Evaluation of an online self-help intervention for people with HIV and depressive symptoms

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26719

Source
NTR

Brief title
Effectiveness of an internet-based self-help intervention for people with HIV and depressive symptoms

Health condition

HIV, aids, depression
depressie, somberheid

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Depressive symptoms: Patient Health Questionnaire 9 (PHQ-9) and the Center of

Epidemiologic Studies Depression Scale (CES-D). Timepoint: pretest, end of intervention/waiting period and 3 and 6 months later.

Secondary outcome

Secondary outcomes are: physical tension; activation (Behavioral Activation for Depression Scale [BADS]); cognitive reappraisal (Emotion Regulation Questionnaire [ERQ]); cognitive coping (Cognitive Emotion Regulation Questionnaire [CERQ]); depressive thoughts (Crandell Cognitions Inventory [CCI]); behavioral coping (Behavioral Emotion Regulation Questionnaire [BERQ]); coping self-efficacy; goal adjustment (Goal Disengagement and Reengagement Scale); personal growth; symptoms of anxiety (Generalized Anxiety Disorder 7 [GAD-7]); negative life events (Life Events Scale); motivation to start with the intervention; compliance; dropout and reasons for dropout; medical data; and user satisfaction. Secondary outcomes will be measures at the pretest and at the 3 posttests.

As potential moderators of treatment outcome demographic variables (such as gender and age), clinical and psychological characteristics (such as severity of depressive symptoms at baseline) will be tested.

Mediator variables and the dependent variable will be measured three times during the intervention/waiting period, at the pretest and the first posttest. The following mediator variables will be assessed in the study: activation (2 items of the BADS), physical tension (2 items), cognitive reappraisal (2 items of the ERQ), cognitive coping (12 items of the CERQ), goal adjustment (2 items of the Goal disengagement and Reengagement Scale), symptoms of anxiety (PHQ-4), and self-efficacy (2 items). The dependent variable in the mediational analysis is depressive symptoms (PHQ-4).

Study description

Background summary

Background: Many people living with HIV suffer from depressive symptoms. In a previous pilot study, it was found that self-help cognitive behavioural therapy (in booklet format) was effective in treating depressive symptoms in people with HIV. We developed an online self-help program in Dutch and English (based on the booklet) for people with HIV and depressive symptoms. Besides the main question regarding the effectiveness of the program aimed at lowering depressive symptoms, sub-questions will focus on moderators of treatment success (for which patients is the program especially beneficial?) and mechanisms of change underlying treatment outcome (which mediators affect the outcome of treatment?).

Methods: The effectiveness of the program will be investigated by comparing the intervention group with a waiting list control group in a randomized controlled design, by including a pretest and three posttests. The self-help program contains four main components: activation, relaxation, changing maladaptive cognitions, and goal attainment. Participants with mild to moderate depressive symptoms will work on the program for six to ten weeks during which a coach will provide motivational support by telephone once a week. Participants in the control condition will receive weekly minimal support from a coach during eight weeks and after the second posttest they can also get access to the self-help program. Participants will be recruited in the Netherlands. Depressive symptoms and possible mediators (e.g. activation, cognitive coping, self-efficacy and goal adjustment) will be assessed by self-report three times during the intervention/waiting period and at the pretest and first posttest.

Discussion: The proposed study aims to evaluate the effectiveness of an online self-help intervention for people with HIV and depressive symptoms. If the intervention is shown to be effective, the program will be implemented and consequently many patients with HIV could be reached and psychological care for these patients may be improved.

Study objective

In the proposed study we will investigate the effectiveness of an online self-help intervention for people living with HIV and depressive symptoms in a randomized controlled trial. Additionally, moderators and mediators of treatment outcome will be assessed.
We expect that the self-help program will decrease depressive symptoms, when compared to a control group. This difference between the intervention and control group should be visible post intervention and at follow-up. We expect significant results with medium effect sizes.

Study design

Pre-screening in HIV treatment centers and referral to the researchers = Start study

Pretest = T0

3 times during intervention/waiting period (week 1, 3 and 5)

After the intervention/waiting period = T1

3 month follow-up = T2

6 month follow-up = T3 (only in intervention group)

Intervention

Intervention: "Living positive with HIV": Online self-help program to decrease depressive symptoms. The intervention includes telephone coaching once a week. The program lasts 6-10 weeks, 1-2 hours a week.

The self-help intervention is grounded in the theories of self-regulation and stress-coping, incorporating techniques of CBT and stress-management. The content of the program reflects four main components: activation, relaxation, changing maladaptive cognitions, and goal attainment.

Control condition: waiting-list control group with minimal support from a coach during 8 weeks. Participants in the control group can start with the intervention after 5 months.

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Eligibility criteria

Inclusion criteria

- Being HIV positive.

- The presence of mild to moderate depressive symptoms (defined as PHQ-9 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 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:	N/A , unknown

Recruitment

NL

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

Type:	Anticipated

Ethics review

Positive opinion

Date:	11-09-2015
Application type:	First submission

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
NTR-new	NL5298
NTR-old	NTR5407
Other	ABR number 48373 : Aids Fonds: file number 2013027

Study results