Guided Act and Feel Indonesia (GAF-ID): online behavioral activation intervention for depression in Indonesia

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

Samenvatting

ID

NL-OMON20980

Bron
NTR

Verkorte titel
GAF-ID

Aandoening

Depressive disorders, including major depressive disorder and persistent depressive disorder.

Ondersteuning

Primaire sponsor: - University of Groningen

- Utrecht University
Overige ondersteuning: - Indonesia Endowment Fund for Education, Ministry of Health, Republic of Indonesia (Beasiswa Pendidikan Indonesia, Lembaga Pengelola Dana Pendidikan, Kementerian Keuangan, Republik Indonesia)

- University of Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

PRIMARY OUTCOME:

Self-reported symptoms of depression at post-treatment, 10 weeks from baseline, measured using Patient Health Questionnaire-9 (PHQ-9)

Toelichting onderzoek

Achtergrond van het onderzoek

The World Health Organization (WHO) initiated the Mental Health Gap Action Programme (mhGAP) aiming to provide a coherent strategy for closing the gap between what is urgently needed and what is available in low and middle income countries (LMICs). Internet-based treatment is a promising strategy that can be made available to relatively large numbers of people, now that internet access is increasing throughout the world.

In the present study, we will examine the effectiveness of a guided internet-based behavioral activation intervention for depression in Indonesia, called Guided Act and Feel Indonesia (GAF-ID). The GAF-ID consists of 8 modules and can be completed over an 8 week period. Participants in GAF-ID group will receive online feedback on assignments by trained lay counselors who will also provide supportive phone contact to encourage and reinforce participants to work in the program. They will work under supervision of licensed clinical psychologists. The GAF-ID will be compared to online-delivered minimal psychoeducation (PE) without support.

Participants with depression (N=312) will be randomly assigned to either GAF-ID or PE. Stratified randomization will be used based on sex (male and female) and depression severity (moderately severe to highly severe depression based on PHQ-9 category, scored ≥15 (Kroenke et al., 2001) will be randomized separately from the rest).

The primary outcome is the reduction of depression symptoms as measured by PHQ-9 at post-intervention (10 weeks from baseline), and the overall assessments including the

secondary, potential mediators and moderators, and additional assessments will be done at baseline, post-intervention (10 weeks from baseline), follow-ups (3 months and 6 months from baseline), as well as bi-weekly (once every two weeks) during the intervention.

To our knowledge, this is the first randomized controlled trial study in Indonesia that examines the effectiveness of an internet-based intervention guided by lay counselors for depression. This study might be a starting point for bridging the mental health gap in Indonesia and might offer potential for other LMICs to bridge this gap.

Doel van het onderzoek

The guided internet-based behavioral activation intervention is expected to show favorable effects in comparison to online-delivered minimal psychoeducation without support in participants with depressive disorders, as shown by the results on primary outcome.

Onderzoeksopzet

This study proposed an RCT with an intervention period of 8 weeks and several measurement points:

- Baseline (t0): All measures (primary outcome, all secondary outcomes, all potential mediators and moderators, all additional measures)

- Bi-weekly/once every two weeks (weeks 2, 4, 6, 8): primary outcome, a selection of the potential mediators and moderators (VAS, PANAS, BADS-SF)

- Post-intervention (t0+10 weeks): primary outcome, all secondary outcomes, a selection of the potential mediators and moderators (VAS, PANAS, BADS-SF)

- Follow-up (t0+3 months): primary outcome, all secondary outcomes (except SCID-5 interview), a selection of the potential mediators and moderators (VAS, PANAS, BADS-SF)

- Follow-up (t0+6 months): primary outcome, all secondary outcomes (except SCID-5 interview), a selection of the potential mediators and moderators (VAS, PANAS, BADS-SF)

Onderzoeksproduct en/of interventie

INTERVENTION GROUP: 8 weekly modules of internet-based behavioral activation intervention, an adapted version of the Dutch internet-based behavioral activation intervention called Act and Feel (Bockting & van Valen, 2015). The content consists of understanding the basic background of behavioral activation and psychoeducation about depression, monitoring mood and behavioral activities, expanding potential mood independent pleasurable activities, recognizing and overcoming difficulties with expanding activities, psychoeducation on the impact of avoidance behaviors, and developing a personal relapse prevention plan.

Dose: weekly lessons with automatized feedback provided through the online program, along with personalized feedback by the lay counselor on the assignments via the online program. In addition, lay counselors will have brief contact via phone calls to reinforce and encourage participants to work in the online program (weekly during the first 4 weeks and at weeks 6 and 8) in order to enhance adherence to the program and to prevent attrition. The calls do not take more than 20 minutes each and there is no option for a face-to-face contact.

Duration: advised to do over 8 weeks.

Mode of administration: via website on the following address www.actandfeelindonesia.com

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CONTROL GROUP: online-delivered minimal psychoeducation without additional support. Presented as a short online leaflet, consisting basic information about depression and practical tips on how it can be handled, representing information that can be easily and freely accessed online outside of this program.

Dose: one time administration with general instruction

Duration: one time, with no further restriction on the duration of use.

Mode of administration: via website on the following address www.actandfeel.com

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Meet cut-off score of ≥10 on the PHQ-9 (Kroenke, Spitzer, & Williams, 2001)

- Meet criteria for a diagnosis of major depressive disorder or persistent depressive disorder on the SCID-5 (First, Williams, Karg, & Spitzer, 2015)

- Age ≥16 years

- Proficient in Indonesian language

- Have fluency to use the internet

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Current or previous mania or hypomania episode

- Current or previous psychotic disorder

- Current substance use disorder

- Current acute suicidality

- Currently following a weekly or more intensive psychological intervention (non-medication) for mental health complaints

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2016
Aantal proefpersonen:	312
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-07-2016
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	NL5733
NTR-old	NTR5920
Ander register	Tarumanagara University Human Research Ethics Committee : PPZ20152002

Resultaten

Samenvatting resultaten

Arjadi, R., Nauta, M.H., Scholte, W.F., Hollon, S.D., Chowdhary, N., Suryani, A.O. & Bockting,

C.L.H. (2016). Guided Act and Feel Indonesia (GAF-ID) – internet-based behavioral activation intervention for depression in Indonesia: study protocol for a randomized controlled trial. Manuscript submitted for publication.