

# **WHAT WOMEN WANT**

## **Partners' Preference Study:**

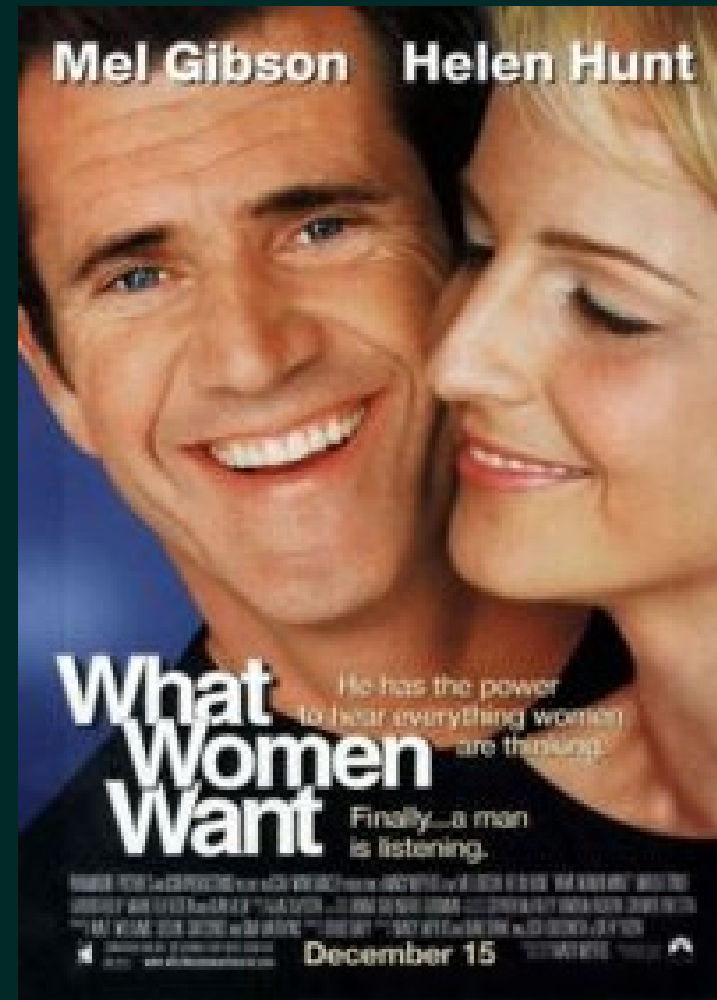
An examination of preference  
for tadalafil or sildenafil  
from the heterosexual partners' perspective

**Helen M Conaglen & John V Conaglen**

Sexual Research Trust

# What women want

- Not exactly what the Mel Gibson / Helen Hunt 2001 movie portrayed...but
- “He has the power to hear everything women are thinking. Finally ... a man is listening!”



# Background

- Oral medications for erectile dysfunction used for 10 years now
- Substantial research on male response and effective nature of medications
- Little data about women's experience
- Less data about how treatment affects a couple and their relationship
- Importance of understanding women's perspective

# Partner input important



# Previous studies

- Some retrospective
  - Review of partner's responses to treatment efficacy questions:
    - 'Was your partner able to:
      1. achieve an erection?
      2. penetrate?
      3. achieve successful intercourse?' [Althof et al., 2006]
  - FEMALES study of sexual frequency, experiences before and after partner's PDE5i therapy [Fisher et al., 2005]

# Previous studies

- Some qualitative
  - UK interviews of men with ED [Tomlinson & Wright, 2004]
  - NZ interviews of women whose partners had ED [Conaglen & Conaglen, 2008]
- Prospective studies involving partners
  - Placebo controlled studies assessing treatment satisfaction in partners as well as efficacy for men with ED [Edwards et al., 2006; Rosen et al., 2006]

# Impact of erectile difficulties



*YOU DIDNT SAVE ANYTHING  
FOR RETIREMENT DID YOU??*

# Preference studies

- Men's preference for tadalafil or sildenafil citrate

[Govier et al., 2003; Ströberg et al., 2003; Eardley et al., 2005]

- Preference ratings of physicians, patients & partners for tadalafil or sildenafil citrate – only 12% of partners

[Lee et al., 2006]

- Guidelines for preference studies

[Mulhall & Montorsi, 2006]

# Preference: Minimizing study bias

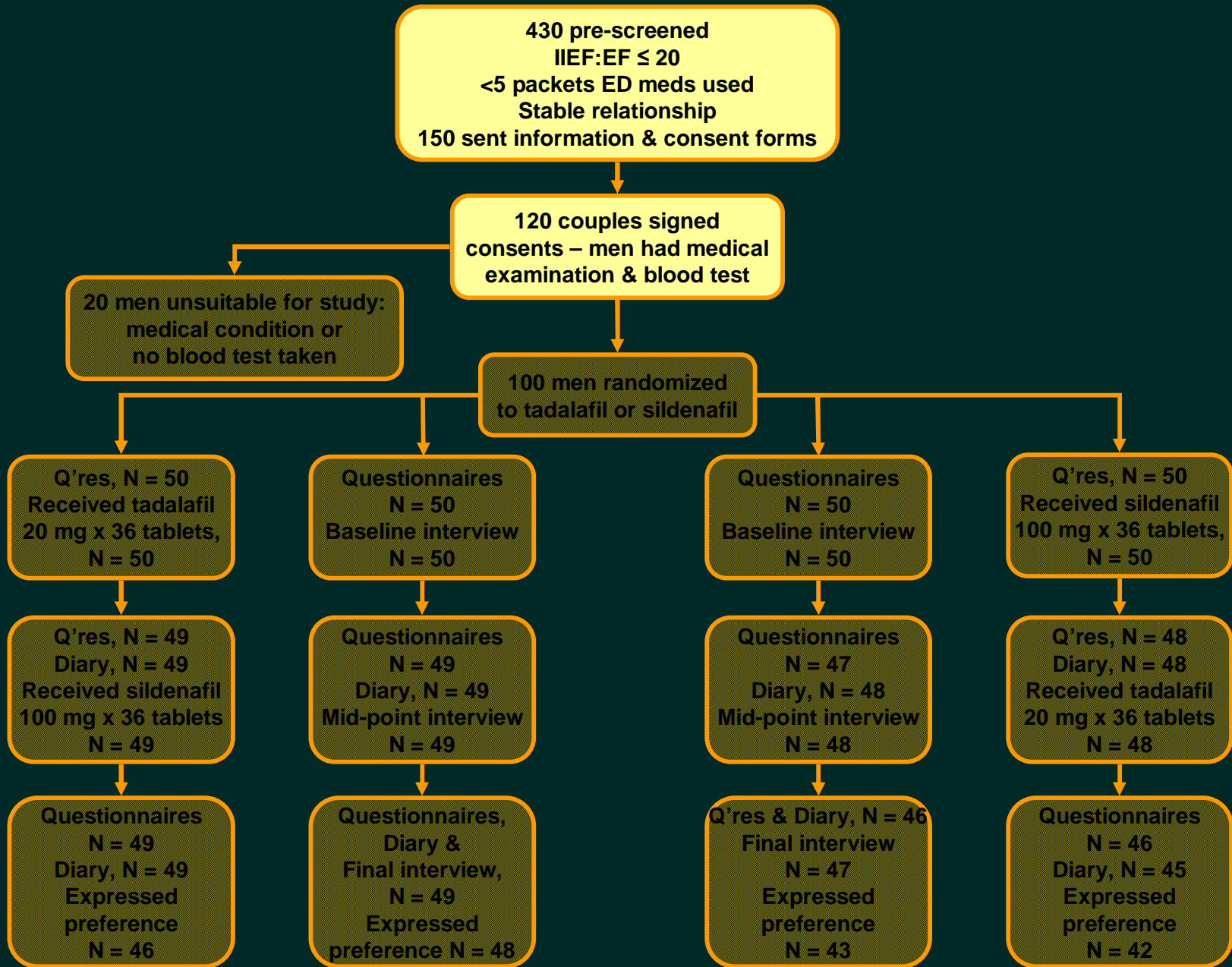
- Crossover design essential
- Randomized order of drug use
  - to deal with carry-over effects
- Equal period of drug use, equivalent maximal dose
- Patient instructions
  - For both: Dose, No nitrates, max 1/day, effective time-frame, sexual stimulation necessary
  - For Viagra: Fatty foods & alcohol may diminish drug effect
- Preference questions at each stage of study
- PDE5 inhibitor naïve participants
  - i.e. not already biased

## Study aims

- Understand whether women expressed same preference as found in men's studies
- Reasons for the women's preference
- Examine the effect of oral treatment not only on the man, but also his partner and their relationship

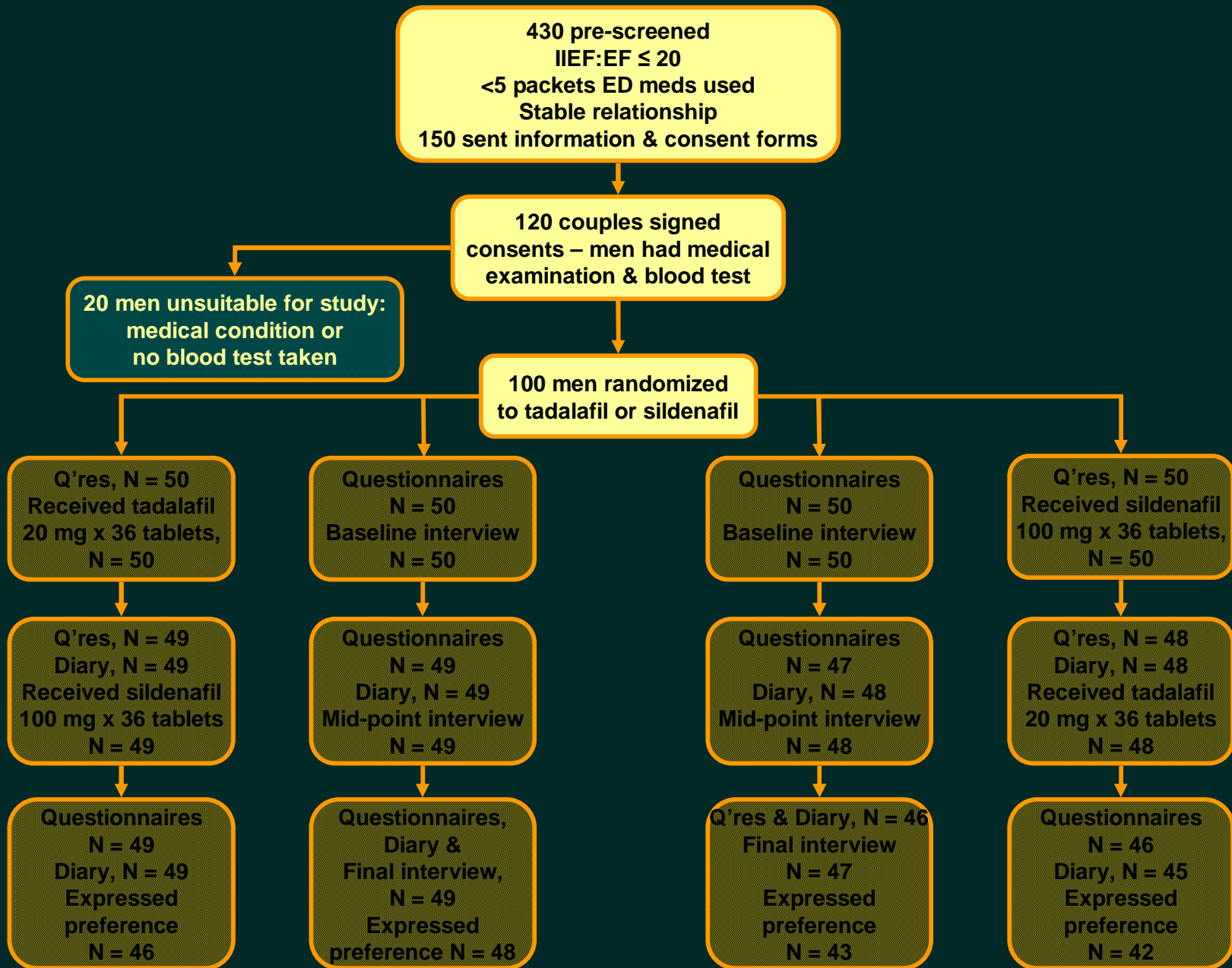
## Study design

- Prospective, repeated measures, open-label cross-over study of sildenafil and tadalafil for the treatment of erectile dysfunction
- Focus on women's preference and experience of the two 12-week medication phases



# Male screening

- Participants relatively naïve to use of PDE5 inhibitors
  - Excluded men who had used >5 packets of study drugs
- Medical screening to ensure appropriateness of therapy using the study medications
- 0800 hr blood draw for males to determine normal levels of testosterone [T] and prolactin [PRL]
  - T reference range 9-30 nmol/L [280-1080 ng/dL]
  - PRL reference range <450 mIU/L
- 3 tablet trial (randomly sildenafil or tadalafil) for those with no previous use of either drug to ensure some response
  - Unethical to involve men with little response in study



# Participants

- 100 heterosexual couples, stable relationships
- Men's ages ranged 40 to 80 years
  - Mean =  $57.1 \pm 8.5$
- Women's ages ranged 33 to 74 years
  - Mean =  $52.7 \pm 8.9$
- Median relationship duration for couples: 25.0 years
  - Range 0.25 – 52.0
- Erection problems for median of 2 years
  - Range 0.25 - 16+
- Women's menstrual status:
  - 24% menstruating, 16% peri-menopausal, 36% menopausal, 21% other (hysterectomy, post-menopausal)

# Male participants PMH

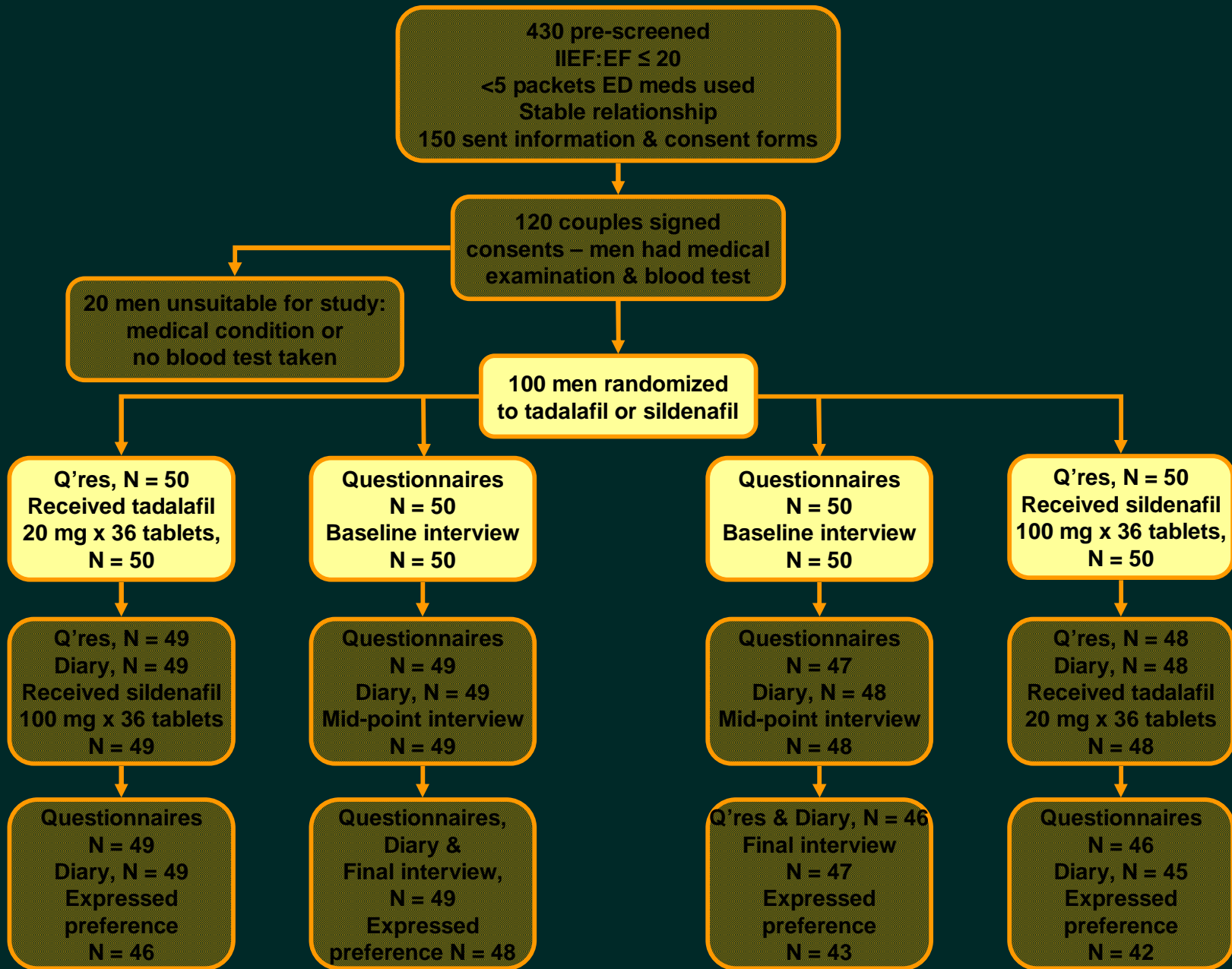
- BMI: range 18.6 - 40.8
  - Normal: 17
  - Overweight: 49
  - Obese: 30
- Diabetes mellitus: 17
  - Type 1 = 2; Type 2 = 15
- Hypertension: 33
- Hyperlipidemia: 23
- Depression: 27

# Methods

- Couples randomised for men to receive either tadalafil or sildenafil for three months then crossover to alternate medication [T–S or S–T]
- Recorded face-to-face interviews of women at baseline, mid-point and end-of-study
- Couples completed baseline, 12 week & 24 week questionnaires
- Sexual events diaries kept by women & partners during both treatment phases

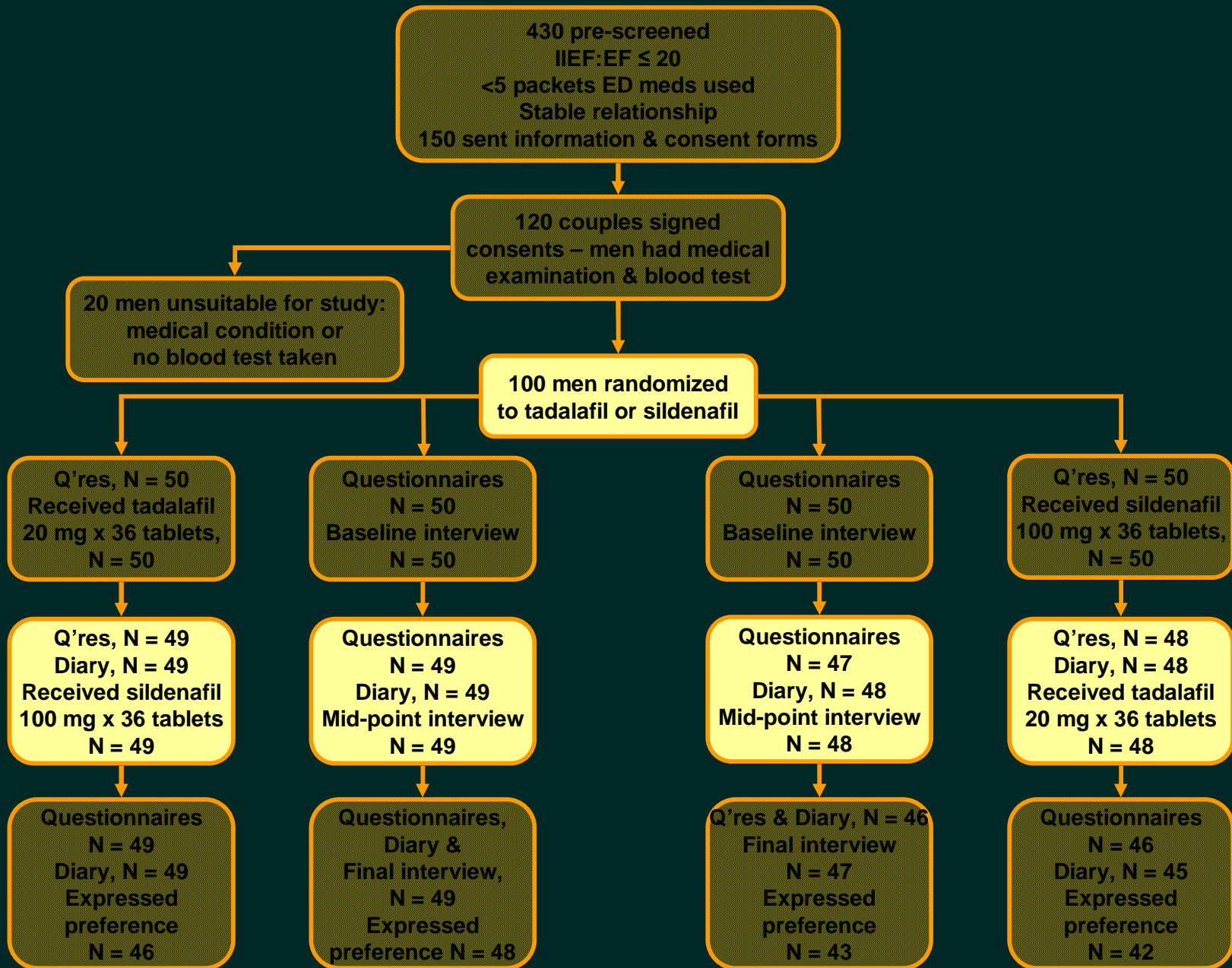
# Methods

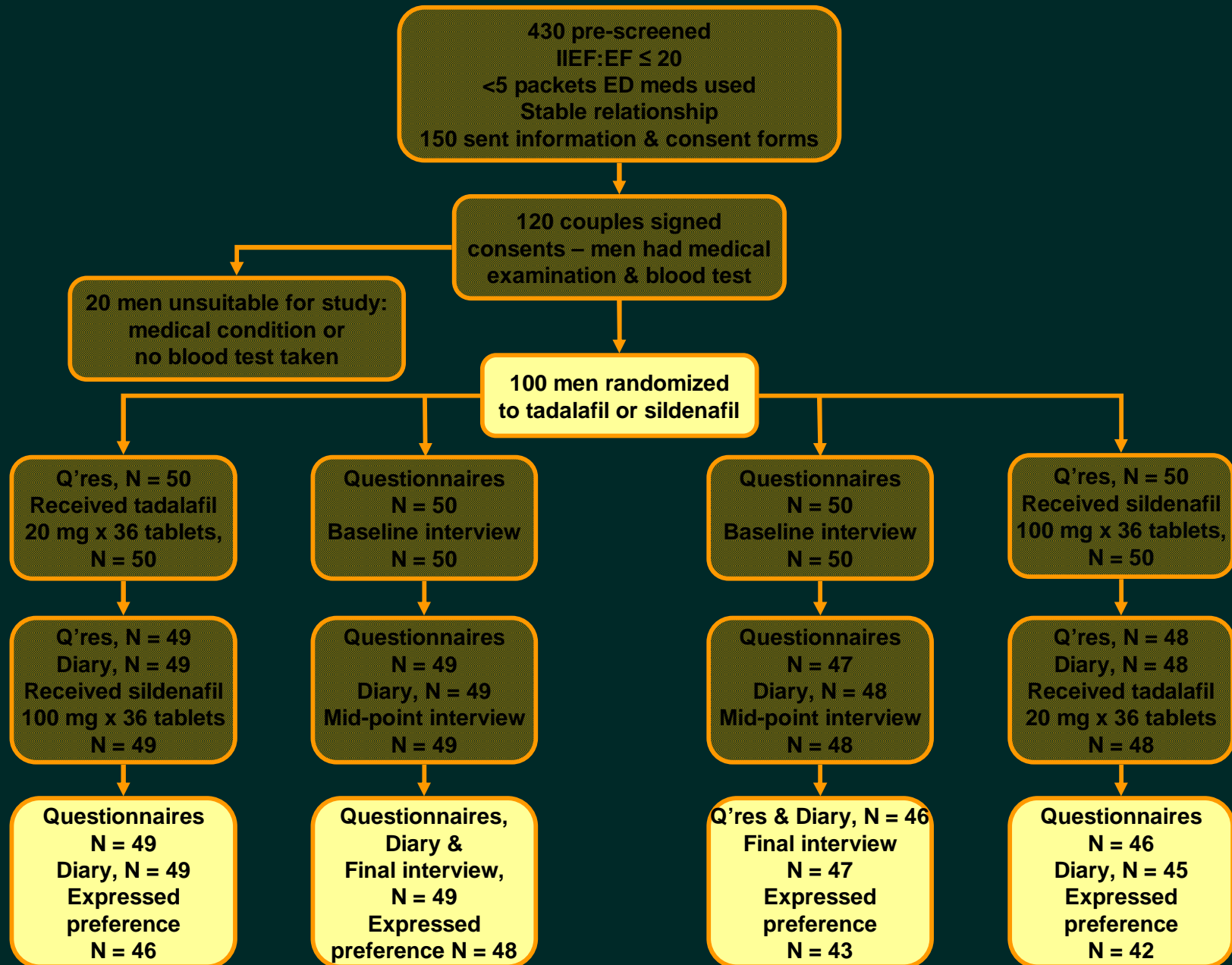
- Couples randomised for men to receive either tadalafil or sildenafil for three months then crossover to alternate medication [T–S or S–T]
- Recorded face-to-face interviews of women at baseline, mid-point and end-of-study
- Couples completed baseline, 12 week & 24 week questionnaires
- Sexual events diaries kept by women & partners during both treatment phases



# Measures

- Female sexual function index [FSFI]
  - Scale measures sexual desire, arousal, lubrication, orgasm, satisfaction, pain, and full scale sexual function
- International index of erectile function [IIEF]
  - Scale measures erectile function [EF], orgasm function [OF], sexual desire [SD], intercourse satisfaction [IS], overall satisfaction [OS] and full scale sexual function





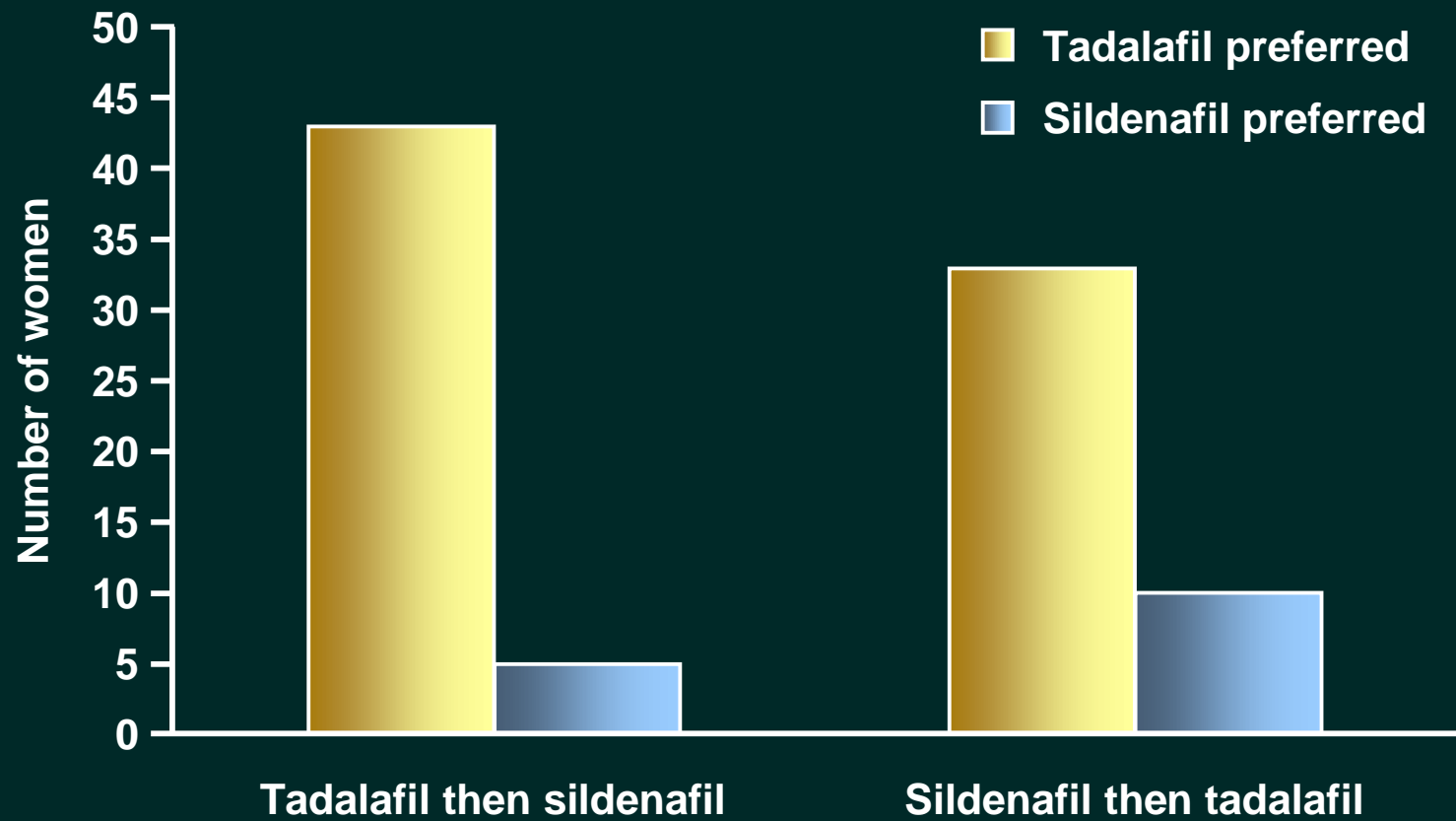
# How preference was determined

- Baseline interview covered
  - Current sexual relationship
  - Nature and development of ED
  - Treatment or adjustment for ED so far
- Mid-point specifically asked for preference between 'drug used during phase 1' and 'no drug'
- End-of-study asked:
  - 'At last interview you preferred drug x over no drug. Now do you prefer drug x or drug y or no drug?'
  - Then: 'What are your reasons for that preference?'
- Responses tabulated under question headings, and specific response patterns reported

# Results: preference expressed

- Women
  - 76 (79.2%) women preferred tadalafil
  - 15 (15.6%) women preferred sildenafil
  - 4 (4.2%) women said either drug OK
  - 1 (1%) woman said neither drug OK
    - 4 withdrawals
- Men
  - 71 (76.3%) preferred tadalafil
  - 17 (18.3%) preferred sildenafil
  - 5 (5.4%) men expressed no preference
    - 3 men no data, 4 withdrawals

# Women's preference by groups



# Reasons for tadalafil preference

- Sex felt more relaxed, less pressure [n=58, 76%]
  - #47 "Don't feel so pressured"
  - #56 "Much more relaxed"
  - #52 "I know he won't get frustrated, so it made me more relaxed, because I know he was enjoying it."
- More satisfaction [n=55, 72%]
  - #21 "Very satisfied. Part of being fulfilled myself is seeing him fulfilled."
  - #86 "Very much at top end...in terms of the atmosphere and other things it's very much better..."
- More natural or spontaneous [n=33, 43%]
  - #55 "Can make love when we want to make love"
  - #23 "Much more natural and spontaneous"

# Reasons for tadalafil preference

- **Drug lasted longer [n=29, 38%]**
  - # 20 "Cialis better because it lasted longer and no pressure. Much more natural."
  - #100 "Better because of a window open - longer time, so it was not 'a waste' if not used."
- **Better communication [n=26, 34%]**
  - #10 "Good. I would usually give him the tablets, I liked being in control of that a bit, instead of waiting for him to surprise me."
  - #16 "Didn't communicate about timing of tablets- preferred it that way."
- **Stress free [n=22, 29%]**
  - #2 "More natural, less stressful"

# Reasons for tadalafil preference

- Increased sexual frequency [n=22, 29%]  
#10 "Much more, 2-3 times per Cialis tablet."
- Increased romance [n=21, 28%]  
#53 "More romantic and sets the mood."
- More flexible, choice of time available [n=13, 17%]  
#77 "Allows second chance if too tired or stressed"
- More effective (harder, fuller, more reliable)  
[n=11, 14%]  
#9 "He is able to hold an erection much longer, the erections are stronger and we are able to have more foreplay."
- Multiple events from one tablet [n=8, 10%]  
#90 "More bang for buck, 2-3 days use"

# Reasons for sildenafil preference

- More effective (harder, fuller, more reliable) [n=13, 87%]
  - #40 "Viagra has been better for us...Cialis not as reliable"
  - #49 "Definitely more intense; good."
  - #67 "It was more instantaneous; it had a stronger effect more quickly."
- More satisfaction [n=6, 40%]
  - #32 "Made him last longer so therefore it was nicer for me."
  - #54 "Enjoyment greater."
- Sex felt more relaxed, less pressure [n=1, 7%]
- Better communication [n=1, 7%]
- Increased sexual frequency [n=1, 7%]

## Other points made

- Many women thought effect of drug on their relationship was much wider than just efficacy in sexual situation [n=48]
- Majority of women thought partners would continue to use ED medication [n=78]
- About 1 in 4 women concerned about cost of medications [n=21]
  - Swedish study suggest most difficult for low income couples [Ströberg et al.,2007]

# FSFI

- Improvements for all women baseline to mid-point of study:

---

Desire	$t(98) = -1.09$	$p = 0.28$
<b>Arousal</b>	<b><math>t(98) = -4.50</math></b>	<b><math>p &lt; 0.001</math></b>
<b>Lubrication</b>	<b><math>t(98) = -3.46</math></b>	<b><math>p &lt; 0.001</math></b>
<b>Orgasm</b>	<b><math>t(98) = -3.96</math></b>	<b><math>p &lt; 0.001</math></b>
<b>Satisfaction</b>	<b><math>t(98) = -6.81</math></b>	<b><math>p &lt; 0.001</math></b>
<b>Pain</b>	<b><math>t(98) = -2.76</math></b>	<b><math>p &lt; 0.01</math></b>
<b>Full scale</b>	<b><math>t(98) = -4.93</math></b>	<b><math>p &lt; 0.001</math></b>

---

# FSFI

- Improvements for all women mid-point to end-of-study:

---

Desire	$t(98) = 0.79$	$p = 0.43$
<b>Arousal</b>	<b><math>t(98) = 2.54</math></b>	<b><math>p &lt; 0.01</math></b>
Lubrication	$t(98) = 0.84$	$p = 0.40$
Orgasm	$t(98) = 1.92$	$p = 0.57$
<b>Satisfaction</b>	<b><math>t(98) = 2.26</math></b>	<b><math>p &lt; 0.05</math></b>
Pain	$t(98) = 0.79$	$p = 0.43$
<b>Full scale</b>	<b><math>t(98) = 2.06</math></b>	<b><math>p &lt; 0.05</math></b>

---

# FSFI

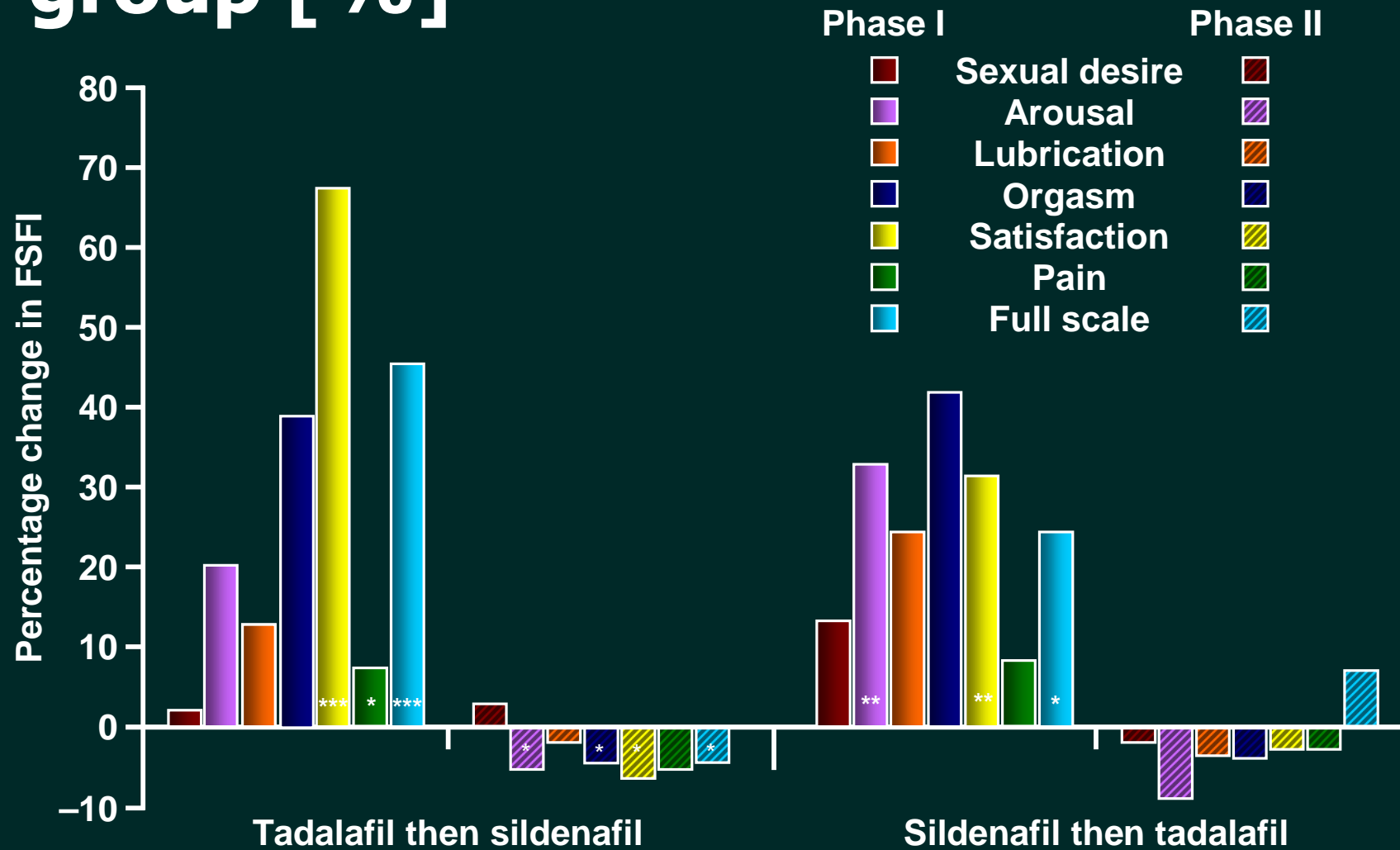
- Improvements for all women baseline to end-of-study:

---

Desire	$t(98) = -0.25$	$p = 0.81$
<b>Arousal</b>	<b><math>t(98) = -2.09</math></b>	<b><math>p &lt; 0.05</math></b>
<b>Lubrication</b>	<b><math>t(98) = -2.75</math></b>	<b><math>p &lt; 0.01</math></b>
<b>Orgasm</b>	<b><math>t(98) = -2.08</math></b>	<b><math>p &lt; 0.05</math></b>
<b>Satisfaction</b>	<b><math>t(98) = -4.93</math></b>	<b><math>p &lt; 0.001</math></b>
<b>Pain</b>	<b><math>t(98) = -2.18</math></b>	<b><math>p &lt; 0.05</math></b>
<b>Full scale</b>	<b><math>t(98) = -3.10</math></b>	<b><math>p &lt; 0.01</math></b>

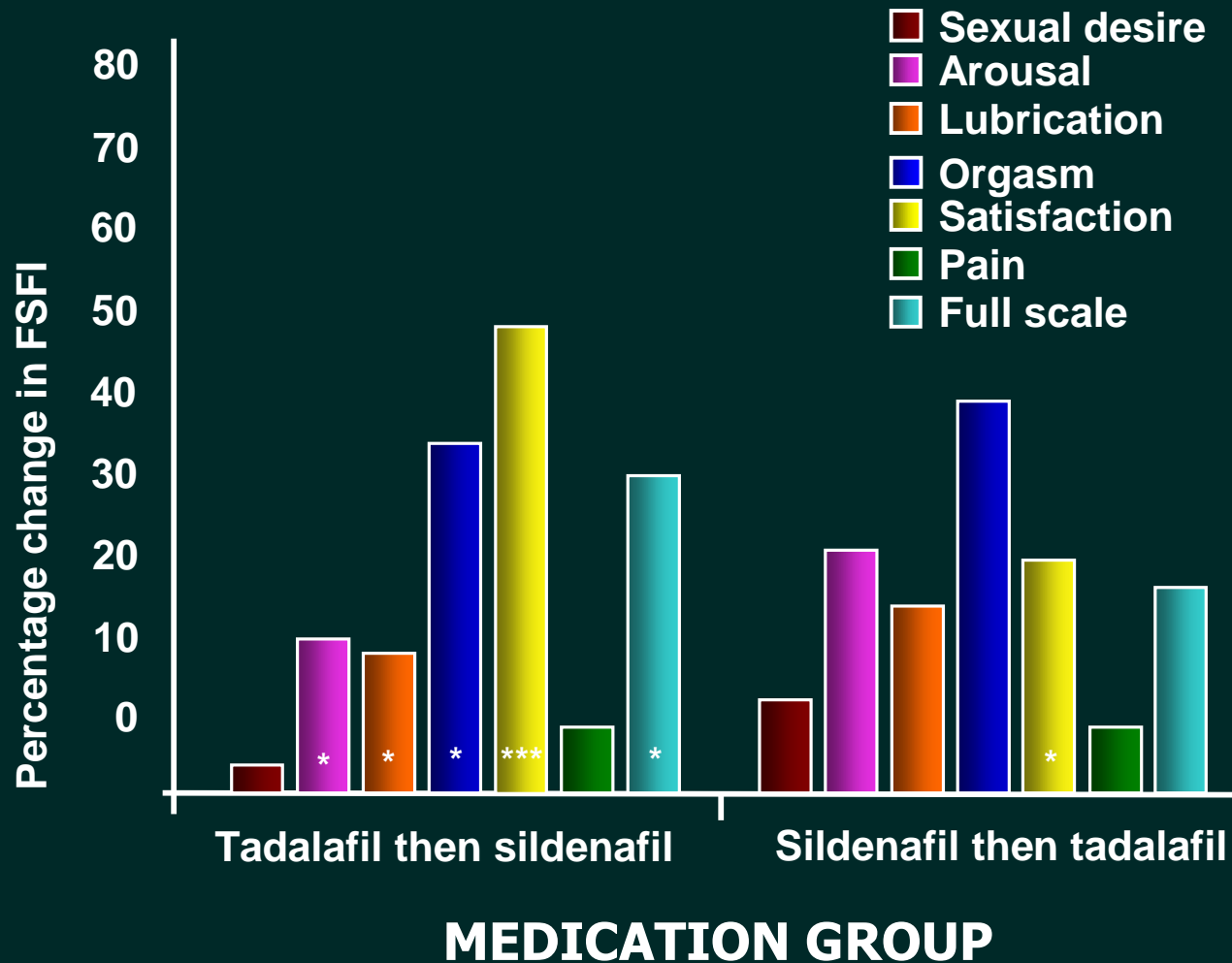
---

# Change in FSFI by medication group [%]



\*  $p < .05$ ; \*\*  $p < .01$ ; \*\*\*  $p < .001$

# Overall % change in FSFI baseline to end of study



\*  $p < .05$ ; \*\*\*  $p < .001$

## Did drug taken make a difference?

- All IIEF sub-scale changes all significant regardless of which drug group men in [T→S or S→T]
- No significant differences in IIEF-EF whilst using specific drugs:
  - Mean EF using tadalafil:  $23.86 \pm 7.27$
  - Mean EF using sildenafil:  $23.53 \pm 6.90$

# Diary records

- Used to calculate tablet use, overall events, events/week, days between events

	Tadalafil	Sildenafil
Average number of tablets used/phase	22.46 ± 9.91	22.46 ± 10.44
Average number of events/phase	33.52 ± 24.25	30.92 ± 24.13
Average number of events/week	2.54 ± 1.83	2.39 ± 1.91
Average number of days between events	4.64 ± 7.59	5.12 ± 4.99

No statistically significant differences

# Does age make a difference?

- Do older people prefer a shorter or longer acting PDE5i?

## Case presentation

- 78 yr old male married for 52 yrs
- Excellent relationship
- Erectile dysfunction for 8 years
- Had sex once a week
- Wants a PDE5i
- Which is their preferred option?  
Viagra or Cialis?

## ED treatments in older couples

- Cut data for older participants
  - Males >64 yrs, n = 23 couples
- Preference – same for women and men
  - 17 (77.3%) preferred tadalafil
  - 5 (21.7%) preferred sildenafil
  - 1 neither
- Significant increases in satisfaction for men and women

# Reasons for preference

- Sex felt more relaxed, less pressure, stress free
  - #36 "More time to relax and do things"
  - #52 "I know he won't get frustrated, so it made me more relaxed, because I know he was enjoying it."
- More satisfaction
  - #13 "I can have satisfaction; I can choose. I didn't have the choice with Viagra."
  - #71 "Gentler, more comfortable, more satisfied"
- More natural or spontaneous
  - #71 "More satisfied; Cialis was gentler, more comfortable, more natural."
  - #96 "Cialis was tamer, milder... more enjoyable sexual activity"
- Drug lasted longer
  - #3 "Harder erections, lasted longer"
- Better communication
  - #94 "More flexible, better communication"

# Younger & older couples compared

	Younger <50 n = 24	Older >64 n = 23	
Months with ED	32.0 ± 31.0	48.5 ± 50.8	<i>ns</i>
Screen EF	9.8 ± 5.9	13.5 ± 5.6	<i>p&lt;.03</i>
Her preference	Cialis: 18 (75%)	Cialis: 17 (74%)	
His preference	Cialis: 17 (77%)	Cialis: 17 (74%)	
No significant differences between treated groups			

## Strengths & limitations

- Community volunteers, not from specialist clinics
- Single centre – less variability
- NZ context similar to USA – DTC advertising
- PDE5i naïve men & partners
- 93% of men responded to PDE5i
- Standardised measures
- Detailed recorded interviews
- Both in relationship wanted to enhance sex lives
  - May not be representative of all couples

## Conclusions

- Women and their partners expressed a clear preference for tadalafil
- Treating the partner's ED had a significant positive effect on the women's sexual function and intimacy
- More research is essential to understand the complex dynamics involved in couple's relationships in the treatment of ED

# Thank you to

- Participants
- Dr Warrick White
  - assisted in development of project
- Gaelle Dutu
  - helped with statistical analysis
- Funding sources:
  - Waikato Clinical School Summer Studentships
  - Investigator Initiated Trial Grant from Eli Lilly to Sexual Research Charitable Trust

# The 5 minute ED assessment

- Define the sexual problem
  - Erectile Dysfunction
  - Early morning erections
- Duration & progression
- Impact on man & partner – relationship issues
- Stressors
  - Performance anxiety, work, partner, etc.
- Review drugs
  - $\beta$  blockers, thiazides, antidepressants etc
- Cardiac disease & nitrates
- Arrange 0800h Testosterone & Prolactin
- Ask to see partner

# Initial Treatment

- PDE5i tablets
  - Need to allow at least 4-5 attempts
- Discuss - mode of action
  - Need for sexual stimulation
  - Side-effects
    - Headaches
    - Flushing
    - Indigestion
    - Nasal stuffiness
  - Nitrates contra-indicated & the heart

## Paper

- Journal of Sexual Medicine, Vol 5 (5), 1198-207. May 2008
- Available online
  - Doi:10.1111/j.1743-6109.2008.00774.x.

Email: [helen@tpc.org.nz](mailto:helen@tpc.org.nz)

# Medical Mandatories

Cialis® is an UNFUNDED PRESCRIPTION MEDICINE, for which charges will apply, for the treatment of erectile dysfunction in men.

Contains tadalafil 10 & 20mg.

Sexual stimulation is required for Cialis to work.

Do not use when taking nitrates for angina or where there is known heart disease like heart failure or heart rhythm disturbances, low or uncontrolled blood pressure, or recent history of stroke.

Use with caution when taking alpha 1 blockers such as doxazosin.

Caution in kidney or liver disease or conditions which predispose to persistent erection of the penis like certain blood disorders.

Not to be used by women.

Possible side effects are headache, dyspepsia, back & muscle pain, rhinitis, flushing and dizziness.

Before prescribing please review full Approved Product Information.

Full PI is available from Elli Lilly.

For further product information check the datasheet on [www.medsafe.govt.nz](http://www.medsafe.govt.nz) or call 0800 36HOURS/364687. Eli Lilly, Auckland. TAPS NA2997