A real-time and real-world intervention focusing on stress and reward

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Schizophrenia and other psychotic disorders
Study type	Interventional

Summary

ID

NL-OMON47082

Source
ToetsingOnline

Brief title
INTERACT

Condition

- Schizophrenia and other psychotic disorders

Synonym
at-risk mental state for psychosis; early psychosis

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: European Research Council (ERC)

Intervention

Keyword: ACT, ARMS, ESM, RCT

Outcome measures

Primary outcome

The study*s main parameters are (sub-)clinical symptoms and general and social functioning, as measured with the experience sampling method (ESM), questionnaires and interviews.

Secondary outcome

Stress-reactivity, reward-experience, and overall positive affect, as measured with ESM.

Study description

Background summary

Despite attempts to prevent or delay transition to chronic psychosis with antipsychotic medication or traditional cognitive behavioural therapy (CBT), individuals with an at-risk mental state (ARMS) or a first episode psychosis (FEP) present with poor functioning and high levels of general psychopathology, even in the absence of transition. Acceptance and commitment therapy (ACT; a next generation CBT) is aimed at changing the relationship between the individual and his 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 the individuals using mobile technology, which could substantially increase the treatment effects.

Study objective

The current project aims to investigate the efficacy of a new form of treatment that integrates ACT in the daily-lives of ARMS individuals using a small digital device (PsyMate®). We hypothesise the ARMS and FEP individuals who receive the experimental treatment to improve on measures of clinical and

general functioning, stress-reactivity, and reward-experience compared to individuals who receive a control treatment.

Study design

A multi-centre randomised controlled trial (RCT) with three arms i) daily-life ACT and treatment as usual, ii) cognitive behavioral therapy as usual, and iii) treatment as usual, with measurements at pre-intervention, post-intervention, and follow-up at six, 12, and 24 months post-intervention.

Intervention

Participants in the daily-life ACT group will receive one psychoeducation session and seven ACT sessions, embedded in a nine-week period during which they are trained to apply the skills learned during the sessions to their daily lives with help of a PsyMate®. Participants. All groups will receive TAU from the clinic or institution they are admitted to.

Study burden and risks

There are no health-risks associated with participation. The total time investment for participation during the intervention period depends on group relatedness.

There will be five moments of assessment of our main study parameters each using interviews and questionnaires and six-day ESM periods. These measurements will be equal for all groups and require a time investment of approximately 28 hours in total, divided over a period of two years. Given that all participants are expected to benefit from participation, the burden should be considered acceptable.

Those participants who were randomised in the Daily-life ACT group receive an additional 8 therapeutic sessions of 45 minutes to 1 hour and are expected to practice ACT exercises daily under the guidance of the PsyMate.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Age 16-65 years
2. Mental competence*
3. Sufficient command of the Dutch language to understand and follow instructions
4. PQ score >6
+
5. An ARMS as assessed by the CAARMS or the SPI-A
OR
6. diagnosis first episode psychosis

Exclusion criteria

1. Diagnosis of alcohol or drug dependence or abuse (based on sections K & L of Mini International Neuropsychiatric Inventory)
2. Severe endocrine, cardiovascular or brain disease
3. diagnosis of organic psychosis

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2015
Enrollment:	101
Type:	Actual

Ethics review

Approved WMO Date:	07-07-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-06-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-03-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-10-2016

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-06-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24803
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL46439.068.13
Other	NRT 16177
OMON	NL-OMON24803