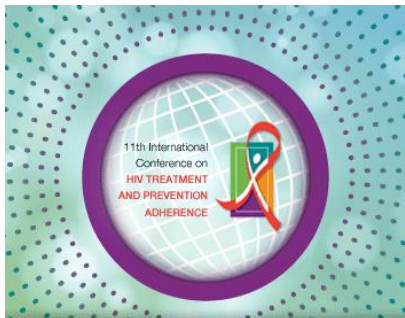


A Telemedicine-delivered Cognitive Behavioral Therapy for Adherence and Depression (CBT-AD) in HIV-positive women in the Deep South

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Disclosure



- Relevant Financial Relationship(s):

None

Women and HIV in the US



- Women represent 25% of HIV infections in the US, with Women of color being disproportionately affected
- 1.49% of Black Women in the US (18-49yrs old) are HIV positive (22 times the rate of White Women)
- 69% of HIV-positive women evidence prolonged symptoms of depression compared to 45% of men

Women and HIV in the South



- Seven of the 10 states with the highest case rates among women are located in the South
- Southern states comprise 67% of all HIV/AIDS cases among rural populations
- Access to reliable transportation has been identified as one of the main barriers to access and adherence to HIV care

Sweet Home Alabama



- 55 of Alabama's 67 counties are considered rural
- 7 counties, all rural, have no hospital
- 55% of the population lives in a federally designated mental health professional shortage area
- Average wait time to see a psychiatrist: 3 months

Alabama Rural Health Association, 2012; Bureau of Clinician Recruitment and Service, Health Resources and Services Administration (HRSA), U.S. Department of Health & Human Services, [HRSA Data Warehouse: Designated Health Professional Shortage Areas Statistics, as of April 28, 2014](#).

Telemedicine

- Telecommunication used to provide clinical health care at a distance
- Interactive telemedicine provides real-time interactions between provider and patient
- Beneficial for people living in isolated/remote communities
- Patient can be seen by a specialty care health provider without having to travel long distances



Objectives

- To culturally adapt an evidence-based psychotherapy for adherence and depression to HIV-positive African American women residing in rural Alabama
- To assess the feasibility and acceptability of a telemedicine delivered psychotherapy

Methods

- Time-matched Pilot Randomized Controlled Trial (RCT) (CBT-AD vs. supportive psychotherapy) via Telemedicine
- HIV-positive women seeking care at 4 outpatient clinics located in Alabama between 2014-2016
- **Inclusion/Exclusion Criteria:**
 - Female + ≥ 19 yrs + HIV-positive
 - Seeking care at one of the clinics + on ART
 - Screened positive on the CES-D + confirmatory dx using the Mini International Neuropsychiatric Inventory (MINI)
 - Substance abuse or mental disorder interfering w/ therapy
 - No prior cognitive behavioral therapy treatment within the last 12 months

Clinic/Study Sites

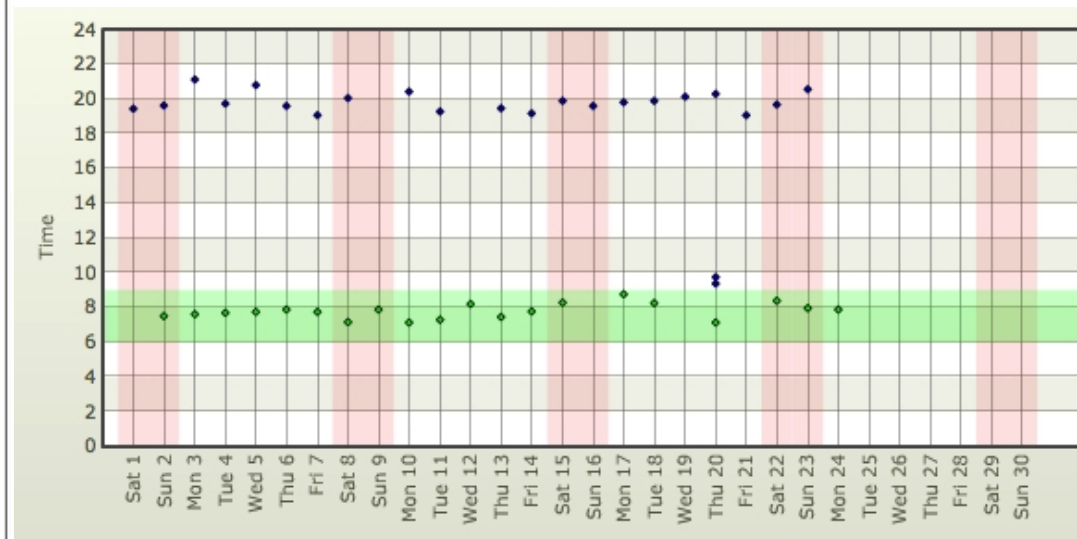


- Birmingham (UAB)
- Montgomery
- Dothan
- Selma
- Tuscaloosa

Analysis

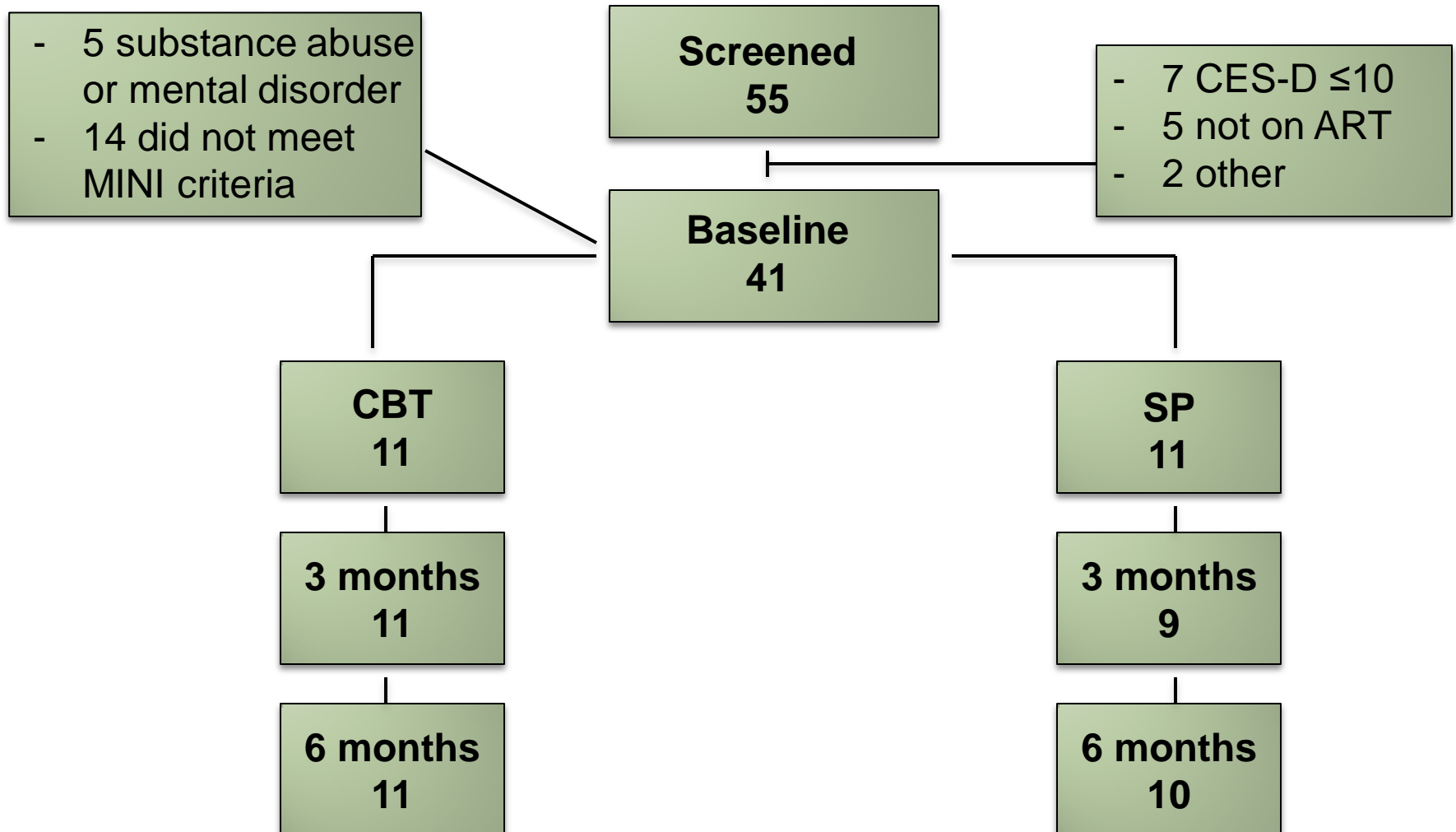
- **Main outcomes:**
 - Feasibility of intervention (process evaluation)
 - Acceptability of intervention (quantitative and qualitative assessment)
 - Preliminary effect on depression and ART adherence
 - Depression: CES-D
 - Adherence: Wisepill (real-time adherence monitoring device)

Wisepill



Slide courtesy Jessica Haberer

Feasibility: Enrollment & Retention



Results - Patient Characteristics

Patient Characteristics	Total (N=22)	CBT (N=11)	SP (N=11)	P-value
Age (yrs), mean (SD)	45.8 (± 11.8)	48.6 (± 11.3)	43 (± 12)	0.278
Year of HIV dx (yr), mean (SD)	2006 (± 6.9)	2005 (± 8.2)	2007 (± 5.6)	0.476
ART initiation (yr), mean (SD)	2008 (± 5.6)	2008 (± 5.6)	2008 (± 5.7)	0.824
CD4 count <200 cells/ μ l, N (%)	2 (9.1)	1 (9.1)	1(9.1)	1
HIV VL <200 copies/ml, N (%)	19 (86.4)	10 (90.9)	9 (81.8)	1
Ever being dx w/ depression, N (%)	15 (68.2)	9 (81.8)	6 (54.5)	0.362

Results - Patient Characteristics

Patient Characteristics	Total (N=22)	CBT (N=11)	SP (N=11)	P-value
Marital Status, N (%)				0.051
Single	6 (27.3)	5 (45.5)	1 (9.1)	
Married/w/ partner	7 (31.8)	1 (9.1)	6 (54.5)	
Separated/Divorced/Widowed	9 (40.9)	5 (54.5)	4 (36.4)	
Education, N (%)				0.087
< High School	4 (18.2)	1 (9.1)	3 (27.3)	
High School Graduate/GED	6 (27.3)	3 (27.3)	3 (27.3)	
Some college/Technical training	9 (40.9)	6 (63.6)	2 (18.2)	
College Graduate	3 (13.6)	0	3 (27.3)	
Income w/n the last year <\$10,000, N (%)	12 (54.5)	6 (54.5)	6 (54.5)	1

Results - Feasibility and Acceptability

Patient Characteristics	Total (N=22)	CBT (N=11)	SP (N=11)	P- value
# weeks of intervention, mean (SD)	11.5 (± 1)	11.6 (± 0.7)	11.3 (± 1.2)	0.550
# weeks to complete intervention, mean (SD)	14.7 (± 4.3)	13 (± 2.7)	16.3 (± 5)	0.071
Client Satisfaction (CSQ-8; 8-32), mean (SD)	30.7 (± 3.8)	29.6 (± 5.3)	31.8 (± 0.4)	0.829
Acceptability Ratings (1- 100), mean (SD)				
Depression counseling	97.2 (± 5.4)	96.4 (± 7)	98 (± 3.1)	0.503
HIV Tx adherence counseling	96.6 (± 12.8)	94.7 (± 17.6)	98.5 (± 5)	0.506
Telemedicine			87.5 (± 7.8)	0.442
Wisepill	85.1 (± 13.5)	83 (± 17.3) 96.2 (± 6.8)	90.2 (± 15.7)	0.261

Results - Acceptability (Quotes)

- *“...also, for you guys, if it wasn't for you, I would be done. I would be lost. Can I do it over again?...”*
- *“...told a couple friends I liked it and how I enjoyed it already. They felt I was doing better, you know, coming to you and also my family thought so also...”*
- *“...it was a great help, to me. It really was, and it brought out in me some things I didn't even know—some things that I was bothered with, I didn't even know I was...”*

Results - Depression and Adherence

Outcomes	Total (N=22)	CBT (N=11)	P- value	SP (N=11)	P- value	δ P- value
CES-D (0-60), mean						
Baseline	36.4	37.5		35.3		0.543
Change 13 weeks	-16.2	-17.6	<.0001	-14.8	<.0001	0.542
Change 24 weeks	-14	-14	<.0001	-14	<.0001	0.997
Wisepill, % past week adherence						
Baseline	71.2	89.6		51.3		0.003
13 weeks	-2.6	-9.2	0.393	5.9	0.478	0.270
24 weeks	-21.2	-34.5	0.053	-4.3	0.743	0.17
Wisepill, % past week adherence + behavioral corr.						
Baseline	89.6	94.8		84.4		0.239
Change 13 weeks	3.9	-5.2	0.584	13	0.126	0.156
Change 24 weeks	2.2	-7.8	0.150	12.6	0.077	0.025

Conclusions

- The delivery of a Telemedicine-delivered psychotherapy is feasible and acceptable among HIV-positive women living in the rural South.
- The use of Wisepill as an adherence monitoring device within this population needs to be further evaluated.
- The efficacy of the intervention needs to be tested in a large scale clinical trial using ART non-adherence or uncontrolled virus as an entry criteria.

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- HIV care providers and staff at participating clinics
- Study Participants

NIMH

- 1 R34 MH097588-01



CBT for Adherence and Depression (CBT-AD) in HIV

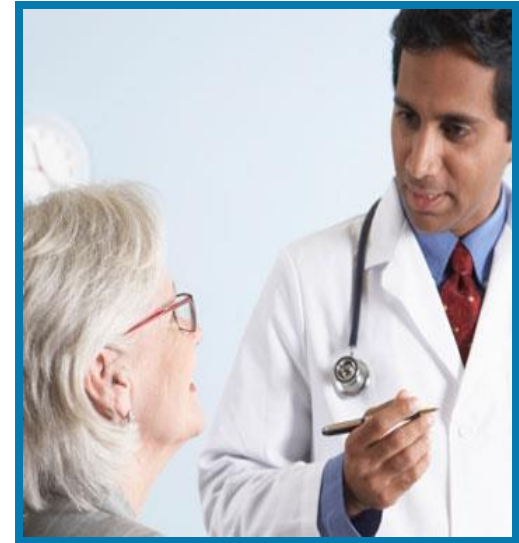
- Life-Steps (1 session)
- Psychoeducation/Motivational Interviewing about CBT for Depression (1 session)
- Behavioral Activation/Activity Scheduling (1 session)
- Adaptive thinking (3 sessions)
- Problem Solving (3 sessions)
- Relaxation/Diaphragmatic Breathing (1 session)

Each session builds on the previous session and each session integrates adherence skills.



Life-Steps*

- Psychoeducation/Motivation for Adherence
- Getting to Appointments
- Communication with Treatment Team
- Coping with Side Effects
- Obtaining Medications
- Formulating a Daily Medication Schedule
- Storing Medications
- Cue Control Strategies for Taking Medication
- Guided Imagery/Rehearsal
- Handling Slips in Adherence
- Review



*Safren SA, Otto MW, Worth J. Life-Steps: Applying cognitive behavioral therapy to HIV medication adherence. *Cogn Behav Pract.* 1999;6:332-341.

Barriers to Telemedicine Use

- Equipment Cost
- Technical Training
- Evaluation Time
- Quality of transmitted records/clinical information



Telemedicine/Computer Use

Patient Characteristics (N=33)	N	%
Prior Telemedicine Use		
Yes	6	18
Are you comfortable using a computer?		
Yes	22	67
Prior Skype use		
Yes	5	15
Own a cell phone		
Yes	32	97
Own a smart phone		
Yes	4	12

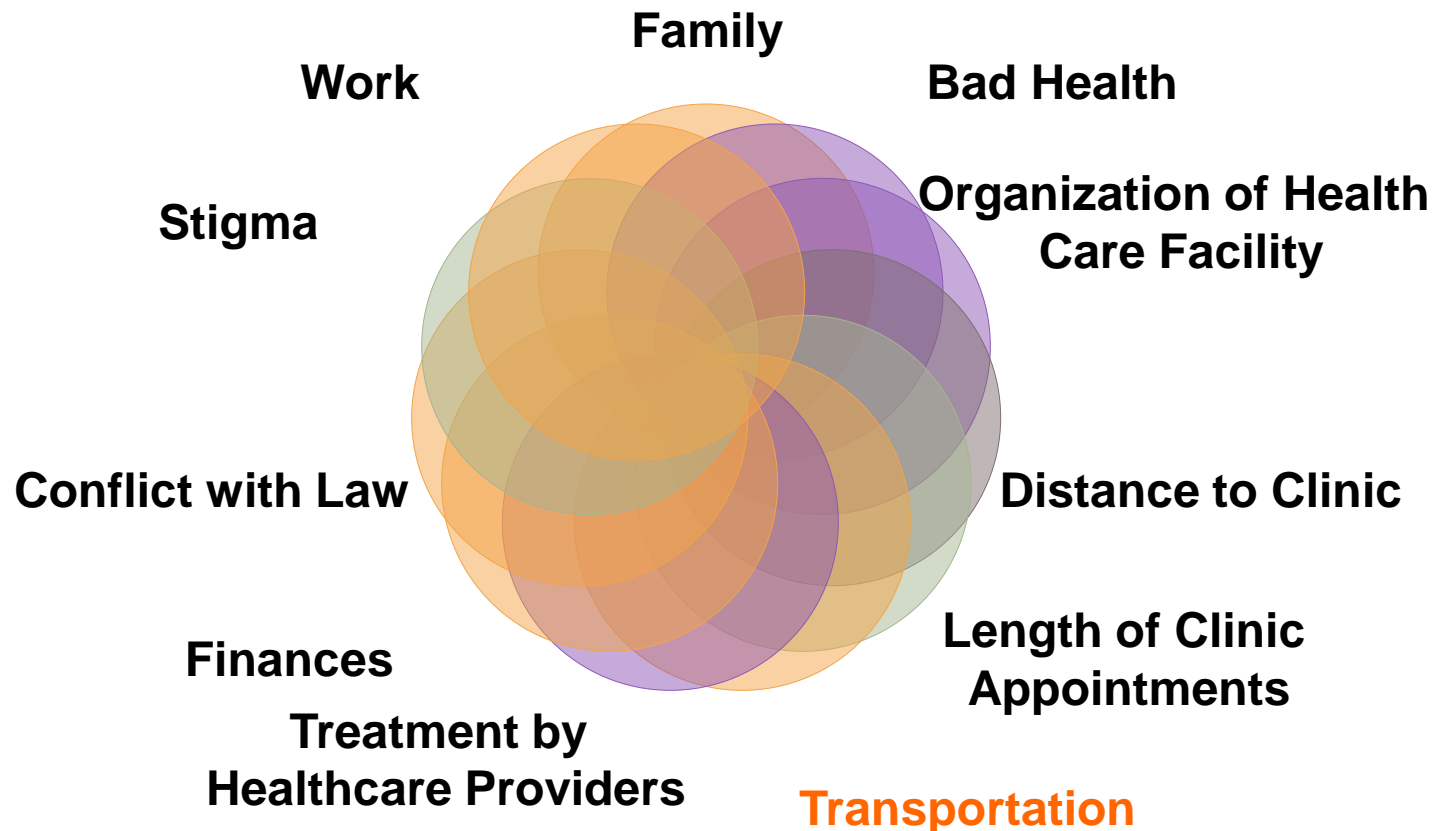
Transportation

“The only thing that ever happened to me to where I couldn’t make it was if I didn’t have enough money for gas, that particular time, I would just reschedule my appointments....Or, if I had car trouble.”

R34 - Telemedicine to improve depression and adherence in HIV+ women in the rural South

- To conduct **formative research** among HIV-infected women and HIV care providers to inform the cultural adaptation of the CBT-AD intervention for HIV-infected women in rural areas of Alabama;
- To **systematically adapt the CBT-AD intervention** to HIV-infected depressed women residing in rural Alabama and telemedicine technology, using an iterative open-label – non-randomized process.
- To **assess the feasibility, acceptability and preliminary efficacy** of the adapted CBT-AD in reducing depression and improving ART adherence and retention in care among HIV-infected depressed women via a pilot randomized controlled trial (RCT).

Barriers to retention-in-care among HIV-infected Women



Conceptual Framework

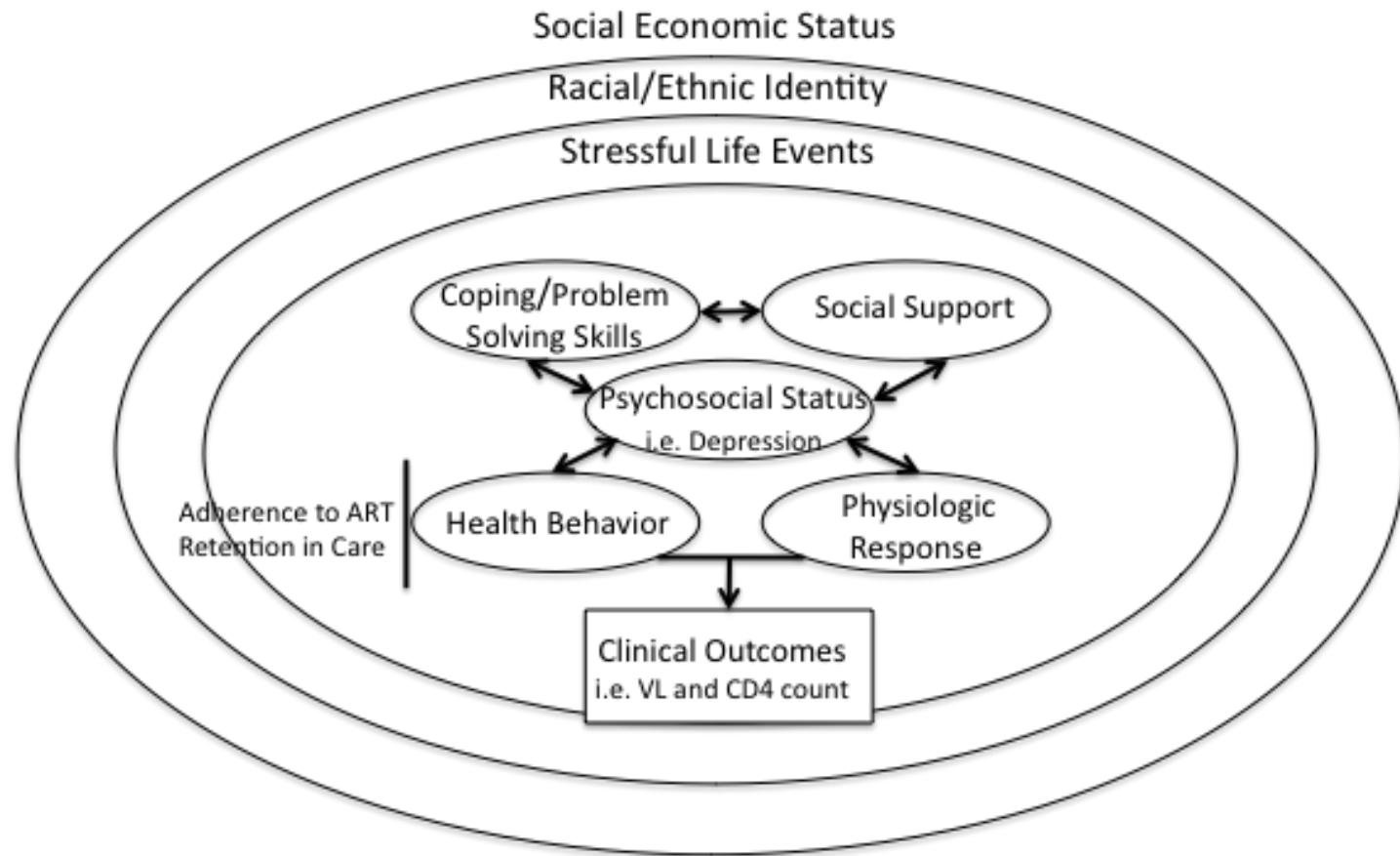


Fig. 1: Social Ecological Model of Behavior Change, Conceptual Framework for Depression, Adherence and Retention to Care (modified and adapted from Katz, 2008)

Wireless monitoring devices



The SIMpill® SMART



The technology

- Device components
 - Microchip to record time-date stamp (like a MEMS cap)
 - SIM card and a rechargeable battery
 - Pill container insert (2 or 7 compartments)



The technology

- Data
 - Transmission via GPRS with SMS back up
 - Hosted by Wisepill in Cape Town or locally
 - Accessible via the web with customizable reports
- Functionality
 - Positive control via early morning “heartbeat”
 - Each transmission includes battery level, signal strength, air time
 - Capacity for SMS reminders

Choice of Wisepill

- Availability of developer
- Flexibility of software
- Portability of the device
- Works in remote settings (e.g. Africa)

Challenges

- Looking for the absence of a signal
- Battery life
- SIM cards
 - Unexpected expiration
 - Registration requirement
- Network availability
 - Delayed transmission resulting in “false interruptions”
 - Need for SMS back-up
- Frozen modem

Challenges

- Data cleaning
- Potential for stigma/unintended disclosure
- Cost
- Importantly, no reported problems with
 - Diversion
 - Med refills

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