Onderzoek naar het gebruik van drie online trainingen voor slapen, stress en piekeren met begeleiding in de huisartsenpraktijk voor het verminderen van depressieve klachten

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The reach of online interventions for depression is relatively low among people with a low socioeconomic status (SES) as compared to people with a high SES. The hypothesis is that the participation rate of patients with a lower socioeconomic...

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

Samenvatting

ID

NL-OMON25383

Bron
Nationaal Trial Register

Aandoening

Depression, sleep, stress, worry, anxiety, mental health, health literacy, socioeconomic, SES, prevention

Depressie, slaap, stress, piekeren, angst, psychische gezondheid, gezondheidsvaardigheden, sociaaleconomisch, preventie

Ondersteuning

Primaire sponsor: Trimbos-institute - Netherlands Institute of Mental Health and Addiction
Overige ondersteuning: ZonMw - Preventieprogramma 5

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The (difference in the) participation rate of patients with a lower SES is the primary outcome.

Participation is defined as:
participating in at least 1 face-to-face session with a GP nurse (as registered by the GP nurse) and engaging with at least 2 exercises in the online CDMIs (as determined with the user data of the online CDMIs).

A lower SES is defined as :
1. The highest completed educational level is secondary vocational education (in Dutch: MBO) or lower, and/or
2. The respondent is unemployed (looking for work) and lives in a neighbourhood with a negative status level score, and/or:
3. The total gross family income of the respondent is below €1100/1550 (based on the guaranteed minimum income in the Netherlands of July 2017), whereby the amount depends on the living arrangement of the respondent (living alone or as a single parent: 1100, living together with other adults: 1550), and lives in a neighbourhood with a negative status score.

Status level scores of the neighbourhood will be assessed by asking respondents their four digit zip-code. The Netherlands Institute for Social Research provides status scores for every zip-code. For this study the status level scores of 2016 will be used. A negative status level score indicates a lower than the Dutch average status level score of the years 1998-2016.

Toelichting onderzoek

Achtergrond van het onderzoek

RATIONALE

Depression is major public health concern. Currently available interventions for preventing and reducing depression have proven to be effective, However, the reach of these interventions needs to be improved, and their implementation in primary care needs to be stimulated and supported, especially among people with a low socioeconomic status (SES).

OBJECTIVE

The main objective is to evaluate whether a SES-sensitive implementation strategy improves the participation rate (i.e. reach) of lower SES patients in the blended online CDMIs as compared to a regular implementation strategy. Secondary objectives are to evaluate the implementation process, to monitor and evaluate psychological complaints and well-being over time, and to evaluate the difference in costs associated with both implementation strategies.

STUDY DESIGN

The study is a pragmatic cluster randomised controlled trial, conducted in primary care.

Study population: GP nurses will be recruited through two collaborating parties in this project, working in the primary care field and employing GP nurses. All adult (18+) patients of the participating primary care practices who present to their (participating) GP nurse with sleep, worry or stress complaints, have access to internet, and have sufficient proficiency of the Dutch language.

Intervention (if applicable): The blended online CDMIs will be offered in both conditions. The difference between de experimental and control condition is the implementation strategy being used. In the experimental condition GP nurses will be trained to implement the online CDMIs with a SES-sensitive implementation strategy, while a regular implementation strategy applies to the control condition. The implementation strategies involve activities that are aimed at the GP-nurses and at the patients they see.

MAIN STUDY PARAMETERS:

The primary outcome is the difference in the participation rate of patients with a lower SES between the SES-sensitive and the regular implementation strategy. Participation is defined as participating in at least 1 face-to-face session with a GP nurse and engaging with at least 2 exercises in the online CDMIs. Secondary outcomes include process indicators of the implementation process (satisfaction, feasibility, fidelity and adherence) and the impact on depressive complaints (PHQ-8), sleep problems (JSEQ), stress (PSS-10), worry (PSWQ), anxiety (GAD-7) and well-being (WHO-5).

NATURE AND EXTENT OF THE BURDEN AND RISKS ASSOCIATED WITH PARTICIPATION, BENEFIT AND GROUP RELATEDNESS

229 patients will be assessed three times by online self-reported questionnaires: at baseline (T0), 3 months after baseline (T1) and 12 months after baseline (T2). A substantial part of the

baseline questionnaire and follow-up questionnaires of the study are already part of the intake and follow-up questionnaires of the online CDMIs. In addition, we will conduct in-depth interviews with 10 patients to illicit experiences with the intervention. This study is very unlikely to have any negative side effects or risks to participants. Both groups will have access to an evidence-based online interventions for stress, sleep and worry complaints with guidance from their GP nurse. Moreover, all participants have access to standard usual care delivered by their GP/GP nurse. Participants in the intervention condition may receive more active, directive, and SES-specific guidance than the control condition.

Doel van het onderzoek

The reach of online interventions for depression is relatively low among people with a low socioeconomic status (SES) as compared to people with a high SES.

The hypothesis is that the participation rate of patients with a lower socioeconomic status to the blended online complaint-directed mini-interventions will increase using a lower-SES implementation strategy in comparision to a regular implementation strategy.

Onderzoeksopzet

Quantitative (online questionnaires):

1. At baseline

2. 3 months after baseline

3. 12 months after baseline

Qualitative (interviews with 10 patients): 1 to 6 months after baseline.

In the interviews we will illicit patient's experiences with the intervention, their preferences for the delivery of the intervention in primary care, and factors that they deem relevant for the sustained (successful) implementation of the intervention

Onderzoeksproduct en/of interventie

The online CDMIs will be offered with guidance from a GP (mental health) nurse in both conditions. The difference between the experimental and control condition is the implementation strategy being used. In the experimental condition, GP nurses will be trained to implement the online CDMIs with a SES-sensitive implementation strategy, while a regular implementation strategy applies to the control condition. The implementation strategies involve activities that are aimed at the GP nurses and at the patients they see.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, an individual must:

- experience sleep problems, worry or stress

- have access to internet

- have sufficient proficiency of the Dutch language

- provide informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- having an acute or urgent comorbidity (ascertained by the GP or GP nurse)

- sleep problems with a somatic cause (e.g. sleep apnea)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	10-01-2018
Aantal proefpersonen:	228
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-11-2017
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	NL6595
NTR-old	NTR6812
Ander register	ZonMw : 50-53120-98-025

Resultaten