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

No registrations found.

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

Summary

ID

NL-OMON25383

Source
Nationaal Trial Register

Health condition

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

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

Sponsors and support

Primary sponsor: Trimbos-institute - Netherlands Institute of Mental Health and Addiction
Source(s) of monetary or material Support: ZonMw - Preventieprogramma 5

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

-Depressive complaints will be measured using the 8-item Patient Health Questionnaire (PHQ-8) .

- Sleep problems will be measured with the 4-item Jenkins Sleep Evaluation Questionnaire (JSEQ) .

- Stress will be assessed as measured by the 10-item Perceived Stress Scale (PSS-10)

- Worry will be assessed using the 11-item Penn State Worry Questionnaire (PSWQ).

- Anxiety symptoms will be measured with the 7-item Generalized Anxiety Disorder Scale (GAD-7).

- Well-being will assessed as measured by the 5-item World Health Organization Well-Being Index (WHO-5)

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

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

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	10-01-2018

Enrollment:	228
Type:	Anticipated

Ethics review

Positive opinion Date:	12-11-2017
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	NL6595
NTR-old	NTR6812
Other	ZonMw : 50-53120-98-025

Study results