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Effectiveness of Acceptance and Commitment Therapy (ACT)-based therapy

Submission date
20/05/2016

Recruitment status
No longer recruiting

Registration date
22/08/2016

Overall study status
Completed

Last Edited
01/09/2025

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Mental disorders are impairing for the individual and are associated with low quality of life and reduced well-being. Treatment resistance (inadequate response to treatment) occurs in 25% -50% of patients. Acceptance and Commitment Therapy (ACT), a further development of traditional behavioral therapy, may offer a starting point for treatment-resistant patients precisely because the therapy does not attempt to eliminate symptoms. Instead, the therapy helps the patient to stop the unsuccessful struggle by fostering the willingness to openly experience emotions and thoughts as such. ACT has shown promising results even with highly impacted patients suffering from diverse psychological disorders. What remains unknown is whether and to what extent ACT transfers to treatment-resistant, chronic (long-term) patients treated in routine in- and out-patients treatment settings. Furthermore, the mechanisms underlying treatment success or failure remain largely unknown. This study will therefore examine the effectiveness of ACT treatment for patients with treatment-resistant disorders.

Who can participate?
Inpatients and outpatients aged 18 – 65 presenting for specialized treatment in a psychiatric university clinic

What does the study involve?
Both the inpatient unit and outpatient units of the Universitären Psychiatrischen Kliniken in Basel both apply Acceptance and Commitment Therapy. The treatment program in the inpatient unit involves intensive psychotherapy, individually and in groups. Treatment in the outpatient unit consists of individual intensive psychotherapy. The goal is to limit treatment to 3 months on average, however the length differs by individual, and is determined by clinical necessity. In addition, the patients are followed-up once they leave the clinic after 1, 4, 9 and 12 months.

What are the possible benefits and risks of participating?
Participants can obtain a summary of their responses that will be shared with their treatment provider. The results will inform us about the processes involved in successful and unsuccessful treatment. Participation in the assessment procedures of this study is not known to be associated with any risks.

Where is the study run from?
Universitäre Psychiatrische Kliniken Basel (Switzerland)

When is the study starting and how long is it expected to run for?
May 2016 to February 2021

Who is funding the study?
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung (Switzerland)

Who is the main contact?
Prof. Andrew Gloster

Study website
https://psychologie.unibas.ch/en/faculty/centers/clinical-psychology-and-intervention-science/teaching/master/choose-change/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EKNZ: 165/13

Study information

Scientific Title
Effectiveness of Acceptance and Commitment Therapy (ACT)-based therapy

Study objectives

Effectiveness:
1. The Acceptance and Commitment Therapy (ACT)-specific intervention will lead to significant positive changes in two treatment settings (i.e., inpatient and outpatient).

Moderator variables:
2. Psychological flexibility will moderate the negative impact of stressors such that it will be buffered in patients who show high levels in psychological flexibility.

Long-Term Course and Outcome:
3. Positive changes observed between pretest and post-test will remain stable for 12 months following treatment in the ACT-condition.
4. The percentage of patients who successfully apply treatment processes following treatment will differ between the in- and out-patient settings. However, irrespective of setting, those patients who apply the processes will have less relapse.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethikkommission Nordwest- und Zentralschweiz, May 2016; Ref: EKNZ: 165/13

Study design
Effectiveness study with two non-randomized treatment arms (i.e., inpatient and outpatient) consisting of self-referring patients

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Transdiagnostic, treatment-resistant patients, presenting for specialized in- and out-patient treatment

Interventions
Both the inpatient unit and outpatient units of the Universitären Psychiatrischen Kliniken in Basel will both apply Acceptance and Commitment Therapy. The treatment program in the inpatient unit involves intensive psychotherapy, individually and in groups. Treatment in the outpatient unit consists of individual intensive psychotherapy. Patients self-present for treatment and there is no randomisation. The goal is to limit treatment to 3 months on average,

however the length differs by individual, and will be determined by clinical necessity, and cannot be guaranteed a priori.

The study includes a pre-, post- and follow-up measurement. The follow up (FU) assessments will take place after 1, 4, 9 and 12 months.

Intervention Type
Other

Primary outcome measure
1. Symptoms: Brief Symptom Checklist (BSCL)
2. General Functioning: World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0; 12-item version)
3. Well-Being: Mental Health Continuum (MHC-SF)

Primary outcomes are measured at baseline, post, and 12 months follow up.

Secondary outcome measures
Measures of:
1. Psychological flexibility/emotional avoidance
2. Depression
3. Worry
4. Anxiety/fear
5. Obsessions and compulsions
6. Social Interaction
7. Social fear
8. Process of psychological flexibility
9. Committed action
10. Cognitive fusion
11. Mindfulness
12. Values
13. Meaning of life
14. (Problematic) emotion regulation
15. Overall social support
16. Relationship satisfaction
17. Social network quality
18. Values
19. Perceived stress
20. Daily stress
21. Prosocial behaviors
22. Cooperation
23. Expectancy

Secondary outcomes are measured at baseline, post and 12 months follow up. Process measures of psychological flexibility, social interactions, social network quality, and daily stress are additionally measured at 1, 4 and 9 month follow-up.

Overall study start date
01/05/2016

Completion date

01/02/2021

Eligibility

Key inclusion criteria
1. Individuals 18 – 65 years of age
2. Inpatients and outpatients presenting for specialized treatment in a psychiatric university clinic
3. A history of at least one course of previous therapy
4. Signed letter of consent

Added 20/06/2019:
Some patients without previous therapy experience were included to enable full modelling of patients from those without treatment experience to those with treatment experience.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
170

Total final enrolment
200

Key exclusion criteria
1. Less than 18, greater than 65 years of age
2. Inability to understand the local language (German) in written form
3. Inability to complete the study design

Date of first enrolment
01/05/2016

Date of final enrolment
08/11/2019

Locations

Countries of recruitment
Switzerland

Study participating centre
Universitäre Psychiatrische Kliniken Basel
Switzerland
4012

Sponsor information

Organisation
University of Basel (Switzerland)

Sponsor details
c/o Prof. Dr Andrew Gloster
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Sponsor type
University/education

Website
https://psycho.unibas.ch/fakultaet/personen/profil/person/andrew-gloster/

ROR
https://ror.org/02s6k3f65

Funder(s)

Funder type
Research organisation

Funder Name
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/06/2019	12/06/2019	Yes	No
Results article		06/04/2023	11/04/2023	Yes	No
Results article		31/05/2023	01/06/2023	Yes	No
Results article		24/03/2021	01/09/2025	Yes	No