

Depression And HIV/TB In Southern Africa: A Mixed Method Evaluation of An Integrated Primary Care Mental Health Programme In Eswatini

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Abstract

Background: Depression and comorbidity with chronic illnesses is common in Southern Africa, yet there are major treatment gaps. This study evaluates the intervention 'Healthy Activity Program' to bridge this gap, which involves training non-specialist nurses in depression: including identification, counselling based on behavioural activation theory and structured referral. This intervention aims to be integrated into routine primary healthcare services for HIV/TB. The patient cohort were people living with HIV and/or tuberculosis (TB) (PLHIV/TB) in rural Eswatini.

Aims: To assess the feasibility and acceptability of this intervention and concepts of depression in this setting.

Methods: This is a pragmatic mixed methods evaluation of a pilot integrated service.

Results: 324 PLHIV/TB were screened for depression, with 19% (62/324) screening positive. Attendance to counselling declined over time, with 16/62 attending the minimum 5 sessions. Qualitative results indicated acceptability, yet concerns around feasibility.

Conclusions: The 'Healthy Activity Program' represents a promising option to manage the treatment gap for depression in PLHIV/TB. However, task-shifting onto non-specialist healthcare professionals with the aim to integrate care for these conditions in primary care, without increasing staff capacity, is a barrier to implementation. Realistic and pragmatic assessments of capacity and workforce are essential.

Background

Depression is the most common mental health condition worldwide, including in Sub-Saharan Africa (SSA) (1). Estimated prevalence of mental disorders in low- and middle-income countries (LMIC) is high, yet data is scanty and mental health systems limited and under-resourced (2–4). WHO's Mental Health Gap Action Programme (mhGAP) outlines the majority of people living with mental health conditions in LMIC do not have access to psychological care (5). Providing basic care for depression in non-specialist primary care is a global priority (6,7). Evidence about how best to provide this is scarce from Africa (8).

HIV and TB have a profound impact on health in SSA. Approximately 800,000 new HIV infections were diagnosed in 2017 in Eastern/Southern Africa, bringing the total population living with HIV (PLHIV) in this region to an estimated 20.6 million (UNAIDS, 2018). 2018 TB incidence in the WHO Africa Region was 2.4 million (WHO, n.d.). 72% of global HIV/TB co-infections occur there (11).

HIV/TB are risk factors for depression/anxiety (12,13). An estimated over one-third of PLHIV in SSA live with depression (13,14). Stigma and discrimination, family life and financial impacts intersect with sequelae of disease and treatment, posing substantial risks to mental health (13,15). These mental health conditions are poorly recognised and vastly under-treated (12,13,16,17). Good quality integrated

care is key, with the potential to improve both mental health outcomes and HIV/TB treatment adherence (18,19).

Eswatini is a small country in southern Africa, with a population of around 1 million(20). The Lubombo region is predominately rural with poverty prevalent. Despite middle-income status, Eswatini is an economically unequal country, with over 60% of the population living below the national poverty line (21,22). It has one of the highest HIV rates in the world at 27.4% of adults, with the highest rates in Lubombo (23,24). TB rates are high, with over 4200 new cases reported nationally in 2017, an estimated 70% in PLHIV (25). Public mental health care is centralised in Eswatini, with 1 psychiatrist and (at the time of study) 2 psychologists working in 1 public National Psychiatric Referral Hospital, too far and expensive to travel for many, especially from rural Lubombo. The gap in basic mental health care nationally, while not recorded, is significant.

This study aims to assess whether the 'Healthy Activity Program' (HAP), a psychological intervention developed in India (26,27), can be feasibly delivered to PLHIV/TB with depression within the existing primary healthcare system in Lubombo. It seeks to explore acceptability amongst healthcare workers and patients. This study contributes to filling the gap in knowledge of mental health intervention delivery in resource-poor settings.

Methods

This study evaluated a modified version of an evidence-based (by randomised controlled trial) intervention (26,27). The intervention involves training non-specialist primary healthcare staff in the identification of depression and, for those identified as having depression, using a structured manual-assisted counselling based on Behavioural Activation Theory +/- referral for further care. Counselling consisted 30-60 minutes 1:1 sessions in the clinic with activity 'homework' between sessions. Key modifications from the original study were (1) reduce counsellor's manual size; (2) omit patient manual (replacing vital content with handouts) (3) modify Indian-specific content (4) change counselling intervals from weekly to fortnightly. Modifications were made in recognition of capacity of nurse counsellors and patients, including limited literacy in the latter group, and were reviewed by individuals involved in the original study. The intervention, including participants, setting and process is further described in **Table 1**, using 'Template for Intervention Description and Replication' (TiDier) guidelines (28).

Table 1 – TiDier table for the 'Healthy Activity Program' Intervention

Number	Title
	Summary
1.	Contextualised and structured intervention package ('Healthy Activity Programme') for depression management in primary care, including screening, identification, counselling and referral. The counselling was adapted from behavioural activation theory, a psychological method advocated in the WHO's mhGAP. Further information is available on request.
2.	<p>WHY</p> <p>Task-shifting mental health interventions to non-specialist healthcare workers is recognised to be key to managing the gap in mental health care provision (1). The HAP model was developed to be delivered in non-specialist primary healthcare. In Eswatini, this was by nurses providing HIV/TB (and other routine) care. This care is predominately provided by nurses in this setting.</p>
3.	<p>WHAT</p> <p>Procedures: A Technical Working Group (TWG) consisting of national stakeholders in HIV/TB and mental health, in addition to the participating nurse counsellors, was convened to assist with the design and delivery of this study. They were held regularly throughout the study period. A modified form of the HAP, with shorter treatment duration (see main text methods section for modifications), was developed to be suitable and feasible for the local context, where it was conducted by clinic nurses.</p> <p>Training: A 7-day training package was delivered over two weeks. The first week involved four days of training[1] provided by a team from the Eswatini Psychiatric Team in the national Mental Health Desk Guide, a pre-existing resource outlining a standard approach to the management of mental health conditions in Eswatini, provided for participating nurses not already trained on this. Thereafter, all participating nurses received three days of practical training in HAP delivery. 16 nurses and 2 nursing assistants were trained. Feedback from training, including, in this setting seldomly-used role play, was overwhelmingly positive.</p> <p>Materials: The contextualised HAP manuals and National Mental Health Desk Guides were provided at training. In addition, the following resources were available: patient-held record cards; clinic record cards; activity record calendars and plans (to support patients to monitor their 'health activities'); paper 'Patient Health Questionnaire' (PHQ)-9 forms in English and SiSwati (to screen and monitor depression); study protocol summaries for stakeholders; '8 healthy activity' posters for clinic walls). All are available in here: https://comdis-hsd.leeds.ac.uk/resources/tools-tips-and-guides/. All resources were reviewed with stakeholders prior to the intervention being delivered. These resources were accompanied by protocols to indicate when and how participating counsellors were expected to refer complex clients.</p>
4.	<p>WHO</p> <p>Participants: (eligibility criteria) All patients >18y presenting for routine HIV or TB follow-up to any of the participating sites (see under 'where') were eligible for the study. Patients currently undergoing treatment for mental health problems and pregnant patients were excluded.</p> <p>Screeners: Additional staff in clinics of differing cadres, including expert clients and nursing assistants, received ad-hoc brief training from the research assistant during clinics visits, to support the nurse-counsellors to routinely screen patients using the PHQ-9</p>

Counsellors: Participating nurses attended 2 training sessions (See under 'what'). All nurses were working in community or hospital TB/HIV clinics (see under 'where') and had varying degrees of nursing experience. A minority had any previous mental health experience or training (either in nursing college or in post-qualification in-service training). All nurses maintained their usual duties during this pilot (i.e. counselling was additional to this). Nurses that received HAP training and provided counselling are referred to as 'counsellors' or 'nurse counsellors' in this text going forward.

Monitoring and Mentoring: Data collection, monitoring of progress or issues and mentoring was provided by a fulltime research assistant (with community psychology background) employed for this pilot

Supervision: Routine remote supervision of the nurse counsellors was planned with a clinical psychologist initially working at the National Psychiatric Referral Hospital that could be contacted directly to discuss any complex patients.

Doctors (referrals directed to local doctors): Doctors involved in this study would have received the standard non-mental health specialist medical training and were working in the regional referral hospital (with no specialist mental healthcare). Any further mental health education was not recorded and is highly variable.

Trainers: Training was provided by the national lead (and sole) psychiatrist (senior medical officer), senior nurse (matron) and a psychologist working in the National Psychiatric Referral Hospital, a public health doctor (in-country research lead) and the research assistant.

5. *HOW*

Screening: Patients were screened using the PHQ-9 tool to identify depression. This tool was chosen as it was already being advised by the national HIV programme and it had been validated in broadly comparable areas of South Africa, although not in Eswatini (Bhana, et al 2015). It was translated into SiSwati. Where possible, patients were encouraged to self-administer. Additional staff members at the participating sites were trained to consent patients to participate in the study and then administer the PHQ-9 in addition to capturing basic demographic information. Consistent with the National Mental Health Desk Guide, it was agreed that patients exceeding a PHQ-9 threshold of 10 would be eligible for HAP and that those scoring 15+ or reporting suicidal thoughts would be referred for a review by a doctor to consider antidepressants, in addition to HAP.

Treatment: Patients who screened positive were invited to receive a course of HAP counselling, a brief psychological intervention based on 'behavioural activation', the psychological theory that espouses that mood will improve if rewarding activities are undertaken. The counselling should follow three phases: 'getting to know the patient' (1-2 sessions), 'encouraging activities' (3-5 sessions) and 'ending well' (1 session). 5-8 sessions were advised, each session 30-60minutes. Where possible, patients were encouraged to attend the first appointment on the day of the positive screen, or else they were invited to reattend soon after. In order to build a therapeutic relationship, each patient received a course of HAP from the same counsellor. Follow-up appointments and appropriate 'homework' tasks for the patient to complete were agreed at the end of each session. Initially, we planned that sessions be at least every two weeks. Patients were re-screened using PHQ-9 at the beginning of each appointment. Those with high scores or suicidal thoughts (PHQ>15 or Q9 positive) would be referred to see a doctor. Once the score had fallen <10 for two consecutive appointments, patients could be discharged, provided they had completed at least five sessions. Patients would not be provided with financial assistance to attend appointments.

Referrals: Referrals were to the regional referral hospital (Good Shepherd Hospital) general outpatient's department, where patients would be seen by a non-specialist doctor. This followed routine care and procedures for referrals from clinics to doctors. These doctors

would either see and discharge or, if required refer to their mental health clinic, staffed by a prescribing psychiatric nurse, or to the National Psychiatric Referral Hospital.

6. WHERE

8 sites in the Lubombo region of Eswatini were pragmatically and purposefully selected to participate. These were selected by the regional health office (decentralised Ministry of Health team). This was due to nurse training or availability to attend training and to include the regional hospital and a geographical spread of health centres and including different management and funding models - Governmental, Private and Faith-based. The intervention was offered in 7 of the 8 sites: 5 rural clinics and 3 urban^[2] sites: 1 clinic and 2 within the regional referral hospital (Good Shepherd Hospital, in its HIV/TB clinics).

7. WHEN and HOW MUCH

The target was to screen all patients attending HIV/TB clinic in all capacitated clinics (i.e. those with at least one HAP trained nurse). Thereafter all screened, consenting patients were to be offered 5-8 sessions of counselling, at 2-weekly intervals. Sessions should last approx. 30 minutes, in a 3-phased structure.

8. TAILORING

All counselling sessions were tailored to the individual, as per standard behavioural therapies. Depending on response and patient choice, the sessions could be terminated from session 5.

9. MODIFICATIONS

Screening was not carried out systematically – see results. All eligible patients initially consented to counselling, but not all attended – see results. In initial stages of the intervention, it was recognised that sessions every two weeks (as originally planned) was not feasible for patients, so this was changed to monthly sessions.

One unwell and poorly compliant patient was provided with basic travel expenses at the request of her Counsellor.

Supervision with the Clinical Psychologist was not well used, and the routine schedule dropped after only a few weeks, deferring to ad-hoc supervision when needed. The reasons behind this are not fully clear, and are likely a combination of nurse counsellor workload, unclear chains of command and a lack of clarity on what should be escalated. This is discussed more fully under 'limitations'.

Fidelity to these intervention protocols was monitored during regular monitoring visits by the research assistant (initially every 2 weeks, moved to every 4 mid-way through the pilot due to challenges in travel to remote rural clinics). Fidelity to intervention content (i.e. in counselling) was assessed only in initial sessions and not with all counsellors (due to logistical issues) and, while not formally graded, was deemed by the research assistant to be sufficiently adherent to our guidance.

This pragmatic pilot assesses the feasibility of adherence to this guidance as part of its evaluation, and therefore this is further discussed in the results section of the main text.

^[2] Lubombo is a predominately rural region, by 'urban' we are referring to the main town, Siteki, which has an estimated population of 6000.

This is a mixed-methods study. Basic quantitative service data on attendance, demographics and PHQ-9 scores was recorded and analysed using descriptive statistics (percentage, mean, median) on Microsoft Excel by the 2 lead authors. See table 2 for demographic data collected. Data was collected using bespoke tools developed for this study. These were purposefully developed to align with HIV care notes, in that each counsellor and each patient received a short paper form (detailing attendance/appointments, PHQ-9, counselling duration and notes, co-morbidity and demographics), kept in facility and by the patient respectively. The research assistant periodically collected the above data in person from the facility-held notes.

Qualitative results were obtained via interviews with 16 patients and 6 nurse counsellors, purposively sampled to ensure diversity of characteristics including gender, treatment site and, for patients, PHQ-9 score. Patient participants were approached initially by their counsellor, using a convenience sample, with no inclusion/exclusion criteria other than being eligible for the intervention. Nurse counsellors, again using a convenience sample, were approached by the research assistant during routine study discussions, with the only inclusion/exclusion criteria that they were delivering counselling in this intervention. Interviews were undertaken at healthcare facilities. Patient travel costs were reimbursed (max. E200). Interviews were conducted in English by the research assistant with a siSwati translator. The research team developed semi-structured interview topic guides with a priori themes/codes and suggested probing questions. Counsellor and patient topic guides were similar, both covering interviewee understandings of depression and experience of the study including training (counsellors only), recruitment/screening and counselling. Patients were asked about their medical history, experiences of living with HIV/TB and, if relevant, experience of antidepressants. Interview topic guides were piloted, with minor language changes. Interviews occurred May-August 2018. Interviews lasted 30-60 minutes, were audio-recorded, transcribed and coded by 3 researchers according to the coding framework developed from interview themes. Given the similarity of counsellor and patient topic guides, main codes were the same for both groups, although allowances were made for sub-codes differing by group. All coded texts were checked independently by the in-country lead researcher. A framework analysis approach (29) was used and a matrix developed with all coded texts under each theme per participant. The data under each theme was synthesised by two researchers, again independently checked by the lead researcher. All processes were discussed by this team to increase process validity and reliability.

Data management and ethics

All participants gave informed, signed consent. Identifiable information was kept in a locked cabinet. Each participant was allocated a unique number, linked to their name on the consent form, allowing study withdrawal. Digital information was held on password-protected laptops.

Results

Quantitative

Data was collected for 9 months of follow-up: March–October 2018. In March-April, 324 patients receiving either antiretrovirals or TB medication were screened using the PHQ-9 at 8 sites across Lubombo. 1 site withdrew early due to staffing issues. At all sites routine screening was encouraged and advice given on managing practical/logistical barriers, however in practice screening was ad-hoc, depending on staff capacity, availability and engagement. 62 patients screened positive (PHQ-9 ≥ 10), indicating a depression prevalence in this sample of approximately 19% (62/324). Patient variables are shown in **table 2**.

Table 2 Demographics and Basic Information of all patients screened and those screened positive (i.e. PHQ-9 ≥ 10). Percentages are given based on recorded data (i.e. excluded missing records) for each variable. Percentages are not given when denominator <100 .

Variable	Screened n (% of total recorded data)	Screened positive n (% prevalence, apart from age, where range is given). Prevalence is not given if total screened <100
Total	324	62
Gender	Recorded Data = 304	Recorded Data = 60
Female	199 (65.5%)	46 (23.1%)
Male	105 (34.5%)	14 (13.3%)
Age	Recorded Data = 291	Recorded Data = 59
Median Age (Range)	38 years (18 – 78 years)	36 years (18 – 71 years)
Education Level	Recorded Data = 282	Recorded Data = 60
Primary	145 (51.4%)	35 (24.1%)
Higher	137 (48.6%)	25 (18.2%)
Marital Status	Recorded Data = 300	Recorded Data = 60
Married	136 (45.3%)	22 (16.2%)
Single	131 (43.7%)	30 (22.9%)
Divorced/Separated/Widowed	33 (11%)	8
Employment	Recorded Data = 276	Recorded Data = 60
Yes	115 (41.7%)	13 (11.3%)
No	161 (58.3%)	47 (29.2%)

Diagnosis		
HIV	Recorded Data = 310	Recorded Data = 60
	303 (97.7%)	56 (18.4%)
TB	Recorded Data = 308	Recorded Data = 60
Drug-Sensitive TB	8 (2.6%)	2
Drug-Resistant TB	9 (2.9%)	8

A higher proportion of those diagnosed with depression were women (77%) (note however that overall more women (63%) were screened than men); were not currently employed (78%) and had education up to primary level only (58.3%). 99% screened were PLHIV (93% of those screening positive). The numbers for TB are too small to make any assertions, but 8/9 people screened with drug-resistant TB had moderate-severe depression. 12/17 of those with TB were PLHIV, in line with national findings (25).

All 62 patients were enrolled and accepted counselling. 2 patients were thereafter withdrawn (their site withdrew), thus 60 were offered counselling. The median screening PHQ-9 was 13 (IQR 11-16.75). **Table 3** shows this breakdown. 27 individuals (44%) answered positively to question 9 (Q9), on suicidal ideation. 34 patients (55%) should have been referred as per the guideline (PHQ-9[≥]15 or Q9 positive), yet 13 were recorded as referred (11 to a doctor, with 5 prescribed antidepressants).

Table 3 – Breakdown of PHQ-9 scores on screening

PHQ-9 score	PHQ-9 interpretation	Number of Patients (% of all screened, 324)	Suggested outcome (as per the pilot protocol)
0 - 9	No/Mild depression	262 (80.8%)	Re-screen in 3 months
10 - 14	Moderate depression	41 (12.7%)	Offer HAP Counselling
15 - 19	Moderate/Severe depression	15 (4.6%)	Offer HAP Counselling Refer to doctor
20 +	Severe Depression	6 (1.9%)	Offer HAP counselling Refer urgently to doctor
Question 9 positive	Suicidal Ideation	27 (8.3%)	Refer urgently to doctor

52 patients attended at least 1 counselling session. Attendance dropped over time (**figure 1**). PHQ-9 was filled at each session and, of those attending, median and range PHQ-9 scores decreased over time (**figure 2**). The median interval between sessions was 29 days (IQR 24.5-45) (excluding between screening-counselling session 1 (S1) as this was 0 in 87% of patients). Mean session length was 27 mins. The session interval was modified to be monthly (from fortnightly) early in the evaluation to coincide with HIV/TB medication collection and as shorter proved unrealistic due to patient transport, time and finances. The number of patients attending within 4 weeks decreased over time (50% patients attending counselling S2; 60% attending S3; 15% attending S4; 25% attending S5).

Qualitative

Table 4 – Characteristics of Interviewees

Variable	Nurse Counsellors (n=6)		Patients (n=15)	
Gender	Male	2	Male	5
	Female	4	Female	10
Setting (of interview and counselling provision)	Community Clinic	4	Community Clinic	9
	Hospital Clinic	2	Hospital Clinic	6
Baseline PHQ-9 (patients only)	-		10-14	9
			15+	6
Employed (patients only)	-		Employed	1
			Unemployed	15
Diagnosis (patients only)			HIV	11
			TB	0
			HIV and TB	4
Marital Status (patients only)			Married	6
			Unmarried	9

Table 4 shows interviewee characteristics.

9 codes were identified a priori, each comprising 2–7 ‘sub-codes’. An ‘other’ code allowed for emergent themes. All codes are summarised:

1. Intervention Context

1. Understanding depression
2. HIV/TB and depression
3. Existing support and treatment
4. Barriers/facilitators to scale up

2. Intervention Experiences

1. Screening and Diagnosis
2. Referrals and Antidepressant Use
3. Counselling

Interview findings are discussed below using this framework. C1-C6 denotes nurse counsellors, P1-P15 patient responses. Counsellors and patients expressed similar views, albeit often using different terms,

reflecting their joint sociocultural experiences but different levels of medical education. Where views diverged, this is made clear in the text below.

1) Intervention Context

Depression, while often not named (with no direct translation into SiSwati) was recognised by counsellors and patients – both in patients/themselves and in their communities. Multiple factors in this setting, including especially HIV, were recognised to have significant impacts on wellbeing. Despite this, both groups identified few or no prior strategies or management for depression in their settings, reinforcing concerns about a treatment gap. Counsellors identified contextual barriers to scaling up this intervention, including workload, time, travel and availability of complementary services.

Understanding Depression

All interviewees understood depression as affecting mood and function. Counsellors emphasised biological/circumstantial causes whereas patients discussed feelings e.g. hopelessness, *“fail to think straight”* (P10), *“heavy load on my chest”* (P9). Suicide was mentioned by all but 1 counsellor. Patients did not use this term, yet discussed death associated with depression: *“before [counselling] my life span was shortened, but [now] my life span has extended, now I am able to plan for the future”* (P5); *“if it wasn't for the study maybe I would have been dead by now”* (P15).

HIV/TB and Depression

All interviewees discussed the psychological impact of HIV/TB. One counsellor summarised: *“it really destroys the individual, mentally, emotionally, social [sic] and otherwise”* (C6). Patients discussed ostracism: *“my dishes were separated and no-one would touch anything from me, no-one would eat with me, it was a very bad life”* (P6). Social isolation, stigma and family issues were common, including suggestions of abuse (the latter discussed only by female participants) *“he no longer treats me like he used to in the past, probably it's because he knows I am positive...he is abusive”* (P7). A recurrent fear was that people would *know* or find out through medication, side-effects or visible symptoms: *“everyone now knows that [the patient] ha[s] HIV and this makes them depressed”* (C3) This was discussed concerning non-adherence, alongside depression itself: *“you feel weak...sometimes you feel like even not even taking your medication”* (P6).

Existing Support and treatment

All counsellors expressed pre-pilot challenges in managing depression: *“it was so frustrating because you would see that this person has got a problem but you did not have skills...to help them”* (C2). They reported lack of training, protocols and systems: *“we were not given the time and actually the tools to assess their state of mind”* (C3).

Patients expressed concerns around confidentiality and cultural and social norms around discussing mood: *"in my culture it is not allowed to disclose the problems you have in your household with your husband"* (P11); *"I never like to tell people my problems because others tend to judge you...if you tell them your problems they start telling others"* (P4).

Barriers/facilitators to scale up

Overall, by both groups, it was felt this service should be scaled up: *"in the future everyone should get this service...people are dying because of stress out there"* (P15), but that logistics prevent this. Challenges included staff capacity, privacy and space, patients not attending sessions and patient finances affecting healthcare access (travel/time off work). Time was a recurrent issue for counsellors: *"it takes a lot of time for them to go through that process ... patients will be...impatient because they will be wanting to go because they've taken so much time in the clinic going through the process of refilling their medication and now you want to go for a forty minute session of counselling..."* (C1) and patients: *"I'm a seasonal worker so I cannot come every month it might disturb my job"* (P15). Counsellors recommended further task-shifting/increasing workforce capacity, sensitisation and engaging stakeholders and the general public.

Counsellors raised concerns around creating awareness of a condition associated with poverty and/or traumatic experiences, yet lacking appropriate services: *"...[patients] needed financial assistance...we try... but we could not help them"* (C5); *"our clients here [have] problems which are a bit...difficult and HAP doesn't really get into them so deep"* (C1).

2) Intervention Experiences

Counsellors and patients indicate that they found screening, diagnosis and counselling broadly acceptable, albeit with some concerns about the need to repeat PHQ-9 assessment at each session. Counsellors appreciated the clear guidance on when to refer (although referral pathways remain an issue as outlined in the quantitative data and discussed further below).

Screening and Diagnosis

Generally, both counsellors and patients found the PHQ-9 *easy* and *helpful* to identify depression. Patients reported diagnosis as *shock/unexpected* sometimes followed by anticipation: *"it made me have something to live for, it made it clear that there was help on the way"* (P14); *"they gave me hope"* (P15), whereas some struggled: *"I was hiding the feeling...I didn't like them asking me what is wrong, I wanted it to be a secret"* (P4); *"you feel like you are being exposed"* (P6). Counsellors discussed logistical issues including lacking capacity to systematically screen due to workload, lack of space and privacy and issues with language *"most clients felt it's a bit difficult for them even if they were siSwati speakers"* (C1).

Referral

Counsellors responded favorably to the referral guidelines: *"before...we were not really sure when to refer, but after HAP now we can be able to...assess...cases that needs to be referred and cases that you can handle yourself"* (C2), yet reported challenges to monitor whether patients attended, with no mechanism to confirm referral.

Counselling

In both groups there was increased awareness of depression: *"it enlightened us to understand what the patients were going through"* (C3); *"only counselling made me aware, I was not thinking straight"* (P1). Counsellors found counselling fulfilling: *"when you do justice to your client, you also feel happy"* (C3). All patients and three counsellors reported mood improvements. Both patients and counsellors deemed the use of 'behavioural activation' helpful, with patients suggesting activities, however some requiring more sociocultural sensitivity: *"what surprised me is when the counsellor told me to go and exercise because how was I going to exercise as I normally work"* (P9); *"[patients] would come back without doing the given tasks stating that they thought they were not important"* (C3). There were suggestions of positive impacts on medication adherence: *"it was educated [sic] and changed my perception towards the pills"* (P1).

On the PHQ-9, asked at each session to monitor response, counsellors expressed concerns: *"patients become used to the tool and they lie"* (C6). In general, patients found the tool useful: *"it is constructive to me, so that we can know where I have a problem"* (P8); *"it helps...if the questionnaire was not present it was going to be hard to open up"* (P5), although counter-responses existed: *"at times answering it always is exhausting"* (P11); *"..maybe today they will ask me different questions but to no avail, but I realised every day it was the same question"* (P12).

Discussion

This study contributes important evidence to WHO's call to improve mental health for all(30) in a particularly at-risk group, in a relatively little-studied setting. It furthers understanding of integration of mental health into primary care, in addition to advocating for a low resource, replicable method to do this.

This study found depression to be common among PLHIV/TB in this context. Our analysis indicates that, while there are some potential real benefits to HAP in this setting, there are caveats in terms of feasibility and acceptability for patients and the health system.

Feasibility and Acceptability

Qualitative results suggest acceptability of this programme, but it should be noted the lack of qualitative evidence from patients not attending counselling weakens this assertion. There were positive accounts of

HAP on patient lives, mood and wellbeing. However, the quantitative results indicate that patients did not attend a suggested course (5-8 sessions) in 9 months of follow-up. While a degree of attrition may be expected in psychological therapies, this is potentially excessive.

There were concerns about the validity and reliability of the PHQ-9 used in this way, where it is not validated. Median PHQ-9 scores dropped sharply after one session, suggestive of a factor other than treatment effectiveness. While this study does not aim and is not powered to assess effectiveness, these findings raise questions around this use of this tool, despite validity in similar settings (31, see, for example, 32–34). Interviews with counsellors introduced speculation as to whether initial scores were artificially inflated due to misunderstandings (there is no term for depression in siSwati and questions proved complex to translate); transient interference of HIV/TB symptoms or medication side-effects, thus causing the PHQ-9 to improve rapidly at later sessions. This is conjecture, however these concerns align with previous evidence, where a risk of false positives in screening tools for depression among PLHIV was recognised in a review across Africa (35). This complicates any assessment of feasibility, as it is unclear whether our patient selection was correct. Alternatively, there were concerns that patients purposefully lowered their scores, in order to please the counsellor or expedite the end of the sessions, with implications on acceptability. Such concerns could be addressed with a randomised controlled trial, which we recommend for this context.

Concerns expressed by healthcare professionals about the sustainability of this intervention centred around their capacity, space and workload, reinforced by one site withdrawing early in the study. Nurses have little spare capacity and a large number of competing priorities, inhibiting their ability to deliver >30-minute sessions while providing care to other patients. A feasibility study carried out in neighbouring South Africa with a similar intervention for people living with HIV/Diabetes found similar rates of feasibility and acceptability for 'designated' (alongside usual duties) and 'dedicated' (sole responsibility) healthcare workers(36). A further small study (n=14) in South Africa suggested acceptability and a positive impact on adherence of this intervention but again concerns around feasibility (in this case around provider fidelity to the intervention)(37). Another study in Zimbabwe implemented more supervision, mentoring and allocated time for their nurse counsellors for this intervention(38) and indicated better treatment adherence. These additional support measures may improve feasibility, acceptability and patient adherence. None of these relatively small studies are conclusive, however they indicate that integration *is* feasible into routine care, but that a careful balance of workload and healthcare support is required. These studies also involved other/lay health cadres, which was a suggestion raised by our counsellors and one we advocate is pursued in further research.

Issues around referrals could be interpreted two-fold: firstly, that patients did not want or could not attend or secondly, referral pathways and quality accessible secondary mental health care were lacking. These indicate a lack of acceptability (by patients) and/or feasibility (insufficient mental health infrastructure).

Prevalence

Almost 1/5 screened PLHIV/TB were diagnosed with depression, with a high proportion of suicidal ideation. These small numbers should be interpreted cautiously yet earnestly, given alignment with existing evidence (39) and reinforcement by qualitative results. HIV/TB and poverty, traumatic events, familial and community pressures intersect placing this population at a high risk of mental disorders. Our findings support the view that HIV/TB-related stigma increases the risk of mental disorders and adversely affect HIV (40) and TB (41) outcomes, findings replicated in Eswatini (42).

Limitations

This was a small pilot in line with values and aims of 'implementation research': pragmatic, operation and collaborative (43). There are benefits to this methodology, yet, alongside its relatively small scale, limitations warrant discussion. In all stages of this study, this approach impeded ideal implementation, including participating clinic and nurse selection; lack of systematic screening and an inability to follow-up missing information affecting data completeness. The low number of patients referred to a doctor was concerning, yet there is no longitudinal data to assess their follow-up or management. Upon questioning, many counsellors reported that patients refused referral due to cost of travel or unspecified reasons.

Interviews were only feasible with patients who attended counselling, meaning experiences of those not attending were not captured, limiting our conclusion on acceptability. Informal discussions with healthcare staff suggest non-attendance was due to a combination of factors, including patients' lacking time; lack of a cultural norms around counselling and organisational issues meaning counsellors were not aware patients were present, although this is conjecture. For future longer term follow up of this intervention, this needs to be a key focus of investigation and follow-up.

Fidelity to intervention delivery over time was insufficiently assessed in this pragmatic pilot, and this weakens our understanding of both acceptability and feasibility. The mean session length (27mins) indicates some alignment with suggested timings and interviews indicated some fidelity, however it is difficult to adequately assess how HAP counselling differed from the more unstructured support routinely provided by nurses in these settings, especially over time. This warrants further monitoring in future studies.

Finally, the clinical psychologist was not effectively or appropriately used, with reasons not fully understood. Supervision and mentoring are important elements of task-shifting and may have improved safety, quality, fidelity and feasibility.

Recommendations for policy and practice

This pilot study shows substantial unmet needs and potential benefits of this approach, yet also feasibility concerns. Training non-specialist healthcare staff in common mental disorders is recognised globally as essential to managing the treatment gap (44) and integration with HIV/TB care is critical

(12,45). But there are meaningful human resource constraints. Implementation needs to be realistic, sensitive and pragmatic. In an integrated service and in the absence of additional staff, there is an opportunity cost to other services that may be inappropriate. Wider education and community engagement are necessary to reduce stigma and raise the profile of mental disorders in a manner that supports acceptance of talking therapies. These findings broadly align with similar research (46).

Conclusion

This intervention is promising and generates useful recommendations on feasibility. Real-life application is tempered by health system resources and capacity, workforce availability and training constraints. Patients' ability to complete a course is limited by travel cost, time and social barriers – all issues not unique to Eswatini. This small study is an incremental step to understand challenges, complexities and successes of implementing a contextualised mental health package into a setting with little alternative access to care for common mental health problems, but with great need.

Abbreviations

C1-C6 denotes nurse counsellors, P1-P15 patient responses in the qualitative results section

HAP – Healthy Activity Program

HIV – Human Immunodeficiency Virus

LMIC – Low and Middle Income Countries

mhGAP - WHO's Mental Health Gap Action Programme

PHQ-9: Patient Health Questionnaire for depression, using 9 questions

PLHIV – People Living with HIV

PLHIV/TB – People Living with HIV and/or TB

SSA – Sub-Saharan Africa

TB – Tuberculosis

TiDier - Template for Intervention Description and Replication

TWG – Technical Working Group

WHO – World Health Organization

Declarations

Ethics Approval and consent to participate: The study was approved by the University of Leeds ethics board (MREC16-153) and the Eswatini National Health Research Review Board (17/01/2018, no assigned number).

Consent for Publication: All participants gave informed, signed consent, available in SiSwati and English and read out to those that could not read. Identifiable information was kept in a locked cabinet. Each participant was allocated a unique number, linked to their name on the consent form, allowing study withdrawal. Digital information was held on password-protected laptops.

Availability of data: The datasets generated and/or analysed during the current study are not publicly available due to regulations in Eswatini, but are available from the corresponding author on reasonable request.

Competing Interests: The authors declare that they have no competing interests

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Figures

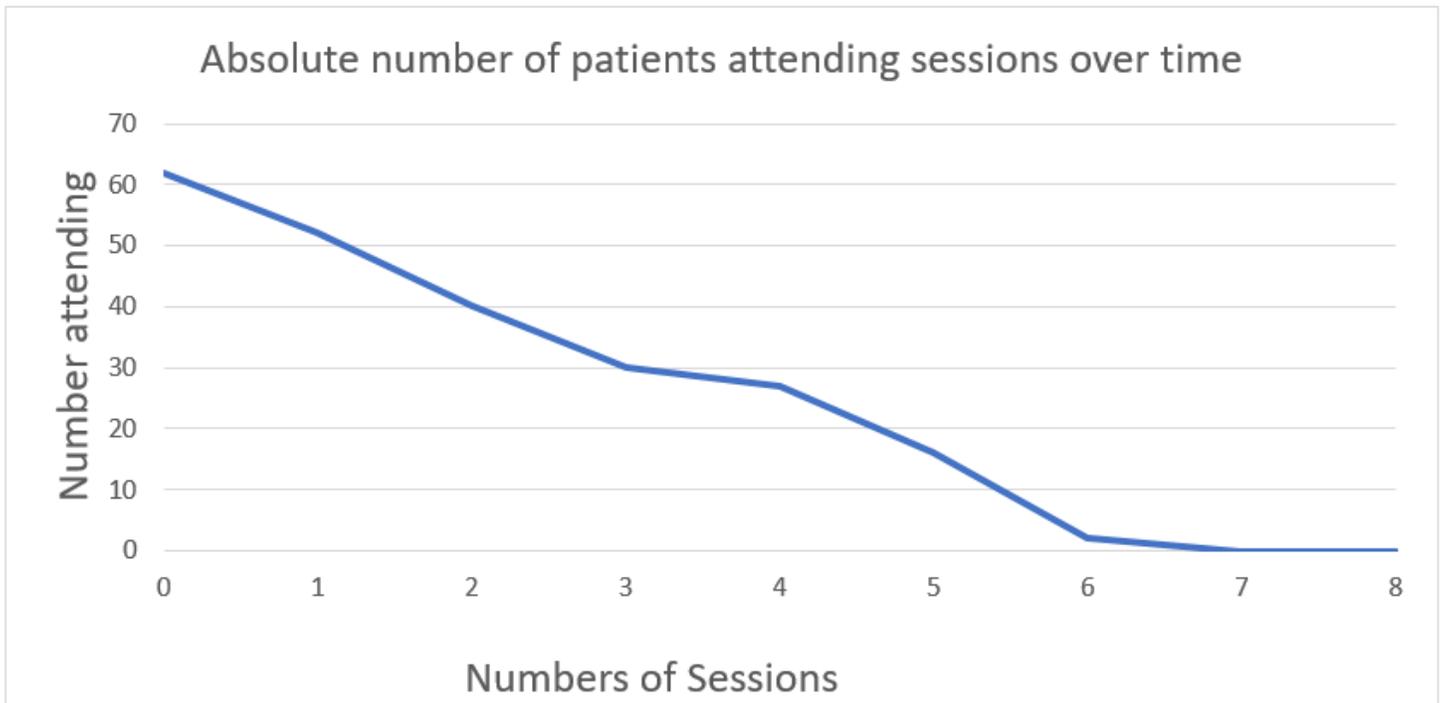


Figure 1

Absolute number of patients attending sessions over time

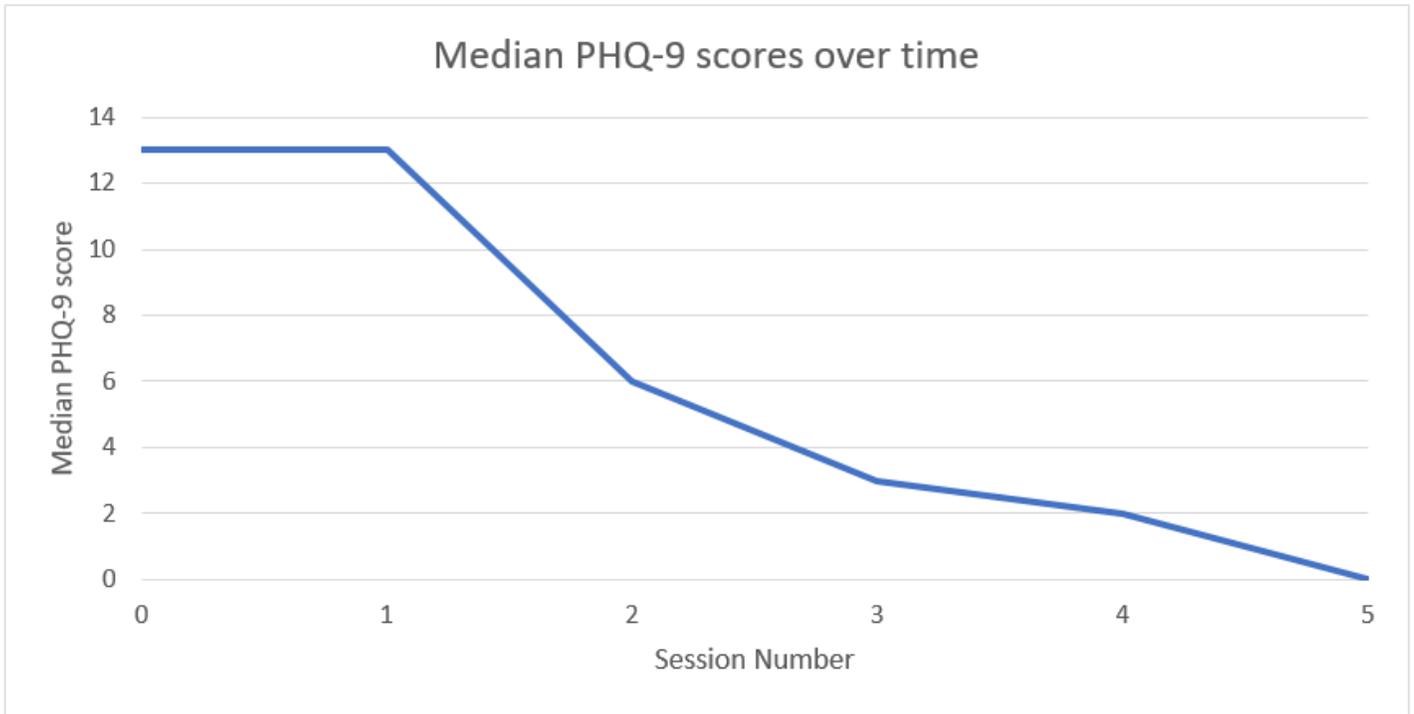


Figure 2

Median PHQ-9 scores over time of those attending counselling. Session '0' is at screening. The same median for session '0' and '1' is due to the majority of patients having their first counselling session on the day they were screened.