CARE+

Best Evidence – Risk Reduction
Good Evidence – Medication Adherence

INTERVENTION DESCRIPTION

Target Population
- HIV clinic patients who are antiretroviral treatment-experienced

Goals of Intervention
- Reduce HIV transmission risk
- Improve adherence to antiretroviral therapy

Brief Description

CARE+ is an individual-level, interactive, computer-based counseling intervention. During each HIV clinic visit, patients first complete an assessment of their sex behavior, substance use, mental health, and medication adherence risks via a tablet computer. Based on the risk-assessment responses, the computer program provides participants with tailored feedback and loads videos, with separate versions for heterosexuals and men who have sex with men (MSM), which showcase skills around HIV disclosure, medication adherence, safer sex, substance abuse, male/female condoms, condom use negotiation, working with providers, HIV natural history and antiretroviral treatment mechanisms. The intervention content consists of consequence-framed messages, social-cognitive role modeling, with actor-portrayed peers demonstrating healthy behavior in the videos, and messages emphasizing commitment to behavior change. After viewing the videos, participants develop plans for medication adherence and safer sex. At the end of each session, participants receive a personalized printout that summarizes feedback and provides the health plan and referral phone numbers.

Theoretical Basis
- Information Motivation Behavior Theory
- Transtheoretical Model
- Motivational Interviewing
- Social Cognitive Theory

Intervention Duration
- Four sessions lasting approximately 25-to-30-minutes each*, delivered at 3-month intervals over 9 months

Intervention Settings
- Public HIV clinic and AIDS service organization

Deliverer
- Computer program

Delivery Methods

- Counseling
- Feedback
- Goal setting/plan
- Printed material
- Referral
- Skills building
- Video

INTERVENTION PACKAGE INFORMATION

An intervention package for CARE+ is available through [Resources Online Inc](http://care.ronline.com). at the following website: http://care.ronline.com

EVALUATION STUDY AND RESULTS

The original evaluation study was conducted in Seattle, WA between 2006 and 2008.*

Key Intervention Effects

- Reduced sexual transmission risk
- Improved medication adherence

Study Sample

The baseline study sample of 239 patients living with HIV is characterized by the following:

- *55% white, 29% black or African American, 12% American Indian or Alaska Native, 9% Hispanic/Latino, 9% other race, 2% Asian, 1% Native Hawaiian or other Pacific Islander*
- *89% male, 11% female*
- *74% MSM (83% of men are MSM)*
- *Median age of 45 years*
- *15% did not complete high school, 45% graduated high school or obtained a GED, 40% completed more than high school*
- *100% treatment-experienced*
- *43% adherent to > 95% of doses*
- *61% with undetectable HIV-1 RNA viral load (< 30 copies/mL)*

Recruitment Settings

University-affiliated public health clinic and a large AIDS service organization

Eligibility Criteria

Persons living with HIV were eligible if they were at least 18 years of age, on antiretroviral therapy, could understand spoken English, did not have thought disorders, and were not currently participating in other ART adherence or prevention-with-positives studies.

Assignment Method

Persons living with HIV (N = 239) were randomized to 1 of 2 study arms: CARE+ (n = 120) or a standard-of-care comparison (n = 119).

Comparison Group

The standard-of-care comparison group received 4 assessment-only sessions, scheduled during clinic visits and delivered via a tablet computer.

Relevant Outcomes Measured and Follow-up Time

- Sexual transmission risk in the past 3 months (defined as unprotected sex† or condom use with errors) was measured at 3, 6 and 9 months post-initiation of intervention.
- Medication adherence behavior (defined as self-reported medication adherence by the 30-day visual analog scale) was measured at 3, 6, and 9 months post-initiation of intervention.
- Viral load was measured at 3, 6, and 9 months post-initiation of intervention and was assessed as undetectable (< 30 copies/mL) or detectable.

Participant Retention

- CARE+ Intervention
  - 94% retained at 3 months post-initiation of intervention
  - 88% retained at 6 months post-initiation of intervention
  - 86% retained at 9 months post-initiation of intervention

- Standard of Care Control
  - 93% retained at 3 months post-initiation of intervention
  - 91% retained at 6 months post-initiation of intervention
  - 89% retained at 9 months post-initiation of intervention

Significant Findings

- Across the four assessments (baseline to 9 months post-initiation of intervention), intervention participants reported a significantly greater reduction in sexual transmission risk than comparison participants (Generalized Estimation Equation [GEE] estimate = -0.08, SE = 0.04, p = 0.0398).
- Intervention participants were also significantly less likely than comparison participants to report sexual transmission risks at 6 months post-initiation of intervention (Adj OR = 0.58, 95% CI = 0.35 – 0.95, p = 0.0297) and at 9 months post-initiation of intervention (Adj OR = 0.46, 95% CI = 0.25 – 0.84, p = 0.0117).
- Across the four assessments (baseline to 9 months post-initiation of intervention), intervention participants reported a significantly greater increase in self-reported medication adherence than comparison participants (GEE estimate = 0.68, SE = 0.34, p = 0.0456).

Considerations

For Medication Adherence:

- This study fails to meet the best-evidence criteria for medication adherence due to no imputation of missing data and analytic sample size < 40 per arm for both significant biologic adherence outcomes (i.e., $\log_{10}$ or undetectable viral load).
- Among the subgroup of participants with detectable viral load (> 30 copies mL) at baseline (n = 89), several intervention effects (all p-values < 0.05) were observed. However, these findings did not meet the efficacy criteria because analytic sample size was <40 per arm.
  - Intervention participants reported a significantly greater reduction in Log_{10} viral load than comparison participants across the 4 assessments; at 6 months and at 9 months post-initiation of intervention.
  - Intervention participants were significantly more likely than comparison participants to self-report higher medication adherence at 9 months post-initiation of intervention.

- Participants lost to follow up had significantly lower adherence (p = 0.009) and higher viral load (p = 0.003) at the baseline assessment.*

*Information obtained from author
†Unprotected sex measured as sex without a condom

REFERENCES AND CONTACT INFORMATION

Kurth, A. E., Spielberg, F., Cleland, C. M., Lambdin, B., Bangsberg, D. R., Frick, P. A., . . . Holmes, K. K. (2014). Computerized counseling reduces HIV-1 viral load and sexual transmission risk: Findings from a randomized controlled trial. *JAIDS Journal of Acquired Immune Deficiency Syndromes, 65,* 611-620.

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