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# **TWO-ARM, PROSPECTIVE, OPEN-LABEL, PILOT STUDY OF FLIBANSERIN VERSUS FLIBANSERIN AND SEX THERAPY IN WOMEN WITH HSDD**

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# DISCLOSURES

- Consultant/Advisory Board: AMAG Pharmaceuticals, Strategic Science & Technologies
- Research: AbbVie, AMAG Pharmaceuticals, BTL Industries, Ipsen, Lipocine, TGI
- Speakers bureau: AMAG Pharmaceuticals, Clarus
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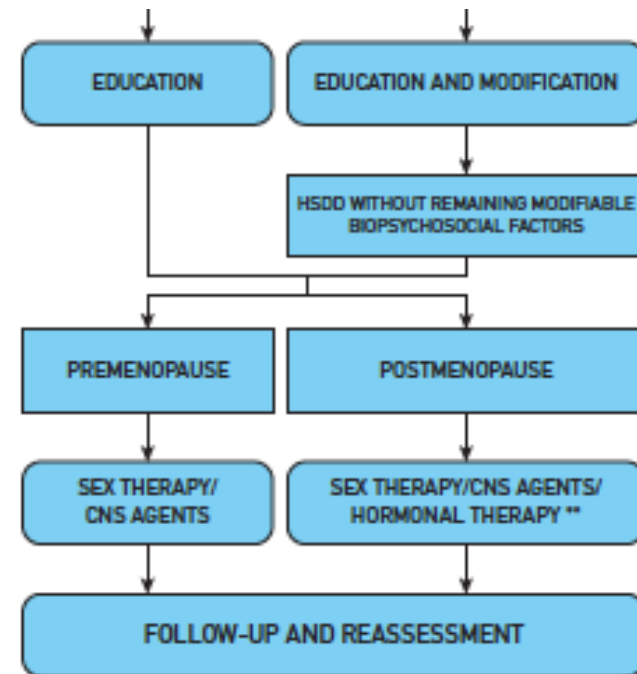
# INTRODUCTION

- HSDD most common sexual dysfunction for women
- Flibanserin (MSAA) first FDA-approved treatment for HSDD
- Biopsychosocial assessment/treatment
- ISSWSH POC addresses different Tx modalities resulting in improvement of HSDD



# AIM

- To compare efficacy of:  
flibanserin alone  
flibanserin and sex therapy



## ISSWSH Process of Care Treatment Modalities

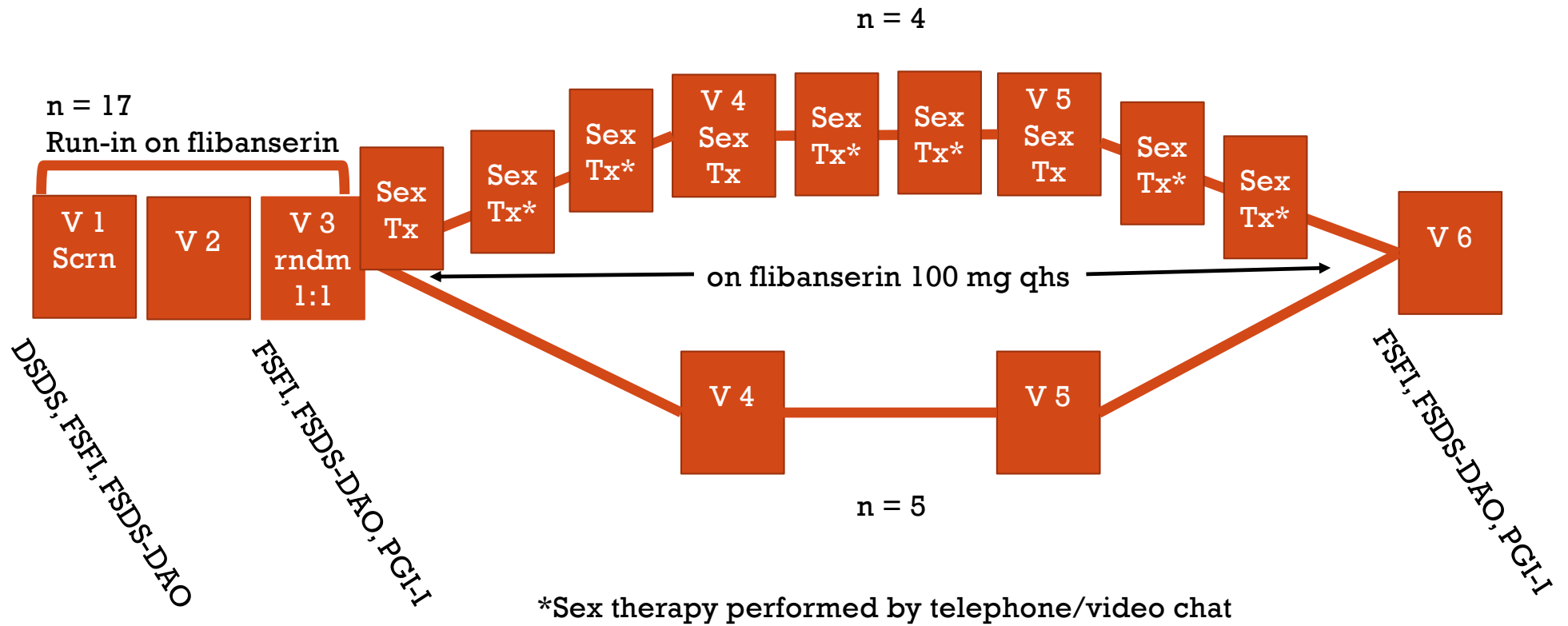


# METHODS

- Inclusion
  - $\geq 18$  years old
  - Biologic-based HSDD as primary sexual complaint
  - FSFI  $< 26$ ; desire domain  $< 4.8$
  - FSDS-DAO  $> 18$
  - yes to questions 1-4 on the DSDS, question 5 risk factors not responsible for HSDD
- Exclusion
  - has sexual pain
  - used flibanserin in the last 6 months
  - history of alcohol or drug abuse, uses tobacco
  - using androgen therapy
  - is pregnant, nursing, or planning to become pregnant over next 6 months
  - taking a mild or strong cytochrome P450 3A4 (CYP3A4) inhibitor
  - history of liver impairment



# METHODS



# RESULTS

- FSFI total scores significantly higher for combined flibanserin/sex therapy compared to flibanserin alone ( $p = 0.03$ )
- FSFI domain scores consistently higher in group receiving flibanserin/sex therapy (not statistically significant)
  - desire
  - arousal
  - lubrication
  - orgasm
- Scores similar for both groups:
  - distress
  - satisfaction
  - pain



# LIMITATIONS

- Small n
- Only responders were randomized
- More research needed





# CONCLUSIONS

- Adding sex therapy to flibanserin in responders significantly increased overall sexual function compared to flibanserin treatment alone
- Suggests multidisciplinary treatment paradigm may result in better treatment outcomes in patients with HSDD

