

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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26719

Bron

Nationaal Trial Register

Verkorte titel

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

Aandoening

HIV, aids, depression
depressie, somberheid

Ondersteuning

Primaire sponsor: Leiden University

Overige ondersteuning: Aids Fonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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)

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Leiden University, Faculty of Social Sciences, Clinical Psychology

Sanne van Luenen
Wassenaarseweg 52

Leiden 2333 AK
The Netherlands

071-5277957

Wetenschappelijk

Leiden University, Faculty of Social Sciences, Clinical Psychology

Sanne van Luenen
Wassenaarseweg 52

Leiden 2333 AK
The Netherlands
071-5277957

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-02-2015
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	11-09-2015
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	NL5298
NTR-old	NTR5407
Ander register	ABR number 48373 : Aids Fonds: file number 2013027

Resultaten