

Efficacy of Family Constellations in the General Population (NCT05051462)

Methodology, Statistical Analysis Plan, & Consent Form

Approved: Feb 25, 2021

Design and procedure

The study will be a randomized, waitlist-controlled trial. Considering the non-diagnosis-specific nature of the intervention, the a priori selected primary outcome will be general (non-diagnosis specific) psychopathology. The 80 participants will be randomly assigned in a 1:1 ratio to attend a systemic/family constellation seminar either in the intervention group or in the waitlist control group, the members of which will be offered the same intervention after completing the 2nd follow-up questionnaire (approximately 6 months after the baseline assessment). The assessment protocol will include a pre-intervention assessment, a follow-up approximately 4 weeks after the intervention, and finally six months post-intervention.

The G-Power software (Faul et al., 2009) was used for a priori power analysis. The results for repeated measures mixed-design analysis of variance (ANOVA) suggested that a total sample size of 78 participants (39 participants per study arm) will be sufficient to detect a medium effect (cf. Hedges' g of 0.531 reported in a relevant meta-analysis) for the primary outcome variable, that is, non-diagnosis specific psychopathology with a power of 80% at a significance level of .05.

The random sequence assigned to participants will be generated by a professional outside of the study team, using the Research Randomizer web-based application (<https://randomizer.org>). Due to the nature of the intervention, blinding for either intervention providers or participants will not be possible.

Participants

Participants of the study will be recruited in Hungary via paid social media advertisements targeting the capital (considering the location of the participating intervention providers). Inclusion criteria will be being at least 18 years old and willingness to participate in a family/systemic constellation seminar on a date determined by the randomization process but no other date during the study period. Exclusion criteria will be current mental disorder diagnosed by a healthcare professional and recent (<1 year) prior participation in a family/systemic constellation seminar in

another setting. Beyond the opportunity to participate in the intervention free of charge, participants will be offered a small financial compensation (total of HUF 5,000; equivalent to 4.5 hours of work at before-tax minimum hourly wage at the time) for their time in relation to completing the three fully online study questionnaires. All participants will give their written informed consent upon enrollment.

Given that family/systemic constellations are hardly ever prescribed in any setting, we will focus on the effect of participation in the intervention (per-protocol analysis) instead of the effect of assignment to intervention (intention-to-treat paradigm). Significant efforts will be made to encourage participants to complete the questionnaires at both follow-up assessment points (two follow-up emails, three attempted phone calls, and finally a text message to the participant's cell phone).

Intervention and providers

The intervention will be administered in a group setting in which approximately 15-25 participants, unknown to each other, will meet for a one-time, 2-to-3-day, facilitator-led workshop. Each constellation will start with a brief interview between the 'active' client ('issue holder') and the facilitator to clarify the individual's goal with the intervention. This will be followed by a decision about which members/elements of the client's (inter)personal system will play a significant role in the issue presented, and these will be represented by other group members during the constellation. The representatives (including the client's representative) will be positioned in the room by the client initially, with spatial distances, angles, and body postures meant to correspond to the client's inner image of the system ("problem constellation"). This will allow the facilitator to identify the dynamics beneath the client's presenting concern, while at the same time help the client reflect on their internal experience from a more objective, partially external point of view (as they will be observers and not participants of their constellation at this point). This part of the process will be largely non-verbal, focusing on what participants will begin to experience as being part of the structure created by the active client.

Next, the representatives will be asked by the therapist about their physical sensations, feelings, and thoughts they have while in their positions. Rearrangements, spatial adjustments, and brief, ritualized conversations will be made based on the principles of healthy functioning within a system until a constellation is identified that offers a resolution or relief for the client who at this point might enter and actively engage in the constellation if they feel ready to do so. Ideally, this "solution constellation" will provide a new, more adaptive framework for the client to feel, think, and behave in the given system.

Adherence to a previously developed intervention protocol will be evaluated by observers from the study team who will be independent of the clinicians providing the intervention. The manual will consist of 19 procedures, eight obligatory elements for the workshop in its entirety, as well as seven obligatory and four optional items for the individual constellations focusing on a given client. Overall treatment integrity will be calculated as the percentage of completed treatment components defined by the manual.

Measures

To assess sociodemographic characteristics, questions will be administered to assess participants' gender, age, relationship/marital and employment status, as well as educational attainment. Respondents will also be asked at baseline about their prior experience with systemic constellations and at both follow-ups whether they participated in constellation seminars outside of the study context (to assess study protocol violation). Free-text questions will also be asked to explore – both positive and negative – intervention effects from the participants' perspective.

The Hungarian version of the Brief Symptom Inventory will be used to measure an individual's overall psychopathology level. This tool consists of 53 items covering 9 symptom dimensions: Somatization, Obsessive-compulsive symptoms, Interpersonal sensitivity, Depression, Anxiety, Hostility, Phobic anxiety, Paranoid ideation, and Psychoticism. As a global measure of pathology and distress, the General Severity Index (GSI, mean of all items) will be used in the present study.

The Hungarian version of the SCOFF screening test will be used to measure non-disorder-specific risk level for eating disorders. This assessment tool consists of five yes-or-no type questions assessing eating disorder symptoms or risk factors. At least two positive answers (score of 2) indicate a high likelihood of an eating disorder.

The Generalised version of the Screener for Substance and Behavioral Addictions (SSBA-G) will be used to assess addiction severity. The SSBA-G is a 8-item screening tool measuring functional impairment resulting from both substance and behavioural addictions. It covers four addiction characteristics (excessive involvement, loss of control, compensatory function, and associated problems in important life domains) and measures addiction severity through a general description for substance-related (4 items) and behavioural addictions (4 items).

The Hungarian version of the EXIS.pers will be used to assess the subjective experiences of the individual in their personal social system (e.g. family, circle of friends). This 12-item scale covers four dimensions in relation to 1) belonging (a sense

of being part of a given social system; 2) autonomy (ability to demarc boundaries based on the belief that the renegotiation of roles, rights, and responsibilities is possible); 3) accord (acceptance of one's social system the way as it is); and 4) confidence (trust in the individual's and their social system's ability to cope with emerging difficulties).

The Hungarian version of the Meaning in Life Questionnaire will be used to assess meaning in a respondent's life as an eudaimonic wellbeing indicator. The scale consists of 10 items; five items measuring Presence of Meaning, while the other five capturing Search for Meaning. The Hungarian 5-item version of the WHO Well-being Index will be used to measure participants' overall subjective well-being as a hedonic indicator of wellbeing. Finally, the Hungarian version of the 5-item Satisfaction with Life Scale will be used to measure global life satisfaction.

Data analysis

All analyses will be carried out using SPSS for Windows, Version 28. Baseline characteristics of study completers versus drop-outs as well as study arms will be compared using independent sample t-test (continuous variables) and the chi squared (categorical variables) test. Effect size will be expressed using Cohen's d (t-test) and Cramer's V (chi squared test). Repeated measures ANOVAs will be conducted to investigate the effect of the interaction between time and study group, considering all three assessment points. Post hoc analyses from these ANOVAs will be used to investigate within-group differences over time. In the omnibus analyses, effect size will be expressed by eta squared, while in the post hoc tests, Cohen's d will be used to express effect size.

Consent form

(Translated from Hungarian, official language of the study)

Dear Interested Participant,

Below you will find a summary of the purpose, methods, and the benefits and risks associated with participating in our research on the efficacy of family constellations. We are aware that this document is not brief, but we kindly ask that you carefully study the entire text to make an informed decision about your participation.

PURPOSE OF THE STUDY

The purpose of our research is to better understand the mid-term effects of family constellations, including both positive and potential negative outcomes. The study will be led by two clinical psychologists who are independent of the professionals facilitating the family constellation sessions (also mental health professionals with doctoral degrees). The study has been approved by the Research Ethics Committee of the Institute of Psychology at Károli Gáspár University (approval number: XXXX).

WHAT DOES PARTICIPATION IN THE STUDY INVOLVE?

The study involves the completion of three questionnaires: the first before the family constellation, the second 3-4 weeks after the family constellation, and the third six months after the family constellation. Participation in the study is voluntary and can be discontinued at any point. As compensation for the effort involved in completing all three questionnaires, you will be entitled to: 1) participate for free in a family constellation weekend with one of the psychotherapists involved in the research; 2) receive a payment of 5000 HUF (either in cash or by e-transfer) for completing all three questionnaire sets; and 3) receive information about the aggregated data and results after the study is completed.

By completing the questionnaires, you are also consenting to the use of your data in an anonymous and aggregated manner (with no individual identification) for statistical analysis, and for publication in a scientific format. All data you provide will be handled with strict confidentiality and will not be disclosed to any third party, except for the administrative assistants in the study (two psychology students under the supervision of the investigators). Your contact details (phone number, email) will be destroyed after the study is concluded.

WHAT HAPPENS DURING A FAMILY CONSTELLATION WORKSHOP?

Family constellations are a form of group psychological counseling aimed at uncovering, understanding, and potentially modifying family patterns and repetitions. Participants come to the group with personal or psychological issues they are willing to share with the group leader and fellow group members. Using the family constellation method, the group leader works with the help of group members to symbolically represent and reframe the main participant's personal issue. A typical weekend session includes 16-20 participants, and everyone will have the opportunity to be the "main focus" of a constellation while also participating as helpers in other people's processes. Each session usually runs from 9 AM to 6 PM both days of the weekend, with a one-hour lunch break.

POTENTIAL BENEFITS AND RISKS OF FAMILY CONSTELLATIONS

There has been little empirical research on the effects of family constellations so far. The available data suggest that family constellations are safe, and the vast majority of participants retrospectively evaluate the experience positively, with favorable changes occurring in one or more areas of their lives (e.g., improved family relationships, reduced depressive symptoms, increased self-confidence and self-acceptance).

At the same time, some participants report a subjective worsening of their condition in similar areas, though it is still unclear whether this is directly related to their participation in family constellations or due to unrelated external events (e.g., losing a job, the death of a family member). The primary goal of the study is to learn more about these effects; therefore, it is important that participants complete all three questionnaires. If you, as a participant, feel that the family constellation leads to negative consequences in your life that you have difficulty handling alone, the study leaders are committed to providing psychological support to you during this process.

WHO ARE THE GROUP LEADERS PARTICIPATING IN THE STUDY?

Dr. Mária Angster: Clinical psychologist, psychotherapist

She currently leads family constellation groups with more than 20 years of experience. She is also involved in the teaching and research of family constellations and has published several books, book chapters, and articles on the topic.

Dr. Edit Jakubovits: Anesthesiologist, hypnotherapist, psychotherapist, family constellator

She is currently an assistant professor at the Institute of Psychology at Károli Gáspár University and has been running a private psychology practice for over 15 years, working with both individuals and groups.

WHO ARE THE INVESTIGATORS?

Dr. Barna Konkolj Thege: Clinical and research psychologist at a Canadian psychiatric hospital (Waypoint Centre for Mental Health Care) and assistant professor at the Department of Psychiatry at the University of Toronto. He is a member of several academic journal editorial boards. His main research areas are addiction, psychological measurement, psychosomatics, and the effectiveness of family constellations.

Dr. Gergely Sándor Szabó: Health psychologist, integrative hypnotherapist, psychodrama leader. He is currently an assistant professor at the Institute of Psychology at Károli Gáspár University and conducts research. His research areas include altered states of consciousness, psychological effectiveness studies, and psycho-oncology. He has been providing individual and group counseling for 10 years.

WHO CAN PARTICIPATE IN THE STUDY?

The study is open to individuals who are over 18 years old, currently do not suffer from a mental disorder diagnosed by a doctor or psychologist, and have not participated in a family constellation within the last year. Participants also agree to:

- participate in a 2-day family constellation workshop, which they will be randomly assigned to by the study leaders (possible dates: XX, XX, XX, XX);
- acknowledge that they cannot choose the specific date for the family constellation and must attend the assigned session (the study leaders will notify them of the chosen weekend at least one month in advance);
- acknowledge that they cannot choose between the two designated family constellation group leaders;
- complete the study questionnaire package at the start of the study, one month later, and another 5 months after (a total of 3 occasions, each completion takes about 30 minutes);
- not to participate in any family constellation outside the study during the six-month duration of this study.

I have understood the information about the research and have decided to participate based on this. I also declare that:

- I am over 18 years old;
- I do not currently suffer from any mental illness diagnosed by a mental health professional;
- I have not participated in a family constellation in the past year;
- I am able and willing to make myself available on the 2 days assigned to me by the study leaders for my participation in the family constellation; and
- I agree not to participate in any family constellation outside the study during the study period.

Yes No

Your name: _____

Email address: _____

Phone number: _____

After submitting your application, you will be notified by email about further details. If you have any further questions or comments about the research, please feel free to contact us.

Dr. Gergely Sándor Szabó, affiliation, contact details

Dr. Barna Konkoly Thege, affiliation, contact details