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THE TREATMENT OF ACUTE PSYCHOSIS WITHOUT NEUROLEPTICS: SIX-WEEK PSYCHOPATHOLOGY OUTCOME DATA FROM THE SOTERIA PROJECT

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SUMMARY

Background: Today's treatment of acute psychosis usually includes short-term hospitalization and anti-psychotic drug treatment. The Soteria project compared this form of treatment (control) with that of a small, home-like social environment, usually without neuroleptics (experimental).

Method: Newly diagnosed, young, unmarried persons with DSM-II schizophrenia were randomly assigned to treatment in two experimental and two control settings. Subjects and families were assessed at admission on 29 independent variables. Treatment environments were studied by means of Moos', COPES or WAS scales. Three dependent six week psychopathology outcome measures were collected.

Results: The groups were comparable on 25 of 29 admission variables. The environments of the two experimental and two control settings were different from each other. The milieus were similar to each other within each condition. At six weeks, psychopathology in both groups had improved significantly, and similarly, and overall change was the same.

Conclusion: Specially designed, replicable milieus were able to reduce acute psychotic symptomatology within six weeks, usually without antipsychotic drugs, as effectively as usual hospital ward treatment that included routine neuroleptic drug use.

INTRODUCTION

The Soteria Project, a study emphasizing the psychosocial treatment of newly identified persons with schizophrenia without neuroleptics in small family-like non-hospital residential settings has not published new outcome data since 1979. This paper will describe and discuss short-term (6 week) psychopathology outcome data from 45 experimental and 55 control patients not previously reported.

Previous reports of outcome from the Soteria Project (Matthews *et al.* 1979; Mosher *et al.* 1975; Mosher & Menn, 1978a) have focused principally on two-year follow-up data from the first cohort of Soteria treated subjects treated in the study's original facility between 1971 and 1976. The present report describes combined results from a second and third cohort of subjects treated in two different project houses between 1976 and 1980 (the original one and a replication facility) in two adjacent counties in the San

Francisco Bay area. The control subjects were treated on the psychiatric wards of the two respective counties' public general hospital. The experimental and control cohorts treated in the two different counties were combined in the data analysis because: they were selected and studied in the same way; there were no significant within group (experimental and control) differences in baseline characteristics across counties; and the two experimental and two control treatment environments were similar to each other. Emanon, the replication facility, closed in 1980. Soteria House closed in 1983 when the last research grant ended.

We have chosen to look at our 6 week outcome data for several reasons:

1. We hypothesized that the experimental subjects, most of whom did not receive neuroleptic drugs between admission and the six week assessment point, would have higher levels of psychopathology as compared with the hospital and neuroleptic treated control subjects. The six week comparison provides the opportunity to compare the influence of a purely psychosocial treatment strategy with that of a psychotropic drug oriented short-term hospital based intervention.
2. Since the advent of short inpatient stays (averaging 10–15 days) in the 1970s, the establishment of truly therapeutic milieus in general hospital psychiatric wards has been seriously hampered. Developing close relationships with line staff on hospital wards, who can pass on the setting's "culture," is difficult during such short periods of time. In addition, short stays have made the routine use of neuroleptic drugs almost mandatory for acute symptom control in psychotic patients. While clearly an effective short term strategy, such patients are at risk for both short and long term drug side effects and toxicities – the most devastating, of course, is tardive dyskinesia (Kane *et al.* 1984).

If a psychosocial intervention could be shown to be effective relatively rapidly (6 weeks in this instance) then a case could be made for expanded use of special psychosocially oriented treatment milieus, with minimal or no use of neuroleptics, for at least a subset of persons labeled as having schizophrenia. Provision for a true non-neuroleptic treatment option for acute psychosis would avoid or minimize the problems encountered with the use of psychotropic drugs.

3. After more than a decade of experience dealing with acutely psychotic unmedicated individuals we want to focus more attention on the most difficult and creative part of our work in the Soteria Project; the early phase of helping very disturbed and disturbing people get their lives back on track through the use of human relationships and interaction within specially created social contexts.

RESEARCH DESIGN

A. Sample selection

All subjects were obtained from two emergency screening facilities that are part of the CMHC complexes containing the hospital wards that admitted and treated the control subjects in the study. Anyone meeting the following basic criteria was a potential study candidate:

1) Clearly schizophrenic
2) Deemed in need of hospitalization

3) No more than one previous hospitalization for 4 weeks or less with a diagnosis of schizophrenia
4) Age 18–30 (either sex)
5) Unmarried, separated, widowed or divorced
6) No complicating medical problem

The selection criteria were designed to provide us with a relatively homogeneous sample of individuals diagnosed schizophrenic, but a group at risk for prolonged hospitalization or chronic disability. Early onset and being unmarried have both been shown to be modestly predictive of long term disability (Strauss *et al.* 1977).

Initial screening and assessment

Subjects meeting study selection criteria were identified without knowledge of the group to which they would ultimately be assigned. Study requirements were explained, and informed consent was obtained from the patient and his family, or significant other, if available. All consenting subjects were then interviewed in detail by the project's independent research evaluator. This assessment included:

DSM II diagnosis

The project's research diagnosis must confirm the ER clinician's original diagnosis of schizophrenia for the subject to be included in the study. At 72 hours post-admission a final diagnostic assessment was made. All three diagnosticians had to agree the person had schizophrenia for the subject to be included in the study.

Diagnostic symptom check list

A list of seven cardinal symptoms of schizophrenia (thought or speech disorder, schizophrenic motor behavior, paranoid ideation, blunted or inappropriate emotion, disturbance of social behavior and interpersonal relations, hallucinations and delusions) had to be present for inclusion in the study. This scale was used as a screening device in the original large scale collaborative psychopharmacology study of neuroleptics in newly admitted patients. However, only *two* of seven symptoms were required for inclusion in that protocol (Cole *et al.* 1964).

The following measures obtained at admission are *not* used for purposes of inclusion/exclusion:

Feinberg-Strauss-Bartko (1974) Schizophrenia scale

A five point sign and symptom scale to identify persons with schizophrenia.

Certainty of diagnosis

A diagnostic interview based 7-point scale that asks the interviewer to rate his/her degree of certainty that the patient is schizophrenic.

Based on Vaillant's (1964) scale, three variables are included; duration of symptoms (greater or less than 6 months) and presence or absence of confusion and precipitating events.

GLOBAL PSYCHOPATHOLOGY

"Considering your total clinical experience how mentally ill is this subject at this time?"

1 = Normal, not at all ill

2 = Borderline mentally ill

3 = Mildly ill

4 = Moderately ill

5 = Markedly ill

6 = Severely ill

7 = Among the most extremely ill

Figure 1

Paranoid/nonparanoid status
A short scale for rating paranoid schizophrenia (Venables & O'Connor, 1959).

Premorbid adjustment
Assessed in two ways; interview reported schizoid life style and The Goldstein (1971) Scale for Adolescent Social Adjustment.

Global severity (Figure 1)
A seven point measure of overall psychopathology (Mosher *et al.* 1971).

Basic demographic data were also recorded. Within a week of admission a member of the research team visited the subject's home to obtain a detailed description of the patient's and family's psychiatric and social history. Again, the form is one that was developed and used in a variety of studies by the Psychopharmacology Research Branch of the NIMH (Boothe *et al.* 1971).

C. Treatment assignment
After completion of the initial interview the subject was randomly assigned to the experimental (Soteria, established in 1971, in Santa Clara Co. or Emanon, established in 1974, in San Mateo Co.) or control group (Valley Medical Center in Santa Clara or Chope Hospital in San Mateo), all in California.

D. Milieu assessment
The project used Moos' (1974, 1975) Ward Atmosphere (WAS) and Community Oriented Program Environment Scales (COPES) to assess systematically the staff and

GLOBAL IMPROVEMENT

"Compared to subject's condition at admission, how much has this person changed?"

1 = Very much improved

2 = Much improved

3 = Minimally improved

4 = No change

5 = Minimally worse

6 = Much worse

7 = Very much worse

Figure 2

patient's perceptions of the milieus at 6 monthly intervals. The COPES is the same 100 item true-false self-report scale as the WAS but with the words "community program" substituted for "hospital ward" on each item. Hence, the WAS was obtained from the two general hospital wards that treated the control subjects and the COPES from the two facilities that treated the experimental subjects.

The design, psychometric characteristics, types of results, profile typologies, and relationships to outcome obtained from the instruments utilized in this study have been detailed by Moos (1974, 1975). Briefly, data from these scales are grouped into 10 variables and 3 supra-ordinate clusters; involvement, support, spontaneity, ("relationship" variables) autonomy, practicality, personal problem orientation, tolerance of anger ("treatment" variables), order and organization, program clarity and staff control ("administrative" variables) (see Figures 3–6).

This measure is to a milieu study as accurate, reliable drug dosage is to a psychopharmacologic one. That is, it systematically assessed, over time, the perceived milieu characteristics of the special experimental houses and usual hospital wards. It allowed the study to describe the experimental milieus and test whether or not the two different settings were similar in their characteristics. This is also true for the control settings but, in addition, obtaining this data from them allowed the project to determine the ways that the experimental and control settings differed. This differentiation between the milieus was critical to a study that attempted to deliver a specially designed, unique, social environment as its principal therapeutic ingredient.

Outcome assessments

Independent research evaluators interviewed all the subjects at 6 weeks regardless

Table 1
10 demographic independent variables

	Experimental N = 45	Control N = 55	Test
Sex (Male)	69%	71%	$\chi^2 = 0.00$, ns
Age	21.9	21.5	$t = 0.56$, ns
Race (White)	75%	68%	$\chi^2 = 0.21$, ns
Religion (those citing an affiliation)	84%	88%	$\chi^2 = 0.03$, ns
Education (some college)	56%	39%	$\chi^2 = 2.11$, ns
Work (some work exp.)	80%	82%	$\chi^2 = 0.00$, ns
Parents' education (either parent college grad.)	49%	26%	$\chi^2 = 4.00$, $p < .05$
Father's occupation (high status, mgr. or prof.)	53%	30%	$\chi^2 = 4.48$, $p < .05$
Mother working (outside the home)	40%	18%	$\chi^2 = 4.22$, $p < .05$
Parents' marriage (original family intact)	64%	61%	$\chi^2 = 0.01$, ns

of where they were currently living (community, hospital, experimental facilities). They rated overall level of psychopathology on the seven point scale used at admission (Figure 1) and degree of improvement since admission based on a 7 point scale (Figure 2).

RESULTS

A. Subjects

Data from all patients who remained in treatment at the experimental facilities for 28 days or more (N = 45) and 7 days or more (N = 55) in the control settings are reported here. Study subjects leaving before these times were judged to have not received a fair trial of the assigned treatment (non-drug special milieu or drug-hospital ward). This procedure is analogous to minimum therapeutic dosage standards set in psychopharmacologic studies.

B. Admission characteristics

Ten demographic, 5 psychopathology, 7 prognostic and 7 psychosocial independent variables (29 total) were assessed at admission and comparisons between experimental and control groups performed (Tables 1, 2, 3, and 4). There were only 4 significant intergroup differences: fathers of experimental subjects had more education and higher status jobs than fathers of control subjects; more mothers of experimental subjects were

Table 2
Five psychopathology independent variables

	Experimental N = 45	Control N = 55	Test
Carpenter Strauss Bartko scale (certainty of schiz., 1–12)	8.2	8.6	t = 1.46, ns
Venables & O'Connor paranoia scale (0–25)	20.4	20.7	t = 0.42, ns
Symptoms diagnostic of schizophrenia (Cole *et al.*, 0–7)	5.3	5.5	t = 1.15, ns
Certainty of diagnosis of schizophrenia (Mosher *et al.*, 1–7)	5.9	5.9	t = 0.19, ns
Global psychopathology (Mosher *et al.*, 1–7)	5.1	5.3	t = 1.53, ns

working outside the home than mothers of control subjects; and fewer experimental subjects had positive family relationships (as judged by the research staff) than control subjects. Note: these four are parental, not subject, characteristics.

C. Milieu

Only staff scores are reported here (see Wendt *et al.* 1983 for other analyses). As may be seen in Figure 3, the milieus of the two experimental facilities, as assessed by the COPES scale, were remarkably similar. The milieus of the two control hospital wards (WAS scale) (Figure 4) were also similar in configuration, but less so (as expected) than those

Table 3
Seven prognostic independent variables

	Experimental N = 45	Control N = 55	Test
Acute onset (symptoms less than 6 mos.)	53%	67%	$\chi^2 = 1.48$, ns
Presence of confusion (in admission interview)	80%	76%	$\chi^2 = 0.04$, ns
Schizoid pre-morbid adjustment	44%	36%	$\chi^2 = 0.38$, ns
Presence of precipitating events	60%	56%	$\chi^2 = 0.03$, ns
History of previous hospitalization (for mental illness)	47%	55%	$\chi^2 = 0.36$, ns
Family history of mental illness (mother, father, or sibling)	40%	52%	$\chi^2 = 0.82$, ns
Goldstein adolescent adjustment scale (7–35)	20.0	21.9	t = 1.30, ns

Table 4
Seven psychosocial independent variables

	Experimental N = 45	Control N = 45	Test
Living independently (prior to admission)	47%	35%	$\chi^2 = 1.05$, ns
Work or school (full or part time)	36%	49%	$\chi^2 = 1.30$, ns
Primary income from work	29%	40%	$\chi^2 = 0.69$, ns
Number of friends (scale, 0–6)	2.2	2.6	$t = 1.26$, ns
Number of contacts with friends (per week, scale 0–6)	1.8	2.1	$t = 0.92$, ns
Sexual intercourse (at least once)	26%	21%	$\chi^2 = 0.23$, ns
Positive family relationship (judged by research staff)	21%	45%	$\chi^2 = 4.54$, $p < .05$

of Soteria and Emanon. As may be seen in Figures 5 and 6, the social environm... the two experimental facilities were significantly different (standard score diff... ≥ 10) from their respective hospital control wards on eight of the ten COPE... measured variables. They were similar only on the variables of personal pr... orientation and tolerance of anger.

D. Six-week outcome (Table 5)

As shown in Table 5, both groups had comparable levels of psychopatholog... t = .05, ns) and degree of improvement since admission (2.5, t = .15, ns).

Both experimental and control groups evidenced highly significant reduc... symptom levels between admission and 6 weeks (Experimental: 3.5 − 5.1 = −1.... t = 6.49, p < .001, Control: 3.5 − 5.3 = 1.8, paired t = 9.95, p < .001). These ... change were not significantly different from each other (t = 0.86, ns, Table 5). ... equivalent levels of change occurred despite very different use of neuroleptic me... in the two groups. As also may be seen in Table 5, 98% of control subjects ... antipsychotics during their entire initial hospital stays while only 12% of experim... subjects did ($\chi^2 = 70.8$, p < .001, Table 5). Sixty seven percent of experimental ... never received neuroleptics during their initial 6 weeks of residential care. In co... every control subject received them ($\chi^2 = 50.7$, p < .001, Table 5).

E. Neuroleptic drug utilization in experimental subjects and outcome (Table 6)

In the analysis reported here we collapsed the drug treatment variable into ... categories that allow all our data on neuroleptic drug usage to be used and that ... clinical common sense: Little or no drug treatment ("no substantial neuro... treatment") defined as *no* or less than 7 days of continuous neuroleptic drug ... and "substantial" drug treatment, combining the categories of greater than 7 d...

Table 5
Six week outcome data. Psychopathology and medication

	Experimental N = 45	Control N = 55	Test
Global psychopathology (Mosher *et al.*, 1–7)	3.5	3.5	n = 39, 50 t = 0.05, ns
Global psychopathology (change from admission)	−1.6	−1.8	n = 39, 50 t = 0.86, ns
Global improvement (change from admission)	2.5	2.5	n = 39, 50 t = 0.15, ns
Continuous neuroleptic drug treatment	12%	98%	n = 42, 55 $\chi^2 = 48.4$, $p < .01$
Substantial neuroleptic drug treatment (>7 days)	31%	100%	n = 42, 55 $\chi^2 = 50.9$, $p < .01$
Any neuroleptic drug treatment	33%	100%	n = 42, 55 $\chi^2 = 70.8$, $p < .01$

continuous drug treatment. Psychopathology scores decreased significantly and similarly in both treatment groups (−1.9, t = 5.35, p < .001; −1.0, t = 4.06, p, .01). Within the experimental group global psychopathology scores for the 25 subjects who received no substantial neuroleptics during this period showed significantly greater improvement on this measure than did the scores of the 12 who received them (t = 2.05, p < .05) (Table 6). No such comparison is possible within the control group because all of these subjects received substantial or continuous drug treatment during this period.

DISCUSSION

This report presents evidence for two types of replication in the Soteria project:

1) A second facility ("Emanon") was established in which the staff's perception of the social environment (COPES scores) is nearly identical to the staff perception of the milieu of the original facility.

2) The six week psychopathology outcome data from these randomly assigned cohorts of subjects replicates almost exactly the findings of the original 1971–76 cohort. In the original study sample, reported by Mosher and Menn in 1978(b) admission level of psychopathology was 5.2 ± 1.2 (N = 31) for the experimental group and 5.3 ± 0.8 (N = 23) for the controls. At 6 weeks they were 3.9 ± 1.5 (N = 30) and 3.9 ± 1.5 (N = 21) again, a significant, but similar decline in levels of psychopathology in both groups. In terms of medication status, none of the original experimental subjects received continuous neuroleptic drug treatment while all of the controls did during their initial 6 weeks in the study.

Our ability to replicate both the environments and short term clinical results lends evidence to the usefulness of these specially designed environments for newly identified persons with schizophrenia.

In 1964 the Psychopharmacology Collaborative Study Group (Cole *et al.* 1964) published the first definitive large scale study that showed neuroleptic drug treatment

Table 6
Experimental subjects' change in global psychopathology (admission to 6-weeks) by drug status

	Admission	6-weeks	Change*
No substantial neuroleptic drug treatment (none, or <7 days)	5.0	3.1	1.9* N = 25, t = 5.35, p < .001
Substantial neuroleptic drug treatment (>7 days, or continuous)	5.2	4.2	1.0 N = 12, t = 4.06, p < .01

* Note: change for experimental subjects with no substantial neuroleptic drug treatment is greater than the change for experimental subjects with substantial neuroleptic drug treatment (N = 25, 12, t = 2.05, p < .05).

to be strikingly more effective than placebo in reducing psychotic symptomatology in acute schizophrenic patients. There have been many replications since. Why, when our subject selection and diagnostic criteria were more stringent than those used in that seminal study, do we find that treatment of acute schizophrenia *without* antipsychotic drugs is as effective as treatment with them?

We believe the answer to this critical question appears to be that the special social environments of the experimental facilities are very different from those of psychiatric wards in general hospitals. Their particular characteristics seem to make them therapeutic for acutely psychotic individuals.

In terms of the COPES/WAS data, high levels of perceived involvement, support, spontaneity, autonomy and low levels of practicality and staff control seem to address the therapeutic needs of acutely psychotic persons.

In addition, personality test data from Soteria project staff show them to be significantly more tolerant, flexible and non-judgmental when compared with hospital ward staffs (Hirschfeld *et al.* 1977; Mosher *et al.* 1973). As staff attitudes and behavior are crucial to the development and maintenance of the special cultures it appears that the project's focus on interpersonal phenomenology promoted a "low key" approach. This is consistent with how Ciompi *et al.* (1992) describe the therapeutic process at Soteria Bern.

Finally, from a more strictly clinical perspective the experimental environments very effectively performed the five milieu functions described by Mosher and Burti (1994) as being most important for the care of the acute phase of psychosis. They are: control of stimulation; respite or asylum; protection or containment; support; and validation. When present they result in an environment that is quiet, safe and predictable (Figure 2). Again, Ciompi (1992) describes Soteria Bern's milieu similarly. In contrast, it is extremely difficult for busy, short stay psychiatric wards in general hospitals to provide this type of environment.

What are some of the particulars of the therapeutic *process* that makes these settings conducive to the reduction of psychopathology as effectively as neuroleptics?

The small size and adequate undistracted staff of the experimental setting made them immediately available and flexibly responsive. Consistent with a phenomenologic stance, staff were given specific permission to "let be", "be with", and "do with". There was no

SOTERIA

MILIEU FUNCTIONS: EARLY*

1. Control of stimulation
2. Respite or asylum
3. Protection or containment
4. Support
5. Validation

(Results in a quiet, safe, predictable environment)

*From Mosher & Burti, 1994

Figure 7

pressing need to do anything. The potential healing value of human relationships was given primacy. Interest in understanding the inner life of the residents (Soteria's word for patients) was central to the work. Nearly anything was possible, but the umbrella expectation of change, of problem resolution, of reintegration, was always present. Psychosis was normalized, contextualized and framed in developmental terms. Maybe most importantly the houses felt like home to the participants.

WHAT ARE THE QUESTIONS THAT MAY BE RAISED ABOUT THIS STUDY?

1. The patients in the study weren't *really* schizophrenic. We are still not sure what "real" schizophrenia is. The changes this diagnostic group underwent between DSM II, III, IIIR and IV attest to this. What matters in this study is that the experimental and control groups were selected by the same criteria and were almost exactly the same on every baseline variable measured. The significant differences between the experimental and control groups were parental characteristics. It is, of course, possible that they were different on some variable(s) we didn't measure.
2. The results were due to the placebo or "Hawthorne" effect. We know that interest, enthusiasm, context and expectations influence behavior. These were used consciously in the design of these environments. That these milieus are able to produce similar results in three groups of patients (Cohort I – 1971–76, Cohorts II and III 1976–80) treated in two facilities over a nine year span mitigates against their being the results of mere enthusiasm.
3. Such settings are too costly and difficult to design and implement to be of use to a system of care. *Per diem* costs of such facilities generally run about 1/5 of that of psychiatric wards in general hospitals. This paper includes data from subjects treated in

a replication of the original experimental research setting. The senior author has replicated modified versions of these settings in three additional communities. The NIMH has proposed that such facilities ("Crisis Residences") be included in an array of community support services (Stroul, 1987).

Based on these data, and the well known short and long term toxicities of neuroleptic drugs, we are led to recommend that mental health systems include in their array of services a Soteria-type facility for newly diagnosed psychotic patients. The only sure way to prevent T.D. is not to give neuroleptics. Such facilities would allow us to minimize the risk of T.D. while providing special care for patients just entering the system. Such care might also help reduce the rate of long term disability and use of expensive hospital beds.

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