistical analyses were performed using SPSS, version 22. Level of significance was set on a 5% significance level for all analyses. Effect sizes were computed as Cohen's d (37), based on the pooled SD.

Figure 1: Recruitment and participants flow-chart

RESULTS

Drop-out analyses revealed no differences between completers and drop-outs in demographic characteristics, pre-treatment stress and anxiety scores or working alliance (Table I). Therefore statistical analyses were performed with the completer's dataset consisting of 58 women. Sample characteristics of the women in the completer's dataset are presented in Table

II. 31 participants were randomly assigned to the IB-CBSM, 27 to the control condition. Most women lived in Germany, were married and had no living child at the time of their pregnancy. About 90% of the participants reported a high educational level. Women in the IB-CBSM and the control condition did not differ in any of the assessed demographic variables.

Table I: Drop-out analyses

	Total	Completer	Drop-out	Sig. (p)
Sample size N	93	58	35	
Age in years	32.68 (3.70)	32.53 (3.49)	32.91 (4.08)	.634 (NS)
Gestational week at time of program start	28.43 (3.27)	28.69 (2.75)	28.00 (3.99)	.372 (NS)
Nationality				.790 (NS)
German	50 (53.8)	32 (55.2)	18 (51.4)	
Swiss	30 (32.2)	19 (32.8)	11 (31.4)	
Other	13 (14.0)	7 (12.0)	6 (17.2)	
Marital status				.099 (NS)
Married	71 (76.3)	41 (70.7)	30 (85.7)	
Unmarried	22 (23.7)	17 (29.3)	5 (14.3)	
Education				.372 (NS)
University	60 (64.5)	38 (65.5)	22 (62.9)	
Secondary school, college and higher vocational training	20 (21.5)	14 (24.2)	6 (17.1)	
Vocational training	13 (14.0)	6 (10.3)	7 (20.0)	
Number of children				.419 (NS)
None	58 (64.4)	38 (65.5)	20 (57.1)	
One or more children	35 (37.6)	20 (34.5)	15 (42.9)	
PSS pre-treatment	70.07 (16.40)	69.28 (15.97)	71.37 (17.25)	.553 (NS)
STAI-S pre-treatment	50.34 (12.55)	48.45 (10.95)	53.49 (14.45)	.079 (NS)
STAI-T pre-treatment	43.32 (10.89)	42.50 (10.81)	44.69 (11.04)	.351 (NS)
WAI after module 2	3.20 (0.76) N=53	3.21 (0.74) N=42	3.18 (0.87) N=11	.925 (NS)
WAI after module 3	3.29 (0.74) N=49	3.24 (0.77) N=41	3.53 (0.55) N=8	.315 (NS)
WAI after module 4	3.59 (0.64) N=43	3.59 (0.67) N=39	3.50 (0.25) N=4	.579 (NS)
WAI after module 5	3.56 (0.79) N=40	3.55 (0.81) N=37	3.81 (0.46) N=3	.587 (NS)

Note: NS, Not significant

Table II: Demographic characteristics,completer's dataset

	IB-CBSM	Control	Total	Sig. (p)
Sample size N	31	27	58	
Age in years	32.90 (3.49)	32.11 (3.50)	32.53 (3.49)	.393 (NS)
Gestational week at time of program start	28.32 (2.96)	29.11 (2.47)	28.69 (2.75)	.280 (NS)
Nationality				.592 (NS)
German	19 (32.8)	13 (22.4)	32 (55.2)	
Swiss	9 (15.6)	10 (17.2)	19 (32.8)	
Other	3 (5.1)	4 (6.9)	7 (12.0)	
Marital status				.268 (NS)
Married	20 (34.5)	21 (36.2)	41 (70.7)	
Unmarried	11 (19.0)	6 (10.3)	17 (29.3)	
Education				.511 (NS)
University	22 (37.9)	16 (27.6)	38 (65.5)	
Secondary school, college and higher vocational training	7 (12.1)	7 (12.1)	14 (24.2)	
Vocational training	2 (3.4)	4 (6.9)	6 (10.3)	
Number of children				.864 (NS)
None	20 (34.5)	18 (31.0)	38 (65.5)	
One or more children	11 (19.0)	9 (15.5)	20 (34.5)	

Note: NS, Not significant

Stress/anxiety reduction, patient satisfaction and working alliance

Levels of stress and anxiety decreased significantly in both conditions from pre- to post-treatment measures(PSS: $F(1,50)=37.287$, $p<.001$; STAI-S: $F(1,50)=40.140$, $p<.001$; STAI-T: $F(1,50)=15.586$, $p<.001$). All analysis showed no group differences or group x time effects(PSS: $F(1,50)=.182$, $p=.672$; STAI-S: $F(1,50)=.109$, $p=.743$; STAI-T: $F(1,50)=.539$, $p=.466$).Participating women showed high (IB-CBSM: $M=3.41$, $SD=.44$) to moderate (control condition: $M=2.82$, $SD=.58$) patient satisfaction according toTempier et al. and Greenwood et al.(38, 39). The referred WAI ratings indicated high (IB-CBSM: $M=3.51$, $SD=.69$) and medium (control condition: $M=3.05$, $SD=.72$) working alliance values as defined by Jasper et al.(40). Women in the IB-CBSM reported statistically significant higher patient satisfaction ($U(27,31)=165$, $p<.001$; Cohen's $d=1.15$) and overall WAI scores ($t(56)=2.476$, $p=.016$;

Cohen's $d=.65$) than participants in the control condition. Results of the WAI subscales analyses showed that participants in the IB-CBSM group rated working alliance in the subscale task ($t(56)=3.820$, $p<.001$; Cohen's $d=1.00$) and goal ($t(56)=2.377$, $p=.021$; Cohen's $d=.63$) significantly higher than the participants in the control condition, whereas the bond scale showed no differences between the groups ($U(27,31)=370$, $p=.449$; Cohen's $d=.12$)(Table III).

Table III: Stress, anxiety, satisfaction and working alliance (between group differences)

	N	IB-CBSM (M, SD)	Control (M, SD)	Total (M, SD)	Sig. (p)
Sample size		31	27	58	
PSS pre-treatment	58	69.23 (17.46)	69.33 (14.39)	69.28 (15.97)	.980 (NS)
STAI-S pre-treatment	58	48.32 (10.22)	48.59 (11.93)	48.45 (10.95)	.926 (NS)
STAI-T pre-treatment	58	43.48 (10.34)	41.37 (11.41)	42.50 (10.81)	.462 (NS)
PSS post-treatment	52	53.00 (15.40)	55.91 (13.90)	54.29 (14.69)	.483 (NS)
STAI-S post-treatment	52	38.62 (9.44)	39.52 (8.61)	39.02 (9.01)	.724 (NS)
STAI-T post-treatment	52	37.10 (8.81)	37.91 (7.95)	37.46 (8.37)	.733 (NS)
Patient satisfaction	58	3.41 (.44)	2.82 (.58)	3.14 (0.58)	.000 ***
WAI	58	3.51 (.69)	3.05 (.72)	3.30 (0.74)	.016 *
WAI task	58	3.06 (.80)	2.23 (.86)	2.68 (.92)	.000 ***
WAI goal	58	3.53 (.70)	3.06 (.80)	3.31 (.78)	.021 *
WAI bond	58	3.95 (1.06)	3.86 (.85)	3.91 (.96)	.449 (NS)
WAI after module 2	42	3.42 (.71)	2.95 (.70)	3.21 (0.74)	.041 *
WAI after module 3	41	3.48 (.71)	2.96 (.77)	3.24 (0.77)	.032 *
WAI after module 4	39	3.75 (.59)	3.34 (.73)	3.59 (0.67)	.060 (NS)
WAI after module 5	37	3.67 (.87)	3.37 (.69)	3.55 (0.81)	.273 (NS)

Note: NS, Not significant; * $p<.05$; *** $p<.001$

Associations between working alliance and the outcome parameters stress/anxiety reduction and patient satisfaction.

Table IV reveals the correlations of the WAI scores and the PSS, STAI-S and STAI-T residual gain scores. Significant correlations could be found between PSS and STAI-T residual gain scores and the overall WAI as well as between all three stress/anxiety reduction outcomes and the WAI subscale task and goal in the IB-CBSM condition (c.f. Table III). Furthermore, the STAI-T residual gain score showed a significant correlation with the WAI subscale bond. In the control condition no significant correlations could be measured between WAI scores and

the stress/anxiety reduction parameters. Patient satisfaction shows significant associations with the overall WAI and the WAI subscale task and goal in both conditions. Again no significant correlation could be recorded between satisfaction and the bond subscale (c.f. Table III).

Table IV: Correlations of the WAI scores with the PSS, STAI-S and STAI-T residual gain score as well as patient satisfaction in the IB-CBSM and control condition

Variable	PSS residual gain score		STAI-S residual gain score		STAI-T residual gain score		Patient satisfaction	
	IB-CBSM	Control	IB-CBSM	Control	IB-CBSM	Control	IB-CBSM	Control
WAI	.451*	.331	.352	.003	.501**	.019	.684**	.428*
WAI task	.528**	.296	.480**	-.146	.457*	.052	.776**	.447*
WAI goal	.575**	.243	.418*	.046	.484**	-.054	.647**	.612**
WAI bond	.007	.275	.029	.134	.391*	.051	.300	.066

Note: * $p < .05$; ** $p < .01$

Predictive value of working alliance, symptom reduction and group for satisfaction

WAI was a significant predictor of patient satisfaction ($R^2 = .398$, $F(1,50) = 33.060$, $p < .001$). In the overall regression model of WAI, group and symptom reduction, WAI was predictive for the criterion patient satisfaction ($\beta = .455$, $t(50) = 4.191$, $p < .001$). Also, the IB-CBSM condition was significantly predictive for patient satisfaction ($\beta = .399$, $t(50) = 3.930$, $p < .001$). Symptom reduction was not a significant predictor in the overall model ($\beta = .149$, $t(50) = 1.442$, $p = .156$; Table V).

Table V: Summary of Hierarchical Linear Regression for patient satisfaction (N=52)

Variable	B	SE (B)	β	t	Sig. (p)
WAI	.338	.081	.455	4.191	.000
IB-CBSM	.413	.105	.399	3.930	.000
Symptom reduction	.003	.002	.149	1.442	.156

Note: $R^2 = .554$

To test the mediating role of working alliance for patient satisfaction, a mediator analysis was performed. Group condition was positively related to patient satisfaction ($\beta = .213$,

$t(56)=4.383$, $p<.001$) and WAI ($\beta=.462$, $t(56)=2.477$, $p=.016$). Additionally, the proposed mediator WAI was positively related with patient satisfaction ($\beta=.169$, $t(56)=6.347$, $p<.001$). Results confirmed the partial mediating role of WAI regarding the relation between group condition and patient satisfaction ($\beta=.079$, $CI=.022$ to $.174$). A partial mediation of WAI was confirmed since the direct effect of group condition on patient satisfaction controlling for WAI remains significant ($\beta=.135$, $t(56)=3.434$, $p=.001$; Figure 2).

Figure 2: Indirect effect of group on patient satisfaction through working alliance

Note: * $p<.05$; ** $p<.01$; *** $p<.001$

A two-way analysis of variance showed a main effect of low vs. high WAI and group condition (except module 5) on patient satisfaction over the program process (module 2: $WAI_split F(1,38)=7.593$, $p=.009$, $group F(1,38)=5.255$, $p=.028$; module 3: $WAI_split F(1,37)=8.960$, $p=.005$, $group F(1,37)=7.273$, $p=.010$; module 4: $WAI_split F(1,35)=11.345$, $p=.002$, $group F(1,35)=17.005$, $p<.001$; module 5: $WAI_split F(1,33)=10.812$, $p=.002$, $group F(1,33)=3.835$, $p=.059$); i.e., women with high WAI ratings and women in the IB-CBSM condition had higher patient satisfaction ratings (module 2: high WAI $M=3.41$, $SD=.48$, IB-CBSM $M=3.39$, $SD=.44$; module 3: high WAI $M=3.43$, $SD=.53$, IB-CBSM $M=3.39$, $SD=.46$; module 4: high WAI $M=3.53$, $SD=.46$, IB-CBSM $M=3.50$, $SD=.43$; module 5: high WAI $M=3.49$, $SD=.48$, IB-CBSM $M=3.41$, $SD=.44$), whereas women with low WAI

ratings and women in the control condition had lower patient satisfaction ratings throughout the program (module 2: low WAI $M=2.97$, $SD=.37$, control $M=3.00$, $SD=.45$; module 3: low WAI $M=2.84$, $SD=.56$, control $M=2.79$, $SD=.63$; module 4: low WAI $M=2.99$, $SD=.43$, control $M=2.90$, $SD=.43$; module 5: low WAI $M=2.95$, $SD=.39$, control $M=2.97$, $SD=.51$). The interaction effect was non-significant over all modules.

DISCUSSION

The aim of this study was to analyze stress/anxiety reduction, patient satisfaction and patient's working alliance of women in IB-CBSM. It was expected that the use of the non-specific distraction exercises of the control condition actually do not meet the needs of the client to the same extent like in the IB-CBSM condition. This is also underlined by the results of patient satisfaction which is significantly lower in the control condition. However, it is surprising that the control group, despite non-agreement with individual needs and low WAI and satisfaction rating, benefits in a similar manner as the IB-CBSM regarding stress/anxiety reduction. The most obvious explanation for this effect is that in the control condition, the reduction of stress and anxiety seems to work in a different way than in the IB-CBSM condition. The control condition, by definition, was not designed to meet the needs of anxious women with PTL, but based solely on the concept of distraction. Some studies, however, showed that specifically used distraction exercises can also show positive effects regarding psychological distress (41, 42) even in a group of women with PTL (43). However, it must be noted that in both conditions spontaneous remission could have led to a reduction in symptoms. Despite the equivalence of IB-CBSM or the control condition in terms of efficacy, it is important to consider patient satisfaction when choosing interventions for a target group. In our study, IB-CBSM clearly outperforms the control condition in this regard.

As explained, an adapted version of the WAI-SR was used, which specifically distinguished between the agreement with goal and task components of the online program and the working

alliance with the therapist. Regarding WAI subscales, results pointed out that the participants in the IB-CBSM group rated working alliance significantly higher in both the task and the goal subscale, whereas the bond scale showed no differences between the groups. This last result indicates that participants in both conditions felt equally well with the therapeutic support that they have received. The associations of working alliance and stress/anxiety reduction in the IB-CBSM showed significant correlations predominantly with the task and goal subscale. However, this does not mean that the alliance with the therapist is not important, because for women who participate in the study it could have been obvious that the distraction exercise in the control condition has nothing to do with the actual stress/anxiety reduction. Nevertheless, the observed finding, that the accordance of the program with task and goal components is crucial for therapy outcome, underlines that in the development of guided self-help approaches, the fit between the intervention program and the needs of the participants seems especially important. Recent advancements in the field of internet-based interventions follow this attempt in form of tailoring program elements in relation to the problems and needs of the participants (35). Also in regard to the recent study, some more tailored program elements would have been helpful. A first step in this direction could be the provision of additional modules with detailed information about comorbid symptoms (e.g. sleep problems) for processing depending on the individual needs.

Regarding patient satisfaction, it was shown that WAI explained nearly 40% of the variance in patient satisfaction. The strong predictive effect of working alliance on satisfaction with the program is in line with the results of Leibert et al. (44), who showed that working alliance significantly predicted respondent satisfaction with internet-based treatments. This result substantiates the importance of working alliance for satisfaction with psychotherapeutic treatments and was further supported by the partial mediation of working alliance on the relationship between group condition and patient satisfaction. Therefore, it can be assumed in line with Hirsh et al. (17) that more satisfying therapeutic interventions require working

alliance parameters, e.g. a high level of agreement with the treatment. The analysis of associations with the WAI subscales indicated also with regard to patient satisfaction significant correlations with task and goal components. To learn more about the role of the WAI subscales, it could be interesting in further analysis to look at the specific predictive and mediating value of the WAI subscales separately.

In accordance with the results of McLeod (19) and Hirsh et al. (17), the present study has shown that the relation between these factors of working alliance and patient satisfaction is stronger than the effect of the actual symptom reduction on patient satisfaction. This underlines the assumption that the measures of agreement with working alliance parameters actually could have a stronger influence on satisfaction than the objectively quantifiable effectiveness in terms of symptom reduction. Women with high WAI ratings over the program as well as women in the IB-CBSM reported significantly better patient satisfaction scores than women who had low WAI ratings or women who were assigned to the control condition. Interestingly, this effect was observable as early as the second treatment module.

Limitations

With regard to our sample size, our results are to be considered as preliminary and although no differences between completers and drop-outs could be found the high drop-out rate (nearly 38%) of our study should be mentioned as a further limitation. Drop-out reasons were birth before pre-treatment measure, pregnancy complications, lack of time and elusiveness of the participants throughout the program. Another limitation is that the wide gestation age included in the study and the stressors which vary depending on gestational age may result in different stress levels. At the stage of early pregnancy uncertainty and fear of an abortion are predominant. During pregnancy these stress factors often change and concerns about the child's health, fear of childbirth or the postpartum period become increasingly important and can enhance the perceived stress level. Furthermore the inclusion of a waiting list control group into the study design would have been promising to provide more

detailed information about the progress of psychological distress parameters.

Conclusion

To our knowledge the recent study is the first to evaluate an intervention with an IB-CBSM for pregnant women with PTL. Our results, although preliminary due to the small sample size, indicate that with an IB-CBSM adequate psychological support can be provided to these women. The results highlight the importance of the working alliance and especially the agreement with goal and task components for internet-based stress management both with respect to stress/anxiety reduction as well as patient satisfaction. Besides the circumstance that the fit with the program seems to be essential, it is worthy to point out that building up a good working alliance is generally crucial but especially if the intervention is actually geared to the specific needs of the target population.

ACKNOWLEDGMENTS

We would particularly like to thank all the women who participated in the study, as well as the medical staff, the study midwives and the research assistants contributing to this study. The research project is supported by the Swiss National Science Foundation. Grant number: CR13I1_135060. Trial numbers of the research project: Swiss National Science Foundation (SNSF): Registration number: 135060 and Forsbase online Research inventory: Registration number: 11134

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APPENDICES

A Adapted Client Satisfaction Questionnaire

- [1]="Wie beurteilen Sie die Qualität des TOPAS Trainingsprogramms?";
- [2]="Haben Sie mit dem TOPAS Trainingsprogramm eine Behandlung erhalten, die Sie wollten?";
- [3]="In welchem Masse hat das TOPAS Trainingsprogramm Ihren Bedürfnissen entsprochen?";
- [4]="Würden Sie einer Freundin das TOPAS Trainingsprogramm empfehlen, wenn sie ähnliche Hilfe benötigen würde?";
- [5]="Wie zufrieden sind Sie mit dem Ausmass der Hilfe, welche Sie erhalten haben?";
- [6]="Hat das TOPAS Trainingsprogramm Ihnen dabei geholfen, angemessener mit Ihren Problemen umzugehen?";
- [7]="Wie zufrieden sind Sie mit dem Programm insgesamt?";
- [8]="Würden Sie das TOPAS Programm wieder nutzen?";

B Adapted Working Alliance Inventory

- [1]="Durch das TOPAS Online Trainingsprogramm ist mir klarer geworden, wie ich mich verändern kann."
- [2]="Was ich im TOPAS Trainingsprogramm mache, eröffnet mir neue Sichtweisen auf mein Problem."
- [3]="Ich glaube meine Psychologin mag mich."
- [4]="Ich weiß, was ich als Ergebnis des TOPAS Trainingsprogramms erwarten kann."
- [5]="Meine Psychologin und ich achten einander."
- [6]="Die Ziele des TOPAS Trainingsprogramms stimmen mit meinen Zielen überein."
- [7]="Ich spüre, dass mich meine Psychologin schätzt."
- [8]="Die Ziele des TOPAS Trainingsprogramms sind wichtige Ziele für mich."
- [9]="Meine Psychologin interessiert sich wirklich für mein Wohlergehen."
- [10]="Ich spüre, dass das, was ich im TOPAS Trainingsprogramm tue, mir helfen wird, die von mir gewünschten Veränderungen zu erreichen."
- [11]="Das TOPAS Trainingsprogramm hilft mir zu verstehen, welche Veränderungen gut für mich wären."
- [12]="Ich glaube, dass es richtig ist, wie ich im Rahmen des TOPAS Trainingsprogramms an meinem Problem arbeite."