Enhancing HIV Outcomes: Nurse-Delivered Cognitive-Behavioral Interventions

Nancy R. Reynolds, PhD, RN, FAAN
Professor & Associate Dean for Global Affairs
Johns Hopkins School of Nursing
Objective

- Overview of the scope
- Review of my program of research developing and testing nurse-delivered cognitive-behavioral interventions
- Future directions
What are nurse-delivered cognitive behavioral interventions and why are they important?
Cognitive Behavioral Intervention

In general.....

• A merging of cognitive and behavioral approaches
• Are designed to help individuals examine and understand the thoughts and feelings which influence behaviors
• The ultimate goal of CBI is to facilitate how to recognize and change undesirable feelings, such as anxiety and anger, that drive maladaptive or destructive behaviors
• CBI strategies are focused on increasing positive behaviors, reducing undesirable or inappropriate behaviors, and promoting self-control, and problem-solving
Cognitive Behavioral Interventions as applied in context of HIV

- Improve self-care/self-management
- Adherence to antiretroviral medication/PrEP
- Smoking cessation
- Substance use
People living with HIV often face challenges in achieving adequate adherence to their medications.
Poor adherence to treatment of chronic illnesses is a worldwide problem of striking magnitude.

Typically, adherence rates of 80% or more are needed for optimal therapeutic efficacy.

On average, 50% of medications for chronic diseases are not taken as prescribed.¹

The impact of poor adherence grows as the burden of chronic disease grows worldwide – the vulnerable and marginalized are disproportionately affected.

“Increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments”

How?
Adherence is a dynamic behavior influenced by a matrix of interrelated factors that change over time.
Reasons people do not take medications as prescribed are complex and multi-dimensional.

Reasons for non-adherence vary by person.
A host of research has established that there are many different interrelated factors associated with poorer adherence and treatment failure

- Side effects and pill burden
- Stigma
- Lack of social support
- Patient-provider relationship and clinic environment
- Access, transportation, cost
- “Forgetting”
- Mental health (e.g., depression, anxiety, substance use disorder)
- Beliefs

Strategies for Enhancing Adherence

- Educational (necessary, but not sufficient!)
- Reminder strategies (e.g., text message reminders)
- Management /reduction side effects
- Reduce complexity of regimen
- Family/peer support
- Directly observed therapy (DOT)
- Monetary incentives
- Cognitive-Behavioral
“We’ve known for over 50 years that providing information alone to people does not change their behavior.”

– Victor Strecher, Univ. of Michigan School of Public Health
The tailored intervention approach has several essential components:

1. It is delivered by nurse
2. It is patient-centered - provides the patient with an individualized cognitive-behavioral program that is congruent with patients’ social and cultural context
3. It improves early recognition of problems that may interfere with medication adherence
4. It builds proactive (sustainable) problem solving and self-care skills to aid participants and their family members to overcome factors that may impede engagement in care
The tailored intervention approach has several essential components (continued):

4. **It is practical**
   - The intervention can be delivered by nurses in established clinics
   - The intervention is delivered by phone which offers several potential advantages
     - Flexible
     - Private, non-stigmatizing;
     - Improves access to health care counseling between clinic visits
     - Suitable for persons with low literacy
Steps:

- Step 1. Assess dimensions of illness representation, knowledge, motivation and behavioral skills
- Step 2. Assess responses to the questions
- Step 3. Set up conditions for perceptual change
- Step 4. Introduce replacement perceptions and alternate behaviors

Individualized, delivered over time
Eliciting descriptions of illness representation

- **Assess Cause**: “Can you tell me about your HIV and why you are beginning a new HIV therapy regimen?”

- **Assess Identity**: “Do you know anyone else who has HIV? Are they taking HIV medicines? “How has the medicine affected the way they feel? How have you been feeling since you have had HIV? “How do you expect the medicines to affect you?”

- **Assess Consequences**: “Do you have any particular concerns about taking HIV medications?” “How do you think your HIV will affect you if you don’t take any medicine?”

- **Assess Cure/Control**: “How effective do you expect your HIV medicines to be in controlling your HIV? “Do you think it is important for you to take the medicines exactly as they are ordered? “Have you had difficulties taking your medicines as ordered previously?”

- **Assess Timeline**: “How long do you expect you will need to take your HIV medicines?”
A better overall treatment effect was observed in the treated (telephone group) \( (p = 0.023) \) in comparison with standard care.

Reynolds et al. JAIDS, 47: 2008
Nurse-delivered telephone intervention to Ohio and Illinois ADAP participants

Percent adherence (MEMS) in treatment-naïve and treatment-experienced subjects

Percent with Undetectable HIV-1 RNA

P ≤ 0.05

* Participants starting new regimen—both tx-naïve and experienced enrolled

Significant difference in adherence between intervention arms among treatment-naïve, but not treatment-experienced.
A Randomized Trial of Enhanced Nursing Phone Support to Improve Self-Management and Outcomes of ART

**Purpose:**

To test an enhanced version of the phone intervention.

To evaluate whether the intervention will result in improved virologic suppression in (ARV) treatment-experienced individuals who have a history of non-adherence and are starting a new ART regimen.

**ENTRY**

N=296

**1:1 RANDOMIZATION**

Stratified by parent studies

**ARM A**

(N=148)

Usual ACTG Site Care + Enhanced Nursing Telephone Support x 48 weeks

**REPEATED OBSERVATIONS**

Weeks 12, 24, 48, 72

**ARM B**

(N=148)

Usual ACTG Site Care

**REPEATED OBSERVATIONS**

Weeks 12, 24, 48, 72
Factors Associated with Perfect Adherence (per VAS) at Week 24 (n=40, 25 (63%) <100% adherence)

Univariable
- Week 12 adherence (VAS) (OR 25.5, p<.001)
- Depression (CES-D) (OR 1.31, p<.001)
- Illness Representation (Perceptions) (OR 1.15, p<.001)

Multivariable
Both Depression and Illness Representation (Perceptions) remained significant when adjusted for each other.

Note:
None of the participants with <100% adherence by VAS at week 12 had perfect adherence at week 24. Due to limited data, we could not assess week 12 adherence (VAS) in multivariable models.

HIV Health Care

System initially characterized by marked shortage of accessible health care that meets basic accepted standards for HIV care and limited emphasis on HIV prevention.
Preventing & Treating HIV Comorbidities in India: Multi-tiered Strategy for Women (NIMH, R21MH100939, Reynolds/Chandra, co-PIs)

Integrating HIV and Depression Self Care to Improve Adherence in Perinatal Women (NIMH, R21MH098667, Reynolds, PI)

Testing mHealth interventions to improve the prevention and treatment outcomes of women in India who are affected by HIV and inter-related mental health and psychosocial risk factors

Reynolds, et al., 2016, BMC Health Serv Res; Chandra et al., 2016, Arch Womens Ment Health; Duggal et al, 2018, AIDS Patient Care STDs.
Specific Aims

1. To adapt a theoretically-driven, empirically-supported intervention protocol to the cultural and social context of women living with HIV and mental health risk factors and clinic delivery sites in India.

2. To implement a pilot study to assess the feasibility, acceptability and safety of the adapted intervention and explore how treatment efficacy...
Phase 1 findings

- 100% had access to cell phones (most family phone)
- The women found it highly desirable to receive treatment related counseling by cell phone from a trained provider
- 70% preferred **not to receive** automated messages/reminders
- The majority cited low literacy as a problem in receiving text messages
Examples Phase 1 interview data

“My husband had it first now he denies... he says that you are involved in indecent things. I can swear to anyone I haven’t done anything wrong... This is true. My father has taught me ethics. Now I cry a lot because of this marriage. I am broken inside, what should I do (women’s eyes get wet). Now, my husband is not seeing me, he maintains distance while talking”.

R: “Lot of changes took place [after my HIV test]....I am less happy, depressed and scared...Now I don’t smile or talk much.

I was feeling low and sad. I felt like why should I take medicine?

R: “My husband doesn’t behave properly there are always fights....lately I have thought of ending my life. We fight a lot now days, I don’t want this life.... I wonder what mistake I made!”
Phase 2: Design and Procedures

40 participants (screened positive for HIV and depression) randomized to one of the two arms in the third trimester of pregnancy (≥ 28 weeks-delivery)

The key components of this integrated care intervention are:

1. Providing the patient with an individualized program that is congruent with patients’ social and cultural context;
2. Integrate depression screening and HIV treatment and adherence in the context of perinatal care,
3. Facilitate proactive problem solving to aid participants in overcoming factors that may impede their engagement in treatment,
4. Improve early recognition of depressive symptoms and referral to clinic for treatment of depression,
5. The nurse plays a mediating role between the health system and its beneficiaries
HIV Capacity-Building

Partnership:

Brown-UGhana-Tufts-Yale

PRESS RELEASE

African and U.S. Universities Partner to Tackle Development Challenges across Africa

USAID provides funding to higher education partnerships to jointly address national and regional development challenges; build in-country educational capacity; maximize resources and on-the-ground knowledge between African & U.S. institutions.
A bioecological pediatric HIV disclosure intervention in Ghana - "SANKOFA“ NICHD, R01HD074253, Paintsil/Reynolds co-PIs)

Primary aim is to test a disclosure of HIV-status to children intervention among families in Ghana and adherence and mental health outcomes.

- Interdisciplinary bi-national team with policymakers
- Theory-guided cognitive-behavioral intervention adapted by focus group interviews and socio-cultural context
- Makes use of available resources. Intervention is multi-level, customizable, sustainable

Paintsil et al, 2020, JAIDS; Catlin et al, 2015, JAIDS; Reynolds et al, 2015, AIDS; Ratcliffe et al., BMC Public Health. 2020; Farthing et al., AIDS Behav, 2020; Nichols et al., 2019, AIDS Care; Ofori-Atta, 2019, AIDS Care.
Results

- Children in the treatment group had significantly greater disclosure at each time point ($p<0.001$).

- They were 4.1 times more likely than the control group to have been disclosed to by 1 year (51.4% vs 16.24%; $p<0.001$; un-adjusted HR=4.1: 95% CI, 2.7–6.0).
Pediatric HIV Disclosure Benefits Study - Sankofa 2 (NICHD, R01 HD103512, Paintsil/Reynolds co-PIs)

- Build on the successful Sankofa trial
- Testing the intervention in a pragmatic, stepped wedge cluster randomized trial in 12 “real-world” HIV pediatric clinics in Ghana to determine effectiveness, health benefits, cost and obtain information to inform scale-up and sustainability
- Recruiting dyads of 720 children (ages 7-18) and their caregivers
- Findings will further a scientific understanding of the mechanisms of action, cost, and individual and organizational-level facilitators and barriers to effective and sustainable delivery of the intervention in a variety of clinical settings
....Other nurse-delivered cognitive-behavioral interventions
“Life-Steps” Safren et al.

- Cognitive-behavioral therapy for adherence and depression (CBT-AD)
- Integrates adherence counseling with CBT for depression (e.g., Safren et al., 2001, 2009, 2014)
- Approx. 11 sessions
- Successful at both increasing adherence and reducing depression in individuals with HIV and depression
- Recently, nurses trained to deliver the intervention at public HIV clinics (Safren et al., 2021)
Individuals who completed CBT-AD sessions (n=80) were 2.5 times more likely to achieve undetectable viral loads than those who received usual care (N=81)

Log HIV viral load

Navarra et al. (2019). A Cognitive Behavioral Intervention for Youth Living With HIV (EASYPAS)

Three consecutive, 60-minute, weekly group sessions delivered by the PI with the assistance of a trained research assistant (RA)

- **Session 1** Knowledge of HIV treatment and related beliefs, perceived barriers and facilitators of ART adherence, and strategies for effective ART self-management discussed.

- **Session 2** Skills and resources needed to adhere (i.e., alarms and pharmacy prepackaging of ART, available support systems)

- **Session 3** *Reinforcing factors* contributing to sustained, positive behavioral change operationalized as the development of Internet appraisal skills

Poor rates recruitment and retention – not feasible
Protocol of a study to determine the efficacy of the SUPA intervention for increasing uptake and adherence to ART (Horne et al., 2019)

3 key elements:
• Communicate a common-sense rationale for ART
• Elicit and address specific Necessity beliefs and Concerns about ART
• Identify and address practical barriers to ART uptake and adherence

4 tailored treatment support sessions delivered by a Research Nurse (RN) utilizing a collaborative Cognitive Behavioural Therapy (CBT) and Motivational Interviewing (MI) approach
A Systematic Review of Nurse-Led Antiretroviral Medication Adherence Intervention Trials: How Nurses Have Advanced the Science

Lambert, Crystal Chapman PhD, CRNP, ACRNP; Galland, Brooke BS; Enriquez, Marthe PhD, APRN, FAAN; Reynolds, Nancy R. PhD, RN, ANP, FAAN

Author Information

Journal of the Association of Nurses in AIDS Care: May-June 2021 - Volume 32 - Issue 3 - p 367-372
doi:10.1097/JAN.0000000000000247

Abstract

Antiretroviral therapy (ART) is essential to achieving viral suppression and improving health and clinical outcomes in persons living with HIV. Despite the effectiveness of ART and many promising evidence-based ART adherence interventions, viral suppression rates continue to be less than optimal. Nurses play pivotal roles in HIV care management, yet their role in the development and delivery of evidence-based adherence interventions has received little attention. Therefore, this review examined the contributions of nurses to ART adherence research and delivery. We found that nurse-led and nurse-facilitated interventions can be effective in fostering ART adherence in persons living with HIV. Considering the role nurses play in HIV care management and the effectiveness of interventions involving nurses, more nurse-led and nurse-facilitated interventions to address ART adherence are indicated. However, there is a need for further research to examine multilevel interventions and comparative cost and effectiveness of nurse-delivered ART interventions with other forms of delivery.
A Systematic Review of Nurse-Led Antiretroviral Medication Adherence Intervention Trials: How Nurses Have Advanced the Science

Lambert, Crystal Chapman; Galland, Brooke; Enriquez, Maithe; Reynolds, Nancy R. Journal of the Association of Nurses in AIDS Care 32(3):347-372, May-June 2021. doi: 10.1097/JNC.0000000000000247

Flow diagram of inclusion and exclusion of publications
Key characteristics of studies reviewed:

- Study samples that ranged in size from 20 to 2,172
- Most (12/23) were conducted in the United States. Other study sites in: China, Estonia, Kenya, the Netherlands, and Tanzania
- Most of the studies tested interventions that were delivered at the individual level exclusively (21/23)
- All but one study (Sarna et al., 2008) used a form of cognitive behavioral therapy or motivational interviewing and provision of information to build knowledge, motivation, and skills (e.g., problem solving) to enhance adherence behavior
- The interventions varied in length as well as frequency of delivery

doi: 10.1097/JNC.0000000000000247
Key characteristics of studies reviewed:

- Each of the interventions was delivered in full, or in part, by a nurse
- Most studies did not report why a nurse was used for delivery of the intervention
- Most of the studies did not identify what level of educational preparation the nurse had or whether the nurse was expected to bring a certain set of competencies to the delivery of the intervention

Key observations of studies reviewed:

- Results suggest that nurses can provide effective delivery of cognitive behavioral ART adherence intervention content.
- The nurse-delivered interventions had a positive effect on adherence or HIV viral outcomes or both.
- HOWEVER, a great deal of heterogeneity of study designs and methodologies. As such, it is difficult to assess whether the variance in the nurse-delivered adherence intervention study outcomes is due to the intervention content, the target population, characteristics of the nurse interventionist, or the measurements and analytic approach used.
- Few of the studies addressed cost, and none of the studies compared delivery of the intervention by a nurse with another type of provider or different levels of nurse preparation.

Conclusions

- Adherence to antiretroviral therapy is essential to achieve optimal HIV health outcomes, yet continues to be a significant unmet challenge for optimizing patient outcomes.
- Nurse-delivered cognitive behavioral interventions can be an effective and practical.
- In general, nurses are underutilized. Nurses comprise nearly half of the health care workforce, yet only a small number of ART adherence trials have used nurses as interventionists.
- Nurses are well-positioned to deliver and lead cognitive-behavioral medication adherence interventions integral to routine clinical care.
- There is a need for more research to examine the comparative effectiveness of intervention approaches and cost benefits.
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September 15-16, 2022 • Virtual