

# Evaluation of a booklet self-help intervention for people living with HIV and depressive symptoms

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The proposed study seeks to investigate the effectiveness of a booklet self-help program in the treatment of depressive symptoms among people living with HIV. We will compare the booklet self-help program with an attention only control condition. In...

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Anders
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON19871

### Bron

Nationaal Trial Register

### Verkorte titel

A booklet self-help intervention to reduce depressive symptoms among people living with HIV in Botswana

### Aandoening

Depression, HIV infection

## Ondersteuning

**Primaire sponsor:** Leiden University

University of Botswana

**Overige ondersteuning:** University of Botswana

## Onderzoeksproduct en/of interventie

## **Uitkomstmaten**

### **Primaire uitkomstmaten**

Depressive symptoms as measured by the Patient Health Questionnaire-9 (PHQ-9) and the Center for Epidemiologic Studies Depression Scale (CES-D). Timepoints: Pretest, End of intervention at 8 weeks and follow-up 3 months later.

## **Toelichting onderzoek**

### **Achtergrond van het onderzoek**

Background: The treatment of mental health issues among People Living with HIV (PLH) in Botswana is yet to be addressed. A recent study revealed that depressive symptoms are highly prevalent in a sample of PLH in Botswana. Based on empirical findings of a study that investigated intervention targets for PLH in Botswana, a self-help program in booklet format, in Setswana and English languages was developed, composed of cognitive-behavioral techniques, coping skills interventions and goal adjustment training. We will investigate the program for effectiveness in the treatment of depressive symptoms among PLH. Additionally, we will investigate treatment moderators and mediators. The current paper describes the study protocol.

Methods/design: A randomized controlled trial will be conducted to compare the booklet self-help program with an attention only control condition, by including a pretest, posttest and follow-up. We aim to enroll 200 participants with mild to moderate depressive symptoms into the study. The content of the self-help program contains the following main components: activation, relaxation, changing maladaptive cognitions, and the attainment of new personal goals. This content is covered over six lessons to be completed in maximum eight weeks. It uses a combination of psycho-education, assignments, and exercises. The participants will work on the program 1-2 hours every week for six weeks (maximum eight weeks). Coaches will offer support and motivate participants. For both groups depressive symptoms and possible mediators will be measured three times during the intervention, and at pretest, post-test and follow-up.

Discussion: If the intervention is found to effectively treat depressive symptoms, it will be implemented and thus help improve the psychological health of PLH in Botswana.

### **Doel van het onderzoek**

The proposed study seeks to investigate the effectiveness of a booklet self-help program in the treatment of depressive symptoms among people living with HIV. We will compare the booklet self-help program with an attention only control condition. In addition, we will investigate treatment moderators and mediators of treatment outcome.

We expect that the booklet self-help program will reduce depressive symptoms among people with HIV when compared to the attention-only control group. We expect to see this

difference at post-test and follow up.

## **Onderzoeksopzet**

Pre-screening will be conducted at the HIV treatment centers and participants referred to the researchers for further screening.

Pretest= T0

3 times during the intervention/ waiting period (Week 1, 2 and 4)

After the intervention/ Waiting period=T1 (week 8)

3 month follow-up= T2

## **Onderzoeksproduct en/of interventie**

Intervention: "Living a positive life with HIV": The booklet self-help intervention employs CBT and stress management techniques and is based on self-regulation and stress-coping theories. The content of the booklet self-help program contains four main components: activation, relaxation, changing maladaptive cognitions, and the attainment of new personal goals.

This content is covered over 6 lessons to be completed in maximum 8 weeks. The participants will work on the program 1-2 hours every week. It uses a combination of psycho-education, assignments, and exercises. Coaches will offer support and motivate participants. participants in the control group will receive minimal support offered by a coach for 8 weeks. The control group can start the intervention after 5 months.

## **Contactpersonen**

### **Publiek**

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## Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Being HIV positive
- Presenting with mild to moderate depressive symptoms (that is; a score greater than 4 and less than 20 on the Patient Health Questionnaire-9 (PHQ-9))
- Aged 18 years and older
- Having sufficient knowledge of the Setswana or the English language
- Having a telephone
- Availability for the eight weeks following enrollment into the study to work on the intervention.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Having (almost) no symptoms of depression (a score of 4 or less on the PHQ-9)
- Presenting with severe cognitive impairments, such as forgetfulness
- Being in the first six months post HIV-diagnosis
- Suicidality as determined by a score of  $\geq 1$  on the suicide item of the PHQ-9.

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

### Deelname

Nederland	
Status:	Anders
(Verwachte) startdatum:	10-09-2018
Aantal proefpersonen:	200
Type:	Onbekend

## Ethische beoordeling

Positief advies	
Datum:	10-08-2018
Soort:	Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

Register	ID
NTR-new	NL7229
NTR-old	NTR7428
Ander register	Health Research Development Committee (Ministry of Health, Botswana) : HPDME 13/18/1

## Resultaten