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# The Psychosocial Effects of Systemic / Family Constellations (NCT03233958)

Study Protocol, Statistical Analysis Plan, & Consent Form
(all translated from Hungarian, official language of the study)

Study approved: June 19, 2017

**The Psychosocial Effects of Systemic / Family Constellation:**

**An Observational Follow-up Study**

## I. STUDY PROTOCOL

### *Background and aims*

Family / systemic constellation therapy is a short-term group psychotherapy aiming to help clients better understand and resolve their conflicts within their personal systems, which in turn might lead to a decrease in psychopathological or functional somatic symptoms (Hellinger, 2003). The personal system addressed is most often the family but other inter- or intrapersonal systems (e.g., ego parts, victim-perpetrator dyads) can also be the target of the intervention. This therapeutic modality was developed in Germany in the early '90s integrating elements of – among others – psychodrama, family sculptures, contextual therapy, and certain South-African aboriginal traditions (Butollo et al., 2017) and has become particularly popular in Europe and South America and even became part of the public health care system in certain countries. Compared to its use by thousands of therapists of various theoretical and professional backgrounds all over the world, little effort has been made to generate empirical data regarding the effectiveness and safety of this intervention.

We believe that the large discrepancy between the relatively high level of penetration into the practice of complementary and alternative medicine versus the low quantity of evidence on effectiveness stems largely from academic psychology's reluctance to engage with at least two metaphysical / anthropological postulates of family constellation therapy. Firstly, the theory of family constellation therapy assumes that an individual's mental and physical health might be significantly influenced by major life events of other members of the personal system even if they lived generations before (e.g., the death of a mother during childbirth might have an effect on her descendants' anxiety level and reproductive success for several generations even if the original event has never been talked about in the descendant's life). While – due to recent developments in epigenetics and the better understanding of transgenerational trauma (Kellermann, 2013) – this and similar concepts are less shocking to the academic community than they were 3-4 decades ago when family constellation therapy was developed, they are still in sharp contradiction with the common understanding that the etiological factors of any physical or mental illness are to be sought in bio-psycho-social events, situations, or conditions occurring or existing around and after the individual's conception.

The second distinctive feature is that the theory of family constellation therapy assumes that the life-altering, relevant pieces of information are 'stored' and somehow can be 'downloaded' not just automatically and unconsciously by the members of the same system but intentionally by outsiders as well (Preiss, 2015). This accessibility of system-relevant information makes it possible that participants of the single-occasion intervention (who are unknown to each other) are able to perceive and verbalize thoughts, physical perceptions, emotions associated with the history of the system, often unknown even to the recipient of the given constellation. This somewhat 'mystical' re-presentation of unknown facts and hidden dynamics makes it possible for the recipient of the constellation to better understand the etiology of their mental or physical symptoms and intentionally change these very same dynamics. How this storage and access of system-relevant information occurs is highly debated and uncertain; the most-widely held

explanation of these processes use the morphic / morphogenic field and -resonance concepts (cf. storage) of the biologist Rupert Sheldrake (Sheldrake, 2011) in combination with the function of mirror neurons (cf. way of accessing stored information by non-members of the system) (Lahore, 2009).

Regardless of whether we fully understand the exact mechanisms of action of a therapeutic modality and if its certain assumptions fit the contemporary paradigms of health sciences, we argue that collecting empirical data on an intervention's effectiveness and safety is a public health necessity, especially if it is so widely used as family constellation therapy is (and it certainly could provide further impetus to the study of the mechanisms of action and the potential reconsideration of the accuracy of our paradigms).

The very limited number of previous prospective, peer-reviewed studies into family constellation therapy's therapeutic effectiveness reported that the intervention was effective in reducing general, non-diagnosis-specific psychopathology and psychological distress (Hunger et al., 2015; Krüger & Schmidt-Michel, 2003; Weinhold et al., 2013) as well as improving quality of life and functioning in interpersonal relationships (Hunger et al., 2014; Hunger et al., 2015).

The aim of the present study was to collect and analyze further data from the real life setting on family constellation therapy's effectiveness in improving mental health and its tolerability 1) using a mid-term time frame (≥6 months) to evaluate client outcomes, 2) employing active monitoring (not just passive surveillance) of potential iatrogenic effects, and 3) providing information on the presence or absence of therapist effects.

***Participants and procedure***

Participants of the study will be recruited in Hungary from individuals in the general population who will express their intent to participate in a 2-day family constellation workshop on a fee-for-service basis (private setting) with one of the three professionals participating in the study. All three intervention providers will be highly trained in both general mental health care delivery (one therapist with a background in clinical psychology, while the other two will be trained in medicine) and family constellation therapy (10-20 years of experience). Participation in the study will be voluntary and will occur as a combination of online and paper-pencil data collection after participants give their informed, written consent. Neither the therapists nor the participants will receive financial compensation for their participation.

The assessment protocol will include a pre-intervention assessment, a follow-up approximately 4 weeks after the intervention (this time is estimated to be necessary for the single-occasion, 2-day workshop to have most of its effects; cf. the focus on changes in perceived quality of interpersonal relationships and related mental health symptoms), and finally, six months post-intervention. Significant efforts will be made (follow-up email and three attempted phone calls) to encourage participants to complete the questionnaires at both follow-up assessment points.

***Intervention***

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-day, facilitator-led workshop. Each constellation will start with a brief interview between the facilitator and the active client 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 will 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 at this point). This part of the process will be largely non-verbal, focusing on what participants begin to experience as being part of the structure created by the active client (cf. Orban 2008).

Next, the representatives will be asked by the therapist about their physical sensations, feelings, and thoughts they will 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 will offer a resolution or relief for the client (who at this point might become an active participant of 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 (Hunger et al. 2015).

### *Measures*

*Ad hoc items to assess sociodemographic characteristics and iatrogenic effects*

To assess sociodemographic characteristics, questions will be administered to assess participants' sex, age, relationship/marital status, and educational attainment. A couple of free-text questions will also be asked to participants to explore potential iatrogenic effects (T2 & T3, Did you experience any negative change in relation to your mental or physical health during or since the family constellation workshop?). If respondents answer affirmatively to the second question, it will also be asked if they believe the changes are associated with their participation in family constellation therapy (yes, no, or unsure).

*Brief Symptom Inventory (BSI)*

The Hungarian version (Urbán et al. 2014) of the BSI (Derogatis & Spencer 1993) will be used to measure an individual's overall psychopathology level. This tool consists of 53 items covering nine symptom dimensions: somatization, obsessive-compulsive symptoms, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation, and psychoticism. Out of the three global measures of pathology and distress, the General Severity Index (GSI, mean of all items) will be used in the present study.

*Experience in Personal Social Systems Questionnaire (EXIS.pers)*

The Hungarian version of the EXIS.pers (Hunger et al. 2017) will be used to assess the subjective experiences of the individual in their personal social system (e.g., family, circle of friends).

*Patient Health Questionnaire-15 (PHQ-15)*

The Hungarian version of the PHQ-15 (Kroenke et al. 2002) will be used to evaluate the intrusiveness of somatic symptoms and a tendency toward somatization. The assessment tool contains 15 items, each addressing a frequently occurring mild, physical symptom such as back pain or trouble sleeping.

*SCOFF*

The Hungarian version (Dukay-Szabó et al. 2016) of the SCOFF screening test (Morgan et al. 2000) will be used to measure non-disorder-specific risk level for eating disorders. At least two positive answers (score of 2) will indicate a high likelihood of an eating disorder (Dukay-Szabó et al. 2016).

*Ad hoc items to assess addiction severity*

In the absence of a concise and validated, broad-focus screening tool to assess the severity of both substance-related and behavioral addiction problems, a 4-item ad hoc tool will be created for the purposes of the present study. One question each will refer to the past-month frequency of substance use and excessive behaviors, while further two questions will explore the extent to which participants perceive that their substance use or excessive behaviors cause problems in their lives.

*Meaning in Life Questionnaire (MLQ)*

The Hungarian version (Martos & Konkolÿ Thege 2012) of the MLQ (Steger et al. 2006) will be used to assess both the presence of and search for meaning in a respondent's life as eudaimonic wellbeing indicators. While the former is an indicator of positive mental health, the latter is typically considered as an indicator of ill mental health and therefore, higher scores indicate less favorable mental status. The scale consists of 10 items (5 items measuring both subconstructs).

*WHO Well-being Index (WBI-5)*

The Hungarian (Susánszky et al. 2006), 5-item version of the WHO Well-being Index (Bech et al. 1996) will be used to measure participants' overall subjective well-being as a hedonic indicator of wellbeing.

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## II. STATISTICAL ANALYSIS PLAN

All analyses will be carried out using SPSS for Windows. Baseline characteristics of study completers versus drop-outs will be compared using the Mann-Whitney U (age) and the chi-squared (categorical variables) test. Effect size will be expressed using effect size r (Mann-Whitney U test) and Cramer's V (Chi-squared test). Considering the likely non-normal distribution and occasionally ordinal nature (SCOFF) of the outcome variables, the effectiveness of the intervention will be investigated using Wilcoxon paired sample tests in the primary analyses. Separate comparisons will be made to explore potential changes from baseline to 4-week post-intervention as well as baseline to 6-month follow-up. Effect size r will be computed to express the magnitude of the changes.

Given that the normality assumption is relatively rarely examined and therefore parametric tests are used most often in effectiveness research, to facilitate inter-study comparability, repeated measures ANOVAs will be conducted as secondary analyses to investigate the main effect of time considering all three assessment points. For similar reasons, means and standard deviations (instead of medians and interquartile ranges) will be reported as descriptive data to allow easier comparisons across studies. A further set of ANOVAs will be run to investigate therapist effects. In these secondary analyses, effect size will be expressed by eta squared.

The Reliable Change Index (RCI) will be used to examine the clinical significance of changes on the individual level. Given the uncontrolled nature of the current study's design, a metric will be chosen that considers the tendency of regression to the mean, a threat to the validity of effectiveness studies without a control group. For this reason, the Edwards–Nunnally method will be used to examine the reliability of changes over time (Bauer et al. 2004).

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## III. CONSENT FORM

Dear Participant,

By completing the following questionnaire, you are contributing to a study aimed at a more precise understanding of the medium-term effects of family constellations and participation in them. The study is led by two research psychologists (see below), who are independent of the professionals conducting the family constellations. The study has been approved by the Research Ethics Committee of the Institute of Psychology at Károli Gáspár University of the Reformed Church under registration number XXXX.
The study includes the completion of three questionnaires: the first before the family constellation, the second 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 your efforts in participating in the study (by completing all three questionnaires), you are entitled to: 1) participate for free in one additional family constellation, without processing your own issue (as a "helper"); 2) receive written feedback from us, based on your data, showing which areas we measured have shown changes in your condition.
By completing the questionnaires, you also give your consent for your data to be anonymously analyzed and statistically processed in aggregate form (i.e., without individual identification) and published in a scientific format. All the data you provide will be treated with strict confidentiality and will not be shared with any third parties, except for the administrative assistants of the study (psychology students under the supervision of the study investigators). Your contact details (phone number, email) will be deleted after the study concludes.
If you have any further questions or comments regarding the research, please feel free to contact us (in this case, please tear off this information sheet with our contact details and take it with you)!

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