# Evaluation of a Web-Based Program to Improve Adherence to HIV Medications

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## The Challenge

- Despite advances in the treatment of HIV and the advent of antiretroviral (ARV) medications, adherence to medications continues to be a significant problem.
- Effectiveness of ARV medication is wholly dependent on adherence
- If taken as prescribed ARV treatment leads to reduced viral load, greater immune system functioning and prolonged life for those living with HIV

## The Challenge
(cont.)

- Recent advances have been made in strategies to improve adherence to medical regimens
- Life Steps, developed by Steve Safren, is a single-session, in-person cognitive-behavioral HIV medication adherence program
- Life Steps has been shown effective in a clinical trial
- However, in-person adherence interventions present challenges for efficiency and scalability, require significant staff time, and may not be available in remote locations

## A Solution

- Develop a web-based adaptation of the Life Steps program
- Test the effectiveness of the program with an HIV+ sample in a real world setting
- Measure adherence using multiple methods including electronic pill cap, self report, and viral load

## Life Steps for Managing Medications and Stress

- The program includes each of the nine Life Steps modules
- The program also includes modules on stress and mood management adapted from a previous ISA program
- A multi-media program, fully audio-narrated, with interactive assessments, animation, graphics, and real life testimonials
- Users are guided through the program by “Steve,” and adherence counselor

# Life Steps Program Content

***Welcome & Introduction***

***Life Steps for Medication Adherence***

- Understanding Medication Adherence
- Communicating with Your Treatment Team
- Getting to Appointments
- Coping with Side-Effects
- Obtaining Medications
- Formulating a Daily Schedule
- Using Cue Control Strategies
- Handling Slips
- Review

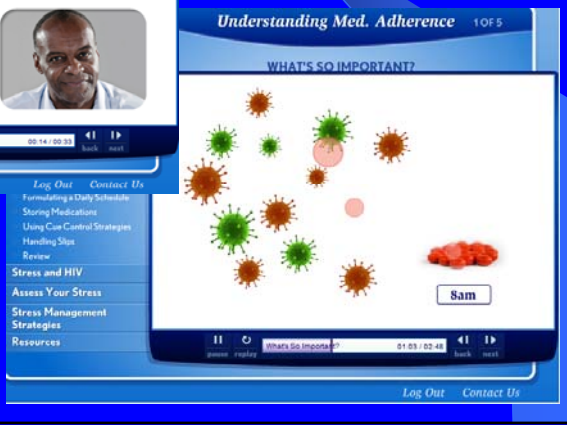
***Stress and HIV***

***Assess Your Stress***

***Stress Management Strategies***

# The Program


"Steve" the on-screen adherence counselor narrates the program




Graphics and animation are also included

# Testimonials


Real people testimonials are included throughout the program

# Interactive Forms and Video


Interactive forms help users overcome barrier


Video vignettes allow users to practice skills

# Life Steps Randomized Trial

- Inclusion criteria:
  - HIV+
  - Taking ARV medication
  - Not actively engaged in clinic medication adherence
  - Viral load >48
- Outcome measures:
  - Primary Outcome Measure:
    - Adherence based on MEMS (Medication Event Monitoring System)
  - Secondary Outcome Measures:
    - Viral Load (taken as a routine part of treatment)
    - Self-Report Measures of Adherence, Adherence Self Efficacy, Symptoms of Stress, HIV-Specific Stress, Mood, and Substance Abuse

# Sample

- 168 HIV+ individuals meeting the inclusion criteria who receive services at a clinic in Washington, DC
- Majority male (72%) and African American (82%)
- Mean age = 46 (range 19-69)
- Majority earned less than $30,000/year and had been HIV+ for more than 10 years

# Outcome Measures

**Adherence**

- Electronic Pill Cap - MEMS® 6 *Medication Event Monitoring System (AARDEX)*
- Used with ARV Medication (If taking more than 1 ARV, then used with the ARV medication most difficult to take as prescribed)
- Pill cap opening monitored throughout the project; data read whenever the participant came to the clinic
- Adherence calculated as % doses taken/% dosed prescribed

**Viral Load**

Data collected as a routine part of medical care during the study period was available for 148 participants

**Self Report (Baseline, 3, 6 and 9 months)**

AIDS Clinical Trial Adherence Measure (4 day recall), Self-Efficacy for Appropriate Medication Use Scale (SEAMS), Symptoms of Distress, HIV-AIDS Stress Scale, Positive and Negative Affect Schedule (PANAS), Alcohol Use, Drug Use

# Analyses

- Random Coefficients Model (RCM) comparing the linear slopes over time in the two study conditions.
- Analysis followed intent-to-treat (ITT) principles
- Multiple imputation using NORM program (less than 10% missing data on MEMS primary outcome variable)

# MEMS Findings

Results show a significant treatment effect on medication adherence ($t = 2.03$, $p < .05$), as the control group adherence declined significantly more than the program group.

**Treatment Effect on Percent of Prescribed Number of Doses Taken**

| | Unstandardized Effect | SE | t value | p-value |
|---|---|---|---|---|
| Fixed Effects | | | | |
| Initial Adherence Rate for Control Group | 85.20 | 2.96 | 28.80 | <.001 |
| Difference between Conditions in Initial Adherence Rate | -2.67 | 4.07 | -0.66 | .509 |
| Change in Adherence Rate for Control Group | -.053 | .002 | -3.22 | .001 |
| Difference Between Conditions in Change in Adherence Rate | .053 | .026 | 2.03 | .042* |

# MEMS Findings

- The decline in adherence rate was significantly steeper in the control condition versus the program condition. The control group adherence declined 21% (from 85% to 66%)
- The program group also declined significantly, but only by about 12% (from 83% to 73%)

# Dosage

The percentage of prescribed doses taken was analyzed by total number of Life Steps modules completed. The effect was in the desired direction, and although not significant, it was indicative of a trend (t = 1.667, p = .096).

**Effect of Program Usage on Percentage of Prescribed Doses Taken**

| Fixed Effects | Unstandardized Effect | SE | t value | p-value |
|---|---|---|---|---|
| Initial Adherence Rate (before Completing any Modules) | 84.485 | 2.489 | 33.942 | <.001 |
| Difference between Conditions in Initial Adherence Rate | -.244 | .524 | -.466 | .641 |
| Average Change in Adherence Rate | -.037 | .022 | -1.700 | .089 |
| Change in Adherence Rate for Each Module Completed | .004 | .002 | 1.667 | .096 |

# Viral Load

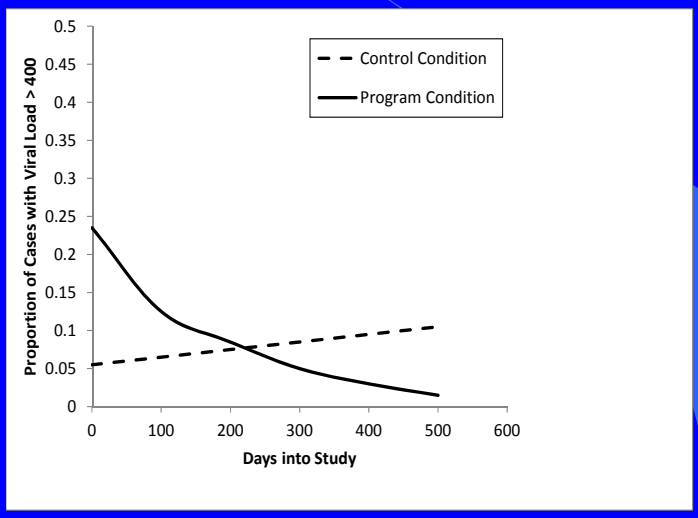
**Treatment Effect on Viral Load over Time**

| Fixed Effects | Unstandardized Effect | SE | t value | p-value |
|---|---|---|---|---|
| Initial Viral Load for Control Group | -2.212 | .336 | -6.586 | <.001 |
| Difference between Conditions in Initial Viral Load | .954 | .430 | 2.221 | .026 |
| Change in Viral Load for Control Group | .001 | .001 | .511 | .609 |
| Effect of Program on Change in Viral Load | -.003 | .002 | -2.263 | .024 |

Using a cut off of VL > 400, there was a significant treatment effect, with the treatment condition VL scores decreasing significantly more than scores from the control condition (t = -2.263, P = 0.024).

# Viral Load

**Viral Load by Condition**




# Additional Analysis

- No significant differences found across gender, race or time on ARV medication
- No significant difference between program and control group participants on the self report measures

## Summary

- Patients given the web-based Life Steps program had significantly higher adherence rates than patients in the control group
- While adherence declined for both groups, the decline was significantly greater for the control group
- Patients in the Life Steps program group also had decreased viral loads.
- No differences across gender, race or time on HIV medication indicates a robust intervention
- Dose response relationship, while not significant, was suggestive of a potential relationship

## Why Didn't Adherence Increase?

- Our sample started out fairly adherent (over 80% adherent) in contrast to other studies where adherence started at 50%-70%
- Use of the MEMS cap may have increased adherence during the baseline period creating a ceiling effect

# Implications

- A web-based medication adherence program based on the in-person Life Steps intervention created by Safren and his associates can be a useful tool for helping HIV infected patients maintain medication adherence
- While the digital divide remains a concern, Internet usage among low income, African Americans is increasing
- Barriers to utilization are greatly reduced when the program is used within a clinic setting in addition to outside the clinic
- Thus web-based programs are promising tool to help increase adherence among HIV+ patients

# Further Questions

*For questions about this project please contact*:

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