8th International Conference on HIV TREATMENT AND PREVENTION ADHERENCE

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Pilot Controlled Trial of the Adherence Readiness Program

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Background

- Premium on patients being ready to adhere well at start of treatment
  - Initial learning re. pill taking is more resistant to change
  - Limit the development of adherence problems down the road
  - Limit the need for increasingly limited resources to support adherence
  - Increased risk of greater resistance pool in community (treatment as prevention; starting ART ASAP)

Background

- There are no established methods for determining adherence readiness prior to a patient starting ART
  - Providers cannot accurately predict
  - Self-report measures not accurate enough to inform decisions to prescribe or defer treatment
- Safest approach is to provide adherence training to all patients starting treatment
  - But need to tailor amount to individual needs of the patient, so that training is more effective and conserves limited resources

Adherence Readiness Program

- Based on IMB model of health behavior
- Pre-treatment: up to 4 one-week practice trials that mimic ART plus counseling to **determine readiness**
  - 85+% adherence needed in a single PT to start ART
- Early treatment: Adherence counseling to **sustain readiness**
  - Weeks 2 and 4 after start of ART
  - Education about importance of adherence
  - Problem solving to overcome barriers
  - Enhance social support for adherence
  - Use of MI to address negative attitudes
  - Tailor regimen to daily routine
  - Side effect management
- Maintenance: Periodic check-ins (Weeks 8 and 16) with added biweekly counseling support as needed (tailoring)

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Study Design

- Study setting: CARE Clinic in Long Beach, CA
- Eligibility criteria
  - Starting or restarting ART (at least 2 months off)
  - Detectable viral load
- Primary assessments at Week 8 (post core training sessions) and Week 24 (post maintenance)
- Primary outcomes:
  - Undetectable HIV viral load
  - MEMS adherence
    - Dose-taking (% prescribed dose taken)
    - Dose-timing (% prescribed doses taken on time)
    - 85% used as cutoff for "optimal" adherence

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Study Design

- 60 participants randomized (29 ARP; 31 usual care)
  - 54 started ART (24 ARP; 30 usual care)
- ITT analysis included only those starting ART
  - 5/6 non-starters had indicators of non-readiness
  - 11/54 dropped out prior to Week 24 (4 ARP; 7 UC)
- Interpretation of intervention effects focused on:
  - Effect size estimates
  - Clinical meaningfulness (10% difference for continuous; 15% difference for group proportions)
  - Not statistical significance (due to low power)

Sample Characteristics

	Total (N=54)	ARP (N=24)	Control (N=30)
Mean Age	38.6	39.2	38.2
Male	94%	96%	93%
Some college education	52%	63%	43%
Non-white	70%	71%	70%
Employed	26%	17%	33%
Frequent substance use	52%	33%	67%
Mean CD4 count	306	283	325
ART naive	70%	67%	73%
Once-a-day dosing	82%	82%	83%

Intervention Effects at Week 8

	ARP	Usual Care	p	Effect Size
Mean doses-taking adherence %	89.4	83.4	.21	.41
Optimal (85+%) dose-taking adherence	75.0%	56.7%	.27	.39
Mean dose-timing Adherence %	78.3	70.7	.20	.39
Optimal (85+%) dose-timing adherence	45.8%	23.3%	.09	.50

Intervention Effects at Week 24

	ARP	Usual Care	p	Effect Size
Mean doses-taking adherence %	88.8	83.0	.20	.40
Optimal (85+%) dose-taking adherence	54.2%	43.3%	.58	.22
Mean dose-timing adherence %	81.0	67.0	.04	.67
Optimal (85+%) dose-timing adherence	50.0%	16.7%	.02	.75
Undetectable HIV viral load	62.5%	43.3%	.18	.41

Adherence and Viral Load at Week 24

	Detectable	Undetectable	p
Mean doses-taking adherence %	86.6	83.9	.56
Optimal (85+%) dose-taking adherence	60.7%	60.0%	.99
Mean dose-timing Adherence %	76.6	67.8	.21
Optimal (85+%) dose-timing adherence	50.0%	20.0%	.10

Summary

- Our findings revealed mostly medium to large effect sizes on pill taking adherence
  - Strong effects on dose-timing adherence (d = .40 - .75)
  - More modest effects on dose-taking adherence (d = .22 - 40)
- A clinically meaningful effect (and medium effect size) of the intervention on undetectable viral load
- Observed effect sizes compare favorably to the average effect size (d=.19) found in the meta-analysis by Amico et al. of HIV adherence interventions like ARP that do NOT first screen for adherence problems

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Summary

- Dose-timing adherence was more closely related to complete viral suppression compared to dose-taking adherence
  - Dose-timing is a more precise measure (of which dose-taking is a subcomponent)
  - Few studies focus on dose-timing adherence, though some (Gill et al., 2010) have shown similar results

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Limitations

- Intervention administered by clinicôs adherence counselor
  - Generalizability
  - Contamination risk (conservative estimate)
- Small sample size and limited power
  - Findings are only preliminary
  - Unable to examine potential confounders among variables that differentiated the groups

Conclusions

- Findings provide support for promising effects of ARP on both adherence and viral suppression
- Evaluation in larger RCT is warranted, buté
  - Need to strengthen effects on dose-taking adherence
  - Strengthen durability of effects
- Need for greater emphasis on dose-timing adherence in ART adherence research

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