The effects of Apps on Mental and Physical wellbeing (AMP)

Gepubliceerd: 20-03-2020 Laatst bijgewerkt: 18-08-2022

Research Question 1: Do mental health apps improve mental wellbeing? This question will be investigated by testing the following hypothesis: There will be an interaction between condition (allocation to one of the 4 apps vs. no-app control; between...

Ethische beoordeling Niet van toepassing **Status** Werving gestart

Type aandoening -

Onderzoekstype Interventie onderzoek

Samenvatting

ID

NL-OMON22862

Bron

NTR

Verkorte titel

AMP

Aandoening

n.a.: apparently healthy individuals will be enrolled.

Ondersteuning

Primaire sponsor: None (University-based research project)

Overige ondersteuning: Nona - University-based

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Mental health, measures by the Mental Health Continuum questionnaire.

Toelichting onderzoek

Achtergrond van het onderzoek

Smartphones are increasingly used to promote physical and mental wellbeing. Numerous downloadable applications ("apps") have been developed to improve physical and mental wellbeing utilizing mobile devices (mHealth) and these apps can be accessed via most smart phone operating systems. The potential of these apps to produce positive changes in either physical or mental wellbeing remains insufficiently understood. The primary goal of this project is to evaluate: (a) whether apps targeting psychological factors produce improvements in mental wellbeing; and (b) whether individual characteristics prior to the use of these apps predict app effectiveness in improving mental wellbeing. A pre-post repeated measures design will be used in which four publicly available and "free" (no-payment) apps are compared and a fifth group will comprise of a no-app control condition. Participants will use the app for 2 weeks and will provide self-report data at baseline (prior to randomization), and at 1, 2 and 4 weeks follow-up.

Doel van het onderzoek

Research Question 1: Do mental health apps improve mental wellbeing? This question will be investigated by testing the following hypothesis: There will be an interaction between condition (allocation to one of the 4 apps vs. no-app control; between-subjects factor) and time (pre- and post-app use assessments of the Mental Health Continuum questionnaire (MHC; within-subjects factor). Data will be analyzed using analysis of variance (general linear model) using a 5 x 2 mixed model design. Data will be analyzed using an intention-to-treat approach with carry-forward of missing values.

Ancillary Research Questons: Additional analyses will be conducted examining: (a) the nature of the mental health apps (i.e., whether or not users are encouraged to engage in specific behaviors or whether only self-monitoring is involved); (b) which psychological measures might function as explanatory variables for changes in MHC scores; (c) which app-related characteristics (e.g., user-friendlyness) play a role in the effectiveness of the app; and (d) other health outcomes (e.g., physical activity, sleep quality, and physical health status & symptoms).

Onderzoeksopzet

Baseline (pre-randomization), 1, 2 and 4 weeks follow-up.

Onderzoeksproduct en/of interventie

Four open access, no-cost (free), publicly available apps will be compared with a no-app control condition and also among themselves (see hypothesis for details). After the initial assessments, participants will be randomized to one of the 4 apps or the control condition, and they will use the app for 2 weeks. The four 'active' apps focus on: daily monitoring of

emotions, meditation, mindfulness, and keeping a gratitude diary.

The project was reviewed and approved by the Ethics Review Board (ERB) of the Tilburg School of Social and Behavioral Sciences (project #: RP110) and does not require full METC review. The project was reviewed and approved for compliance with GDPR regulations.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

(1) age > 18 years; (2) access to a smartphone; (3) sufficient understanding of the English language (i.e., US 8th grade reading level or equivalent: the informed consent document and all apps will be in English); and (4) not a student in this particular research project (all other students are eligible); and (5) providing informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

There are no a priori exclusion criteria.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel: Factorieel

Toewijzing: Gerandomiseerd

Blindering: Open / niet geblindeerd

Controle: Geneesmiddel

Deelname

Nederland

Status: Werving gestart

(Verwachte) startdatum: 20-03-2020

Aantal proefpersonen: 500

Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting

Based on the nature of this study, there are no plans to share the data beyond the research team. The reasons are three-fold: 1) privacy related (participants use their personal cell phone as part of this study); 2) practical (the research team does not have the resources to prepare selected datasets for other researchers), and 3) because participants use their personal cell phones, we cannot rule out that data collected in this project will be linked to databases from (for-profit) third parties with an interest in the apps or cell phones used by the participants.

Ethische beoordeling

Niet van toepassing

Soort: Niet van toepassing

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 NL8471

Ander register Tilburg University: RP110

Resultaten

Samenvatting resultaten

Publications will primarily include the scientific literature and if appropriate the lay press.