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Therapist-led and self-led one-session virtual reality exposure therapy for public speaking anxiety with consumer hardware and software: A randomized controlled trial

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ABSTRACT

Public speaking anxiety (PSA) is a common condition which can be treated effectively with exposure therapy. However, inherent difficulties in stimuli presentation and control limits dissemination and the therapeutic potential. Virtual Reality (VR) technology has the potential to resolve these issues and provide a scalable platform for self-help interventions. No previous study has examined whether this can be achieved using the first generation of consumer VR hardware and software. In the current trial, n = 25 + 25 participants were randomized to either one-session therapist-led VR exposure therapy for PSA followed by a four-week internet-administered VR to in-vivo transition program, or a waiting-list. Linear mixed effects modeling revealed significant, large (within Cohen's d = 1.67) decreases in self-reported PSA. The waiting-list was then given access to an internet-administered, self-led version of the same VR exposure therapy to be conducted at home, followed by the same transition program. Dual-slope mixed effects modeling revealed significant, large (d = 1.35) decreases in self-reported PSA. Results were maintained or improved at six- and twelve-month follow-ups. We show for the first time that low-cost, off-the-shelf consumer VR hardware and software can be used to conduct exposure therapy for PSA, both in the traditional, previously impractical one-session format, and in a novel self-led, at-home format.

1. Introduction

Anticipatory anxiety and in-situ fear of public speaking (public speaking anxiety, PSA) is a common form of social anxiety: one third of the general population reports excessive anxiety when speaking to a larger audience, and a third of this group report some clinically significant distress or impairment due to their PSA (Stein, Walker, & Forde, 1996). Although the association between PSA and the wider clinical presentation of social anxiety disorder (SAD) has been the subject of much debate (Blöte, Kint, Miers, & Westenberg, 2009), the extant literature does suggest that there are two broad social anxiety subgroups: those with both interaction and performance anxiety (generalized SAD), and those with only performance anxiety, of which PSA is the most common form (Bögels et al., 2010). In the DSM-5, this distinction is recognized with the novel performance only-specifier for SAD (American Psychiatric Association, 2013; Dalrymple & D'Avanzato, 2013) and research suggests that this PSA-only SAD group may share more similarities with specific phobia than generalized SAD with regards to developmental pathways and presentation. This includes an onset later in life (Mannuzza et al., 1995), being more likely to remember a traumatic fear-conditioning event (Stemberger, Turner, Beidel, & Calhoun, 1995), experiencing a stronger psychophysiological response in-situ (Heimberg, Hope, Dodge, & Becker, 1990; Levin et al., 1993), and being likely to attribute their fear to this heightened psychophysiological response (Hofmann, Ehlers, & Roth, 1995).

Exposure therapy, involving systematic, graded exposure to feared stimuli in a controlled setting (Craske, Treanor, Conway, Zbozinek, & Vervliet, 2014), is a well-established, efficacious treatment of anxiety disorders, both as a component of cognitive behavior therapy (CBT) and as a stand-alone intervention (Norton & Price, 2007). In the one-session

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treatment (OST) format, which is highly efficacious in the treatment of specific phobias (Andersson et al., 2009; Haukebø et al., 2008; Ollendick & Davis, 2013; Öst, Hellström, & Kåver, 1992; Öst, Brandberg, & Alm, 1997; Öst, Alm, Brandberg, & Breitholtz, 2001; Wolitzky-Taylor, Horowitz, Powers, & Telch, 2008; Zlomke & Davis, 2008), all exposure is conducted in the therapy room together with a therapist during a single three-hour session (Öst, 1989). When conducting exposure therapy for animal phobia or phobias of natural phenomena (enclosed spaces, heights etc.), the presentation and required control of stimuli material is seldom an issue. In the case of PSA, however, this would require access to a controllable audience of sufficient size to evoke a fear response. This makes it impractical to conduct PSA exposure in the therapy room, which presumably has hindered the development and dissemination of OST, and other in-session exposure therapies for PSA.

Virtual Reality (VR) technology has the potential to solve this issue. In essence, VR technology creates the immersive experience of being present in a computer-generated environment by having two stereoscopic displays cover the entire visual field (thereby also withholding sensory information from the outside world), the contents of which is interactive to the head movement of the user, creating the illusion of depth sight and being able to look around the virtual world. Stereo audio, hand controllers and eye trackers can be used to create an even more immersive experience. The complete control of the virtual environment enables unique possibilities to conduct exposure therapy using VR (Lindner et al., 2017). In its simplest form, VR exposure therapy (VRET) involves presenting a virtual version of the feared stimulus (Botella, Fernández-Álvarez, Guillén, García-Palacios, & Baños, 2017), which can be combined with more traditional therapeutic components, e.g. a real-life therapist situated nearby directing the exposure through voiceover instructions and controlling the virtual environment, as has been the case in the majority of past VRET research (Gega, 2017).

Virtual audiences have been shown to be successful in eliciting a sufficient fear response to enable exposure therapy (Owens & Beidel, 2015), and several high-quality, randomized controlled trials have examined the efficacy of VRET for social anxiety, typically finding effect sizes in the range of Cohen's d > 1 (P. L. Anderson et al., 2013; Bouchard et al., 2017; Kampmann et al., 2016; Wallach, Safir, & Bar-Zvi, 2009). Several non-randomized and/or non-controlled studies provide additional support for the efficacy of VRET for social anxiety (Anderson, Rothbaum, & Hodges, 2003; Anderson, Zimand, Hodges, & Rothbaum, 2005; Bouchard et al., 2017; Harris, Kemmerling, & North, 2002; Moldovan & David, 2014; Morina, Brinkman, Hartanto, Kampmann, & Emmelkamp, 2015; Stupar-Rutenfrans, Ketelaars, & van Gisbergen, 2017). Despite the promising results of these previous studies, VR as a therapist tool has yet to see widespread spread among clinicians. This can likely be explained by therapists' attitudes towards and knowledge of VR therapy (Schwartzman, Segal, & Drapeau, 2012; Segal, Bhatia, & Drapeau, 2011), and, primarily, by limitations of the past generation of VR hardware and software. Until recently, VR hardware was inaccessible, expensive (often costing more than 10,000 USD) and required an equally expensive high-end computer to run it, as well as a high degree of technical proficiency to develop the exposure paradigm and operate the equipment. As of 2016, there are now several off-the-shelf, consumer VR platforms, along with user-friendly development environments for developing the VR exposure paradigms (Lindner et al., 2017). This technological development promises to revolutionize the ubiquity and accessibility of VR therapist tools, as well enabling the development and widespread dissemination of VR self-help applications (Miloff et al., 2016). However, before such use can be recommended for clinical settings, this approach needs to be validated.

In the current randomized controlled trial, we address the limitations of past VRET research by studying whether off-the-shelf consumer VR hardware and software can be used to conduct efficacious VRET for PSA, both in the traditional therapist-led format, and as a novel

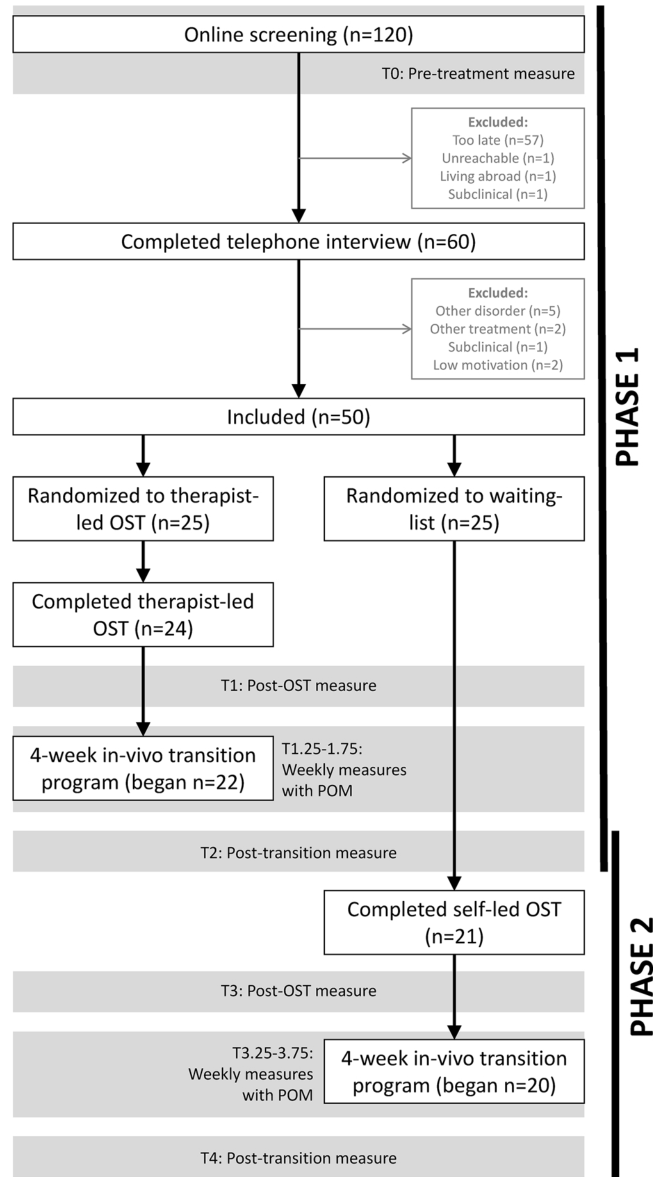

Fig. 1. Study flowchart.
Analyses conducted according to intention-to-treat principle. POM: Primary outcome measure.

internet-administered self-led intervention, in both cases packaged as a single three-hour session followed by an online, four-week therapist-supported VR to in-vivo exposure transition program.

2. Methods

2.1. Ethics and preregistration

This trial received ethical approval from the Stockholm Regional Ethical Review Board (DNR: 2016/1990-31) and was pre-registered at Clinicaltrials.gov (NCT03001154).

2.2. Procedure and sample

See Fig. 1 for flowchart. Participants were recruited from the general public using both television and newspaper appearances, as well as advertisements on public bulletin boards at university campuses, with the aim of recruiting a diverse sample (Lindner, Nyström, Hassmén, Andersson, & Carlbring, 2015). Potential participants were directed to a dedicated website that provided information on study design, as well as inclusion and exclusion criteria. To enter the study, participants needed to create an anonymous account and answer the screening battery serving as pre-treatment measure. Potential participants seemingly meeting inclusion criteria, and no exclusion criteria, were contacted and scheduled for a clinical interview over the telephone (First, Spitzer, Miriam, & Williams, 2002), conducted by one of the four therapists, to assess diagnostic status and confirm absence of exclusion criteria. Inclusion criteria included scoring ≥60 on a novel (as of yet not validated) 18-item brief version of the Personal Report of Public Speaking Anxiety (Hook, Smith, & Valentiner, 2008) and self-rated clinically significant impairment or distress due to PSA. A cut-off on the PRPSA, rather than on the primary outcome measure, was used to inform inclusion as not to artificially constrain baseline variance. Further inclusion criteria included being at least 18 years old, residing in Sweden, having an adequate grasp of Swedish, the possibility and motivation to travel to Stockholm university on one occasion, internet access and having a VR-compatible smartphone (e.g. featuring a gyroscope) running Android or iOS. Exclusion criteria included other major mental disorder (major depression, bipolar disorder, psychosis, alcohol or drug use disorder), ongoing non-stable psychoactive medication or any ongoing psychological treatment, and lack of stereoscopic vision or a balance problem that would hinder the VR experience (all self-reported).

Randomization was performed upon inclusion decision, in five batches, by an independent researcher through random assignment to a pre-specified random allocation scheme, ordered using a true random generator (www.random.org) in blocks of varying sizes. Participants were assessed, enrolled and notified of randomization decision continuously during the recruitment phase, until target sample size had been met. See Table 1 for sample characteristics. Participants randomized to therapist-led OST were scheduled for the treatment session as soon as possible, which took place in a room at Stockholm University. Approximately one week after the treatment session, participants completed the post-OST measure online, upon which they were given access to the first module of the four-week VR to in-vivo transition program, during which they completed weekly measures of the primary outcome measure. At the end of this period, participants completed post-treatment measures. Participants randomized to self-led OST were informed that their treatment would commence after a five-week waiting-period; during this period, participants completed measures at equivalent time-points as the therapist-led arm. When the waiting period was over, participants were sent a free VR headset by mail and scheduled their self-led OST session, followed by a VR to in-vivo transition program and data collection procedure mirroring that of the therapist-led group. Participants in both groups were invited to complete follow-up measures approximately six and twelve months (n = 29 and n = 22 completers, respectively) after the last participant received treatment.

Table 1
Sample characteristics.

Variable	Therapist-led OST (n = 25)	Waiting-list / Self-led OST (n = 25)
Female: n (%)	20 (80)	16 (64)
Age: mean (SD)	30.84 (6.63)	31.88 (7.91)
Marital status: n (%)		
Single	7 (28)	8 (32)
Married/partner	18 (72)	17 (68)
Highest education: n (%)		
Secondary	10 (40)	10 (40)
Tertiary	15 (60)	14 (56)
PhD	0 (0)	1 (4)
Occupation: n (%)		
Study	10 (40)	5 (20)
Work	13 (52)	19 (76)
Other	2 (8)	1 (4)
Met DSM-5 criteria for SAD: n (%)	19 (76)	20 (80)
Met SAD performance-only specifier criteria: n (%)	10 (40)	15 (60)
Prior psychological treatment: n (%)	17 (68)	13 (52)
Prior psychological treatment for PSA: n (%)	4 (16)	6 (24)
Prior or ongoing psychoactive medication: n (%)	8 (32)	9 (36)
Prior or ongoing psychoactive medication for PSA: n (%)	4 (16)	4 (16)

2.3. Interventions

2.3.1. Therapist-led OST

The treatment program was developed for the current study and grounded in a CBT conceptualization of PSA as a vicious circle of catastrophic beliefs leading to physiological reactivity and self-attention, resulting in avoidance and safety behaviors, and subsequent poor performance and/or biased recall, maintaining and fueling catastrophic beliefs. The program emphasizes the promotion of inhibitory learning by disproving catastrophic beliefs (Hofmann, 2007) through exposure (Craske et al., 2014), rather than the physiological habituation typical of traditional exposure therapy (A. Baker et al., 2010), and also directly targets self-attention and biased recall through mental imagery-enhanced audio feedback (Nilsson & Lundh, 2016). Psychoeducational material was inspired by the SOFIE self-help manual for SAD (Andersson et al., 2006) that has been used in more than a dozen efficacy trials (Boettcher, Carlbring, Renneberg, & Berger, 2013) and is implemented in routine care in Sweden (El Alaoui et al., 2015). Speech (exposure) exercises were inspired by those used in a previous study on in-vivo exposure OST of PSA (Hindo & Gonzalez-Prendes, 2011), and lasted between one and three minutes each. Exercises were either artificial in nature, such as counting back aloud from 100 or saying words beginning on a certain letter, with the aim of demonstrating a therapeutic principle; or naturalistic, e.g. holding an unprepared speech for two minutes on a random topic. Speech exercises were conducted with no or little preparation time, with the rationale that unprepared speeches are typically associated with greater anticipatory anxiety and that excessive speech preparation and reading line-by-line are common safety behaviors.

The three-hour session began with 15 min of initial psychoeducation and functional analysis, followed by a sequence of approximately eight exposure exercises with different speech tasks of increasing severity. Therapists were encouraged to tailor the later exercises to the idiosyncratic catastrophic beliefs of the participant. Each exposure task began with the therapist providing instructions and extracting catastrophic beliefs that could be tested during exposure. The participant then put on the VR headset and carried out the exercise while audio recording. Immediately afterwards, the participant removed the VR headset and evaluated the performance together with the therapist. The participant then listened to the audio recording with eyes shut and using mental imagery to imagine seeing themselves in the third person in the same virtual environment performing the speech being listened too. This component was added since previous research has shown that using audio feedback to reduce self-attention promotes reduced performance anxiety (Nilsson & Lundh, 2016). After listening to the recording, the performance was once again evaluated with the aim of making discrepancies and disproven catastrophic beliefs explicit. Treatment then proceeded with the next exercise. The last 15 min of the session was used to summarize and prepare for the bridging to in-vivo exposure.

The VR equipment used in the therapist-led intervention was a Samsung Gear VR headset (1st generation) running on a Samsung Galaxy Note 4 smartphone. The headset was used and available only during the session. An off-the-shelf application (VirtualSpeech), available on both the Google Play (formerly Android Market) and Apple App store digital distribution platforms, was used for stimuli presentation. This application was explicitly designed for public speaking practice and not as exposure therapy stimuli. Three PSA scenarios were used: an auditorium (large audience seated at some distance), a meeting room (small audience seated at close distance), and a wedding reception (medium audience seated at a medium distance). All scenarios featured video-recorded audience members (as opposed to computer generated graphical presentations that risk inducing the uncanny valley phenomena (Seyama & Nagayama, 2007)), animated on a continuous loop but not interactive to any user behavior, overlaid on a static 360° background image. Time in the VR environment was minimized in order to avoid rapid familiarization to the VR environment independent of performing exercises. No application usage data could be extracted; exact time spent in VR (and head movement when therein) could therefore not be recorded, but is estimated to have been 20–30 minutes in total during the session.

2.3.2. Self-led OST

After completing the waiting period and the associated measures, participants were provided with basic information about how the OST was to be conducted (equipment needed, how to download the application, time required etc.) through an online treatment platform (Vlaescu, Alasjö, Miloff, Carlbring, & Andersson, 2016) and instructed to schedule the OST to a later time and day, which was communicated to their assigned therapist who then made the online OST module accessible just prior to the scheduled time. The at-home OST intervention was designed to be as similar as possible to the therapist-led intervention in terms of the psychoeducation provided, exercise instructions, and planning and evaluation format. Participants completed the at-home OST intervention without communicating with their therapist. The OST modules, as well as the in-vivo transition program that followed, were made available using the same online treatment platform. Participants were mailed a simple Google Cardboard headset (costing approximately 5 USD a piece), to be used with their own smartphone, along with a printed copy of the planning and evaluation form for use during the OST. In addition to having participants record and evaluate their idiosyncratic catastrophic beliefs with every exposure exercise, they were also instructed to create their own tailored exposure exercises in the later part of this treatment section, in order to mimic the tailoring done in the therapist-led intervention.

2.3.3. In-vivo transition program

Approximately one week after the OST, upon completion of the post measurement, participants in both arms were given access to the first part of the same four-module online program promoting transition to in-vivo exposure. Modules were made available sequentially once a week, regardless of last module completion. All four modules included the same online exercise planning and evaluation form, which the therapist monitored. Participants were instructed to plan, perform and evaluate two in-vivo exposure exercises per week. Example exercises included arranging own meetings and presenting, attending public meetings and asking questions, and pretending to talk on the phone in front of people on the bus or train. Further VR exposure was not discouraged, but the need for a transition to in-vivo exposure was made explicitly. In addition to exercise planning and evaluation forms, each module included a brief psychoeducation section repeating and extending key PSA and treatment concepts: module one focused on the transition from VR and in-vivo exposure, module two on safety behaviors, module three on catastrophic beliefs, and module four on planning for the future and relapse prevention and management. Inactive participants were reminded by their therapist by secure message or telephone to schedule and complete exposure exercises. In addition to sending reminders, therapists answered questions when asked, and reinforced and encouraged adherence, as is typical in guided internet interventions (Andersson et al., 2008; Paxling et al., 2012).

2.3.4. Therapist

Four therapists (one clinical psychologist [PL] and three final-year MSc students in clinical psychology [SF, JA and MS]) conducted treatments: all four conducted therapist-led OST session and two administered the self-led OST sessions. The same therapist that conducted the therapist-led OST session, or administered the self-led OST session, followed participants through the transition program. All therapist had training and experience in conducting exposure therapy; the three student therapists participated in a four-hour training workshop prior to their first session and were supervised by the clinical psychologist.

2.4. Measures

2.4.1. Primary outcome measure

The total score of the Public Speaking Anxiety Scale (PSAS) (Bartholomay & Houlihan, 2016) served as the primary outcome measure. The PSAS features 17 items with a five-step Likert-type item response format, scored 1–5, with verbal anchors at 1 (“Not at all”) and 5 (“Extremely”). The original English version was translated into Swedish, with an independent back-translation to English to ensure quality of translation. The PSAS covers cognitive, behavioral and physiological aspects of PSA, and is reported to have high internal consistency ($\alpha = 0.94$) and high convergent validity as indicated by a high correlation ($r = 0.84$) with other validated measures of PSA (Bartholomay & Houlihan, 2016). In the current study, internal consistency was initially somewhat low ($\alpha = 0.55$ at baseline) but markedly higher after treatment ($\alpha = 0.89$).

2.4.2. Secondary outcome measures

Two secondary outcome measures were included to cover wider aspects of social anxiety. The full width of SAD symptoms was assessed using the total score of the Liebowitz Social Anxiety Scale Self-Rated (LSAS-SR) (S. L. Baker, Heinrichs, Kim, & Hofmann, 2002). The eight-item version of the Brief Fear of Negative Evaluation Scale (BFNE) featuring only straightforward items (Carleton, Collimore, McCabe, & Antony, 2011) was included to measure fear of negative evaluation. Additional secondary outcomes covered depressive symptoms, measured using the Patient Health Questionnaire 9 (PHQ-9) (Kroenke, Spitzer, & Williams, 2001), and general anxiety symptoms, measured using the Generalized Anxiety Disorder 7-item (GAD-7) (Spitzer, Kroenke, Williams, & Löwe, 2006). These were included to measure the specificity of treatment effects and generalized impact on a wider set of mental health indices. Finally, a measure of subjective quality of life, the Brunnsviken Quality of Life scale (BBQ) (Lindner et al., 2016), was also included. Established Swedish translations of each questionnaire were used (Hedman et al., 2010; Johansson, Carlbring, Paxling, & Andersson, 2013; Mörtberg & Andersson, 2013). In the current study, internal consistencies were all high at baseline (BFNE $\alpha = 0.93$, LSAS-SR $\alpha = 0.94$, BBQ $\alpha = 0.77$, PHQ-9 $\alpha = 0.83$, GAD-7 $\alpha = 0.89$).

2.4.3. In-vivo exposure exercises during transition period

To examine whether performed in-vivo exposure exercises moderated symptom decrease during the transition period, number of planned and completed in-vivo exposure exercises were extracted from the online platform from the $n = 43$ participants who began this treatment phase. Completion of an exercise was defined as responding to the post-exercise evaluation part of the same form used for planning. Since missing data on the post-exercise part could result from either not completing the exercise, or just not completing the form, we considered both planned (total = 232) and completed (total = 176) exercises as potential moderators, replacing missing data with zeroes in the latter variant. Both raw numeric count (ranging 0–7) and binary (thresholded at zero or above) moderator variables were investigated since linear effects could not be assumed.

2.4.4. Treatment satisfaction and negative effects

At the post-transition measurement for each arm, treatment satisfaction was measured using the total score of the Client Satisfaction Questionnaire 8-item version (Larsen, Attkisson, Hargreaves, & Nguyen, 1979). Negative effects of treatment (Rozental et al., 2014) were measured using the Negative Effects Questionnaire (Rozental, Kottorp, Boettcher, Andersson, & Carlbring, 2016), with the most commonly endorsed items (negative effects) reported.

2.5. Analyses

Outcome data were analyzed on an intention-to-treat basis using linear mixed effects models (Hesser, 2015), with restricted maximum likelihood estimation, unstructured random effects covariance matrices, and random slopes and intercepts. Data was assumed to be missing at random and effect sizes thus calculated on observed data. A linear time variable, corresponding to treatment period (0 = pre, 1 = post-OST, 1.25–1.75 = weekly during in-vivo transition program, and 2 = post-treatment) rather than measurement sequence due to the two-part nature of the intervention and a better fit with actual data, along with a binary trial arm variable (0 = waiting-list group, 1 = treatment group), were included, making beta values of the time × group effects interpretable as the difference in slopes (decrease in score) between groups per treatment period. For the second phase of the trial, piece-wise mixed models were used to examine the difference in slopes between the waiting list and treatment period for the self-led arm. Long-term effects were analyzed using generalized estimating equations (GEE) models, a factorial time predictor, and available data only, since trends could not be assumed to be linear and missing data estimation using random slopes and intercept modeling is inappropriate when only two measurement points for the same linear trend are available (Hesser, 2015).

Explorative moderation analyses were performed on the primary outcome using only available data, with no imputations. Moderation was investigated by including either planned or completed number of exercises, as either a numeric or binary variable, as a lagged time-varying predictor in the mixed effects model examining the main effect of time during the treatment period (five time-points), such that a significant main effect of the moderator can be interpreted as additional reduction in the outcome if an exposure exercise had been completed during the week that preceded the measurement. Since initial analyses suggested group × moderator interaction effects in opposite directions, these analyses were conducted on each treatment group separately.

3. Results

3.1. Attrition, missing data and program engagement

Almost all participant, n = 22 in therapist-led arm and n = 20 in the self-led arm ($\chi^2 = 0.60$, p = .44), began the transition program after completing the OST session (and waiting-list if applicable). Percentage of missing data was at most n = 7 in any group at any time-point (Table 2). In all mixed models, the fitted regression lines, calculated under the missing at random assumption, overlapped the 95% confidence interval of the corresponding observed group means, revealing good model fit and supportive of the missing at random assumption. Overall, compliance with the transition program was low, yet varied considerably among participants. Percentage of opened transition program modules was very similar across groups: on average, each module was opened by 68% in the therapist-led group and 70% in the self-led group. Total number of exposure exercises, both planned and completed, ranged between zero and 19, with a recommended minimum of eight during the entire period (two per week). There was a trend towards the self-led group reporting less planned exposure exercises during the transition period (M = 3.28 [SD = 4.29] versus M = 6.04 [SD = 5.86]; t = 3.19, p = .063); this trend was weaker when only considering completed exercises (M = 2.44 [SD = 4.18] versus M = 4.60 [SD = 4.77]; t = 2.72, p = .095).

3.2. Therapist-led OST with online transition program vs. waiting-list

The conditional mixed model capturing the first phase of the trial revealed no main effects of treatment group (B = −0.16, SE = 1.50, p = .918) or time (B = −1.11, SE = 0.72, p = 0.127), but a significant interaction effect such that participants in the therapist-led arm decreased their PSAS score by an average of 6.90 points (95% CI: −8.99 to −4.79, SE = 1.04, p < .001) more than the waiting-list arm per treatment step. See panel A of Fig. 2. Analyzing the treatment steps separately revealed a 6.17 observed point difference (95% CI: 1.96–10.38) between groups after the therapist-led OST (or equivalent waiting time), corresponding to between-group effect size of d = 0.83 and a within-group effect size of d = 0.77. The difference between groups increased to a 12.99 point difference (95% CI: 8.06–17.93) at the end of the in-vivo transition program (or equivalent waiting time), corresponding to between-group effect size of Cohen's d = 1.50 and a within-group effect size of d = 1.67. Mixed effects modeling of secondary outcomes revealed small but significant reductions in the therapist-led group compared to the waiting-list group on general social anxiety and fear of negative evaluation, but not on quality of life, depression or general anxiety; see Table 3 for details.

3.3. Self-led OST with online transition program

The differential two-slope mixed model capturing the second phase of the trial revealed a significant difference between the waiting-list slope and treatment slope of 6.57 points (95% CI: 4.08–9.06, SE = 1.20, p < .001) per treatment step. See panel B of Fig. 2. Analyzing the treatment steps separately revealed an observed, un-adjusted within-group difference of 8.91 point (95% CI: 5.97–11.84) after the self-led OST, corresponding to a within-group effect size of d = 1.38. The observed within-group difference increased to a 15.7 un-adjusted point difference (95% CI: 10.27–21.13) at the end of the in-vivo transition program, corresponding to a within-group effect size of d = 1.35 as a result of increasing standard deviations. Mixed effects modeling of secondary outcomes using the same two-slope model revealed a change after treatment-onset only on the LSAS-SR but no other outcome; see Table 3 for details.

3.4. Effects of in-vivo exposure during transition period

In the therapist-led arm, past-week in-vivo exposure exercises were associated with a significantly lower PSAS score using three out of four definitions, as hypothesized. No such associations were found in the self-led arm. On the contrary, there was a trend (p = .08) towards past-week in-vivo exposure exercises being associated with higher PSAS scores, using two out of the four definitions. See Table 4 for details.

3.5. Long-term effects

Long-term effects were examined in factorial GEE models featuring post-transition, six and twelve month follow-up data, with the middle measurement set as the reference time level with which the other measurements were contrasted. On the PSAS, results revealed a significant interaction effect post-transition to six-month (B = 7.75, SE = 2.81, p = .006) such that the therapist-led group experienced a larger decrease between these time points than the self-led group. Running unconditional models for each arm separately showed that the 5.77 (SE = 2.14, p = .007) decrease in PSAS score post-transition to six-month in the therapist led-arm was significant, while the score of the self-led arm remained the same (p = .279). The difference between the six- and twelve month follow-up was not significant in any arm and was the same for both arms.

Table 2
Observed means, standard deviations and n missing for primary outcome (PSAS) at each time-point.

			Therapist-led OST (n = 25)			Waiting-list / self-led OST (n = 25)		
Time 1	Time 2	Description	M	SD	N missing	M	SD	N missing
0	0	Baseline	71.32	5.50	0	71.36	5.35	0
1	0	After therapist-led OST, or equivalent waiting time	64.71	8.93	1	70.88	5.36	0
1.25	0	First week of in-vivo transition, or equivalent waiting time	61.00	10.30	5	71.00	4.61	1
1.50	0	Second week of in-vivo transition, or equivalent waiting time	58.60	8.56	5	70.26	6.30	2
1.75	0	Third week of in-vivo transition, or equivalent waiting time	56.11	10.32	7	69.32	6.41	0
2	0	After in-vivo transition program, or equivalent waiting time	56.29	10.49	4	69.28	5.80	0
3	1	After self-led OST				59.95	8.97	4
3.25	1.25	First week of in-vivo transition				60.21	10.43	6
3.5	1.50	Second week of in-vivo transition				58.22	10.87	7
3.75	1.75	Third week of in-vivo transition				55.33	11.11	7
4	2	After in-vivo transition program				52.90	11.14	5

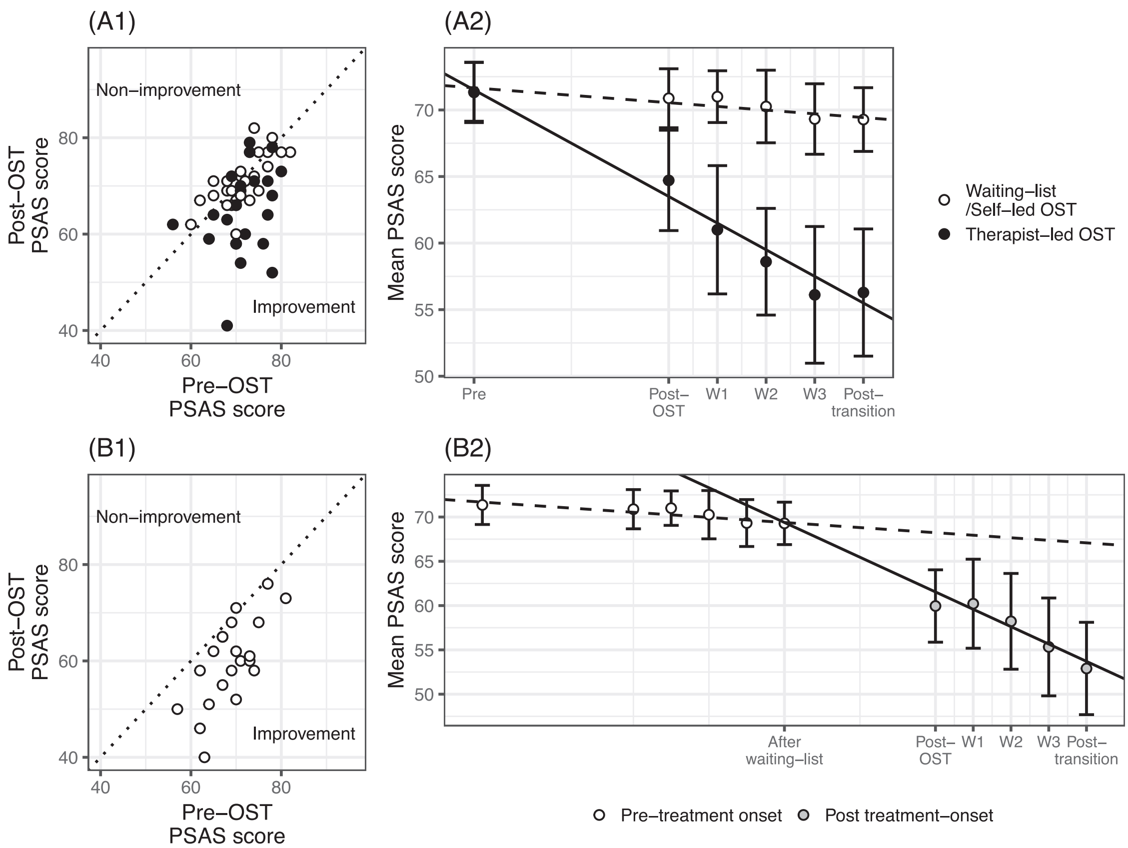

Fig. 2. Changes in primary outcome over time.
(A1) Brinley scatterplot of individual PSAS values pre- and post-therapist-led OST in both groups. (A2) Group mean PSAS scores over time and fixed effects slopes. (B1) Brinley scatterplot of individual PSAS values pre- and post-self-led OST. (B2) Mean PSAS scores pre- and post-treatment-onset and fixed effects slopes.

On secondary outcome measures, the only significant interaction effect was on change in LSAS score between the six- and twelve month follow-ups ($p < .001$) such that while the self-led arm increased in score (B = 6.82, SE = 2.89, p = .018), the therapist-led arm decreased (B = 6.13, SE = 1.99, p = .002). A single significant main effect of time was found, such that self-led arm reported a significant increase in score on the BBQ between the six- and twelve month follow-ups (B = 8.9, Se = 4.39, p = .043). In sum, with one exception, post-treatment results were either maintained or improved during the follow-up period. See Fig. 3.

3.6. Treatment satisfaction and negative effects

The two treatment arms reported similar levels of treatment satisfaction (ΔM = 1.84 [95% CI: -0.97—4.65], F[1,39] = 1.75, p = .19). The two treatment arms also reported similar numbers (ΔM = 1.11 [95% CI: -1.13—3.36], F[1,39] = 1.01, p = .322) of negative effects, with a mean score of 4.17 (SD = 3.55) out of a maximum possible 32. As can be expected in exposure treatment, the negative effect with the highest frequency was "I felt like I was under more stress" (endorsed by 56% of the sample). Two additional statements were endorsed by more than 25% of the sample: "I experienced more anxiety" (34%) and "I felt that the treatment did not suit me" (29%).

4. Discussion

This is the first study to investigate the efficacy of using consumer, off-the-shelf VR hardware and software to conduct exposure therapy for PSA, both in the traditional therapist-led format and as a self-led, at-home treatment. Both treatment variants led to large, immediate

Table 3
Secondary outcome measures.

Phase #1: Therapist-led treatment versus waiting-list				Phase #2: Waiting-list versus adjusted self-led treatment slopes			
LSAS-SR	**B**	**SE**	**p**	**LSAS-SR**	**B**	**SE**	**p**
(Intercept)	50.65	4.17	0.00	*(Intercept)*	50.57	3.75	0.00
Time	−0.76	1.35	0.58	*Waiting-list slope*	−0.52	1.51	0.73
Group	6.46	5.90	0.28	*Adj. treatment slope*	−4.97	2.19	0.03
Time × Group	−5.65	1.97	0.01				
BFNE	**B**	**SE**	**p**	**BFNE**	**B**	**SE**	**p**
(Intercept)	29.93	1.49	0.00	*(Intercept)*	29.95	1.57	0.00
Time	−0.60	0.55	0.28	*Waiting-list slope*	−0.64	0.41	0.14
Group	2.74	2.11	0.20	*Adj. treatment slope*	−0.82	1.05	0.44
Time × Group	−2.15	0.80	0.01				
PHQ-9	**B**	**SE**	**p**		**B**	**SE**	**p**
(Intercept)	5.77	0.90	0.00	*(Intercept)*	5.75	1.00	0.00
Time	−0.54	0.39	0.17	*Waiting-list slope*	−0.49	0.32	0.14
Group	0.35	1.27	0.78	*Adj. treatment slope*	0.18	0.64	0.78
Time × Group	−0.17	0.56	0.77				
GAD-7[a]	**B**	**SE**	**p**	**GAD-7**[a]	**B**	**SE**	**p**
(Intercept)	5.81	0.78	0.00	*(Intercept)*	5.76	0.89	0.00
Time	−0.58	0.34	0.09	*Waiting-list slope*	−0.45	0.34	0.20
Group	−0.41	1.11	0.71	*Adj. treatment slope*	0.01	0.62	0.99
Time × Group	0.68	0.50	0.18				
BBQ	**B**	**SE**	**p**	**BBQ**	**B**	**SE**	**p**
(Intercept)	53.83	3.97	0.00	*(Intercept)*	53.70	3.36	0.00
Time	3.40	1.83	0.07	*Waiting-list slope*	3.77	1.69	0.03
Group	5.36	5.62	0.35	*Adj. treatment slope*	−2.80	2.65	0.30
Time × Group	0.61	2.66	0.82				

B: (unstandardized) parameter estimate; SE: standard error.
[a] Random slopes omitted due to convergence error.

Table 4
Moderating effects of in-vivo exposure exercises.

Moderator definition	Self-led arm			Therapist-led arm		
Planned: Numeric	**B**	**SE**	**p**	**B**	**SE**	**p**
(Intercept)	60.44	2.13	0.00	64.08	1.85	0.00
Time	−7.30	2.54	0.01	−7.37	1.84	0.00
Time-lagged moderator	0.72	0.41	0.08	−0.94	0.35	0.01
Planned: Binary	**B**	**SE**	**p**	**B**	**SE**	**p**
(Intercept)	60.81	2.13	0.00	64.11	1.86	0.00
Time	−7.32	2.55	0.01	−7.24	1.84	0.00
Time-lagged moderator	0.52	0.97	0.59	−3.13	1.36	0.02
Completed: Numeric	**B**	**SE**	**p**	**B**	**SE**	**p**
(Intercept)	60.55	2.11	0.00	63.87	1.85	0.00
Time	−7.37	2.55	0.01	−7.87	1.86	0.00
Time-lagged moderator	0.84	0.47	0.08	−0.81	0.39	0.04
Completed: Binary	**B**	**SE**	**p**	**B**	**SE**	**p**
(Intercept)	60.67	2.12	0.00	63.70	1.84	0.00
Time	−7.32	2.55	0.01	−7.96	1.90	0.00
Time-lagged moderator	1.23	1.07	0.25	−1.73	1.37	0.21

B: (unstandardized) parameter estimate; SE: standard error.

improvements in PSA that were comparable across formats. Effects increased further during the internet-administered VR to in-vivo transition period.

Our results replicate past studies showing high efficacy of VRET for social anxiety (Anderson et al., 2013; Bouchard et al., 2017; Kampmann et al., 2016; Wallach et al., 2009), yet also show, for the first time, that this efficacy can be achieved also using off-the-shelf consumer VR hardware and software that could be acquired by any clinician at a negligible cost. This constitutes an important step in translating experimental VR interventions into treatments that can be used in routine clinical practice by ordinary clinicians (Gega, 2017; Lindner et al., 2017). With one recent exception (Stupar-Rutenfrans et al., 2017), past VRET interventions for social anxiety have almost exclusively been therapeutically conservative in the sense that although VR was used for stimuli presentation, treatment was still led by a therapist. With the advent of consumer VR hardware and software comes the possibility to design self-contained VR applications for direct use by patients for self-help purposes (Lindner et al., 2017). The current study employed a hybrid approach, wherein the VR exposure stimulus material was separate from the therapeutic material, which was provided via an online platform (Vlaescu et al., 2016). This approach mirrors the common form of internet-based psychological self-help treatments that have been developed over the last decade (Andersson et al., 2008; Andersson, 2016), albeit with the addition of VR to allow exposure to be conducted in immediate conjunction with reading the treatment material, rather than having to be planned for a separate occasion. If the results of the current study are replicated, this would suggest that currently available internet-based treatments for SAD (Boettcher et al., 2013; El Alaoui et al., 2015) may benefit from being supplemented with VR exposure tools.

Additionally, our results suggest that by including therapeutic material directly in the application, and designing a therapeutic progression sequence, it may be possible to create efficacious interventions for PSA that are not just self-led, but self-contained, automated self-help applications, as has been done recently with spider phobia (Miloff et al., 2016). The dissemination potential of such interventions would be limited only by the adoption rate of consumer VR devices, which may in the future may become as ubiquitous as smartphones are today. Whether such self-led and self-help VR treatments can achieve the same efficacy as therapist-led VR treatments is therefore an important area for future research (Lindner et al., 2017). The current study was neither powered nor designed to directly compare therapist-led to self-led treatment and the effects were therefore not directly statistically contrasted. However, overlapping confidence intervals of effects suggest there being at least no large differences between the two interventions, in congruence with meta-analytic findings showing that internet interventions are as efficacious as traditional, face-to-face CBT (Carlbring, Andersson, Cuijpers, Riper, & Hedman-Lagerlöf, 2017).

Our rationale for evaluating the OST format for PSA, made possible by VR stimuli material, was that (non-generalized) PSA, in many

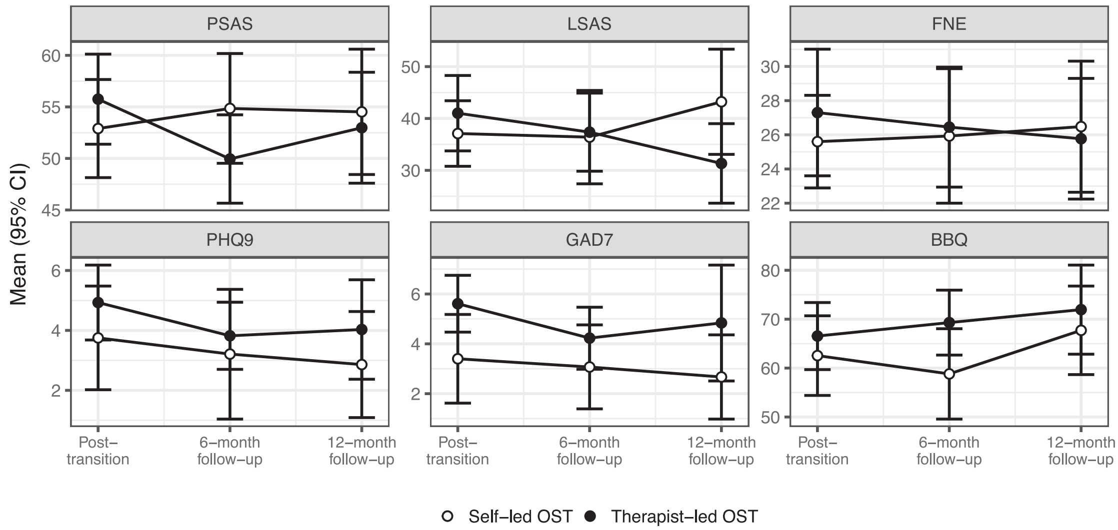

Fig. 3. Six- and twelve month follow-up results.

important aspects, is more similar to specific phobia than generalized SAD (Heimberg et al., 1990; Hofmann et al., 1995; Levin et al., 1993; Mannuzza et al., 1995; Stemberger et al., 1995). While the therapist-led OST effect size was found to be large, it was not as large as those typically seen in OST for animal phobias (Andersson et al., 2009; Haukebø et al., 2008; Ollendick & Davis, 2013; Öst et al., 1992, 1997; Öst et al., 2001; Wolitzky-Taylor et al., 2008; Zlomke & Davis, 2008). Future research will need to examine the impact in PSA treatment of generalized SAD symptoms that cannot easily be targeted in VR exposure (e.g. fear of negative evaluation), and whether PSA symptom reduction is specific to a certain domain (fear of physiological response, catastrophic beliefs about performance, etc.). VR technology enables in-session exposure together with a therapist to stimuli previously impractical or impossible to expose to in-vivo; while this will likely work equally well also with other disorders in which exposure would otherwise need to be scheduled between-session, the efficacy of the one-session format per se with other disorders will most likely be contingent on other factors (e.g. eliciting arousal, general and VR-specific difficulty in targeting catastrophic beliefs, etc.) that varies between anxiety disorders.

In line with our hypothesis, symptom decrease continued in a linear fashion after the OST session, during the four-week VR to in-vivo transition program. This finding emphasizes the importance of including transition components in VR treatments (Gega, 2017), an aspect that has been somewhat neglected in past VRET research. As hypothesized, our exploratory moderation analysis identified an effect of in-vivo exposure exercises on outcomes such that having planned or completed at least one exposure exercise in the week prior to measurement was associated with an additional symptom decrease. Surprisingly however, this association was found only in the arm that received therapist-led OST. The most parsimonious interpretation of this finding is that the self-led OST intervention, while leading to a similar initial decrease in PSA symptoms, was not as successful in preparing participants for the real-life exposure that followed. This interpretation is congruent with the lack of effects on fear of negative evaluation found in this arm, which was identified in the therapist-led arm. Also, while PSA improvement in the self-led arm was maintained at the six-month follow-up, the therapist-led arm continued to improve. The design of the current study limits our ability to infer which aspect of the difference in OST presentation that is the likely primary contributor to this divergence in effects: the written material it-self, the tailoring potential, generic therapist effects, hardware quality and subsequent degree of VR presence, etc. Identifying and disentangling the impact of each aspect is an important topic for future research into non-traditional VR treatments.

4.1. Limitations

This study has some limitations in need of recognition. First, although powered to detect a large between-group effect size, the relatively small sample means that caution should be exercised in generalizing our findings to the broader population with elevated PSA scores. Psychiatric comorbidity was not systematically examined using diagnostic interviews and self-reported comorbidity was grounds for exclusion, further potentially limiting the generalizability of findings to cases of severe PSA. Congruently, the self-reported depressive and general anxiety symptoms were found to be low at baseline, meaning that there was little room for improvement, which could explain the non-significant changes on these measures following treatment. With the exception of clinician-rated diagnostic status used for descriptive purposes, all data was self-rated. The use of an off-the-shelf VR application means that no application usage data (e.g. total time spent in VR) could be collected and compared across groups. No data was collected on continued VR exposure during the in-vivo transition program and only the self-led OST group had guaranteed access to continued VR exposure during this period. Finally, our explorative analyses on the moderating effects of in-vivo exposure exercises during the transition period may have been under-powered.

5. Conclusions

We conclude that it is possible to use currently available, off-the-shelf, low-cost consumer VR hardware and software to conduct efficacious exposure therapy for PSA, both in the traditional, yet previously impractical one-session format with in-session exposure, and as a novel type of self-led, at-home intervention.

Conflicts of interest

None of the authors have any commercial or other ties to the developers of the application used for stimuli presentation. Use of the application was for research purposes and strictly non-commercial. Author PL has received consulting fees from Mimerse, a technology company that develops VR applications for clinical use, not involved in the current study. The other authors report no conflicts of interest.

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