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Enhancing HIV Outcomes: Nurse-Delivered Cognitive-Behavioral Interventions

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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 problemsolving



Cognitive Behavioral Interventions as applied in context of HIV

- Improve self-care/self-management
- Adherence to antiretroviral medication/PrEP
- Smoking cessation
- Substance use

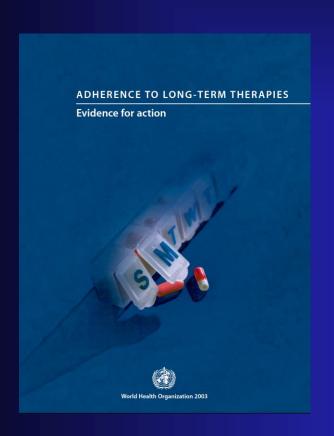


People living with HIV often face challenges in achieving adequate adherence to their medications

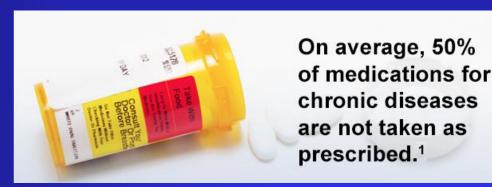




Poor adherence to treatment of chronic illnesses is a worldwide problem of striking magnitude



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



World Health Organization. (2003). Adherence to long-term therapies: evidence for action. World Health Organization https://apps.who.int/iris/handle/10665/42682



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"

World Health Organization. (2003). Adherence to long-term therapies: evidence for action. World Health Organization. https://apps.who.int/iris/handle/10665/42682

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

Reynolds, Current HIV Research, 2004; Langebeek et al. BMC Medicine 2014, 12:142; WHO, 2013



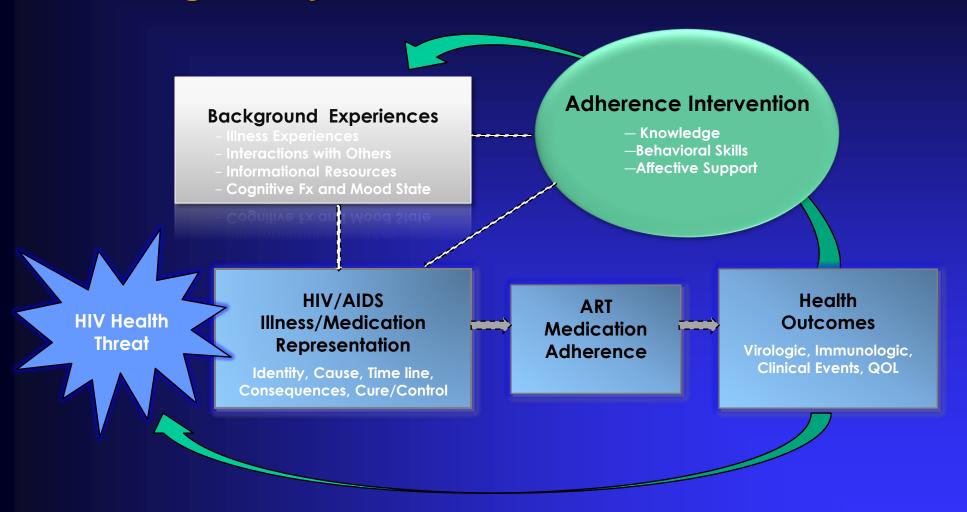
Strategies for Enhancing Adherence

- 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

Self-Regulatory Model of ART Adherence



Reynolds, N.R. (2003). The problem of antiretroviral adherence: a self-regulatory model for intervention. <u>AIDS Care, 15, 117-124.</u>

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

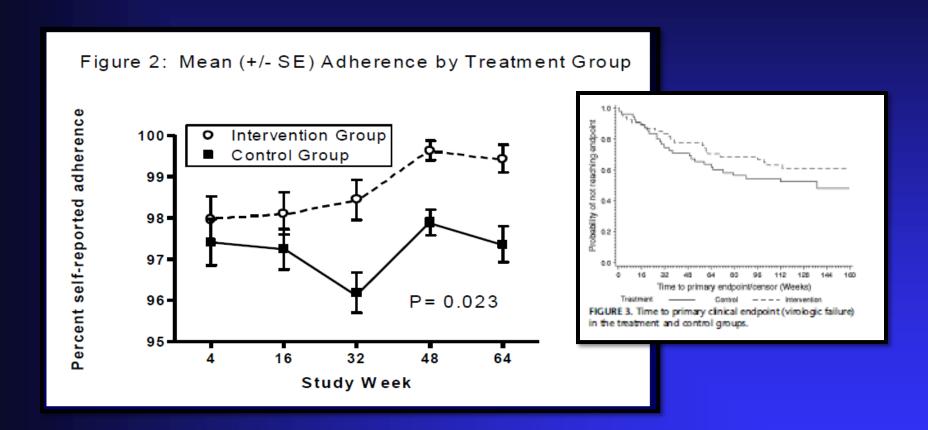
Individualized, delivered over time



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?"

ACTG 731 Telephone support to improve ART medication adherence intervention: A multi-site RCT



A better overall treatment effect was observed in the treated (telephone group) (p = 0.023) in comparison with standard care

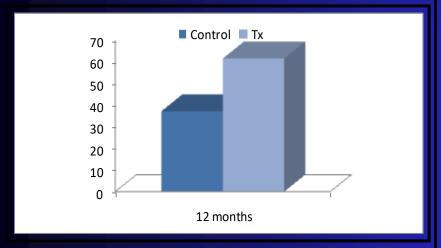


Nurse-delivered telephone intervention to Ohio and Illinois ADAP participants

R01 NR05108

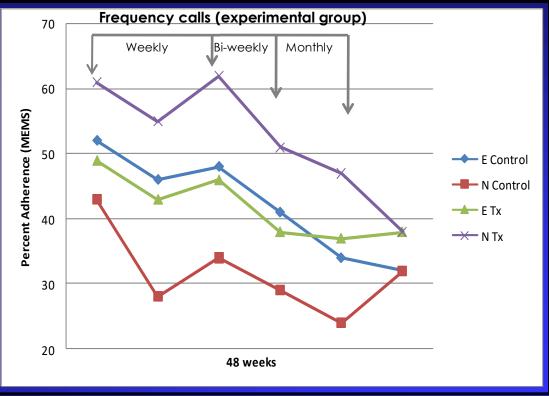
Percent adherence (MEMS) in treatmentnaïve and treatment-experienced subjects

Percent with Undetectable HIV-1 RNA



 $P \le 0.05$

* 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

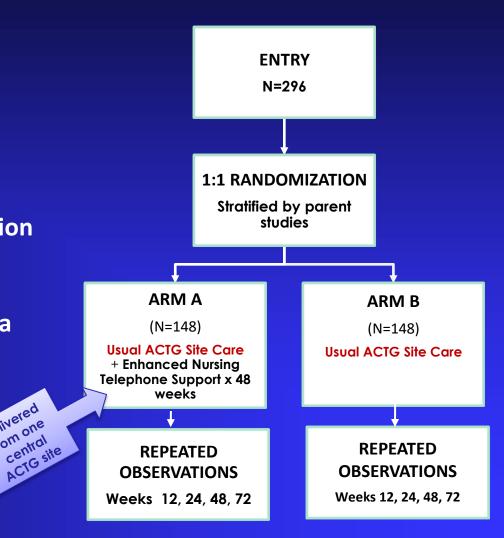
from one central

Purpose:

To test an enhanced version of the phone intervention.

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

A5251





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 Represenation (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.

Robbins et al. (2016) Characteristics associated with virologic failure in high-risk HIV-positive participants with prior failure: a post hoc analysis of ACTG 5251. HIV Clinical Trials, 17, 165-1172.

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-Pls)

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.

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Specific Aims

- To adapt a theoretically-driven, empricallysupported intervention protocol to the cultural and social context of women living with HIV and mental health risk facrors and clinic delivery sites in India
- 2. To implement a pilot study to assess the feasibility, acceptability and safety of the adapted intervention and <u>explore</u> 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 <u>not to receive</u> 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?

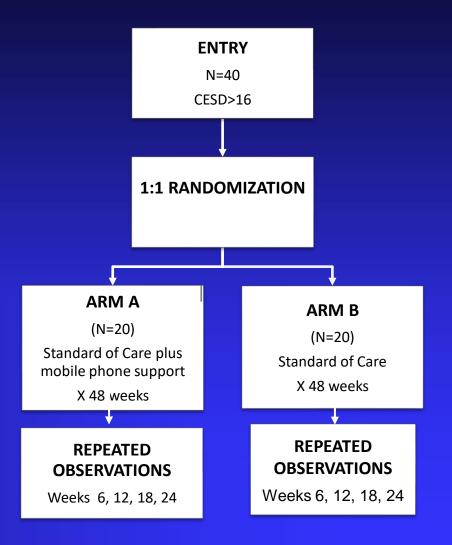
R: "My husband doesn't behave properly there are always fights....lately I have thought of ending my life. We fight a lot now days, I don't want this life.... I wonder what mistake I made! "

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 weeksdelivery)

The key components of this integrated care intervention are:

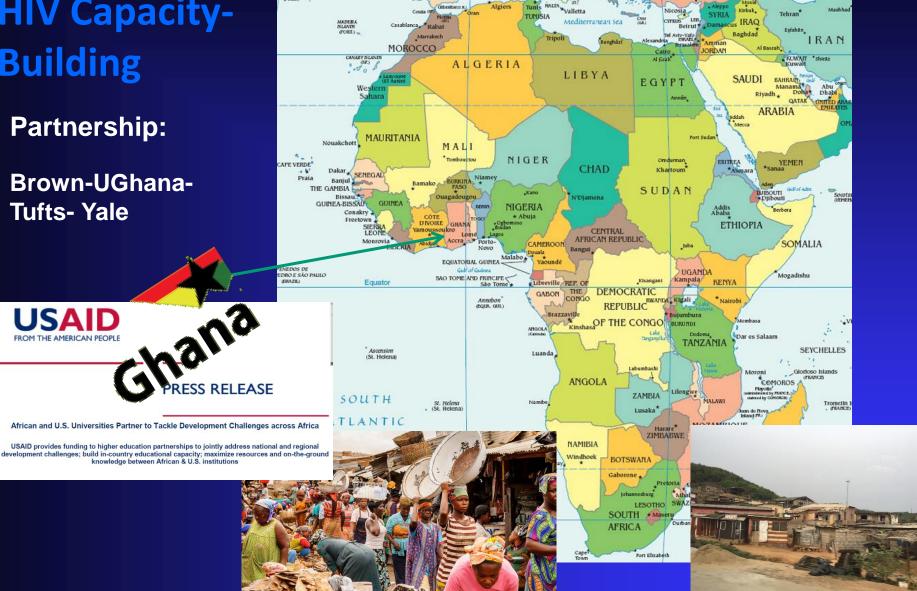
- (1) providing the patient with an individualized program that is congruent with patients' social and cultural context;
- (2) integrate depression screening and HIV treatment and adherence in the context of perinatal care,
- (3) Facilitate proactive problem solving to aid participants in overcoming 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



A bioecological pediatric HIV disclosure intervention in Ghana - "SANKOFA" NICHD, R01HD074253, Paintsil/Reynolds co-Pls)



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



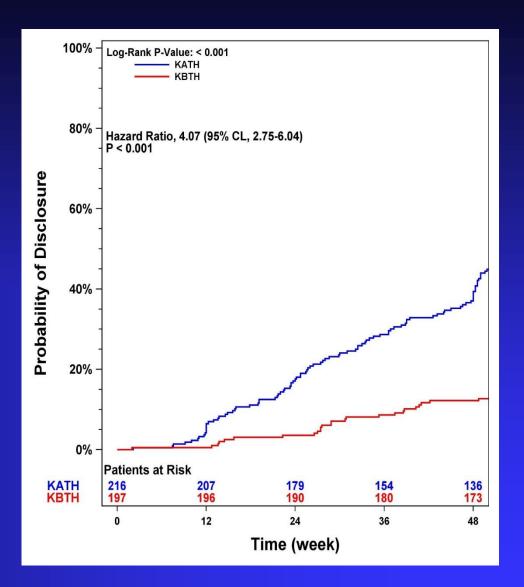


- Interdisciplinary bi-national team with policymakers
- Theory-guided cognitive-behavioral intervention adapted by focus group interviews and socio-cultural context
- Makes use of available resources. Intervention is multi-level, customizable, sustainable

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-Pls

- 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





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....Other nurse-delivered cognitive-behavioral interventions

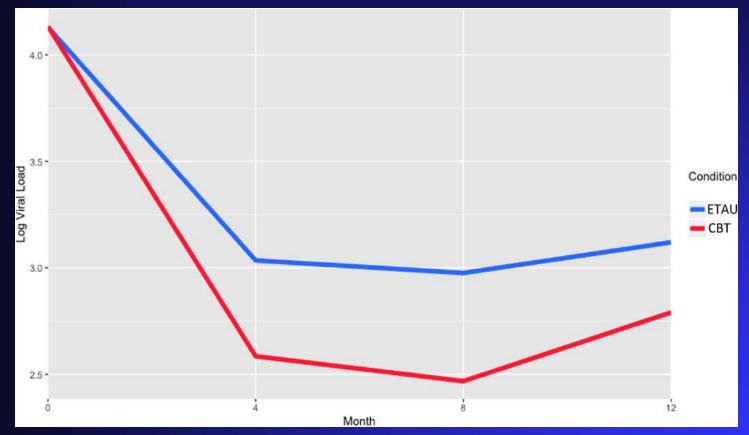




"Life-Steps" Safren et al.

- 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)



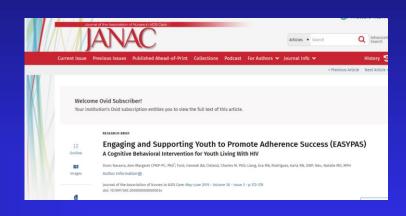
Log HIV viral load

Journal of the International AIDS Society, Volume: 24, Issue: 10, First published: 28 October 2021, DOI: (10.1002/jia2.25823)

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 selfmanagement 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

BMC Public Health

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Study protocol | Open Access | Published: 08 July 2019

Protocol of a two arm randomised, multi-centre, 12month controlled trial: evaluating the impact of a Cognitive Behavioural Therapy (CBT)-based intervention Supporting UPtake and Adherence to antiretrovirals (SUPA) in adults with HIV

R. Home $\stackrel{[S]}{=}$, E. Glendinning, K. King, T. Chalder, C. Sabin, A. S. Walker, L. J. Campbell, I. Mosweu, J. Anderson, S. Collins, R. Jopling, P. McCrone, H. Leake Date, S. Michie, M. Nelson, N. Perry, J. A. Smith, W. Sseruma & V. Cooper On behalf of the SUPA Group

<u>BMC Public Health</u> 19, Article number: 905 (2019) | <u>Cite this article</u> 1810 Accesses | 2 Citations | 1 Altmetric | Metrics

Abstract

Background

Delay to start antiretroviral therapy (ART) and nonadherence compromise the health and wellbeing of people living with HIV (PLWH), raise the cost of care and increase risk of transmission to sexual partners. To date, interventions to improve adherence to ART have had limited success, perhaps because they have failed to systematically elicit and address both perceptual and practical barriers to adherence. The primary aim of this study is to determine the efficacy of the Supporting UPtake and Adherence (SUPA) intervention.

Methods

This study comprises 2 phases. Phase 1 is an observational cohort study, in which PLWH who are ART naïve and recommended to take ART by their clinician complete a questionnaire assessing their beliefs about ART over 12 months. Phase 2 is a randomised controlled trial (RCT) nested within the observational cohort study to investigate the effectiveness of the SUPA intervention on adherence to ART. PLWH at risk of nonadherence (based on their beliefs about ART) will be recruited and randomised 1:1 to the intervention (SUPA intervention + usual care) and control (usual care) arms. The SUPA intervention involves 4 tailored treatment support sessions delivered by a Research Nurse utilising a collaborative

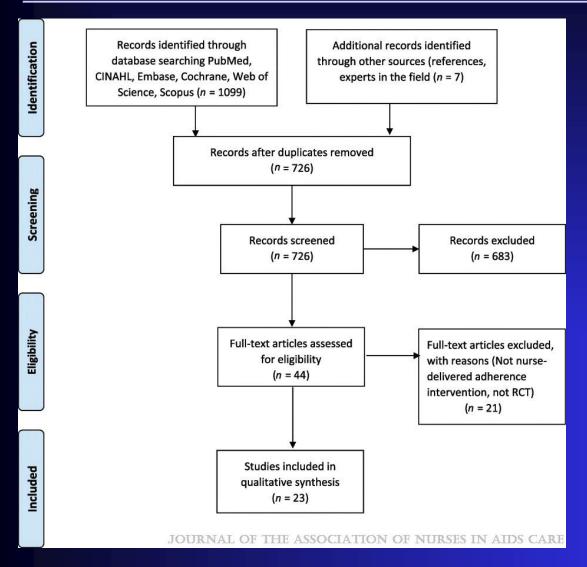
bmj.n1105.full (2).pdf



bmj.n1105.full (1).pdf



A Systematic Review of Nurse-Led Antiretroviral Medication Adherence Intervention Trials: How Nurses Have Advanced the Science



Flow diagram of inclusion and exclusion of publications

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

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

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

Lambert et al. Journal of the Association of Nurses in AIDS Care 32(3):347-372, May-June 2021

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 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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