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European Society for Sexual Medicine
25 Year Anniversary

A new method using an electronic masturbation device and a mobile app for the treatment of premature ejaculation: A prospective, multicenter case series.

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Objectives

The aim of this study is to report the outcomes and safety of a new Cognitive Behavioral (CB) method for the treatment of premature ejaculation (PE), known as MYHIXEL MED, which uses the electronic masturbation device MYHIXEL I® and a mobile app with an exercise program focused on pelvic floor muscle control training.

Methods

A prospective, multi-center case series was performed. The present study included 15 patients aged 24-47 (mean: 38.3) that met diagnostic criteria for lifelong PE including intravaginal ejaculatory latency time (IELT) of ≤2 minutes and had a Premature Ejaculation Diagnostic Tool (PEDT) score of ≥11. The primary outcome measures were the fold increase (FI) of IELT; calculated by dividing the geometric mean IELT value after treatment by the geometric mean IELT value at the start of treatment both using a stopwatch-measured method.

Results

The FI average of the IELT for the 15 participants was 7.38.
Nine of the 15 participants no longer met the criteria for the diagnosis of PE at study endpoint.

Conclusions

Results provide support for the efficacy of this novel CB method for the treatment of PE. During the study, no side effects were observed in participants, which poses as a great advantage in comparison to oral pharmacologic treatments. Although the subjects of the study had a stable partner, the MYHIXEL MED program was developed individually and online without the need for collaboration on the partner's behalf which would allow it to be used in patients with PE without a stable partner or for those who are reluctant to include their partners in the treatment. This method may have the potential to become a new non pharmacological treatment option for PE

Figure 1. The electronic masturbation device MYHIXEL I® and a mobile app MYHIXEL MED with exercise program.

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GD). The onset of the pubertal physical changes in transgender youth usually leads to a worsening of GD, distress and psychological functioning. GnRHas reduce suffering caused by pubertal development, leaving the body in a neutral state and allowing these adolescents to explore their gender identity.
Aims: The aim of the present study is to compare psychological functioning before and after GnRHas treatment in a sample of adolescents with GD assessed at the Florence Gender Incongruence Unit and to demonstrate that GnRHas are effective in relieving distress caused by the development of secondary sex characteristics.
Methods: Fourteen gender dysphoric adolescents were evaluated at 0, 3 and 6 months after the start of GnRHas (triptorelin 3,75 mg every 28 days). The evaluation included physical examination, blood samples and psychometric tests, such as: Youth Self Report (YSR) to measure psychological functioning; Multi-Attitude Suicide Tendency Scale (MAST) to define suicide risk; Beck Depression Inventory (BDI) to evaluate depressive symptoms.
Results: Triptorelin effectively suppressed puberty in adolescents with GD. In fact, GnRHa treatment caused a decrease in Tanner stage and a suppression of gonadotropins levels ($p < 0.05$). After 6 months of treatment adolescents with GD reported significant lower levels of internalizing problems as well as a decrease of suicide risk and depressive symptoms ($p < 0.05$).
Conclusion: Although the small size of the sample, this is the first study performed in Italy presenting data on a follow-up of gender dysphoric adolescents treated with triptorelin. The present study confirmed the efficacy of GnRHas treatment in the clinical management of GD in adolescents.

P-06-16

DEALING WITH THE INTERSECTION BETWEEN INTELLECTUAL DISABILITY AND GENDER DYSPHORIA. A CASE OF FEMALE-TO-MALE CIVIL IDENTITY CHANGE

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Context / objectives: Transgender and gender nonconforming people (TGNC) have been progressively more recognized over the last two decades, in particular due to an improvement in public information that eases their ability to expose their gender identity and coming-out. Very little research has been conducted on TGNC with intellectual disability.
Methodology: Qualitative case study. We discuss a case of a mentally disabled 28 years old female, sent by her private psychiatrist for follow-up in hospital sexology consultation.
Results: Born from an uneventful pregnancy, she was registered as a female. It was quickly noticed a delay in walking and great difficulty in learning, reaching a low level of education. At the time of the menarche (14 years old) she felt a lot of discomfort with her body, trying to hide the feminine characteristics; she preferred male clothes or dressing in androgynous fashion, and wanted to be perceived as a boy. At age 26 she identified herself with a person with gender dysphoria interviewed on television and realized that it was possible to fulfill her desire. Her parents reacted negatively and took her to the psychiatrist, who directed her to the sexology consultation. Demonstrating intellectual difficulties, he asked to be treated as male. His discomfort inherent to the incongruity between his body and his gender identity was evident. The consultation team intervened with his parents, which allowed some behavioral changes, facilitating the adoption of more masculine roles. After 2 years he was already treated by his male name at work, and began a hormone treatment with good adaptation, while changing his civil identity.
Conclusions: Despite the clinical difficulties in diagnosing gender dysphoria in intellectually disabled people, we can assume the responsibility of accompanying and guiding TGNC people on their way to reach psychological individual and social well-being.

P-06-17

THE COMPARISON BETWEEN THE EFFICIENCY OF PHARMACOTHERAPY AND COGNITIVE BEHAVIORAL THERAPY IN SEXUAL ADDICTION AND RELAPSE PREVENTION IN SAMPLE OF ARABIAN MEN

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Background and aim: To examine effectiveness of pharmacotherapy and cognitive behavior therapy in the treatment of sexual addiction
Methods: This is a cross-sectional study included 59 outpatients Arabic males, diagnosed as they suffering from sexual addiction according to the DSM-III-R, Their ages ranged from 20 to 45 years with mean age 28.5 ± 5.1. The study population was recruited among Arabic men attending Mutmaena psychiatric center. The sample was divided into three groups, first group (A) treated by CBT and pharmacotherapy in combination. The second group (B) treated by pharmacotherapy alone .The third group (C) treated by CBT alone. All groups were assessed primary by male Sexual Addiction Screening Test (SAST), Automatic Thoughts Checklist, Negative Health Beliefs Questionnaire, secondary outcomes were assessed by(SAST), and the Satisfaction And Social Efficacy Treatment Questionnaire (SASETQ) designed by the researcher.
Results: There is no significant intra-group differences were found in terms of baseline assessment. Main results were asignificant decreases of sexual addiction severity from before to after treatment on (SAST) a decrease in the number of problematic sexual behaviors during the course of therapy. A high attendance rate of 93% and a high treatment satisfaction score on (SASETQ) also were found,There was no significant discrepancy between the first and the second group, There was a clear significant discrepancy between the first and third group, for all the study variables and itś phases of assessment especially follow up. There was a clear degree of differences among the second and the third group, through the different phases of post-assessment, which refers to the great efficacy and effectiveness of pharmacotherapy in Treating sexual addiction
Conclusions: Available evidence suggests that pharmacotherapy seemed to ameliorate the symptoms of sexual addiction and was superior to CBT at 6-months. therefore might be a feasible treatment option

22st Congress of the European Society for Sexual Medicine: P-07 New Developments Section & New Technologies and Sexual Function

P-07-1

A NEW METHOD USING AN ELECTRONIC MASTURBATION DEVICE AND A MOBILE APP FOR THE TREATMENT OF PREMATURE EJACULATION: A PROSPECTIVE, MULTICENTER CASE SERIES

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Objectives: The aim of this study is to report the outcomes and safety of a new Cognitive Behavioral (CB) method for the treatment of premature ejaculation (PE), known as MYHIXEL MED, which uses the electronic

masturbation device MYHIXEL I® and a mobile app with an exercise program focused on pelvic floor muscle control training

Methods: A prospective, multi-center case series was performed. The present study included 15 patients aged 24-47 (mean: 38.3) that met diagnostic criteria for lifelong PE including intravaginal ejaculatory latency time (IELT) of $\leq$2 minutes and had a Premature Ejaculation Diagnostic Tool (PEDT) score of $\geq$11. The primary outcome measures were the fold increase (FI) of IELT; calculated by dividing the geometric mean IELT value after treatment by the geometric mean IELT value at the start of treatment both using a stopwatch-measured method.

Results: The FI average of the IELT for the 15 participants was 7.38.

Nine of the 15 participants no longer met the criteria for the diagnosis of PE at study endpoint.

Conclusions: Results provide support for the efficacy of this novel CB method for the treatment of PE. During the study, no side effects were observed in participants, which poses as a great advantage in comparison to oral pharmacologic treatments. Although the subjects of the study had a stable partner, the MYHIXEL MED program was developed individually and online without the need for collaboration on the partner's behalf which would allow it to be used in patients with PE without a stable partner or for those who are reluctant to include their partners in the treatment

This method may have the potential to become a new non pharmacological treatment option for PE

P-07-3

TELESURGERY: A MODERN TAKE ON HISTORICAL SURGICAL EDUCATION

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Objective: We describe two telesurgery educational events that were conducted in 2019 and discuss the impact of telesurgery on surgical education

Methods: In April 2019, the implantation of an artificial urinary sphincter for the treatment of post-prostatectomy stress urinary incontinence was conducted as a telesurgery teaching event. This procedure was aired over the internet and observing physicians provided commentary and submitted questions via a live on-line chat room. In June 2019, two separate surgeries demonstrating the implantation of an inflatable penile prostheses were aired back-to-back via internet live stream; again, questions and comments from observers were submitted via chat room. In the case of the artificial urinary sphincter procedure, the operating surgeon responded to questions via the chat room (through an un-scrubbed assistant). In the case of the two penile implants, the surgeon responded directly to queries by voice. All three patients signed consents for recording and streaming their procedures.

Results: The total physician viewers, for all events, was 773. These physicians watched from 33 different countries across the globe. The penile implant procedures allowed non-physician participants; this accounted for an additional 98 viewers. During the artificial urinary sphincter surgery, over 30 questions/comments were submitted. A total of 15 questions/comments were submitted during the penile prosthesis surgeries. Average view time was 31.8 minutes per procedure.

Conclusion: Telesurgery as a tool for surgical education is a viable option. With high-speed internet connectivity now commonly available, the case, as it unfolds, is easily accessed. Real time queries and comments from viewers are possible. We recommend surgical societies such as the ESSM, and surgical educators, invest effort and resources into developing telesurgery as one method of educating future and current surgical practitioners.

P-07-4

ONLINE DATING 2.0: AFFECTION OR ATTRACTION?

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Objective: The purpose of this study was to gather information about the motives for online dating: Did people sign up mostly for affection (i.e. psychosocial needs) or attraction (i.e. lust)?

Methods: A total of $N = 24{,}089$ members ($n = 2{,}608$ female, $n = 21{,}481$ male) of a German online-dating website were online surveyed. Age of participants was clustered (18-30, 31-40, 41-50, 51-60, and >60 years) and information about their relationship status (monogamous relationship vs. non-monogamous or "open" relationship vs. single) was gathered. Reasons for joining an online-dating website was operationalized by items of either affectionate reasons (e.g. "I am searching for someone who accepts me for who I am") or attraction reasons (e.g. "I am looking for sex/ONS/affair").

Results: Most female members (41.5%) were 41 to 50 years old, whereas most male members (31.3%) were 31-40 years old. In regards to their relationship status, members self-reported the following reasons to have joined: 54.7% of female members who are single self-reported affection reasons, whereas 21.3% of single male members did. Of members in non-monogamous relationships, 16.3% of the women and 9.7% of the men self-reported to have joined for affection reasons. Of those who are in committed monogamous relationships, 20.1% of women and 9.7% of men stated that they joined for affection reasons.

Conclusion: These answers suggest that singles - whether male or female - join online-dating websites also to meet their psychosocial needs, women more than men. It could also be that people in non-monogamous relationship do not seek to fulfill psychosocial needs as much as singles do, because trust and acceptance could be a given to live in an "open" relationship and hence they seek more attraction or sex-related dates (respectively: less affection or psychosocial need driven interactions) compared to people who live in monogamous relationships.

P-07-5

SEXTING AND NEW CYBERSEX ROLES THROUGH SOCIAL MEDIA

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[4]Mind Psychologies, Sevilla, Spain

Objectives: Cybersex refers to all kind of sexually related initiatives in cyberspace that allow real-time interactions to become aroused, bring to orgasm or help in simultaneous masturbation. Sexting is the transmission of sexually explicit messages, images or videos of oneself, usually by cell-phone. The aim of this study is to present the results of a survey that analyzes Sexting as the most common way of online interaction.

Methods: An online multiple-choice survey was designed to record the number of persons currently practicing Sexting by using Telephone calls, Whatsapp, Telegram, Messenger or IG Direct. Participants were classified in Female/Male, Hetero/Homo/Bisexual, Single/Coupled, and divided in age groups (18-25, 26-40, >40). Data were collected from March'19 to July'19 through an anonimous web questionnaire, analyzed by percentage and discussed in a multidisciplinary group. Survey is still underway.

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PLOS ONE

RESEARCH ARTICLE

Efficacy of Sphincter Control Training and medical device in the treatment of premature ejaculation: A multicenter randomized controlled clinical trial

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Abstract

A new line of treatment for premature ejaculation (PE) based on the use of masturbation aid device in combination with behavioral techniques has emerged in recent years. We report a multicenter randomized clinical trial with a parallel group design to determine the effectiveness of an electronic device called Myhixel I© in the treatment of PE. Forty patients who met the criteria for the diagnosis of lifelong PE, were assigned to two treatment groups completed the Sphincter control training (SCT) program in eight weeks. The only difference between groups was the use of the device. The main measure was the "fold increase" (FI) of the intravaginal ejaculatory latency time (IELT). The geometric means of IELT show, at the end of the treatment at week 8, a superiority of the device group. The mean FI 4.27 (SD 2.59) at the end of treatment for the device group was clearly higher than obtained in the previous clinical trial, in which a specific medical device was not used. No side effects were observed and it required little therapeutic input and no partner involvement. The SCT program in combination with the Myhixel I© is an effective treatment for PE.

Introduction

Premature ejaculation (PE) is one of the most frequent male sexual dysfunctions [1]. Despite the recent emergence of evidence-based definitions and new PE subtypes, its true prevalence remains ambiguous [1, 2]. This ambiguity surrounding PE is in part due to the difficulty in conducting and interpreting research in the absence of a standardized universal definition that adequately encompasses the characteristics of these patients.

Regarding pharmacological treatment, the evidence so far confirms the efficacy and safety of dapoxetine *(LOE 1a)* and other selective off-label serotonin reuptake inhibitors (SSRIs) *(LOE 1a)*, especially paroxetine and used daily. Some topical anesthetics have also been shown

MYHIXEL I devices + 30 bottles of lubricant, so there is no existing conflict of interests.The "New Wellness Concept" is the manufacturer of the Myhixel I ® device investigated in our study. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Competing interests: I have read the journal's policy and the authors of this manuscript have the following competing interests: Rodríguez is a consultant of New Wellness Concept and has not received compensation for this work; he is acting as an expert witness. Marzo is the thesis director of Rodríguez and he is acting as an expert witness and Piqueras is the thesis codirector of Rodríguez and he is acting as an expert witness. Picazo, Reina,Hidalgo y Tornero has no conflict of interest. This does not alter our adherence to PLOS ONE policies on sharing data and materials.

to be effective *(LOE 1b)*, and to date, SSRIs are considered first-line treatments despite their side effects [3, 4].

In relation to behavioral treatments (BTs), the evidence is very limited *(LOE 2b)*, although there is an improvement in the results when drugs are combined with BT, in contrast to the exclusive use of drugs [5, 6].

Most studies investigating the efficacy of different behavioral methods do not meet the standards of evidence-based medicine, since they are nonrandomized trials without a control group, use small samples, without adequate follow-up, and/or employ diversity of starting definitions of PE [5, 6].

Despite this limitation, interest in behavioral methods has renewed in the last decade, with the emergence of new underlying hypotheses related with the rol of the bulbospongiosus muscle and the external urethral sphincter in the ejaculatory reflex, and the implementation of new technologies and treatment protocols. Among its advantages are the absence of side effects; the ability to address aspects of PE that medication does not address; the potential to maintain their results as learning, avoiding relapses when stopping the medication; greater access to them; and its implementation without the need to go to the consultation and without the participation of the partner [7, 8].

These new treatment programs combine adaptations of Semans' (1956) classical behavioral technique of stopping and starting [9] with the use of electronic devices to help masturbation.

In 2019, one randomized controlled clinical trial in which it was implemented a new protocol of cognitive-behavioral treatment for PE called Sphincter Control Training (SCT) were published within this new line of treatment that also provide evidence of its efficacy. The SCT is designed based on hypothesis of Rodriguez (2017) regarding opening of the external sphincter that prevents the formation of the prostate pressure chamber and interferes with the emission phase of ejaculatory reflex [10]. A sex toy not specifically designed for this treatment was used in this first trial [7] to determine the efficacy of SCT.

For this reason and to improve the effectiveness of the method we developed a medical device in collaboration with the company New Wellness concept S.L specifically designed to the SCT.

Consequently, the objective of this new multicenter randomized controlled clinical trial with two parallel groups is to determine whether the latest version of the SCT program by Rodríguez et al., for the treatment of PE, can benefit from the use of a new electronic device especially designed for this program, registered with the FDA as a medical device, which includes new functions such as vibratory stimulation of the penis and the reproduction of intravaginal temperature, given the type of stimulation produced by the masturbation device would make it possible to more easily transfer what was learned to coital relationships by helping men develop greater control, and as a result of using a vibrator during masturbation desensitization can also be achieved in line with this hypothesis, Zamar 2012 [11].

It was hypothesized that the participants of the group that used this new device together with the Sphincter Control Training (SCT) program would achieve a significantly greater improvement in the outcome measures than the participants of the group without a device, as well as better results than in the series of previous studies with this same SCT program in which commercial devices were used [7, 12].

Materials and methods

A CONSORT-revised 2010 [13] compliant multicenter randomized controlled trial (RCT) parallel group design was used to compare the SCT group with the SCT group plus the device. The attached research protocol was approved by the Research Ethics Committee of the

Hospital General Universitario José María Morales Meseguer (José María Morales Meseguer University General Hospital) of Murcia (Spain) (EST: 27/19) and is registered with ClinicalTrials.gov (Identifier: NCT04012437).

The first registration in ClinicalTrials.gov ID: NCT04012437 was on 9 July 2019. The approval of this Ethic committee EST: 27/19 was in 16 June 2019 and we began the patient recruitment in last week July 2019.

The authors confirm that all ongoing and related trials for this intervention are registered.

Participant recruitment

Prior to the commencement of the trial, power calculations were conducted to determine the minimum sample size informed by the published RCT trial design on PE for psychotherapeutic intervention [14].

We therefore aimed to recruit a minimum sample of 40 participants to allow us to detect population treatment differences with a statistical power of .80 and an alpha level set at P = .05, 1-tail test. The recruitment of patients was developed during July and August 2019 through a health marketing campaign that included radio, press and social networks announcements. We considered all the subjects who complete the study, so the attrition rates were equivalents in both groups and the results don't return significant modifications.

A total of 50 subjects from all over Spain were recruited, of which 40 completed all phases of the study, with ages between 20 and 52 years of age (M = 34.94 years, SD = 7.826) Table 1.

Inclusion criteria

The study inclusion criteria to be selected were as follows: being over 18 years old, being in a heterosexual relationship for at least the last 6 months, having a score $\geq$ 11 in the PEDT (Premature Ejaculation Diagnostic Tool) [15] and a mean stopwatch record time self-reported IELT $\leq$ 2 minutes.

Exclusion criteria

The study exclusion criteria included history of alcohol abuse or dependence, having received medication or psychological treatment for PE in the last 6 months, suffering from diabetes or habitual use of recreational drugs (except tobacco and caffeine).

Procedure

All subjects interested in participating were contacted by email or telephone, and questionnaires such as the PEDT, initial interview and sociodemographic data, along with the template for time records, were sent by email. They were also asked for a first stopwatch time record of

Table 1. Sociodemographic baseline data (mean ± sd) in patients with premature ejaculation who completed all phases of the study.

	GWtD	GWD	*p*- value	*Eta-squared* (ηp^2)
Number of subjects	21	19		
Age (years) (mean ± SD)	32.76 ± 7.10	38.00 ± 7.99	.04	.112
Duration of the relationship (years)	8.88 ± 5.76	11.60 ± 8.31	.25	.016
IELT baseline (SD)	79.76 ± 33.53	70.81 ± 32.89	.33	.018
PEDT baseline (SD)	14.00 ± 2.70	18.07 ± 1.38	.000	.408

GWtD Group: SCT exercise program; Group GWD: SCT exercise program + electronic device SD: Standard deviation. P-value Student's t-test independent samples Accepted level of significance $p<0.05$.

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ejaculatory latency times (IELT) for 2 weeks, and once these data were received, those who met the selection criteria were randomly assigned to the two groups, using the online free version software GraphPad Prism. It randomly scrambles a set number of participants among a set number of treatment slots. So each treatment always gets assigned the same number of participants. Then, they were asked to sign an informed consent before starting the intervention phase.

The subjects were free to leave the study at any time and did not receive financial compensation for participating, although subjects from the device group (GWD) were allowed to keep the device once the study was completed. At the end of the study, subjects without the device (GWtD) were also given the opportunity to use the device to perform the activities. In GWD all the patients excluded after randomization did not send us an informed consent before starting the intervention phase then, no treatment was applied at all and there are no data available after randomization.

In GWD of the six patients excluded after randomization four of them did not send us an informed consent before starting the intervention phase and the other two patients dropped out of the study before they received any treatment and there are no data available after randomization.

Both treatment groups completed the latest version of the 8-week SCT program Table 2.

This exercise program was developed individually with all subjects, with the only difference between both groups being the use of an electronic device to aid masturbation called Myhixel I (Fig 1), which, given its characteristics, allowed the anatomical reproduction of the vaginal introitus, reached a temperature of use between 36 and 37 degrees Celsius, and allowed the option of applying a vibration on the glans during exercises.

The SCT program consists of four different exercises and an educational session. Its objective is to provide patients with greater knowledge, awareness and control of the external sphincter of the urethra and its role in the ejaculatory reflex. The activities seek that men learn to delay the ejaculatory reflex, preventing the formation of the prostatic pressure chamber by relaxing the external sphincter during intercourse [7].

The subjects of both groups received by email an educational video presentation on the role of the external sphincter in ejaculation and the importance of its control, as well as cards and explanatory videos with each of the 4 SCT exercises along with a template for activity and IELT records. Doubts about the exercises could be consulted via email.

Table 2. Sphincter Control Training program (SCT).

SCT method		
Timeline	**Activity**	**Procedure**
Week 1	"Discovering the pelvic floor"	Educational session: Video role of pelvic musculature in the ejaculatory reflex.
		Masturbation 3 times a week paying attention to the role of the pelvic musculature, external urethral and anal sphincter
Week 2,3,4	"Feedback of the external sphincter with stops and starts"	Masturbation 3 times per week with 4 active stops per exercise of maximum 30 seconds relaxing external anal and urethral sphincters at each stop.
Week 5,6	"Feedback of the external sphincter without cessation of stimulation"	Masturbation 3 times per week without cessation of stimulation with 4 moments of relaxation by exercise of the external anal and urethral sphincters before ejaculatory eminence.
Week 7,8	"Feedback of the external sphincter with intercourse movements"	Masturbation 3 times per week without ceasing stimulation with 4 moments of relaxation by exercise of the external anal and urethral sphincters before ejaculatory eminence with intercourse movements.

https://doi.org/10.1371/journal.pone.0257284.t002

Fig 1. Device MYHIXEL I. International patented device SKU MX_PA_000. EAN 8437019695019. Dimension length: 113 mm. Width: 113 mm. Height: 203 mm. Diameter 91 mm. Weight 630 grams. Materials: thermoplastic elastomer, ABS silicone. Type of battery Lithium. Charger type, USB + Magnet (Waterproof).

https://doi.org/10.1371/journal.pone.0257284.g001

Once the completed records of each activity were sent, all the necessary material for the next activity was sent to them by email.

After the last record of activity, the PEDT questionnaire was administered again.

Measurements

Fold increase in IELT. As the main measure, the FI in the IELT was used, which was calculated using the geometric mean (GM)* of the posttreatment IELT (period B), calculated with the recorded times of the last two weeks of treatment, divided by the geometric mean of the IELT at the beginning of the treatment that served as the baseline (period A), calculated with the times of the two weeks of records prior to the random assignment to each group, FI = (GM of 8S)/(GM of prtr) [16].

Geometric mean was calculated using mean of natural logarithm with each of the IELT calculated by the subject in each phase. The geometric mean uses its transform for its interpretation once expressed in seconds.

PEDT. For the diagnosis and as a secondary measure, is a tool originally validated in the Spanish-speaking population, among other. The PEDT was used, consisting of five items that evaluate difficulty delaying ejaculation, ejaculation before the patient desires, ejaculation with little stimulation, frustration related to premature ejaculation and opinion of the partner on ejaculation. The test-retest reliability is .82, and all items discriminate in a statistically significant way between patients with PE and without PE, with a cut-off score for this diagnosis [15].

Statistical analysis

First, to verify that there was no difference between the groups, prior to treatment, the mean difference of the IELT of each group was calculated using the Mann-Whitney U test.

To analyze the difference between the two groups, a covariance analysis (ANCOVA) of the difference between GWtD and GWD of their geometric means was performed at the first 4 weeks, as well as at 8 weeks. The dependent variable is the geometric mean, the treatment was considered as a factor and the pre-IELT score as a covariate.

Afterwards, to compare how each of the groups had evolved, intragroup comparisons were made, using Wilcoxon signed rank test of related samples, between the previous values of the IELT and its geometric mean both at 4 and 8 weeks.

As a complementary measure to check the differences in the evolution of the two groups, Student's t-test of independent samples was also calculated comparing the differences between the two groups in the FI value.

To perform the calculations, the statistical package IBM SPSS Statistics Base 22.0.

Results

Subjects

Of a total of 53 subjects who were contacted, 50 were randomly assigned by recruitment order on a 1:1 basis to the two treatment groups, 25 to the GWtD (SCT program) and 25 to the GWD (SCT program + electronic device). The experimental mortality was 24.52% since 40 subjects completed all phases of the study, and their data were analyzed. The subjects analyzed were n = 21 for the GWtD and n = 19 for the GWD (Fig 2).

IELT and fold increase

Table 3 shows the IELT throughout the study.

The calculation of the Mahalanobis distances indicated the existence of two outliers, one of the GWtD and another of the GWD in the variables corresponding to FI. The calculations, from now on, were carried out without these two subjects.

The Mann-Whitney U test on the IELT variable of the baseline did not show significant differences between the treatment groups prior to the intervention (p = .0.93).

Subsequently, the geometric mean for both groups of the first four weeks of treatment (4wk) was compared using the ANCOVA test, finding significant differences (F: 1.35, 10.10; p = .003) in the increase in IELT experienced by the GWD subjects compared to the GWtD subjects.

Then, the geometric mean of the first eight weeks of treatment (8wk) was calculated, and the two groups were compared using the ANCOVA test, finding significant differences (F: 1.35, 13.27; p = .001) in the increase experienced by the GWD (geometric mean = 251.52, SD = 110.71) compared to that experienced by the GWtD (geometric mean = 166.28, SD = 98.37).

The differences between the pretreatment values (PRTR) and the values at four weeks of treatment (4wk) were also analyzed for each of the groups using—Wilcoxon signed rank test. The results indicate that there are significant differences in both the GWtD ($p < .05$) and the GWD ($p < .05$) between both measures.

Next, the differences between the values corresponding to the first four weeks of treatment (4wk) and the values at the end of treatment (8wk) were also analyzed using an intragroup comparison for both.

The results showed that in both groups GWtD ($p < .05$) and GWD ($p < .05$), there were significant differences between the pretest and the posttest.

Next, the variable called FI was created, which relates the measurements obtained during the weeks prior to treatment (PRTR) with those obtained after 4 (4wk) and 8 (IELT _8wk)

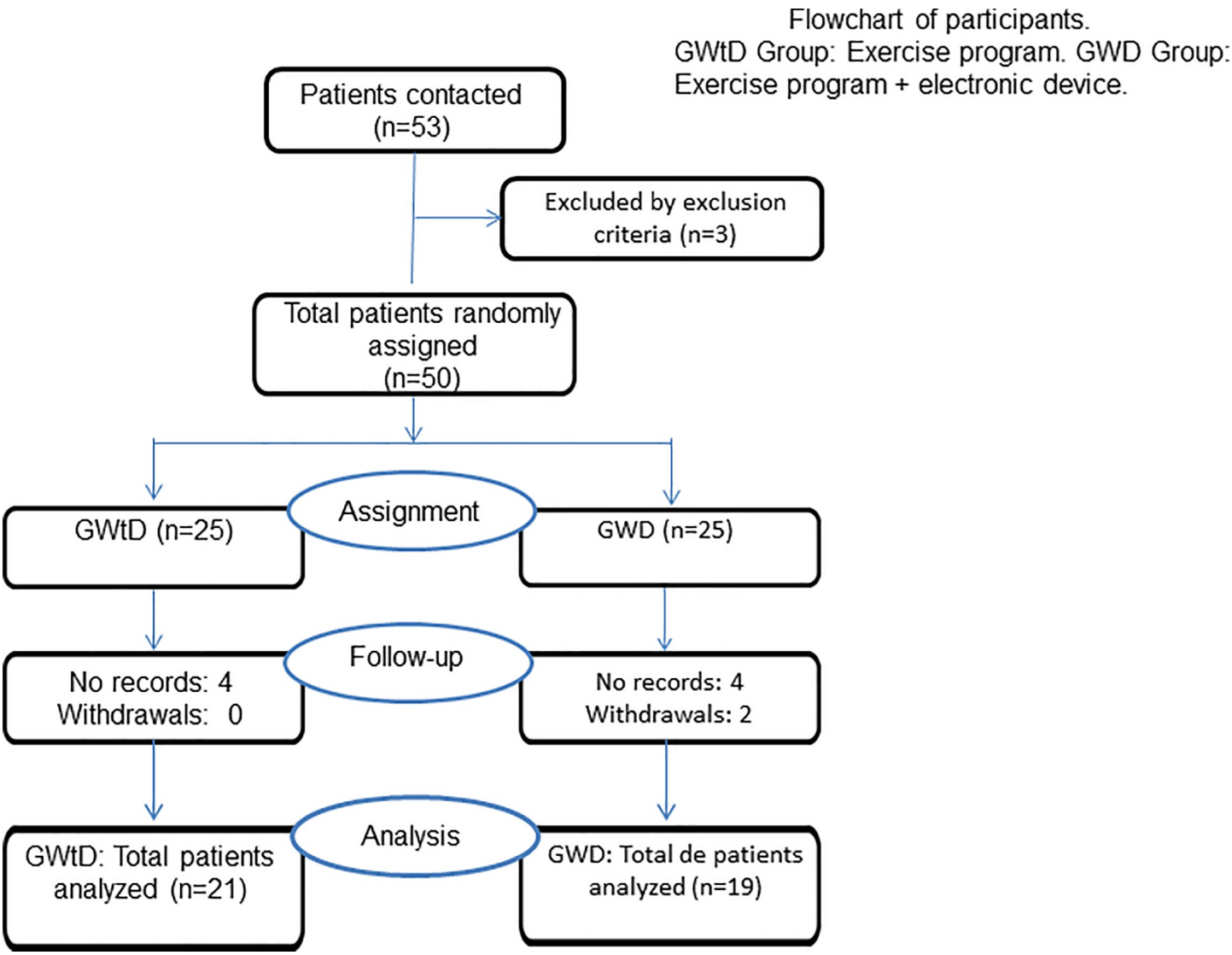

Fig 2. Flowchart of participants. GWtD Group: Exercise program. GWD Group: Exercise program + electronic device.

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weeks of treatment using the expression FI = (Mean Geometric of 8wk or 4wk)/ (Geometric Mean of PRTR).

Using Student's t-test, the FI of both groups was compared at week 4 ($p = .006$) and week 8 ($p = .001$) of treatment, finding significant differences between the GWtD and the GWD in both cases.

PEDT

Fig 3 shows the analysis of the scores for the PEDT.

First, the T test was performed for independent samples that showed significant differences in the PEDT_PRE variable between the means of the GWtD and the GWD group ($t\ 34 = -5.49$; $p < .05$). However, the T test for independent samples does not show significant differences in the PEDT_POST variable between the GWD and GWtD means ($t\ (36) = 1.48$; $p = .14$).

Table 3. Intravaginal Ejaculatory Latency Times (IELT) and Fold Increase (FI) during the study.

		GWtD	GWD	*p-value*
IELT	Pretreatment(PRTR)	79.76 (33.63)	70.81 (32.89)	.093
Geometric	4 weeks(4 wk)	110.23 (54.06)	161.82 (89.67)	.111Ĩ .003†
mean (SD)	*p*- value (prtr/4 wk)	.001 ǂ	.000 ǂ	
	8 weeks (8wk)	166.28(98.37)	251.52 (110.71)	.022 Ĩ .001†
	p- value (4wk/8 wk)	.000 ǂ	.000 ǂ	
Fold Increase (SD)	4 weeks (prtr/4 wk)	1.43(.49)	2.71 (1.94)	.006 Ĩ
	8 weeks (prtr/8 wk)	2.09 (.72)	4.27 (2.59)	.001 Ĩ

† Covariance analysis

ǂ Wilcoxon signed rank test related samples

Ĩ Mann-Whitney U test of independent samples

Ĩ Student´s t test

GWtD Group: Exercise program. GWD Group: Exercise program + device.

SD: Standard Deviation

Accepted level of significance p<0.05.

https://doi.org/10.1371/journal.pone.0257284.t003

Subsequently, Student's t test was performed for related samples that showed significant differences between the pre- and post- in the GWtD (t 2 = 4.10; p = .001) and GWD (t 14 = 13.09; p < .05).

Discussion

This is the second randomized clinical trial developed to measure the efficacy of SCT, a promising cognitive-behavioral treatment program. Unlike the previous clinical trial of 2019 [7] in

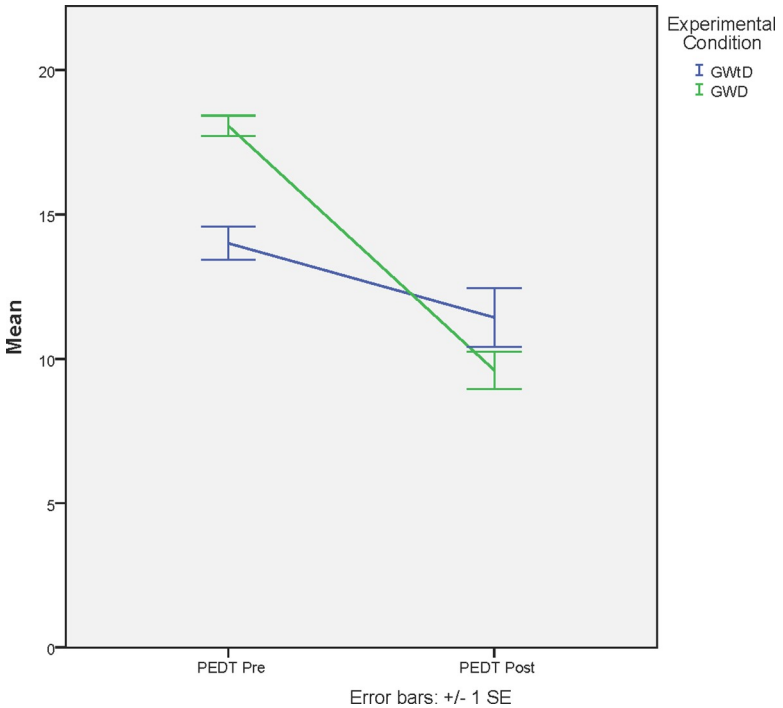

Fig 3. Pre-post PEDT between groups. Means in PEDT between GWD and GWtD. *Significant differences with p <0.025.

https://doi.org/10.1371/journal.pone.0257284.g003

which a device cataloged as a sex toy was used, in this case, an electronic device to aid masturbation specially designed for this program cataloged by the FDA as a class 2 medical device was used. In the previous clinical trial, Rodriguez et al. [7] also used a parallel group design with two treatment groups and measured the SCT program and the possible benefit of performing these exercises in combination with a commercial device for aiding masturbation. The SCT was designed for men to develop greater awareness and control over the external sphincter of the urethra and is based on the hypothesis that relaxation of the sphincter makes it difficult to initiate the emission phase of the ejaculatory reflex by preventing formation of the prostatic pressure chamber. The results showed significant differences between the two treatment groups at the end of the treatment in favor of the group that used the device and obtained a fold increase (FI) of 2.69. The authors attribute these differences between both groups to two factors, one to a possible effect of desensitization given the greater friction and pressure of the penis during exercises with the device and another to a greater ease of generalizing what was learned during the exercises to their sexual intercourse, since the device generated stimuli very similar during training to those produced in the penis during intercourse [7].

In that same year, Ventus [17] published another randomized clinical trial in which two parallel treatment groups and a waiting list control group were used to measure the effectiveness of vibrator-assisted start-stop exercise (VSS) programs and another version of the same program called VSS + which included psychoeducation and exercises to increase interoceptive awareness. One of the objectives was also to develop greater awareness of the pelvic floor muscles by the subjects to try to relax this as a form of control over ejaculation. In both treatment groups, they used a small hand-held vibrating device to perform stop and start exercises 3 times per week for 6 weeks, which had already been used in several case series [18]. The Swedish version of the Checklist for Early Ejaculation Symptoms (CHEES) was used as the main measure [19]. The study also includes a follow-up at 3 and 6 months. The results show significant differences in posttreatment self-reported PE scores between the two treatment and control groups, and these reductions in PE symptoms were also maintained in the follow-ups. No significant difference was found at any time during the intervention between the two treatment groups that used the VSS and VSS + programs [17]. The authors attribute these results, as in other case studies with this same device, to a desensitization effect as a mechanism of action [18].

As in the first trial that using SCT program [7], the geometric means of IELT show a superiority of the SCT treatment program in combination with the use of the device over the group that did not use the device [7].

These superiorities are at the end of the treatment at week 8, where although significant improvements are observed in the IELT for both groups over the pretest, there are still significant differences between the two.

The mean FI at the end of treatment for the GWD was clearly higher than that obtained in the previous clinical trial, in which a specific medical device was not used, ranging from 2.69 to 4.27 in the latter [7].

During the study, no side effects were observed in either of the two treatment groups, which are a great advantage in relation to first-line treatments for PE with SSRIs, since it is one of the main causes of its abandonment [20].

The differences found between both treatment groups can be attributed, as in the previous clinical trial, to the use of the device to aid masturbation. The improvement in the FI recorded in this test in relation to that of 2019 can be attributed to the characteristics of the medical device used on this occasion, specifically the interior design and the materials faithfully reproduce the vaginal introitus, reaching a use temperature of between 36 and 37 degrees Celsius, to

which the inclusion of a vibratory stimulation of the penis very similar to that used by Jern in his clinical trial must be added [17].

Although the study subjects had a stable partner, the SCT program is developed individually and online without the need for collaboration on the part of the partner, which would allow it to be used in patients with PE without a stable partner or who are reluctant to include their partners in treatment or see a health professional [7].

The main limitation of this study are the use of PEDT that is a diagnostic tool and it is not designed to compare the efficacy of PE treatments other limitation is the lack of follow-up at 3 and 6 months of the treatment groups to determine the need or not to continue with the exercise to maintain the improvement found, both in the IELT and in the control perceived. Determining this issue is important since the need for continuous use is another of the main reasons for abandoning current treatments with SSRIs [20].

Although proper random assignment prevents selection bias, it does not guarantee that the groups are equivalent at baseline. Random allocation instead ensured the two groups were not systematically biased, although the score of PEDT show meaningful differences between groups (see Table 2). The online free version software GraphPad Prism used for random assignment did not allow us to conduct the Berger Exner test to determine if faulty randomization was the cause. The two groups were not systematically different (their allocation was not biased) even though they were unequal. However this may affect the internal validity and implies a further limitation of the study.

In the analysis of the data we used a per protocol approach because there were some specific reasons that led to the exclusion of ten of fifty patients from the full analysis set, as none received any treatment and no data are available after randomization.

Studies with a larger sample size and longer follow up that including new PE subtypes will be necessary to provide more evidence for this new treatment strategy for PE.

Conclusions

We can conclude that this new cognitive-behavioral strategy for the treatment of PE, in which the SCT exercise program is combined with the use of a new electronic medical device to help masturbation, obtains satisfactory results.

Supporting information

S1 Checklist. Checklist of information to include when reporting a randomized trial.
(DOC)

S1 Protocol. Study protocol trial in English. ISM-SCT-2019-01.
(PDF)

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P-07 NEW DEVELOPMENTS SECTION & NEW TECHNOLOGIES AND SEXUAL FUNCTION | VOLUME 17, ISSUE 6, SUPPLEMENT 2, S212-S213, JUNE 01, 2020

22ND CONGRESS OF THE EUROPEAN SOCIETY FOR SEXUAL MEDICINE: P-07 NEW DEVELOPMENTS SECTION & NEW TECHNOLOGIES AND SEXUAL FUNCTION

P-07-1 A New Method Using an Electronic Masturbation Device and a Mobile App for the Treatment of Premature Ejaculation: A Prospective, Multicenter Case Series

- J.E. Rodríguez
- H. Harvey
- L. Reina
- G. Hidalgo
- M. Culebras
- C. Casado

PlumX Metrics

DOI: https://doi.org/10.1016/j.jsxm.2020.04.361

FULL ARTICLE

A NEW METHOD USING AN ELECTRONIC MASTURBATION DEVICE AND A MOBILE APP FOR THE TREATMENT OF PREMATURE EJACULATION: A PROSPECTIVE, MULTICENTER CASE SERIES

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Objectives: The aim of this study is to report the outcomes and safety of a new Cognitive Behavioral (CB) method for the treatment of premature ejaculation (PE), known as MYHIXEL MED, which uses the electronic masturbation device MYHIXEL I® and a mobile app with an exercise program focused on pelvic floor muscle control training

Methods: A prospective, multi-center case series was performed. The pre- sent study included 15 patients aged 24-47 (mean: 38.3) that met diagnostic criteria for lifelong PE including intravaginal ejaculatory latency time (IELT) of 2 minutes and had a Premature Ejaculation

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Diagnostic Tool (PEDT) score of !11. The primary outcome measures were the fold increase (FI) of IELT; calculated by dividing the geometric mean IELT value after treatment by the geometric mean IELT value at the start of treatment both using a stopwatch-measured method.

Results: The FI average of the IELT for the 15 participants was 7.38.

Nine of the 15 participants no longer met the criteria for the diagnosis of PE at study endpoint.

Conclusions: Results provide support for the efficacy of this novel CB method for the treatment of PE. During the study, no side effects were observed in participants, which poses as a great advantage in comparison to oral pharmacologic treatments. Although the subjects of the study had a stable partner, the MYHIXEL MED program was developed individually and online without the need for collaboration on the partner's behalf which would allow it to be used in patients with PE without a stable partner or for those who are reluctant to include their partners in the treatment

This method may have the potential to become a new non pharmaco- logical treatment option for PE

Identification

DOI: https://doi.org/10.1016/j.sxm.2020.04.361

001

#ERECTILEDYSFUNCTION: 5-YEAR COMPREHENSIVE ANALYSIS OF THE TWITTER DISCUSSIONS ASSOCIATED WITH ERECTILE DYSFUNCTION

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Introduction: Social media is transforming the landscape of men's health as patients experiencing erectile dysfunction (ED) increasingly turn to the internet for health-related information. Men with ED readily access medical information online, interact with healthcare practitioners virtually, and even engage in therapeutic decision making via online marketplaces.

Objective: To perform quantitative and qualitative analysis of Twitter discussions using the hashtag #erectiledysfunction.

Methods: Twitter activity was analyzed between February 2015 and June 2020 via Symplur, a healthcare social media analytics tool. Aggregated Twitter data for #erectiledysfunction was analyzed for content and user engagement. Twitter activity was measured using total number of tweets, tweets per month, and total number of users. User characteristics were classified using geography, profession, organizational affiliation, credentials, as well as user influence. Twitter influence was determined using the Symplur rank, an algorithm that quantifies the influence of a given user associated with a given hashtag. Tweet content was evaluated by aggregating information including Twitter engagement metrics such as retweets, top shared links, associated hashtags, and frequently used words.

Results: A total of 89,833 tweets and 22,130 users were identified in association with #erectiledysfunction between February 2015 and June 2020. Over the study period, #erectiledysfunction appeared in 1.9 tweets per hour, used in 4 tweets on average per user, and reached a total of 242,388,630 impressions. The overall number of users tweeting #erectiledysfunction increased from 3,700 users in 2015 to 22,100 users by June 2020. The proportion of tweets by previous users (i.e., users tweeting #erectiledysfunction after their first time) increased by 11.8% every year (p=0.001). However, there was no difference in the average number of new users tweeting #erectiledysfunction (i.e., first tweet) over time (p=0.760). Among the top 100 influencers, the most common health care stakeholders included 40% physicians, 16.4% media outlets (e.g., scientific journals), and 13.6% advocacy organizations (e.g., academic societies). Patients represented 1% (1 of 100) of the top 100 influencers. Common words associated with #erectiledysfunction tweets were "men," "treatment," and "causes." In addition, popular associated hashtags included #ED, #menshealth, and #impotence.

Conclusions: Social media platforms foster dynamic health discussions amongst users online. Our analysis demonstrates that #erectiledysfunction has a significant presence on Twitter with notable engagement from physicians and other prominent healthcare stakeholders. Interestingly, our data suggest that patients or non-health care stakeholders interested in ED have yet to adopt Twitter as a platform for discussion. Nonetheless, the present study demonstrates that over the span of 5 years Twitter discussions related to ED are attracting users within the professional urological community with users who tweet #erectiledysfunction more than once dominating the discussion compared to new users joining the conversation.

Disclosure: Work supported by industry: no. A consultant, employee (part time or full time) or shareholder is among the authors (Metuchen Pharmaceuticals, Antares Pharma, Boston Scientific, and Endo Pharmaceuticals).

002

NEW COGNITIVE BEHAVIORAL TREATMENT FOR DELAYED EJACULATION USING A MASTURBATION AID DEVICE AND MOBILE APP: A CASE STUDY

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Introduction: Delayed ejaculation (DE) is a poorly defined disorder with different etiologies, 25% of patients have primary a psychological cause. Different psychosexual therapy strategies have been described for DE but with limited evidence supporting their efficacy.

Objective: Our aim was to examine the potential effectiveness of a new cognitive behavioral treatment for DE which uses an exercise apps program in combination with an electronic masturbation device with 3 types of sleeve.

Methods: A 36-year-old male with diagnostic of DE acquired was encouraged to make an exercise program using a mobile app and a medical device. This patient had no co-morbid mental diagnoses and urologist reject organic etiology, the average masturbation ejaculatory latency time measure by stopwatch record during 2 weeks was 260 seconds. Three month before visit our clinic he started a relationship with a 40 years old woman, he attempted 12 sexual intercourse and none were successful. The patient used a device Myhixel II®, a lubricant called Myhixel Lube® and Myhixel App® during 9 weeks. The patient had to use the device until he ejaculated with three different sleeves. First he needs to move up and down repeatedly and increase the speed using his stronger hand. After it's using his non dominant hand and last exercise of the protocol had to masturbate keeping his hand still and use his body to move. As a main outcome, measure used the percentage of sexual intercourse attempts that were successful, determined fro`m an ejaculation during sexual intercourse in less than 15 min.

Results: First intercourse successful was in week 4 of treatment, the last 2 weeks of exercises he was able to ejaculate inside his partner 100% of the time in less than 15 min; the percentage of intercourse successful during month after finish protocol exercise was 81%.

Conclusions: This treatment could be a suitable alternative when the cause of DE is a masturbation style that cannot be replicated with a partner using her hand, mouth, anus or vagina. This factor has been frequently reported in DE primary psychological cause. In relation to the actual treatment, the masturbation retraining with this device has three big advantages, the first one who does not need the collaboration on the part of the couple, the second one who lacks side effects and the third one that it is not necessary to come to the consultation of a specialist. Further research is needed to establish the effectiveness of this new treatment for DE.

Figure 1. Myhixel II®. Masturbation aid device.

Disclosure: Work supported by industry: no. A consultant, employee (part time or full time) or shareholder is among the authors (Myhixel).

findings suggest that BDNF may play a role in the etiology of PE. This is the first study in the literature where the serum level of BDNF was evaluated in premature ejaculators. Further studies are needed to clarify this relationship.
Disclosure: Work supported by industry: no.

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EVALUATION OF A NEW COGNITIVE-BEHAVIORAL TREATMENT FOR PREMATURE EJACULATION USING A MASTURBATION AID DEVICE: A CASE SERIES

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Introduction: Current evidence suggests that Cognitive Behavioral therapy (CBT) has a limited role in the contemporary management of premature ejaculation (PE). New CBTs appear as a result of the technological development by the sexual toys industry worldwide in recent years.
Method: The present study included 10 patients' ≥18 years that met diagnostic criteria for PE including intravaginal ejaculatory latency time (IELT) of ≤2 minutes and had a Premature Ejaculation Diagnostic Tool (PEDT) score ≥11. The participants completed Sphincter Control Training (SCT) over 7 weeks using a medical device called Myhixel I (Figure1). This exercise program was developed individually with all patients. As a main outcome used the geometric mean IELT over the 7 weeks treatment period increased from a baseline (Fold increase).
Objective: The aim of this study was to determine the efficacy and safety of a new Cognitive Behavioral Treatment (CBT) for the Premature Ejaculation (PE) called Sphincter Control Training (SCT) using a medical device designed to the treatment.
Results: Geometric mean average IELT significantly increased in participants from 79,06 seconds at baseline to 216,21 seconds at study endpoint. Fold increase (FI) average IELT of the 10 participants was 2,89. Six of the 10 participants did not meet the criteria for the diagnosis of PE at study endpoint.
Conclusions: FI average IELT at the end of the treatment for the participants was similar to that obtained in other clinical trials with dapoxetine, which is the only effective and safe oral on-label treatment for PE approved in more than 50 countries. During the study, no side effects were observed in participants, which is a great advantage in relation to oral SSRI treatments. SCT in combination with Myhixel I can be an effective and safety exercise program for patients suffering PE. These elements must be corroborated in larger series.
Disclosure: Work supported by industry: yes, by Myhixel.

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THE EFFICACY AND SAFETY OF DAPOXETINE / SILDENAFIL COMBINATION THERAPY IN THE TREATMENT OF MEN WITH PREMATURE EJACULATION AND ERECTILE DYSFUNCTION – DAP-SPEED STUDY

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Introduction: Premature ejaculation (PE) and erectile dysfunction (ED) are the most prevalent sexual disorders in men. ED is commonly reported among patients with PE.Although recent guidelines recommend to treat ED first in men with both PE and ED, this recommendation is not based on evidence and there is limited data about the efficacy and safety of dapoxetin / sildenafil combination therapy for these patients.
Objective: The aim of this study is to evaluate the clinical efficacy and safety of the dapoxetine / sildenafil combination (Dapoxil 30/50 mg film-coated tablet) in the treatment of patients with PE and concomitant ED.
Methods: In a single-center, single-arm, open-label clinical study, 74 patients with lifelong / acquired PE and ED were included between October 2016 to September 2017.Patients received on demand dapoxetine / sildenafil (30/50 mg film-coated tablets) 1-3 hours before sexual intercourse for 4 weeks (2 days a week and no more than once a day). All patients were instructed to record their intravaginal ejaculatory latency time (IELT). They were also instructed to complete Premature Ejaculation Diagnostic Tool (PEDT), Premature Ejaculation Profile (PEP) and International Index of Erectile Function-Erectile Function (IIEF-EF) score before and after the treatment. At the end of the study, patients were assessed with global impression of change (GIC) for the treatment satisfaction.
Results: The study was completed with 53 patients (71.62%). Mean age of the patients was 45.32±10.05. Before the treatment, geometric mean IELT of the patients was 22.72±15.16 seconds, mean PEDT score was 16.85±2.42, mean PEP score was 3.36±1.12and IIEF-EF score was 13.17±3.33. At the end of the 4-week treatment period, statistically significant improvements were observed in the mean IELTs, PEP and IIEF-EF scores compared to the patients' pre-treatment values (69.47±103.34;$p<0.001$, 9.92±2.36;$p<0.001$, 24.60±3.96; $p<0.001$ respectively). According to the GIC, 81.13% of the patients were satisfied with the treatment. Non-serious adverse event occurred in 10 patients and 6 of these patients dropped out the treatment (11.32%). The most common adverse events were headache and flushing.
Conclusions: The dapoxetine/ sildenafil combination therapy significantly improves the IELT values and patient reported outcome measures of PE patients who also suffer from ED. Although several side effects were reported, these were mild and reversible.
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PROFESSION IS AN INDEPENDENT PREDICTOR OF TESTOSTERONE LEVELS IN MEN

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Introduction: Studies of serum testosterone levels in men usually control for BMI and age, as these factors are easily obtained from the medical record. Many other factors that influence testosterone levels (e.g., stress, physical activity, chemical exposures and altered circadian rhythm), however, are often difficult to quantify and are not included in multivariate analyses. Men spend a significant portion of their waking hours at work, where they may have significant exposure to this second group of factors. Thus, we hypothesized that profession would significantly influence serum testosterone levels.
Objective: Determine whether profession is independently associated with serum testosterone levels.
Methods: All full-time employed, adult males who participated in the National Health and Nutrition Examination Survey (NHANES 2011-2012) who had serum testosterone levels were included in the analysis. Profession was categorized into 23 different categories (Table 1). Men were excluded if they had incomplete data, history of anabolic steroid use, current testosterone use, or history of cancer. Professions with fewer than 10 subjects were also excluded (n=1, Armed Forces). Testosterone levels were log transformed for analysis then back transformed to present in their original units. Serum testosterone levels were adjusted for BMI, age, ethnicity, household income, education level, and diabetes status. One-way ANOVA was used to