Inference Based Approach, treatment for paranoia *
A replicated randomized single-case A-B-phase design

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Primary objectives:Is IBA an effective treatment for patients with paranoia, that is, does IBA result in reduction of paranoia symptoms?Secondary objectives:Does insight improve after IBA treatment (i.e. insight in psychosis)?

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

Summary

ID

NL-OMON52536

Source
ToetsingOnline

Brief title
Inference Based Approach, treatment for paranoia.

Condition

- Schizophrenia and other psychotic disorders

Synonym
Paranoia, suspicion

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Centraal (Amersfoort)

Source(s) of monetary or material Support: De verrichter (GGzCentraal afdeling wetenschappelijk onderzoek) financiert het onderzoek

Intervention

Keyword: IBA, Paranoia, Single-case design, Treatment

Outcome measures

Primary outcome

- The State Social Paranoia Scale (SSPS) is a validated and reliable questionnaire for measuring persecutory Ideations (Freeman, et al., 2007). Dutch translation by Veling (2010). It*s a brief self-report questionnaire that consist of 10 items. Patient score from 1 (do not agree) to 5 (totally agree). Higher scores indicate greater levels of paranoid thoughts. Examples of questions: *someone was hostile towards me*, *someone had bad intentions towards me*.

Secondary outcome

- The Green Paranoid Thoughts Scale (GPTS) is a validated and reliable questionnaire for measuring the severity of paranoia (Green et al., 2008). Dutch translation by Van Der Gaag and Ferwerda (2008). There is a cuts-off score of 68 to make a distinction between clinical and subclinical paranoia. It*s a self-report questionnaire. It consist of part A and part B, both exist of 16 items. Example of questions: *I was convinced there was a conspiracy against me*, *I was sure someone wanted to hurt me*. The questions are about the last month and about feelings and thoughts about others. Patients score the extent of the feeling from 1 (not at all) to 5 (totally). Higher scores indicate higher levels of paranoia

- The Insight Scale for psychosis (PI) PI, is a quick self-report that is

reliable, valid and sensitive to individual difference and change. The aim of

the PI is to measure changes of insight over time (Birchwood et al., 1994).

Dutch translation by Van Der Gaag, Bervoets & De Boer, 1994). It consist of 8

items. The scoring system is simple (yes, no or unsure). Example of questions:

you do not need medication, *you are mentally well*.

Study description

Background summary

According to Freeman paranoia is having unfounded thoughts that others are deliberately intending to cause harm (Freeman, 2016). Paranoia is common in the general population, at least 10-15% of the people experience paranoid thoughts (Freeman, 2007). This varies from mistrust and suspiciousness to persecutory delusions. Persecutory delusions are the severest within the paranoia spectrum and it is a frequent symptom in psychosis. More than 70% of the patients with a first psychosis experience persecutory delusions (Coid et al., 2013) and at least 50% of the people with schizophrenia (Sartorius et al., 1986; Cutting, 1997 cited in Green et al., 2008). Paranoia can be severe and lead to being withdrawn from social activity, distress, fear, anxiety and lower quality of life (Freeman, 2016).

The available research on the treatment for psychosis (generally also aiming to decrease paranoia) shows in general a medium effect-size for either pharmacotherapy or Cognitive Behavioural Therapy (CBT). More effective treatment options for patients with paranoia are sorely needed.

The Inference Based Approach (IBA) might be a promising alternative. IBA is an effective treatment for patients with OCD, especially for patients with OCD with poor insight (O* Conner et al., 2016; Visser et al., 2015). IBA is based on the assumption that people with OCD misjudge the actual state of affairs and therefore feel the need to perform compulsions (H. Visser, et al., 2015). The patient gives credibility to doubt that comes from imagination and fail to integrate sensory information in their decision making processes. IBA teaches patients to rely on sensory information in the here and now.

It is, for various reasons, argumented and hypothesized that IBA is a possible effective treatment for paranoia. First of all, a person with paranoia has the

perception that he is currently in danger, even when there is no real threat. IBA teaches the patient to recognize the differences between being absorbed in imagination and relying on reality information. Another reason why IBA might be an effective treatment is that paranoia thrives when odd internal sensations and perceptions provoke fearful explanations (presumably the peculiar narrative mentioned above). The high physiological arousal associated with anxiety is mistaken to indicate external threat (Freeman, 2016). IBA teaches the patient to rely on his senses and not on the imagination of a fearful state.
Because IBA aims at improving reality testing and seems to be especially effective for OCD with poor or absent insight, which in fact is difficult to distinguish from psychosis it stands to reason that it might be effective for paranoia to.

This study is a pilot to provide knowledge wether IBA is indeed an effective treatment for patients suffering from paranoia. It*s the first time worldwide that IBA will be investigated within this specified population of people suffering from paranoia.

Study objective

Primary objectives:
Is IBA an effective treatment for patients with paranoia, that is, does IBA result in reduction of paranoia symptoms?

Secondary objectives:
Does insight improve after IBA treatment (i.e. insight in psychosis)?

Study design

A replicated randomized single-case design.

In such designs, repeated observations are recorded for a single person on the dependent variable of interest, and the treatment can be considered as one of the levels of the independent variable. The observations are recorded repeatedly during a baseline phase (A phase) and an intervention phase (B phase). Changes during both phases are being compared for each single case. Phase designs can be randomized by listing all possible intervention start points and then randomly selecting one of them for conducting the actual experiment (Michiels & Onghena, 2018).
In the current study, the target symptom is recorded on a daily basis, starting at inclusion (T0). The start of the B phase will be randomized over 20 possible assignments in week 2-5 after T0. This way the guidelines of Kratochwill and colleagues (2010) are met.

Intervention

IBA intervention for 20 weekly sessions of 45 minutes.

In IBA treatment patients try to discover that in the situations in which they experience anxiety and/or anger related to suspiciousness, a peculiar overwhelming narrative (that is typically a narrative consisting of aberrant reasoning processes) pops up in their mind and overrules integration of sensory information. And they learn that this is qualitatively very different from their general frame of mind (active whenever they experience no suspiciousness). They learn to anticipate on getting absorbed in those kind of narratives, that is to recognize and to stop and wait at the moment on which naturally relying on *here and now sensory information* transposes to relying on imagination. The patient further learns to defend him- or herself against the absorbing effect of imagination by recognizing the typical aberrant reasoning processes and discovering how each of it overrules perception. This way the patient with paranoia can learn that there is no real threat in the here and now and therefore no need for anxiety, anger and safety behaviour.

Study burden and risks

Burden associated with participation during the 'study-intake'
- During the study-intake a semi-structured interview (SCID) will be conducted and the patient fill in the Green Paranoid Thoughts Scale (GPTS) the Insight Scale for psychosis (PI). In total, with the informed consent procedure and explaining the study it will takes about 60 minutes.

Burden associated with the baseline phase (phase A)
- Participant will fill-in the State Social Paranoia Scale (SSPS) on a daily basis.This takes about 2-3 minutes. The baseline phase depends on the randomization of the startpoint of the treatment. This can vary between week 2 and week 5.

Burden associated with the treatment phase
- At the start of the treatment the patient will fill in the GPTS and the PI.
- Participants will fill-in the SSPS on a daily basis
- IBA intervention for 20 weekly sessions of 45 minutes.
- At the end of the treatment the patient will fill-in the GPTS and the PI.

Follow-up
- The patient will fill-in the GPTS and the PI.

Anticipated risk factors:*
1. Distress from receiving IBA treatment*Subjects may experience distress, anxiety or fatigue during IBA treatment, which can be expected by undergoing any form of psychotherapy. However, we expect no additional risk factors when compared to CBT, the standard clinical care.
2. Distress from study assessments and questionnaires.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Primary DSM-5 diagnosis in the psychotic spectrum measured with the SCID-5
- Paranoia score of 68 or above on the dutch translation of the Green Paranoid Thoughts Scale; GPTS)
- Age 18 or above
- Medication must be stable for a time of a month

Exclusion criteria

- No sufficient command of the Dutch language
- Mental retardation
- Acute suicidality (defined as someone having suicide thoughts, plans and/or

preparations to ending their life)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-05-2021
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO

Date:	01-09-2020
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
Other	nader te bepalen
CCMO	NL70402.068.20