



Berner Fachhochschule  
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# Soteria Research

## Towards a new methodological paradigm

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# Effectiveness Research in Psychiatry

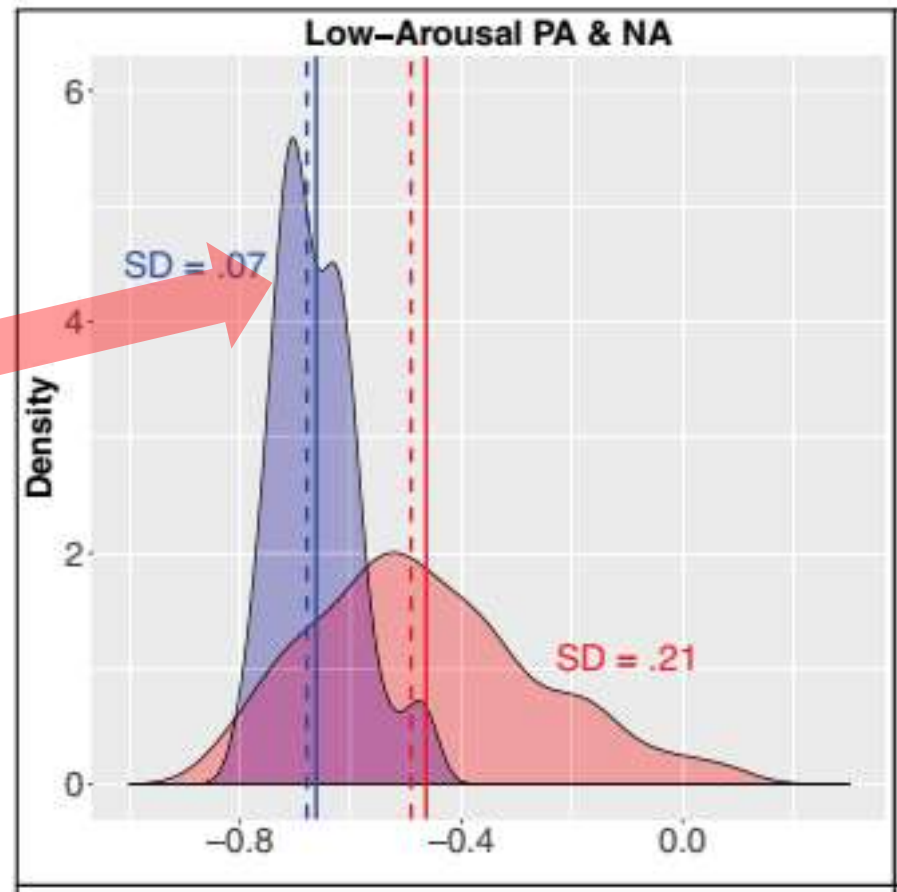
- ▶ Randomised controlled trials/observational studies
  - ▶ Study designs focus on group effects/average values
  - ▶ Apply standardised outcome indicators
  - ▶ Assume a sufficiently large sample size (power)
  - ▶ Assume the presence of an adequate control group
  - ▶ Assume the irrelevance of study participants' preferences
- ▶ Studies generally have rigid inclusion and exclusion criteria (low external validity)
- ▶ Study endpoints often have no relevance for users
- ▶ Differences between the results of experimental conditions often have no clinical relevance
- ▶ Psychiatric interventions have a low effect size on average
- ▶ Complexity of the intervention is usually not adequately modelled

# Issues in Effectiveness Research in Psychosocial Settings

- ▶ These are complex interventions that are not manualised and generally cannot demonstrate model fidelity
- ▶ The samples are small
- ▶ There is a lack of control groups/conditions
- ▶ It is difficult to depict the perspective of the user/affected person; recovery instruments are not really adequate
- ▶ Results cannot usually be generalised

# The Ergodicity Problem (Inter-/intraindividual)

Bimodal  
distribution

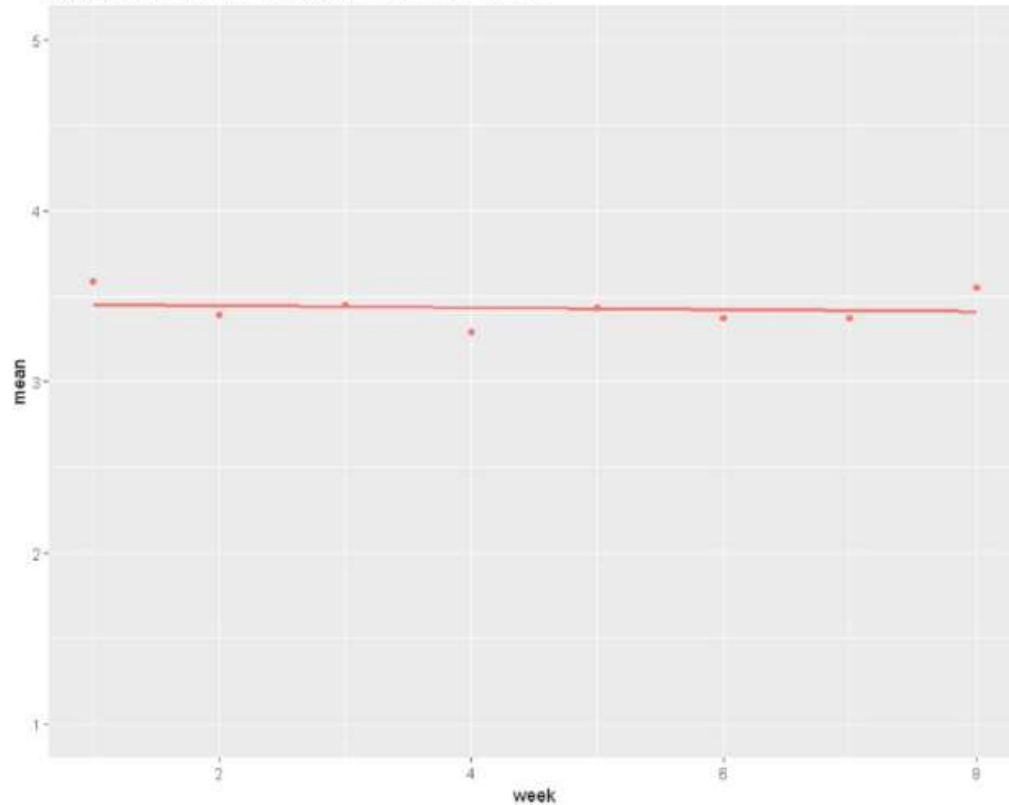


PA/NA:  
positive affect/  
negative affect

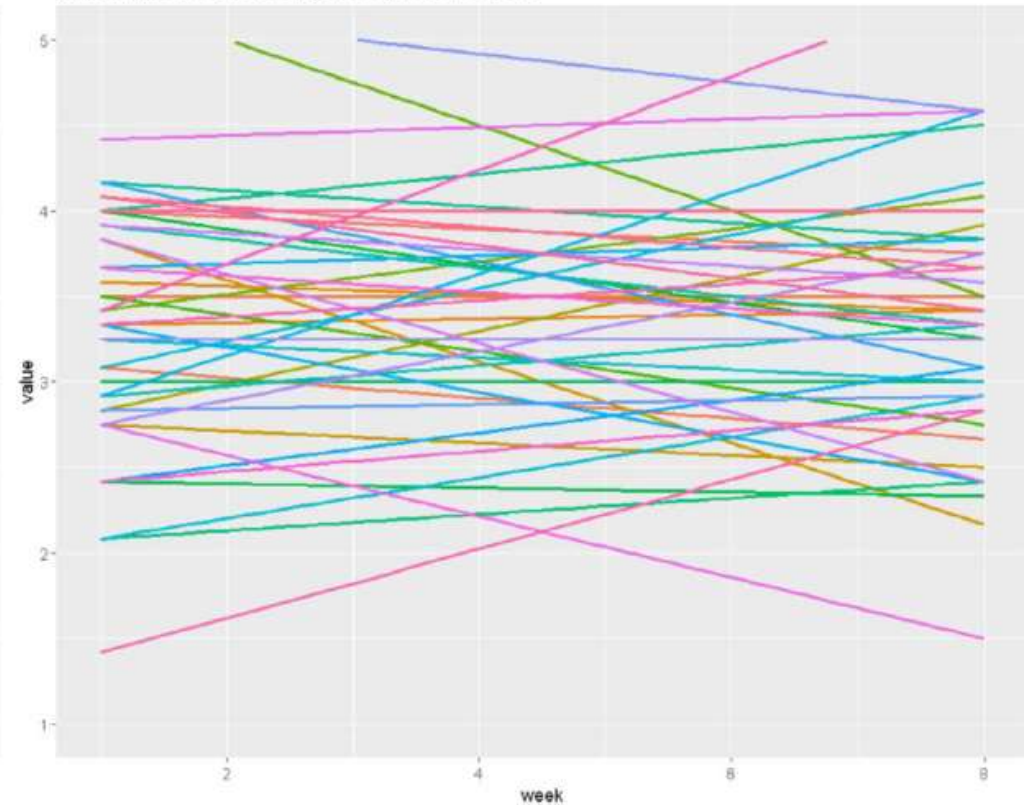
Fisher AJ, Medaglia JD, Jeronimus BF. Lack of group-to-individual generalizability is a threat to human subjects research. *Proc Natl Acad Sci U S A*. 2018; 115(27):E6106-E6115. doi: 10.1073/pnas.1711978115.

# Group Average Over Time vs. Individual Courses

Aggregated trend for '1 being present' over 8 weeks



Individual trends for '1 being present' over 8 weeks



Gloster AT et al: When Average Isn't Good Enough: Identifying Meaningful Subgroups in Clinical Data. Cognitive Therapy and Research 2024; <https://doi.org/10.1007/s10608-023-10453-x>

# Individuality of Recovery Perspective– Methodological Consequences

- ▶ “Recovery, because it is about a unique person’s life, should be expected to vary considerably from person to person with the core of that recovery having meanings which are deeply subjective for each person. Recovery for one person may mean to gain social status or a feeling of worth. For others recovery may be intimately tied to attaining housing and work. To recover from psychosis for others may involve the recapture of a sense of purpose, and that sense of purpose would naturally have to vary between persons. What makes up one person’s purpose could be meaningless or noxious to another recovering person.”

Lysaker P et al. Recovery from Psychosis: Emerging Definitions, Research and Select Clinical Application, in: Carpiniello B et al. (eds.), Recovery and Major Mental Disorders, Comprehensive Approach to Psychiatry 2, Cham: Springer 2022, 99-116

“The lack of adequate and valid instruments is a problem. Since there is no consensus on the recovery concept, measures vary in their conceptual foundations and recovery domains.”

Bejerholm U & Roe D (2018): Personal recovery within positive psychiatry, Nordic Journal of Psychiatry, DOI: 10.1080/08039488.2018.1492015

# Current State of Soteria Research

- ▶ “The studies included in this review suggest that the Soteria paradigm yields equal, and in certain specific areas, better results in the treatment of people diagnosed with first- or second-episode schizophrenia spectrum disorders (achieving this with considerably lower use of medication) when compared with conventional, medication-based approaches.”

Calton T, Ferriter M, Huband N, Spandler H. A systematic review of the Soteria paradigm for the treatment of people diagnosed with schizophrenia. Schizophr Bull. 2008 Jan;34(1):181-92

- ▶ “The only notably improved outcome, reported in a number of different publications, was that Soteria decreased the average dose of daily and total antipsychotic. Given the high doses used at the time, this finding, in a small sample, should come as no surprise. The quality of these studies (only one RCT), with allegiance bias, selective reporting of results across numerous publications, and lack of clarity throughout, makes interpretation difficult.”

Jauhar S, Lawrie SM. What is the evidence for antipsychotic medication and alternative psychosocial interventions for people with acute, non-affective psychosis? Lancet Psychiatry. 2022 doi: 10.1016/S2215-0366(21)00293-5.

# Methodological Issues of Recent Soteria Effectiveness Research

- ▶ Study design: Group comparisons (intervention/control group)
  - ▶ Comparison with conventional inpatient settings
  - ▶ Superiority hypothesis not appropriate
  - ▶ Small number of cases/low statistical power
  - ▶ No matching in observational studies (selection bias)
- ▶ Strong focus on conventional outcome indicators
  - ▶ Psychopathology/psychotic relapses
  - ▶ Re-admissions
  - ▶ Pharmaceutical dosage
  - ▶ Questionable relevance for users
- ▶ Lack of independence of researchers from Soteria movement



# Soteria: Therapeutic Ingredients

To begin with, when dealing with patients, a set of principles should be established: Do no harm. Treat patients with dignity and respect. Guarantee asylum, quiet, and shelter. And, perhaps most important, the notion that recovery from psychosis is possible in a predictable social environment, interpersonal relationships. The most basic tenet is “being with”—an attentiveness that involves “stepping into the other person’s shoes” so that a shared meaningfulness of the psychotic experience can be established via a relationship. This requires unconditional acceptance of the experience of others as valid and understandable within the historical context of each person’s life—even when it cannot be consensually validated. The Soteria approach also

Physical environment

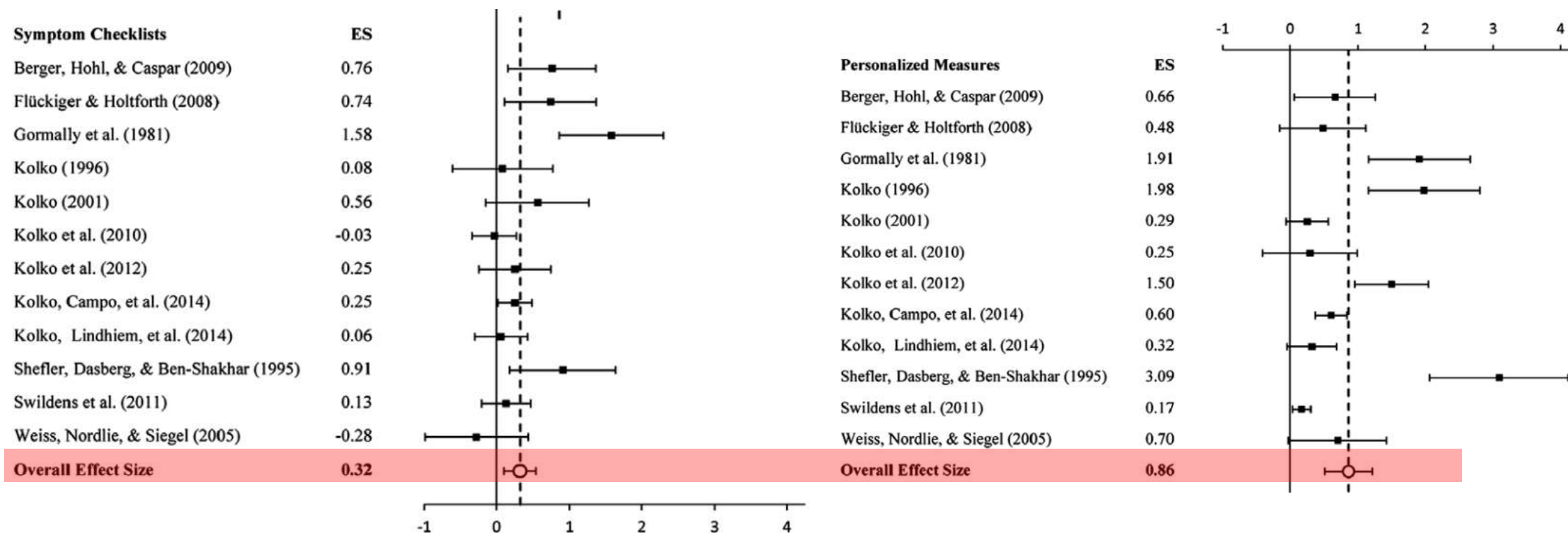
Atmosphere

Therapeutic relation

Recovery

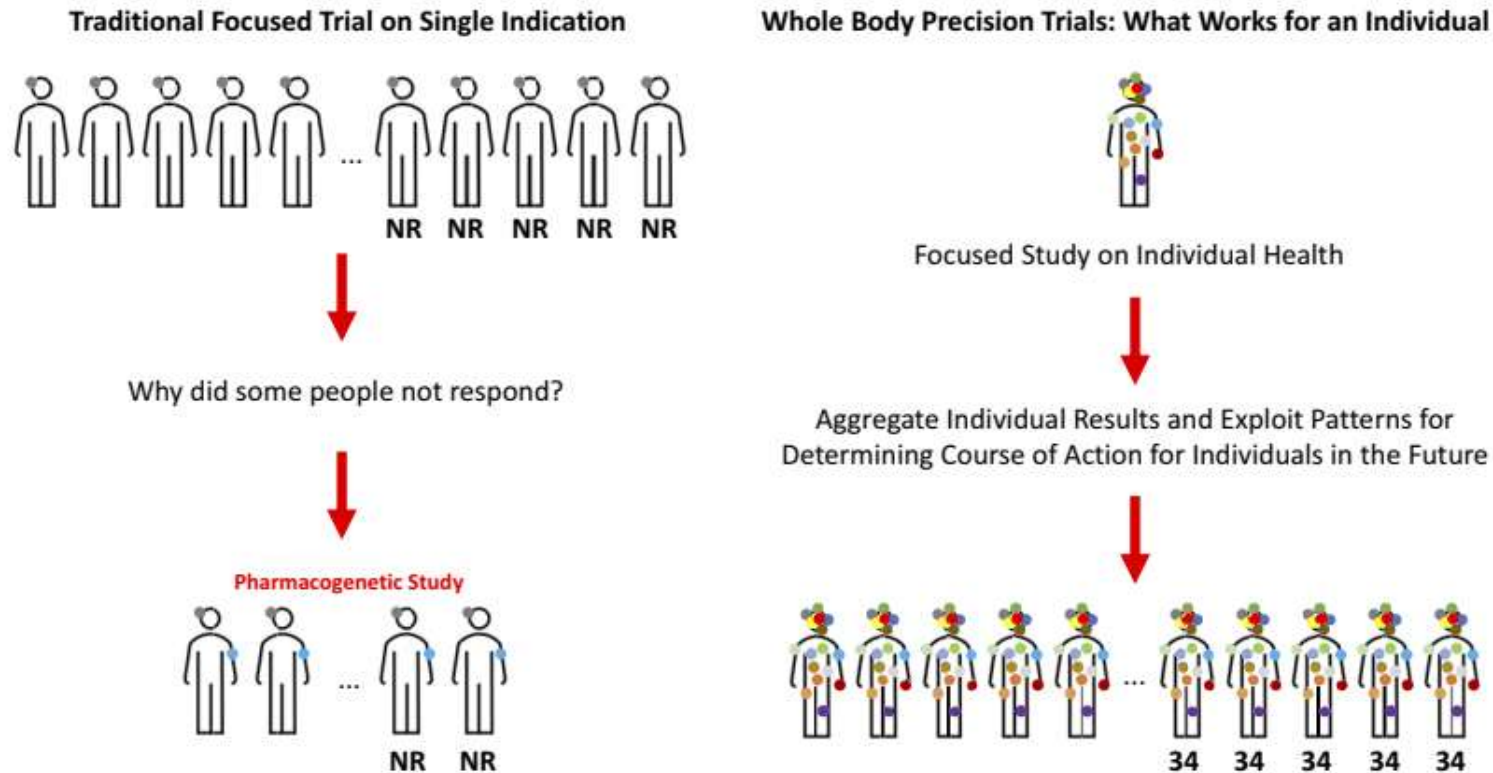
Mosher LR, Bola JR: Soteria-California and Its American Successors: Therapeutic Ingredients. *Ethical Human Psychology and Psychiatry*, 6 (2004), 7-23

# Meta-Analysis Psychotherapy: Effect Sizes of Symptom-Checklists vs. Personalised Indicators



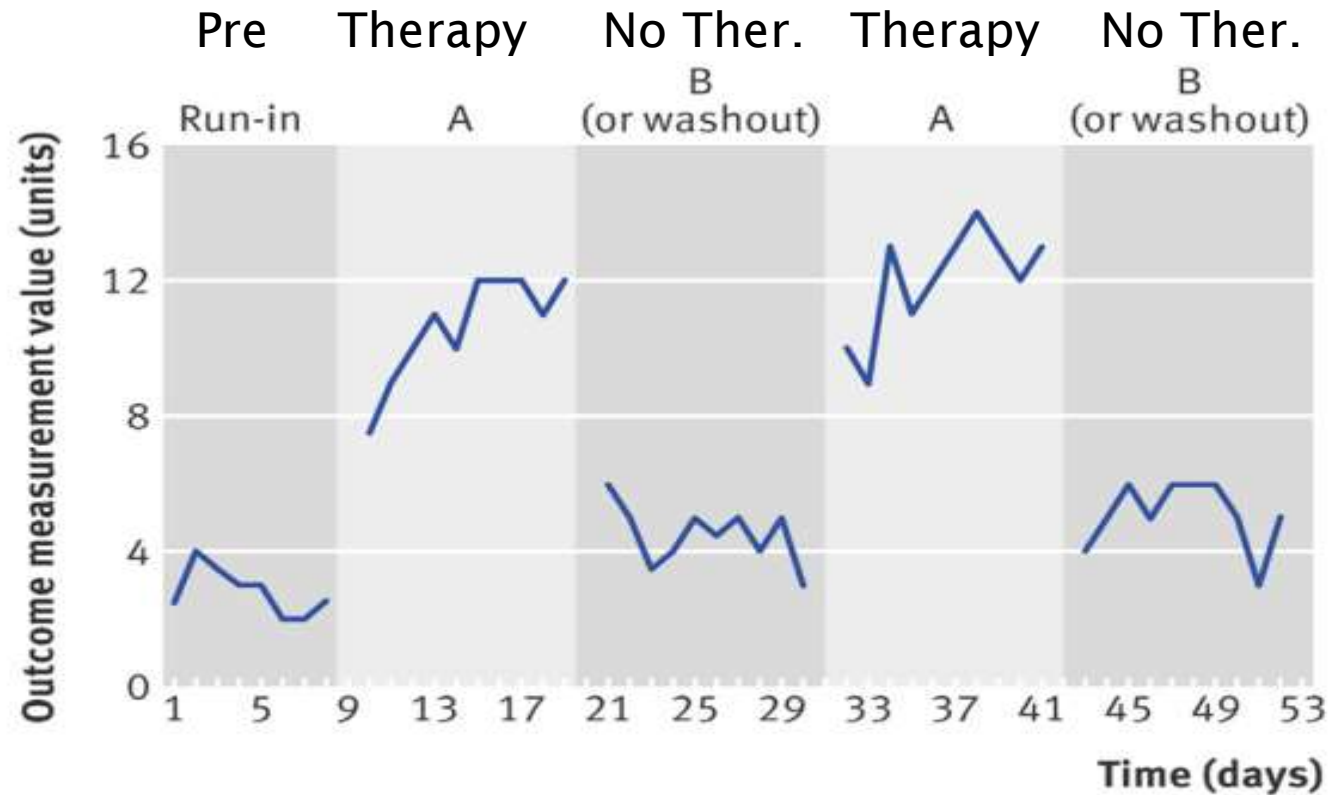
Lindhiem O, Bennett CB, Orimoto TE, Kolko DJ. A Meta-Analysis of Personalized Treatment Goals in Psychotherapy: A Preliminary Report and Call for More Studies. *Clin Psychol (New York)*. 2016 ;23(2):165-176. doi: 10.1111/cpsp.12153

# N=1 Trials in Precision Medicine (vs. Group Comparisons)



Schork NJ et al.: (2023). Exploring human biology with N-of-1 clinical trials. Cambridge Prisms: Precision Medicine,1, e12, 1–9, <https://doi.org/10.1017/pcm.2022.1>

# N-of-1 Study Design (idealtypical)



**Fig. 2.** N-of-1 trial pictorial; suggested visual representation of data from an individual N-of-1 trial.

# Mixed Methods Single Case – Results Example

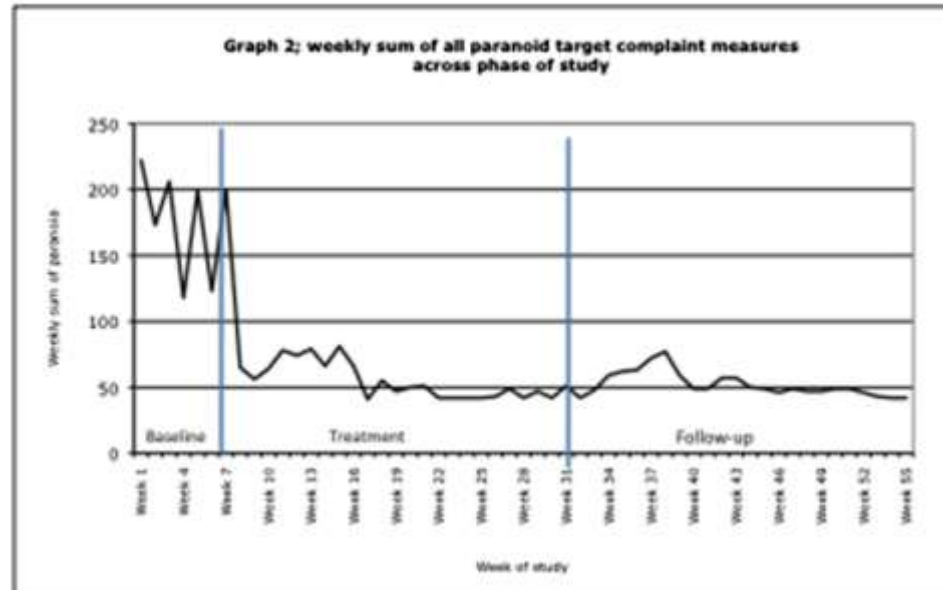


Table 3. Summary of changes reported at post-treatment Change Interview

| Key change                             | Expectancy for change              | Change mechanism; therapy or out-of-therapy event | Likelihood of change without therapy |
|--|------------------------------------|---|--------------------------------------|
| Seeing people differently now          | Very much surprised by this change | Therapy   | Very unlikely without therapy        |
| Being able to manage paranoid thoughts | Very much surprised by this change | Therapy   | Very unlikely without therapy        |
| Stopping playing 'the game'            | Very much surprised by this change | Therapy   | Very unlikely without therapy        |

# Research Paradigm for Social Psychiatry Settings and Interventions (Soteria, Open Dialogue, Peer Support, Recovery etc.)

- ▶ Complex but individualised intervention meets personalised outcomes
- ▶ Mixed methods approach: participants report about the achievement of their preferred outcomes and give reasons for this
- ▶ Replacement of the control group with the control condition of experience (ideally) before the start of the intervention
- ▶ Significance is achieved through the number of interviews and duration of data collection (ideally several weeks/months after the end of the intervention
- ▶ )Results are generally not generalisable; it is about the effect of a defined intervention for specific people
- ▶ Ideally, the start of the intervention can be randomised

# Individualised Soteria Effectiveness Study (Start September 2024)

- ▶ Study design: Self-controlled mixed methods design
- ▶ The participants are also their own controls
- ▶ Quantitative
  - ▶ N-of-1 design/single case study
  - ▶ Outcome indicators personalised by users
  - ▶ Multiple measurement time points (before admission, twice during stay, after discharge)
- ▶ Qualitative
  - ▶ Qualitative longitudinal study
  - ▶ Multiple measurement points (identical to quantitative methodology)
- ▶ Study registration with Open Science Framework



# Methods

- ▶ Recruitment of 2x10 people (with/without migration background) before/during admission to Soteria Bern
- ▶ Conducting four qualitative and quantitative interviews per person
- ▶ Initial interview ideally before admission; alternatively retrospective based on the last time before admission; two interviews during stay, one interview approx. four to six weeks after discharge
- ▶ Quantitative interviews according to PSYCHLOPS: problems and goals
- ▶ Thematic analysis according to Braun & Clarke
- ▶ Intra- and inter-individual analyses



# Interview Topic Guides

- ▶ Customised versions by time: Pre, During, Post
- ▶ Topics:
  - ▶ Reasons for entering Soteria
  - ▶ Experiences and evaluation of Soteria
  - ▶ Psychological problems and their change by time point
  - ▶ Goals and goal achievement by time point
  - ▶ Reference is made to previously mentioned problems/goals as well as the possibility for new mentions
  - ▶ Justification of the quantitative changes in problems and achievement of goals

# Personalised quantifiable Indicators - PSYCHLOPS

Pre Admission

a Choose the problem that troubles you most. *(Please write it in the box below.)*

b How much has it affected you over the last week? *(Please tick one box below.)*

Not at all affected    0    1    2    3    4    5    Severely affected

During Stay

a This is the other problem you said troubled you when we first asked. *(Therapist - please write it in the box below.)*

b How much has it affected you over the last week? *(Please tick one box below.)*

Not at all affected    0    1    2    3    4    5    Severely affected

# Feasibility Study –Thematic Analysis

## Physical environment/Atmosphere

"So I came to see it and I really liked the concept. It's more like a family, you don't feel like a number like in some of the bigger ones. It's just smaller, more compact and certainly offers me a safety framework, which I need at the moment..."

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"And it's more like a shared flat, it's not like a clinic for me now."

"...and the room is also a super retreat"

# Feasibility Study –Thematic Analysis

## Community

"The size of the flat share is almost too big for me. There are almost too many people and, ehm, without now, I'm struggling to get involved and it's just like in the structure, you're supposed to do chores and you're supposed to go shopping and I realise that I can't do that any more."

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"I was actually just around people more because I felt like, hey, I don't have to sit in my room all day listening to music and thinking."

"But it helps me personally when I have panic attacks when I'm in a group."

# Feasibility Study – Longitudinal Mixed Methods Analysis

Please select the topic that has occupied you the most. On a scale from 1 (least) to 5 (most): How much has the issue affected you in the last week?

| Topic               | Retrospective | During Stay | After Discharge |
|---------------------|---------------|-------------|-----------------|
| What is my illness? | 5             | 4           | 3               |

After discharge

“Ehm what is my illness. Unfortunately, I still don't understand it very well, but I think I understand it better and I'm glad that I have it. Because it makes me more creative. Ehm and therefore a 3.”

# Feasibility Study – Longitudinal Qualitative Analysis

- ▶ Retrospective
  - ▶ "Yes, I was wide awake but also a bit paranoid. Ehm, I was thinking clearly but I heard voices. I was able to express myself clearly, but at the same time I was also a little irritated and angry. Which perhaps manifested itself in a bit of aggression."
- ▶ During the stay
  - ▶ "I practised going out in groups or travelling alone on the bus. And I can do that much better now than when I came here. I enjoy going for walks again and so on. So even the symptoms like paranoia are pretty much gone. Ehm, the mistrust has also diminished and yes, the only thing that's still a bit there are sometimes a few voices. But slightly weakened and not negative."
- ▶ After discharge
  - ▶ "I've been much better recently. As far as the schizophrenia is concerned. And I was more stable, so I really had everything, more motivation again, I managed everything myself again and so on."

# Results of the Feasibility Study

- ▶ Research design could be implemented without any problems in principle
- ▶ Interviews prior to admission generally not possible due to participants' acute crisis; therefore only retrospective interviews analysed
- ▶ Interviews were able to clearly illustrate the changes in various aspects of the participants (e.g. everyday problems, dealing with mental health problems) and certain potential for improvements at Soteria Bern
- ▶ Limitations: Interviews at the beginning often characterised by considerable cognitive limitations and memory problems

# N = 1 Studies (randomised) in the Evidence Hierarchy

**Table 1**  
**A Hierarchy of Strength of Evidence for Treatment Decisions**

- 
- *N*-of-1 randomized trial.
  - Systematic reviews of randomized trials.
  - Single randomized trial.
  - Systematic review of observational studies addressing patient-important outcomes.
  - Single observational study addressing patient-important outcomes.
  - Physiological studies (studies of blood pressure, cardiac output, exercise capacity, bone density).
  - Unsystematic clinical observations.
- 

Guyatt GH, Busse JW: The Philosophy of Evidence-Based Medicine. In: Montori VM (ed.): Evidence-Based Endocrinology, Totowa NJ: Humana Press 2006, 25-24



# Conclusions

- ▶ Soteria research reaches considerable limits with conventional research methods
- ▶ A complex but individualised intervention meets personalised goals/problems and expectations
- ▶ The adaptation of the N=1/single case methodology can overcome many of the methodological problems
- ▶ The individual effect of Soteria can be personalised for the participants
- ▶ The method allows limited generalisations
- ▶ The method can be extended by randomising participants and the time of entry into Soteria

Many thanks

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