Evaluation of an evidence-based, Internet-supported self-help program for people living with HIV suffering from mild to moderate depressive symptoms.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON41852

Source
ToetsingOnline

Brief title
Evaluation of an online intervention for people with hiv and depression.

Condition

- Viral infectious disorders
- Mood disorders and disturbances NEC

Synonym
blue, sad

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: Aids Fonds

Intervention

Keyword: Depression, E-health, HIV, Self-help intervention

Outcome measures

Primary outcome

Main study parameters/endpoints: We will examine the change in depressive symptoms from baseline to the posttests in both groups as measured by the Patient Health Questionnaire 9 (PHQ-9; Kroenke, Spitzer, & Williams, 2001) and the Center of Epidemiologic Studies Depression Scale (CES-D; Radloff, 1977).

Secondary outcome

Secundary outcomes are: physical tension; activation (Behavioral Activation for Depression Scale [BADS]; Kanter, Mulick, Busch, Berlin, & Martell, 2007); cognitive reappraisal (Emotion Regulation Questionnaire [ERQ]; Gross & John, 2003); cognitive coping (Cognitive Emotion Regulation Questionnaire [CERQ]; Garnefski, Kraaij, & Spinhoven, 2001); depressive thoughts (Crandell Cognitions Inventory [CCI]; Crandell & Chambless, 1986); behavioral coping (Behavioral Emotion Regulation Questionnaire [BERQ]; Kraaij & Garnefski, 2012); self-efficacy; goal adjustment (Goal Disengagement and Reengagement Scale, Wrosch, Scheier, Miller, Schulz, & Carver, 2003); personal growth; symptoms of anxiety (Generalized Anxiety Disorder 7 [GAD-7]; Spitzer, Kroenke, Williams, & Löwe, 2006); negative life events (Life Events Scale, Garnefski & Kraaij, 2001); motivation to start with the intervention; compliance; dropout and

reasons for dropout; medical data; and user satisfaction. Cost-effectiveness will be evaluated by using the PHQ-9 (scores will be transformed to Short Form (36) Health Survey (SF-36; Ware & Sherbourne, 1992) quality of life scores) and the Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness (TiC-P; Bouwmans et al., 2013).

With regard to all secondary outcomes, we will study the pre- versus post-treatment changes.

The following variables will be tested as potential moderators of treatment outcome: demographic variables (gender, age, educational level), severity of depressive symptoms at baseline (PHQ-9 and CES-D), previous episodes of depression, time since HIV diagnosis, use of medication, cognitive coping (CERQ), and motivation to start with the intervention.

Mediator variables and the dependent variable will be measured every two weeks during the intervention, at de pretest and at the three posttests. The following mediator variables will be assessed in the study: activation (BADS), physical tension, cognitive reappraisal (ERQ), cognitive coping (CERQ), depressive thoughts (CCI), goal adjustment (Goal disengagement and Reengagement Scale), and self-efficacy. The dependent variable is depressive symptoms (PHQ-9).

Study description

Background summary

Many people living with HIV (PLH) suffer from depressive symptoms. In previous research, it was found that self-help (in booklet format) cognitive behavioural therapy (CBT) is effective in treating depression in PLH. We are currently developing an online self-help program (based on the booklet) for PLH and depressive symptoms. In this study we will investigate the effectiveness of the self-help program. We expect that the program is effective in reducing depressive symptoms in PLH.

Study objective

The main objective of this study is to investigate the effectiveness of the self-help program compared to a waiting-list control group in reducing depressive symptoms. Secondary objectives include the investigation of moderators and mediators of treatment outcome and the investigation of the cost-effectiveness of the intervention.

Study design

The study is a randomized controlled trial with a pretest and three posttests.

Intervention

The self-help program consists of four components: activation, relaxation, changing irrational cognitions and goal attainment. The intervention group will follow the self-help program for six to eight weeks, 1-2 hours a week. They will receive weekly motivational support from a coach by telephone. The waiting-list control group will receive minimal support from a coach, through weekly telephone calls. They can follow the program after the second posttest (after 5 months).

Study burden and risks

Participants in the intervention group will (probably) benefit from working on the self-help program, their depressive symptoms will decrease. Participants in the control group receive minimal support during the first 5 months, some participants will improve during this time. Other participants may worsen in these first months; their depressive symptoms may increase. Therefore, a coach will monitor their well-being (also the participants in the intervention group) and will follow a protocol with guidelines that describe what to do in which situations. Furthermore, participants have to complete multiple questionnaires during the study, every two weeks. This takes time for participants (10-30

minutes per assessment). When the outcome of the study is that the self-help program is effective in decreasing depressive symptoms in PLH, we will implement the self-help program for PLH.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Being HIV positive;
* The presence of mild to moderate depressive symptoms (defined as PHQ-9; Kroenke et al., 2001 score >4 and < 20);
* Age 18 and older;
* Sufficient knowledge of the Dutch or English language;
* Access to the Internet;
* Having an e-mail address;

* Available for the next 8 weeks to work on the intervention.

Exclusion criteria

* Being in the first half year post HIV-diagnosis;
* Having severe cognitive impairments (e.g. forgetfulness);
* The presence of severe depressive symptoms (defined as PHQ-9; Kroenke et al., 2001, score of 20 or higher);
* Prominent suicide ideation (indicated by a score >1 on the suicide item of the PHQ-9);
* The absence of depressive symptoms (indicated by a PHQ-9 score of 4 or lower).
* Treatment by a psychologist or psychiatrist at the moment;
* Use of antidepressants for less than 3 months or change of type or dose of antidepressants in the past 3 months.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2015
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	16-09-2014

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl
Approved WMO Date:	11-03-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	24-11-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL48373.058.14