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March 2020 | Volume 2 | Issue 1

Contents

Editorial

Research Articles

Politics and Education

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Clinical Psychology in Europe

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Editorial

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The Field of Psychotherapy: Over 100 Years Old and Still an Infant Science

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Keywords

clinical trials, therapy alliance, clinical training, practice-research gap, psychotherapy integration, RDoC

Although the field of psychotherapy has been in existence for well over 100 years, we have not yet reached the point of becoming what sociologists of science have called a "mature" science. Sociologists who study the evolution of different scientific enterprises have defined a mature field as one where there is not only the *cutting edge*–where new contributions are being made–but also an agreed-upon *core or consensus*. Although there is often disagreement among those contributing to the cutting edge of a mature science, there nonetheless remains the agreed-upon core. In the field of psychotherapy, although there are clinicians and researchers who have been working at the cutting edge, what we lack is an agreed-upon core or consensus. In essence, even after more than 100 years, psychotherapy is still considered an infant science.

One of my first experiences in recognizing the disjointed nature of psychotherapy occurred when I was in graduate school way back in the 1950s when I was traumatized by Paul Meehl over diner. As I have described elsewhere:

> Meehl paid a visit to our program, delivered a colloquium, and spent some time with us graduate students. I was fortunate enough to be among a small group of students that went out to dinner with him. This was a rare treat, especially since I had read virtually everything Meehl had written, and had enormous respect for his insights on research, practice, and the philosophy of science. Indeed, he was my role model. At one point during the evening, someone asked him the question about the extent to which his clinical work was informed by research. Without any hesitation, he replied, "Not at all." As someone who was

> struggling to adopt the identity of scientist–practitioner, I left this memorable dinner disheartened. I don't think I ever fully recovered. The challenge of how we could close the gap between research and practice has stayed with me all these years, and because I am attracted to challenges–my experiential colleagues would probably call it "unfinished business"–I have continued to be intrigued with the integration of research and practice. (Goldfried, 2015, pp. 1086-1087).

One can most assuredly forgive Meehl for not making use of research in his clinical work; there was relatively little research on psychotherapy in the 1950s. However, the gap between research and practice continues to exist, even though there is now an extraordinary amount of research on psychotherapy. However, the researchers complain that the clinicians are not making use of their findings, and the clinicians are complaining that the researchers are not studying issues that are relevant to their therapeutic practices. And although there are many professionals in the field who are trying to close this gap, it nonetheless continues to exist.

Another most significant factor that prevents the field of psychotherapy from forming a core is that we think in terms of schools of therapy rather than basic processes or principles. That the field of psychotherapy is made up of so many different schools of therapy also means that these views compete with each other. Although some therapists maintain that diversity is good, sociologists of science have characterized a field with competing schools of thought as being "immature."

There are several factors that motivate the development of competing schools. Relatively little professional credit goes to those who simply repeat what has already been said in the past. After all, careers are made by *making* history, not *knowing* it. In the field of psychotherapy, there are also social, personal, and economic factors that operate as well. However, developing still another new school of therapy is working at the cutting edge, and does nothing to contribute to an agreed-upon core. In essence, the field of psychotherapy has been spinning its wheels by proliferating different approaches to therapy.

We seem to be more interested in what is "new" than what is "old." Here again, what is new is at the cutting edge and therefore is more likely to be rewarded. When a new school of therapy is proposed, it often comes with its own set of theoretical jargon (e.g., "observing ego," "metacognition," "decentering," "reflective functioning"). One of the unintended consequences of developing new terms for old phenomenon is that clinical and research contributions on a given topic may disappear by virtue of the fact that the keywords used to search the literature change. Thus, to talk about "values" as an important phenomenon in therapeutic intervention can mask earlier work on encouraging patients to identify and express their needs. Thus, a "new wave" of therapy that comes up with new terms for old phenomena may wash away relevant keywords, such as "assertiveness."

Although I most certainly do not propose that I have *the* answer to how the field of psychotherapy might move forward, there nonetheless are directions I believe might be pursued (for further details please refer to Goldfried, 2019). I have no doubt that one day the field of psychotherapy will develop an agreed-upon core or consensus, using a common language that facilitates communication to all.

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Research Articles

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Only the Lonely: A Study of Loneliness Among University Students in Norway

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Abstract

Background: Loneliness is a major public health concern among college and university students, the evidence is inconsistent regarding whether there is an increasing trend or not. Furthermore, knowledge of the demographic determinants for loneliness are limited. The present study assesses recent trends of loneliness from 2014 to 2018, and explores demographic risk indicators of loneliness among students.

Method: Data was drawn from two waves of a national student health survey from 2014 and 2018 for higher education in Norway (the SHoT-study). In 2018, all 162,512 fulltime students in Norway were invited to participate and 50,054 students (69.1% women) aged 18-35 years were included (response rate = 30.8%). Loneliness was measured by "The Three-Item Loneliness Scale" (T-ILS) and one item from the Hopkins Symptom Checklist-25 (HSCL-25).

Results: Age showed a curvilinear association with loneliness, with the youngest and oldest students reporting the highest level of loneliness across all measures. Other significant demographic determinants of loneliness were being female, single and living alone. There was a considerable increase in loneliness from 2014 (16.5%) to 2018 (23.6%, $p < .001$), and the increase was particularly strong for males, for whom the proportion of feeling "extremely" lonely had more than doubled.

Conclusion: The high rate of loneliness and the increasing trends indicate the need for preventive interventions in the student population.

Keywords

loneliness, students, young adults, partnership status, student accomodation

Highlights

- Loneliness among Norwegian university students increased from 2014 to 2018, particularly for males.
- Students in transitional periods, both the youngest and oldest reported the most loneliness.
- Being single and living alone were risk factors for loneliness.

Loneliness reflects the subjective feeling of disconnectedness and not belonging, and is often characterized as "a perceived discrepancy between desired and actual social relationships" (Portnoy, 1983). Loneliness is associated with more health problems (Hayley et al., 2017), and has been linked to an increased mortality risk (Holt-Lunstad, Smith, Baker, Harris, & Stephenson, 2015). Loneliness has often been thought of as a concern that peaks in older age. However, recent evidence has shown that the developmental trajectory is more U-shaped, with young adults having the highest levels of loneliness (Luhmann & Hawkley, 2016), followed by a second peak in older age groups.

The transition from adolescence to young adulthood makes college and university students a particularly vulnerable group for feelings of loneliness (Diehl, Jansen, Ishchanova, & Hilger-Kolb, 2018). This may be related to developmental-specific risk factors, such as moving away from home and their local community, and re-establishing new social networks. Surprisingly, the epidemiology of loneliness in young people has received scant attention. Knowledge of risk indicators and vulnerable subgroups are important in order to promote preventive actions. If loneliness is limited to, or peaks at the actual transition from moving away from home, a decline in loneliness over time should be expected among more senior students, which has been demonstrated in a German University sample (Diehl et al., 2018).

A recent UK study of 18-year-old twins found that loneliness was equally common across sexes and socioeconomic status (SES) (Matthews et al., 2019), whereas others have found both higher (Mounts, 2004) and lower (McWhirter, 1997) levels of loneliness among men. This inconsistency was also confirmed in a recent meta-analysis (Mahon, Yarcheski, Yarcheski, Cannella, & Hanks, 2006). In the general population, loneliness is more prevalent among adults without partners (Beutel et al., 2017), and also students living alone report more loneliness compared to those living in dorms or with a partner/friend (Diehl et al., 2018). Still, the literature remains sparse on the issue of identifying risk indicators of loneliness among young adults.

It has been suggested that the prevalence of loneliness is increasing, but very few studies have examined this over time (Cacioppo, Grippo, London, Goossens, & Cacioppo,

2015). A study of older Dutch people showed no change in loneliness from 2005 to 2010, with the exception of a subgroup of individuals with activity limitations, where the trend was increasing (Honigh-de Vlaming, Haveman-Nies, Groeniger, de Groot, & van 't Veer, 2014). A similar stable pattern was observed in a Swedish study of an elderly population (Dahlberg, Agahi, & Lennartsson, 2018). In contrast, there was a rising rate of loneliness among Danish adolescents from 1991 to 2014, with the largest increase being observed among adolescents from families with high SES (Madsen et al., 2019).

This study addressed three main questions in a large nationally representative sample of young people: (1) what demographic factors are associated with loneliness in young adult college and university students? (2) How does partnership status offer protection from feelings of loneliness? and (3) Has the rate of loneliness changed from 2014 to 2018 in this population?

Method

Procedure

The SHoT study (*Students' Health and Wellbeing Study)* is a national student survey for higher education in Norway. The main aim of the survey is to monitor students' health, wellbeing and psychosocial environment. The survey has been carried out three times (2010, 2014 and 2018), and the two most recent waves (2014 and 2018) were used in the present study.

The SHoT2014 study was conducted by the three largest student welfare organizations (*Sammen* [Bergen], *Sit* [Trondheim] and *SiO* [Oslo and Akershus]) in collaboration with, and with participation from, the 10 largest student welfare organizations in Norway, also targeting full-time Norwegian students < 35 years of age. Data for the *SHoT2014* study were collected electronically using a web-based platform in the period from 24 February 2014 to 27 March 2014. An invitation email containing a link to an anonymous online questionnaire was sent to 47,514 randomly selected students and stratified by study institutions, faculties, and departments. The overall response rate was 28.5% and included 13,525 students.

The SHoT2018 was initiated by the three largest student welfare organizations (*Sammen* [Bergen and surrounding area], *Sit* [Trondheim and surrounding area] and *SiO* [Oslo and Akershus]), representing all student welfare organizations in Norway and done as a joint effort between these student welfare organisations and the Norwegian Institute of Public Health (NIPH). Data were collected between February 6 and April 5, 2018 and all fulltime Norwegian students aged between 18 and 35 years taking higher education (both in Norway and abroad) were invited to take part. The survey data were collected electronically through a web-based platform and some institutions allocated time during classes for the students to complete the set of questionnaires. For the SHoT2018 study,

162,512 students fulfilled the inclusion criteria, of whom 50,054 (30.8%) students completed the online questionnaires (Sivertsen, Råkil, Munkvik, & Lønning, 2019).

Ethics

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. All procedures involving human subjects/patients were approved by the Regional Committee for Medical and Health Research Ethics in Western Norway (no. 2017/1176 [SHOT2018]). Informed consent was obtained electronically after the participants had received a detailed introduction to the study. Approvals for conducting the *SHoT2014* studies were granted by the Data Protection Officer for research at the Norwegian Centre for Research Data.

Instruments

Demographic Information

All participants indicated their sex and age. In the current study, age was used both as a continuous and categorical variable, the latter employing the following age categories (18-20 years, 21-22 years, 23-25 years and 26-35 years). Participants were also asked about their relationship status (response options: "single", "girl-/boyfriend", "cohabitant", and "married/ registered partner"), as well as their accommodation status (response options: "living alone", "living with partner", "living with friends/others in a collective", and "living with parents"). Participants were categorized as an immigrant if either the student or his/her parents were born outside Norway. Finally, all students indicated if they were living or studying abroad.

Loneliness

Loneliness was measured by one item of the depression subscale of the HSCL-25 (Derogatis, Lipman, Rickels, Uhlenhuth, & Covi, 1974) in 2014 and 2018. *In the past two weeks, including today, how much have you been bothered by feeling lonely?* The response alternatives were "not at all", "a little", "quite a bit", and "extremely".

In SHoT2018 loneliness was assess using an abbreviated version of the widely used UCLA Loneliness Scale, "The Three-Item Loneliness Scale (T-ILS)" (Hughes, Waite, Hawkley, & Cacioppo, 2004). The T-ILS include the following three items, each rate along a 5-point Likert scale ("never", "seldom", "sometimes", "often", and "very often"). *For each question below, please indicate how often you have felt that way during the last year: 1) How often do you feel that you lack companionship? 2) How often do you feel left out, and 3) How often do you feel isolated from others?* The T-ILS has displayed satisfactory reliability and both concurrent and discriminant validity. (Hughes et al., 2004) In addition

to analysing each of the three T-ILS items separately, we also calculated a total score, adding the three items together. The Cronbach's alpha of the T-ILS total score was .88.

Statistics

IBM SPSS version 25 (SPSS Inc., Chicago, IL, USA) for Mac was used for all analyses. Chi-square tests and logistic regression analysis were used to examine differences in the three loneliness items across demographical characteristics. Analysis of Variance (ANOVA) were conducted to examine potential polynomial/curvilinear associations between loneliness and age group by entering quadratic terms. We also used the Curve Estimation command in SPSS to test both the linear and curvilinear association between age as a continuous variable and overall loneliness. ANOVAs were also used to examine the T-ILS total score against the demographic variables. Effect sizes (pooled *SD*) were calculated using the Cohen's *d* formula (Cohen, 1988). Pearson's chi-squared tests were used to test for significant changes in loneliness over time. Missing values were handled using listwise deletion.

Results

Descriptive Characteristics

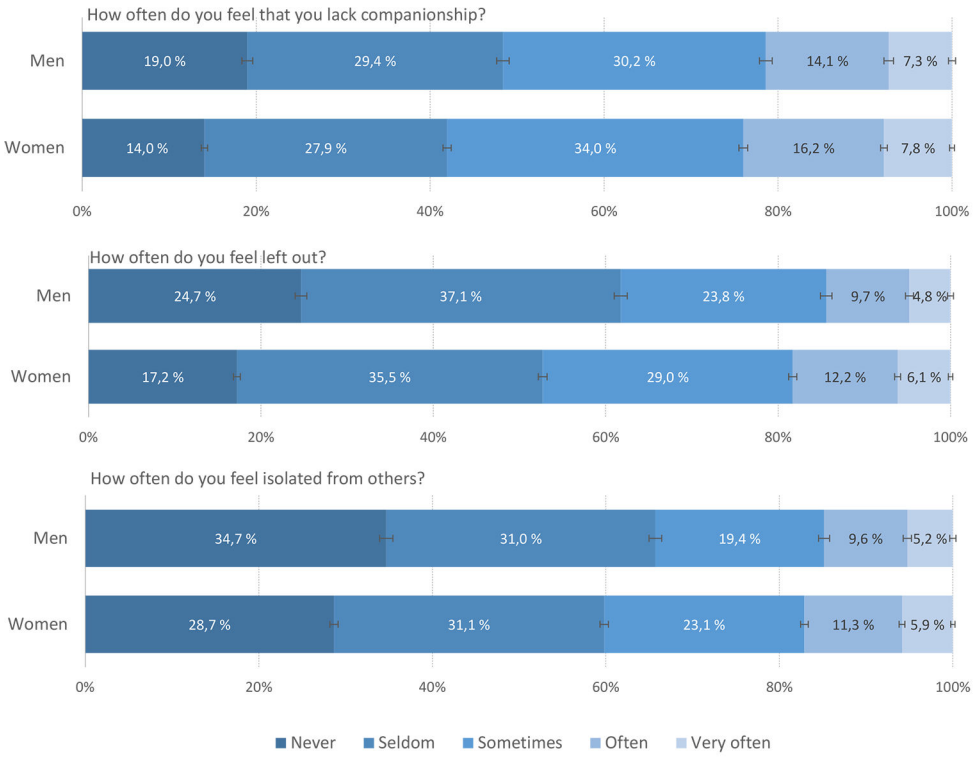
Compared to all invited students – 58.1% women (n = 93,267) and 41.9% men (n = 67,558) – the current sample included a larger proportion of women (69.1%) than men (30.9%). The mean age was 23.2 (SD = 3.3).

Loneliness in SHoT2018

The response patterns of the three loneliness items are detailed in Figure 1. Almost one in four students (21% in males and 24% in females) felt that they lacked companionship "often" or "very often". The corresponding estimates for the items "feeling left out" and "feeling isolated" were slightly lower, with 14%-15% in women and 17-18% in men (see Figure 2 for details). One in ten students (10.1%) reporting "often/very often" on all three items (females: 10.6% and males: 8.8%). All sex differences were statistically significant (p < .001).

Figure 1

Response Pattern of the Three Loneliness Items in the T-ILS Among College/University Students in the SHoT2018 Study



Note. Error bars represent 95% confidence intervals.

Loneliness and Age

Figure 2 shows the prevalence of the three loneliness items across the different age groups. As indicated by the dotted trend lines, there was a significant curvilinear relationship (all *p*s < .001) on all forms of loneliness for both men and women; both the youngest and oldest age-groups reported higher levels of both lacking companionships, feeling left out and feeling isolated (see Figure 2 for details). Table 1 shows the results from the logistic regression analyses. For example, compared to being 23-25 years old, female students aged between 18 and 20 years had 1.38 higher *OR*, 95% CI [1.29, 1.48], of reporting that they lacked companionship. There were significant sex × age interactions for all three loneliness items (see Table 1 for more details). As detailed in Table 2, analysing the T-ILS total score continuously showed a similar pattern U-shaped, with small Cohen's *d* effect-sizes.

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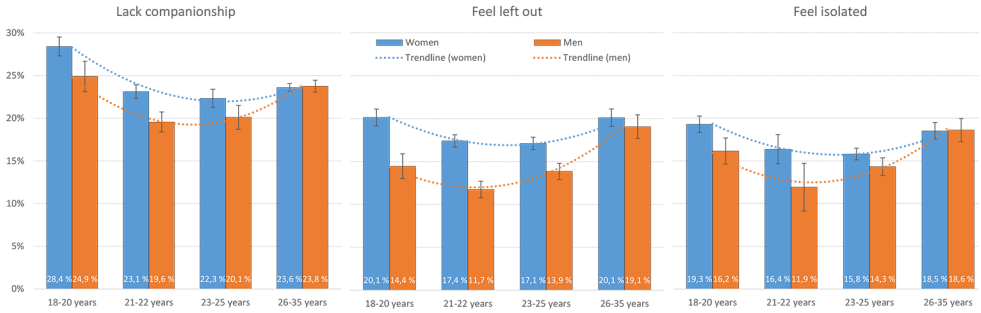
Table 1

Odds-Ratios (ORs) of Demographic Factors Associated With Loneliness ("Often" or "Very Often") Among Norwegian University Students

	Lack companionship				Left out				Isolated			
	Women		Men		Women		Men		Women		Men	
Demographic factor	***OR***	**95% CI**	***OR***	**95% CI**	***OR***	**95% CI**	***OR***	**95% CI**	***OR***	**95% CI**	***OR***	**95% CI**
Age group	Sex interaction: Wald (*df*) = 11.41(3), *p* = .010				Sex interaction: Wald (*df*) = 29.70(3), *p* < .001				Sex interaction: Wald (*df*) = 25.28(3), *p* < .001			
18-20 years	1.38***	1.29, 1.48	1.32***	1.17, 1.48	1.22***	1.13, 1.32	1.05	0.91, 1.21	1.27***	1.18, 1.38	1.15*	1.01, 1.32
21-22 years	1.05	0.98, 1.12	0.97	0.87, 1.07	1.02	0.95, 1.10	0.82**	0.73, 0.93	1.04	0.97, 1.12	0.81***	0.72, 0.91
23-25 years	1.00		1.00		1.00		1.00		1.00		1.00	
26-35 years	1.07*	1.00, 1.16	1.24***	1.11, 1.38	1.22***	1.12, 1.32	1.47***	1.30, 1.65	1.21***	1.11, 1.32	1.37***	1.22, 1.54
Relationship status	Sex interaction: Wald (*df*) =159.58(3), *p* < .001				Sex interaction: Wald (*df*) = 88.48(3), *p* < .001				Sex interaction: Wald (*df*) = 82.32(3), *p* < .001			
Single	1.61***	1.39, 1.86	2.85***	2.14, 3.81	1.01	0.74, 1.18	1.59**	1.18, 2.14	1.18*	1.01, 1.39	1.65***	1.23, 2.21
Boy-/girlfriend	1.27**	1.09, 1.48	1.24	0.92, 1.68	1.02	0.74, 1.19	0.90	0.66, 1.22	1.05	0.90, 1.24	0.85	0.62, 1.16
Cohabitant	1.05	0.90, 1.22	0.91	0.67, 1.25	1.10	0.94, 1.29	1.08	0.79, 1.48	1.10	0.93, 1.29	0.94	0.69, 1.28
Married / registered partner	1.00		1.00		1.00		1.00		1.00		1.00	
Accommodation status	Sex interaction: Wald (*df*) = 86.75(3), *p* < .001				Sex interaction: Wald (*df*) = 32.32(3), *p* < .001				Sex interaction: Wald (*df*) = 36.86(3), *p* < .001			
Alone	1.96***	1.82, 2.11	3.85***	3.37, 4.39	1.26***	1.17, 1.37	1.99***	1.74, 2.28	1.50***	1.39, 1.62	2.44***	2.13, 2.80
With partner	1.00		1.00		1.00		1.00		1.00		1.00	
With friends / others in a collective	1.24***	1.16, 1.32	2.08***	1.85, 2.35	0.79***	0.74, 0.84	1.02	0.90, 1.15	0.85	0.80, 0.92	1.15*	1.02, 1.31
With parents	1.45***	1.31, 1.59	2.74***	2.33, 3.34	1.18**	1.07, 1.31	1.57***	1.32, 1.88	1.35***	1.21, 1.49	1.75***	1.46, 2.09
Immigration status	Sex interaction: Wald (*df*) = 3.77(1), *p* = .052				Sex interaction: Wald (*df*) = 0.16(1), *p* = .688				Sex interaction: Wald (*df*) = 1.65(1), *p* = .422			
Norwegian	1.00		1.00		1.00		1.00		1.00		1.00	
Immigrant	1.48***	1.35, 1.61	1.72***	1.51, 1.95	1.45***	1.32, 1.59	1.40***	1.20, 1.62	1.44***	1.31, 1.59	1.55***	1.34, 1.79
Studying abroad	Sex interaction: Wald (*df*) = 1.26(1), *p* = .262				Sex interaction: Wald (*df*) = 6.14(1), *p* = .013				Sex interaction: Wald (*df*) = 2.52(1), *p* = .112			
No	1.00		1.00		1.00		1.00		1.00		1.00	
Yes	1.19**	1.06, 1.35	1.04	0.84, 1.28	1.16*	1.02, 1.33	0.80	0.61, 1.04	1.16*	1.01, 1.33	0.92	0.71, 1.18

Figure 2

Loneliness Prevalence ("Often"/"Very Often") Stratified by Age-Group in Male and Female Students



Note. The curves show the polynomial/curvilinear trendline (order 2).

Table 2

Demographic Factors Associated With Loneliness (T-ILS Sum Score) Among Norwegian University Students

	Women			Men		
Demographic factor	***M***	***SD***	**Cohen's *d*[a]**	***M***	***SD***	**Cohen's *d***
Age group						
18-20 years	7.90	3.11	0.12	7.32	3.10	0.15
21-22 years	7.60	3.00	0.02	6.87	2.93	Reference
23-25 years	7.55	2.98	Reference	7.07	3.02	0.07
26-35 years	7.66	3.19	0.04	7.50	3.26	0.20
Relationship status						
Single	7.78	3.05	0.17	7.62	3.15	0.36
Boy-/girlfriend	7.58	3.00	0.10	6.53	2.78	0.01
Cohabitant	7.52	3.08	0.08	6.52	2.88	0.01
Married / registered partner	7.27	3.07	Reference	6.49	3.04	Reference
Accommodation status						
Alone	8.25	3.16	0.25	8.09	3.26	0.52
With partner	7.49	3.07	0.01	6.48	(2.91)	Reference
With friends / others in a collective	7.47	2.92	Reference	7.02	2.92	0.18
With parents	7.86	3.22	0.13	7.36	3.30	0.28
Immigration status						
Norwegian	7.61	3.03	Reference	7.08	3.05	Reference
Immigrant	8.17	3.19	0.14	7.73	3.24	0.05
Studying abroad						
No	7.63	3.05	Reference	7.13	3.07	Reference
Yes	8.03	2.99	0.13	7.24	2.84	0.04

[a]Cohen's *d* effect sizes (pooled *SD*) were calculated for each demographic variable using the category with the lowest T-ILS score (sex specific) as the reference group.

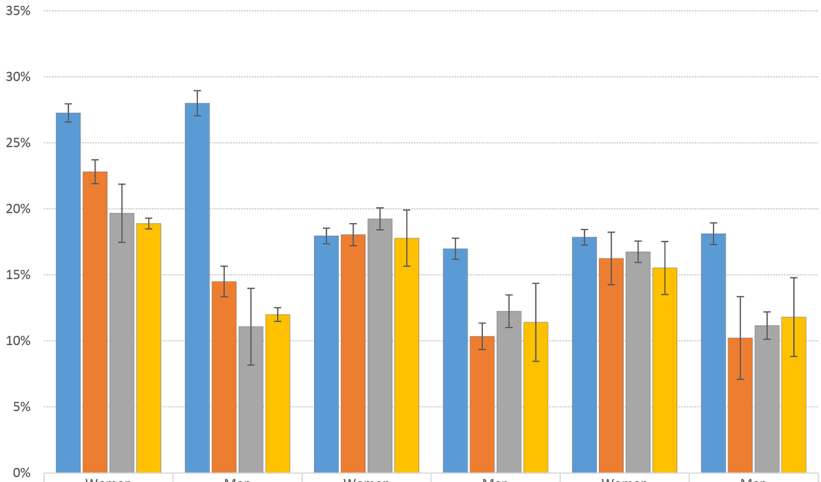
When analyzing the association between age as a continuous variable and overall loneliness, similar findings were observed. There was a statistically significant quadratic (curvilinear) association between continuous age and overall loneliness, $F(2, 48685) = 12.91$, $p < .001$, but there was no evidence of a significant linear association, $F(1, 48686) = 1.48$, $p = .224$).

Loneliness and Relationship Status

Single students reported more often that they *lacked companionship* compared to students with another relationship status, a tendency that was especially pronounced for single male students, *OR* = 2.85; 95% CI [2.14, 3.81], see Table 1 for details. And whereas *feeling left out* was also more prevalent in single male students, relationship status was not significantly associated with *feeling left out* in female students. In terms of feeling isolated, single male students reported higher levels of isolation, whereas relationship status was less clearly associated with feeling isolated in female students (see Figure 3 for details). There were significant sex × relationship interactions for all three loneliness items (all *p*s < .001). Analyses of the T-ILS total score showed a similar pattern (see Table 1 for details).

Figure 3

Loneliness Prevalence ("Often"/"Very Often") by Relationship Status in Male and Female Students



	Women	Men	Women	Men	Women	Men
	Lack companionship		Left out		Isolated	
Single	27,3 %	28,0 %	18,0 %	17,0 %	17,9 %	18,1 %
Boy-/girlfriend	22,8 %	14,5 %	18,0 %	10,3 %	16,2 %	10,2 %
Cohabitant	19,7 %	11,1 %	19,2 %	12,2 %	16,7 %	11,2 %
Married / registered partner	18,9 %	12,0 %	17,8 %	11,4 %	15,5 %	11,8 %

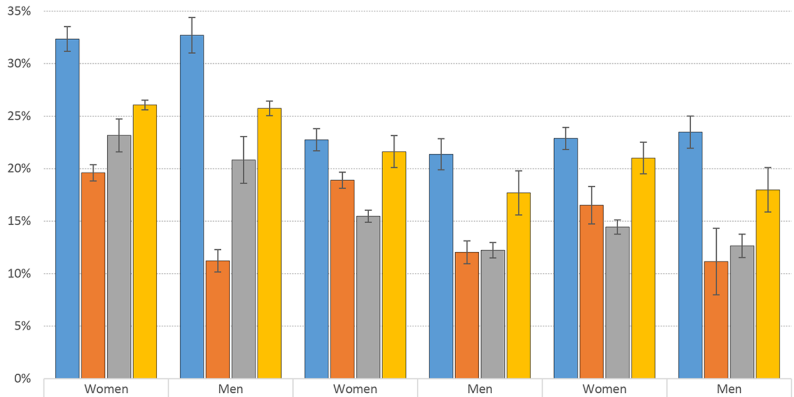
Note. Error bars represent 95% confidence intervals.

Loneliness and Accommodation Status

Similar to the findings for relationship status, also accommodation status was significantly associated with loneliness. Both female and male, but especially male students living alone had the highest loneliness scores across all three items. Students living with their parents more often reported lacking companionship, feeling left out and isolated compared with students living with a partner/friends (see Figure 4 for details). There were significant sex × accommodation interactions for all three loneliness items (all *p*s < .001). Analyses of the T-ILS total score showed a similar pattern (see Table 1 for details).

Figure 4

Loneliness Prevalence ("Often"/"Very Often") by Accommodation Status in Male and Female Students



	Lack companionship		Left out		Isolated	
	Women	Men	Women	Men	Women	Men
Alone	32,3 %	32,7 %	22,8 %	21,4 %	22,9 %	23,5 %
With partner	19,6 %	11,2 %	18,9 %	12,0 %	16,5 %	11,2 %
With friends / others in a collective	23,2 %	20,8 %	15,5 %	12,2 %	14,4 %	12,6 %
With parents	26,1 %	25,7 %	21,6 %	17,7 %	21,0 %	18,0 %

Note. Error bars represent 95% confidence intervals.

Loneliness and Studying Abroad

As detailed in Table 1, females students living/studing abroad had significantly higher odds of reporting loneliness across all three T-ILS items, whereas a similar pattern was not observed for male students. However, a significant sex × studying abroad interaction was only observed for "feeling left out" (see Table 1 for details).

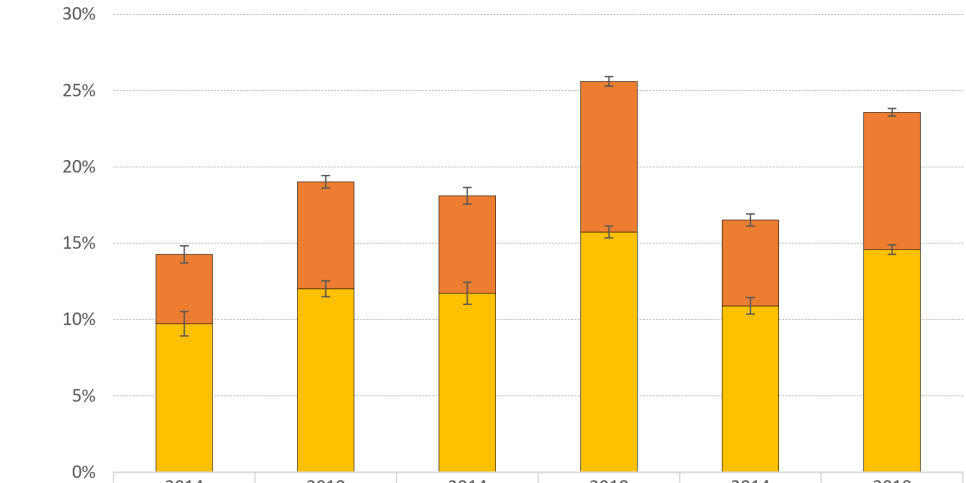
Trend of Loneliness From 2014 to 2018

Figure 5 shows the prevalence of loneliness across from 2014 to 2018. There was a significant overall increase in students reporting feeling lonely ("quite a bit", or "extremely")

from 2014 (16.5%) to 2018 (23.6%; $p < .001$). The increase was evident in both men and women, and across both response categories (see Figure 5 for details).

Figure 5

Prevalence of Loneliness (From the HSCL-25) From 2014 to 2018 by Sex



	Men		Women		Total	
Extremely	4,5 %	7,0 %	6,4 %	9,9 %	5,6 %	9,0 %
Quite a bit	9,7 %	12,0 %	11,7 %	15,7 %	10,9 %	14,6 %

Note. Error bars represent 95% confidence intervals.

Discussion

This large national survey from 2018 of Norwegian fulltime students found that feelings of loneliness were common. Age showed a curvilinear association with loneliness, with the youngest and oldest students reporting the highest level of loneliness across all indicators of loneliness. Other significant demographic determinants of loneliness were being female, single, living alone and studying abroad. There was a considerable increase in loneliness reported by the 2018 cohort compared to the 2014 cohort, and this effect was particular strong for males, for whom the proportion of feeling "extremely" lonely had more than doubled.

The findings confirm that loneliness is frequently experienced among college and university students, as indicated by 14-24% of the students responding that they "often" or "very often" lacked companionship, felt left out, or felt isolated. In line with a previous German study (Diehl et al., 2018), we found that loneliness peaked among the youngest students (aged between 18-20 years), possibly as a result of the transition to university

life. However, a second peak in loneliness was found among the oldest age group (26-35 years). This may be related to a second transitional period towards the end of the studies, in preparation for moving into full-time work. It may also be that these individuals are establishing new relationships after a transition into work and they identify less with student life and are spending less time in student social activities at this stage.

Being in a close relationships was associated with less loneliness among the students, comparable to the protective effect of close relationships in the general population (Beutel et al., 2017). For students, their living situation is a period-specific buffer against loneliness, with students sharing accommodation reporting less loneliness than those that live alone, a finding which also is in line with a previous German university study (Diehl et al., 2018).

The complex associations between sex and loneliness may be understood in light of the inconsistencies in sex differences in previous studies (Mahon et al., 2006). The general pattern is that female students report more loneliness than men across most categories, especially in the younger age groups, while the difference is attenuated in the oldest student group. Some risk factors had differential effects across sexes, including a stronger association between relationship status and loneliness among men, with single men being a noteworthy high-risk group. Similarly, living alone was also a stronger risk factor for men than women. Overall, it seems that men are more sensitive to the structural factors and relationship status for loneliness than females. This may also indicate that interventions should be attentive toward sex-specific risks, and it might be that differential interventions are needed. Future interventions studies could explore if men show a more beneficial more effect of structural interventions such as organised activites and housing, while women might respond better to strengthening social relationships. Women reporting more loneliness than men may also be a result of woman may more easily acknowledging feelings of loneliness, due to less social consequences of lonliness for woman (Borys & Perlman, 1985).

We found a substantial increase in reported loneliness from 2014 to 2018. While there is limited studies reporting on trends, a Danish study found a similar pattern from 1991 to 2014 among adolescents (Madsen et al., 2019). The effect in that study was strongest for the high SES groups. Although we have no information on family SES in the current study, all the included participants are pursuing higher education. Two studies of elderly have reported an opposite pattern, with loneliness decreasing over time (Honigh-de Vlaming et al., 2014; Lempinen, Junttila, & Sourander, 2018), but it might very well be that the trends are different across age groups, and this limits the comparison. The recency of the present study also precludes comparison to others in the same time period. It is uncertain if this is an ongoing trends, but the next planned wave of the SHoT study in 2022 will give new and valuable information on the longer trajectories of loneliness over time. What the drivers of this increase may be is also uncertain. It may reflect a general increase in mental distress, with recent evidence from the same dataset

as the current study showing that both sleep problems and self-harm have increased across the same time period (Sivertsen, Hysing, et al., 2019; Sivertsen, Vedaa, et al., 2019).

The generalizabilty of the findings to the whole student population should be done with care given the relatively modest response rate for the SHoT2014 (29%) and SHoT2018 (31%). In relation to this, the issue of sample comparability is important. As the surveys in 2014 and 2018 included somewhat different welfare organizations and institutions, a recent report using the same datasets, performed detailed sensitivity analyses of the HSCL-25, comprising only institutions that were included in both surveys (Knapstad et al., 2019). The results from these analyses showed near-identical effect-sizes of the trend data, suggesting that the two samples from 2014 and 2018 are comparable.

Regarding the representativeness of the sample in comparison to the total student population in Norway, the SHoT2018 study consisted of 69% females, compared to 58% of all those who were invited. As such, this may represent a bias for the overall estimates, which is why we mainly present gender-specific results. In contrast, the age distribution was almost identical between the invited and the participating student, thus supporting the representativeness of the sample (Sivertsen, Vedaa, et al., 2019). Rather, it may be more appropriate to emphasize the relative differences between men and women, as well as different age cohorts and sociodemographic factors found in the current study, as these estimates are less prone to selection bias. The cross-sectional nature of the SHoT2018-study precludes conclusions on temporal order and causality. For instance, being lonely might reduce the chances for cohabiting, and thus loneliness might be a predictor of accomodation status and not its consequence. The loneliness measure is a three item, psychometrically sound measure, but a more nuanced understanding could have been gained by a more thorough assessment.

Future studies should investigate risk and protective factors for loneliness over and beyond demographic characteristics. Both individual characteristics of the students as well as systemic characteristics of the teaching situation should be investigated to increase our understanding of what constitutes risks for loneliness in this group to inform preventive interventions. The digital society may be one aspect that could account for the increase in loneliness and should be investigated further (Odacı & Kalkan, 2010) Further, if the trend of increasing loneliness will further strengthen in the coming years or will attenuate should be investigated in the present study as well as other epidemiological studies of students

The findings also have notable implications. The rise in loneliness over a four year period warrants concern, and should be met with preventive actions. The demographic determinants identified in this study could give indications of high risk groups to target, including the transitional periods and those living alone. There might be a need for interventions to target male and female students diffentially.

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Optimizing Expectations About Endocrine Treatment for Breast Cancer: Results of the Randomized Controlled PSY-BREAST Trial

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Abstract

Background: Medication side effects are strongly determined by non-pharmacological, nocebo mechanisms, particularly patients' expectations. Optimizing expectations could minimize side effect burden. This study evaluated whether brief psychological expectation management training (EXPECT) optimizes medication-related expectations in women starting adjuvant endocrine therapy (AET) for breast cancer.

Method: In a multisite randomized controlled design, 197 women were randomized to EXPECT, supportive therapy (SUPPORT), or treatment as usual (TAU). The three-session cognitive-behavioral EXPECT employs psychoeducation, guided imagery, and side effect management training. Outcomes were necessity-concern beliefs about AET, expected side effects, expected coping ability, treatment control expectations, and adherence intention.

Results: Both interventions were well accepted and feasible. Patients' necessity-concern beliefs were optimized in EXPECT compared to both TAU and SUPPORT, $d = .41$, $p < .001$; $d = .40$, $p < .001$. Expected coping ability and treatment control expectations were optimized compared to TAU, $d = .35$, $p = .02$; $d = .42$, $p < 001$, but not to SUPPORT. Adherence intention was optimized compared to SUPPORT, $d = .29$, $p = .02$, but not to TAU. Expected side effects did not change significantly.

Conclusion: Expectation management effectively and partly specifically (compared to SUPPORT) modified medication-related expectations in women starting AET. Given the influence of expectations on long-term treatment outcome, psychological interventions like EXPECT might provide potential pathways to reduce side effect burden and improve quality of life during medication intake.

Keywords

expectation management, nocebo effect, psychological intervention, side effect, adjuvant endocrine treatment, breast cancer, oncology

Highlights

- Expectation management (EXPECT) optimizes expectations prior to endocrine therapy for breast cancer.
- EXPECT improved necessity-concern beliefs, coping and control expectations and adherence intention.
- EXPECT was partly more effective than the supportive therapy control condition.
- Expectation management provides a pathway to reduce side effect burden during long-term medication.

Medication side effects are substantially determined by mechanisms which are not directly attributable to the pharmacodynamics of the treatment. These non-specific side effects are well-known from the nocebo phenomenon which manifests itself when adverse effects occur after placebo intake (Barsky, Saintfort, Rogers, & Borus, 2002). Nocebo effects may also emerge as part of routine treatments. Hence, non-specific medication side effects might aggravate the impact of specific side effects (Rief, Bingel, Schedlowski, & Enck, 2011).

Nocebo-related side effects are predominantly determined by psychological mechanisms, most relevantly patients' expectations (Webster, Weinman, & Rubin, 2016). Expectations are influenced by treatment information, social observation, and other learning processes through negative experiences with prior medication intake (Colloca & Miller, 2011). Analogous to expecting treatment benefits, patients also develop expectations about potential adverse events (Laferton, Kube, Salzmann, Auer, & Shedden-Mora, 2017), and form beliefs about their medication's necessity and possible concerns (Horne, Weinman, & Hankins, 1999). These side effect expectations and medication beliefs are linked to the actual occurrence of side effects of cancer treatments (Colagiuri & Zachariae, 2010; Nestoriuc et al., 2016), and other therapies (Faasse & Petrie, 2013; Nestoriuc, Orav, Liang, Horne, & Barsky, 2010). Importantly, side effect expectations and medication beliefs not only predict long-term quality of life, but also medication non-adherence (Horne et al., 2013; Nestoriuc et al., 2016; Pan et al., 2018).

As expectations are potentially modifiable factors, optimizing patients' treatment expectations has been put forward as a novel strategy to improve treatment outcome and minimize side effect burden (Bingel, 2014; Heisig, Shedden-Mora, Hidalgo, & Nestoriuc, 2015; Laferton et al., 2017; Nestoriuc et al., 2016). First evidence from experimental studies suggests that psychological expectation management can effectively improve participants' expectations regarding anti-cancer treatments (Heisig, Shedden-Mora, Hidalgo, & Nestoriuc, 2015), reduce pain (Peerdeman et al., 2016) and even reverse nocebo effects (Bartels et al., 2017). To date, the PSY-HEART-trial (Rief et al., 2017) showed that brief expectation management prior to open-heart surgery successfully changes expectations (Laferton, Auer, Shedden-Mora, Moosdorf, & Rief, 2016), improves long-term disability, quality of life and reduces the length of hospital stay (Auer et al., 2017).

This study employs expectation management in patients undergoing adjuvant endocrine therapy (AET) for breast cancer. AET is the state-of-the-art treatment for hormone-receptor-positive breast cancer. Intake for at least five years improves disease-free survival and time to recurrence (Burstein et al., 2014). Despite its proven clinical efficacy, non-adherence rates ranging from 28% to 73% within the 5-year intake period have been reported (Murphy, Bartholomew, Carpentier, Bluethmann, & Vernon, 2012). As low adherence is associated with poorer survival (Hershman et al., 2011), ensuring patients' adherence is crucial. Side effects such as arthralgia, hot flushes, weight gain, and loss of libido can substantially reduce quality of life (Cella & Fallowfield, 2008) and cause treatment discontinuation (Demissie, Silliman, & Lash, 2001). Side effects occur related to the specific pharmacodynamics of AET (e.g., hot flushes are caused by the deprivation of estrogen), but can also be treatment-unrelated (e.g., dizziness) (Gibson, Lawrence, Dawson, & Bliss, 2009). Relevantly, side effect expectations predict the actual occurrence of cancer treatment side effects (Colagiuri & Zachariae, 2010), long-term quality of life, and non-adherence in AET (Nestoriuc et al., 2016; Pan et al., 2018).

The aim of this study was to evaluate whether a three-session psychological expectation management training (EXPECT; von Blanckenburg, Schuricht, Albert, Rief, & Nestoriuc, 2013; von Blanckenburg et al., 2015) optimizes patients' AET-related expectations when starting AET. This study reports the pre- to post-intervention change of expectations of the PSY-BREAST trial (expectation-focused PSYchological pre-treatment intervention to improve outcome in BREAST cancer treatment). EXPECT was compared to a psychological control intervention (supportive therapy, SUPPORT), and treatment as usual (TAU). It is hypothesized that EXPECT but not SUPPORT and TAU improves expectations regarding the prescribed AET medication and its side effects, the expected ability to cope with potential side effects, and treatment control expectations. Secondly, it is hypothesized that only EXPECT improves the intention to adhere to AET.

Method

Study Design

This was a three-arm multisite (two centers with four clinics), randomized controlled trial. It was registered at ClinicalTrials.gov (NCT01741883). Ethical approval was obtained from the respective local ethics committees (Marburg, Hamburg). Outcomes for this analysis were compared between baseline and post-intervention (Figure 1). A detailed description of the design is provided in the study protocol (von Blanckenburg et al., 2013). After study inclusion, patients were randomly assigned to receive EXPECT, SUPPORT, or TAU. Treatment as usual (TAU) in all groups consisted of the general guideline-based oncologic regime in the certified breast cancer centers, usually surgery and radiation, followed by adjuvant endocrine treatment with tamoxifen or third-generation aromatase inhibitors (Kreienberg et al., 2012). The decision of the type of AET mainly depended on the women's menopausal status. All patients were offered one session basic psycho-oncological support by a trained psycho-oncologist of the hospital staff. After discharge, patients were treated in an outpatient setting by a gynecologist, general practitioner, and if desired, a psycho-oncologist with up to 12 sessions. Patients were allocated in a 1:1:1 ratio stratified according to the Hospital Anxiety and Depression Scale (sum score ≤13 vs. >13) and type of medication (aromatase inhibitor vs. tamoxifen).

Participant Enrollment

Data were collected between November 2012 and May 2015 at the Philipps University of Marburg and the University Medical Center Hamburg-Eppendorf, Germany. Patients were recruited post-surgery during their hospital stay. Included were women aged 18-80 years, with hormone-receptor-positive breast cancer or ductal carcinoma in situ to whom first-line adjuvant endocrine treatment with tamoxifen or third generation aromatase inhibitors was prescribed. Further inclusion criteria were the ability to give informed consent and sufficient German language skills. Exclusion criteria were advanced breast cancer, the presence of any other cancer or comorbid somatic illness causing predominant disability, severe psychiatric illness (e.g., psychosis, checked by structured psychiatric interview, mini-DIPS), and adjuvant chemotherapy.

After providing written informed consent, all patients received a medication information leaflet accompanied by an oral briefing by trained research assistants. This previously validated information illustrated the mode of action, the desired effects, and potential side effects of AET in order to homogenize knowledge (Heisig, Shedden-Mora, von Blanckenburg, et al., 2015). The information briefing was followed by baseline assessment and randomization. Outcome assessors (trained research assistants) were blinded to group allocation throughout the study. For this analysis, the sample of n = 197 patients will allow the detection of small effect sizes, f(V) = .11, with 80% power and α = .05.

Psychological Interventions

Patients received three individual weekly or bi-weekly treatment sessions of 50-75-minutes by a clinical psychologist, followed by up to three 15-minutes booster phone calls at one, three, and six months. A detailed description of the interventions can be found in the study protocol (von Blanckenburg et al., 2013) and case report (von Blanckenburg et al., 2015). All therapists received regular supervision by experienced psycho-oncologists. Therapist allegiance evaluated via video ratings was considered as high (Appendix).

EXPECT – Expectation Management Training

EXPECT is based on cognitive-behavioral therapy and aims to prevent nocebo-related side effects from AET by optimizing treatment-related expectations. The focus on side effects is counterbalanced by therapeutic work towards strengthening beliefs of treatment control, benefit, and necessity. EXPECT is manualized; however, topics are adapted to the patient's individual expectations using a personalized intervention booklet. The three sessions have the following goals and topics:

Session 1. Psychoeducation about AET (mode of action, benefits, potential side effects) is given. The impact of expectations and the nocebo effect are discussed. The aim is to strengthen beliefs about AET's necessity while keeping concerns at a realistic minimum (Heisig, Shedden-Mora, von Blanckenburg, et al., 2015). An imagery exercise guides the patients towards visualizing the expected benefits of AET.

Session 2. Coping strategies for managing the three individually most feared side effects are developed (Mann et al., 2012). These include behavioral techniques, cognitive strategies, and management of specific triggers. Strategies are summarized in a written problem-solving scheme, and patients are encouraged to create a practical 'tool-box'.

Session 3. To strengthen resources for the medication intake period, resourceful activities (e.g., gardening) are encouraged. To support defocusing from side effects, attention control strategies are discussed. To enhance effective patient-doctor communication, patients receive a communication skills training. At the end of the session, the tool-box and all previous topics are reviewed.

Booster calls. The three booster calls aim to provide therapeutic support during the first months of medication intake. Patients are encouraged to apply the learned coping strategies for side effects, which are adapted if necessary.

Supportive Therapy (SUPPORT)

Supportive therapy was designed as an active psychological control condition to account for general therapeutic factors such as the therapist's attention and the patient-therapist relationship (Markowitz, Manber, & Rosen, 2008). It allows distinguishing specific effects of EXPECT from psychological placebo effects. It applies common factors of psychotherapy such as elicitation of affect, empathy, and reflective listening. In contrast to EXPECT, no explicit theoretical framework and no expectation-targeted interventions

are provided. Each session is structured into three phases: the beginning (inquiring about relevant topics), the therapeutic dialog (encouraging the patient to talk about any theme of affective valence), and the ending (revising addressed themes). The booster calls are conducted analogously to EXPECT, with focus on the patient's emotional state.

Assessment

Patients' Expectations

Medication-related expectations about AET were assessed using the Necessity-Concern Balance as measured by the Beliefs about Medicines Questionnaire (BMQ; Horne et al., 1999). A difference score ranging from -4 to 4 is calculated by subtracting the mean expected necessity scale (5 items) from the mean expected concerns scale (6 items) (Horne et al., 2013). Positive scores indicate stronger necessity beliefs than concerns (≈ functional balance).

The mean intensity of 44 expected side effects was assessed using the General Assessment of Expected Side Effects Scale (GASE-expect; Nestoriuc et al., 2016) which measures the expected intensity of 23 general and 21 AET-specific side effects on a 0 ('not present') to 3 ('severe') scale.

The expected ability to cope with the potential 44 expected side effects in case of their presence was assessed on a 1 ('expect to cope badly') to 4 ('expect to cope very well') scale.

Treatment control expectation was assessed with the respective item ('How much do you think your AET can help your breast cancer?') from the Brief Illness Perception Questionnaire (B-IPQ), ranging from 0 ('not at all') to 10 ('extremely helpful'). (Broadbent, Petrie, Main, & Weinman, 2006)

Adherence Intention

Adherence intention was assessed with the question 'How certain are you about starting the endocrine therapy?' rated on a 7-point scale (from 1 'very unsure' to 7 'very sure').

Sociodemographic and Medical Variables

Age, education, and marital status were assessed. Medical variables, namely menopausal status, and breast cancer tumor stage were retrieved from the hospitals' patient records. Patients provided information on their prescribed AET and existing medical comorbidities. The presence and intensity of 44 current somatic complaints were assessed on a 0 to 3 scale using the GASE (Rief, Barsky, et al., 2011).

Patients' Evaluation of the Intervention

Patients evaluated the intervention on nine statements rated from 1 ('do not agree at all') to 6 ('fully agree'). The general satisfaction with the intervention, specific components

of EXPECT, and therapeutic components imminent to supportive therapy were assessed. Potential adverse events of the interventions were assessed with an open-ended question.

Treatment fidelity was assessed by asking patients how often they practiced the imagery exercise on one 1 ('daily') to 5 ('not at all') scaled item. Additionally, participation in booster sessions was assessed.

Therapeutic alliance was rated by patients and therapists after each session with two questions (the intervention has helped me / the patient, the psycho-oncologist understands me / the patient felt understood) from 1 ('do not agree at all') to 6 ('fully agree').

Data Analysis

To examine whether EXPECT resulted in improved expectations compared to SUPPORT and TAU, we computed linear mixed models with treatment group, time (pre- vs. post-intervention) and treatment group by time as fixed effects and a random intercept for subject-specific effects with a restricted maximum likelihood estimation and an autoregressive residual matrix. All analyses were adjusted for study site, age, type of AET, breast cancer tumor stage, and physical symptoms (GASE) as fixed effects. For the hypothesized treatment group by time interaction, pairwise comparisons were reported. Pre-post-tests were performed to indicate improvements within a group.

Missing values on single items ranged from 0 to 3.5% and were imputed using the EM-algorithm. Missing data points at post-intervention were estimated within the linear mixed model using the full intention-to-treat sample. Effect sizes were calculated as differences in mean growth rates between the groups, divided by the product of standard error by square rooted number of participants in TAU (Feingold, 2009). Significance level for all analyses was set at $\alpha = .05$. Statistical analyses were performed using SPSS Statistics 24.

Results

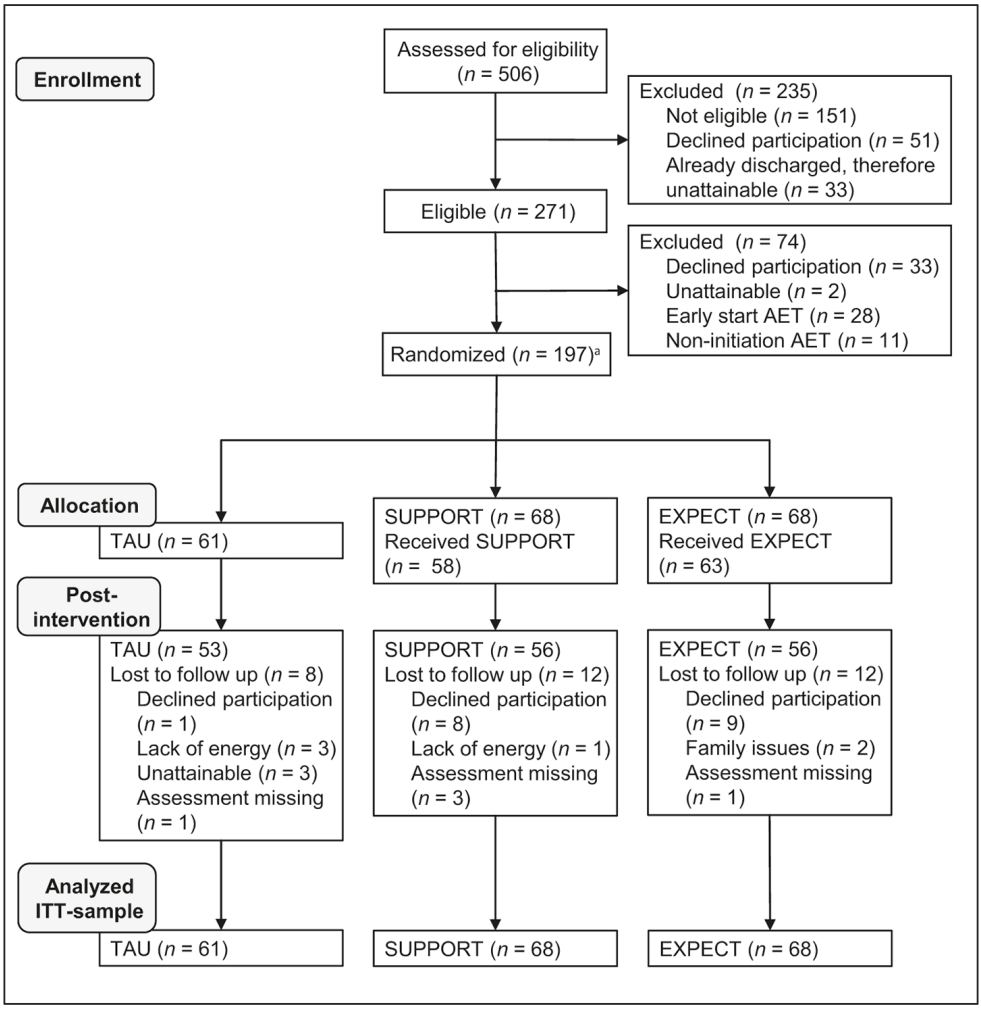
Participant Flow

Of 506 women assessed for eligibility, 271 were eligible for study participation, 197 patients were randomized analyzed as the ITT-sample (Figure 1). Of those, 165 completed post-intervention assessment (83.8%).

Women who discontinued AET before post-intervention assessment (EXPECT: $n = 0$; SUPPORT: $n = 4$; TAU: $n = 2$), and women who did not start the intervention (EXPECT: $n = 5$, SUPPORT: $n = 10$), but completed post-assessment were included in the analyses to avoid selection bias. Fifty-four women (79.4%) in EXPECT and 55 women (80.9%) in SUPPORT received all three sessions.

Figure 1

Patient Flow (CONSORT)



Note. AET = adjuvant endocrine treatment; TAU = treatment as usual; SUPPORT = supportive therapy; EXPECT = expectation management training.
[a]Of n = 203 randomized patients, 6 were identified as non-eligible post-randomization and therefore excluded.

Baseline Characteristics

All baseline sociodemographic and clinical characteristics were comparable across the groups (Table 1).

Table 1

Demographic and Clinical Sample Characteristics

Variable	EXPECT (n = 68)	SUPPORT (n = 68)	TAU (n = 61)	Comparison $F \mid \chi^2$	p
Demographics					
Age in years, *M* (*SD*)	56.46 (8.92)	58.44 (8.40)	59.64 (10.74)	$F(2, 197) = 1.92$	.15
At least 13 years of education, *n* (%)	24 (35.8)	28 (41.8)	21 (34.4)	$\chi^2(2) = 0.85$	.65
Married/with partner, *n* (%)	42 (61.8)	45 (66.2)	36 (59)	$\chi^2(2) = 0.72$	.70
Clinical symptoms					
Peri-/Post-menopausal, *n* (%)	49 (72.1)	53 (77.9)	48 (78.7)	$\chi^2(2) = 0.96$	.62
Tumor stage UICC, *n* (%)				$\chi^2(4) = 3.49$	.48
I	41 (60.3)	42 (61.8)	44 (72.1)		
II	23 (33.8)	24 (33.8)	16 (26.2)		
III	4 (5.9)	2 (2.9)	1 (1.6)		
Type of AET, *n* (%)				$\chi^2(2) = 2.19$	.34
Tamoxifen	37 (54.4)	35 (51.5)	39 (63.9)		
Aromatase Inhibitors	31 (45.6)	33 (48.5)	22 (36.1)		
Medical comorbidities, *n* (%)				$\chi^2(4) = 0.76$	.94
0	25 (36.8)	23 (33.8)	19 (31.1)		
1 or 2	35 (51.5)	38 (55.9)	36 (59)		
≥ 3	8 (11.8)	7 (10.3)	6 (9.8)		
Number of current somatic complaints (GASE)					
M (*SD*)	11.10 (6.70)	9.34 (6.20)	9.98 (7.11)	$F(2, 197) = 1.22$	.30
Range	0 - 31	0 - 26	0 - 29		
Intensity of current somatic complaints (GASE)					
M (*SD*)	0.33 (0.24)	0.30 (0.25)	0.31 (0.25)	$F(2, 197) = 0.32$	.73
Range	0 - 3	0 - 3	0 - 3		

Note. EXPECT = expectation management training; SUPPORT = supportive therapy; TAU = treatment as usual; AET = Adjuvant endocrine therapy; UICC = Union for International Cancer Control; GASE = General Assessment of Side Effects Scale.

The majority of the women were diagnosed with tumor stage I (64.5%). The most frequent comorbidities were hypertension (32.0%), thyroid diseases (25.9%), and joint or dorsal pain (18.3%). Most common baseline somatic symptoms comprised pain or sensitivity of the breast (71.6%), sleeping problems (52.3%), and fatigue (50.5%).

Changes in Patients' Expectations

The *necessity-concern balance* at baseline was rather positive in all groups (Table 2).

Table 2

Outcome Measures at Baseline and Post-Intervention

				EXPECT vs. TAU			EXPECT vs. SUPPORT		
Outcome	**EXPECT**	**SUPPORT**	**TAU**	***t***	***p***	***d***	***t***	***p***	***d***
Medication beliefs: necessity-concern balance (BMQ; range -4-4)				3.33	< .001	0.43	3.15	< .001	0.40
Baseline	0.68 [0.43, 0.93]	0.82 [0.57, 1.06]	0.77 [0.51, 1.04]						
Post-intervention	1.06 [0.79, 1.33]	0.63 [0.36, 0.90]	0.54 [0.27, 0.83]						
Expected side effects, mean intensity (GASE-expect; range 0-3)				-1.69	.092	-0.22	-0.66	.51	-0.09
Baseline	0.56 [0.48, 0.64]	0.50 [0.42, 0.59]	0.47 [0.38, 0.55]						
Post-intervention	0.53 [0.44, 0.62]	0.51 [0.42, 0.60]	0.54 [0.45, 0.63]						
Expected coping ability, mean (GASE coping; range 1-4)[a]				2.45	.015	0.35	1.44	.15	0.21
Baseline	3.49 [3.39, 3.58]	3.53 [3.44, 3.63]	3.61 [3.51, 3.72]						
Post-intervention	3.63 [3.53, 3.74]	3.56 [3.46, 3.66]	3.55 [3.44, 3.66]						
Expected treatment control (B-IPQ; range 0-10)				3.27	< .001	0.42	1.65	.10	0.21
Baseline	7.43 [6.89, 7.98]	7.51 [6.97, 8.05]	7.91 [7.33, 8.48]						
Post-intervention	7.73 [7.14, 8.31]	7.11 [6.53, 7.69]	6.79 [6.18, 7.40]						
Adherence intention (range 1-7)				1.85	.065	0.24	2.27	.024	0.29
Baseline	6.05 [5.73, 6.37]	6.37 [6.05, 6.69]	6.32 [5.98, 6.66]						
Post-intervention	6.66 [6.30, 7.01]	6.27 [5.91, 6.62]	6.33 [5.97 -6.70]						

Note. Values indicate estimated marginal means [95% CI]. Analyses are adjusted for study side, age, type of AET, breast cancer tumor stage, and baseline physical symptoms. Statistical comparisons (*t*- and *p*-values) refer to the pairwise comparisons of the treatment group by time interaction. EXPECT = expectation management training; SUPPORT = supportive therapy; TAU = treatment as usual.

[a]Sample size for analysis $n = 172$ (25 patients did not expect any side effects).

A significant group by time interaction indicated an improved necessity-concern balance in EXPECT compared to both TAU and SUPPORT, estimated mean difference = 0.61, 95% CI [0.25, 0.98], $p = .001$; 0.57, 95% CI [0.21, 0.93], $p = .002$, respectively (Figure 2).

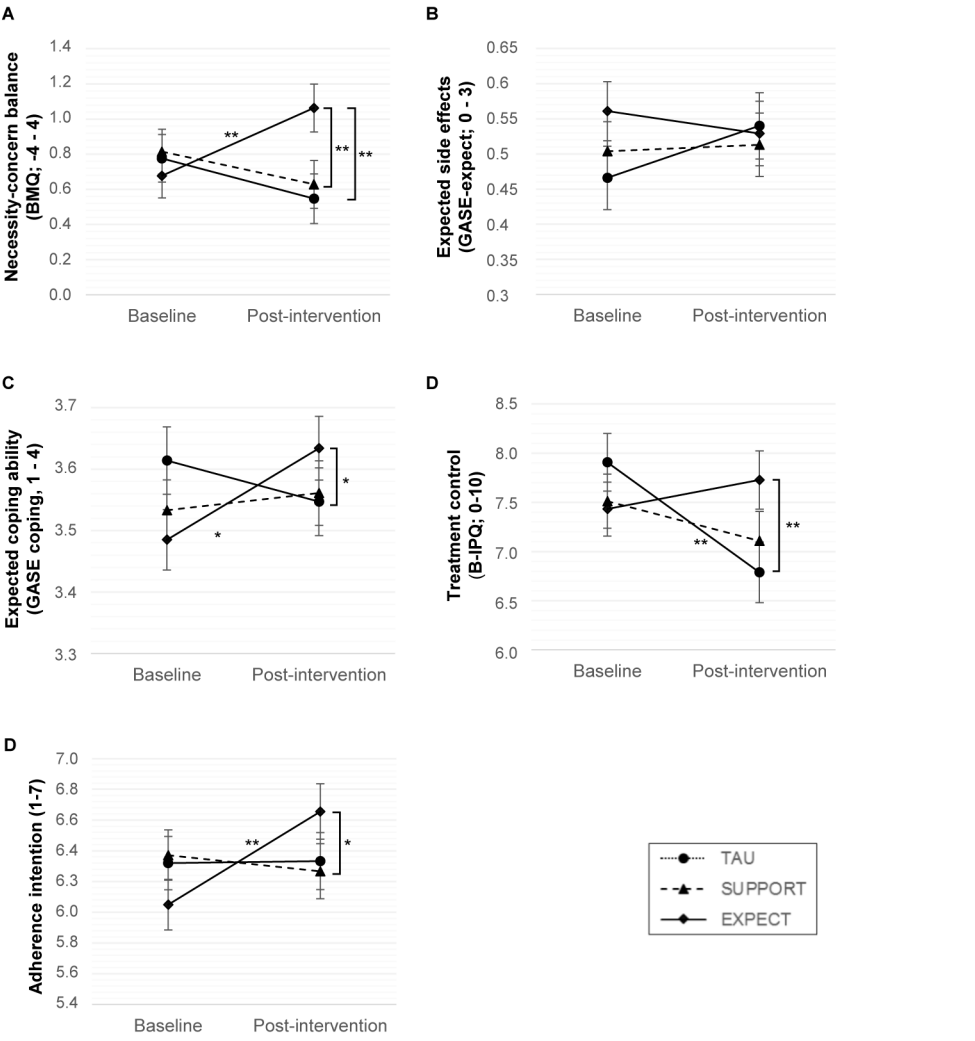
Pre-post within-group comparisons indicated that significant improvements in the necessity-concern balance only occurred in EXPECT but not in TAU and SUPPORT, 0.38, 95% CI [0.13, 0.64], $p = .003$; -0.23, 95% CI [-0.49, 0.03], $p = .085$; -0.19, 95% CI [-0.44, 0.07], $p = .147$. When the scales were analyzed separately, EXPECT showed an increase of necessity beliefs compared to SUPPORT and in trend to TAU, 0.27, 95% CI [0.00, 0.54], $p = .049$; 0.25, 95% CI [-0.03, 0.53], $p = .075$, respectively. EXPECT reported a reduction of concerns compared to TAU and SUPPORT, -.37, 95% CI [-.59, -.14], $p = .002$; -.30, 95% CI [-.53, -.08], $p = .008$.

Mean expected side effects at baseline were low. Non-significant group by time interactions indicated that the groups did not differ, EXPECT vs. SUPPORT: -0.04, 95% CI [-0.16, 0.08], $p = .51$; vs. TAU: -0.11, 95% CI [-0.23, 0.02], $p = .092$. Pre-post comparisons showed no significant change over time in any group.

The *mean expected ability to cope with potential side effects*, which was analyzed for 172 patients who expected at least one of the 44 side effects, was high at baseline. A

Figure 2

Expectations at Baseline and Post-Intervention



Note. Values shown are estimated marginal means (error bars: ± 1 standard error) from linear mixed models. TAU = treatment as usual, SUPPORT = supportive therapy, EXPECT = expectation management training. Numbers after scale names indicate the range.
$^{*}p < .05$. $^{**}p < .01$

significant group by time interaction indicated improved coping expectations in EXPECT compared to TAU, but not to SUPPORT, 0.22, 95% CI [0.04, 0.39], $p = .015$; 0.12, 95% CI

[-0.05, 0.29], p = .15. Pre-post comparisons indicated that coping expectations significantly improved in EXPECT, but not in TAU or SUPPORT, 0.15, 95% CI [0.03, 0.27], p = .013; -0.07, 95% CI [-0.20, 0.06], p = .30, 0.03, 95% CI [-0.09, 0.15], p = .65.

Treatment control expectations at baseline were moderately high. A significant group by time interaction indicated that EXPECT developed significantly higher treatment control expectations compared to TAU, but not to SUPPORT, 1.41, 95% CI [0.56, 2.27], p = .001; 0.70, 95% CI [-0.14, 1.54], p = .10. Pre-post comparisons indicated that treatment control expectations declined in TAU, but did not change in EXPECT or SUPPORT, -1.12, 95% CI [-1.73, -.51], p < .001; 0.30, 95% CI [-0.30, 0.89], p = .33; -0.40, 95% CI [-1.00, 0.19], p = .18.

Changes in Adherence Intention

Adherence intention at baseline was high (Table 2). EXPECT developed a significantly higher intention to adhere to their AET compared to SUPPORT, and in trend compared to TAU, 0.71, 95% CI [0.09, 1.33], p = .024; 0.59, 95% CI [-0.04, 1.22], p = .065 (Figure 2). Pre-post comparisons indicated that adherence intention significantly increased in EXPECT, but not in TAU and SUPPORT, 0.61, 95% CI [0.17, 1.04], p = .007; 0.01, 95% CI [-0.44, 0.47], p = .96; -0.11, 95% CI [-0.54, 0.33], p = .63, respectively.

Patients' Evaluation of the Intervention

The general satisfaction was very high in both groups, while the EXPECT-specific components (e.g., feeling more prepared to face AET side effect) were evaluated more positively in EXPECT (Figure 3). SUPPORT-specific components (e.g., easier to cope with emotions) were evaluated non-significantly better in SUPPORT.

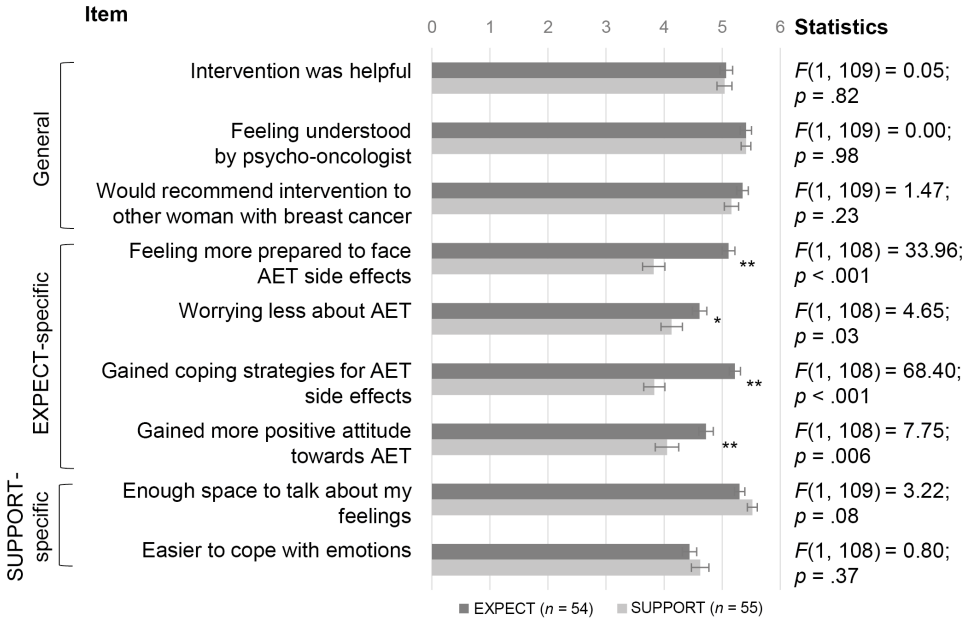
Regarding *adverse events* of the interventions, 14 patients in EXPECT and 13 patients in SUPPORT reported at least one adverse event. In EXPECT, patients reported: organizational issues (4), the number of sessions being too few (4) or too many (1), too much focus on adverse events (2), emotional distress (1), needing more recommendations on coping with side effects (1), and having no need for the intervention (1). In SUPPORT, patients reported: organizational issues (4), too little focus on AET (3), too much focus on possible adverse events (1), the number of sessions being too few (1), needing more recommendations on coping with side effects (1), emotional distress (1), and wish for being asked more questions (1).

Regarding *treatment fidelity*, 39 patients in EXPECT (70.9%, 55 datasets available) practiced their individual protective image developed in the intervention at least once a week. Moreover, at least one booster session was taken up by 52 patients (76.5%) in EXPECT and 51 patients (75%) in SUPPORT.

Regarding *therapeutic alliance*, patients in both groups highly agreed that the intervention had helped them, EXPECT: M (SD) = 5.70 (0.40); SUPPORT: 5.62 (0.47), and that

Figure 3

Patients' Evaluation of EXPECT and SUPPORT Interventions



Note. General = general satisfaction with the intervention; EXPECT-specific = specific components of expectation management training; SUPPORT-specific = therapeutic components imminent to supportive therapy. Statistics are between-group comparisons (ANOVAs).
$^{*}p < .05$. $^{**}p < .01$.

they felt understood, 5.43 (0.52); 5.30 (0.61). Therapists fully agreed that the intervention might have helped the patient, EXPECT: 5.07 (0.75); SUPPORT: 4.73 (1.09), and that patients felt understood, 5.27 (0.70); 5.32 (0.61). Patient and therapist ratings showed medium correlations across both groups, item help: $r = .408$, $p < .001$; item understanding: $r = .317$, $p < .001$).

Discussion

This randomized controlled trial investigated whether a brief expectation-focused psychological intervention (EXPECT) optimizes patients' medication-related expectations before starting AET for breast cancer. In summary, patients' necessity-concern beliefs about AET were significantly optimized in EXPECT as compared to both TAU and

SUPPORT. Expected coping with side effects and expected treatment control were significantly optimized compared to TAU but not to SUPPORT. Expected adherence was significantly optimized compared to SUPPORT but not to TAU. Expected side effects did not change significantly.

As predicted, patients receiving EXPECT developed more positive AET-related expectations compared to both SUPPORT and TAU. In particular, patients in EXPECT increased their necessity beliefs and reduced their concerns, while necessity-concern beliefs remained unchanged in the other groups. This result is highly relevant given that dysfunctional necessity-concern beliefs are associated to poorer medication adherence (Horne et al., 2013), which in turn predicts morbidity and mortality in breast cancer (Hershman et al., 2011). The relevance of these changes is underpinned by the increase in adherence intention compared to SUPPORT and in trend to TAU, which is a good predictor of actual adherence (Manning & Bettencourt, 2011). Accordingly, compared to TAU, patients receiving EXPECT expected to cope better with possible side effects and had higher expectations that AET could control their illness.

To our knowledge, this is the first study investigating expectation change in cancer treatment. Our findings are in line with previous evidence from the PSY-HEART trial targeting expectations prior to cardiac surgery (Laferton et al., 2016; Rief et al., 2017), an RCT addressing illness perceptions after myocardial infarction (Broadbent, Ellis, Thomas, Gamble, & Petrie, 2009), and experimental pain research (Peerdeman et al., 2016). All showed that patients' expectations can be effectively changed through brief interventions using expectation management, verbal suggestions, imagery, or conditioning. In breast cancer, an acupressure band combined with expectation-enhancing information reduced nausea after chemotherapy in patients with high levels of expected nausea, but the authors did not report expectation change (Roscoe et al., 2010). In our opinion, thoroughly assessing expectation changes is highly relevant to understand how interventions work, and whether postulated etiological mechanisms are actually targeted. While there are effective approaches to support patients in coping with cancer-associated stress, pain, and fatigue (Antoni et al., 2009), few directly address coping with side effects of cancer treatment (Mann et al., 2012) and target patients' expectations as a relevant etiological factor.

With small to moderate effect sizes, EXPECT was specifically superior to our psychological control condition (SUPPORT) in changing medication beliefs and improving adherence intention. In contrast, changes in coping and treatment control expectations did not significantly differ between EXPECT and SUPPORT. While most effects indicated in the assumed direction, proving superiority to a strong, active control condition like supportive therapy might need larger sample sizes. Thus, EXPECT can be considered effective compared to TAU and partly superior to SUPPORT for some of the expectation measures.

Contrary to our hypothesis, the mean intensity of expected side effects did not change significantly, for which two aspects might be relevant. Firstly, discussing side effects might not actually reduce their expected intensity. Importantly, our study shows that the guided therapeutic attention on side effects is not harmful, as might be feared by physicians and patients. This is in line with studies showing that the assessment of side effect expectations does not increase their occurrence (Colagiuri et al., 2013). However, we will carefully monitor the occurrence of adverse effects in our trial (von Blanckenburg et al., 2013). Secondly, ceiling effects due to low baseline side effect expectations might explain the lack of changes. It is possible that our provision of standardized comprehensive information about AET to all patients already lowered side effect expectations (Heisig, Shedden-Mora, von Blanckenburg, et al., 2015).

With regard to the patients' evaluation, both interventions were well accepted and perceived as highly helpful, while all EXPECT-specific elements were rated as more achieved in EXPECT. Thus, the interventions can be regarded as specific in targeting the aimed mechanism from the patients' perspective. Importantly, the therapeutic alliance from both the patients' and the therapists' perspective was perceived as very supportive.

Few patients experienced adverse events of the intervention, of which most were of organizational nature. Two patients in EXPECT feared that the focus on possible adverse events might make them more sensitive to actually experiencing them. While there was no overall increase in side effect expectations in our study, these concerns need to be taken seriously and addressed in nocebo-focused expectation management interventions. Taken together, the evaluation shows that both interventions were well accepted and feasible within guideline-based breast cancer care.

Study Limitations

The results of this RCT need to be interpreted in light of potential limitations. First, while the sample was recruited from four independent sites and resembled a typical early-stage breast cancer sample (Burstein et al., 2014; Murphy et al., 2012), a sample selection bias due to declining participation or non-initiation of AET might limit generalizability. Second, the GASE-expect scales need further psychometric evaluation. Lastly, larger samples might be needed to detect smaller differences between EXPECT and SUPPORT.

Clinical Implications

In conclusion, this RCT is the first study to show that expectations regarding breast cancer treatment can be effectively changed via a brief psychological intervention. Expectation management proved to be a feasible, well-accepted, effective intervention that was partly superior to the psychological control condition. It could easily be implemented in routine care for women with early-stage breast cancer.

In this study, certain aspects of expectations such as the necessity-concern balance, coping and treatment control expectations seemed more amenable to change. Certainly, more validated assessment methods of patients' expectations are needed, for which our proposed integrative model of patients' expectations (Laferton et al., 2017) might provide a framework. Moreover, patients' expectations result from a dynamic interaction of cognitive processes and experiences with medication intake (Wiech, 2016) and thus might change with the actual experience of AET intake. Therefore, investigating expectation change more systematically seems worthwhile (Heisig, Shedden-Mora, Hidalgo, & Nestoriuc, 2015; Kube, Rief, Gollwitzer, & Glombiewski, 2018).

The long-term effects of these optimized expectations within the PSY-BREAST trial regarding side effect burden, quality of life, and medication adherence (von Blanckenburg et al., 2013) will be reported elsewhere. Moreover, the course of expectations during long-term AET intake and their impact on the above mentioned outcomes will be reported elsewhere. Investigating whether expectations and beliefs can be effectively changed through brief interventions is the first important step towards improving long-term outcomes during AET treatment, and allows for analyzing the effects of expectations changes on clinical outcomes.

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Competing Interests: Winfried Rief is Editor-in-Chief of Clinical Psychology in Europe but played no editorial role for this particular article. Apart from that, the authors have declared that no competing interests exist.

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Appendix: Therapist Allegiance

Video ratings of 46 (of 330 available) randomly selected therapy session videos (14%; 24 of EXPECT, 22 of SUPPORT equally selected from the three sessions) were performed by two trained independent raters following a standardized protocol. Ten specific items for EXPECT and SUPPORT assessed objective allegiance on a 1 ('not present') to 3 ('strongly present') rating-scale (e.g., adherence to manual and structure of sessions, therapeutic attitude). Overall, the mean ratings (with standard deviations in parenthesis) of treatment allegiance in EXPECT and SUPPORT were 2.91 (0.11), and 2.98 (0.05). The percentage in which the two raters fully agreed in their rating of a video was 92% for EXPECT and 99% for SUPPORT.

Subjective allegiance was rated by the therapist after each session on one item scaled from 1 ('low') to 4 ('high'). The mean subjective allegiance ratings in EXPECT and SUPPORT were 3.25 (0.78), and 2.94 (0.33). Thus, therapist subjective and objective allegiance to the respective manuals can be regarded as high.

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Long-Term Stability of Benefits of Cognitive Behavioral Therapy for Obsessive Compulsive Disorder Depends on Symptom Remission During Treatment

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Abstract

Background: Cognitive behavioral therapy (CBT) is an effective treatment for obsessive-compulsive disorder (OCD) and may afford stable long-term improvements. It is not clear, however, how stability or symptom recurrence can be predicted at the time of termination of CBT.
Method: In a 1-year follow-up intention-to-treat study with 120 OCD patients receiving individual CBT at a university outpatient unit, we investigated the predictive value of international consensus criteria for response only (Y-BOCS score reduction by at least 35%) and remission status (Y-BOCS score ≤ 12). Secondly, we applied receiver-operating characteristic (ROC) curves in order to find an optimal cut-off score to classify for deterioration and for sustained gains.
Results: Response only at post-treatment increased the likelihood of deterioration at follow-up compared to remission at an odds ratio of 8.8. Moreover, ROC curves indicated that a post-treatment score of ≥ 13 differentiated optimally between patients with and without symptom deterioration at follow-up assessment. The optimal cut-off score to classify for any sustained gains (response, remission, or both) at follow-up relative to baseline was 12. Importantly, previous findings of generally high long-term symptom stability after treatment in OCD could be replicated.
Conclusion: The findings highlight the clinical importance of reaching remission during CBT, and suggest that a recently published expert consensus for defining remission has high utility.

Keywords

obsessive-compulsive disorder, Y-BOCS, cut-off score, expert consensus, follow-up

Highlights

- A 1-year follow-up study with OCD patients having received a CBT trial was conducted.
- Achieving a Y-BOCS score ≤ 12 at termination of treatment decreases the risk of future deterioration.
- The study supports a rationale to treat OCD patients until reaching remission status.
- The study confirms the criterion for remission in OCD recently published as an expert consensus.

Cognitive behavioral therapy (CBT) is an effective treatment for obsessive-compulsive disorder (OCD). Its efficacy in randomized-controlled trials (RCT; Olatunji, Davis, Powers, & Smits, 2013; Öst, Havnen, Hansen, & Kvale, 2015) and its effectiveness in routine clinical practice (Hans & Hiller, 2013) have been confirmed in meta-analyses. According to follow-up data, treatment gains are largely maintained after treatment, but in randomized controlled trials, slight increases of average symptom scores from post-treatment to follow-up are observed at group level (Olatunji et al., 2013; Öst et al., 2015). However, follow-up data from routine care are still rare, especially for individual outpatient therapy (Cabedo, Carrió, & Belloch, 2018; Hans & Hiller, 2013; Hansen, Kvale, Hagen, Havnen, & Öst, 2019).

The Yale-Brown Obsessive-Compulsive Scale (Y-BOCS) interview (Goodman et al., 1989a; Goodman et al., 1989b) has been established as the "gold standard" to measure OCD symptom severity, and is commonly used as a primary outcome measure (Öst et al., 2015). Effect sizes based on Y-BOCS group mean scores are therefore useful for comparisons between studies and interventions, and allow observing within-group changes. However, group mean scores do not reflect individual improvement (Hiller, Schindler, Andor, & Rist, 2011; Jacobson, Follette, & Revenstorf, 1984), which is especially important in research on routine clinical practice. In order to address this issue, Jacobson and Truax (1991) proposed a definition of clinically significant improvement by combining statistically significant changes in individual symptoms (Reliable Change Index, RCI) with subclinical symptom levels. This makes it possible to determine individual response (without remission), remission, and deterioration. Since clinically significant change depends on the reliability of the measure and the variance in the relevant population, cut-off scores for remission varied between 7 and 16 across published studies (Öst et al., 2015). Subsequently, Mataix-Cols et al. (2016) published an international expert consensus on change assessment in OCD, in which treatment response was defined as a reduction in Y-BOCS scores by at least 35% and an improvement score of 1 (“very much improved”) or 2 (“much improved”) on the Clinical Global Impression scale (CGI, Guy, 1976). For remission, a Y-BOCS score of < 13 and CGI severity ratings of 1 (“normal,

not at all ill") or 2 ("borderline mentally ill") must be achieved. These criteria have been adopted in recent research (Hansen et al., 2019) and may prove influential for future clinical decisions in OCD treatment. Yet, it remains unclear whether these consensus criteria have clinical utility and are able to predict individual long-term stability.

Prediction of post-treatment response and remission on the basis of pre-treatment Y-BOCS scores has been investigated by means of signal detection analyses (Farris, McLean, Van Meter, Simpson, & Foa, 2013). Criteria evaluation for predicting outcome at follow-up, however, is missing. Prospective studies on depressive disorder and social phobia suggest that incomplete remission at post-treatment predicts relapse at follow-up (Judd et al., 1998; Paykel et al., 1995; Van Ameringen et al., 2003). In line with these results, two studies with OCD patients have shown that "partial remission" compared to "full remission" at the end of treatment predicts relapse during follow-up periods of one to five years (Braga, Cordioli, Niederauer, & Manfro, 2005; Braga, Manfro, Niederauer, & Cordioli, 2010; Eisen et al., 2013). One of these studies (Eisen et al., 2013), however, did not use Y-BOCS scores for the evaluation of clinical status. In the other, full remission required a Y-BOCS score of < 8 (Braga et al., 2005; Braga et al., 2010), which is much stricter than the consensus Y-BOCS cut-off score for remission (≤ 12). It is therefore unclear whether the protective effect of "full remission" can also be found when applying the less strictly defined remission criterion. Prediction of long-term stability is of major importance for clinical practice, because under routine conditions the criterion for terminating individual psychotherapy is often not specified in advance. Treatment may be continued until a "good enough level" (GEL) is achieved (Barkham et al., 2006; Falkenström, Josefsson, Berggren, & Holmqvist, 2016), which is often defined subjectively by patient and therapist. Clinical decisions, however, should also be informed by empirical research. In addition to testing the predictive value of categorical variables such as remission or response, it is also worthwhile to determine the exact post-treatment Y-BOCS scores that separate patients with stable treatment gains from those with loss of gains in the follow-up period, or patients with long-term improvements in relation to pre-treatment levels from those without such improvements. If good prediction is possible on the basis of a single, widely-used and easy-to-apply instrument, the cut-off scores can inform clinical decisions on whether to terminate or to continue CBT.

In the present study, we conducted a 1-year follow-up assessment in a relatively large sample of OCD patients, who had received individual CBT under routine conditions of the German health care system. Our main goals were: 1.) testing whether patients achieving the consensus Y-BOCS cut-off score for remission at post-treatment are less likely to experience significant symptom increase at follow-up compared to unremitted responders, 2.) determining a post-treatment Y-BOCS cut-off score that differentiates optimally between patients who deteriorate from post-treatment to follow-up and those whose initial improvement remains stable, and 3.) determining a post-treatment Y-BOCS cut-off score that predicts for any sustained gains (response, remission, or both) at

follow-up. A secondary aim was to provide further data for evaluations of average and individual symptom changes from pre- and post-treatment to follow-up in a treatment setting typical for routine care in many countries.

Method

Participants

Study participants had terminated individual cognitive behavioral therapy (CBT) at a university outpatient unit (Hochschulambulanz für Psychotherapie und Psychodiagnostik der Humboldt-Universität zu Berlin) between December 2013 and May 2017. Referrals to the outpatient unit were made according to routine clinical care procedures. Patients who prematurely discontinued CBT (non-completers) were not excluded and the last observation was carried forward to estimate post-treatment scores (interim-assessments were done every 20 sessions). General study inclusion criteria were: primary diagnosis of OCD, age between 18 and 70 years, and a minimum pre-treatment Y-BOCS total score of 16. Due to general admission policies of the outpatient unit, patients with comorbid psychotic disorders, borderline personality disorder, or substance dependency (life time) were not referred. Three patients were excluded from analysis due to missing Y-BOCS-data at both pre- and post-treatment. During the study period, a total of 207 patients fulfilled the inclusion criteria and were contacted by telephone for follow-up assessments. Among these, 51 (24.6%) patients could not be reached and 36 (17.4%) declined to participate. 120 patients participated in the phone interview (58.0% of the total sample), and 96 of them completed additional online questionnaires (46.4% of the total sample).

Participants (n = 120, 75 female, 104 therapy completers) and non-participants (n = 87, 49 female, 70 therapy completers) in the follow-up interview did not differ significantly in terms of gender (p = .392), therapy completer status (p = .252), or other demographic and clinical variables (see Table 1). For both participants and non-participants, the most common comorbid mental disorders were present or remitted depressive disorders and anxiety disorders. Twenty-four patients of the total sample suffered from personality disorders (see Table 2). 73 patients took psychotropic medications at admission (35.3%), 55 at post-treatment (26.6%); the most common medications were selective serotonin reuptake inhibitors (SSRIs) and other antidepressants. The study protocol was approved by the local review board of Humboldt-Universität zu Berlin (protocol number 2016-33) and met the ethical standards of the revised Declaration of Helsinki. All participants provided written informed consent.

Table 1

Demographic and Clinical Variables of Participants and Non-Participants in Follow-up Assessments

	Participants Assessment t_{FU}		Non-Participants Assessment t_{FU}		*t*-test for independent samples		
Variable	***n***	***M* (*SD*)**	***n***	***M* (*SD*)**	***df***	***t***	***p***
Age	120	32.3 (9.5)	87	31.5 (9.9)	181.0	0.59	.558
Age of symptom onset	109	17.1 (8.8)	81	17.1 (7.6)	183.2	0.02	.986
Age of disorder onset	110	23.1 (9.6)	78	22.4 (8.5)	117.3	0.58	.558
Duration of therapy (hours)	119	41.0 (17.6)	87	42.3 (20.7)	167.4	-0.45	.653
Socio-economic status	112	9.6 (3.7)	79	9.2 (4.2)	154.2	0.77	.443
GAF t_{pre}	118	55.8 (10.1)	86	53.3 (11.2)	171.0	1.66	.099
Y-BOCS t_{pre}	120	23.3 (4.6)	87	24.4 (4.7)	182.0	-1.74	.083
Y-BOCS t_{post}	120	11.9 (7.3)	87	13.7 (7.7)	178.8	-1.69	.092
OCI-R t_{pre}	118	27.1 (13.0)	87	29.4 (12.4)	190.1	-1.31	.193
OCI-R t_{post}	120	14.4 (12.0)	85	17.7 (13.5)	167.2	-1.78	.078
BDI-II t_{pre}	119	18.9 (11.2)	87	20.4 (10.8)	188.8	-0.97	.336
BDI-II t_{post}	120	9.8 (8.7)	84	10.9 (11.3)	148.6	-0.78	.438
BSI-GSI t_{pre}	119	0.98 (0.5)	87	1.01 (0.6)	178.0	-0.37	.712
BSI-GSI t_{post}	120	0.60 (0.5)	85	0.70 (0.6)	163.2	-1.17	.245

Note. GAF = Global Assessment of Functioning; Y-BOCS = Yale-Brown Obsessive-Compulsive Scale interview score; OCI-R = Obsessive Compulsive Inventory - Revised; BDI-II = Beck Depression Inventory II; BSI-GSI = Global Severity Index of the Brief Symptom Inventory; pre = pre-treatment; post = post-treatment; FU = 1-year follow-up.

Table 2

Most Common Comorbid Mental Disorders and Medication Status at t_{pre} and t_{post}.

	Participants Assessment t_{FU}		Non-Participants Assessment t_{FU}	
Condition	***n***	**%**	***n***	**%**
≥ 1 comorbid mental disorder	76	63.3	51	58.6
present depressive disorder	40	33.3	29	33.3
remitted depressive disorder	28	23.3	20	23.0
any anxiety disorder	41	34.2	15	17.2
Personality disorder	12	10.0	12	13.8
Psychotropic medications t_{pre}	45	37.5	28	32.2
Psychotropic medications t_{post}	35	29.2	20	23.0

Note. pre = pre-treatment; post = post-treatment; FU = 1-year follow-up.

Treatment

CBT was administered by nineteen licensed psychotherapists, who had completed at least three years of training in CBT. Treatments were bound to the general conditions for psychotherapy in the public German health care system. The legal framework allowed up to 66.7 hours (80 units of 50 minutes each) per treatment. Therapists were instructed to apply CBT including exposure and response prevention (ERP) according to the national guideline for evidence-based treatment (Hohagen, Wahl-Kordon, Lotz-Rambaldi, & Muche-Borowski, 2014). Adherence was not formally controlled and treatment was not manualized, but therapists received weekly supervision by one of four experienced CBT therapists. Therapy sessions usually lasted 50 minutes and took place once or twice weekly, yet therapists were free to adjust session length when implementing exposure and to reduce session frequency at the end of treatment. Treatment was terminated by consensus of patient and therapist based on clinical criteria. Patients who abandoned treatment without the approval of their therapist were classified as non-completers.

Assessment

One-year follow-up status of patients (t_{FU}) was assessed by telephone-based interviews and internet-based self-report questionnaires. Analyses also included data from routine assessments at admission (t_{pre}) and termination of therapy (t_{post}), and for non-completers, from interim-assessments.

Telephone interviews were conducted by trained master level psychology students, who were supervised by an experienced psychotherapist (B.R.). Interviews included the German version of the Y-BOCS interview to assess OCD symptom severity (Goodman et al., 1989a; Goodman et al., 1989b; Hand & Büttner-Westphal, 1991). Internet-based assessments included the Obsessive Compulsive Inventory - Revised (OCI-R, Foa et al., 2002) as a secondary outcome measure of OCD symptoms, the Beck Depression Inventory II (BDI-II, Beck, Steer, & Brown, 1996) to measure current depression, and the Brief Symptom Inventory (BSI, Derogatis & Melisaratos, 1983) to assess general psychological distress using its Global Severity Index.

Routine assessments at admission (t_{pre}) included the German version of the Structured Clinical Interviews for DSM-IV mental disorders and personality disorders (SCID-I, SCID-II, First, Gibbon, Spitzer, Williams, & Benjamin, 1997; First, Spitzer, Gibbon, & Williams, 1995), and a socio-economic status scale (Lampert & Kroll, 2009). In order to assess symptom course, Y-BOCS interview, OCI-R, BDI-II, BSI, the clinical global impression scale (CGI, Guy, 1976) and the global assessment of functioning (GAF, Jones, Thornicroft, Coffey, & Dunn, 1995) were administered before the first and after the final therapy session. Interim assessments were conducted every 20 sessions and used to estimate post-treatment data for non-completers without post-treatment assessments (n = 10; last-observation-carried-forward method). Interim assessments were also used

to estimate post-treatment scores for four therapy completers with missing data. All clinical interviews at admission and post-treatment were conducted by trained clinical psychologists.

Data Analysis

We analyzed data using R version 1.0.44. Participants and non-participants were compared using independent two sample *t*-tests (two-sided). Fisher's exact test was applied to compare nominal data. Effect sizes were calculated using Cohen's *d* with pooled standard deviations. Changes over time were compared with paired *t*-tests (two-sided). We used the expert consensus criteria (Mataix-Cols et al., 2016) for Y-BOCS scores to define remission (total score ≤ 12), response (reduction ≥ 35%), and non-response (reduction < 35%), but did not apply the CGI improvement scale (see also Hansen et al., 2019). We used the Reliable Change Index (RCI, Jacobson et al., 1984) to define statistically meaningful deterioration (e.g. Bablas, Yap, Cunnington, Swieca, & Greenwood, 2016; Han, Geffen, Browning, Kenardy, & Geffen, 2011; Kraus, Castonguay, Boswell, Nordberg, & Hayes, 2011). To calculate the RCI, an internal consistency of α = .79 (Moritz et al., 2002) was used as the reliability of the Y-BOCS. Stability was defined as the absence of significant deterioration. Logistic regression analysis was used to contrast response without remission (response only) and remission at post-treatment to predict deterioration at follow-up. As we were interested in stability after initial improvement, patients with no response during treatment were not considered in this analysis. Additionally, we applied receiver-operating characteristic (ROC) curves using R package OptimalCutpoints (López-Ratón, Rodríguez-Álvarez, Cadarso-Suárez, & Gude-Sampedro, 2014) in order to find the best post-treatment Y-BOCS score classifying for deterioration versus stability at follow-up. ROC curves were also used to find the optimal post-treatment cut-off score classifying for sustained gains (response, remission, or both; $n = 77$) at follow-up. The score that reached a maximum Youden index (J = Sensitivity + Specificity - 1; Youden, 1950) was considered as optimal cut-off.

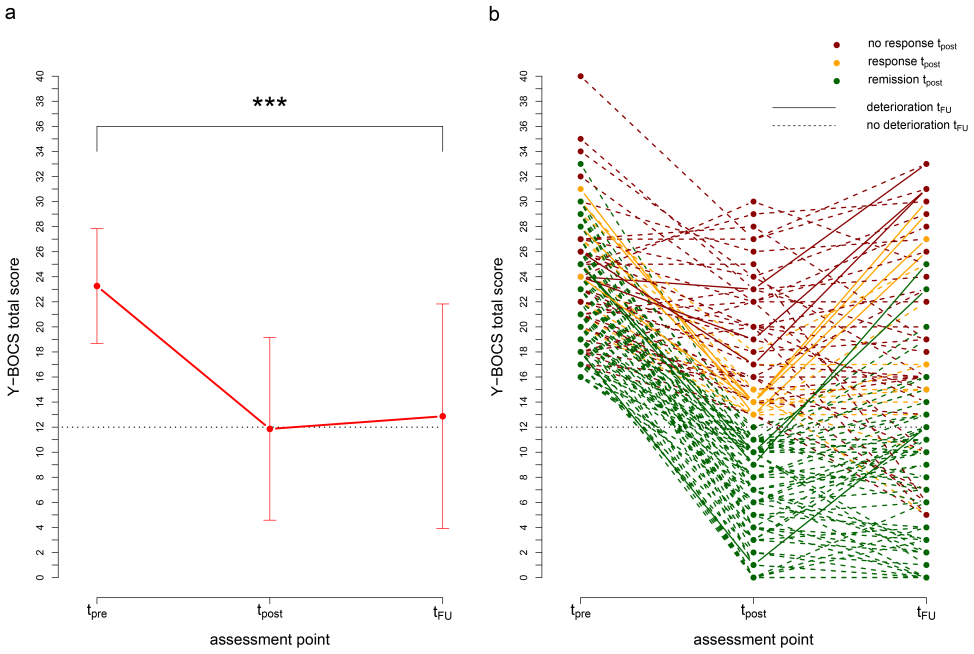
Results

Average Symptom Change

On group level, the Y-BOCS score decreased significantly from pre-treatment to post-treatment, $t(119) = 17.23$, $p < .001$, with a mean reduction of 11.4 points and a large effect size of Cohen's $d = 1.87$ (Figure 1a, Table 3). Symptom severity was also significantly reduced from pre-treatment to one-year follow-up, $t(119) = 13.75$, $p < .001$, $d = 1.46$. The increase of the mean Y-BOCS score from post-treatment to follow-up was small, but close to significance, $t(119) = -1.79$; $p = .076$, $d = -0.12$ (see Figure 1a).

Figure 1

Average and Individual Symptom Change



Note. a) Mean Y-BOCS total scores at pre-treatment (t_{pre}), post-treatment (t_{post}) and follow-up (t_{FU}). b) Individual remission, response only and non-response at post-treatment (according to the expert consensus) and significant deterioration (according to Reliable Change Index) from post-treatment to follow-up. Error bars indicate standard deviations.
***p < .001.

Similarly, secondary outcome parameters showed significant reductions from pre-treatment to post-treatment (OCI-R: $t(234) = 7.82$; $p < .001$, $d = 1.01$; BDI-II: $t(222.99) = 7.03$; $p < .001$, $d = 0.91$ and BSI-GSI: $t(236.01) = 5.62$; $p < .001$, $d = 0.73$), and from pre-treatment to follow-up (OCI-R: $t(208.32) = 8.40$, $p < .001$, $d = 1.14$; BDI-II: $t(196.88) = 4.15$; $p < .001$, $d = 0.57$; and BSI-GSI: $t(207.95) = 5.21$; $p < .001$, $d = 0.71$). No significant change from post-treatment to follow-up was observed for OCI-R, $t(205.13) = 0.83$, $p = .409$, $d = 0.11$; for BDI-II, $t(168.30) = -1.71$, $p = .089$, $d = -0.24$; and for BSI-GSI, $t(204.06) = -0.12$, $p = .903$, $d = -0.02$; (see Table 3).

Table 3

Mean Differences and Effect Sizes From Pre-Treatment and Post-Treatment to Follow-up

Measure	n_{FU}	M_{FU} (*SD*)	M_{post} (*SD*)	$d_{post\text{-}FU}$	M_{pre} (*SD*)	$d_{pre\text{-}FU}$
Y-BOCS	120	12.9 (9.0)	11.9 (7.3)	-0.12	23.3 (4.6)	1.46
OCI-R	94	13.1 (11.3)	14.4 (12.0)	0.11	27.1 (13.0)	1.14
BDI-II	96	12.3 (12.0)	9.8 (8.7)	-0.24	18.9 (11.2)	0.57
BSI-GSI	96	0.61 (0.5)	0.60 (0.5)	-0.02	0.98 (0.5)	0.71

Note. Y-BOCS = Yale-Brown Obsessive-Compulsive Scale interview score; OCI-R = Obsessive Compulsive Inventory - Revised; BDI-II = Beck Depression Inventory II; BSI-GSI = Global Severity Index of the Brief Symptom Inventory; pre = pre-treatment; post = post-treatment; FU = 1-year follow-up.

Individual Improvement

The course of symptoms from pre-treatment to post-treatment and follow-up was heterogeneous across patients (Figure 1b). Table 4 displays the numbers of patients with non-response, response without remission (response only), and remission at post-treatment and follow-up. Adopting the RCI for deterioration, Table 5 shows the numbers of participants with Y-BOCS score stability and deterioration at follow-up broken down by their outcome category at post-treatment. The relationship between outcome category (remission, response only, non-response) at post-treatment and stability at follow-up is illustrated in Figure 1b.

Table 4

Number of Non-Responders, Responders Without Remission and Remitters for Post-Treatment and Follow-up

	Outcome category at 1-year follow-up (t_{FU})			
Outcome category at t_{post}	No response	Response only	Remission	Σ_{post}
No response	27	3	7	37 (30.8%)
Response only	8	4	2	14 (11.7%)
Remission	8	9	52	69 (57.5%)
Σ_{FU}	43 (35.8%)	16 (13.3%)	61 (50.8%)	120 (100%)

Note. Response only = Response without remission; post = post-treatment; FU = 1-year follow-up.

Table 5

Change During Follow-up: Number of Stable and Deteriorated Participants at Follow-up Broken Down by Their Outcome Category at Post-Treatment

	Change during 1-year follow-up (t_{FU})		
Outcome category at t_{post}	**Stability**	**Deterioration**	**Σ_{post}**
No response	34	3	37 (30.8%)
Response only	10	4	14 (11,7%)
Remission	66	3	69 (57.5%)
Σ_{FU}	110 (91.7%)	10 (8.3%)	120 (100%)

Note. Response only = Response without remission; post = post-treatment; FU = 1-year follow-up.

Prediction of Long-Term Outcomes

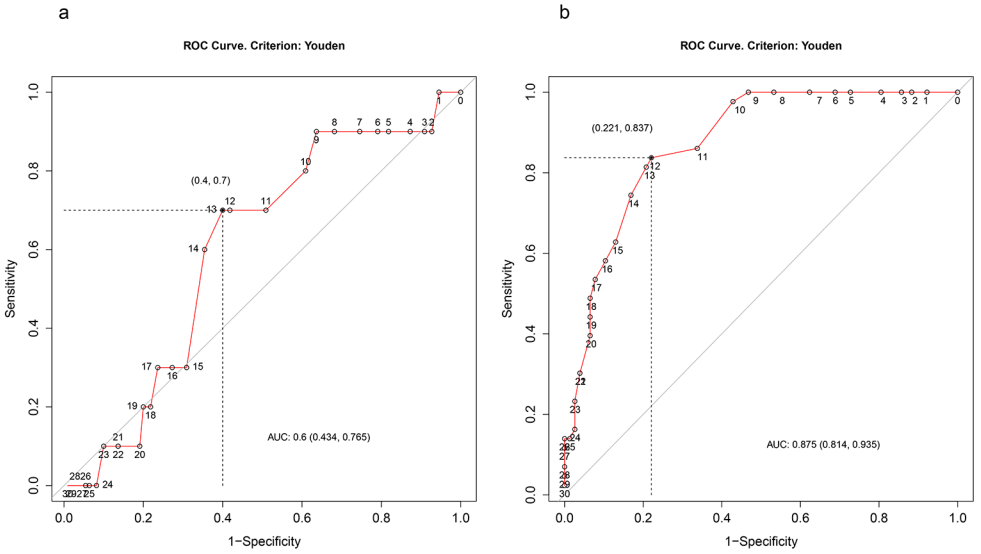
Compared to remission, response only significantly predicted deterioration at follow-up (B = 2.17, SE = 0.84, $\chi^2(1)$ = 6.58, p = .010, Odds Ratio (OR) = 8.8, CI = 1.71 - 50.65, Wald χ^2 = 6.77, p = .009). Nagelkerke's R-squared of this model was .174 (Hosmer-Lemeshow R^2 = .137, Cox-Snell R^2 = .076). The inclusion of Y-BOCS scores at pre-treatment as predictor did not improve the model significantly, B = 0.13 (SE = 0.11), p = .235. Initial Y-BOCS scores did not predict deterioration, OR = 1.1 (CI = 0.92 - 1.44, Wald χ^2 = 1.41, p = .245).

Cut-off Scores

The Y-BOCS score at post-treatment that best predicted significant deterioration versus stability was 13 (sensitivity = .70; specificity = .60), indicating that participants with a score higher than or equal to 13 were more likely deteriorated at follow-up (see Figure 2a). Interestingly, the optimal cut-off score predicting sustained gains (relative to baseline) was 12 (sensitivity = .83; specificity = .78), suggesting that a Y-BOCS score of 12 or less at the time of treatment termination predicts sustained benefits at one year follow-up (see Figure 2b).

Figure 2

Cut-off Points on the Y-BOCS



Note. Receiver-operating characteristic (ROC) curves with optimal cut-off points on the Y-BOCS at post-treatment to classify a) for deterioration (vs. stability) at follow-up and b) for sustained gains (response, remission, or both) at follow-up. AUC = Area under the ROC curve.

Medication and Subsequent Outpatient Therapy

Sixty-seven patients were free of psychotropic medications from post-treatment to follow-up. Twenty patients discontinued medications after post-treatment, but seven of them were again medicated at follow-up. Thirty patients were medicated continuously from post-treatment to follow-up. For three patients, data about medication at follow-up was missing. Most common were SSRIs (n = 33). A significant association between medication status (no medication, discontinued, discontinued and medicated again, continuously medicated) and outcome category at follow-up was observed (p = .015), with higher remission rates for medication-free patients and discontinuers (61.2% and 69.2%) than for continuously medicated patients (26.7%). No significant association could be observed for medication status and deterioration (p = .402) at follow-up assessment.

Eighteen patients sought additional outpatient therapy of more than five sessions after post-treatment. Subsequent therapy was neither correlated with outcome category at post-treatment (p = .067), nor at follow-up assessment (p = .086), but at both assessment points, patients without remission sought additional therapy more frequently than remitters on a trend level.

Discussion

The present study aimed to examine whether remission status and symptom levels at post-treatment are predictive for long-term stability of improvements after cognitive behavioral therapy for OCD. In addition, we intended to evaluate the general effectiveness of individual cognitive behavioral therapy in a sample of 120 patients by conducting a follow-up assessment one year after termination of treatment in routine clinical practice.

Applying the recently published Y-BOCS consensus criteria (Mataix-Cols et al., 2016) to classify patients as non-responders, responders, or remitters showed that response only at post-treatment was associated with a significantly higher likelihood for deterioration. Among the patients who benefited from CBT, those who achieved remission by the end of treatment had a considerably higher chance of maintaining initial improvement. Given the fact that stability and deterioration were defined by absence or presence of reliable changes (RCI), the criterion variable was not confounded with the consensus criteria. While similar findings have been shown in previous studies, these applied different remission criteria (Braga et al., 2005; Braga et al., 2010; Eisen et al., 2013). To our knowledge, the present findings are the first to show the predictive value of the consensually recommended Y-BOCS cut-off score, and thus confirm its validity in terms of long-term stability.

Considering that different cut-off scores have proven to predict long-term stability, we sought to determine a Y-BOCS score at post-treatment that best predicts deterioration versus stability one year later. Receiver-operating characteristic (ROC) curves pointed to a cut-off point of ≥ 13 for classifying for future deterioration. As stability until follow-up may not be sufficient to assume long-term improvement, we finally determined a cut-off score to classify for sustained benefits at follow-up relative to pre-treatment. The resulting cut-off score of ≤ 12 implies that patients with a Y-BOCS score of twelve or lower at post-treatment are likely to show long-term therapy benefits compared to patients with higher scores. Notably, the identified critical symptom levels are almost identical to the proposed expert consensus cut-off score for remission.

These findings highlight the utility of a Y-BOCS cut-off score of ≤ 12 for defining remission status at post-treatment and add to previous evidence that subthreshold symptom severity protects patients with mental disorders from later deterioration (Braga et al., 2005; Braga et al., 2010; Judd et al., 1998; Paykel et al., 1995; Van Ameringen et al., 2003).

The results have implications for both etiological models and clinical practice. Different etiological models (Kalanthroff, Abramovitch, Steinman, Abramowitz, & Simpson, 2016; Robbins, Gillan, Smith, de Wit, & Ersche, 2012; Salkovskis, 1999) emphasize that compulsions contribute to the maintenance or worsening of symptoms. A reduction of symptom severity below a critical threshold may therefore weaken these dynamics. In clinical practice, the question of how to proceed if patients achieve response but not remission during the scheduled duration of psychotherapy is central. Ethical considerations may support continuation of treatment until remission is achieved. However, while

there is research on treatment of non-responders to pharmacological therapy (Albert et al., 2018; Denys, van Megen, van der Wee, & Westenberg, 2004; Pallanti, Hollander, & Goodman, 2004), there is little data on the treatment of patients who failed to reach remission status during CBT.

As we observed large effect sizes for pre-post (d = 1.87) and pre-FU (d = 1.46) periods, we were able to confirm previous findings of long-term effectiveness of individual outpatient CBT in OCD (Cabedo et al., 2018; Hans & Hiller, 2013; Hansen et al., 2019). Although our results suggest that reduced symptom levels are maintained from post-treatment to follow-up, we did observe a slight, non-significant increase in symptoms. Recurrence of OCD symptoms after treatment termination has been found in previous follow-up studies (Anderson & Rees, 2007; Barrett, Healy-Farrell, & March, 2004; Bolton & Perrin, 2008), yet not consistently (Rufer et al., 2005). The slight increase in the present study may be explained by inferior long-term symptom stability of the small group of patients that achieved response without remission: while most patients who remitted (75.4%) or did not respond (73.0%) at post-treatment remained in the same outcome category at follow-up, only 28.6% of responders remained in this category one year later. Very few patients with response (without remission) at post-treatment achieve remission one year later (14.3%), which illustrates again that response only at post-treatment indicates insufficient treatment.

One limitation of the present study stems from the treatment setting under routine conditions. Particularly, treatment did not follow a specific manual and therapy adherence was not controlled. The mean duration of therapy was longer than in most RCTs. Note, however, that "high intensity interventions" with more than 30 therapist-hours per patient have been found to yield superior effect sizes for treatment outcome compared to low and medium intensity (National Collaborating Centre for Mental Health, 2006). In the present study, the relatively long duration results from individual treatment planning, consideration of comorbid disorders, and termination of treatment on the basis of a consensual decision of patient and therapist. The duration is comparable to the average duration of outpatient psychotherapy in the public health care system in Germany (Lutz, Wittmann, Böhnke, Rubel, & Steffanowski, 2012). Thus, our data derive from treatment conditions that are typical for the German and similar health care systems and may provide high ecological validity.

Sample size constitutes another limitation, as, at post-treatment, we observed only 14 patients in the category of response without remission, and only ten participants with deterioration at follow-up. Although, considering the large number of remitted patients that indicates an overall very successful treatment, larger sample sizes would increase the statistical power of predictions of critical subgroups. Future follow-up studies should also address life events, other therapies, and medications that may influence symptom stability. Furthermore, longer follow-up intervals might enable us to make conclusions about predictors of long-term treatment benefits.

In summary, the present results suggest that the symptom level reached when terminating treatment is critical for the future course of illness. A post-treatment Y-BOCS score < 13 optimally predicts higher individual likelihood for stability one year later. This cut-off almost perfectly fits with the expert consensus criterion for remission of OCD. Thus, such a remission criterion may be a useful instrument in aiding decision making in routine clinical practice, in particular for terminating or continuing treatment.

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The Paths to Children's Disordered Eating: The Implications of BMI, Weight-Related Victimization, Body Dissatisfaction and Parents' Disordered Eating

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Abstract

Background: Being the target of peer victimization is frequent among children categorized as overweight and obese and is thought to play a central role in disordered eating behavior development. In accordance with a previous theoretical model, this cross-sectional study aimed to replicate among children the mediating role of weight-related victimization from peers and body dissatisfaction in the association between body mass index (BMI) and children's disordered eating attitudes and behaviors (CDEAB), while also taking into account the contribution of parents' disordered eating attitudes and behaviors (PDEAB).

Methods: Participants were 874 children aged between 8 and 12 years old who were recruited in elementary schools. Height and weight were measured and used to calculate BMI. Self-reported questionnaires were used to measure weight-related victimization, body dissatisfaction, CDEAB and PDEAB.

Results: For both girls and boys, a path analysis showed no direct effect of BMI on CDEAB, but a significant indirect effect was found, indicating that weight-related victimization and body dissatisfaction mediated this relationship. In addition, the indirect effect of weight-related victimization and body dissatisfaction remained significant even when controlling for PDEAB.

Conclusion: While weight itself appears to be insufficient to explain CDEAB, weight-related victimization may lead children to see their weight as problematic and develop disordered attitudes and behaviors toward eating. This suggests that weight-related victimization from peers and body dissatisfaction must be taken seriously and that preventive and intervention efforts must be pursued.

Keywords

weight-related victimization, disordered eating behaviors, body dissatisfaction, body mass index, children, cross-sectional study

Highlights

- Body weight *per se* seems insufficient to explain children's disordered eating attitudes and behaviors (CDEAB).
- Weight-related victimization and body dissatisfaction mediate the association between BMI and CDEAB.
- Parents' DEAB is associated with CDEAB.
- The tested paths from BMI to CDEAB appear to be globally the same for boys and girls.

Despite decades of efforts to prevent overweight and obesity, its prevalence is on the rise among children in developed and in developing countries (Ng et al., 2014). Children categorized as overweight or obese are at an elevated risk for disordered eating (Tanofsky-Kraff et al., 2004). Some public health programs designed to prevent overweight actually use weight stigmatization as a tool to sensitize people to the consequences of obesity (e.g., Georgia's Strong4Life campaign; Teegardin, 2012). However, these programs may be counterproductive and instead increase weight-related victimization. In return, experiencing weight-related victimization may contribute to disordered eating among youth who present with overweight or obesity (Libbey, Story, Neumark-Sztainer, & Boutelle, 2008). Although there is existing literature linking weight-related victimization and eating behaviors, no research has examined this association while taking into account parents' disordered eating, which has been extendedly related to children's disordered eating (Scaglioni, Salvioni, & Galimberti, 2008). The current study mostly replicates previous work by assessing the mediating roles of weight-related victimization from peers and body dissatisfaction in the association between body mass index (BMI) and children's disordered eating, and extends past reports by controlling for parents' disordered eating.

Weight-related victimization includes cognitive and behavioral aspects. The cognitive aspect covers bias and stereotyping based on one's weight. This leads to the belief that individuals categorized as overweight are lazy, lack self-discipline, have poor willpower, and show defects of intelligence and character. The behavioral aspect of weight-related victimization can materialize in verbal, physical and relational victimization, such as teasing, bullying, pushing and social exclusion (Puhl & Latner, 2007). Some studies demonstrated that children as young as 3 years old may be victimized because of their weight (Cramer & Steinwert, 1998; Rodgers, Wertheim, Damiano, Gregg, & Paxton, 2015). Therefore, weight-related victimization may start at a very young age. During the school years, weight-related victimization behaviors become frequent and mostly impact overweight children (see Puhl & Heuer, 2009; Puhl & Latner, 2007 for a review). For instance,

many studies have shown that children and adolescents categorized as overweight are at a greater risk of being teased about their weight by school peers, educators, family members and peers of family members compared to their counterparts categorized as normal weight (Brixval, Rayce, Rasmussen, Holstein, & Due, 2012; Hayden-Wade et al., 2005; Neumark-Sztainer et al., 2002).

Among all weight-related victimization behaviors, teasing has been largely studied, most likely because it is common among youth (Hayden-Wade et al., 2005). Weight-related teasing is associated with various negative psychosocial consequences in children and adolescents, such as loneliness and preference for sedentary-isolative activities, social anxiety, poor quality of life and depression (Hayden-Wade et al., 2005; Juvonen, Lessard, Schacter, & Suchilt, 2017; Stevens, Herbozo, Morrell, Schaefer, & Thompson, 2017). Weight-related teasing also seems to be the starting point for many negative consequences related to eating and weight problems in adolescents. For example, parents, siblings and peer teasing were linked to body dissatisfaction in girls and to drive for muscularity in boys (Schaefer & Blodgett Salafia, 2014). Furthermore, weight-related teasing has been linked to the drive for thinness and disordered eating behaviors such as binge-eating, compensatory behaviors, and dietary restraint (Cook-Cottone et al., 2016; Haines, 2006; Neumark-Sztainer et al., 2002; Zuba & Warschburger, 2017). A recent longitudinal study noted that weight-related teasing in adolescence predicted resorting to disordered eating behaviors as a coping strategy, which in turn resulted in a higher body mass index (BMI) or into obesity 15 years later (Puhl et al., 2017).

Recently, the effect of weight-related teasing on disordered eating behaviors was validated in a few prospective studies. Most of these studies seemed to build their prospective design on a pioneering study by Thompson, Coovert, Richards, and Johnson (1995). Thompson and colleagues (1995) proposed a path analysis with a sample of girls aged 13-18 years old. In their model, the level of obesity at the baseline influenced weight-related teasing at the baseline, which further influenced body image (weight and appearance dissatisfaction) at the 3-year follow-up. Furthermore, body image at the 3-year follow-up influenced disordered eating behaviors such as bulimic behaviors and dietary restraint at the 3-year follow-up. Jendrzyca and Warschburger (2016) presented a similar comprehensive model of disordered eating behaviors in children. In their prospective design, 1,486 children aged 6-11 years old in Germany completed height and weight measurements (used for BMI calculation) and questionnaires related to eating, weight and body image (weight-related stigmatization, including weight-related teasing, body dissatisfaction and disordered eating behaviors) twice with a one-year interval. For girls, BMI at the baseline was significantly associated with the baseline weight-related stigma, which predicted body dissatisfaction one year later, which in turn predicted disordered eating behaviors, also at the one-year follow-up. For boys, a different pattern was found. BMI at the baseline was significantly associated with the baseline weight-related stigma, and body dissatisfaction at the one-year follow-up predicted disordered eating behaviors

at the one-year follow-up, but baseline weight-related stigma did not predict body dissatisfaction at the one-year follow-up. Using a similar model, Pryor and colleagues (2016) found that children categorized as overweight and targeted by peers' victimization between 6 and 12 years old tended to be less satisfied with their bodies (they wanted to be thinner) and to report increased depression and anxiety at 13 years old.

Thereby, some authors implied that weight-related victimization should be included in a comprehensive model of disordered eating behaviors development (Jendrzyca & Warschburger, 2016). However, most available studies have only targeted adolescent populations. Furthermore, studies tend to report mixed results regarding possible sex specific effects, and parental influences are often overviewed. However, parents' eating behaviors have a major influence on their children's eating behaviors, especially at a younger age (Scaglioni, et al., 2008; Ventura & Birch, 2008; Wertheim, Martin, Prior, Sanson, & Smart, 2002; Wertheim, Mee, & Paxton, 1999). Therefore, to better assess (and not overestimate) the influence of weight-related victimization and body dissatisfaction in a comprehensive model of disordered eating behaviors in children categorized as overweight or obese, the influence of parents' eating behaviors should be considered.

The present study aimed to examine the mediating role of 1) weight-related victimization from peers, as perceived by children, and 2) body dissatisfaction in the association between BMI and children's disordered eating attitudes and behaviors (CDEAB) among 8-12 years old boys and girls, controlling for parents' disordered eating attitudes and behaviors (PDEAB). It was expected that a higher BMI would be associated with greater CDEAB, mediated by perceived weight-related victimization and body dissatisfaction (serial) for both boys and girls. Moreover, it was hypothesized that PDEAB would be positively associated with CDEAB.

Method

Participants

Participants were 874 children aged between 8 and 12 years old and one of their parents. They were recruited from 27 public elementary schools located in two urban areas in the province of Quebec, Canada. The sample was composed of 44% boys and 56% girls. Their mean age was 10.29 (*SD* = 1.19). Among the sample, 1.5% of the children could be classified in the underweight category, 69.3% in the normal weight category, 20.9% in the overweight category and 8.3% in the obese category. Regarding weight-based victimization, 24.4% of children reported having been teased about their weight at least once. The participating parents were mostly mothers (86%). Their mean age was 39.65 years old (*SD* = 5.69), and their mean BMI was 26.23 (*SD* = 5.04). Almost all of the children were born in Canada (95%) and came from a family where their parents were either married or living in a common-law relationship (83%). On average, these children came from wealthy and

educated families. Nearly a third had an annual family income of $100,000 or more, which was over the average wage (approximately $73,000) in the province of Quebec (Statistics Canada, 2019). Furthermore, almost the half of the children had a parent with a university diploma, while about 35% of the population of the province of Quebec had achieved an academic degree (Crespo, 2018).

Procedure

The children were recruited to participate in a study about body weight, body image and eating and physical activity habits. The study was presented to them in class. Interested children were given an envelope containing both parents and children questionnaires, as well as informed consent form. Both the children and parents were asked to complete questionnaires at home (approximately 45 minutes for parents and 30 minutes for children). Parents were instructed to let their children fill autonomously the questionnaires. Children returned the completed questionnaires to their teacher, and were met individually at school by a trained research assistant to collect their anthropometric (height and weight) measures. All of the parents gave written informed consent (approved by University's Institutional Review Board of Laval University) prior to their inclusion in the study, and children provided their assent to participate. The children who completed the questionnaires were included in a lottery drawing to win a $100 gift card to a sports shop.

Measures

Children's BMI

Height and weight were measured individually and out of sight of the children's peers and only one time as recommended by Lohman, Roche, and Martorell (1988), and trained research assistants used a metric scale and a numeric weighing scale. Height was measured to the nearest 0.1 centimeter and weighed to the nearest 0.2 pound. Measurements in pounds were then transformed into kilograms. Gender specific BMI-for-age *z* scores were computed based on the World Health Organization recommendations (WHO Multicentre Growth Reference Study Group, 2006). The children's BMI was classified into four categories (underweight, normal weight, overweight, or obese) still according to the WHO recommendations. These categories were used to describe the sample and for the mean comparisons, and BMI *z*-scores were used as a continuous variable in the path analyses.

Perceived Weight-Related Victimization by Peers

Perceived weight-related victimization was measured with a question adapted from the Children's Social Experience Questionnaire (Crick & Grotpeter, 1996). The question "How often does another child say negative things about your weight?" was answered on a

5-point Likert scale ranging from 1 (never) to 5 (all the time). A higher score indicated a higher level of perceived weight-related victimization by peers.

Body Dissatisfaction

Body dissatisfaction was evaluated with two questions inspired by Collins (1991). One evaluated actual body perception (How would you describe your body? With answers ranging from 1 "far too thin" to 5 "far too big"), while the other evaluated desired body (How would you like your body to be? With answers ranging from 1 "a lot thinner" to 5 "a lot bigger"). We further subtracted the desired body from the actual body perception. The discrepancy between the perceived and the desired body provided an indication of the level of body dissatisfaction, with a negative score reflecting a desire for a thinner body and a positive score reflecting a desire for a larger body.

Children's Eating Attitudes Test

The children's version of the Eating Attitudes Test (ChEAT; Maloney, McGuire, & Daniels, 1988) was used to measure disordered eating attitudes and behaviors. The ChEAT is a 26-item self-report questionnaire, with a 6-point Likert scale ranging from 1 (never) to 6 (always). The total score was used. A higher score reflects more disordered eating attitudes and behaviors. Its reliability and concurrent validity have been demonstrated previously (Maloney, McGuire, Daniels, & Specker, 1989; Smolak & Levine, 1994). The Cronbach's alpha was .79 in the present sample.

Eating Attitudes Test

The Eating Attitudes Test (EAT-26; Garner, Olmstead, Bohr, & Garfinkel, 1982) was used to measure parents' disordered eating attitudes and behaviors. The EAT is a 26-item self-report questionnaire which uses a 6-point Likert scale ranging from 1 (never) to 6 (always). The total score was used. A higher score reflects more disordered eating attitudes and behaviors. The questionnaire has adequate reliability (Koslowsky et al., 1992). The Cronbach's alpha was .87 in the present study.

Statistical Analyses

Prior to analyses, all variables' distributions were inspected, and appropriate transformations were applied when needed in order to respect the basic assumptions. First, *t*-test and ANOVA analyses were run to compare the children on the three study dependent variables (weight victimization, body dissatisfaction and CDEAB) based on their sex and BMI category. Afterward, the proposed model was tested with a path analysis using Mplus version 7.0 (Muthén & Muthén, 2012). Path analysis is a statistical method that allows the simultaneous testing of both direct and indirect associations among different variables (Kline, 2011).

In this model, BMI was used as an independent variable with both weight-related victimization and body dissatisfaction as mediators (serial mediation), and CDEAB was used as the dependent variable. PDEAB was included as a control variable. Because standard errors underlying indirect effects (i.e., product terms) are known to be skewed, we instructed Mplus to generate 1000 bootstrap samples from the data to create indirect effects with bias-corrected 95% confidence intervals (CIs; MacKinnon, Lockwood, & Williams, 2004). Indirect effects would only be found to be significant if the CIs would not include zero.

To determine whether the model provided a good fit for the data, three indices recommended by Hu and Bentler (1999) were used: the Comparative Fit Index (CFI), the standardized root mean square residual (SRMR), and the root mean square error of approximation (RMSEA). The determined threshold values indicating a good fit are CFI ≥ .95, SRMR ≤ .08, and RMSEA ≤ .06 (Hu & Bentler, 1999). A good fit of the model can also be identified by a nonsignificant $\chi 2$ value (Tabachnick & Fidell, 2001).

Results

Mean Comparisons

The results from *t*-tests and ANOVAs, as well as means and standard deviations, are presented in Table 1. Weight-related victimization was similar for boys and girls but significantly differed across weight statuses. Children categorized as obese reported more frequent weight-related victimization compared to children categorized as underweight, normal weight and overweight (all p values < .001). Children categorized as overweight also reported more victimization than peers categorized as normal weight (p < .001). Body dissatisfaction differed between boys and girls, as well as across weight statuses. As expected, girls were significantly more dissatisfied with their body than boys. Children categorized as obese were more dissatisfied with their body than children categorized as underweight, normal weight and overweight (all p values < .01). Children categorized as overweight were also more dissatisfied than children categorized as normal weight (p < .001). Finally, for CDEAB, girls reported significantly higher scores than boys. Across weight statuses, children categorized as obese reported more disordered eating attitudes and behaviors than children categorized as overweight or normal weight (all p values < .01).

Table 1

Means and Standard Deviations by Sexes and by Weight Categories

	Sex				Weight category								*t*	*F*
	Girls		Boys		Under-weight		Normal		Over-weight		Obesity			
Variable	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*	Sex	Weight category
Weight-related victimization	1.40	0.80	1.36	0.74	1.23	0.60	1.24	0.58	1.53	0.88	2.17	1.19	-0.72	39.50***
Body dissatisfaction	0.62	0.95	0.49	0.84	0.75	1.29	0.36	0.74	0.80	0.94	1.64	1.05	-2.17*	59.04***
CDEAB	6.44	5.56	5.55	3.98	5.62	4.31	5.52	4.19	6.49	5.50	9.40	7.59	-1.60*	10.20***

Note. N = 874 children. CDEAB = children's disordered eating attitudes and behaviors.
*p < .05. ***p < .001.

Path Analyses

Pearson's correlations between the variables studied are presented in Table 2. The proposed theoretical model was first tested with path analyses separately for both boys and girls. The results showed very similar patterns among boys and girls. Therefore, we expected the models to be invariant with regard to sex and we performed multigroup tests. The nonsignificant adjusted difference of the chi-square, $\chi^2(5) = 6.579$, $p = .254$, showed that the model was invariant by sex on all the tested paths except the BMI-body dissatisfaction one. That is, the tested paths were similar for boys and girls, but the path between BMI and body dissatisfaction was slightly different regarding the strength of the association, $\beta = .33$ ($p < .0001$) for girls and $\beta = .18$ ($p = .003$) for boys. Since this minor sex difference did not affect the direction nor the signification of the association between BMI and body dissatisfaction, a single model will be presented for girls and boys for the sake of parsimony.

Table 2

Pearson's Correlations Between Studied Variables

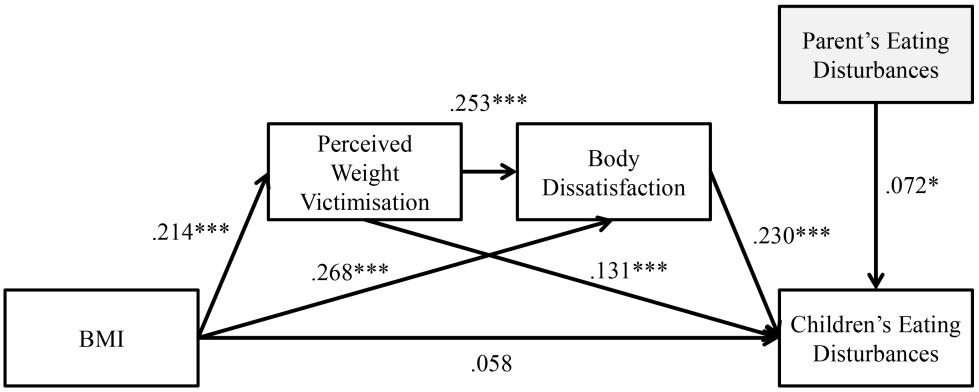
Variable	1	2	3	4	5
1. CDEAB	–	.09**	.16**	.22**	.29**
2. PDEAB		–	.08*	.04	.05
3. BMI			–	.21**	.32**
4. Weight-related victimization				–	.31**
5. Body dissatisfaction					–

Note. N = 874 children. CDEAB = children's disordered eating attitudes and behaviors. PDEAB = parents' disordered eating attitudes and behaviors.
*p < .05. **p < .01.

The fit indices revealed that the tested model provided a good fit to the data: CFI = .99, SRMR = .02, RMSEA = .03. The nonsignificant chi-square value also indicated that the data were adequately represented by the model, $\chi^2(3) = 5.59$, $p = .133$. The model with standardized path coefficients is presented in Figure 1. The model explained 11% of the variance of the main dependent variable (CDEAB; $R^2 = .11$).

Figure 1

Relationships Among Studied Variables in Boys and Girls, With Standardized Coefficients



Note. $N = 874$ children.
$^{*}p < .05$. $^{**}p < .01$. $^{***}p < .001$.

In this model, BMI did not have a direct effect on CDEAB (β = .06; $p = .097$). Rather, three different paths (indirect effects) were statistically significant: 1) BMI was associated to CDEAB through weight-related victimization and body dissatisfaction (β = .01, 95% bootstrap CI [.001, .005]; 2) BMI was associated to CDEAB through perceived weight-related victimization (β = .03, 95% bootstrap CI [.003, .012]; and 3) BMI was associated to CDEAB through body dissatisfaction (β = .06, 95% bootstrap CI [.010, .021]. The results of the path analyses further confirmed the relevance of adding the control variable PDEAB, since its positive association with CDEAB was significant (β = .07; $p < .05$).

Discussion

The aim of this study was to mostly replicate previous work (Jendrzyca & Warschburger, 2016; Thompson et al., 1995) by examining the mediating role of weight-related victimization from peers as perceived by children aged 8 to 12 years old and body dissatisfaction in the association between BMI and CDEAB, and to extend previous studies by taking into account the contribution of PDEAB. Overall, the results confirmed our hypotheses and

revealed that BMI was associated with disordered eating only through its associations with perceived weight-related victimization and body dissatisfaction. Parental disordered eating was also associated with higher disordered eating among children.

First, the level of perceived weight-related victimization and body dissatisfaction were significantly different across weight statuses. Children categorized as overweight or obese reported more weight-related victimization and body dissatisfaction compared to children categorized as normal weight. This is consistent with what others have previously reported (Brennan, Lalonde, & Bain, 2010; Neumark-Sztainer et al., 2002; Puhl & Latner, 2007). The level of perceived weight-related victimization was similar for boys and girls, but girls were significantly more dissatisfied with their body than boys were. This may be because girls, even at this age, present a higher risk of being exposed to media and beauty pressure, resulting in higher preoccupation with their weight and body shape. It could also be that for boys, body dissatisfaction kicks in later or that it may be more about looking fit and muscular than looking thin (Barlett, Vowels, & Saucier, 2008; Brennan et al., 2010; Dion et al., 2016; Thompson & Chad, 2000).

Even though girls reported more body dissatisfaction than boys did, the same trajectory from BMI to CDEAB applied for both sexes, since the model was, globally, statistically invariant in regard to sex. Considering that BMI had no direct effect on CDEAB, weight *per se* appears to be insufficient to explain the development of disordered eating attitudes and behaviors. Most likely, it is the negative experience, mostly interpersonal, associated with being categorized as overweight or obese that may influence children and adolescents to see their weight as problematic. As demonstrated in this study, high BMI was associated with CDEAB through the indirect effect of perceived weight-related victimization and body dissatisfaction. Furthermore, BMI was also associated with CDEAB through the indirect effect of perceived weight-related victimization and body dissatisfaction separately. Along with the findings of Jendrzyca and Warschburger (2016), the present results suggest that weight-related victimization and body dissatisfaction might play a key role in the likelihood of developing disordered eating attitudes and behaviors for children who present as overweight or obesity. This highlights the need to fit in, as children grow older, and the important effect that these relationships with peers have on children. In addition, it may provide a clue about why body dissatisfaction is different between girls and boys. This might be likely because the importance of interpersonal experiences may change greatly from childhood to adolescence and differently for girls and boys. However, the cross-sectional design of the present study calls for caution, and additional prospective studies are needed to confirm those hypotheses.

The fact that our study took into account the contribution of PDEAB was an important strength. While the association between PDEAB on CDEAB does not need to be proven further (Scaglioni et al., 2008; Ventura & Birch, 2008; Wertheim et al., 2002; Wertheim et al., 1999), it still has to be considered when predicting CDAEB in order to avoid overestimating the effect that weight-related victimization has on it. Had we not

statistically controlled for PDEAB, one could have thought that the association between BMI, weight-related victimization, body dissatisfaction and CDAEB may be explained by parental influences. However, although parents may influence the development of disordered eating in their children as they approach adolescence, these youths may be even more affected by their experiences with peers. As they get older, negative experiences such as weight-related victimization can seriously affect the way children evaluate themselves and push them to try to modify their weight and appearance to like themselves better and better fit in their peer group (Vander Wal, 2012). Another strength of this study was to target elementary school girls and boys. Studies that focus on weight-related victimization and body dissatisfaction have previously targeted, for the most part, high school adolescents. It appeared important to replicate the results from adolescents' studies with younger children since disordered eating attitudes and behaviors can be adopted early and can be especially harmful (Goldschmidt, Aspen, Sinton, et al., 2008). The recruiting process is another important element of this study. To favor a diversified sample, 874 children from 27 public elementary schools were included in our path analysis. Finally, it was a great strength to use objective anthropometric measures because parents are likely to misreport their children's weight and height (Brault, Turcotte, Aimé, Côté, & Bégin, 2015).

Some limitations of this study should be considered. First, as mentioned earlier, the cross-sectional design does not allow for drawing causal conclusions. However, the paths proposed follow a logical cascade in time that has already been demonstrated in a prospective design (Jendrzyca & Warschburger, 2016). Second, weight-related victimization from peers and body dissatisfaction were measured with single items. Moreover, no specific time frame was given in the question assessing victimization. The use of validated questionnaires for our two mediating variables would have significantly enhanced internal validity. Since the same measurement limitation applies to the prospective study of Jendrzyca and Warschburger (2016), future studies may benefit from testing weight-based victimization and body dissatisfaction with complete validated scales. Nonetheless, despite the limitation that represents the use of single item measures (i.e., underestimation of the strength of the tested associations; Menzel et al., 2010), the present study successfully detected statistically significant effects between studied variables, which suggests robust associations. Another limitation stems from the representativeness of the sample. Indeed, higher-educated wealthy families were over represented. Since disordered eating behaviors and body dissatisfaction have been previously found to be higher in high socioeconomic status (SES) children compared to low SES children (Adams et al., 2000; O'Dea & Caputi, 2001), it would be of great interest to replicate our results in a more diversified sample in terms of SES. Additionally, it would be of great interest to assess victimization from different points of view, (i.e., reported not only from children but also from teachers and parents) to verify whether it is weight victimization *per se* which is associated with negative psychological outcomes or feeling victimized. Different

sources of comments should also be studied, since parental comments on weight might be very harmful for young people (Neumark-Sztainer et al., 2010).

Conclusion

This study adds to the limited data currently available in the field of the early development of disordered eating behaviors (before adolescence). An important contribution of this study was to consider the implication of PDEAB in a comprehensive model of eating attitudes and behaviors in children. A model in which weight-related victimization experienced by children was associated with body dissatisfaction and disordered eating attitudes and behaviors was replicated. While weight itself appears to be insufficient to explain disordered eating, interpersonal experiences might be what influence children to see their weight as problematic and adopt disordered attitudes and behaviors toward eating. This suggests that weight-related victimization from peers and body dissatisfaction must be taken seriously and that prevention and intervention efforts must be pursued.

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Integrating Cognitive Behavioral Group Therapy and Psychodrama for Social Anxiety Disorder: An Intervention Description and an Uncontrolled Pilot Trial

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Abstract

Background: Cognitive behavioral therapy (CBT) is generally considered to be the most effective psychological treatment for social anxiety disorder (SAD). Nevertheless, many patients with SAD are still symptomatic after treatment. The present pilot study aimed to examine integrating CBT, with a focus on cognitive and behavioral techniques, and psychodrama, which focuses more on experiential techniques into a combined treatment (CBPT) for social anxious patients in a group format. This new intervention for SAD is described session-by-session.

Method: Five adult female patients diagnosed with social anxiety disorder participated in a twelve-session CBPT in a group format. Pretest and posttest scores of social anxiety, avoidance, spontaneity, cost and probability estimates of negative social events, depression, and quality of life were compared, as were weekly assessments of fear of negative evaluation.

Results: Results demonstrated a significant reduction of the fear of negative evaluation and social anxiety symptoms. It is noteworthy that also the scores of the probability and cost estimates decreased. However, there were no significant differences between pre and post measures in any of other measures.

Conclusion: The current study suggests that group CBPT might be an effective treatment for SAD. However, our sample size was small and this was an uncontrolled study. Therefore, it is necessary to test this intervention in a randomized controlled trial with follow-up assessments.

Keywords

integrating therapies, cognitive behavioral therapy, psychodrama, social anxiety disorder, clinical trial

Highlights

- This study describes integrating cognitive behavioral therapy and psychodrama (CBPT).
- CBPT significantly reduced fear of negative evaluation and social anxiety.
- Three of the five patients have a clinically significant change on the LSAS after the treatment.
- CBPT also changed estimates of social cost and the probability of negative social events.

Social anxiety disorder (SAD) is one of the most common mental disorders, with a 13% lifetime prevalence (Kessler, Petukhova, Sampson, Zaslavsky, & Wittchen, 2012). Recent research shows that the prevalence of SAD in Iran is approximately 10% (Talepasand & Nokani, 2010). Depression is highly comorbid with SAD and more than half of the patients report lifetime major depression (Brown, Campbell, Lehman, Grisham, & Mancill, 2001). SAD is associated with increased functional disability, substantial economic inactivity, and a lower quality of life (Patel, Knapp, Henderson, & Baldwin, 2002). Therefore, it is important to treat SAD effectively.

Several meta-analyses show that cognitive behavioral therapy (CBT) is the most effective psychotherapy for SAD (Hofmann & Smits, 2008; Mayo-Wilson et al., 2014). CBT is an eclectic approach based on a combination of techniques from cognitive and behavioral theories (Harwood, Beutler, & Charvat, 2001). Cognitive behavioral group therapy (CBGT), as developed by Heimberg and Becker (1991, 2002) is an efficacious and evidence-based treatment for SAD. The effect of CBGT on social anxiety symptoms has been demonstrated in meta-analyses (Barkowski et al., 2016; Mayo-Wilson et al., 2014). CBGT usually consists of cognitive restructuring, exposure and homework assignments (Coles, Hart, & Heimberg, 2005; Heimberg & Becker, 2002). Judgmental biases such as beliefs about the cost and probability of negative social events play an important role in the maintenance of SAD (Clark & Wells, 1995; Heimberg, Brozovich, & Rapee, 2010; Hofmann, 2007; Morrison & Heimberg, 2013). There is an association between CBT treatment and a reduction in probability or cost estimates for individuals with SAD (Foa, Franklin, Perry, & Herbert, 1996; Gregory, Peters, Abbott, Gaston, & Rapee, 2015; Hofmann, 2004; Lucock & Salkovskis, 1988; Poulton & Andrews, 1994). Hence, CB(G)T is an effective treatment for SAD. However, 25-50% of patients with SAD show little or no improvement after treatment (Davidson et al., 2004; Heimberg et al., 1998; Hofmann & Bögels, 2006). Thus, many patients remain symptomatic after completing treatment, and it is clear that there is room to improve interventions to enhance clinical outcomes for SAD.

We propose that CBT and psychodrama can be integrated to enhance treatment effects. Psychodrama is an action-based method of group psychotherapy, developed

by Jacob Levy Moreno (Moreno, 1946). In psychodrama, patients use role-playing to dramatize their psychological and social problems rather than just talking about them (Blatner, 2000). Furthermore, psychodrama can enhance the potency of therapeutic alliance and create a therapeutic bond between group members by letting patients engage in role-playing and the playing of auxiliaries in the other members' enactment, and by evoking emotions during action (Orkibi, Azoulay, Regev, & Snir, 2017). Several studies with non-SAD samples on the combination of CBT and psychodrama demonstrated that CBT and psychodrama could be integrated (Boury, Treadwell, & Kumar, 2001; Hamamci, 2002, 2006; Treadwell, Kumar, & Wright, 2002). There are several reasons why psychodrama techniques can enhance therapy outcome for SAD patients as well. First, several acting techniques in psychodrama do not occur in CBGT but might be helpful, because they involve experiential learning (see Table 2 for a description of typical psychodrama techniques and their goals for treatment of SAD), whereas the focus of traditional CBT is on cognitive and behavioral learning. Second, there is increasing evidence that (traumatic) childhood experiences contribute to the development of SAD (Arrindell, Emmelkamp, Monsma, & Brilman, 1983; Blöte, Miers, & Westenberg, 2015; Bruch & Heimberg, 1994; Kuo, Goldin, Werner, Heimberg, & Gross, 2011; Simon et al., 2009). Psychodrama provides an opportunity to reenact a negative social interaction from the past as if it occurs in the present, but now in the safe setting in which the patient has more control over what is said and done. This might, in turn, change the patient's beliefs, feelings, and attitudes about the traumatized situation (Treadwell & Kumar, 2002). Third, socially anxious people devote effort to control the expression of feelings and suppress their emotions to minimize the chance of making social transgressions and elicit rejection by others (Kashdan & Steger, 2006). They also report a fear of experiencing emotions and more negative beliefs about the consequences of emotional expression (Spokas, Luterek, & Heimberg, 2009). In psychodrama, a safe environment is created which can help patients to express their inhibited emotions and examine the accuracy of their beliefs about the negative outcomes of this. Finally, according to Moreno's theory, anxiety decreases by increasing spontaneity. In CBT-terms, spontaneity can be seen as the opposite of avoidance and inhibition that is central to SAD. One of the aims of psychodrama is to increase spontaneity.

There is no research to demonstrate that CBT and psychodrama can be integrated into the treatment of social anxiety disorder. The main aim of this pilot study is to describe the intervention and examine the integrated group CBT-psychodrama protocol (labelled CBPT) to treat social anxious patients and to get a first impression of its effectiveness. We hypothesized that CBT and psychodrama can be successfully integrated and that this integration is effective in improving fear of negative evaluation, the characteristic feature of SAD, which was measured by the Brief Fear of Negative Evaluation Scale (BFNE), and social anxiety symptoms, which were measured by the Liebowitz Social Anxiety Scale (LSAS). Furthermore, integrating psychodrama and CBGT might be efficacious for SAD

because they focus on separate mechanisms. Psychodrama focuses on increasing spontaneity and decreasing avoidance behavior through role-playing. CBGT, on the other hand, focuses on decreasing cognitive biases associated with SAD and decreases avoidance behavior through exposure. The CBPT, therefore, might offer a broader treatment which might also affect depression, an often comorbid disorder with SAD, and increase the quality of life in patients suffering from SAD.

Method

Participants

Six patients with a primary diagnosis of social anxiety disorder were included in this study; all were diagnosed with the Structured Clinical Interview for DSM 4th ed (SCID-I, Farsi Version; First, Spitzer, Gibbon, & Williams, 2012). Participants were recruited through the media and poster advertisements. One participant dropped out of the study because she found a full-time job before the first session, and was therefore not included in the analysis. All the patients were females, living in Tehran. The mean age of the five patients was 36.6 (age range = 21-63; *SD* = 17.89). Three of them were diagnosed with generalized and two of them with specific SAD. An Iranian ethical committee (reference number IR.UMSHA.REC.1394.521) approved the protocol on February 27, 2016, and all patients gave their written informed consent prior to their inclusion in the study. This study is a preparatory pilot for an RCT that included the CBPT protocol as an arm. The RCT was preregistered at a trial register (IRCT2016032321385N1). Inclusion criteria were SAD as a primary diagnosis, age between 18 and 65 years, ability to read and understand the questionnaires and the interview. Exclusion criteria were comorbid psychotic or bipolar disorder, lifetime history of schizophrenia or bipolar disorder, a high suicidality risk, antisocial or borderline personality disorder, a comorbid diagnosis of substance abuse or dependence. Furthermore, unwillingness to stabilize medication for the duration of the study was an exclusion criterion as well.

Procedures and Measures

Social anxiety was assessed with the clinician-administered version of the LSAS (Liebowitz, 1987) at pre and posttests by an independent assessor and the Brief Fear of Negative Evaluation Scale (BFNE; Rodebaugh et al., 2004; Weeks et al., 2005) was completed before the treatment and also after every treatment session (thus in total there were 13 measurements). Additionally, the patients were assessed at pre and posttests on the following outcomes: social avoidance with the Social Avoidance and Distress Scale (SADS; Watson & Friend, 1969); spontaneity with the Personal Attitude Scale-II (PAS; Kellar, Treadwell, Kumar, & Leach, 2002); and cost and probability estimates of negative social events with the Outcome Probability Questionnaire (OPQ; Uren, Szabó,

& Lovibond, 2004) and the Outcome Cost Questionnaire (OCQ; Uren et al., 2004). Depression was measured with the Beck Depression Inventory (BDI; Beck, Steer, & Brown, 1996), and quality of life was measured with the Quality of Life Inventory (QOLI; Frisch, Cornell, Villanueva, & Retzlaff, 1992).

For the several questionnaires, no Persian version existed (e.g., Quality of Life Inventory, Outcome Probability Questionnaire, Outcome Cost Questionnaire, and Personal Attitude Scale-II). Therefore, these were translated and back-translated to ensure the adequacy of the translation.

Finally, therapists used a session report form to record the procedures used in the session, such as the name of the protagonist and the auxiliaries, the type of therapeutic techniques that were used (e.g., role reversal, cognitive challenging), and also patients' feedback on the therapy session.

Primary Outcomes

The Brief Fear of Negative Evaluation Scale (BFNE; Rodebaugh et al., 2004; Weeks et al., 2005), is a self-report measure consisting of 12 items on a 5-point Likert scale (1 = *strongly disagree*, 5 = *strongly agree*). An example question is: "I am afraid that others will not approve of me". The BFNE has excellent internal consistency (Cronbach's alpha > .92) and validity in clinical samples (Weeks et al., 2005).

The Liebowitz Social Anxiety Scale – clinician-administered version (LSAS; Liebowitz, 1987) is a 24-item interview that assesses fear and avoidance, in social interactions (e.g., talking with people you don't know very well) and performance situations (e.g., returning goods to a store). The items are on a 4-point-Likert scale (0 = *never*, 3 = *usually*). The LSAS has shown good test–retest reliability, internal consistency, and convergent and discriminant validity (Baker, Heinrichs, Kim, & Hofmann, 2002; Fresco et al., 2001; Oakman, Van Ameringen, Mancini, & Farvolden, 2003; Rytwinski et al., 2009).

Secondary Outcomes

The Social Avoidance and Distress Scale (SADS; Watson & Friend, 1969) is a self-report inventory with 28-item that includes 14 items to assess social avoidance (e.g., I often want to get away from people) and 14 items to assess social anxiety (e.g., I often feel on edge when I am with a group of people). All items are rated as true or false. Cronbach's alpha reliability coefficient was .90 and the test-retest reliability was .77 in a study by Watson and Friend (1969).

The Personal Attitude Scale-II (PAS; Kellar, Treadwell, Kumar, & Leach, 2002) is a self-report measure of spontaneity. An example item is: "I am at ease when meeting new people". It has 66 items on a 5-point Likert scale (0 = *strongly disagree*; 4 = *strongly agree*). Cronbach's alpha reliability coefficient of internal consistency was .92 and the test-retest reliability was .86 in a study by Kellar et al. (2002).

The Outcome Probability Questionnaire (OPQ) and the Outcome Cost Questionnaire (OCQ) (Uren, Szabó, & Lovibond, 2004) are two self-report questionnaires consisting of 12 items. The OPQ assesses an individual's probability estimate of the occurrence of negative social events (e.g., how likely would be for you at a party, others will notice that you are nervous?). The OCQ then asks about the same negative social events but here individuals are asked to indicate how costly it would be if these events were actually to occur (e.g., how distressing would be for you if at a party, others will notice that you are nervous?). Both questionnaires have items on a 9-point Likert scale (0 = *not at all likely/distressing*; 8 = *extremely likely/distressing*). The internal consistency of both instruments is good (Cronbach's alpha ≥ .90) (Uren et al., 2004).

The Beck Depression Inventory-II (BDI-II; Beck, Steer, & Brown, 1996) is a 21-item self-report inventory that measures the severity of symptoms of depression in the previous two weeks (e.g., loss of energy, worthlessness). A good internal consistency (Cronbach's alpha = .92), and test-retest reliability have been shown in several studies (Beck, Steer, & Carbin, 1988; Beck et al., 1996).

The Quality of Life Inventory (QOLI; Frisch, Cornell, Villanueva, & Retzlaff, 1992) is a 16-item self-report questionnaire that includes 16 areas that are related to the overall happiness of life (e.g., work, health). The survey asks the participants to describe first the importance (0 = *not at all important*, 2 = *very important*) and then satisfaction (+3 = *very satisfied*, -3 = *very dissatisfied*) of each area. For each area quality of life is measured by multiplying the importance with the satisfaction which can range from -6 to +6. The internal consistency is high, Cronbach's alpha between $\alpha = 0.77$ and $\alpha = 0.89$, and the one month test-retest reliability is between $r = 0.80$ and $r = 0.91$ (Frisch et al., 1992).

Intervention

The CBPT therapists integrated cognitive restructuring and exposure with psychodrama techniques. The CBPT group underwent 12 weekly sessions each lasting 2.5 hours with five patients and two therapists (one male and one female). The therapists received training in the integrated psychodrama and CBT protocol, were trained in and had experience with conducting both psychodrama and CBGT. Furthermore, an expert in CBPT had weekly supervision meetings with the therapists to ensure the quality of the treatment. The CBPT treatment consisted of four phases: (1) an initial preparatory interview (2) building group cohesion and introduction of cognitive restructuring (Sessions 1 and 2), (3) CBT and psychodrama (Sessions 3 through 11), and (4) conclusion (the 12th session).

The treatment starts with an individual treatment orientation interview in which group treatment procedures and fear of participation in group sessions are discussed. This interview prepares patients for group sessions and makes them familiar with one of the therapists (Heimberg & Becker, 2002). Session 1 and 2 are devoted to creating a safe atmosphere in which patients can share their feelings and thoughts with other members of a group, and to the building of group cohesiveness. The sessions are based

on Heimberg and Becker's (2002) CBGT protocol and are used as basic training in cognitive restructuring. In the first session, the therapists present CBPT therapy for social anxiety and briefly explain the primary treatment techniques. Next, the session focuses on the identification of automatic thoughts. At the end of the session, patients share their individual problems, and goals and homework are assigned, which is a recording of automatic thoughts during the following week. The second session is devoted to developing cognitive restructuring skills of patients and to introduce thinking errors by practicing with the recorded automatic thoughts form. The therapists teach patients how to dispute cognitions and replace negative automatic thoughts with more helpful cognitions. Therapists also inform and prepare patients for initiation of the role-playing in the third session. At the end of the session, homework is assigned again, which is to label thinking errors in the identified automatic thoughts and to practice with cognitive restructuring (Heimberg & Becker, 2002).

Session 3 to 11 follow the stages of classical psychodrama, which includes warm-up, action, and sharing. Before the warm-up stage, the therapists review homework in order to identify automatic thoughts and thinking errors and use Socratic questioning to help patients with finding a more rational response. The warm-up stage facilitates a safe, supportive and creative atmosphere at the beginning of every session by doing warm-up techniques to prepare patients for action. During the warm-up stage, the therapists ask patients to do a verbal or non-verbal warm-up practice (Weiner & Sacks, 1969). For example, patients are encouraged to get up, move around and select someone to meet as if they have never met them before, but to meet them without using words. After this warm-up stage, the individual who will act as the protagonist is identified (see Table 1 for a description of typical psychodrama roles).

Table 1

Description of Typical Psychodrama Roles

Roles	Description
Protagonist	The main character, the session is focused on his/her problem.
Auxiliary Ego	An auxiliary ego is a person that has an important role in the situation chosen by the protagonist in the group and is played by a group member.
Audience	Other patients who observe the action are called audience.
Stage	A semi-circle of chairs is put in the room to create a stage so that the protagonist can act in front of the patients.

Each patient is protagonist at least once during the treatment. The therapist can ask who is ready to work as a volunteer. Alternatively, the therapists can select a protagonist

based on what they observed during the preparation in warm-up stage (e.g., sometimes patients express their performance anxiety in the warm-up stage verbally or non-verbally which is appropriate for the selection of the protagonist) or based on information revealed during sharing phase of the previous session (Kumar & Treadwell, 1986).

In the action stage of the therapy sessions, the therapists create a scene with the protagonist, in which an anxiety-provoking situation is acted out. Although role-playing can be an element of CBT, the most important difference between psychodrama and CBT is the aim of role-playing and the manner in which it is executed. In CBGT, role-playing focuses on the thinking process and is used as exposure to change irrational thoughts. In psychodrama, role-playing focuses on emotional expression and it is used to evoke and release emotions (Fisher, 2007). The role-playing can involve past as well as future situations but also feared situations that did not actually happen (Karp & Farrall, 2014). The protagonist can select the auxiliary ego (see Table 1) from the group members. During the action stage, therapists can use various psychodrama techniques, as described in Table 2.

However, during this stage therapists use CBT techniques as well. For example, therapists might shortly stop the scene and use cognitive restructuring to provide alternative thoughts so role-playing can be continued with these alternative thoughts. Which psychodrama technique is used depends on the type of anxiety-provoking situation and is chosen by the therapists with the protagonist's agreement. For example, role reversal is suitable for social interactions (e.g., talking with strangers, dating, and meeting unfamiliar people), and mirroring is suitable for performing in front of others (e.g., public speaking). Double is used to identify automatic thoughts that can be used for cognitive restructuring and is often used in situations in which someone feels observed (e.g., eating or drinking in front of others, writing in public, going to parties, being at the center of attention, and using public toilets). Finally, empty chair and soliloquy are suitable for traumatic situations where it is helpful to express suppressed emotions.

The last part of each session is sharing or closure. This is a time for patients to discuss the effects the action of the scene had on them and share their feelings and thoughts with the group. The therapists use cognitive restructuring techniques after the action stage to identify automatic thoughts and help patients to correct thinking errors that occurred during role-playing. At the end of each session, the therapists ask patients to provide feedback on therapy session. They also assign exposure in vivo as homework for the protagonist. The other participants not receive homework.

The twelfth and last session is again based on Heimberg and Becker's (2002) protocol and is divided into two parts. The first half is used for practicing with additional exposure, role-playing, and cognitive restructuring. In the second half, the therapists and patients review their development during treatment. That is, they discuss situations that may still be problematic and suggest rational responses can be beneficial in these

situations. Finally, therapists help patients to set goals for situations after the end of the formal treatment (Heimberg & Becker, 2002).

Table 2

Description of Psychodrama Techniques and Their Goals for Treatment of SAD

Description	Techniques	Goal
Role reversal	Two individuals first roleplay a situation. Next, the protagonist and the antagonist are asked to change the positions and play the other's role.	Experiencing the role of the other person results in Cognitive change. It helps to correct biased beliefs about how one comes across to others.
Double	A patient of the group plays the protagonist's inner self and gives a voice to the protagonist's feelings, thoughts or needs, usually by standing behind the protagonist. The protagonist can accept or reject double's offers.	Identify automatic thoughts and express suppressed thoughts and feelings during role-playing. It helps the protagonist to explore and expose his/her cognitive distortions.
Empty Chair	The protagonist can talk to an imaginary person that is represented by an empty chair.	Express negative as well as positive feelings.
Mirroring	The auxiliary ego plays the role of the protagonist for a short time. The protagonist stands aside and watches an immediate action and see his/her own behavior, body language and interactions with the other as in a mirror.	Observe themselves through the eyes of the audience works as immediate feedback from the audience (Hammond, 2014) to gain a more realistic view from others' judgment about his/her performance.
Soliloquy	A monologue in which the patients can express their thoughts and feelings to the audience.	Practice expressing their suppressed thoughts and feelings to the audience to relieve negative beliefs about emotional expression and decrease emotional suppression.

Statistical Analysis

In total, there were 10 missing values in the BFNE score that were completed each session (6.5 percent). We used a linear mixed model to handle these missing values, which allowed us to still examine if there was an effect of time on the session-by-session BFNE scores. The fixed part included an intercept and a linear effect of time (the pretest BFNE and the scores after completing each treatment session coded as 0, 1, 2, ..., 12), the repeated part an autoregressive ARMA11 covariance structure. The effect size of the fixed time effect was expressed as r ($r = t/\sqrt{(t^2 + df)}$). We also estimated the effect size of the pre-post change in terms of Cohen's d which is pre-post change calculated on the basis of the estimated effects of the linear mixed model, divided by the pretest standard deviation (Morris, 2008). The pretest and posttest scores of the other outcomes were

compared with paired sample *t*-tests (see De Winter, 2013, for the validity of the *t*-test with small samples). Pre-post effect sizes were calculated in terms of Cohen's *d* = mean pre-post change divided by pretest standard deviation (Morris, 2008), and Hedges' *g* (see Table 4 note for the formula). Hedges' *g* is smaller than conventional Cohen's *d* but has less bias.

Results

Primary Outcomes

A linear mixed model analysis showed that the intervention resulted in a significant reduction of fear of negative evaluation, see Table 3. The pre-post effect size estimated from the linear mixed model on the BFNE was Cohen's *d* = 1.16.

Table 3

Linear Mixed Model Estimates [and 95% Confidence Interval] of Fixed Effects With BFNE as Dependent Variable

						95% CI		Effect Size		
Parameter	***b***	***SE***	***df***	***t* (*n*)**	***p***	***LL***	***UL***	***r***	**Cohen's *d* (BL)**	**Cohen's *d* (ML)**
Intercept	37.64	2.46	6.64	15.28	< .001	31.75	43.53			
Time	-0.68	0.22	11.94	-3.16	.008	-1.15	-0.21	.67	1.16	1.32

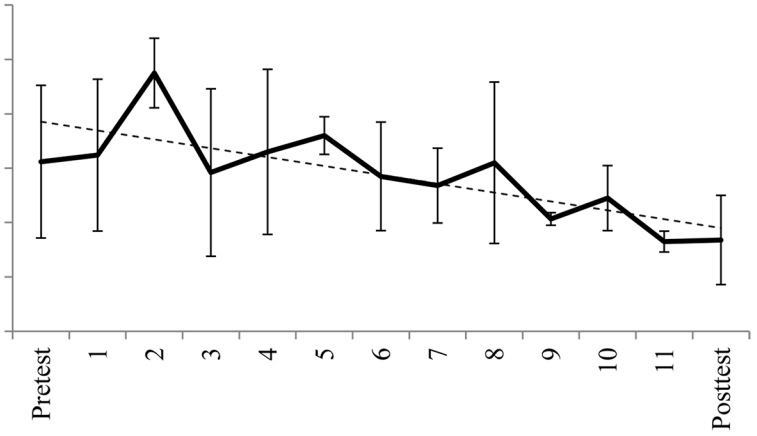
Note. CI = confidence interval; *LL* = lower limit; *UL* = upper limit; effect size for the fixed effect $r = t/\sqrt{(t^2 + df)}$. Cohen's *d* (BL) = |b (time)* 12/SD baseline|. Cohen's *d* (ML) = |standardized beta (Time) * (standardized Time at pretest − standardized Time at posttest)| (Lorah, 2018).

Figure 1 illustrates that although the mean score of the BFNE increased after the second session, it then decreased till the end of the treatment. Figure 2 shows the individual BFNE scores per assessment and indicates that in 4 of the 5 participants there was a reduction in BFNE scores. The dots in the figure show at which session each participant had a protagonist role. In 7 of the 10 instances, there was an immediate reduction in BFNE scores after the session.

There was also a significant decrease in social anxiety symptoms assessed with the LSAS (see Table 4).

Figure 1

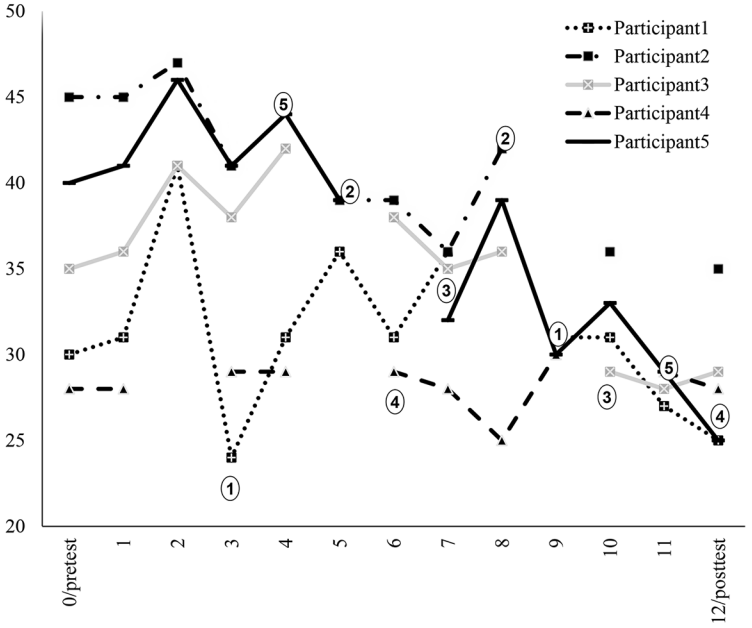
Observed and Estimated (by the Linear Mixed Model) Mean and Standard Deviation (SD) of BFNE Every Session by Assessment



Note. There was a significant linear decrease over time in BFNE scores.

Figure 2

Individual BFNE Scores Over the Period of Treatment



Note. Dots show who is a protagonist in the session.

Table 4

Pretest and Posttest Comparison for the CBPT Intervention

	Pre		Post			*M* difference [CI 99%]			Cohen's	Hedges'
Scale	*M*	*SD*	*M*	*SD*	*t* (4)	*LL*	*UL*	*p*	*d*	*g*
BFNE	35.60	7.02	28.40	4.10	2.86	-4.39	18.79	.046	1.03	0.82
LSAS	99.40	16.99	58.40	24.81	3.82	-8.44	90.44	.19	2.41	1.93
SADS	14.40	5.64	11.80	7.73	1.31	-6.56	11.76	.261	0.46	0.37
PAS	133.20	13.88	131.60	17.21	0.20	-34.67	37.87	.849	-0.12	-0.09
OPQ	56.20	23.18	35.80	16.63	3.22	-8.74	49.54	.032	0.88	0.70
OCQ	64.80	23.47	47.00	26.67	5.95	4.03	31.57	.004	0.76	0.61
BDI	19.60	5.86	12.60	8.20	2.03	-8.82	22.82	.111	1.19	0.96
QOLI	29.40	21.31	36.00	25.17	-0.88	-41.13	27.93	.429	0.31	0.25

Note. Observed Means *(M)* and Standard Deviations *(SD)* for the Pre and Post assessment points; results of *t*-test analyses *(t, p-value)* and effect sizes Cohen's *d* and Hedges' *g*. BFNE = Brief Fear of Negative Evaluation; LSAS = Liebowitz Social Anxiety Scale; SADS = Social Avoidance and Distress Scale; PAS = Personal Attitude Scale-II; OPQ = Social cost and probability by the Outcome Probability Questionnaire; OCQ = Outcome Cost Questionnaire; BDI = Beck Depression Inventory; QOLI = Quality of Life Inventory. Cohen's *d* was estimated as *d* = (mean pre-post change)/(pretest *SD*). Hedges' *g* was calculated as follows: $g = J^{*}d$, with *d* = Cohen's *d*; $J = (1 - 3/(4^{*}df\text{-}1))$; *df* = *N*-1. The sign of the effect size was chosen so that a positive effect size indicates improvement and negative effect size represents worsening.

Secondary Outcomes

There was a significant decrease in outcome probability and outcome cost questionnaires. However, there was no significant difference in social avoidance, spontaneity, depression, and quality of life after completing treatment. The test statistics, as well as the effect sizes, are presented in Table 4.

Reliable Change and Clinical Significant Change

To estimate the rates of clinical significant improvement, we computed the reliable change, clinical significant change, and cutoffs as suggested by Jacobson and Truax (1991) on the primary outcome measures. Moreover, because our sample is too small, we used standard error and test-retest values of two Iranian studies with large samples for BFNE (*SE* BFNE 4.49 from Tavoli, Melyani, Bakhtiari, Ghaedi, & Montazeri, 2009), and LSAS[1] (*SE* LSAS 11.07 from Atrifard et al., 2012). Reliable change (RC) was calculated as difference between post and pretest divided by standard error of change. An RC rate greater than 1.96, is considered as improvement (Jacobson & Truax, 1991; see Table 5). Clinically significant change (CSC) consists of reliable change and a posttest score that falls within mean ± two standard deviations of non-anxious sample, which was 39.86 ±

1) This was self-report LSAS.

2*18.98 for LSAS, and 28.7 ± 2*5.9 for BFNE, again using data from two larger studies (Atrifard et al., 2012; Tavoli et al., 2009). As can be seen in Table 5, three of the five patients with LSAS and two of the five patients with BFNE have a clinical significant change after the treatment.

Table 5

Within-Participant Changes for the CBPT Intervention on the Primary Outcomes

	BFNE					LSAS				
Participants	**Pre**	**Post**	**change**	**RC**	**below c = 30.97**	**Pre**	**Post**	**change**	**RC**	**below c = 57.57**
1	30	25	5	N	Y	80	52	28	Y	Y
2	45	35	10	Y	N	104	86	18	Y	N
3	35	29	6	N	Y	83	34	49	Y	Y
4	28	28	0	N	Y	116	37	79	Y	Y
5	40	25	15	Y	Y	114	83	31	Y	N

Note. RC = Reliable Change; BFNE = Brief Fear of Negative Evaluation; LSAS = Liebowitz Social Anxiety Scale (LSAS); Y = yes; N = no.

Feedback From Patients

In the course of the treatment, role reversal and double were the most frequently used techniques in CBPT based on therapists' post-session reports. After sessions, patients reported that role reversal was a helpful technique that enables them to expose themselves to anxiety-provoking social situations. They further reported that cognitive restructuring as it was integrated into techniques in the action stage, helped them to understand CBT concepts in a more experiential way. Patients also experienced some warm-up techniques (e.g., forming a band by playing their invisible musical instruments) as anxiety-provoking and embarrassing situations, but they finally evaluated them as helpful warm-up techniques to decrease anxiety.

Discussion

CBPT balances a focus on cognition and behavior through CBT techniques, and emotion during psychodrama techniques in action. The results from this pilot study supported that integrating CBGT and psychodrama might be considered as a new treatment for patients diagnosed with SAD. Also, the fact that patients continued the treatment until the last session indicates that CBPT was acceptable for patients.

The pilot indicated that the treatment was effective in the core area of SAD. Social anxiety, as assessed by the LSAS, reduced significantly from pre to posttest. The current study showed a high effect size on the LSAS (pre-post effect size Hedges' g = 1.93) in comparison to the pre-post effect sizes of other studies using Heimberg's CBGT on the

LSAS (Blanco et al., 2010, g = 0.56; Bjornsson et al., 2011, g = 0.61; Hayes-Skelton and Lee, 2018, g = 0.82; Hedman et al., 2011, g = 0.99; Heimberg et al., 1998, g = 0.75).

Significant improvements were also found on the two cognitive measures of cost and probability estimates of negative outcomes. This suggests that CBPT can change cognitive processing biases to decrease social anxiety in SAD. Our findings are in line with research that reported changes in probability or cost estimates after CBT, which in turn related to therapeutic changes in social anxiety symptoms (Foa et al., 1996; Gregory et al., 2015; Hofmann, 2004; Lucock & Salkovskis, 1988). Hamamci (2002) also showed that integrating CBT and psychodrama techniques leads to a reduction in cognitive distortions related to interpersonal relationships. It is conceivable that the use of psychodrama techniques contributed to a decrease in estimated social cost and probability because it helped patients to experience a disconfirmation of their expectations. However, because in the current study CBT and psychodrama techniques were integrated, it is not clear how much change results from psychodrama techniques alone. Future research should reveal if that CBPT is more effective in decreasing negative beliefs than CBT or psychodrama alone.

Likewise, fear of negative evaluation also reduced during treatment with a pre-post effect size of Hedges' g = 0.82 on BFNE scores, which is in line with the pre-post effect sizes of studies using CBGT in the treatment of SAD (Bjornsson et al., 2011; Heimberg et al., 1998).

The decline of fear of negative evaluation was not consistent in the course of treatment. After the second session, there was an increase in fear. This might be due to the announcement in the second session of the start of in-session exposure and role-playing in the third session. However, the increase was only temporary, and social anxiety decreased significantly till the end of treatment. Fear of negative evaluation decreased immediately after 7 of the 10 sessions in which a patient was the protagonist, showing an overall immediate positive effect of being protagonist on social anxiety symptoms in a small sample. Why being a protagonist was not always followed by a decrease in BFNE is not clear. This might be due to the patients' attitude toward role-playing or the level of expression of emotions, or other factors. Clearly, further work in large clinical trials is required to gain a better understanding of the effects of being the protagonist in social anxious patients.

Next to social anxiety outcomes there were several other outcomes measures. These showed that there were no significant differences between pre and posttest in avoidance, spontaneity, depression symptoms and quality of life. The lack of significant effects on the measure of spontaneity is rather surprising, given the prominent position spontaneity has in the theory of psychodrama. Perhaps the spontaneity measure that we used is not sensitive to change because the items that were used describe spontaneity more as a stable personality trait than a characteristic that can easily be changed during a short CBPT treatment. However, Moreno (1953) noted that especially spontaneity can be

enhanced during psychodrama and that it is an important mechanism of clinical change (Moreno, 1953). Further research is required to examine if the current lack of change in spontaneity is due to the type of measure or if the short integrated CBPT is not suitable to change spontaneity. The lack of significant effects on avoidance, depression, and quality of life might relate to the limited power of this pilot study, as the changes are in the direction of improvement, and are in the range of effect sizes of previous studies, or exceed them. That is, the finding on avoidance, depression, and quality of life are consistent with previous studies: Avoidance with a pre-post effect size of Hedges' g = 0.37 on SADS scores, while Heimberg's studies using CBGT in the treatment of SAD resulted in a pre-post SADS effect size of Hedges' g = 0.29 (Heimberg et al., 1990), and Hedges' g = 0.17 (Heimberg et al., 1998); Depression with a pre-post effect size of Hedges' g = 0.96 on BDI scores, which is in line with previous studies using CBGT in the treatment of SAD that found pre-post BDI effect sizes of Hedges' g = 0.78 (Heimberg et al., 1990), and Hedges' g = 0.82 (Koszycki, Benger, Shlik, & Bradwejn, 2007); Quality of life with a pre-post effect size of Hedges' g = 0.25 on QOLI scores, which is in line with other studies using CBGT in the treatment of SAD finding small pre-post QOLI effect sizes of Hedges' g = 0.28 (Hayes-Skelton & Lee, 2018), and Hedges' g = 0.44 (Koszycki et al., 2007).

An important limitation of the present study is that our sample size was small (5 patients) limiting the external validity of the results. Besides, this was an uncontrolled study and the internal validity study is limited by the lack of a control group. Moreover, the LSAS assessors were not blind to the timing of the interviews (before or after treatment). There was no follow-up assessment into also, thus it is unclear whether the results were maintained or whether there were further changes. This is in particular important for outcomes like avoidance, depression, and quality of life that might show a delayed response to treatment. Furthermore, integrating psychodrama and CBT in therapeutic practice usually includes 16 sessions (Treadwell, Dartnell, Travaglini, Staats, & Devinney, 2016). However, the current CBPT protocol consists of twelve sessions to make it comparable to CBGT in future random clinical trials. Nevertheless, the effects of CBPT might be larger with 16 sessions. Future studies might investigate different lengths of treatment. The results of this pilot are promising, but it is necessary to do research in a randomized controlled trial with follow-up assessments to compare this treatment to CBGT alone and psychodrama alone.

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Clinical Psychology in Europe

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Clinical Psychology in Lithuania: Current Developments in Training and Legislation

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Abstract

This paper presents an overview of the current status in training and legislation of clinical psychology in Lithuania. Clinical psychology training at the university level in Lithuania started soon after the collapse of the Soviet Union in the 1990s and was influenced by the social context and historical-political situation in the country. Currently, legislation for clinical psychology in Lithuania is in progress, and several promising regulations for psychology in health care were introduced in the last decade. However, psychologists, including clinical psychologists, are not licensed in Lithuania. The lack of legislation for psychology is the main obstacle for the recognition and establishment of clinical psychology in the country. In health care, the title 'clinical psychologist' is not common; 'medical psychologist' is the title used instead to refer to both clinical psychologists and health psychologists. We conclude that while the development of clinical psychology in Lithuania is promising, there is still a long way to go to establish clinical psychology as an important profession in Lithuania.

Keywords

Lithuania, clinical psychology, legislation, training, education, policy

Highlights

- University training in clinical psychology started in the 1990s after the collapse of the Soviet Union.
- Legislation for clinical psychology in Lithuania is in progress and issues regarding the title and licensing of clinical psychologists are associated with the lack of regulation of psychology in the country in general.
- In Lithuania, the title 'clinical psychologist' is not used in health care, and the titles of psychologists or clinical psychologists are not protected by law.

Clinical psychology in the Baltic States remains unknown and somewhat of a 'white zone' on the global map of psychology. This paper aims to present the status of clinical psychology in one of the Baltic States – Lithuania, with a brief overview of the training and legislation for clinical psychology in the country. The current paper is an update of the previous reports on the history of Lithuanian psychology (Bagdonas, Pociute, Rimkute, & Valickas, 2008), and is an extension of the overview of Lithuanian clinical psychology published two decades ago (Gailiene, 2000) with a focus on current national developments in clinical psychology. Grounded on the development of clinical psychology in Lithuania this paper is informative in understanding the challenges and diverse pathways of establishing clinical psychology at a national level in different countries.

Historical Background

Lithuania is a country with a population of around three million, situated in the North-Eastern part of Europe. It has been an EU member state since 2004, together with the other two Baltic States – Latvia and Estonia. Lithuania's history is marked by occupations and fights for freedom. Established as the independent Republic of Lithuania after World War I in 1918, Lithuania was occupied by the Soviet army in 1940-1941, followed by Nazi occupation in 1941-1944, and Soviet occupation again in 1944-1990 (Eidintas, Bumblauskas, Kulakauskas, & Tamošaitis, 2015). Lithuania was one of the republics of the former Soviet Union until 1990. The political situation in the country during the Soviet Regime was very restrictive and oppressive. Political violence and oppression that lasted for decades during the Soviet regime resulted in a loss of a large proportion of the population (Eidintas et al., 2015). Narratives of historical traumas are still vivid in the majority of families living in the country (Kazlauskas, Gailiene, Vaskeliene, & Skeryte-Kazlauskiene, 2017; Kazlauskas & Zelviene, 2016). Furthermore, the memory of occupation and fights for freedom continue to have a profound impact on politics, socioeconomic situation, science, and culture in the country up to this day.

The development of clinical psychology in Lithuania was closely related to the political situation of 20th century Europe. In Lithuania, as well as in other post-communist countries in the region, particularly in the former Soviet republics, psychology

was restricted and oppressed by the Soviet regime (Gailiene, 2000). Despite negative attitudes held by the Soviet regime towards psychology, the growing interest in psychology resulted in the establishment of the Lithuanian Psychological Association (LPA) in 1958 (Bagdonas et al., 2008), with almost 300 founding members. The first professional five-year psychology diploma-training program in Lithuania was opened at Vilnius University in 1969, producing the first graduates of this psychology program in 1974. This program was focused on engineering and work psychology, as it was the only way it could be deemed acceptable by the Soviet regime (Gailiene, 2000).

Officially, when psychology training was launched in 1969, it was not possible to study or practice clinical psychology. However, since the very start of the psychology program at the University, psychology students were interested in clinical psychology and first psychologists managed to get positions and started to work in psychiatric hospitals in the 1970s (Bagdonas et al., 2008). During the 1970s and the 1980s, the field of clinical psychology was evolving through the initiatives of local professionals, as well as with the assistance of Lithuanian expats from the United States. During the Soviet era, U.S. psychology professors managed to sneak across the 'Iron Curtain' into Lithuania often under the pretense of visiting relatives and delivered clinical psychology training workshops and supervisions (Bieliauskas, 1977; Gailiene, 2000) which was a significant contribution to the development of clinical psychology at that time.

Training in Clinical Psychology

The Start of Clinical Psychology Training

A turning point in clinical psychology in Lithuania was a two-year master's degree program in clinical psychology launched at Vilnius University in 1994, which marked the start of professional training of clinical psychologists' in Lithuania. This ambitious aim to start the training of clinical psychologists was initiated by a group of psychologists from the Department of Psychology at Vilnius University who had previous interest in clinical psychology and psychotherapy and had relevant clinical experience. The master's degree in clinical psychology program aimed to fulfill the needs of society to have professionally trained clinical psychologists.

Soviet legacy significantly impacted the training of clinical psychologists in Lithuania and the start of clinical psychology training was challenging. Clinical psychology research in Lithuania was almost non-existent during the Soviet occupation. Moreover, research methods and psychological assessment measures were not compatible with international standards due to the 'Iron Curtain' preventing the circulation of knowledge between the former Soviet Union and the rest of the World until the 1990s. Lithuania as part of the Soviet Union experienced even more restrictions in comparison to other Eastern and Central European post-communist countries outside of the Soviet Union

(Gailiene, 2000). Access to international scientific knowledge of psychology, scientific papers, books, or modern assessment measures was restricted in the country until the 1990s. Thus, training in clinical psychology, especially in clinical psychological assessment, was significantly influenced by the Soviet approach to psychopathology and psychiatry. For example, psychological assessment training was focused on the use of Soviet cognitive assessment instruments, which were available at the time but not used outside of the Soviet Union.

Current Clinical Psychology Training

Psychology training is currently regulated by the Ministry of Education and Science of the Republic of Lithuania which approved standards for training of psychology in 2015 (Ministry of Education and Science of the Republic of Lithuania, 2015). The national education standards in psychology are in line with the standards of the other EU member states and in accordance with the European Certificate in Psychology (EuroPsy) which was approved by the European Federation of Psychologists' Associations (EFPA) (European Federation of Psychologists' Associations [EFPA], 2019; Lunt, Peiró, Poortinga, & Roe, 2014). Furthermore, the training of psychologists in Lithuania is based on Bologna regulations for higher education across Europe (Laireiter & Weise, 2019) and includes three cycles: bachelor's degree, master's degree, and doctoral degree.

Psychologists are trained at six universities in Lithuania. Bachelor's degree programs in psychology take 3.5-4 years and master's degree programs take two years to complete with a focus in various areas of psychology, such as clinical, health, educational, work and organizational, and forensic. Psychology degree programs offered at the universities are evaluated and accredited by the national agency responsible for the accreditation of all study programs in the country. LPA does not accredit psychology study programs; however, it was closely involved in the development of the national regulations for the training of psychologists.

The clinical psychology master's degree program in Lithuania is a two-year program with 120 European Credit Transfer and Accumulation Study (ECTS) credits. Content of the program allows students to develop core competencies of clinical psychologists listed by the European Society for Clinical Psychology and Psychological Intervention (EACLIPT) Task Force on 'Competences of Clinical Psychologists' (EACLIPT Task Force On "Competences of Clinical Psychologists", 2019). The majority of the study credits (67 ECTS credits) are dedicated to clinical psychology courses. Additionally, the master's thesis research project is 30 ECTS credits, and supervised practice is 23 ECTS credits, which is a 4-month full-time internship in a clinical setting outside the University. The core courses of the curriculum are all clinical and include counselling skills training; adult and child clinical psychological assessment; introduction to the diversity of approaches in clinical psychology, with psychodynamic, existential, cognitive-behavioral and biopsy-

chosocial approaches equally covered; developmental psychopathology; trauma and crisis psychology; and research methods in clinical psychology.

In Lithuania, around 30 students are admitted to the master's program in clinical psychology annually, and the competition to enter the program is high. The admission numbers to master's degree programs are regulated by the government, but the university and study program committees have the flexibility of establishing admission quotas based on the available resources each year. The majority of students in the clinical psychology program are funded by the state, with up to 30% of students being self-funded. By 2020, more than 400 clinical psychologists have graduated from the clinical psychology program in Lithuania.

For over 25 years, the master's degree program in clinical psychology at Vilnius University remained the only training program for clinical psychologists in Lithuania. However, over the past few decades, other psychology master's degree programs in the field of clinical and health psychology were launched in addition to the aforementioned clinical psychology program at a number of Lithuanian universities. Master's study programs in health psychology were launched at Vilnius University, Vytautas Magnus University and the Lithuanian University of Health Sciences. Furthermore, the master's degree program in counselling psychology was recently launched at Klaipeda University.

There are two four-year doctoral study programs in psychology in Lithuania, one at Vilnius University, and the other is a joint Ph.D. program of Mykolas Romeris University and Vytautas Magnus University. Up to 10 Ph.D. students are admitted annually to both of these programs. Around one-third of all Ph.D. students choose to conduct research in the clinical psychology field. However, as Ph.D. studies in Lithuania are research-based, Ph.D. students are expected to conduct research and publish papers, and no clinical training is included in the program.

Legislation for Clinical Psychology

Issues With the Use of the Title 'Clinical Psychologist'

Due to negative attitudes by the Soviet regime towards clinical psychology and psychotherapy, psychologists were labeled 'medical psychologists' (Gailiene, 2000) since they started to work in health care institutions in the 1970s. All psychologists in national health care are still referred to as 'medical psychologists'. Surprisingly, the term 'medical psychologist' persisted in Lithuania, and resulted in the title 'clinical psychologist' not existing. Thus, according to official statistics, there are zero clinical psychologists in Lithuania, but this is only because the term 'clinical psychology' is not used in the country's health care system. There are, in fact, many graduates of clinical and health psychology programs who work in health care institutions or private practice across the country.

This attitudinal legacy from the Soviet era adds to the confusion in the legislation of clinical psychology in Lithuania. Despite the fact that the masters' degree program in clinical psychology has existed for over 25 years, the profession of clinical psychology is not yet fully recognized or established in Lithuania. The titles 'clinical psychologist' and 'psychologist' in contrast to many other European countries are not protected. Furthermore, the title of clinical psychology is not used in psychology practice but only in training and education.

Introduction of Regulation

There was no regulation for psychologists in health care in Lithuania until 2012 (Ministry of Health of the Republic of Lithuania, 2011). Moreover, there were no minimal training standards set in the field of clinical and health psychology prior to 2012. For decades, it was up to the employer to decide what training standards were considered as training standards to apply for psychologists in health care until the regulation was introduced. When it came to medical psychologists, health care institutions mostly used to employ psychologists with a five-year psychology diploma or master's degree in any area of psychology, but occasionally psychologists with no more than a 4-year bachelor's degree or even 'professionals' without a diploma could be employed before 2012.

It was only in 2012 that psychologists were included in the system of the Lithuanian national accreditation agency for health professions. Consequently, health care institutions could only hire registered medical psychologists with a master's degree in health or clinical psychology. This new regulation was introduced with collaborative efforts between the Ministry of Health and LPA, which insisted that a bachelor's degree in psychology and master's degree with a specialization in health or clinical psychology should be a minimum requirement for psychologists to practice in health care. Several years of a transition period ensured that psychologists who started work before clinical and health psychology training became available in Lithuania and had substantial experience in clinical work could be registered as psychologists eligible to work in the health care setting.

This regulation did not include psychologists working outside the public health care setting, which is why psychologists providing psychological counselling or psychotherapy in private practice are not yet registered or regulated. Psychological services of registered medical psychologists in licensed health care institutions are reimbursed by the National health care insurance. However, due to the lack of staff and resources, access to psychologists' services is restricted and there are long waiting lines. Psychologist's services in private practice outside of health care institutions are not reimbursed by the National health care insurance. In reality, even non-professionals can declare themselves psychotherapists or clinical psychologists and start delivering services in private practice without any formal training in psychology in Lithuania. This is because law in Lithuania

regulates neither the psychologist's profession nor psychological services nor does it protect the psychologist's title.

Debates About the Regulation of Psychology

Legislation for clinical psychologists is part of the national regulation of psychology. Until 2020, psychology in Lithuania was not regulated by national laws and not included in the list of the licensed professions, except for school psychologists working in the national education system (European Parliament, 2016).

Debates about the standards for professional psychologists have been intense for over a decade. There are conflicting opinions among psychologists regarding the minimal training standards or regarding which institutions should license psychologists in Lithuania. Over the past decade, several proposals for a new law have been brought in the Lithuanian Parliament. These proposals included various requirements for minimal training, ranging from licensing psychologists for independent practice with only a bachelor's degree in psychology to requirements of holding bachelor's and specialized master's degree in addition to having one-year experience of supervised practice in the field of intended practice, such as clinical and health psychology, educational psychology, or work and organizational psychology, which would be in line with the EFPA's EuroPsy regulations (European Federation of Psychologists' Associations [EFPA], 2019). While most psychologists in Lithuania agreed that at least a master's degree is needed to be granted a psychologist's license, debates on the licensing agency still are ongoing. Proposals as to which organization should play the role of the licensing agency ranged from self-regulation of professionals by LPA to the establishment of a new Chamber of Psychologists or choosing one of the governmental institutions.

Regulation of Psychologists in Health Care

Despite the lack of regulation on the national level, an important step for psychologists working in public health care was the document 'Medical norm' issued by the Ministry of Health of the Republic of Lithuania in 2018 (Ministry of Health of the Republic of Lithuania, 2018). This document defined the aim, the area of practice, and the methods of psychologists who work in the national health care system under the title of 'medical psychologists'. However, the professional title 'clinical psychologist' was not included in this document. Up until 2020, there has been no clear distinction between health and clinical psychology in terms of regulation and fields of practice in health care. Current legislation in Lithuania allows for graduates of either health or clinical psychology master's programs to work in health care in positions of psychologists in primary care, mental health care, prevention, rehabilitation, or in hospitals with patients who have somatic diseases. The regulation of medical psychologists in health care does not include differentiation between a child and adult psychologists, psychologists who

provide assessment and those who mostly provide psychological counselling or use various methods of psychotherapy.

Clinical Psychology, Psychotherapy, and Psychiatry

The present work focused solely on training and legislation for clinical psychology, therefore, it does not extend to the situation of psychotherapy in Lithuania. There are multiple psychotherapy schools that offer post-diploma training in various psychotherapy approaches in Lithuania, such as cognitive-behavioral, psychodynamic, child psychodynamic, group analysis, existential, gestalt, Jungian analysis, family therapy, and others. Training in specialized psychological therapies for posttraumatic stress disorder (PTSD), such as Eye Movement Desensitization and Reprocessing (EMDR), is also available in the country (Schäfer et al., 2018). Majority of psychologists who work in health care or private practice pursue psychotherapy training after having obtained a master's degree from the university. However, there are no statistics available on how many psychologists have had additional psychotherapy training after the completion of psychology studies at university. The legal distinction between psychotherapy and clinical psychology remains unclear since law in Lithuania does not yet regulate psychotherapy. The relationship between psychiatry and clinical psychology is also not part of this paper. While these fields share a mutual interest in psychopathology and treatment of mental disorders, they also have a history of diverse interactions.

Future Directions

This brief report presented struggles in establishing clinical psychology as a profession in Lithuania, a post-communist EU country. Our review demonstrated that the development of clinical psychology in Lithuania has been rather successful with a history of over 25 years of clinical psychology training available at the university level. Furthermore, regulations and standards for psychologists in health care have recently been introduced in Lithuania. However, our review also revealed controversies surrounding the use of the title 'clinical psychologist' and difficulties in establishing clinical psychology as an important field and profession in Lithuanian society.

Several future directions could be identified for further progress of clinical psychology in Lithuania:

- The term 'clinical psychologist' should be used officially to identify psychologists who provide services in health care and have training in clinical psychology.
- Continuing education in clinical psychology is needed to constantly update the knowledge of psychologists who work in Lithuania. Legislation and licensing of psychological practice should include a formal requirement for continuing education in the field of clinical psychology after university graduation.

- Training of clinical psychologists should be more focused on research. Potentially this could be achieved by more intense international collaboration and learning from countries that have more expertise in research and training in clinical psychology. The staff of clinical psychology programs could focus more on staff exchange with other international institutions to modernize training in Lithuania.

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