SHARING MEDICAL ADHERENCE RESPONSIBILITIES TOGETHER (SMART COUPLES)

Good Evidence – Medication Adherence

INTERVENTION DESCRIPTION

Target Population
- Heterosexual and homosexual HIV-serodiscordant couples, with poor medication adherence in the HIV-positive partner

Goals of Intervention
- Improve adherence to antiretroviral therapy
- Increase social support for adherence to antiretroviral therapy and risk reduction
- Address couple’s sexual transmission concerns
- Address couple’s issues of sex and intimacy

Brief Description
SMART Couples is a couple-level intervention administered to individual couples. The intervention addresses adherence to antiretroviral therapy and safer sex behaviors within the dyad by fostering active support for the HIV-positive partner from their HIV-negative partner, and vice-versa. The intervention included cognitive-behavioral components to identify barriers, reinforce health-care behaviors, and problem-solving strategies to overcome adherence barriers. Key components include education about the importance of adherence to avoid viral resistance and maintain health and identifying patterns of non-adherence, and increasing social support for positive health outcomes.

Theoretical Basis
- Ewart’s social action theory
- Self-regulation theory

Intervention Duration
- Four 45-60 minute sessions over 5 weeks

Delivery Methods
- Exercise
- Discussion
- Instruction

Deliverer
- Nurse practitioner

- Lecture/teach
- Problem solving

INTERVENTION PACKAGE INFORMATION

The intervention package and training are available through Sociometrics Corporation under the name SMART Couples.
EVALUATION STUDY AND RESULTS

The original evaluation was conducted in New York City, NY between 2000 and 2004.

Key Intervention Effects
• Increased medication adherence

Study Sample
The baseline study sample of 215 HIV-positive partners of serodiscordant couples is characterized by the following:
• 62% black or African American, 24% Hispanic/Latino
• 54% male, 46% female
• 74% heterosexual couples, 26% homosexual couples
• Mean age of 42 years
• 63% completed high school or GED
• 100% treatment-experienced
• 100% missed > 80% prescribed doses in past 2 weeks (MEMS)
• 41% participants with undetectable viral load (level not defined)

Recruitment Settings
Public and private HIV outpatient clinics, private medical practices, and community-based organizations

Eligibility Criteria
Couples were eligible if they were HIV-serodiscordant (self-report) with a relationship duration of 6 months or more, both partners were English-speaking, and >18 years of age. The HIV-positive partner was eligible if he/she was in primary care, was taking ART for at least 1 month, and missed > 80% prescribed doses in the 2-week MEMS observation period before study.

Assignment Method
Couples (N = 215) were randomly assigned to 1 of 2 groups: SMART couples (n = 106) or usual care (n = 109).

Comparison Group
Comparison participants received usual care from a multidisciplinary treatment team. Dosing, common side effects, and the importance of adherence to the regimen as prescribed were discussed. Patients were instructed to contact the clinic to speak with either their medical provider or a nurse if they had difficulties with the regimen. Follow-up with the patient’s medical provider usually occurred within 2–4 weeks after initiating a new regimen. When ongoing adherence problems are identified, a member of the treatment team assessed the patient to determine the underlying causes and how to address them. Patients with adherence problems were scheduled to see their medical provider monthly.

Relevant Outcomes Measured and Assessment Time
• Medication adherence behavior (recorded using MEMs caps) was defined as the proportion of prescribed doses taken (without regard to timing) and the proportion of prescribed doses taken within specified time windows during past 2 weeks. Medication adherence was adjusted through participant self-reports of errors in MEMS use, was categorized as > 80%, >90%, and >95%, and assessed at 2 weeks, and 3 and 6 months post-completion of intervention.
Viral load was measured at 2 weeks post-completion of intervention and assessed as undetectable (<50 copies/mL).

**Participant Retention**
- SMART Couples Intervention
  - 85% retained at 3 months post-completion of intervention
  - 83% retained at 6 months post-completion of intervention
- Usual Care Control
  - 86% retained at 3 months post-completion of intervention
  - 86% retained at 6 months post-completion of intervention

**Significant Findings on Relevant Outcomes**
- The change from baseline in the proportion of prescribed doses taken within a specified time window at 3 months post-completion of intervention, as measured by MEMs caps, was significantly greater among the intervention participants than comparison participants (change score $b = -13.17$, $p = .028$; missing data imputed).
- At 3 months post-completion of intervention, the percent of participants with > 90% adherence to prescribed doses taken within a specified time window, as measured by MEMs caps, was significantly greater among intervention participants than comparison participants (12% vs. 2%, $p = .016$; missing data not imputed).
- At 6 months post-completion of intervention, the proportion of prescribed doses taken within a specified time window, as measured by MEMs caps, was significantly greater among intervention participants than comparison participants ($t = 2.24$, $p = .026$; missing data not imputed).

**Considerations**
- This study did not meet the best-evidence criteria due to no significant positive intervention effect on viral load.
- There were several significant intervention findings at 2 weeks after completion of the intervention, including significant group differences in adherence change from baseline to the 2-week assessment in terms of proportion of prescribed doses taken ($p = .021$) and proportion of does taken within specified time windows ($p < .001$); significant group differences in the percentage of participants who took > 80%, > 90%, and > 95% of doses and the percentage of participants who took > 80%, > 90%, and > 95% of doses within specified time windows (all $p < .05$). These findings were not considered as evidence because the assessment time point did not meet the minimum criterion of 1 month post-completion of intervention.
- The MEMS cap was placed on the bottle containing the most complex dosage regimen in terms of the number of doses and pills per day.
- Missing MEMS data at the 6-month assessment was 19%; however, attrition plus missing data did not exceed 40%. There were no differences among participants with or without missing MEMS data in terms of baseline demographics (age, sex, education) and outcome (MEMs Adherence score).*

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