Trial Title: Compassion and Metacognition Based Therapy for Schizotypal Personality Disorder: A Pilot Non-inferiority Randomized Controlled Trial on Repeated Measures.

Internal Reference Number / Short title: Compassion and Metacognition in Schizotypal Personality (CMBT)

Ethics Ref: 032020-07072020

Date and Version No: 01-2021-02-11

Chief Investigator: Simone Cheli

Tages Onlus

Telephone: +393285642442

Email: simone.cheli@tagesonlus.org

Investigators: Gil Goldzweig, The Academic College of Tel Aviv Yaffo, Tel Aviv, Israel

Veronica Cavalletti, Tages Onlus, Firenze, Italy

Cecilia Trevisani, Tages Onlus, Firenze, Italy

Sponsor: Tages Onlus

Via della Torretta, 14, Florence, Italy

Funder: None

Confidentiality Statement

TABLE OF CONTENTS

1. KEY TRIAL CONTACTS

Chief Investigator	Simone Cheli Telephone: +393285642442 Email: simone.cheli@tagesonlus.org
Sponsor	Tages Onlus

	Phone: 055 679037 Email: info@tagesonlus.org
Funder(s)	None
Clinical Trials Unit	Veronica Cavalletti – Tages Firenze (Florence, Italy) Cecilia Trevisani – Tages Bologna (bologna, Italy)
Statistician	Gil Goldzweig – The Academic College of Tel Aviv Yaffo - Israel
Committees	Francesco Velicogna – Tages Onlus, Florence, Italy

2. BRIEF SUMMARY

The purpose of this study is to assess the safety and efficacy of a newly developed psychotherapy for schizotypal personality disorder. This new form of psychotherapy integrates compassion focused therapy and metacognitively oriented psychotherapy.

3. SYNOPSIS

Trial Title	Compassion and Metacognition Based Therapy for Schizotypal Personality Disorder: A Pilot Non-inferiority Randomized Controlled Trial on Repeated Measures.
Internal ref. no. (or short title)	Compassion and Metacognition in Schizotypal Personality (CMBT).
Trial registration	Unique Protocol ID: 03-07072020
Sponsor	Tages Onlus Via della Torretta, 14, Florence, Italy
Funder	N/A
Clinical Phase	Recruiting
Trial Design	Parallel Assignment Randomized Controlled Trial with Repeated Measures
Trial Participants	Minimum Age: 18 Years Being diagnosed with Schizotypal Personality Disorder at SCID-5-AMPD
Sample Size	14
Planned Trial Period	Total lenght: December 15, 2020 - December 20, 2021

	Pre-post evaluation between pre-assessment (1-month before the intervention) and 1 month follow-up.		
Planned Recruitment period	December 15, 2020 - September 30, 2021		
	Objectives	Outcome Measures	Timepoint(s)
Primary		Personality pathology: Total score at PID-5-BF	(i) at 1 month before intervention starts; (ii) once the treatment starts; (iii) 6 measurements at the end of each month of intervention; at 1-month follow-up.
Secondary		Schizotypal Personality Disorder Diagnosis: Diagnosis at the 3rd module of SCID-5-PD interview; General Psychopathology: Total score at SCL-90-R; Metacognition: Total score at MAS-A	Pre-post evaluation between pre-assessment (1-month before the intervention) and 1-month follow-up assessment.
Intervention(s) • IMP(s) • nIMP(s) • Other intervention(s)	Compassion and Metacognition Based Therapy (CMBT): Third Wave Cognitive Therapy targeting metacognitive dysfuctions (through Metacognitively Oriented Psychotherapy) and selfcriticism (through Compassion Focused Therapy). 6-month therapy, including 24 weekly sessions.		
Comparator	Cognitive Behavioral Therapy: Standard Cognitive Behavioral Therapy for Personality Disorders plus Standard Psychopharmacological Treatment. 6-month therapy, including 24 weekly sessions.		

4. ABBREVIATIONS

AE	Adverse event
AR	Adverse reaction

CBT	Cognitive Behavioral Therapy
CFT	Compassion Focused Therapy
CMBT-S	Compassion and Metacognition Based Treatment for Schizotypal Personality Disorder
CI	Chief Investigator
CRA	Clinical Research Associate (Monitor)
CRF	Case Report Form
CRO	Contract Research Organisation
CT	Clinical Trials
CTA	Clinical Trials Authorisation
CTRG	Clinical Trials and Research Governance
DMC/DMSC	Data Monitoring Committee / Data Monitoring and Safety Committee
DSUR	Development Safety Update Report
GCP	Good Clinical Practice
GP	General Practitioner
GTAC	Gene Therapy Advisory Committee
HRA	Health Research Authority
IB	Investigators Brochure
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IMP	Investigational Medicinal Product
IRB	Independent Review Board
MERIT	Metacognitive Reflection and Insight Therapy
MIT	Metacognitive Interpersonal Therapy
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
RES	Research Ethics Service
OXTREC	Oxford Tropical Research Ethics Committee
PI	Principal Investigator
PID-5-BF	Personality Inventory for DSM-5,Brief Form
PIL	Participant/ Patient Information Leaflet
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
RSI	Reference Safety Information
SAE	Serious Adverse Event

SAR	Serious Adverse Reaction
SCID-5-PD	Structured Clinical Interview for DSM-5 Personality Disorders
SCL-90-R	Symptom Checklist – 90 – Revised
SDV	Source Data Verification
SMPC	Summary of Medicinal Product Characteristics
SOP	Standard Operating Procedure
SPD	Schizotypal Personality Disorder
SUSAR	Suspected Unexpected Serious Adverse Reactions
TMF	Trial Master File
TSG	Oxford University Hospitals NHS Foundation Trust / University of Oxford Trials Safety Group

5. BACKGROUND AND RATIONALE

Schizotypal personality disorder (SPD) reflects a pervasive pattern of maladaptive behaviour, which has been suggested to involve either three or four different facets. These include positive features such as ideas of reference, magical thinking and suspiciousness; negative features such as anhedonia and lack of social interest; and cognitive features that involve disorganized thinking and impulsive nonconforming behaviour. SPD has been alternatively considered a personality disorder (PD), a subclinical form of schizophrenia or an expression of the liability for the development of schizophrenia. DSM-5 reports a prevalence of 4.6% in general population, with poor long-term outcomes, including significant impairments in social relationships, work and leisure activities, and a typical declining trajectory in overall functioning. Treatment options are scarce, and a systematic review published in 2018, reported just three psychosocial interventions for SPD. In the last three years, I acted as Principal Investigators of four studies aimed at outlining a novel, evidence-based intervention tailored for SPD. The general aim was to test an integrative psychotherapy rooted in metacognitively oriented psychotherapies and compassion focused therapy. A growing body of research suggests that many diagnosed with personality disorders and psychosis experience deficits in metacognition or the ability to form integrated ideas about themselves and others. They also struggle to regulate their brain's evolved systems for decoding and responding to communication signals, and report a recurrent inability to regulate their arousal when facing internal (e.g. shame) and external (e.g. relations) stimula. Since SPD is a severe mental illness at the crossroads between personality disorder and psychosis, my colleagues and I suggest considering it from these deficits in metacognition and socially evolved systems. We tested how metacognition may be a primary target of a tailored psychotherapy. And we are recently exploring the role of compassion for one's own distress, as a way to strengthen the ability to generate a self-soothing response to suffering. First, together with Paul Lysaker (Indiana University, Indianapolis) and Giancarlo Dimaggio (Center for Metacognitive Intepersonal Therapy, Rome) Dr. Simone Cheli (Tages Onlus) outlined and delivered a pilot study to test the suitability of a metacognitively oriented intervention for patients diagnosed with SPD (Cheli, Lysaker, Dimaggio, 2019). Second, we tested a specifically designed assessment strategy for SPD integrating measures of metacognition, big five, alternative model of personality disorders (Cheli, 2020)). Third, together with Nicola Petrocchi (John Cabot University, Rome) and Veronica Cavaletti (Tages Onlus, Florence) we explored the suitability of online compassion focused therapy interventions for clients with recent early psychotic episodes (Cheli, Cavalletti, Petrocchi, 2020). Four, we recently concluded a study on a large sample of non-clinical young adults (n=2234), aimed at exploring the moderating role of self-soothing and metacognition in the onset of a SPD. All these studies are seemingly supporting the need for a novel, integrative treatment for SPD, that is going to be test in randomized clinical trial.

In conclusion, the collected, even if partial, evidences and my clinical experience in treating SPD, may represent an opportunity for participants to better understand how to outline a treatment plan for an understudied area of psychopathology.

6. OBJECTIVES AND OUTCOME MEASURES

Objectives	**Outcome Measures**	**Timepoint(s) of evaluation of this outcome measure (if applicable)**
Primary Objective To compare the effect of the CMBT-S versus CBT plus standar psychopharmacotherapy for SPD.	• Change in Personality pathology: Total score at PID-5-BF • Schizotypal Personality Disorder Diagnosis: Diagnosis at the 3rd module of SCID-5-PD interview; • General Psychopathology: Total score at SCL-90-R; • Metacognition: Total score at MAS-A	9 measurements: (i) at 1 month before intervention starts; (ii) once the treatment starts; (iii) 6 measurements at the end of each month of intervention; at 1-month follow-up; Pre-post evaluation between pre-assessment (1-month before the intervention) and 1-month follow-up assessment.
Secondary Objectives To assess the safety of CMBT-S in patients diagnosed with SPD	• Dropout rate • Completion rate • Adverse events (suicidal behaviors, self-harm, psychotic episodes) rate	At the end of the intervention: dropout rate (≤10% of subjects), completion rate (≤10% of sessions skipped), adverse event rate ((≤10% of subjects).

7. TRIAL DESIGN

Randomized Controlled Trial with Repeated Measures.

After being informed about the study and potential risks, all patients giving written informed consent will undergo a psychological assessment so as to determine eligibility for study entry. Patients who meet the eligibility requirements will be randomized in a double-blind manner in a 1:1 ratio to new integrative

psychotherapy or treatment as usual (cognitive behavioral therapy plus standard psychopharmacological treatment). One month after the conclusion of the two forms of treatment (both lasting 6 months), patients will have access to the final follow-up assessment.

8. PARTICIPANT IDENTIFICATION

8.1. Trial Participants

Participants with being diagnosed with Schizotypal Personality Disorder at SCID-5-AMPD with minimun age 18 years.

8.2. Inclusion Criteria

- Participant is willing and able to give informed consent for participation in the trial.
- Male or Female, aged 18 years or above.
- Diagnosed with Schizotypal Personality Disorder at SCID-5-AMPD.

8.3. Exclusion Criteria

The participant may not enter the trial if ANY of the following apply:

- Being under psychotherapy or psychopharmacological treatment
- Being diagnosed with schizophrenia and other psychotic disorders
- Being diagnosed with bipolar disorder
- Being diagnosed with intelletual disability
- Being diagnosed with any neurological diseases

9. TRIAL PROCEDURES

9.1. Recruitment

The recruitment centers were selected on the basis of their expertise in treating personality disorders and the presence of a multidisciplinary team. Subjects who during epidemiological studies or clinical assessment procedures report a diagnosis of SPD are approached and asked for their willingness to receive a subsequent assessment for possible entry into the study. Once the informed consent has been read and signed, the inclusion and exclusion criteria for the participants are confirmed. Finally, eligible subjects are randomized through software and assigned to treatment.

9.2. Screening and Eligibility Assessment

An assessment psychologist and a psychiatrist conduct an in-depth assessment of demographic and anamnestic variables and integrate them with the results of psychometric tests and structured interviews.

The maximum time between the assessment, the randomization and the start of the course is one month. Protocol waivers are not permitted.

9.3. Informed Consent

The participanta must personally sign and date the latest approved version of the Informed Consent form before any trial specific procedures are performed.

Written and verbal versions of the Participant Information and Informed Consent will be presented to the participants detailing no less than: the exact nature of the trial; what it will involve for the participant; the implications and constraints of the protocol; the known side effects and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the trial at any time for any reason without prejudice to future care, without affecting their legal rights and with no obligation to give the reason for withdrawal.

The participant will be allowed as much time as wished to consider the information, and the opportunity to question the Investigator, their GP or other independent parties to decide whether they will participate in the trial. Written Informed Consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the Informed Consent. The person who obtained the consent must be suitably qualified and experienced, and have been authorised to do so by the Chief/Principal Investigator. A copy of the signed Informed Consent will be given to the participant. The original signed form will be retained at the trial site.

9.4. Randomisation

A simple computer will generate random number for each participant. CRO will design the randomization schedule and will hold the allocation blind to all the investigators.

9.5. Blinding and code-breaking

Participant, Care Provider, Outcomes Assessor are blinded to the allocation.

9.6. Early Discontinuation/Withdrawal of Participants

During the course of the trial a participant may choose to withdraw early from the trial treatment at any time. This may happen for a number of reasons, including but not limited to:

- The occurrence of what the participant perceives as an intolerable AE.
- Inability to comply with trial procedures
- Participant decision

Participants may choose to stop treatment and/or study assessments but may remain on study follow-up.

Participants may also withdraw their consent, meaning that they wish to withdraw from the study completely. Participants can withdraw completely from the study and withdraw the data and samples collected up until the point of withdrawal. The data and samples already collected would not be used in the final study analysis. (Any limits to this type of withdrawal where, for example analysis of their data or samples has already been integrated into interim results or dose escalation decisions etc. should be explained in the participant information sheet).

9.7. Definition of End of Trial

The end of trial is the point at which all the data has been entered and queries resolved.

10. TRIAL INTERVENTIONS

10.1. Interventions' Description

Cognitive Behavioral Therapy Standard Cognitive Behavioral Therapy for Personality Disorders. Compassion and Metacognition Based Therapy: the intervention is a Third Wave Cognitive Therapy targeting metacognitive dysfuctions (through Metacognitively Oriented Psychotherapy) and selfcriticism (through Compassion Focused Therapy).
Both treatments last 6 months.

11. SAFETY REPORTING

11.1. Adverse Event Definitions

Adverse Event (AE)	Any untoward medical occurrence in a participant to whom the intervention has been administered, including occurrences which are not necessarily caused by or related to that treatment.
Serious Adverse Event (SAE)	A serious adverse event is any untoward medical occurrence that: • results in death • is life-threatening • requires inpatient hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability/incapacity • consists of a congenital anomaly or birth defect*. Other 'important medical events' may also be considered a serious adverse event when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above. NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

12. STATISTICS

12.1. Statistical Analysis Plan (SAP)

Primary outcomes will be evaluated through repeated measures ANOVA. Statistical analyses and reporting will be conducted following CONSORT guidelines, with the primary analyses based on the ITT principle, which considered data from all participants whose baseline data were available. Multiple imputation will be adopted to estimate mid-assessment, post-treatment, and follow-up scores for noncompleters (e.g., those who had missed plus than 10% of sessions, or those who decline to participate in the TAU condition). Additionally, we will also conduct per-protocol (PP) analyses, which refers to inclusion in the analysis of only those patients who strictly adhered to the protocol.

12.2. Sample Size Determination

ANOVA: Repeated measures, within-between interaction has been conducted in order to a priori compute required sample size. As input we estimate (Cheli, 2020) an effect size f equal to 0.37 with a power (1−β err prob) equal to 0.95. Moreover, we considered 9 measurements with at leas a correlation among them equal to 0.50 (PID-5-BF reports a test-restest valuet greater than 0.70). This led to a total sample equal to 12 (critical F= 2.0563726; actual power= 0.9785743). By considering at least 10% of withdrawal we

13. DATA MANAGEMENT

13.1. Source Data

Source documents are where data are first recorded, and from which participants' CRF data are obtained. These include, but are not limited to, personal records (from which mental health history and previous treatment may be summarised into the CRF), clinical and office charts, laboratory and pharmacy records, diaries, microfiches, radiographs, and correspondence.

CRF entries will be considered source data if the CRF is the site of the original recording (e.g. there is no other written or electronic record of data). All documents will be stored safely in confidential conditions. On all trial-specific documents, other than the signed consent, the participant will be referred to by the trial participant number/code, not by name.

13.2. Access to Data

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections.

14. QUALITY ASSURANCE PROCEDURES

14.1. Risk assessment

The trial will be conducted in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures. A risk assessment and monitoring plan will be prepared before the study opens and will be reviewed as necessary over the course of the trial to reflect significant changes to the protocol or outcomes of monitoring activities.

14.2. Monitoring

Regular monitoring will be performed. Data will be evaluated for compliance with the protocol and accuracy in relation to source documents. Following written standard operating procedures, the monitors will verify that the clinical trial is conducted and data are generated, documented and reported in compliance with the protocol, GCP and the applicable regulatory requirements.

14.3. Trial committees

14.3.1 Safety Monitoring Committee

Tages Onlus will conduct a review of all SAEs for the trial reported during the quarter and cumulatively. The aims of this committee include:

- To pick up any trends, such as increases in un/expected events, and take appropriate action
- To seek additional advice or information from investigators where required
- To evaluate the risk of the trial continuing and take appropriate action where necessary

15. PROTOCOL DEVIATIONS

A trial related deviation is a departure from the ethically approved trial protocol or other trial document or process (e.g. consent process or IMP administration) or from Good Clinical Practice (GCP) or any applicable regulatory requirements. Any deviations from the protocol will be documented in a protocol deviation form and filed in the trial master file.

16. ETHICAL AND REGULATORY CONSIDERATIONS

16.1. Declaration of Helsinki

The Investigator will ensure that this trial is conducted in accordance with the principles of the Declaration of Helsinki.

16.2. Guidelines for Good Clinical Practice

The Investigator will ensure that this trial is conducted in accordance with relevant regulations and with Good Clinical Practice.

16.3. Approvals

Following Sponsor approval the protocol, informed consent form, participant information sheet will be submitted to an appropriate Research Ethics Committee (REC), HRA (where required), regulatory authorities (MHRA in the UK), and host institution(s) for written approval.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

16.4. Reporting

The CI shall submit once a year throughout the clinical trial, or on request, an Annual Progress Report to the REC, host organisation, funder (where required) and Sponsor. In addition, an End of Trial notification and final report will be submitted to the REC, host organisation and Sponsor.

16.5. Participant Confidentiality

The study will comply with the General Data Protection Regulation (GDPR) and Data Protection Act 2018, which require data to be de-identified as soon as it is practical to do so. The processing of the personal data of participants will be minimised by making use of a unique participant study number only on all study documents and any electronic database(s), with the exception of the CRF, where participant initials may be added. All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participants' personal data.

17. FINANCE AND INSURANCE

17.1. Funding

Tages Onlus will be the only institution financially supporting the study.

17.2. Insurance

Tages Onlus and single therapists are legally liable for the negligent acts and omissions of their employees. If participants are harmed whilst taking part in a clinical trial as a result of negligence on the part of a member of the trial team this liability cover would apply. In exceptional circumstances an ex-gratia payment may be offered.

18. PUBLICATION POLICY

IPD will be released at the end of the study and will be accessible permanently.
Individual partecipants data underline the results in all the future publications related to the trial will be available after deidentification.

19. REFERENCES

Balaratnasingam S, Janca A. Normal personality, personality disorder and psychosis: current views and future perspectives. Curr Opin Psychiatry. 2015 Jan;28(1):30-4. doi: 10.1097/YCO.0000000000000124. Review. PubMed 25415496

Bora E. Theory of mind and schizotypy: A meta-analysis. Schizophr Res. 2020 Aug; 222:97-103. doi: 10.1016/j.schres.2020.04.024. Epub 2020 May 25. Review. PubMed 32461089

Braehler C, Gumley A, Harper J, Wallace S, Norrie J, Gilbert P. Exploring change processes in compassion focused therapy in psychosis: results of a feasibility randomized controlled trial. Br J Clin Psychol. 2013 Jun;52(2):199-214. doi: 10.1111/bjc.12009. Epub 2012 Oct 24. PubMed 24215148

Cheli S. Assessment and treatment planning for schizotypal personality disorder: A metacognitively oriented point of view. Psychiatr Rehabil J. 2020 Dec;43(4):335-343. doi: 10.1037/prj0000429. Epub 2020 May 28. PubMed 32463252

Cheli S, Lysaker PH, Dimaggio G. Metacognitively oriented psychotherapy for schizotypal personality disorder: A two-case series. Personal Ment Health. 2019 Aug;13(3):155-167. doi: 10.1002/pmh.1447. Epub 2019 Jun 6. PubMed 31169366

Cohen AS, Mohr C, Ettinger U, Chan RC, Park S. Schizotypy as an organizing framework for social and affective sciences. Schizophr Bull. 2015 Mar;41 Suppl 2:S427-35. doi: 10.1093/schbul/sbu195. Review. PubMed 25810057

Debbané M, Eliez S, Badoud D, Conus P, Flückiger R, Schultze-Lutter F. Developing psychosis and its risk states through the lens of schizotypy. Schizophr Bull. 2015 Mar;41 Suppl 2:S396-407. doi: 10.1093/schbul/sbu176. Epub 2014 Dec 29. Review. PubMed 25548386

Dimaggio G, Lysaker PH. Metacognition and mentalizing in the psychotherapy of patients with psychosis and personality disorders. J Clin Psychol. 2015 Feb;71(2):117-24. doi: 10.1002/jclp.22147. Epub 2014 Dec 31. PubMed 25557317

Dimaggio G, Semerari A, Carcione A, Procacci M, Nicolò G. Toward a model of self pathology underlying personality disorders: narratives, metacognition, interpersonal cycles and decision-making processes. J Pers Disord. 2006 Dec;20(6):597-617. Review. PubMed 17192140

Grant P, Green MJ, Mason OJ. Models of Schizotypy: The Importance of Conceptual Clarity. Schizophr Bull. 2018 Oct 15;44(suppl_2):S556-S563. doi: 10.1093/schbul/sby012. Review. PubMed 29474661

Heriot-Maitland C, McCarthy-Jones S, Longden E, Gilbert P. Compassion Focused Approaches to Working With Distressing Voices. Front Psychol. 2019 Feb 1;10:152. doi: 10.3389/fpsyg.2019.00152. eCollection 2019. PubMed 30774614

Kirby JN, Tellegen CL, Steindl SR. A Meta-Analysis of Compassion-Based Interventions: Current State of Knowledge and Future Directions. Behav Ther. 2017 Nov;48(6):778-792. doi: 10.1016/j.beth.2017.06.003. Epub 2017 Jun 21. Review. PubMed 29029675

Kirchner SK, Roeh A, Nolden J, Hasan A. Diagnosis and treatment of schizotypal personality disorder: evidence from a systematic review. NPJ Schizophr. 2018 Oct 3;4(1):20. doi: 10.1038/s41537-018-0062-8. Review. PubMed 30282970

Kramer U, Beuchat H, Grandjean L, Pascual-Leone A. How Personality Disorders Change in Psychotherapy: a Concise Review of Process. Curr Psychiatry Rep. 2020 Jun 9;22(8):41. doi: 10.1007/s11920-020-01162-3. Review. PubMed 32519017

Leaviss J, Uttley L. Psychotherapeutic benefits of compassion-focused therapy: an early systematic review. Psychol Med. 2015 Apr;45(5):927-45. doi: 10.1017/ S0033291714002141. Epub 2014 Sep 12. Review. PubMed 25215860

Lysaker PH, Dimaggio G, Hamm JA, Leonhardt BL, Hochheiser J, Lysaker JT. Disturbances in Self-Experience in Schizophrenia: Metacognition and the Development of an Integrative Recovery-Oriented Individual Psychotherapy. Psychopathology. 2019;52(2):135-142. doi: 10.1159/000495297. Epub 2018 Dec 11. PubMed 30537720

Lysaker PH, Gagen E, Klion R, Zalzala A, Vohs J, Faith LA, Leonhardt B, Hamm J, Hasson-Ohayon I. Metacognitive Reflection and Insight Therapy: A Recovery-Oriented Treatment Approach for Psychosis. Psychol Res Behav Manag. 2020 Apr 2; 13:331-341. doi: 10.2147/PRBM.S198628. eCollection 2020. Review. PubMed 32308511

Lysaker PH, Hamm JA, Hasson-Ohayon I, Pattison ML, Leonhardt BL. Promoting recovery from severe mental illness: Implications from research on metacognition and metacognitive reflection and insight therapy. World J Psychiatry. 2018 Mar 22;8(1):1-11. doi: 10.5498/wjp.v8.i1.1. eCollection 2018 Mar 22. Review. PubMed 29568726

Lucre K, Clapton N. The Compassionate Kitbag: A creative and integrative approach to compassion-focused therapy. Psychol Psychother. 2020 Jul 8:e12291. doi: 10.1111/papt.12291. [Epub ahead of print] Review. PubMed 32639097

Mason OJ. The assessment of schizotypy and its clinical relevance. Schizophr Bull. 2015 Mar;41 Suppl 2:S374-85. doi: 10.1093/schbul/sbu194. Review. PubMed 25810054

Petrocchi N, Cheli S. The social brain and heart rate variability: Implications for psychotherapy. Psychol Psychother. 2019 Jun;92(2):208-223. doi: 10.1111/papt.12224. Epub 2019 Mar 20. Review. PubMed 30891894

Rosell DR, Futterman SE, McMaster A, Siever LJ. Schizotypal personality disorder: a current review. Curr Psychiatry Rep. 2014 Jul;16(7):452. doi: 10.1007/s11920-014-0452-1. Review. PubMed 24828284

Wilson S, Stroud CB, Durbin CE. Interpersonal dysfunction in personality disorders: A meta-analytic review. Psychol Bull. 2017 Jul;143(7):677-734. doi: 10.1037/bul0000101. Epub 2017 Apr 27. Review. PubMed 28447827

Volkert J, Gablonski TC, Rabung S. Prevalence of personality disorders in the general adult population in Western countries: systematic review and metaanalysis. Br J Psychiatry. 2018 Dec;213(6):709-715. doi: 10.1192/bjp.2018.202. Epub 2018 Sep 28. PubMed 30261937

20. APPENDIX A: CONSENT FORM

CENTER FOR PSYCHOLOGY AND HEALTH – TAGES CHARITY

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title:

Principal Investigator: Simone Cheli, PsyD, Tages Charity

Co-Investigator(s): Veronica Cavalletti, PsyD, Tages Charity; Cecilia Trevisani, PsyD, Tages Charity

Faculty Advisor: Francesco Velicogna, PsyD, Tages Charity

You are invited to take part in a research study. This form contains information that will help you decide whether to join the study.

Taking part in this research project is voluntary. You do not have to participate and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

2. PURPOSE OF THIS STUDY

People who are diagnosed with Schizotypic Personality Disorder have difficulty finding adequate support to deal with the many problems resulting from this diagnosis. To date, there are no recognized guidelines for psychotherapeutic treatments. Tages Charity has developed over the last few years a new form of psychotherapy that complements existing evidence-based protocols. The goal of this study is to evaluate the effectiveness of this new form of psychotherapy by comparing it with one that has shown excellent evidence in other forms of personality disorders.

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study?

People over the age of 18 who have received a diagnosis of SPD can participate in the study. It was decided to exclude people who in addition to this diagnosis have received a diagnosis related to the schizophrenic spectrum and neurological disorders. This decision is linked to the fact that we have preliminarily tested the new intervention on people with only the diagnosis of SPD and we do not want to expose the participants to potentially useless interventions.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

People who agree to participate in the study, after talking with the researchers to get all the information they require and having signed the informed consent, will access the following path:

1) They will carry out an interview with a psychologist expert in diagnosis who will evaluate if the person corresponds to the characteristics of inclusion and exclusion. If the person is not eligible, he will be explained why and if he requests it, he will be able to access another psychotherapy path within the Tages Centers.

2) The people who are eligible will instead enter a process called "randomization". This purpose is to assign people to one of the two interventions (the new one being validated and the standard one for other personality disorders) through a computerized procedure. The purpose of this procedure is not to influence the results with personal choices of the researchers or a priori evaluations of the participants.

3) Within one month of the admission assessment, participants will begin the psychotherapy course which will consist of a weekly session of 50-60 minutes with the assigned therapist. The duration of the psychotherapy course is 6 months for a total of 24 sessions. During the interviews the participants will be invited to talk about their problems and their life experiences, as well as to experiment with new coping strategies inside and outside the session.

4) At the end of each month of psychotherapy, participants will be asked to fill in questionnaires to assess their psychological well-being. Similarly, one month after the end of the intervention, the participants will have an interview and a final assessment with the same psychologist who conducted the entrance assessment.

4.2 How much of my time will be needed to take part in this study?

The study has a total duration of 8 months. In the first month, people will only have to take part in the initial assessment lasting about 2 hours. Thereafter, the 6-month psychotherapy course will begin (24 weekly sessions, each lasting a maximum of 1 hour). Finally, one month after the conclusion of the psychotherapy there will be a final assessment lasting about 2 hours.

4.3 If I decide not to take part in this study, what other options do I have?

Participants can withdraw from the study at any time. If available, researchers will be interested in understanding the reasons and offering the possibility of accessing an alternative psychotherapy path to that offered (outside the study).

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

Pathways of diagnostic evaluation or psychological or psychotherapeutic intervention can expose people to denied and unpleasant experiences. The objective of an intervention is in fact to understand the ways that generate suffering and develop alternative strategies. During this process, people can come into contact with disturbing emotions, thoughts and feelings related to the past or the present.

Although this is the purpose of psychotherapy and therapists have experience in this area, people may find some experiences intolerable. If so, they can first discuss it with their therapist, seek advice from the project manager who is a psychologist who is experienced with these issues, or ask to stop the intervention.

Because this study collects information about you, one of the risks of this research is a loss of confidentiality. See Section 8 of this document for more information on how the study team will protect your confidentiality and privacy.

5.2 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. Existing data suggest that you might benefit from a psychotherapy, in terms both of an increase awareness of your ways of thinking and behaving, and of a reduction of your distress.

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 9. “Contact Information”. If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study? You will not receive any compensation for your participation in the study, with the sole exception of the psychotherapy intervention itself.

7.1.1 Will I need to pay anything to be part of the study? To be part of the study, you will not need to pay for anything.

7.2 Who could profit or financially benefit from the study results?

The team's member are paid for their activities by Tages Charity. Such institution does not receive any compensation or financial benefit for this research.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information?

For the purposes of data analysis and publication, all data will be anonymised. Only three people will be able to associate your name and surname with the data collected: the psychologist who will give you the entry and final interview; the psychologist who will conduct his psychotherapy; the psychologist in charge of the study. As registered psychologists, they have a legal and ethical obligation not to disclose your data. Only the psychologist who will act as his psychotherapist will be able to associate what emerged in psychotherapy with his name. All data will be anonymised by the psychologist responsible for the study.

8.2 Who will have access to my research records?

No one other than the people listed in section 8.1 will be able to associate your data with your name. The anonymized data will instead be made available to research institutions that will request it after approval by the Ethics Committee of Tages Onlus.

9. CONTACT INFORMATION

Who can I contact about this study?

Principal Investigator: Simone Cheli

Email: simone.cheli@tagesonlus.org

Phone: +39 3285642442

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

Tages Onlus

Via della Torretta 14, 50137 Firenze, Italy

Telephone: +39 055 679037

E-mail: info@tagesomlus.org

10. YOUR CONSENT

Consent/Assent to Participate in the Research Study

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records and I/we will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information in Section 9 provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____