Couple-focused support for improving HIV medication adherence

CITATION

RESEARCH QUESTION
Does couple-focused support improve HIV medication adherence among patients with poor adherence?

THE STUDY DESIGN
Randomized controlled trial

STUDY SETTING
Two HIV/AIDS outpatient treatments clinics of St Luke’s Roosevelt Hospital Center in New York City August 2000 – January 2004
Approved by the Institutional Review Boards of the New York State Psychiatric Institute and St Luke’s-Roosevelt Hospital Center.
Written informed consent was obtained.

PARTICIPANTS
Included: HIV-serodiscordant couple with a relationship duration of 6 months or more; partners were English-speaking adults (> 18 years of age); HIV-seropositive partner needed to be in primary care, taking ART for at least 1 month and had a baseline adherence level of < 80% of prescribed doses taken within specified time windows
Excluded: No mention of it was made

INTERVENTIONS
**Intervention Group:** A four-session couple-focused adherence program. The intervention was individually administered to each couple by a nurse practitioner through four 45-60 min sessions held over 5 weeks. Intervention consisted of education about treatment and adherence, identifying adherence barriers, developing communication and problem-solving strategies, optimising partner support, and building confidence for optimal adherence

**Control:** Usual care through the medical provider of the HIV-seropositive partner

Patients were followed up to 6 months after the intervention. Assessments took place 8 weeks after baseline, week 20 (3 months) and week 32 (6 months).

OUTCOME
**Primary:** Medication adherence
**Secondary:** Viral load, CD4 cell counts

RISK OF BIAS
(Risk Scale: Low – Moderate – High)

SELECTION BIAS: Low - Moderate
Couples were randomly assigned. A randomisation table was constructed from a random numbers list and stratified by couple type. Allocation concealment not reported. There were no significant differences between the two study arms on socio-demographic variables (Raw data not provided). The only exception was that HIV-seropositive participants in the control arm reported a significantly higher annual income that those in the intervention arm.
PERFORMANCE BIAS: Moderate
(*i.e what else happened that may have affected the result?)
Participants were unblind. Assessors and all other personnel (except for intervention facilitators) were blind to study arm assignment throughout the trial. Participants in the intervention group received additional payment for each intervention session.

DETECTION BIAS: Low - Moderate
Participants were unblind. Assessors and all other personnel (except for intervention facilitators) were blind to study arm assignment throughout the trial. Adherence was measured using the MEMS cap. Viral load and CD4 cell counts were measured. ACASI and CAPI were also used. Interviewers were trained and certified by the study team.

ATTRITION BIAS: Low

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Started</td>
<td>106</td>
<td>109</td>
</tr>
<tr>
<td>Completed trial</td>
<td>88</td>
<td>94</td>
</tr>
<tr>
<td>Loss to follow-up</td>
<td>18 (17.0%)</td>
<td>15 (13.8%)</td>
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</tbody>
</table>

All analyses were conducted according to the intention to treat.

STUDY FINDINGS
Out of 1014 pre-screened 215 randomised.

Medication Adherence

<table>
<thead>
<tr>
<th>Time line</th>
<th>Treatment</th>
<th>Total Doses</th>
<th>Doses taken within specified time windows</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mean adherence (% prescribed doses taken (SD))</td>
<td>Weighted mean difference (95% CI)</td>
</tr>
<tr>
<td>Baseline</td>
<td>I</td>
<td>75 (25)</td>
<td>3 (-3.8; 9.8)</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>72 (26)</td>
<td></td>
</tr>
<tr>
<td>8 week</td>
<td>I</td>
<td>76 (27)</td>
<td>16 (7.8; 24.2)</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>60 (34)</td>
<td></td>
</tr>
<tr>
<td>3 month</td>
<td>I</td>
<td>73 (28)</td>
<td>7 (-1.0; 15.0)</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>66 (32)</td>
<td></td>
</tr>
<tr>
<td>6 month</td>
<td>I</td>
<td>66 (28)</td>
<td>0 (-7.8; 7.8)</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>66 (30)</td>
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</table>

Viral load
As reported, Although viral load in the control group increased by an average of 12000 copies/ml and stayed relatively stable in the intervention group, the difference was not significant.

CD4 count
Reportedly, CD4 cell counts fell slightly for both groups.

ADVERSE EVENTS
No serious adverse events were identified.

COMMENTS
The SMART Couples program did improve medication adherence over usual care. However, the level of improved adherence for many participants was still sub optimal and the effect was attenuated over time.

Prepared by: Karishma Busgeeth
E-mail: Karishma.Busgeeth@mrc.ac.za
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