Een dagelijks-leven interventie gericht op stress en beloning bij vroege psychose

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24803

Bron
NTR

Verkorte titel
INTERACT

Aandoening

At-risk mental state for psychosis (ARMS) or first episode psychosis (FEP)

Ondersteuning

Primaire sponsor: Maastricht University
Overige ondersteuning: European Research Council

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The study’s main parameters are distress related to psychotic experiences, general and social functioning, and (sub-)clinical symptoms as measured with questionnaires and interviews.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Despite treatment with antipsychotic medication or traditional cognitive behavioural therapy (CBT), individuals at early stages of psychotic illness - those with an at-risk mental state (ARMS) or first episode psychosis (FEP) - present with poor functioning and high levels of psychopathology. Acceptance and commitment therapy (ACT) is aimed at changing the relationship between the individual and their complaints through detachment and acceptance. Clinical improvement is achieved as a result of reduced distress and impairment, rather than the other way around. As such, ACT could be a particularly interesting candidate treatment for this vulnerable group. A promising new intervention method includes integration of the treatment in the daily-lives of individuals using mobile technology, which could substantially increase the treatment effects.

Objective: The current project aims to investigate the efficacy of a new form of treatment that integrates ACT in daily-life (ACT-DL) of individuals at early stages of psychotic illness using a smartphone app (PsyMate®). We hypothesise that the individuals who receive the experimental treatment improve on measures of distress related to psychotic experiences, global and social functioning, psychotic experiences, and psychopahtology compared to individuals who receive a control treatment.

Study design: A multi-centre randomised controlled trial with two arms i) ACT-DL inaddition to treatment as usual (TAU) and ii) TAU only, with measurements at pre-intervention, post-intervention, and follow-up at six and 12 months post-intervention.

Study population: ARMS and FEP individuals who seek help at a clinic or institution for (sub-)clinical psychotic experiences.

Intervention: Participants in the ACT-DL group will receive one psychoeducation session followed by seven standard ACT sessions, embedded in an eight-week period during which they are trained to apply the skills learned during the sessions to their daily lives with help of

the PsyMate® smartphone app. Both groups will receive TAU from the clinic or institution they are admitted to.

Main study parameters/endpoints: The study's main parameters are distress related to psychotic experiences, global and social functioning, psychotic experiences, and psychopathology as measured using questionnaires and interviews.

Doel van het onderzoek

We hypothesise that ARMS and FEP individuals who receive the ACT-DL treatment will improve on measures of distress related to psychotic experiences, global and social functioning, psychotic experiences, and psychopahtology compared to individuals who receive TAU only.

Onderzoeksopzet

pre-intervention measurement: T0

intervention measurements: T1.1-T1.8 (during eight-week intervention)

post-intervention measurement: T2

follow-up measurements: T3 (6 months), and T4 (12 months)

Onderzoeksproduct en/of interventie

Participants in the ACT-DL group will receive seven standard group ACT sessions and a psychoeducation session, embedded in an eight-week period during which they are trained to apply the skills learned during the sessions to their daily lives with help of a PsyMate® smartphone app. Both groups will receive TAU from the clinic or institution they are admitted to.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 15-65 years

2. Mental competence

3. Sufficient command of the Dutch language to understand and follow instructions

4. PQ score >6

5. An ARMS or FEP as assessed by the CAARMS

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Presence of drug/alcohol dependence or abuse (based on sections K and L of the Mini International Neuropsychiatric Interview) as primary diagnosis. Exception: early remission criterion according to DSM V is met (“After full criteria for substance/alcohol use disorder were previously met, none of the criteria for substance/alcohol use disorder have been met for at least three months but for less than twelve months (with the exception that the criterion A4, "craving, or a strong desire or urge to use drug in question", may be met.”)
2. Severe endocrine, cardiovascular or brain disease
3. Diagnosis of organic psychosis

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2014
Aantal proefpersonen:	150
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	26-09-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47082
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4107
NTR-old	NTR4252
CCMO	NL46439.068.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON47082

Resultaten

Samenvatting resultaten

T. Vaessen, H. Steinhart, T. Batink, A. Klippel, M. Van Nierop, U. Reininghaus & I. Myin-Germeys (2019): ACT in daily life in early psychosis: an ecological momentary intervention approach, Psychosis.