The TENDAI Study:

Treatment for depression and adherence to ART in people living with HIV in Harare, Zimbabwe

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Overview

- HIV, depression, and non-adherence in sub-Saharan Africa

- Cognitive-behavioral interventions for ART adherence and depression

- Methods and preliminary results of a feasibility study in Harare
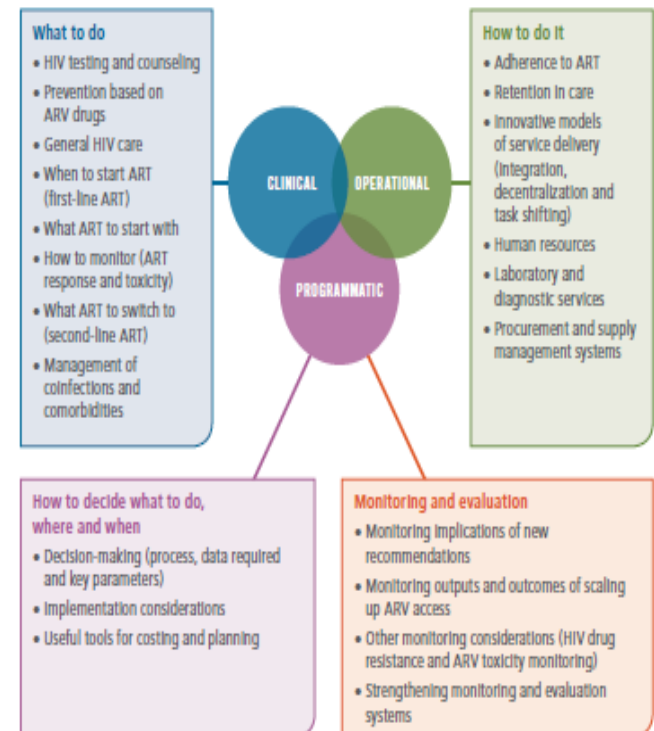
BACKGROUND

- Infections in Sub-Saharan Africa account for 2/3 of the world's total (WHO 2014)

- Average rate of reporting =>90% adherence is 67% in low income countries (Ortego 2011)

- Lifetime prevalence of common mental disorders, including depression, is 22% in low income countries (Steel et al 2014). Depression significantly associated with non-adherence in LIC (Chibanda et al 2014)

- Cognitive-behavioral interventions can improve both adherence & mental health for people on ART with co-morbid depression

- But, lack of research on adapting such interventions for use in Sub-Saharan Africa. Any innovation must have potential for scale-up

Interventions for ART adherence (WHO, 2013)

- Program level approaches: decentralise care to community-based delivery models, reduce costs for patients, simplify regimens and ensure drug supply.

- Individual level approaches: SMS, real time monitoring, peer support, treating comorbid mental disorders, psychosocial support,

- Nothing on motivational and PST interventions

Fig. 1.1 Components of the consolidated guidelines

What to do
- HIV testing and counseling
- Prevention based on ARV drugs
- General HIV care
- When to start ART (first-line ART)
- What ART to start with
- How to monitor (ART response and toxicity)
- What ART to switch to (second-line ART)
- Management of coinfections and comorbidities

How to do it
- Adherence to ART
- Retention in care
- Innovative models of service delivery (integration, decentralization and task shifting)
- Human resources
- Laboratory and diagnostic services
- Procurement and supply management systems

CLINICAL   OPERATIONAL   PROGRAMMATIC

How to decide what to do, where and when
- Decision-making (process, data required and key parameters)
- Implementation considerations
- Useful tools for costing and planning

Monitoring and evaluation
- Monitoring implications of new recommendations
- Monitoring outputs and outcomes of scaling up ARV access
- Other monitoring considerations (HIV drug resistance and ARV toxicity monitoring)
- Strengthening monitoring and evaluation systems

AIMS OF THE STUDY

- Select and adapt an evidence-based intervention for adherence and depression in people living with HIV (PLWH) at risk of treatment failure

- Test the feasibility and acceptability of the intervention

The Intervention: New Direction ("Nzira Itsva")

- Used Life-Steps, evidenced-based cognitive behavioral intervention (CBI) to improve ART adherence (Safren et al 2001, 2009).

- Adapted for local Zimbabwean adult population:

    - Qualitative work to understand barriers to adherence; included cultural factors that influence access to HIV care & adherence; added locally relevant phrases, metaphors, visual aids & illustrations

    - Main barriers identified: getting to clinic, talking to doctor, coping with side effects, getting & storing medication, financial constraints, marital problems, forgetting, depressive rumination,
    nature of job, stigma, comprehension

New Direction Structure

- Set the agenda
- Identify motivation for taking medication
- Review 2-week adherence
- Identify goal for adherence
- Psycho-education, information on HIV and ART using video
- Problem solving
  - Identify barriers to adherence
  - Identify a plan to overcome barriers
- 5 minutes on other issues e.g. unprotected sex
- Sessions 2 – 4 boosters

Differences from Life-Steps approach

- Language

- Greater number of sessions

- Use of an educational video

- Cadre of the interventionist

- Culturally-competent probes

- Integrated with stepped care for depression based on problem-solving therapy (not CBT)
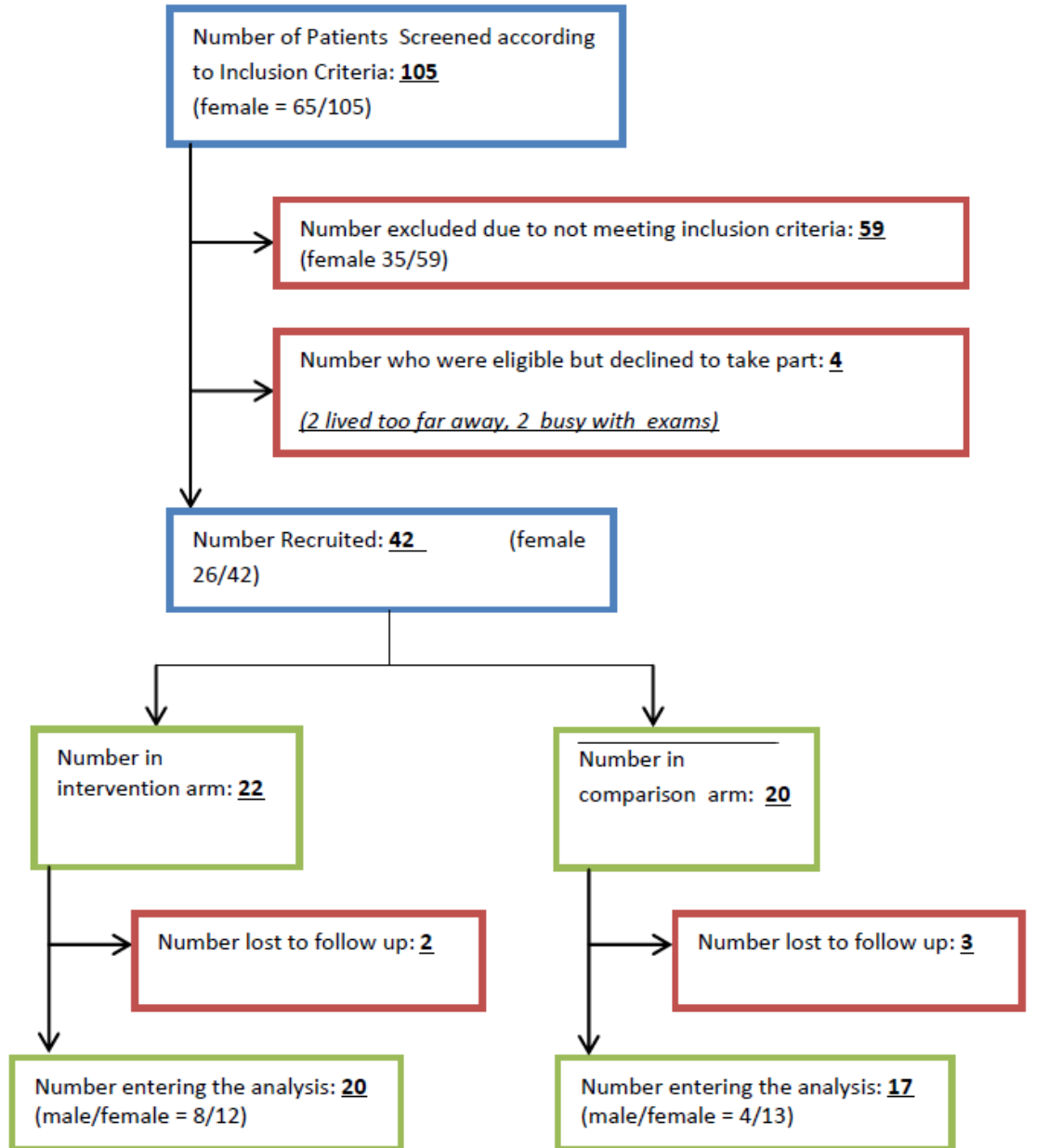
Feasibility study

Inclusion Criteria:

- 18 years of age or above

- On antiretroviral therapy for at least 4 months – pharmacy records

- Score above cut-point for depression on a locally validated scale for depression

- Indicator of poor adherence via any one of: 1) missed clinic appointments; 2) falling CD4 count; 3) self-reported adherence problems; 4) detectable viral load

Some preliminary results

Recruitment & randomisation

- Various methods were used to recruit patients
  - referrals from doctors and other clinical staff most effective

- Out of 105 participants screened, 44% were eligible for the trial, 91% of which consented to take part.
  - recruitment took place over a period of 29 weeks

- The process of randomisation appeared to be highly acceptable to patients, as all eligible patients were willing to be randomised.

Baseline characteristics

	N (%)	mean (sd)
Age (years)		39.2 (11.2)
Gender		
female	13 (59.1)	
male	9 (40.9)	
Marital Status		
married	11 (50.0)	
single	6 (27.3)	
widowed	5 (22.7)	
Highest Education		
pre-primary	0	
primary school	5 (22.7)	
secondary school	16 (72.7)	
high school	1 (4.6)	
tertiary	0	
Time on ART (years)		5.0 (2.9)
ART regimen		
first line	18 (81.8)	
second line	4 (18.2)	

Counsellor fidelity

	N	Mean fidelity rating
Baseline	4	8/18
After additional 2 days training in Shona	4	14/18
After supervised practice on 6 cases	4	17/18

*Spot checks found scores remained at a mean of 17/18 across 6-month period

Session Attendance

Number of sessions completed	N (%)
1	2 (9.1)
5	2 (9.1)
6	18 (81.8)

* Of those who attended 5 or 6 sessions, took a mean of 8.3 weeks (mean) after baseline visit to complete

Outcomes

Depression

Measure	N	Number of participants scoring above cut-point (%)	
		Baseline	Follow-up
Depression Scale (PHQ-9)	13	13 (100)	0 (0)
Local Scale for common mental disorders (SSQ)	20	13 (65)	1 (5)

Electronic Adherence (n=18)

Measure	Number of participants with good adherence (>=90%) N (%)	
	Baseline	Follow-up
Electronic adherence (corrected)	13 (72.2)	16 (88.9)

Self-report adherence*:* Fall in reporting a missed dose in the last month from 6/20 (30%) to 2/20 (10%).

'Depression' : Mean PHQ-9 fell from 13.5 (SD 2.6) to 3.4 (SD 3.3).

Conclusion

- CBI intervention appears to be feasible and acceptable

- Promising impact on pill-taking and depression in those with adherence problems.

- Robust evaluation is needed to evaluate efficacy in public ART facilities in Zimbabwe.

Key Tendai references

- Kidia, K et al (2015). "I was thinking too much": Experiences of HIV-positive adults with common mental disorders and poor adherence to antiretroviral therapy in Zimbabwe. Tropical Medicine & International Health, 20(7).

- Bere, T et al (under review) Cultural adaptation of a cognitive-behavioural intervention to improve adherence to antiretroviral therapy among people living with HIV/AIDS in Zimbabwe: "Nzira Itsva".

- Chibanda, D. et al. (2014). Mental, neurological, and substance use disorders in people living with HIV/AIDS in low- and middle-income countries. JAIDS, (67 Suppl 1), S54-67.

Points for discussion

- Distress or depression/ measurement?

- How best to measure of adherence?

- Efficacy or effectiveness trial? – or both?

Acknowledgements