Mobile screening for major depressive disorder in adults from an ethnically and socioeconomically diverse population.

Published: 06-02-2024
Last updated: 07-04-2024

2. OBJECTIVESThe overarching goal of this proposal is to examine the feasibility and effectiveness of mobile-based screening for MDD. We combine validated screening and interventions for MDD with innovative outreach methods to maximize impact....

Ethical review	Not approved
Status	Will not start
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON56488

Source
ToetsingOnline

Brief title
MOOD

Condition

- Mood disorders and disturbances NEC

Synonym
depression, downheartedness

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Depression screening app Rotterdam

Outcome measures

Primary outcome

Primary outcomes of the trial include participants* quality of life after 24 months compared to the quality of life at the start of the study as measured by the EQ-5D. Although only 3 out of 5 items on this questionnaire relate to mental problems and social functioning, evidence suggests that it is highly sensitive to MDD. Because the fifth question of the EQ-5D has the strongest relation with mental health, we will report outcomes on that question separately as well.

Secondary outcome

We will also examine the occurrence and severity of symptoms as measured by the PHQ, and participant adherence using Kaplan-Meier curves for the proportion of patients completing 0%, >50%, and 100% of tests, patients* experience of screening.

It will also provide invaluable information regarding the duration and severity of MDD symptoms across participants in second and third screening arm, which will be the subject of further study under Aim 2.

Study description

Background summary

Major depressive disorder (MDD) is a relatively common mental disorder, affecting more than 264 million people worldwide (James, Abate et al. 2018)

(Liu, He et al. 2020). MDD is therefore the fourth-largest contributor to the global disease burden and the leading cause of disability worldwide (Kalibatseva and Leong 2011). Nationally representative samples have indicated a global prevalence of MDD of 13,3%, which is influenced by a number of clinical and demographic variables, including age and gender (Abdoli, Salari et al. 2022). Recurrences following an initial depressive episode are particularly problematic with an estimated range from 75 to 90% (Gotlib, Goodman et al. 2020). Costs associated with MDD are widely spread: MDD is linked to a reduced healthy life expectancy and can result in family dysfunction, decreased professional efficiency, and suicide (Yazdkhasti 2010, Steensma, Loukine et al. 2016, James, Abate et al. 2018). In total, this has resulted in an estimated economic impact of more than 100 billion euros per year inside the EU union (Sobocki, Jönsson et al. 2006).

Given the long-term and recurrent nature of MDD as well as its numerous negative consequences, early detection and treatment of MDD may be significantly important (Rohde, Lewinsohn et al. 2013). Screening for MDD can earlier identify individuals requiring support, especially for people who are unlikely to seek it. A number of validated screening technologies are available, and screening is already recommended in several settings (Kroenke, Spitzer et al. 2001) (Siu, Force et al. 2016). Previous studies suggest that screening may effectively reduce MDD symptoms and significantly increased complete remission rates (O'Connor, Whitlock et al. 2009).

While the potential for the prevention of MDD using early screening intervention is substantial (Almeida 2014, Hall and Reynolds-Iii 2014, Park and Zarate Jr 2019) timely intervention remains a challenge in therapeutic settings. As a result, there has to be more clarification in screening protocols regarding the proper screening intervals and follow-up requirements in order to reduce MDD occurrences. To address this gap, the present study emphasizes the importance of investigating the feasibility and effectiveness of screening for MDD by providing a mobile-based screening protocol using a randomized controlled trial (RCT). We hypothesized that a mobile-based screening strategy for MDD evaluated in this study protocol will substantially reduce the burden of MDD over time, improve participants* quality of life, and minimize disparities associated with MDD.

Study objective

2. OBJECTIVES

The overarching goal of this proposal is to examine the feasibility and effectiveness of mobile-based screening for MDD. We combine validated screening and interventions for MDD with innovative outreach methods to maximize impact. Thereby, we hypothesize that the mobile-based screening strategy evaluated in this proposal will substantially reduce the burden of MDD over time, increase participants* quality of life, and decrease MDD-related disparities.

Specifically, we aim to a) evaluate the feasibility and effectiveness of mobile-based screening for MDD in a high-risk adult population, b) examine the impact of subgroup differences in screening participation and effectiveness; c), develop a personalized screening strategy considering a person*s screening history and risk characteristics. Our proposal has the potential to inform practice on the public health impact of screening, including the impact on health inequalities by sex/gender, racial-ethnic background, employment status, and other relevant social economic variables. It will also provide detailed information on the mechanics of MDD across individuals in terms of the duration and severity of symptoms. This can help inform future screening guidelines on the appropriate intervals and follow-up criteria for screening. Ultimately, it may contribute to a lower MDD burden and greater mental health equity in the population.

Specific Aim 1. Evaluate the feasibility and effectiveness of mobile-based screening for MDD in a high-risk adult population.
Under this aim, a randomized controlled trial will be conducted to examine the uptake, health impact and harms-benefits of frequently repeated mobile-based screening. Eligible participants in the age of 18+ years will be recruited via a multi-faceted outreach strategy in the municipality of Rotterdam, particularly from the districts Charlois, Feijenoord (including Kop van Zuid) and Ijselmonde. We will randomize 1575 eligible respondents across three arms, in a 1.5:1:1 fashion. The three arms comprise a control arm, a screening arm with limited participant referral for treatment (after three positive test scores or suicidal ideation), and a screening arm with standard referral for participants with moderate-severe symptoms of major depression (single positive test score). The screening with limited follow-up is vital to get a better understanding of the natural course of symptoms under usual care, and is nonexistent in literature to our knowledge. The screening will be conducted using the 9-item version of the Patient Health Questionnaire (PHQ-9), which has an estimated sensitivity and specificity of 88% given a cutoff score of 10 (Kroenke, Spitzer et al. 2001). The screening measurement will be solicited every four weeks during the first 12 months via the Your Research app (YourResearch 2021). A positive screening test result is considered a PHQ-9 score >=10 (moderate-severe symptoms). Participants with one or three positive results, respectively (depending on the study arm), will receive an automatically suggested notification to contact their general practitioner (GP) The GP has a Praktijk Ondersteuner Huisarts Geestelijke Gezondheidszorg (POH-GGZ) specialist which is the standard point of access for mental health-related care. These specialists can refer patients to psychological therapists in case of further support needs. In addition to the regular collection of PHQ-9 data, we will ask participants once to provide informed consent, socio-demographic information and contact information of their GP. Further, there will be four quality of life measurements (5 questions each, 0, 6, 12, 24 months), and two short screening evaluation surveys (3 questions each, 6, 12 months). The estimated overall time commitment for participants in screening is around 120 minutes. This primary aim will demonstrate the

feasibility and effect in QALY gained for repeated mobile-based screening for MDD. Also, it will provide invaluable information regarding the duration and severity of MDD symptoms across participants within the screenings arms, on which the second research question will be based.

Specific Aim 2. Examine participation differences between subgroups and the impact of screening on disparities.
In this aim, we will use advanced statistical analysis to better understand differences in screening participation and outcomes between study subgroups. This aim provides insight into the effect of screening on MDD-related health disparities. It also provides detailed insight in the mechanics of MDD across different individuals in terms of the duration and severity of symptoms, and therefore inform more personalized screening approaches (aim 3).

Specific Aim 3. Develop a personalized screening strategy considering a person*s screening history and risk characteristics.
This goal will optimize screening intervals and follow-up requirements based on MDD mechanics observations from aim 2. This objective is built on advanced knowledge of simulation, machine learning techniques and cost-effectiveness methodology. To achieve this goal, we will simulate exposure to MDD symptoms in a hypothetical population using the model for the time exposure to symptoms from Aim 2. The simulation will include stochastic variation in the duration and level of MDD symptoms during a 12 month time window, conditional on participant characteristics and prior MDD symptom history. Screening will be superimposed with various possible intervals (1 weeks, 2 weeks, * 52 weeks) and positivity cutoffs (PHQ>=10, *,), and can be varied depending on patient risk characteristics. In the simulations, the assumed diagnostic performance of the test given each positivity cutoff will be derived from Aim 1 data (gold standard for diagnosis is POH-GGZ referral for treatment), and validated against literature (Rizopoulos 2022). Assumed effects of follow-up will also be based on the model for symptom exposure from Aim 2. However, assumed screening and treatment costs will be as assumed in Aim 1, but varied in sensitivity analysis. For adherence, we will compare observed rates and with assumptions of 100% and lower rates. An evolutionary algorithm will be used to optimize screening according to patient characteristics and prior MDD symptom scores (van Duuren, Ozik et al. 2022). We aim to maximize QALY*s gained given different criteria for number of GP referrals per QALY gained (harms-benefit ratio, HBR): Max(INT,POS): Quality of Life, subject to Referrals/QALY < HBR. (INT=interval; POS=positivity criteria).
Once the algorithm converges on an optimal strategy, we will compare the benefits and harms from personalized screening with those for uniform screening (Aim 1). Thereby, we quantify the net benefit from personalization. This goal will provide more information on how frequently to screen, when to refer patients for follow-up, and who should be screened more and less intensively. This has the potential to enhance the balance of screening's risks and benefits, as well as result equality.

Study design

A randomized controlled trial (RCT) involving one thousand and five-hundred and seventy-five (1575) eligible participants in the age of 18+ will be recruited within the municipality of Rotterdam-South (particularly the districts Charlois, Feijenoord and Ijselmonde). Participants will be recruited using various channels tailored to their cultural background, including direct approach by representatives of the community, promotion through general practitioners, local radio, social media and in the public space. RCT will have 3 research arms including one control group, consisting of 675 participants, and two intervention groups consisting of 450 participants each group. Both intervention arm will have 4-weekly screening with either lenient follow-up or screening with stricter follow-up for a time period of one year. Data will be collected via an app designed by Your Research which runs on Microsoft Azure server, as the primary of participants response collection. A dedicated back-up system will serve as a secondary data collection.

Intervention

This research will make use of a personally designed app (YourResearch 2021) solicit for digital informed consent as well as socio-demographic information. Furthermore, both Euro Quality of Life-5D (EQ-5D) and PHQ-9 questionnaires will be solicited via the application on specific time points. In case participants within the screening arm exceed a threshold score of 10 points on the PHQ-9 questionnaire, they will be suggested by the application to contact the POH-GGZ specialist of the GP. Finally, the application features both correct and necessary certificates and classifications.

Study burden and risks

The participants are asked to install the app of the study and then fill in the EQ-5D questionnaire 4 times. The intervention groups are also asked to complete 14x the PHQ-9 and 2x a screening evaluation questionnaire. Each questionnaire takes less than 5 minutes to complete, which means that the load is considered low. Although the questions from the PHQ-9 can be confrontational, the potential health benefits of early detection of depression seem to us to more than compensate for this.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

At least 18 years old
Live in Rotterdam-South
Have a smartphone

Exclusion criteria

Has been previously diagnosed with MDD or related disorder in the past 5 years
or
is still taking related medicine.s.

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	1575
Type:	Anticipated

Ethics review

Not approved

Date:	06-02-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL84280.078.23