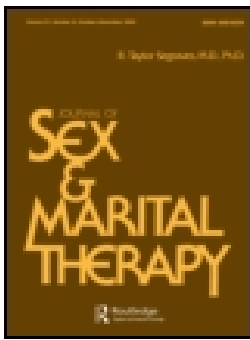


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# **Validation of ‘the change or stop testosterone lowering medication (COSTLow)-scale’ using delphi method among clinical experts**

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## **Abstract**

Guidelines for pharmacological treatment of patients with paraphilic disorders have been developed by a working group of the World Federation of Societies of Biological Psychiatry (Thibaut et al. 2010). With an increasing duration of experience and number of treated patients as well as aging patients, change of or withdrawal from testosterone lowering medications (TLM) has become an important issue. The current study aimed to assess the quality of a structured professional judgement procedure that helps switching or discontinuing especially TLM in patients with paraphilic disorders. We used Delphi method to estimate the quality of ten factors originally proposed by the authors. A total of 30 experts participated in the first stage; 18 experts participated in the second stage. The experts' assessment resulted in an instrument of 15 factors that can be used to structure the process of changing or discontinuing TLM. These factors can be grouped into five broader categories: Age and duration of treatment; therapeutic alliance; psychopathology and risk factors; motivation; compliance; and level of control. The developed scale provides an instrument that can be used to structure the process of changing or discontinuing TLM in patients with severe paraphilic disorders.

*Key words:* Paraphilic Disorder, Sexual Offenders, Androgen Deprivation Therapy, Antiandrogens, GnRH Agonist

## Introduction

Since the late 1960s, men with paraphilic disorders have been treated with Testosterone Lowering Medication (TLM) in Europe and North America. In Europe and Canada, the antiandrogen cyproterone acetate (CPA), and in the United States, mostly medroxyprogesterone acetate (MPA), were used for nearly twenty years before the first case report of treatment with gonadotropin-releasing-hormone (GnRH) agonists was published in 1985 in Germany (Allolio 1985). This was followed by a case series from France (Thibaut et al. 1993, 1996) and a pioneering publication of Rösler and Witztum (1998) in the *New England Journal of Medicine*. Subsequently, GnRH agonists found their way into the regular treatment of men with paraphilic disorders, who were at high risk of committing severe sexual offenses. However, randomized controlled trials are still missing (Briken et al. 2017). Concomitantly, selective serotonin reuptake inhibitors (SSRI) were introduced to the treatment of many psychiatric disorders, including sexual impulse control disorders and paraphilic disorders (Greenberg et al. 1996).

Bradford (2001) and Briken and colleagues (2003) were the first to suggest that the medications should be adjusted according to the severity of the disorder and the respective risk. Without explicitly mentioning Andrew and Bonta's (Andrews and Bonta 2010, Andrews et al. 1990, Bonta and Andrews 2007) Risk Need Responsivity (RNR-) principle these recommendations followed the idea of balancing risk and benefit, taking into account the side effect profile and influence on overall sexuality that result from the medication. In a next step, Guidelines of the World Federation of Societies of Biological Psychiatry (WFSBP) have been developed for both adults (Thibaut et al. 2010) and more recently adolescents (Thibaut et al. 2016).

According to these guidelines, the least invasive pharmacological method – the SSRIs – has only limited side effects and causes changes in sexuality (mainly on deviant sexuality; Bradford 2001): Above all, SSRIs are intended to improve sexual self-control, reduce

impulsivity and also have positive effects on depression. As they are non-hormonal agents, their influence on androgens is negligible. With the next stage of pharmacological intervention, CPA and MPA have a significant effect on testosterone levels in a dose-dependent manner. These steroidal antiandrogens have progestogenic activities in addition to their antiandrogenic effects, which, through feedback effects on the hypothalamo-pituitary axis inhibit the secretion of LH, resulting in a decrease in circulating levels of both testosterone and dihydrotestosterone (DHT). Furthermore, these medications interfere with the binding of DHT (the androgen which plays the dominant role in androgenic response) to androgen receptors and they have been shown to block the cellular uptake of androgens. With the highest levels of severity and risk, the use of GnRH agonists is recommended. They lead to almost complete testosterone suppression to castration level. GnRH analogues cause rapid desensitization of GnRH receptors, resulting in reduction of LH (and to a lesser extent of FSH) and testosterone to castrate levels within 2 – 4 weeks. They do not interfere with the action of androgens of adrenal origin. In addition, GnRH containing neurons project into pituitary and extra-pituitary sites, such as the olfactory bulb or the amygdale. At these latter sites, GnRH is believed to act as a neuromodulator and, through this action, may be also involved in sexual behavior (Jordan et al. 2011). Because of the significant suppression of testosterone serum levels resulting from CPA, MPA and GnRH-agonist treatment, these agents are usually summarized under the term testosterone lowering medications (TLM).

In approximately 2000, 6% of patients convicted for a sexual offence were treated with CPA or GnRH agonists in German forensic psychiatric hospitals (Czerny et al. 2002). Ten years later, around 5% were treated with CPA while the number of patients treated with GnRH agonists increased to nearly 11% (Turner et al. 2013). Furthermore, 11.5% were treated with SSRIs. In Northern American and other European countries, SSRIs were the main treatment as well, but GnRH agonists are also used regularly (Turner et al. 2017). Although it was initially speculated that treatment with GnRH agonists must be life-long (Thibaut et al.

1996), clinical experience has shown the contrary. Forensic psychiatrists in the course of time have found that the GnRH agonists or the antiandrogens must often be withdrawn or switched to other medications like SSRIs. This is due mostly because of severe side effects, e.g., diabetes, high blood pressure, osteoporosis or depression (Turner et al. 2013, Turner and Briken 2018), and not the result of a lack of efficacy.

Although the above-mentioned treatment algorithms are suitable for a successive treatment procedure with regard to the degree of severity of a paraphilic symptomatology, they were found less useful in the decision about switching or discontinuing the medication. As a first step, the authors of the present study used their own longstanding clinical experience to compile factors that could be helpful in providing a structured professional clinical judgment on why, how, and when to switch or discontinue medication in patients with paraphilic disorders. This led to the development of a first version of the **Change or Stop Testosterone Lowering Medications-Scale (COSTLow-Scale; Briken et al. 2015)**. In a second step, these factors should be further reviewed by experts for their usefulness, their relevance and their need for supplements, i.e., other important factors that should be added to the scale.

### **Aim**

The present study is intended to examine how experts assess the quality of the COSTLow-Scale factors with regard to two criteria: (1) the general usefulness of each factor (How useful is it to include this factor into the COSTLow-Scale according to experts' opinion?), and (2) the specific relevance of each factor (How relevant is the factor when making decisions about changing or stopping the use of TLM?). Moreover, we ask for factors that are missed and those that should be removed according to experts' opinion. The original ten factors of the COSTLow-Scale are those shown in table 2.

### **Method**

The primary goal of the COSTLow-Scale is to assist in making an informed professional judgement. Thus, the Delphi method is most appropriate for validation (Ziglio

1996). First developed in the 1950s (Gordon 1994), the Delphi method is a widely accepted method for consensus building among experts (Keeney et al. 2006, Hsu and Sandford 2007). It is an iterative process of an expert survey involving a series of questionnaires. The results of each stage are compiled and returned to the experts to reevaluate their responses in light of the compiled responses of all experts. Individual responses to items are kept anonymous (Somerville 2007) as participants do not meet face-to-face (Creswell 2002). Mitchell (1991) noticed that after the first two stages no essential changes in experts' responses are recorded (Mitchell 1991). Most Delphi studies used samples of 15 to 35 people (Gordon 1994); similar to the rule of thumb of 15 to 30 people for homogeneous groups, e.g., professors from the same discipline (Clayton 1997). There is no standard method for determining consensus of experts' opinions (Hasson et al. 2000, Mitchell 1991).

The present study was conducted between April and October 2017 as an anonymous online survey including two stages. The survey was programmed using "EFS (Enterprise Feedback Suite) Survey" from the company QuestBack AG (<http://www.questback.com>). The survey was approved by the Ethics Committee of the Hamburg Psychotherapist Chamber.

### *Sample*

A total of 30 experts who have proven expertise in treating and/or working with sex offenders and paraphilic patients participated in the first stage. Sample characteristics are shown in table 1. Out of these, a total of 18 experts participated in the second stage.

Both samples reach the required size suggested by several researchers (e.g., Clayton 1997, Gordon 1994).

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please insert table 1 somewhere over here

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### *Procedure*



Known experts were contacted via email including a formal invitation for participation as well as the survey link. When following the survey link, experts were presented with an introductory text, information for participants, and the informed consent form. To participate in the survey, experts had to confirm that they are at least 18 years old and have been working for at least 12 months with at least 4 patients receiving TLM. Furthermore, they had to confirm that they have read, understood, and agree with the informed consent and the declaration of data protection.

Afterwards, we assessed demographic and some control variables (table 1). Then we asked experts to assess the usefulness and the relevance of each COSTLow-Scale factor by using a 5-point-Likert-scale from 1 (not useful/relevant at all) to 5 (totally useful/relevant). At last, experts were asked if there are any additional factors that should be included in the COSTLow-Scale and if there are any factors included that might be negligible. If so, experts were provided with a free text field for their proposals.

#### *Analyses and Aggregating Experts' Opinion*

There are no generally valid guidelines for defining the level of consensus in current literature (Löfmark and Mårtensson 2017). Keeney et al. (2006) suggested a strategy for determining consensus which appears to be commonly accepted. Their recommendation is to define a percentage value to the level of agreement, which is 75% (Keeney et al. 2006). Polit and Beck (2012), however, suggested a range from a liberal 51% to a more conservative 70% level of agreement. In the present study, consensus was considered to have been achieved when 50% of the experts rated a factor in usefulness and relevance as two or higher. This means, the critical value for each factor to reach is a median of two. Written factors that should be added or removed from the scale were discussed by the research group.

#### **Results**

Within the first stage ( $n = 30$ ), all ten factors of the COSTLow-Scale reached the critical median value of two in both usefulness and relevance (table 2). We further received five new

factors that were elaborated in the second stage. Within the second stage ( $n = 18$ ), all 15 factors reached the critical median value of two in both usefulness and relevance (table 3). The final revised version of the COSTLow-Scale can be found in the Appendix (Appendix A).

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please insert table 2 and 3 somewhere over here

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## **Discussion**

With an increasing duration of experience and number of treated patients as well as aging patients, change of or withdrawal from TLM, especially of GnRH agonists, has become an important issue (Turner and Briken 2018). At the same time, the treatment of paraphilic patients with TLM is usually reserved for specialists and, overall, a relatively rare treatment intervention. Therefore, there are relatively few international experts in this area with more extensive experience (Turner et al. 2017). While previous research has identified factors that assist the decision whether or not a paraphilic sexual offender should be treated with TLM (Turner et al. 2014), every single patient, where the medication has to be changed or discontinued, presents the experts with a challenge, since the procedure must always be combined with a careful risk-benefit analysis (Thibaut et al. 2010).

Against the background, the starting point of the present study was a first set of criteria, which should contribute to a structured clinical judgment on the question of change or stopping TLM. These criteria were evaluated in the present study using the Delphi method. During this process the original ten criteria were complemented by five additional factors cited by experts. These 15 factors were re-evaluated. We will now shortly report the rationale behind the factors, which we divided into five subsections.

### *Age and duration of treatment*

Age > 45 years: This item follows the rationale that the risk of committing severe, very violent and sexually motivated sexual offenses at older ages tends to be lower. For example, in the follow-up study on sexual homicide perpetrators by Hill and colleagues (2008), beyond the age of 45, there were no re-offences of sexual homicide. At the same time, it must be pointed out that demarcation on the basis of the age of 45 is of course normative and thus artificially met and not empirically substantiated in a narrower sense. Nevertheless, results of studies on large samples of sexual offenders consistently have shown that recidivism rates significantly decrease in older age groups (e.g., Fazel et al. 2006).

Duration of TLM medication with a sufficient effect for a minimum of 3 years: With longer-term treatment with TLM, in particular GnRH agonists, the testosterone level generally increases only slowly (Koo et al. 2014). From clinical experience, after several years of treatment with GnRH agonists, switching to CPA orally (e.g., 50-200mg, optionally in combination with SSRIs) can often be achieved with sufficient confidence in the patient's compliance to oral medication. Thus, a relative suppression of testosterone can take place, which allows sexual activities with control and absence of paraphilic fantasies and activities.

#### *Therapeutic alliance*

Trustful relationship between treatment provider and patient before starting TLM: The therapeutic alliance is one of the strongest common factors in psychotherapy. It is composed of three components: the bond, the agreement about the goals of therapy, and the agreement about the tasks of therapy (Wampold 2015).

Psychotherapeutic treatment was possible before the beginning with TLM: If a productive psychotherapy was possible before TLM the probability that it will be possible after withdrawal or change of medication is obvious.

Openness relating to sexual interest and activity before the beginning with TLM, increase in openness under TLM: Openness in terms of the patient being willing to confront himself with his own sexual interest and fantasies, e.g., unwanted sexual fantasies, is central

for risk monitoring and management, especially when the possibilities of external control are restricted (e.g., in outpatient settings). Schober et al. (2005) showed that openness in relation to paraphilic fantasies under GnRH-agonists treatment increases which might be caused by the fact that patients experience their fantasies as more controllable.

#### *Psychopathology and risk factors*

No hypersexual disorder (definition by Kafka 2010) or sexual preoccupation (definition STABLE 2007; Hanson et al. 2007): Sexual preoccupation or hypersexuality is a known risk factor (Brouillette-Alarie et al. 2017, Chagraoui and Thibaut 2016, Kingston and Bradford 2013). In combination with a paraphilic disorder or sexual deviance, hypersexuality serves as a strong indicator for TLM treatment. In case of no or a low risk that sexual preoccupation or a hypersexual disorder will return after change of the medication, a change is indicated.

Low degree of violence in paraphilic symptomatology (e.g., no sadistic homicidal fantasies): The risk for change in medication associated with a lower degree of violence is lower, too.

Substantial decrease of the severity of paraphilia (from level 5 and level 4 to level 3 in the WFSBP Guidelines (Thibaut et al. 2010) or from level 2 to 1 in the sexual deviance subscale of the stable 2007 (Hanson et al. 2007)): Level 3 (WFSBP scale) typically represents the severity in paraphilic symptomatology in which the algorithm does not recommend the full dose of CPA or the use of GnRH-agonists.

PCL-Score (Hare 2003) < 25: Severe antisociality or psychopathy is one of the known risk factors for reoffending. The PCL-R is one of the well-established dynamic measurements of psychopathy. According to Hare (2003), PCL-R scores can be categorized into three levels: Values between 0 and 16 indicate a low level, values between 17 and 24 indicate a medium level, and values above 24 indicate a high level of psychopathy.

No acute severe psychopathology (psychotic, manic, high impulsivity): Acute psychopathology besides presenting possible risk factors would also speak against making fundamental changes in the long-term treatment regime.

No acute high-risk (definition e.g., according to the ACUTE 2007; Hanson et al. 2007): The Acute 2007 measures changes in acute risk and would be a possible aid to objectify the acute dynamic in relation to static and stable dynamic risk factors.

### *Motivation*

Desire for non-paraphilic sexuality related to seeking intimacy that is not against the consent or interest of another person (also wanting to have children): This factor considers the patient's desires under a human rights and sexual health perspective (Rainey and Harrison 2008). If the risk-benefit ratio allows it, every human being should have the possibility of having satisfying sexual activities that are not against the interest or consent of another person.

Willing to change to another medication (GnRH → CPA oral → SSRI): Wishes of the patients should be treated seriously and with respect.

### *Compliance and level of control*

Compliance for monitoring effects and side effects: It is helpful if especially the effects on testosterone (increase after withdrawal) can be monitored and related to clinical assessments and self-reports by the patient.

Sufficient level of supervision and control (if necessary) or absolute lack of access to victims: It is helpful if the possible level of control can correspond with a possible increase in risk after withdrawal or change in medication.

### *Application*

The application of the COSTLow-Scale is based on procedures of risk assessment instruments, such as structured professional judgment (SPJ) instruments (e.g., Boer and Hart 2009). SPJ instruments are checklists including risk factors that are interpreted, weighted and

integrated to pass a case specific risk judgment. As in SPJ instruments, every factor of the COSTLow-Scale is rated using a 3-point ordinal rating scale with 2 = definitely present, 1 = possibly or partially present or 0 = absent. At the end, points are added to a sum score and an overall assessment. The higher the sum score, the better substantiated is the overall assessment in which the change or cessation of TLM can be considered as “relatively safe” (two points) or assessed as “possibly indicated” (one point). In the case of non-consent or severe side effects that are untreatable (e.g., severe osteoporosis, anemia, thrombembolia), the medication has to be changed or stopped independently of the achieved value in the COSTLow-Scale.

### **Limitations**

As the potential for a high drop-out rate of participants exists when using the Delphi method (Borg and Gall 1983), only 60% of experts who participated at the first stage of the survey also participated at the second stage. The consensus that was achieved in the present study might be the result of this attrition since experts with divergent views are more likely to drop out (Rowe and Wright 1999). Moreover, the number of experts, especially at the second stage of the survey, was relatively small.

So far, the scale could not be used under real conditions, under which it could be validated in terms of its predictive power. Here the question would be, whether the application shows less rate of re-offence with changes of the medication. At the same time, the satisfaction of users of the scale (e.g., forensic psychiatrists) should be evaluated.

### **Conclusion**

For the first time, the COSTlow Scale provides an instrument that can be used to structure the process of changing or discontinuing TLM in patients with severe paraphilic disorders. The authors are happy to receive further suggestions for changes as well as evaluations.

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In the context of treating and/or working with sexual offenders and paraphilic patients, the COSTLow-R-Scale can support you when making an informed decision about changing or stopping the use of testosterone lowering medications. Please assess the presence of the 15 (or more) factors below by assigning **0 (no)**, **1 (unsure / maybe)** or **2 (yes)** points for each factor. The total score represents the need of changing or stopping the use of testosterone lowering medications. Clear therapeutic indication is given in the case of a patients' non-consent or severe side effects. Based on the total assessment of all factors, choose one of three possible implications for treatment: **(1) Changing medication type**, **(2) Stopping TLM** or **(3) No implications for treatment**.

The abbreviation TLM is used for testosterone lowering medications. These medications cause a decrease of the sex hormone testosterone leading to a reduced sex drive, e.g., Gonadotropin-releasing hormone (GnRH)-agonists, Cyproterone Acetate (CPA) and Medroxyprogesterone Acetate (MPA).

<p style="text-align: center;"><b>The Change or Stop Testosterone Lowering Medication - Revised</b></p> <p style="text-align: center;"><b>(COSTLow-R)-Scale</b></p> <p style="text-align: center;">(Briken P, Bradford J, Cosyns P, Thibaut F, 2018)</p>	<p><b>0 = No</b></p> <p><b>1 = Unsure/</b> <b>Maybe</b></p> <p><b>2 = Yes</b></p>
1. Compliance for monitoring effects and side effects	
2. Openness towards sexual interest and activity before the beginning with TLM, increase in openness under TLM	
3. Low degree of violence in paraphilic symptomatology (e.g. no sadistic-homicidal fantasies)	
4. Substantial decrease of the severity of paraphilia (from level 5 and level 4 to level 3 or from level 2 to 1 in the sexual deviance subscale of the STABLE 2007 (Hanson et al., 2007))	
5. No hypersexual disorder (definition according to Kafka, 2010) or sexual preoccupation (definition according to STABLE, 2007)	
6. Desire for non-paraphilic sexuality including intimacy (also wanting to have children)	
7. Willing to change to another medication (GnRH-agonist → CPA oral → SSRI)	
8. Psychotherapeutical treatment was possible before the beginning with TLM	

9. Trustful relationship between medical health care provider and patient before starting TLM	
10. Duration of TLM medication with a sufficient effect for a minimum of 3 years	
11. PCL-Score (Hare, 1991; 2003) < 25	
12. No acute severe psychopathology (psychotic, manic, high impulsivity)	
13. Age > 45 years	
14. Sufficient level of supervision and control (if necessary) or absolute lack of access to victims	
15. No acute high-risk (definition e.g., according to the ACUTE 2007)	
16. Others _____ (please describe)	
<b>Total Score</b>	

<b><i>In case of ...</i></b>	
Non-consent	<b>Stop TLM!</b>
Severe side effects (e.g., osteoporosis, anemia, thromboembolia) that are untreatable	<b>Stop TLM!</b>

**Informed Decision** (choose one of three possible implications for treatment)

1. Changing medication type from \_\_\_\_\_ to \_\_\_\_\_

2. Stopping TLM

3. Reducing TLM

4. No implications for treatment

Notes & remarks

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Table 1. Sample characteristics for the total sample ( $n = 30$ )

Variables	Total ( $n = 30$ , 100%)		
	$M^a$	$SD^b$	range
Age (in years)	54	9	38-72
Sex	$N^c$		$\%^d$
Male	21		70
Female	9		30
Profession	$N$		$\%$
Psychiatrist	25		83
Psychologist	3		10
Others <sup>e</sup>	2		7
Country	$N$		$\%$
Germany	14		47
USA	2		7
Canada	5		16
Others <sup>f</sup>	9		30
	$M$	$SD$	range
Years of experience in working with sexual offenders	19	9	6-40
Ever prescribed TLM	$N$		$\%$
Yes	27		90
No	3		10
	$M$	$SD$	range
Years of experience in using TLM ( $n = 27$ )	17	9	6-35

Note. <sup>a</sup> Mean value, <sup>b</sup> Standard deviation, <sup>c</sup> Absolute share in the sample, <sup>d</sup> Percentage share in the sample, <sup>e</sup> One endocrinologist; one jurist, <sup>f</sup> Belgium; England; Netherland; Sweden; Switzerland.



Table 2. Experts' assessment (n = 30) on the usefulness and relevance of the COSTLow-Scale factors within the first D stage

Factor	Usefulness				Relevance			
	<i>M</i> <sup>a</sup>	<i>SD</i> <sup>b</sup>	<i>Md</i> <sup>c</sup>	range	<i>M</i>	<i>SD</i>	<i>Md</i>	range
1. Compliance for monitoring effects and side effects	4.2	1.2	5.0	1-5	4.2	1.0	4.0	2-5
2. Openness relating to sexual interest and activity before the beginning with TLM, increase in openness under TLM	4.1	1.0	4.0	1-5	3.9	1.1	4.0	1-5
3. Substantial decrease of the severity of paraphilia (from level 4 to level 3 in the WFSBP guidelines (Thibaut et al., 2010) or from level 2 to 1 in the sexual deviance subscale of the stable 2007 (Hanson et al., 2007))	3.8	0.9	4.0	2-5	3.7	1.1	4.0	2-5
4. No hypersexual disorder (definition Kafka, 2010) or sexual preoccupation (definition STABLE, 2007)	3.6	1.2	3.0	1-5	3.7	1.2	4.0	2-5
5. Desire for non-paraphilic sexuality related to seeking intimacy that is not against the consent or interest of another person (also wanting to have children)	3.7	1.0	4.0	1-5	3.7	1.0	4.0	2-5
6. Willing to change to another medication (GnRH → CPA oral → SSRI)	3.9	1.0	4.0	2-5	3.7	1.0	4.0	1-5
7. Psychotherapeutical treatment was possible before the beginning with TLM	3.4	1.2	3.5	1-5	3.3	1.1	3.0	1-5
8. Trustful relationship between treatment provider and patient before starting TLM	4.0	1.0	4.0	1-5	4.1	1.1	4.0	1-5
9. Duration of TLM medication with a sufficient effect for a minimum of 3 years	3.7	1.1	4.0	2-5	3.5	1.3	3.5	1-5
10. Age > 45 years	3.1	1.2	3.0	1-5	2.9	1.3	3.0	1-5

Note. <sup>a</sup> Mean value, <sup>b</sup> Standard deviation, <sup>c</sup> Median.

Table 3. Experts' assessment (n = 18) on the usefulness and relevance of the COSTLow-Scale factors within the second stage

Factor	Usefulness				Relevance			
	<i>M</i> <sup>a</sup>	<i>SD</i> <sup>b</sup>	<i>Md</i> <sup>c</sup>	range	<i>M</i>	<i>SD</i>	<i>Md</i>	range
11. Compliance for monitoring effects and side effects	4.3	1.0	4.5	1-5	4.2	1.1	4.5	1-5
12. Openness relating to sexual interest and activity before the beginning with TLM, increase in openness under TLM	4.0	1.1	4.0	1-5	3.9	1.1	4.0	1-5
13. Substantial decrease of the severity of paraphilia (from level 4 to level 3 in the WFSBP guidelines (Thibaut et al., 2010) or from level 2 to 1 in the sexual deviance subscale of the stable 2007 (Hanson et al., 2007))	3.7	1.0	4.0	1-5	3.7	1.2	4.0	1-5
14. No hypersexual disorder (definition Kafka, 2010) or sexual preoccupation (definition STABLE, 2007)	3.4	1.5	4.0	1-5	3.6	1.4	4.0	1-5
15. Desire for non-paraphilic sexuality related to seeking intimacy that is not against the consent or interest of another person (also wanting to have children)	4.1	0.7	4.0	3-5	3.7	1.0	4.0	1-5
16. Willing to change to another medication (GnRH → CPA oral → SSRI)	4.1	0.8	4.0	3-5	4.1	0.8	4.0	3-5
17. Psychotherapeutical treatment was possible before the beginning with TLM	3.8	1.2	4.0	1-5	4.4	0.9	5.0	1-5
18. Trustful relationship between treatment provider and patient before starting TLM	4.5	0.9	5.0	3-5	4.2	1.2	5.0	1-5
19. Duration of TLM medication with a sufficient effect for a minimum of 3 years	3.4	1.5	3.5	1-5	3.2	1.3	3.0	1-5
20. Age > 45 years	2.6	1.4	2.0	1-5	2.3	1.2	2.0	1-5
21. Low degree of violence in paraphilic symptomatology (e.g., no sadistic homicidal fantasies)	3.4	1.4	4.0	1-5	3.4	1.3	4.0	1-5
22. PCL-Score (Hare, 1991; 2003) < 25	3.2	1.4	3.0	1-5	3.2	1.3	4.0	1-5

23.No acute severe psychopathology (psychotic, manic, high impulsivity)	4.1	1.2	4.5	1-5	3.8	1.4	4.0	1-5
24.Sufficient level of supervision and control (if necessary) or absolute lack of access to victims	4.3	0.8	4.5	3-5	4.2	0.7	4.0	3-5
25.No acute high-risk (definition e.g., according to the ACUTE 2007)	3.6	1.2	3.5	1-5	3.6	1.3	3.5	1-5

Note. <sup>a</sup> Mean value, <sup>b</sup> Standard deviation, <sup>c</sup> Median.

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