# Evaluation of Medication to Manage Sexual Arousal

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# Sexual Preoccupation & Hypersexuality

"an abnormally intense interest in sex that dominates psychological functioning" (Mann, Hanson & Thornton, 2010 pg. 198)

#### Terms used include:

- Sexual addiction (Marshall, Marshall, Moulden & Serran, 2008),
- Hypersexual disorder (Krueger & Kaplan, 2002)
- Hypersexuality (Kaplan & Krueger, 2010)

Sex addiction is defined as: "a sexual desire disorder characterized by an increased frequency and intensity of sexually motivated fantasies, arousal, urges, and enacted behavior in association with an impulsivity component – a maladaptive behavioral response with adverse consequences" (Kafka, 2010, p. 385).

These terms are not used in order to negate responsibility, however they are helpful when thinking about treatment

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### Prevalence in the community

- Discrepancies in the literature between the terms mean prevalence rates differ; some reasonable estimates are:
  - 3.0% for men and 1.2% for women on scores of compulsive sexual behaviour (used interchangeably with hypersexuality and sexual addiction; Odlaug et al., 2013)
  - 3.1% of women who responded to an online survey were characterised as hypersexual (Klein, Rettenberger & Briken, 2014; Reid, Garos & Carpenter, 2011)
- More recent research has revealed this figure to be increasing: 12.1% of a community male sample (n=8,718) had a TSO of at least 7 (Klein, Schmidt, Turner & Briken, 2015).
- Positive correlational links found between pornography consumption and sexual compulsion and hypersexuality in women (Cates, 2015) – and promiscuity and excessive masturbation (impersonal not passive sex)



# **Current management and treatment of hypersexuality**

- Rule out medical causes
- Consider medication to manage sexual arousal together with therapy / psych treatment

Treated with 2 categories of medication: hormonal and non-hormonal medications medications

Hormonal drug therapy includes anti-androgens (for example, cyproterone acetate) and gonadotropin-releasing hormone (GnRH) analogues (for example, triptorelin). Cyproterone acetate (Androcur) is licensed for the control of libido in severe hypersexuality or sexual deviation in adult men. Triptorelin (Salvacyl) is licensed for the reversible reduction of testosterone to castrate levels in order to decrease sexual drive in adult men with severe sexual deviations.

Non-hormonal drug therapy includes antipsychotics (off-label use) and selective serotonin reuptake inhibitors (off-label use) (Khan et al. 2015). (From NICE, 2017)

# Effectiveness assessed in a prison setting

- Hypersexuality/SP is an enduring psychological risk factor or long term vulnerability for sexual offending (Thornton & Knight, 2015)
- Sexual preoccupation is a significant predictor for sexual, violent and general recidivism (Hanson & Morton-Bourgon, 2004; Hanson, Harris, Scott & Helmus, 2007)
- Results are typically higher in sexual offender populations, with findings suggesting 44% of incarcerated sexual offenders were considered as hypersexual compared to 18% of a matched community sample (Marshall & Marshall, 2006; Marshall, Marshall, Moulden, & Serran, 2008; Marshall, O'Brien, & Kingston, 2009).



#### **Research Context**

HMP Whatton, a treatment prison in the UK, holds approximately 840 adult males convicted of a sexual offence

42% have a sentence of more than four years 56% are serving an indeterminate sentence including life sentence

#### Medication

Prescription guidelines from Professor Grubin

- oFluoxetine, Paroxetine (SSRIs)
- Ocyproterone acetate (CPA, anti androgen)
- oTriptorelin (GnRH agonist)
- •See Winder et al. (2014; 2017) for evaluation



#### **Evaluation**

#### 145 + adult men referred for medication; initial medication was:

•	SSRIs	84
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- F/A 7
- GNRH 2
- under assessment 12
- NONE
   22 (not suitable, not motivated, moving on)

#### **Demographics**

- •Mean IQ (assessed by WASI or, where available WAIS) = 87.07 (sd = 16.15; 58-118) 35 less than 80
- •Mean age = 46.29 (sd = 14.60; 22-83)
- •Mean age at first conviction = 21.54 (sd = 9.49)
- •Nationality: Majority British (reflecting 'norm' popn)
- •History of abuse: Yes, typically bullying, s/p abuse



#### **Evaluation**

#### Risk

Static risk (Risk Matrix 2000) scores:

- •Mean score for sexual risk = 2.9 (mode = 3, High)
  - 36.36 % high
  - 30% very high
- •Mean score for violence risk = 2.08 (mode = 1)
  - Dynamic risk Structured Assessment of Risk and Need (SARN)
    - Typically scored highly on:
      - Sexual preoccupation
      - Inadequacy
      - Poor problem solving
      - Child abuse supportive beliefs
      - Lack of emotionally intimate relationships



#### Measures

#### **Clinical Measures**

- Captured at regular meetings between participants and Dr Kaul (prescribing psychiatrist)
- Data collated during private therapeutic session; used clinically to discuss and tailor medication

#### **Psychometric measures**

Dynamic measures (baseline pre-meds, then approximately every 3 months)

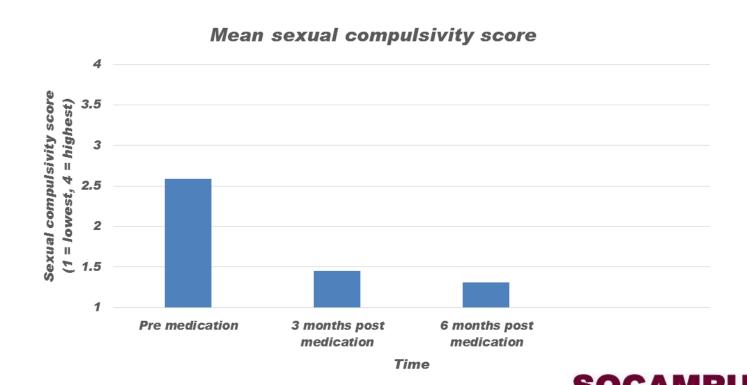
- Sexual Compulsivity Scale (SCS)
  - 10 items; 1-4; used means i.e. between 1-4; 'My desires to have sex have disrupted my daily life'
- Hospital Anxiety and Depression Scale (HADS)
  - Scoring is 0-21 on each sub-scale; caseness 8/21
- Severity Indices of Personality Problems (SIPP 118)

Static measures (conducted once only)

- PAI: Personality Assessment Inventory
  - 22 scales measuring clinical, treatment and interpersonal factors related to personality
- MPI: My Private Interests
  - Short scale measuring offence related sexual interests with 4 subscales 1)
     an obsession with sex; 2) a sexual interest in children; 3) a sexual interest in
     violent sex; and 4) multiple paraphilia.

# **Evidence base in prison – HMP Whatton**

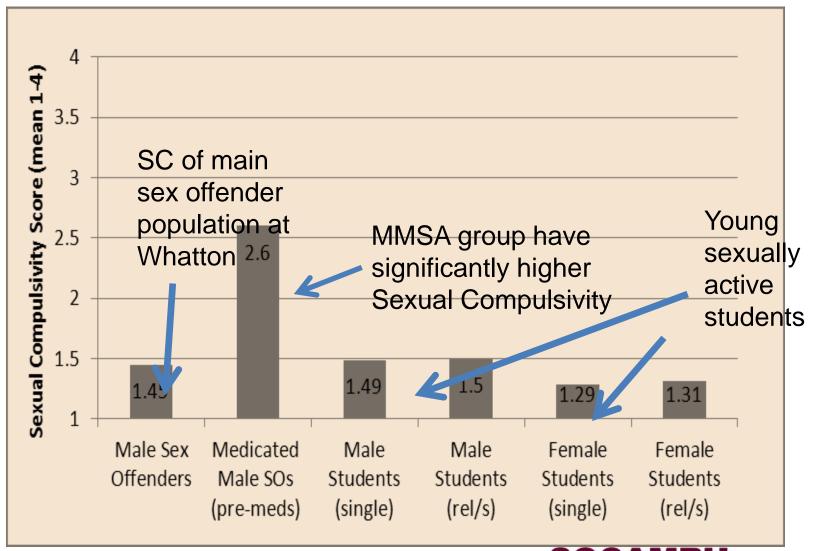
Figure 1: Mean Sexual Compulsivity Scores for participants taking medication to reduce sexual preoccupation: pre-medication, three months post-medication, and six months post-medication.



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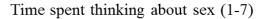
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#### **Sexual Compulsivity**



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### Evidence base in prison



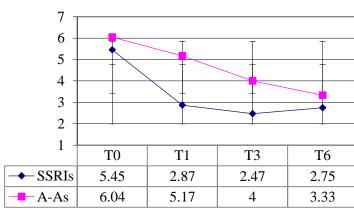
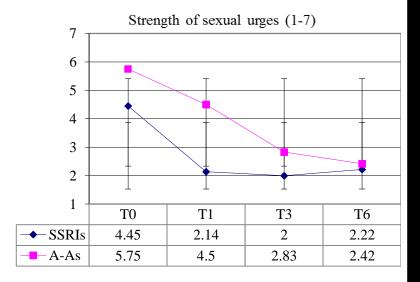


Figure 3 (left): Amount of time currently spent thinking about sex for participants taking (i) SSRIs and (ii) A-As



Ability to distract from sexual thoughts (1-7)

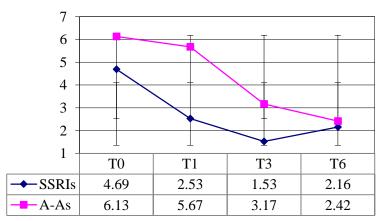


Figure 5 (above): Strength of sexual urges for participants taking (i) SSRIs and (ii) A-As

Figure 4 (left): Ability to distract from sexual thoughts for participants taking (i) SSRIs and (ii) A-As

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### Psychometric Measures (dynamic)

Table 1: Means (SD) for HADS and Sexual Compulsivity scale

	Baseline	Т3	<b>T6</b>
Depression	6.74 (3.91)	4.29 (3.19)	3.82 (3.19)
Anxiety	10.36 (4.31)	6.71 (3.85)	5.89 (3.78)
Sexual Compulsivity	2.59 (0.75)	1.45 (0.50)	1.31 (0.39)



### Psychometric Measures (dynamic)

- Prior to starting medication the research sample more closely resembled the clinical population (admissions to mental health institutes) than the general population on the SIPP-118.
- ➤ The facets most problematic were effortful control, self-reflexive functioning, frustration tolerance, emotional regulation and stable self image.
- ➤ Both statistical and clinically significant change was observed in adaptive personality functioning on all scales by six months post medication. The percentage of reliable change of adaptive personality functioning was between 13.6% and 38.8%, moving functioning from the maladaptive range to the clinically 'normal' range (general population norms).
- The majority of participants had moved into the healthy range of personality functioning within six months of taking medication.



### **BASELINE**SIPP scores VS general population, in-patients, out patients

SIPP-118 Subscale (Lower means more disordered)	Participants ( <i>n</i> =69)	General population (Andrea, 2007) (n=555)	In-patients (Andrea, 2007) (n=555)	Out patients (Andrea, 2007) (n=157)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Emotional regulation	2.40 (0.67)	3.30 (0.61) p=.001	2.44 (0.69) <i>ns</i>	2.78 (0.63) p=.001
Effortful control	2.21 (0.66)	3.16 (0.56) p=.001	2.53 (0.70) p=.001	2.80 (0.71) p=.001
Frustration tolerance	2.38 (0.60)	2.96 (0.56) p=.001	2.24 (0.56) ns	2.36 (0.56) ns
Responsible industry	2.72 (0.69)	3.44 (0.50) p=.001	2.87 (0.67) ns	3.07 (0.69) p=.001
Aggression regulation	3.05 (0.82)	3.66 (0.45) p=.001	3.30 (0.73) p=.013	3.34 (0.66) p=.004
Intimacy	2.46 (0.56)	3.17 (0.60) p=.001	2.68 (0.69) p=.001	2.76 (0.63) p=.001
Enduring relationships	2.53 (0.58)	3.31 (0.58) p=.001	2.47 (0.67) ns	2.54 (0.65) ns
Self-respect	2.59 (0.73)	3.30 (0.59) p=.001	2.36 (0.67) p=.01	2.35 (0.74) p=.008



# CHANGES OVER TIME SIPP scores of participants VS general population

SIPP-118 Subscale (Lower means more disordered)	General pop'n ( <i>n=478</i> )	Participants Baseline ( <i>n</i> =69)		Participants 3 months (n=54)		Participants 6 months (n=41)	
	Mean (SD)	Mean (SD)	T test p value	Mean (SD)	T test p value	Mean (SD)	T test p value
Emotional regulation	3.30 (0.61)	2.40 (0.67)	p=.001	2.78 (0.68)	p=.004	2.99 (0.65)	p=.013
Effortful control	3.16 (0.56)	2.21 (0.66)	p=.001	2.64 (0.65)	p=.001	2.77 (0.70)	p=.001
Frustration tolerance	2.96 (0.56)	2.38 (0.60)	p=.001	2.76 (0.64)	ns	2.86 (0.59)	<u>ns</u>
Responsible industry	3.44 (0.50)	2.72 (0.69)	p=.001	2.96 (0.60)	p=.001	3.13 (0.56)	p=.001
Aggression regulation	3.66 (0.45)	3.05 (0.82)	p=.001	3.25 (0.69)	p=.007	3.38 (0.62)	<u>ns</u>
Intimacy	3.17 (0.60)	2.46 (0.56)	p=.001	2.67 (0.56)	p=.001	2.79 (0.54)	p=.001
Enduring relationships	3.31 (0.58)	2.53 (0.58)	p=.001	2.78 (0.64)	p=.001	2.86 (0.61)	p=.001
Self-respect	3.30 (0.59)	2.59 (0.73)	p=.001	2.87 (0.70)	p=.001	3.15 (0.63)	<u>ns</u>



#### **Conclusions**

- Promising reductions in measures of clinical measures for individuals taking the medication (both types)
- Complementary to psychological treatment, not a replacement
- Provides some support for the notion that personality, and in particular, self-control, are key mechanisms underlying hypersexuality and that the improved management of this could result in improved management of sexual thoughts.
- Hypersexuality may be one psychological and behavioural manifestation of maladaptive self-control, presenting as an inability to manage urges, obsessional sexual thoughts, and poor coping (in the form of depression and anxiety).



# Service user reports: effects of medication

- Sexual preoccupation and associated sexual behaviour
  - Decreased frequency & intensity of sexual thoughts, fantasies and urges
  - Reduction in masturbatory frequency
  - Increased control of sexual thoughts & ability to distract
  - Physical effects
- Obsessive compulsive disorder and depressive symptoms
  - Reduction in symptoms
  - Increased ability to communicate with others and to socialise
- Impulse and emotional control
  - Increased ability to recognise inappropriate sexual thoughts
  - Altered nature of fantasies
  - Improved management of emotions.
- Side effects
  - Tiredness, drowsiness, nausea, constipation and headaches

### Reasons for stopping the medication

- Prior to commencing medication the main reasons for not taking MMSA include:
  - Psychiatrist thinks its not needed
  - Refusal/participant feels sexual thoughts not an issue
  - Anxious about the side effects
  - Other medical issues that need sorting before meds
- Main reasons for discharges from service are release or transfer (often to another MMSA site).
- Other reasons include:
  - Participant stopped collecting or taking meds
  - Participant feels better/no longer feels they need meds/in line with psychiatrist views



### **National Evaluation**

### Ethical approval obtained:

- North Sea Camp (2 referrals and 2 research participants)
- HMP Hull (0 referrals)

### Awaiting NHS ethical approval:

- O HMP USK
- HMP Isle of Wight
- HMP Leyhill
- HMP Frankland



#### Links

- Safer Living Foundation <a href="http://saferlivingfoundation.org/">http://saferlivingfoundation.org/</a>
- Lucy Faithfull Foundation <a href="http://www.lucyfaithfull.org.uk/">http://www.lucyfaithfull.org.uk/</a>
- Stop It Now <a href="http://www.stopitnow.org.uk/">http://www.stopitnow.org.uk/</a>
- Online help for people concerned about accessing images <a href="http://get-help.stopitnow.org.uk/">http://get-help.stopitnow.org.uk/</a>
- Support groups such as Sex Addicts Anonymous <u>http://saauk.info/en/</u>
- NICE guidelines :
- <a href="https://www.nice.org.uk/advice/esuom46/chapter/full-evidence-summary#introduction-and-current-guidance-2">https://www.nice.org.uk/advice/esuom46/chapter/full-evidence-summary#introduction-and-current-guidance-2</a>



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#### **Additional slides**

From here on – to expand on any points raised and possible qs



#### **Testosterone levels**

- 12 participants on Androcur with pre and post tests
- Serum testosterone levels nmol/L

	Mean (SD) nmol/L	Range nmol/L
Pre treatment	13.47 (6.6)	5.3-23.2
Post treatment	5.10 (2.92)	1.1-11.2

- Androcur significantly reduces Testosterone levels p=0.0002
- Pre treatment levels slightly higher than norm



	Key features	Key findings
Service user studies	Aim: To explore the use of anti-libidinals to reduce sexual preoccupation and/or hypersexuality in convicted sexual offenders  Participants: 19 adult male sex offenders  Medication: Anti-androgens, SSRIs or combined  Analysis: Thematic analysis	<ul> <li>Reduced sexual preoccupation &amp; arousal</li> <li>Improved impulse &amp; emotional control</li> <li>Some noncompliance</li> <li>No prior knowledge of medication</li> <li>Concerns about effects &amp; long term use</li> </ul>
Therapist study	Aim: To explore the experiences of individuals involved in the referral of pharmacological treatment and those who work with sexual offenders receiving pharmacological treatment  Participants: 8 intervention staff  Analysis: Thematic analysis	<ul> <li>Offenders' concerns &amp; insight</li> <li>Lack of feedback</li> <li>Lack of awareness about treatment &amp; lack of support</li> <li>Concerns about throughcare</li> </ul>
Offender supervisor study	Aim: To explore the perspectives and experiences of offender supervisors in relation to the pharmacological treatment Participants: 6 offender supervisors Analysis: Thematic analysis	<ul> <li>Offenders' reluctance to engage</li> <li>Lack of feedback</li> <li>Lack of awareness</li> <li>Excluded from treatment process</li> <li>Importance of throughcare</li> </ul>

# Prescribing guidance: Prescribing unlicensed medicines

- 67. The term 'unlicensed medicine' is used to describe medicines that are used outside the terms of their UK licence or which have no licence for use in the UK.<sup>22</sup> Unlicensed medicines are commonly used in some areas of medicine such as in paediatrics, psychiatry and palliative care. They are also used, less frequently, in other areas of medicine.
- 68. You should usually prescribe licensed medicines in accordance with the terms of their licence. However, you may prescribe unlicensed medicines where, on the basis of an assessment of the individual patient, you conclude, for medical reasons, that it is necessary to do so to meet the specific needs of the patient.
- 69. Prescribing unlicensed medicines may be necessary where:
- a. There is no suitably licensed medicine that will meet the patient's need. Examples include (but are not limited to), for example, where :23
- i. there is no licensed medicine applicable to the particular patient. For example, if the patient is a child and a medicine licensed only for adult patients would meet the needs of the child; or
- ii. a medicine licensed to treat a condition or symptom in children would nonetheless not meet the specific assessed needs of the particular child patient, but a medicine licensed for the same condition or symptom in adults would do so; or
- iii. the dosage specified for a licensed medicine would not meet the patient's need; or
- iv. the patient needs a medicine in a formulation that is not specified in an applicable licence.
- b. Or where a suitably licensed medicine that would meet the patient's need is not available. This may arise where, for example, there is a temporary shortage in supply; or
- c. The prescribing forms part of a properly approved research project.
- 70. When prescribing an unlicensed medicine you must:
- a. be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy
- b. take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or ensure that arrangements are made for another suitable doctor to do so
- c. make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine.

# Prescribing guidance: Prescribing unlicensed medicines

Information for patients about the licence for their medicines.

- 71. You must give patients (or their parents or carers) sufficient information about the medicines you propose to prescribe to allow them to make an informed decision.
- 72. Some medicines are routinely used outside the terms of their licence, for example in treating children. In emergencies or where there is no realistic alternative treatment and such information is likely to cause distress, it may not be practical or necessary to draw attention to the licence. In other cases, where prescribing unlicensed medicines is supported by authoritative clinical guidance, it may be sufficient to describe in general terms why the medicine is not licensed for the proposed use or patient population.<sup>24</sup> You must always answer questions from patients (or their parents or carers) about medicines fully and honestly.
- 73. If you intend to prescribe unlicensed medicines where that is not routine or if there are suitably licensed alternatives available, you should explain this to the patient, and your reasons for doing so.
- 74. You should be careful about using medical devices for purposes for which they were not intended.

