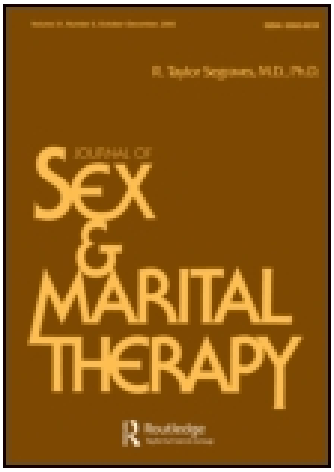

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Evaluation of a Behavioral Treatment Intervention for Premature Ejaculation Using a Handheld Stimulating Device

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Evaluation of a Behavioral Treatment Intervention for Premature Ejaculation Using a Handheld Stimulating Device

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Premature ejaculation is usually considered to be the most common male sexual complaint. Psychosocial treatment interventions have been recommended by clinicians since the 1950s, but concerns have been raised regarding their efficacy, especially so since the introduction of pharmaceutical treatment interventions. However, as noted in reviews and meta-analyses, one reason for these concerns is the lack of methodologically robust studies that have attempted to evaluate the efficacy of psychosocial treatment interventions. The present study aimed to replicate a recent study showing promising results for a behavioral treatment intervention using a handheld, vibrating stimulation device in a variation of the classical stop-start technique first introduced by Semans in 1956. The present study enrolled 11 men and used a randomized wait list–controlled design. Results provide further support for the efficacy of this novel treatment intervention and suggest that effects are stable or improved further 6 months after completing treatment. The present study contributes to the growing number of studies that suggest that psychosocial treatment interventions are promising alternatives to pharmacological treatment.

INTRODUCTION

Men frequently cite premature ejaculation (PE) as their most common sexual complaint. Depending on definition and diagnostic criteria, prevalence rates typically range from about 30% to 1.5% with the most stringent criteria. The diagnostic criteria for lifelong PE proposed by the International Society for Sexual Medicine stipulate that ejaculatory latencies during vaginal intercourse of "about one minute" or less; inability to delay ejaculation on "all or nearly all" vaginal penetrations; and negative personal consequences as key indicators for diagnosis (Althof et al., 2010, p. 2949).

Psychosocial treatment interventions were once the first-line treatment option for PE, and of these, the stop-start technique first described by Semans (1956) and subsequently used in numerous variations is arguably the most common. However, after a meta-analysis of studies of psychosocial treatment interventions for EE (De Amicis, Goldberg, LoPiccolo, Friedman, &

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Davies, 1985), concerns were raised regarding their efficacy, especially in the long term, with the meta-analysis suggesting some initial treatment success, but relapse rates of more than 90% at 3 years posttreatment. It should also be noted that most of the early studies of psychosocial PE interventions had many methodological problems, such as lacking a control group and using small samples (Glina et al., 2007). More recently, a systematic review concluded that there is little evidence to suggest that psychosocial treatment interventions are effective (Melnik et al., 2011). However, the meaning of this conclusion is literal: Melnik and colleagues (2011) identified only four studies that fulfilled inclusion criteria, all of which had relatively small sample sizes and none of which used the same intervention design.

In the United Kingdom, Zamar (2012) developed a behavioral intervention for PE. Early trials involving 58 participants (using psychosexual therapy as a control group) have produced good results after a 6-week intervention, with 11-fold increases in intravaginal ejaculation latency time in 61% of patients over 6 weeks. Treatment benefits were stable over at least 3 months after completed treatment. This intervention is a variation of the stop-start technique, in which masturbation exercises using a handheld, vibrating stimulation device are conducted three times per week over 6 weeks. During every exercise, the patient is instructed to (a) masturbate with the device turned on and placed under the glans penis until he is close to ejaculation and (b) remove the device shortly before ejaculation. This process is repeated three times, then the patient may continue until ejaculation if he chooses. The intervention is described in closer detail on the device manufacturer's website: http://www.aboutpe.com.

The present study aimed to replicate Zamar's (2012) study. I used a randomized, wait list–controlled study design to investigate the efficacy of a novel behavioral treatment intervention for PE, which used a handheld, vibrating stimulation device. I assessed stability of effects at 6 months follow-up after the 6-week training protocol had ended.

METHOD

Participants

I recruited 13 Finnish men between 33 and 65 years of age ($M = 49.3$ years, $SD = 10.2$ years) to participate in a pilot study in the fall of 2012 investigating the efficacy of a novel behavioral treatment for PE. These 13 participants had participated in an epidemiological study I had conducted in the same year. After identifying individuals who were not currently using antidepressant medication (for PE treatment or otherwise), randomly selected individuals were contacted until 13 had given an affirmative response (in total, 18 individuals were contacted and of these, 5 did not wish to participate or did not respond to the initial contact). All participants were in long-term heterosexual relationships and had previously been diagnosed with lifelong PE by a physician specializing in sexual medicine. Participants had indicated that they had previously been using selective serotonin reuptake inhibitor (SSRI) medication (paroxetine, dapoxetine, or both) to treat PE but that they had discontinued drug treatment because of poor efficacy, too many side effects, or both. All participants had stopped using SSRIs at least 6 months before enrolling in the study, with the exception of 1 individual who had used dapoxetine sporadically over 6 months before enrolling in the study. This participant did not use dapoxetine during the study period, and it should be noted that dapoxetine has a very short half-life (Andersson, Mulhall, & Wyllie, 2006),

and this individual's sporadic dapoxetine use was thus unlikely to affect the results of the present study. Of these 13 men, 1 did not participate beyond the first visit, and 1 indicated willingness to participate during initial contact but did not appear for any visits to the clinic. Thus, the final sample size for this pilot study was 11. These were, before beginning the study, randomly assigned to case ($n = 6$) or wait list control ($n = 5$) conditions. Individuals assigned to the wait list control group then received the same treatment intervention after being on the wait list for 6 weeks.

Procedure

Recruited participants were randomly assigned to a treatment group (Group 1) or a wait list control group (Group 2). The treatment intervention consisted of completing a training program with masturbation exercises three times per week for 6 weeks. The training program can be carried out completely candidly (i.e., without informing the partner), and participants were informed that they could decide for themselves whether they told their partner. Moreover, participants were informed that they could incorporate the training regime into partnered sexual activities (e.g., as a part of foreplay) if the training exercises were carried out as instructed. The men themselves carried out the masturbation exercises. The exercises were completed using a small, stimulating device equipped with a battery-powered vibrator (see Zamar, 2012) that was given to participate at the end of a preintervention visit to the clinic. A bottle of water-soluble personal lubricant to be applied to the contact surface of the device before treatment exercises was also given to each participant. During each masturbation exercise, participants were instructed by the author (a clinical psychologist with a specialization degree in sex therapy) to continue until close to achieving ejaculation and then stop until the sensation of impending orgasm recessed. For each exercise session, this was repeated three times, after which the participant was allowed to continue until ejaculation if he wished. All participants were given a demonstration of how to conduct the masturbation exercise with the aid of a penis-shaped object and a Finnish translation of the manufacturer's instruction booklet. In addition, the manufacturer's instruction video was shown to all participants during the preintervention visit. At the end of the preintervention visit, participants were given clear written and oral instructions on how to clean and maintain the device, and they were offered an opportunity to ask any questions or express concerns regarding the training regime. Participants were also advised that they could contact the investigator at any time during the study if they had any further questions. Data were collected at pre- and postintervention visits to the clinic, as well as during a 6-month follow-up after completion of the training regime. In addition, data were collected from the control group during the pre–wait list period meeting. Participants were offered the choice of submitting data through a secure online questionnaire or by postal mail.

All participants provided written informed consent. Participants were informed that participation was voluntary and that they were free to discontinue their participation at any stage without having to declare a reason for doing so. Participants were not offered any reimbursements or monetary rewards for their participation, but they were allowed to keep the device used in the exercises (a stimulation device was priced at around €200 at the time of the study). Before the start of the study, an ethical research permit was obtained from the Ethics Committee of the Abo Akademi University in accordance with the 1964 Declaration of Helsinki.

Measures

Measures of ejaculatory function were collected three or four times from each participant, depending on whether the participant was assigned to the wait list control condition. Participants were given a stopwatch and instructions of how to record ejaculatory latency during one sexual activity with their partner. Participants were instructed to start the stopwatch when first entering their partner (vaginally or anally) and to stop the stopwatch when ejaculation began. They were also informed that their partners could operate the stopwatch, and in that case, to clearly inform the partner when to commence and stop timekeeping. In addition, participants completed the Checklist for Early Ejaculation Symptoms (CHEES; Jern, Piha, & Santilla, 2013). Higher scores on all variables indicate more severe PE symptoms. Participants responded to this questionnaire, which consists of the following five questions:

1. How was your control over ejaculation during sexual intercourse?
2. To what extent did how fast you ejaculated (came) during sexual (vaginal) intercourse cause difficulty in your relationship with your partner?
3. Did you ejaculate with very little stimulation?
4. Did you feel frustrated because of ejaculating before you wanted to?
5. On average, during intercourse, how much time elapsed between when you first entered your partner (vaginally or anally) with your penis and when you first ejaculated?

It is a hybrid measure consisting of items from three existing questionnaires—the Premature Ejaculation Diagnostic Tool (Symonds et al., 2007; two items), the Premature Ejaculation Profile (Patrick et al., 2009; two items), and Multiple Indicators of Premature Ejaculation (Jern et al., 2009; one item). This instrument has very good validity and is the result of an empirical analysis of a clinical sample and of a large, population-based sample of all items in the aforementioned three questionnaires. The five items that constitute CHEES are the five most powerful predictors of PE diagnosis and short ejaculatory latency, in addition to being more up to date with recent changes to diagnostic criteria than any of the three screening tools it is based on. CHEES focuses on five aspects of ejaculatory function: ejaculatory control, PE-induced relationship problems, PE-induced personal frustration, ejaculation latency time, and the degree of which the person ejaculates with very little stimulation, all of which are considered important clinical aspects of PE (e.g., Althof et al., 2010). The five items were added to form a composite variable (CHEES). Scoring ranges from 5 to 25, with higher scores indicating more PE symptoms. Side effects were measured with one open-ended question ("Did you experience any side effects attributable to the treatment?"), which was graded on a scale from 1 to 5 for severity for any symptom described.

Statistical Analyses

All tests of treatment effects were one-tailed. First, to get an overall estimate of change, I compared all pretreatment values (pretreatment values for treatment and control group participants and preintervention start values for control group participants) with all posttreatment values (posttreatment and follow-up values for both groups) while controlling for the dependence of observations from the same individuals using the Generalized Estimating Equations module of SPSS 21.0. This analysis was done to maximize statistical power for detecting the effect of treatment considering the low number of participants in the study.

RESULTS

Global Tests of Treatment Effects

I first compared all pretreatment ELTs with all posttreatment ELTs. The pretreatment ELTs ($n_{\text{observations}} = 16$, $M = 108.50$, $SE = 33.53$) were shorter compared with the posttreatment ELTs ($n_{\text{observations}} = 17$, $M = 222.00$, $SE = 33.99$, Wald $\chi^2 = 4.88$, $p < .014$, $\eta^2 = .22$). Next, I compared pre- and posttreatment CHEES scores. The pretreatment scores ($n_{\text{observations}} = 16$, $M = 15.00$, $SE = 0.66$) were higher compared with the posttreatment ELTs ($n_{\text{observations}} = 19$, $M = 12.84$, $SE = 0.83$, Wald $\chi^2 = 7.44$, $p < .003$, $\eta^2 = .15$) indicating that the participants reported improved ejaculatory function after the treatment. Two participants reported that they did not tell their partners about their participation in the study. There was no difference in terms of baseline or follow-up ELTs between these individuals and the individuals who told their partners about their participation (Fisher's exact test = 4.963, $p = .417$).

Tests of Immediate Treatment Effects

Table 1 illustrates the treatment effects. First, as a manipulation check, I tested whether there were differences between the treatment and control groups before the treatment at Time 1. There were no differences for either the ELTs ($p < .612$) or the CHEES scores ($p < .570$), suggesting that the random allocation to treatment and control groups was successful. Second, I tested whether the ELTs and CHEES scores had changed from Time 1 to Time 2 separately for the treatment (who received treatment during these time points) and control (who did not receive treatment between these time points) group. The treatment group improved measured with the ELTs ($n_{\text{participants}} = 5$: $\text{ELT}_{\text{Time1}}$ $M = 78.40$, $SD = 34.62$; $\text{ELT}_{\text{Time2}}$ $M = 174.40$, $SD = 74.07$, $t[4] = 3.04$, $p < .019$) but not with the CHEES ($n_{\text{participants}} = 5$: $\text{CHEES}_{\text{Time1}}$ $M = 15.20$, $SD = 2.05$; $\text{CHEES}_{\text{Time2}}$ $M = 15.00$, $SD = 1.41$, $p < .419$). The control group did not change during the same time period on regarding either ELTs ($n_{\text{participants}} = 5$: $\text{ELT}_{\text{Time1}}$ $M = 100.00$, $SD = 98.64$; $\text{ELT}_{\text{Time2}}$ $M = 153.80$, $SD = 162.46$, $p < .075$) or CHEES scores ($n_{\text{participants}} = 5$: $\text{CHEES}_{\text{Time1}}$ $M = 15.30$, $SD = 1.86$; $\text{CHEES}_{\text{Time2}}$ $M = 15.30$, $SD = 2.64$, $p < .500$). These results provide partial support for the immediate efficacy of the treatment. Third, I tested whether the ELT and CHEES scores of the control group changed between Time 2 and Time 3 (the control group received treatment between these two time points). The control group did not improve measured with the ELTs ($n_{\text{participants}} = 3$: $\text{ELT}_{\text{Time2}}$ $M = 223.00$, $SD = 186.37$; $\text{ELT}_{\text{Time3}}$ $M = 362.00$, $SD = 198.01$, $p < .295$), but it improved measured with the CHEES ($n_{\text{participants}} = 4$: $\text{CHEES}_{\text{Time2}}$ $M = 15.63$, $SD = 2.93$; $\text{CHEES}_{\text{Time3}}$ $M = 11.50$, $SD = 3.41$, $t[3] = 2.79$, $p < .034$). Again, these results provide partial support for the immediate efficacy of the treatment.

Test of Long-Term Treatment Effects

Next, I looked at the long-term effects of the treatment by comparing the ELTs and CHEES scores from Time 1 (neither the experimental nor the control group had been treated) to Time 4 (follow-up measurements). All participants were tested simultaneously in these analyses. ELTs and CHEES scores improved from Time 1 to Time 4 ($n_{\text{participants}} = 9$: $\text{ELT}_{\text{Time1}}$ $M = 97.56$, $SD = 71.04$; $\text{ELT}_{\text{Time4}}$ $M = 201.78$, $SD = 69.41$, $t[8] = 3.14$, $p < .008$; $n_{\text{participants}} = 10$: $\text{CHEES}_{\text{Time1}}$

TABLE 1
Ejaculatory Function Measures Before and After Assignment to Treatment or Waiting-List Control Conditions

	Group 1	*Group 2*	*Combined*
	Time 1: Pretreatment for Group 1, pre–wait list (6 weeks) for Group 2		
M (ELT in seconds)	77.83	100.00	87.91
SD (ELT in seconds)	30.99	98.64	67.13
M (CHEES)	14.50	15.30	15.00
SD (CHEES)	2.51	1.86	1.41
	Time 2: Posttreatment for Group 1, pretreatment for Group 2		
M (ELT in seconds)	174.40	153.80	
SD (ELT in seconds)	74.07	162.46	
M (CHEES)	15.00	15.30	
SD (CHEES)	1.41	2.64	
	Time 3: Posttreatment for Group 2		
M (ELT in seconds)		362.00	
SD (ELT in seconds)		198.01	
M (CHEES)		11.5	
SD (CHEES)		3.41	
	Time 4: Follow-up (6 months after Time 3) for Groups 1 and 2		
M (ELT in seconds)	172.50	260.33	201.78
SD (ELT in seconds)	30.64	95.97	69.41
M (CHEES)	12.17	12.50	12.30
SD (CHEES)	2.13	4.04	2.83

Note. ELT refers to stopwatch-measured ejaculation latency time during vaginal or anal intercourse. CHEES = Checklist of Early Ejaculation Symptoms (Jern, Piha, & Santtila, 2013). Group 1 is a traditional treatment group, with ejaculatory function measured before and after treatment, as well as at a follow-up 6 months after the treatment period (Time 2) had ended. Group 2 provided an initial measure after a visit to the clinic (Time 1), after which participants in this group were assigned to a 6-week wait list. After 6 weeks on the wait list, they provided another set of measures (Time 2), then began treatment, which was reported at Time 3.

$M = 14.95$, $SD = 2.27$; $\text{CHEES}_{\text{Time4}}$ $M = 12.30$, $SD = 2.83$, $t[9] = 3.12$, $p < .006$). Difference scores for ELT between measurements for each individual are depicted in Table 2. These results provide clear support for the long-term efficacy of the treatment.

Side Effect Profile

No side effects were reported.

DISCUSSION

In the present study, I investigated the efficacy of a novel, behavioral treatment intervention for PE using a wait list control group design. This approach was chosen because it allows for boosting the sample size in the intervention group: Individuals assigned to the wait list control condition received the same treatment afterwards. The results suggest that the device-assisted variation of

TABLE 2
Individual Change in Stopwatch-Measured Ejaculation Latency Time (in Seconds) Between Measurements

Individual no.	*ELT at first measure*	*Change from before to after being placed on wait list (Group 2 only)*	*Change from before to after intervention (both groups)*	*Change from first measure to follow-up (6 months later, both groups)*
1 (Group 1)	89		+13	+121
2 (Group 1)	36		+66	+107
3 (Group 1)	72		+203	+78
4 (Group 1)	65		+118	+85
5 (Group 1)	130		+80	+42
6 (Group 1)	75		Missing	+135
7 (Group 2)	51	−11	Missing	Missing
8 (Group 2)	67	+18	+476	+304
9 (Group 2)	275	+160	−270	−75
10 (Group 2)	69	+80	+211	+141
11 (Group 2)	38	+22	Missing	Missing

Note. ELT refers to ejaculation latency time. A positive (+) change indicates that stopwatch-measured ejaculatory latency has become longer.

Zamar's (2012) stop-start technique clearly has potential as a viable PE treatment alternative. It should also be noted that Carufel and Trudel (2006), in their study using an intervention that was based on a stop-start technique and a functional-sexological intervention, found good results similar to those reported by Zamar (2012), again suggesting that development of psychosocial treatment interventions should be pursued in scientific studies.

Probably because of the small sample size of the present study, I was not able to demonstrate clear-cut results in all between-groups comparisons, and I did not find as clear-cut results as those reported by Zamar (2012). The treatment group (Group 1), which consisted of 6 individuals, showed significant improvement in ejaculatory latency but not in patient-reported outcomes. This pattern was the opposite for Group 2, which consisted of 5 individuals, once they received treatment. When the groups were combined, however, and pretest results were compared with follow-up results, there were clear indications that the treatment had been effective in terms of ejaculatory latency and patient-reported outcomes. In summary, it is encouraging that positive treatment outcomes are detectable even in a sample as small as the one in the present study. Furthermore, treatment benefits appear to be stable or even slightly improved 6 months after completing the intervention.

There was individual variation in treatment response, and some individuals clearly benefited more from treatment than others. Future research endeavors should explore reasons for individual variation in response to psychosocial treatment interventions. As the intervention used in the present study is hypothesized to be effective through desensitizing, a plausible candidate for this could be individual variation in interoceptive awareness (the ability to register and interpret physiological signals): It is possible that individuals with low interceptive awareness are less receptive to desensitizing treatment. It is interesting to note that a recent study showed that mindfulness training aiming to improve interoceptive awareness to sexual stimuli improved scores on psychological factors that are known to affect sexual function negatively, such as self-judgment, attention, and anxiety (Silverstein, Brown, Roth, & Britton, 2011).

Last, the importance of conducting studies with the aim of developing effective alternatives to pharmaceutical PE treatment must be pointed out. Current expert opinion suggests that pharmacotherapy is the best way to clinically manage PE (McMahon, Jannini, Waldinger, & Rowland, 2013). Psychosocial treatment interventions, however, come with obvious advantages in comparison to SSRI treatment. For example, the former is highly unlikely to induce side effects, and does not interact with other medication. While there is clear evidence that SSRI-class drugs have ejaculation-delaying properties, they frequently induce harmful side effects in many individuals, and there is relatively large variation in treatment response between individuals. This is reflected in, for example, discontinuation rates for SSRI-class drugs in naturalistic settings—for example, Salonia and colleagues (2009) reported that around 30% of EE patients prescribed paroxetine chose to discontinue the drug relatively shortly after treatment (in addition to about 20% who refused to begin drug treatment when offered in the first place). Dapoxetine has recently been shown to be associated with even higher discontinuation rates in naturalistic settings, with 90% of PE patients choosing to discontinue the drug within 1 year (Mondaini et al., 2013). Studies of SSRIs in other context (i.e., treatment of mood disorders) have also recently led to growing concerns about their long-term safety (e.g., Andrews et al., 2012).

The present study should be interpreted considering the following limitations. The sample size was very small because of financial and time constraints. The study's budget did not allow for purchase of more than 14 stimulating devices at the time (13 to be given to participants, and one for demonstration purposes). Even so, I detected clear improvement in ejaculatory latency and patient-reported outcomes from baseline to follow-up. Side effects were measured with an open-ended question, which may be considered suggestive. However, this was done in order to keep the questionnaire as brief as possible, and because Zamar (2012) reported that no participants reported any side effects in their trial, suggesting that side effects from this intervention are unlikely. Furthermore, the participants in the present study were relatively old, which may have some implications on the results. However, PE has been shown to have little if any association with age (e.g., Jern et al., 2009; Waldinger, Hengeveld, Zwinderman, & Olivier, 1998) and is stable across age groups (e.g., Laumann, Paik, & Rosen, 1999). Last, our sample included individuals who had not responded to SSRI treatment. It is therefore possible that the participants in the present study were less likely than the average PE patient is to respond to treatment.

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