Fostering Resilience to psychosocial and HIV/STI risk among Indian MSM (Multicentric Study)

Indian PI - Beena Thomas (NIRT)

Co-PIs- Vivek Anand, Alpana Dange (Humsafar Trust)
Sunil Menon (Sahodaran)

US PIs- Steven A Safren, Matthew Mimiaga, Conall O’Cleirigh
Co-I- Kenneth Mayer, Katie Biello
Research Team

• **India-based investigators**
  • Beena Thomas, PhD -- *Principal Investigator*, NIRT
  • Soumya Swaminathan, MD -- *Site Co-Principal Investigator*, ICMR/NIRT
  • Alpana Dange, MA, MPH -- *Site Principle Investigator*, The Humsafar Trust
  • Vivek Anand -- Site *Co-Principal Investigator*, The Humsafar Trust
  • Sunil Menon -- *Consultant*, Sahodaran

• **US-based investigators**
  ▪ Steve A. Safren, PhD -- *M. Principal Investigator*, University of Miami
  ▪ Matthew Mimiaga, ScD, MPH -- *M. Principal Investigator*, Brown University
  ▪ Connall O’Cleirigh, PhD -- *M. Principal Investigator*, MGH/HMS/Fenway Health
  ▪ Kenneth H. Mayer, MD -- *Co-Investigator*, BIDMC/HMS/Fenway Health
  ▪ Katie Biello, PhD -- *Co-Investigator*, Brown University/Fenway Health
  ▪ Andres Bedoya, PhD -- *Co-Investigator*, MGH/HMS
MSM in India

• MSM and hijras/aravanis (transgender women or male–to–female transgender persons) have existed in India for thousands of years.

• This is evident in temple carvings in Konark and Khajuraho (950-1050 AD) that depict homosexuality.
MSM in India

- MSM constitute the 3rd largest core group of PLHIV with 2.7% (NACO 2017).
- Historically, MSM in India are disproportionately affected by HIV and STIs varying from state to state- 4.7% Mumbai, 1.02% Chennai (NACO 2017)
- In addition to increased biological susceptibility (probability of HIV transmission 18 times higher than vaginal intercourse) (Grulich AE 2010, Baggley RF 2010) there are various behavioral risk factors that increase sexual risk
MSM in India

• Although consensual same sex acts among two adults were decriminalised in the landmark Supreme Court judgement on section 377 on 6th September 2018, prevailing socio-religious sanction against same sex relationships leads to MSM being a hidden population

• With the high estimates of MSM in India, studies on prevalence, transmission, interventions to address these concerns are of high public health importance
Key Indian research initiatives

- **Mumbai, Humsafar Trust** (2 prior studies)
  - Mental Health Study: Documenting the exceptionally high rates of distress and mental health problems in MSM
  - Married MSM Study: Documenting the social and sexual networks of MSM who are married to women in Mumbai

- **Chennai, NIRT, and Sahodaran** (2 prior studies)
  - Prevalence Study: Documenting the high prevalence of HIV and sexual risk, and the important psychosocial context in which HIV sexual risk occurs
  - Conceptual model and Pilot Intervention Study (next slides): Conducting a three-phased Indo-U.S. sponsored R21 to develop our self-acceptance based model of self care in the context of pervasive stigma and discrimination facing Indian MSM
Significance of current Study

- MSM are a highly marginalized, stigmatized group in India faced with mental health problems and other psychosocial problems.

- 2010 Humsafar Trust study showed high rates of DSM-IV psychiatric disorders:

<table>
<thead>
<tr>
<th>Mental health disorders $n=150$</th>
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<tbody>
<tr>
<td>Major depressive episodes</td>
</tr>
<tr>
<td>Anxiety disorder</td>
</tr>
<tr>
<td>Suicidal ideation</td>
</tr>
<tr>
<td>29%</td>
</tr>
<tr>
<td>24%</td>
</tr>
<tr>
<td>45%</td>
</tr>
</tbody>
</table>

- Major depressive episodes: 29%
- Anxiety disorder: 24%
- Suicidal ideation: 45%
Chennai Study: Behavioral risk factors & HIV sero-prevalence among MSM (N=210)

• 22% reported at least one UA (unprotected anal sex)
• 8% HIV infected
• 26% participated in an HIV program
• 28% indicated 6-10 partners
• 95% did not know the HIV status of partner
• 19% married (2 HIV+)
Predictors of unprotected anal sex

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Odds Ratio (unadjusted)</th>
<th>P-value</th>
<th>Odds Ratio (adjusted)*</th>
<th>P-value</th>
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<tbody>
<tr>
<td>Education (treated as continuous)</td>
<td>0.68</td>
<td>0.02</td>
<td>0.54</td>
<td>0.009</td>
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<tr>
<td>Participation in any HIV Prevention Interventions in the Past Year</td>
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<tr>
<td>Yes</td>
<td>1.00</td>
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<tr>
<td>No</td>
<td>3.60</td>
<td>0.01</td>
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<td>Weekly Alcohol Consumption</td>
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<td>Yes</td>
<td>2.00</td>
<td>0.05</td>
<td>3.56</td>
<td>0.07</td>
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<td>1.00</td>
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<td>Clinically Significant Depressive Symptoms (CES-D)</td>
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<tr>
<td>Yes</td>
<td>1.97</td>
<td>0.05</td>
<td>2.80</td>
<td>0.02</td>
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<td>No</td>
<td>1.00</td>
<td>-----</td>
<td>1.00</td>
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<tr>
<td>Condom Use Self-efficacy (continuous scale)</td>
<td>0.52</td>
<td>&lt;0.0001</td>
<td>0.40</td>
<td>&lt;0.0001</td>
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Beena Thomas, Matthew J. Mimiaga et al - AIDS Education and Prevention, 2009
Findings: Qualitative data

- Internalized homophobia - not able to accept, guilt
- Saturation of messages on HIV testing and condom use
- Problems related to disclosure to family
- Pressure to get married and have children
- Stigma in health care settings
- Multiple partners
HIV prevention message fatigue

Sense of boredom and dissatisfaction with simple HIV risk reduction messages (saturation)

“We know a lot about HIV for the past 10 years. We have had enough programs on HIV and I should take care of my personal risk—how long will NGOs guide us about this especially. I do not think that any more messages on condom prevention are needed. We are fed up of HIV/AIDS messages—we need more.” – A Double Decker

“It is better not to keep concentrating on HIV.... I think it is important to raise the low self-esteem of MSM.” – A Kothi
Findings contd...

- Police harassment, sexual exploitation
- Negotiating condom use (coercion, alcohol)
- Alcohol intake as a defense to tackle fear, to deal with harassment, coercion by partner
- Intervention to address psychosocial issues rather than only HIV/STI and condom use
Self and Social Acceptance

Participants explained that self and social acceptance affected each other:

“Because of all the stigma and discrimination, kothis begin to dislike themselves [and] have low self-esteem and acceptance. ... I feel scared... and so I have a lot of problems.”

“I told [my family] that that I can’t change myself for their sake. Now they have accepted me. ...We have to stand up for our beliefs. We should not change our sexual identity out of fear of being constantly abused by the family.”
Cultural relevance to intervention (triangulation of qualitative findings)

- Lack of self-acceptance
- Condom distribution and education is not enough
- Un-accepting social environment
- Variation in vulnerability by different sexual identities within MSM
- ‘Pressure to marry’
- Power differences among MSM
Feasibility and Acceptability
Randomized Pilot Trial (Indo-U.S. R21)

• **2 Arm** Pilot Randomized Controlled Trial (N=96)
  
  - **Arm 1 (n=48):** Experimental Condition – Building self acceptance and skills to reduce HIV risk
    * with group and individual sessions
    * plus HIV and STI voluntary counseling and testing
  
  - **Arm 2 (n=48):** Comparison Condition
    * HIV and STI voluntary counseling and testing only
Pilot Study of Self-acceptance Intervention

2 year joint NIH and the ICMR Study (S. Safren and B. Thomas)
- Chennai: NIRT and Sahodaran
- 3 stages of study:
  1. Qualitative focus group and key informant interviews to develop an intervention for high-risk Indian MSM
  2. An open field test of the intervention to optimize content and structure
  3. A pilot RCT to assess acceptability and feasibility

Self-acceptance as a key issue in resilience
- Results from these qualitative analyses informed a self-acceptance based model of resilience to both mental health distress
  - MSM who had greater acceptance of themselves had better mental health and HIV sexual risk outcomes
Conceptual Model (from formative work): Self Acceptance can Protect Against the Socio-Cultural Problems Facing Indian MSM

Indian social structure: institution of FAMILY

Gender role: Indian concept of masculinity

Harassment and discrimination

Childhood sexual abuse

Felt stigma

Social expectations: Marriage and children

Lack of family acceptance

Social stigma

Secrecy

Psychological stressors

Sexual risk

Sexual risk

Mental Health and HIV Risk

Self-acceptance

Mimiaga, Thomas, Closson, Mayer, Betancourt, Menon, & Safren, 2014
Results of Pilot Feasibility Trial (Indo-U.S. R21)

• Condomless Anal Sex: Significant condition by time interaction
  – Suggesting a difference in the rate of change in number of UAS acts in the intervention versus the comparison conditions (p<.0001).
  – Mostly due to 3-month time point, versus 6 month

• STI Incidence at 6 month
  – 17.5% intervention group
  – 28.6% treatment as usual
Overarching theme

Self-acceptance as a resilience factor for MSM in India

• Resilience: an individual's tendency to cope with stress and adversity

• Self-acceptance: An affirmation or acceptance of self in spite of adversity, or weaknesses
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Study Design

Month 1
- First Visit: Survey and HIV/STI testing
- Second Visit: Group assignment and HIV/STI test results
  - Arm #2 - Intervention
  - Arm #1 - Standard of Care
  - 10 Counseling Sessions

Month 12
- 4 Month Visit: Survey
- 8 Month Visit: Survey
- 12 Month Visit: Survey and HIV/STI testing
Study Design

• **N = 608** participants across 2 sites

• **Randomized control study**: 2 arms
  – Arm 1: Standard of care
  – Arm 2: Standard of care + Intervention

• **Intervention structure**:
  – 6 individual sessions; 4 group sessions

• **Assessments**: Baseline, 4-, 8-, and 12-month visits

• **HIV / STI testing**: Baseline and 12-month visits only
Eligibility Criteria

- Assigned male at birth and identifies as male
- 18 years of age or older
- Able to complete the informed consent process
- Identifies as sexual minority man (e.g., kothi, double decker)
- Endorses at least one of following risk factors in the past 4 months:
  - anal sex with 4 or more male partners
  - diagnosis of STI
  - transactional sex activity
  - Condom less sex with HIV-unknown or sero-discordant male partner
Study Recruitment

• Recruitment happened on physical cruising sites such as public toilets, bus stops, etc.

• Some participants are referred by past study clients

• Recruiters also use Facebook groups and WhatsApp groups for recruiting

• Very few contacted study on their own via our social media presence
# Study Enrollment

<table>
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<tr>
<th>Enrollment</th>
<th>NIRT</th>
<th>HST</th>
<th>All Sites</th>
</tr>
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<tr>
<td>Screened and Consented</td>
<td>318</td>
<td>313</td>
<td>631</td>
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<tr>
<td>PRE-randomization Retention Excluded by PI, at Baseline‡</td>
<td>0</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Baselines Completed</td>
<td>318</td>
<td>312</td>
<td>630</td>
</tr>
<tr>
<td>PRE-randomization Retention Lost to Retention/Withdrawn/Excluded by PI</td>
<td>15</td>
<td>7</td>
<td>22</td>
</tr>
<tr>
<td>Randomized</td>
<td>304</td>
<td>304</td>
<td>608</td>
</tr>
<tr>
<td>POST-randomization Retention Deceased/Withdrawn/Excluded by PI</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
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</table>
Intervention Design
Intervention Design

• Each group consisted of up to 8 participants

• Two group facilitators (interventionist & peer counsellor)

• Individual sessions up to 60 minutes; Group sessions up to 120 minutes

• Typical flow through Individual & Group sessions
  • Contact 1: Individual (#1)
  • Contact 2: Group (#1)
  • Contact 3: Individual (#2)
  • Contact 4: Group (#2)
  • Contact 5: Individual (#3)
  • Contact 6: Group (#3)
  • Contact 7: Group (#4)
  • Contact 8-10: Individual (#4-#6)
Intervention Design

Individual Session – 6 Sessions (conducted by interventionist)
- Coming out experience & self-acceptance and taking risk
- Ways to reduce sexual risk behaviour and keep within risk limit
- Sexual trigger management
- Relapse prevention

Group Session – 4 Sessions (conducted by interventionist and peer counsellor)
- Barriers to self-acceptance in MSM; Pressures and dealing with pressures from family & society
- Safe ways to meet men; Alcohol & substance use
- HIV education & HIV/STI vulnerability
- Risk reduction skills & looking to the future
Format of intervention

In sexual risk behaviour session, participant played a board game to assess triggers for sexual risk (i.e., specific events, persons, environment, emotions, situations or objectives which prompted risky sexual behaviour which otherwise was unplanned or unintended by them)
Intervention attendance rates
(n=304)

- **Individual Sessions**
  - Range: 0-6
  - Mean (SD): 4.9 (1.8)
  - Median: 6
  - 67% attended all individual sessions

- **Group Sessions**
  - Range: 0-4
  - Mean (SD): 2.5 (1.5)
  - Median: 3
  - 37% attended all group sessions

56% attended more than half of individual AND group sessions

80% attended more than half of individual AND/OR group sessions
## Assessment Visit
### Follow-up Retention

<table>
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<tr>
<th></th>
<th>4MFU</th>
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<th>8MFU</th>
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<tr>
<td></td>
<td># Done</td>
<td>% Done</td>
<td># Done</td>
<td>% Done</td>
<td># Done</td>
<td>Done %</td>
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<tr>
<td>NIRT</td>
<td>257</td>
<td>84.5%</td>
<td>244</td>
<td>80.3%</td>
<td>255</td>
<td>83.9%</td>
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<tr>
<td>Intervention</td>
<td>129</td>
<td>84.3%</td>
<td>122</td>
<td>79.7%</td>
<td>133</td>
<td>87.6%</td>
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<tr>
<td>Control</td>
<td>128</td>
<td>84.8%</td>
<td>122</td>
<td>80.8%</td>
<td>122</td>
<td>80.3%</td>
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<tr>
<td>HST</td>
<td>253</td>
<td>83.2%</td>
<td>239</td>
<td>78.6%</td>
<td>260</td>
<td>85.5%</td>
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<tr>
<td>Intervention</td>
<td>126</td>
<td>82.9%</td>
<td>123</td>
<td>80.9%</td>
<td>134</td>
<td>88.2%</td>
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<tr>
<td>Control</td>
<td>127</td>
<td>83.6%</td>
<td>116</td>
<td>76.3%</td>
<td>126</td>
<td>82.9%</td>
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<tr>
<td>BOTH</td>
<td>510</td>
<td>83.9%</td>
<td>483</td>
<td>79.4%</td>
<td>515</td>
<td>84.7%</td>
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<tr>
<td>Intervention</td>
<td>255</td>
<td>83.6%</td>
<td>245</td>
<td>80.3%</td>
<td>267</td>
<td>87.9%</td>
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<tr>
<td>Control</td>
<td>255</td>
<td>84.2%</td>
<td>238</td>
<td>78.5%</td>
<td>248</td>
<td>81.6%</td>
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Participant Baseline Characteristics
## Demographics factors

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<tr>
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<th>Total (n=608)</th>
<th>Mumbai (n=304)</th>
<th>Chennai (n=304)</th>
<th>p-value</th>
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<tr>
<td><strong>Mean (SD)</strong></td>
<td></td>
<td></td>
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<tr>
<td>Age, in years</td>
<td>26.2 (6.3)</td>
<td>25.5 (5.6)</td>
<td>27.1 (6.8)</td>
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<tr>
<td>Monthly Income, per 1000 Rupees</td>
<td>8.3 (9.4)</td>
<td>10.6 (0.6)</td>
<td>7.9 (0.5)</td>
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</tr>
<tr>
<td><strong>%</strong></td>
<td></td>
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<td>MSM Subpopulation Identity</td>
<td></td>
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<tr>
<td>Kothi</td>
<td>44.5</td>
<td>17.8</td>
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<td>Double Decker</td>
<td>33.3</td>
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<td>Gay</td>
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<td>Religion</td>
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<td>Hindu</td>
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<td>4.8</td>
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<td>Education</td>
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<td>Graduate or Professional Degree</td>
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<td>8.6</td>
<td>19.7</td>
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<td>Higher Secondary</td>
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<td>15.5</td>
<td></td>
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<tr>
<td>Primary</td>
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<td>3.0</td>
<td>4.3</td>
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<tr>
<td>No Formal Education</td>
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<td>1.6</td>
<td>1.3</td>
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<tr>
<td>Employment Status</td>
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<td>Fulltime</td>
<td>48.4</td>
<td>59.9</td>
<td>36.8</td>
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<tr>
<td>Other</td>
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<td>13.2</td>
<td>1.0</td>
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# Psychosocial factors

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<th>p-value</th>
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<tr>
<td></td>
<td>(n=608)</td>
<td>(n=304)</td>
<td>(n=304)</td>
<td></td>
</tr>
<tr>
<td><strong>Mean (SD)</strong></td>
<td>**</td>
<td>**</td>
<td>**</td>
<td>**</td>
</tr>
<tr>
<td><strong>Self Acceptance Score (range 1-10)</strong></td>
<td>8.4 (2.0)</td>
<td>8.6 (1.9)</td>
<td>8.3 (2.1)</td>
<td>0.078</td>
</tr>
<tr>
<td><strong>Self-Esteem (range 10-40)</strong></td>
<td>31.4 (4.8)</td>
<td>32.8 (4.9)</td>
<td>30.0 (4.3)</td>
<td>&lt;.0001</td>
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<td><strong>Internalized Homophobia (range 0-36)</strong></td>
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<td>11.9 (9.3)</td>
<td>8.7 (8.2)</td>
<td>&lt;0.0001</td>
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<tr>
<td><strong>Depression: CESD-10 score (range 0-30)</strong></td>
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<td>10.3 (6.1)</td>
<td>11.2 (6.8)</td>
<td>0.075</td>
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<td><strong>Alcohol use: AUDIT score (range 0-40)</strong></td>
<td>2.3 (4.2)</td>
<td>2.7 (4.4)</td>
<td>1.9 (4.1)</td>
<td>0.015</td>
</tr>
</tbody>
</table>

- CESD - score of 10 or higher indicates significant depressive symptoms  
  – 56% of sample

- AUDIT – score of 8 or higher suggests harmful drinking  
  – 11% of sample
Sexual risk factors

<table>
<thead>
<tr>
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<th>Total (n=608)</th>
<th>Chennai (n=304)</th>
<th>Mumbai (n=304)</th>
<th>p-value</th>
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<tbody>
<tr>
<td><strong>Mean (SD)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Number of male partners, past month</strong></td>
<td>11.9 (46.3)</td>
<td>18.4 (64.5)</td>
<td>5.5 (7.8)</td>
<td>0.001</td>
</tr>
<tr>
<td><strong>Number of times condom less anal sex with male partners, past month</strong></td>
<td>8.1 (18.3)</td>
<td>14.0 (24.2)</td>
<td>2.2 (3.7)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>%</td>
<td></td>
<td></td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Engagement in Transactional Sex, Past 4 Months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>61.7</td>
<td>91.8</td>
<td>31.6</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>38.3</td>
<td>8.2</td>
<td>68.4</td>
<td></td>
</tr>
<tr>
<td>Participation in any HIV Prevention Interventions, Past Year</td>
<td></td>
<td></td>
<td></td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Yes</td>
<td>51.3</td>
<td>8.3</td>
<td>94.4</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>48.7</td>
<td>91.7</td>
<td>5.6</td>
<td></td>
</tr>
</tbody>
</table>
## Baseline STIs

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Prevalence Ratio** (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Overall N=608</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHL</td>
<td>88</td>
<td>1.62 (1.09-2.41)</td>
</tr>
<tr>
<td>(14.7, 11.9-17.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GON</td>
<td>73</td>
<td>1.93 (1.23-3.05)</td>
</tr>
<tr>
<td>(12.1, 9.5-14.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SYP</td>
<td>94</td>
<td>0.92 (0.63-1.33)</td>
</tr>
<tr>
<td>(15.5, 12.6-18.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ANY BAC</strong></td>
<td>199</td>
<td>1.37 (1.09-1.73)</td>
</tr>
<tr>
<td>(32.7, 29.0-36.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV†</td>
<td>58</td>
<td>1.64 (0.99-2.71)</td>
</tr>
<tr>
<td>(9.5, 7.2-11.9)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CHL = Chlamydia; GON = Gonorrhea; SYP = Syphilis; CAS=Condomles anal sex
x Presence of 1 or more sexually transmitted bacterial infections
** Estimated using Poisson regression, log link, robust variance
Summary of baseline

• Average age of respondents across sites <30yrs

• Differences in sexual identity across sites: Kothis (C:71% vs M: 17%), DDs-(C:27% vs M: 39%) Gay (C:0.7% vs M:41%)

• Higher education profile found in Chennai as compared to Mumbai (p<0.0001)

• Depression scores (56%) in both sites

• Some exposure to HIV programme in Mumbai (94%) vs (8%) in Chennai
Summary of Sexual history

- More transactional sex reported in Chennai (91%) vs Mumbai (31%) p<0.0001

- Higher number of Male partners in Chennai as compared to Mumbai in the past 4 months

- Condom less Anal Sex (CAS) higher in Chennai
Prevalence of HIV/STI

- Overall HIV: >9% in both sites
- Overall STI: >30%
- Never tested for STI: >90%
- Mumbai had a greater prevalence of any STI than Chennai but lesser CAS
Study endpoints

- Primary: STI incidence and condomless anal sex
- Secondary: psychosocial mediators
- Cost effectiveness of the intervention
Take home messages so far...

- Continued high prevalence rates of (untreated) STI and condom less sex among MSM (19% (2009) to >30% (2020))

- Need for STI testing and treatment to be expanded to include gonorrhea, chlamydia and not restricted to syphilis

- HIV prevalence continues to be high? Have the unreached been reached?

- Non participation in HIV prevention interventions continues to be a challenge

- Need to be cautious of socially desirable responses in eliciting sexual history
Take home messages so far...

• MSM continue to present with sexual and psychological issues – depression, stigma, number of male partners, transactional sex which could influence CAS

• Incorporating mental health interventions with biomedical interventions to address depression, stigma, self acceptance

• We will be able to present a model psychosocial intervention programme once the study analysis is complete
The Fostering Resilience Team