Influence of transdiagnostic factors on the course of quality of life in people with complex psychological problems.

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Objective of the quantitative and qualitative study:To gain knowledge about which transdiagnostic factors are associated with dropout from and outcome of intensive high-specialty treatment.Objective of the pilot study:To gain insight into the role...

Ethical review	Approved WMO
Status	Pending
Health condition type	Psychiatric disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON51593

Source
ToetsingOnline

Brief title
Influence of transdiagn. factors on quality of life in psychiatry

Condition

- Psychiatric disorders NEC

Synonym
complex psychological problems

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Centraal (Amersfoort)
Source(s) of monetary or material Support: 0

Intervention

Keyword: psychiatry, quality of life, transdiagnostic, treatment outcome

Outcome measures

Primary outcome

Quality of life (WHO-QOL-Bref en de Eq-5d).

Secondary outcome

Drop-out (Y/N) and severity of psychopathology (BSI).

Study description

Background summary

In third-line highly specialised treatment centres, patients with various complex psychological problems are treated. These patients often have, on the one hand, severe psychological disorders and a chronically lower level of functioning in various areas and, on the other hand, the potential to benefit from intensive psychotherapy. Often there is multimorbidity and the patients have had several evidence-based psychotherapies and pharmacotherapies which were not (permanently) effective. Multidisciplinary guidelines for the treatment of various disorders then prescribe intensive treatment in a highly specialised centre. Unfortunately, these treatments are not always effective and some patients drop out prematurely. This is a problem because these treatments are very expensive and for patients and their families this treatment is their last hope. The aim of this study is to generate knowledge that can contribute to the prevention of early drop-out from intensive high-specialty treatment and to more effective treatment of people with complex psychological problems.
To give an outline of the scope of the problem the following should be noted: Previous research shows that 50-60% of patients with a previously therapy-resistant obsessive-compulsive disorder as their main diagnosis improve substantially after intensive highly specialised treatment (Balachander et al., 2020; Brennan et al., 2014; Siwiec, Riemann, & Lee, 2019; Veale et al., 2016; Van Geijtenbeek de Vos van Steenwijk et al., 2021). A similar proportion (51-64%) of patients with a previously therapy-resistant personality disorder or post traumatic stress disorder as their main diagnosis, recover from intensive highly specialised treatment (Solbakken & Abbass, 2015; Steil, Dyer, Priebe, Kleindienst, & Bohus, 2011; Werbart, Forsström, & Jeanneau, 2012). Thus, in these studies among various patient groups, treatment had no effect in

approximately 40-50%.

We do not know why almost half of the people with complex mental disorders do not recover from such treatments. As outlined above, it applies to different patient groups. It is possible that there is a common cause of limited treatment outcome. A potential explanation is that important transdiagnostic factors are insufficiently addressed in the treatment.

A transdiagnostic approach to psychopathology assumes that the same underlying genetic, neurobiological and psychological mechanisms can lead to and sustain different disorders. Examples of transdiagnostic factors (TDFs) are negative self-image and insufficient emotion regulation skills. TDFs explain chronicity, suicidality and the development of new additional mental disorders (comorbidity) better than the presence of specific mental disorders (Kessler et al., 2011; Naragon-Gainey & Watson, 2011). If TDFs not only predict the development of disorders but also maintain psychopathology, they should be addressed in treatment. TDF intervention is already used in less complex populations. Its success is not inferior to, but also does not appear to be superior to, disorder-specific treatment (McHugh, Murray, & Barlow, 2009). Especially in the most complex populations, in which multimorbidity is present by definition, an addition of transdiagnostic treatment to disorder-specific treatment might be appropriate. However, there is a lack of knowledge in the literature about which TDFs are associated with dropout from and outcome from intensive highly specialised treatment. The aim of the present study is to address this lack of knowledge. This can be done by repeatedly measuring TDFs in a prospective naturalistic cohort study involving patients with complex problems who are intensively treated in a highly specialised centre.

Two core temperament factors, Anxiety/Neuroticism/Behavioral Inhibition and Extraversion/behavioural activation/positive affect, dominate the transdiagnostic literature. Both have a strong genetic basis underlying emotional disorders (Brown, 2007; Brown & Barlow, 2009; Rodriguez-Seijas, Eaton, & Krueger, 2015). In addition, previous research suggests that the following pathological factors are underlying or maintaining various psychological disorders: Childhood trauma(Curran, Adamson, Rosato, De Cock, & Leavey, 2018; K. M. Keyes et al, 2012), insecure attachment style, emotion regulation problems(Aldao, Gee, De Los Reyes, & Seager, 2016), negative self-image (Korrelboom, 2014) intolerance of uncertainty (Dupuy & Ladouceur, 2008; Mahoney & McEvoy, 2012), experiential avoidance (Spinhoven, Drost, de Rooij, van Hemert, & Penninx, 2014), alexithymia (Dimaggio, Vanheule, Lysaker, Carcione, & Nicolò, 2009). There are also indications that deficits in well-being and sense of purpose (C. L. Keyes, Dhingra, & Simoes, 2010; Lamers, Bolier, Westerhof, Smit, & Bohlmeijer, 2012), healthy lifestyle (eating, exercise, resources, sleep)(Zaman, Hankir, & Jemni, 2019), self-compassion (MacBeth & Gumley, 2012) and playfulness (Farley, Kennedy-Behr, & Brown, 2020), are underlying or maintaining psychopathology in people with various mental illnesses.

By following a cohort of patients with complex problems for a period of time and measuring TDFs repeatedly, it can be examined which developments in TDFs are associated with improvements in functioning, quality of life and symptom reduction. This may provide clues as to which TDFs offer the most relevant entry points for treatment in this complex group.

Since, to the best of our knowledge, no knowledge is yet available about which TDFs are associated with the persistence of problems in the group described here, we opted for an exploratory approach.

Study objective

Objective of the quantitative and qualitative study:
To gain knowledge about which transdiagnostic factors are associated with dropout from and outcome of intensive high-specialty treatment.

Objective of the pilot study:
To gain insight into the role of transdiagnostic factors in the treatment of different target groups. Namely, also in a target group of patients with less complex problems, or where despite complex problems a part-time or clinical treatment is not (yet) indicated. This contributes to the adaptation of treatments to specific patient profiles.

Study design

Longitudinal cohort study

Study burden and risks

There is a mild cognitive load due to the duration of the questionnaires.
There is no risk for the participants.

The participants complete the questionnaires during the intake as part of the treatment as usual and then annually for evaluation. Within the framework of the scientific research, subjects will be asked to fill in the questionnaires several times, initially more frequently and later at a lower frequency.
The duration of each measurement for the scientific research is estimated at 75 minutes. An explanation will be given beforehand and permission will be asked by means of an Informed Consent. It will be explicitly stated that participation is voluntary and that the choice made has no consequences whatsoever for the treatment to be followed. In this way, participants are given as much opportunity as possible to make a voluntary choice whether or not to participate in this study. Also during the study, participants can stop his/her participation at any time.
Questionnaires can cause mild disruption, because of the confrontation with certain complaints and/or the (experienced) absence of results, for example.

However, at the same time, the themes of the questionnaires are in line with the complaints and/or the (possible) origin of the complaints and therefore relevant and not new/unknown to the participants. These themes will also be addressed in the treatment.

Contacts

Public
GGZ Centraal (Amersfoort)

Utrechtseweg 266
Amersfoort 3818 EW
NL
Scientific
GGZ Centraal (Amersfoort)

Utrechtseweg 266
Amersfoort 3818 EW
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Adults with serious, chronic and complex psychological problems, who are referred for (day) clinical (or for the pilot study outpatient) treatment within the Center for Psychotherapy and who receive an indication for this tratment based on their intake..

Exclusion criteria

(Mild) intellectual disability / a serious substance-related disorder / a psychotic disorder of being psychotic / suicidal to such an extent that a closed ward is necessary / antisocial behaviour / an autistic disorder / no housing.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	16-10-2022
Enrollment:	225
Type:	Anticipated

Ethics review

Approved WMO

Date:	23-01-2023
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL82232.075.22