

Intervening to increase adherence among HIV+ patients in Northern India

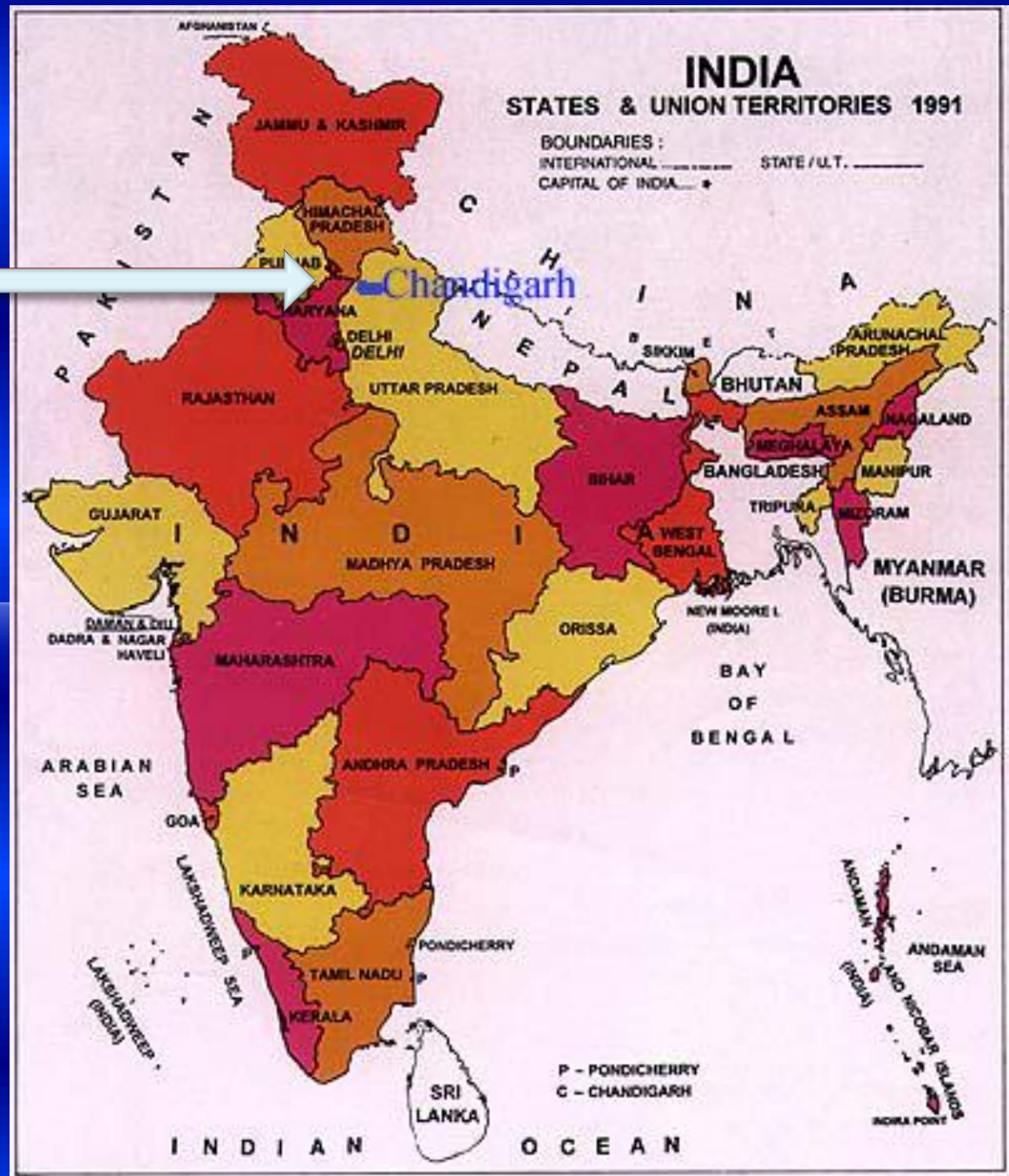


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Chandigarh, India



Background & Significance

INDIA

- Population of nearly 2 billion (WHO, 2007)
- Third largest HIV/AIDS population worldwide, estimated at 2.4 million persons (UNAIDS, 2012)
 - Estimated HIV/AIDS incidence of 0.3% (CDC, 2012)
- HIV is primarily HIV Clade C
- No-cost first-line antiretroviral therapy (ART) provided by the government of India since 2004
 - Decentralized distribution now available
- Only an estimated 158,000 people are receiving ART in India (UNAIDS/WHO, 2008).

Limitations to Health Care Delivery & Access

- Subsidized medication programs have been “partially decentralized”
 - Expand availability of medication to a wider catchment area
 - Provision of HIV services at secondary-level Community Health Centers
 - Reduce reliance on district hospitals as primary providers of HIV care and ART medications

Patients may be required to travel long distances to district hospitals for their monthly ART supply

Family involvement limited by geographical isolation & cost of travel to obtain medications



Geographical limitations reduce access to adequate care and potential for non-adherence

- Especially problematic for symptomatic patients with limited mobility (with lack of support and resources for travel)

Limitations to Accurate Assessment of Adherence

- Provider Assessment of Adherence
 - Patient self-report
 - Clinic visit attendance, pharmacy fill records
- Provider Assessment of Treatment Efficacy
 - Limited funding for viral load assessment
 - Occurrence of Opportunistic Infections
- Patient self-report
 - Often unreliable
 - May be contradicted by objective measures of adherence (pill count, MEMS)
 - May contradict physician estimate, which may be no better than chance

Pilot Study Aims: Jivan Joti

- Assess barriers and facilitators associated with HIV treatment adherence
- Compare the impact of a group-based intervention designed to enhance adherence with an individual enhanced standard of care
- Compare the impact of an immediate-onset vs. delayed-onset group intervention



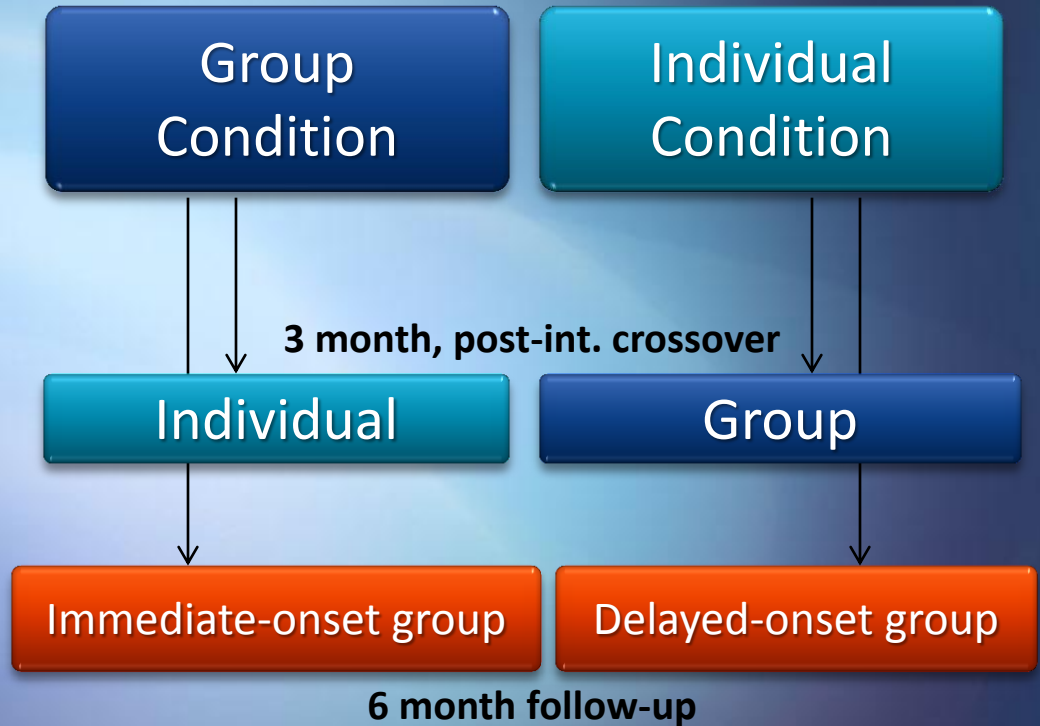
Design

Group Intervention

- Regular provider visits
- 3 monthly facilitator-led 1-hour group sessions
- Content: adherence assessment, information on HIV, ARVs, adherence, communication with providers, HIV-related coping and social support
- n=10 per group

Enhanced Standard of Care

- Regular provider visits
- 3 monthly time-matched individual sessions with study staff
- Content: adherence assessment, HIV-educational videos on healthy living (e.g., nutrition, exercise, relaxation)



Assessments

- **Adherence** was assessed monthly by assessor pill count, pharmacy fill record and current self-reported adherence and skipped doses
- **Barriers & facilitators to adherence** assessed at baseline, 3 & 6 months post baseline.

Design: Methods

- Study & recruitment site : Post Graduate Institute for Medical Education & Research (PGIMER) Immunodeficiency Clinic
- Focus groups & Key informant interviews conducted
- Manualized intervention & assessments adapted to Indian context by team (McPherson-Baker et al., 2001)
- Participants randomized to immediate vs. delayed start of group condition and crossed over to alternate condition after 3 months
- Participants (N = 80)
 - HIV seropositive, male and female (groups were mixed gender)
 - 18 years of age or older (no literacy exclusion)
 - New to ARV use (3 to 12 months of ARV use; no previous NVP use)

Results: Baseline

Demographics

- Mean age = 38.1 ± 8.6 years
- 50% reported at ≤ 9 years of education
- Majority had a monthly income $\leq 3,000$ INR (Indian Rupees \sim \$US75)
- 62% lived in rural area
- 78% married
- 49% had HIV+ spouse
- Mean time since HIV diagnosis = 18.2 ± 24.6 months
- Mean time on ARVs = 6.9 ± 3.0 months
- Males = 70%

Results: Adherence Baseline

- Self report 4 day adherence = 99% were 100% adherent
- Self report past skipped doses in last 3 months = 23% of group and 26% of individual condition participants
- Pill count = More than half of participants were non-adherent (56% group, 54% individual)
 - **Pill count adherence = ± 4 pills of accurate doses by pill count**
- Pill count and self-reported adherence (4 day & skipped doses) were not associated ($r = -0.16$, $p = .15$)
- Time on ARVs ($r = .16$, $p = .17$), distance from clinic ($r = -0.07$, $p = .54$), income ($r = 0.06$, $p = .73$), and having an HIV positive spouse ($\chi^2 = .45$, $p = .51$) were not associated with pill count adherence

Adherence and Psychosocial and Biological Correlates

- Patient-provider communication: change from baseline to follow-up
 - Associated with pill count adherence ($\chi^2 = 4.7$, $p = .04$)
- Self-reported missed doses: changes from baseline to follow-up
 - Associated with change in beliefs about medication ($\chi^2 = 5.1$, $p = .004$)
 - Associated with change in commitment to adherence (Fisher's Exact test, $p = .004$)
 - Associated with change in social support (Fisher's Exact test, $p = .009$)
- Viral load was not associated with adherence ($r = .05$, $p = .63$)
 - Only 25% of participants had detectable viral load (>50 copies)
 - Only 5% had viral load $\geq 1,000$ copies

Results: Longitudinal

- Mid-point - post-intervention

- Mean adherence improved in both conditions
- Pill count adherence did not differ between conditions ($\chi^2 = .07$, $p = .79$)

- Follow-up - six month post-baseline

- Adherence in the immediate onset group condition continued to improve ($\chi^2 = 5.67$, $p = .02$)
- Adherence in the enhanced standard of care delayed group onset participants did not maintain gains from midpoint

- Baseline – six month post-baseline

- Adherence in both conditions improved
- Similar numbers of participants improved in both conditions
- Self-reported missed doses did not improve in either condition

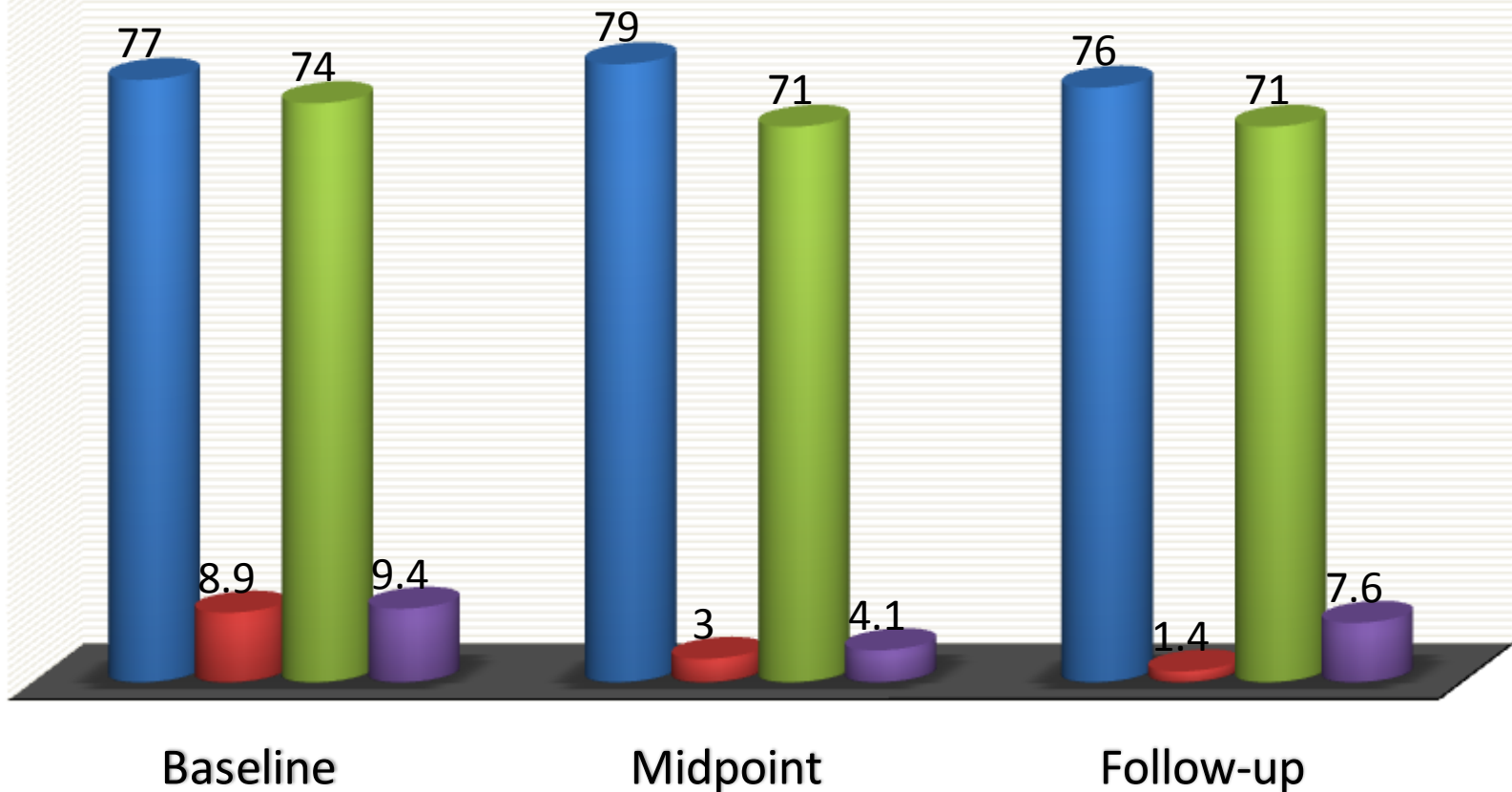
Longitudinal Adherence

Percent Self-Reported (No skipping)
Group

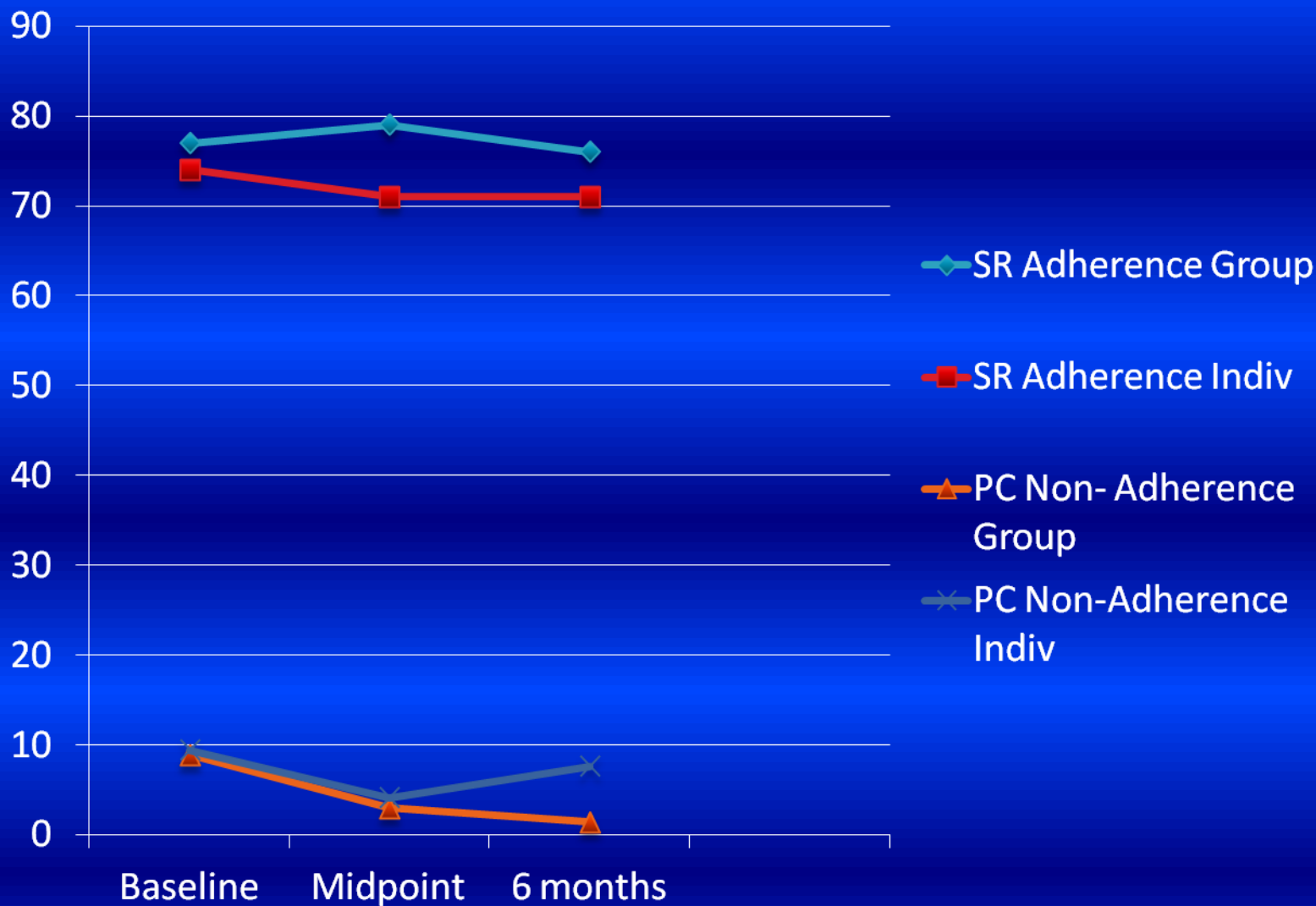
Percent Self-Reported (No Skipping)
Individual

Mean Non-Adh. (pill count) Group

Mean Non-Adh. (pill count) Individual



Longitudinal Level of Adherence



Conclusions

- Patient-provider communication
- Commitment to adherence
- Social functioning
- Social support
- Reduced perceived barriers to medication adherence



Long-term
Adherence

Impact of an immediate versus delayed onset intervention

- Results support the establishment of adherence behaviors early in the use of ARVs
 - The immediate onset group showed improvement over the course of the study, in comparison with the delayed onset group
 - Participants in the individual enhanced SOC condition showed improved adherence but did not maintain gains long-term

*Counting pills may have influenced adherence behavior in the short-term

Conclusions

- Majority of participants were adherent by self-report and pill count
 - High levels of adherence among public hospital patients
- Lack of association between measures of adherence
 - Participants may provide investigators or providers with desirable responses regarding adherence or treatment compliance

Adherence not associated with:

- *Length of time on medication*
 - Contrary to previous studies reporting that less than 24 months of medication use is associated with adherence (Venkatesh, 2010)
- *Spousal Sero-status*
 - Half had a spouse/primary partner living with HIV
- *Travel distance from health clinics or monthly income*
 - More than half of the sample lived in a rural setting and almost all reported very low income

Challenges and Limitations

- Sample size and Cross-over design
 - Small sample precluded the assessment of longer term outcomes or subsamples within conditions
 - Overall adherence scores may have been impacted by a small number of non-adherent participants
 - Future studies should target recruitment of low-adhering participants
- Lack of reliable CD4 and viral load data
 - The importance of accurate and reliable biological assessment should be addressed in resource limited settings
- Limited variability between conditions in pill count adherence values
 - The majority of participants were adherent, which limited variability and statistical analyses

Conclusions and Implications

- Resource limited settings rely on patient self report or provider intuition/evaluation
 - Results support the implementation of interventions enhancing patient-provider communication and accurate assessment of adherence
 - Rapid pill count and calculation may be a useful adjunct for accurate adherence appraisal in the clinical setting
 - Results support the cost effective utility of a group intervention
 - Need for continued exploration of the impact of peer support on adherence and treatment engagement
- The need for targeted interventions for non-adhering patients cannot be over-emphasized
 - Long term adherence may require an early intervention strategy
 - Communication and problem solving strategies may be a key component for successful adherence to “lifelong” medication