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A Systematic Review of the Soteria Paradigm for the Treatment of People Diagnosed With Schizophrenia

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***Background*: The "Soteria paradigm" attempts to support people diagnosed with schizophrenia spectrum disorders using a minimal medication approach. Interest in this approach is growing in the United Kingdom, several European countries, North America, and Australasia. *Aims*: To summarize the findings from all controlled trials that have assessed the efficacy of the Soteria paradigm for the treatment of people diagnosed with schizophrenia spectrum disorders. *Methods*: A systematic search strategy was used to identify controlled studies (randomized, pseudorandomized, and nonrandomized) employing the Soteria paradigm to treat adults and adolescents meeting the criteria for schizophrenia spectrum disorders according to *International Classification of Diseases* and *Diagnostic and Statistical Manual for Mental Disorders* criteria. *Results*: We identified 3 controlled trials involving a total of 223 participants diagnosed with first- or second-episode schizophrenia spectrum disorders. There were few major significant differences between the experimental and control groups in any of the trials across a range of outcome measures at 2-year follow-up, though there were some benefits in specific areas. *Conclusions*: 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. Further research is urgently required to evaluate this approach more rigorously because it may offer an alternative treatment for people diagnosed with schizophrenia spectrum disorders.**

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In the late 1960s and early 1970s, a number of attempts were made to create therapeutic community alternatives to hospitalization for people diagnosed with schizophrenia.[1,2] These tried to understand schizophrenia not as an illness needing medical intervention but rather as an important aspect of an individual's life history.[3] Rather than use in antipsychotic medication as a first course of treatment, such initiatives emphasized the need to allow individuals to go through their experience of psychosis with minimal interference and high levels of support.[4] UK-based initiatives included Kingsley Hall, associated with Laing and colleagues in the Philadelphia Association,[5] and Villa 21, associated with David Cooper.[2] Perhaps less well known is the "Soteria paradigm," which was developed by Mosher and colleagues[6] in the United States. Over the course of its 30-year history, the therapeutic and structural features considered specific to the paradigm have been elucidated in some detail, with the so-called "Soteria critical elements" being disseminated to help inform the development of further Soteria projects (J. Schreiber, personal communication, Mosher,[7] Mosher and Bola[8]). These core principles include the provision of a small, community-based therapeutic milieu with significant lay person staffing, preservation of personal power, social networks, and communal responsibilities, a "phenomenological" relational style which aims to give meaning to the person's subjective experience of psychosis by developing an understanding of it by "being with" and "doing with" the clients, and no or low-dose antipsychotic medication (with all psychotropic medications being taken from a position of choice and without coercion). Unlike many of the other alternative approaches to the treatment of schizophrenia, the Soteria paradigm has been subjected to quantitative empirical enquiry via a randomized controlled methodology. Interest in the Soteria paradigm has grown recently in the United Kingdom, resulting in the formation of a national Soteria Network, the hosting of an inaugural conference, and discussion with regards to establishing a Soteria House.[9] Given that evaluations of the paradigm have reportedly been undertaken in other countries[10] and that it

is attracting renewed interest in both the United Kingdom and other areas of the world, we decided to systematically review the research underpinning this approach.

Aims of the Study

To evaluate the efficacy of the Soteria paradigm for persons diagnosed with schizophrenia using a systematic review of the available empirical evidence.

Methods

We searched Medline, Embase, CINAHL, Psychinfo, and the Cochrane Library for references in all languages using the search terms for schizophrenia and related disorders specified by the Cochrane Schizophrenia Group, together with the term "Soteria." The search included all references up to June 2005. We wrote to experts and organizations with an interest in alternative treatment approaches to schizophrenia and searched the references in each article we obtained, whether included or not, for any additional potentially relevant studies. We searched collections by hand in the Health Sciences Library of the University of Nottingham and the Medical Library of Nottinghamshire Healthcare NHS Trust. The following journals were hand-searched, in their entirety, for the period January 1975 (the year in which the first results from the Soteria paradigm were published) to June 2005: *Acta Psychiatrica Scandinavica*, *The American Journal of Psychiatry*, *Archives of General Psychiatry*, *The British Journal of Psychiatry*, *The Journal of Nervous and Mental Diseases*, *Psychological Medicine*, *Social Psychiatry and Psychiatric Epidemiology*, and *Schizophrenia Bulletin*. These journals were selected on the basis that they were available as complete collections for the study period and represented the journals considered by the study team to have the highest probability of containing articles relating to the Soteria paradigm.

Inclusion Criteria

We included peer-reviewed evaluations of all treatment programs calling themselves Soteria communities, affiliated or associated to the original Soteria community, and adhering to the Soteria critical elements outlined above, in accordance with current best practice guidelines for the conduct of systematic reviews.[11] We also included evaluations of treatment programs without the name Soteria in their title (these studies were identified via the use of the word Soteria in their citation or abstract) but explicitly modeled on the Soteria community and adhering to the aforementioned core therapeutic principles. In an attempt to ensure homogeneity with regard to the putative therapeutic ingredients being assessed, we excluded any studies calling themselves Soteria but not cleaving to the Soteria critical elements. All controlled studies (randomized, pseudorandomized, and nonrandomized) assessing adults and adolescents meeting the *International Classification of Mental and Behavioral Disorders*: *International Classification of Diseases, 10th Revision*[12] criteria for schizophrenia, schizoptypal and delusional disorders, or the *Diagnostic and Statistical Manual for Mental Disorders* (*DSM*) criteria for schizophrenia spectrum disorders, were included. Each identified article was independently examined to determine if it met the inclusion criteria by 2 reviewers (Dr Ferriter and Dr Huband). Details of included studies are shown in tables 1–3. Data were extracted by the same 2 independent reviewers, with a third reviewer (Dr Calton) adjudicating in the event of disagreements. The decision to potentially include nonrandomized studies was taken because many systematic reviews, including those addressing interventions for schizophrenia, conclude that there is insufficient evidence because too few randomized controlled trials (RCTs) have been carried out in the area of interest.[32] This may be particularly true in areas such as minimal medication approaches to the treatment of schizophrenia, where conducting RCTs is likely to be considered a contentious, or possibly inappropriate, course of action. It should also be borne in mind that nonrandomized controlled studies of high quality can produce outcomes that approximate those found in RCTs.[33] Thus, our inclusion of nonrandomized trials reflected our commitment to generating constructive advice for both clinicians and researchers.

Results

We identified 76 references. No language restrictions were applied. After inspection of the full articles or translations from foreign language articles, 56 (74%) were rejected. Table 4 shows the excluded studies and reasons for exclusion. The remaining studies only described 3 cohorts, 2 from Soteria USA and 1 from Soteria Berne. The paucity of data meant that it was not possible to carry out meta-analysis or funnel plots to detect publication bias.

Description of Studies and Methodological Quality

Soteria USA: Mosher et al (1975); Mosher (1976); Mosher and Menn (1975); Mosher and Menn (1977); Mosher and Menn (1978); Mosher and Menn (1982); Mathews et al (1979); Mosher (1991); Mosher et al (1995); Mosher (1999); Bola (1999) Bola and Mosher (2002a); Bola and Mosher (2003); Reference Nos.[13–25] These studies include data on 2 cohorts of patients admitted to Soteria between 1971–1976 and 1976–1979 and compared patients admitted to control group patients admitted to hospital. Bola and Mosher[25] is the most recent and principal source of data. The authors' main claim is better 2-year outcome for patients admitted to Soteria compared with hospital patients.

Table 1. Studies Included in This Review

Study	Design	Description of Treatment Program	Control
Soteria USA (2 cohorts): Mosher et al[13]; Mosher[14]; Mosher and Menn[15]; Mosher and Menn[16]; Mosher and Menn[17]; Mosher and Menn[18]; Mathews et al[19]; Mosher [20]; Mosher et al[21]; Mosher[22]; Bola[23] Bola and Mosher[24]; Bola and Mosher.[25]	Cohort 1: quasi-experimental design, consecutive assignment to treatment or control arm. Cohort 2: randomized controlled trial	Soteria project, USA	General hospital inpatient psychiatric units
Soteria Bern: Ciompi et al[10]; Ciompi[26]; Ciompi and Bernascomi[27]; Ciompi et al[28]; Ciompi et al[29];	Randomization constrained by bed availability	Soteria Berne, Switzerland	Patients not admitted to Soteria because there were no vacancies

There are a number of problems with this portfolio of articles, some of which are explicable in terms of research practice at the time the studies were carried out but others less so. The data are not always presented clearly. The first cohort was allocated to Soteria or control group by alternate admission and today we would describe this as pseudorandomization. The second cohort was described as randomized though the method of randomization is not described. We reproduce their main results table, combining both cohorts, with significant effects

Table 2. Study Characteristics

Study	Inclusion Criteria	Exclusion Criteria	Sample Size	Outcomes
Soteria USA (2 cohorts): Mosher et al[13]; Mosher[14]; Mosher and Menn[15]; Mosher and Menn[16]; Mosher and Menn[17]; Mosher and Menn[18]; Mathews et al[19]; Mosher [20]; Mosher et al[21]; Mosher[22]; Bola[23] Bola and Mosher[24]; Bola and Mosher.[25]	*DSM-II* criteria for schizophrenia.	Not reported	Cohort 1: 79	2-y follow-up: 1. Readmission to 24 h care. 2. Number of readmissions 3. Days in readmission
	Deemed in need of hospitalization 4 of 7 Bleulerian diagnostic symptoms.			4. Global psychopathology scale (Mosher et al[30]) 5. Global improvement scale (Mosher et al[30])
	Not more than 1 previous hospitalization for 30 d or less. Age: 15–32 Marital status: single		Cohort 2: 100	6. Living independently with peers. 7. Ordinal measure of working 8. Functioning subscale of the Brief Follow-up Rating (Sokis [31])
Soteria Bern: Ciompi et al[10]; Ciompi[26]; Ciompi and Bernascomi[27]; Ciompi et al[28]; Ciompi et al[29];	Age 17–35	Drug or alcohol dependency	Treatment: 22	2-y follow-up: 1. Brief Psychiatric Rating Scale 2. Housing situation 3. Job situation 4. Global outcome, 1, 2, and 3 combined 5. Global autonomy
	DSM-III-R criteria for schizophrenia or schizophreniform psychosis.			6. Relapse rate
	At least 2 of 6 symptoms over previous 4 weeks (delusion, hallucinations, though disorder, catatonia, schizophrenic disorders of affect, severely deviant social behavior)	Not compliant with treatment	Control: 22	7. Average medication dose

Table 3. Results and Conclusions

Study	Results	Author's Conclusions
Soteria USA (2 cohorts): Mosher et al[13]; Mosher[14]; Mosher and Menn[15]; Mosher and Menn[16]; Mosher and Menn[17]; Mosher and Menn[18]; Mathews et al[19]; Mosher [20]; Mosher et al[21]; Mosher[22]; Bola[23] Bola and Mosher[24]; Bola and Mosher.[25]	Marginal effects of experimental treatment on 2-y outcomes (30 comparisons) Endpoint $N = 160$ Completers $N = 129$ Completers adjusted for attrition bias $N = 129$ Composite outcome Endpoint NS Completers NS Completers adjusted for attrition bias <0.05 Social functioning Endpoint NS Completers NS Completers adjusted for attrition bias NS Global psychopathology Endpoint NS Completers <0.05 Completers adjusted for attrition bias <0.05 Improved psychopathology Endpoint NS Completers NS Completers adjusted for attrition bias NS Working any Endpoint NS Completers NS Completers adjusted for attrition bias NS Working full time Endpoint NS Completers NS Completers adjusted for attrition bias NS Living alone or with peers Endpoint <0.05 Completers NS Completers adjusted for attrition bias NS Readmission Endpoint NS Completers NS Completers adjusted for attrition bias <0.05 Number of readmissions Endpoint NS Completers NS Completers adjusted for attrition bias NS Days in readmission Endpoint NS Completers NS Completers adjusted for attrition bias NS	"Soteria treatment resulted in better two-year outcomes for patients with newly diagnosed schizophrenia spectrum psychoses …"
Soteria Bern: Ciompi et al[10]; Ciompi[26]; Ciompi and Bernascomi[27]; Ciompi et al[28]; Ciompi et al[29];	Only 2 outcomes showed significant differences between the 2 groups: mean daily dose of medication ($P < .01$) and total dose of medication ($P < .05$)—(9 comparisons)	"The two-year outcome revealed no significant differences between Soteria patients and controls …."

Note: NS, not significant.

reported at the conventional $P < .05$ level, and marginal effects (reported at the $P < .10$ level in the original article) shown as not significant. The results are shown for completing participants with data up to the 2-year follow-up ($N = 129$) and endpoint analysis, which included additional data on participants who had not completed to the end of follow-up ($N = 160$) where last observations were used. There were 179 participants admitted to the combined studies and data from the 19 drop-outs were not included. They also include results for completers adjusted for attrition bias but we are not sufficiently familiar with their statistical method to comment on it. There was also no sample size calculation, and it would be useful to carry out a retrospective sample

Table 4. Excluded Articles

Study	Reason for exclusion
Ahern and Fisher[34]	Description of the PACE philosophy[a]
Ahern and Fisher[35]	Description of the PACE philosophy[a]
Bola and Mosher[36]	Comment[b]
Bola et al[37]	Book chapter[b]
Carpenter and Buchanan[38]	Comment[b]
Chamberlin[39]	Obituary[a]
Ciompi[40]	Review[b]
Ciompi[41]	General discussion article[b]
Dauwalder[42]	Book chapter[b]
De Crescente[43]	Obituary[a]
Delaney[44]	Review[b]
Fabre[45]	General discussion article[b]
Gosden[46]	General discussion article[b]
Greenblatt and Budson[47]	Edited symposium[b]
Guazzeli et al[48]	A review of outcomes in an experimental community in Italy for the mentally ill. It was not clear that all the critical elements of the Soteria model were present. Also no control group.[b]
Harangozo[49]	On the future direction of psychiatry in Hungary[a]
Hirschfeld et al[50]	Participants were staff not patients. Comparative study of personality characteristics of staff at Soteria and 2 traditional mental health programs[b]
Johnson[51]	Book review[a]
Mazzola[52]	Not about the Soteria model[a]
Mosher et al[53]	Study is of psychological characteristics of staff working at Soteria[b]
Menn and Mosher[54]	Book chapter[b]
Mosher and Menn[55]	Book chapter[b]
Mosher and Menn[56]	Book chapter[b]
Mosher and Menn[57]	Book chapter[b]
Mosher and Menn[58]	Book chapter[b]
Mosher and Menn[59]	Book chapter[b]
Mosher[60]	General discussion article[b]
Mosher and Menn[61]	Book chapter[b]
Mosher[62]	Book chapter[b]
Mosher and Hendrix[63]	Obituary[a]
Mosher et al[64]	Report[b]
Mosher and Burti[65]	Book chapter[b]
Mosher[66]	Book chapter[b]
Mosher[67]	Book chapter[b]
Mosher and Bola[68]	Book chapter[b]
Mosher and Bola[69]	General discussion article[b]
Mosher[70]	Book chapter[b]
Mosher[71]	Book chapter[b]
Mosher[7]	Book chapter[b]
Mosher[72]	Book chapter[b]
Mosher and Bola[8]	Discussion of therapeutic ingredients within Soteria paradigm[b]
Peltzer and Machleidt[73]	Description and limited data improvement rates of traditional African healing centers. No comparator group[a]
Scharfetter[74]	General discussion article[b]
Schneider et al[75]	Book[b]
Sharfstein[76]	Editorial[b]
Smith[77]	General discussion article[b]
Thomas[78]	General discussion article[b]
Wendt[79]	Book chapter[b]
Wilson[80]	Book chapter[b]
Wilson[81]	Book chapter[b]
Wilson[82]	Book[b]
Wilson[83]	Book chapter[b]
Wilson[84]	General discussion article
Windgasssen and Tolle[85]	Comment[b]
Zapotoczky and Wenzel[86]	Book[b]
Ciompi et al[87]	Book[b]

Note: PACE, Personal Assistance in Community Existence.
[a]The cited article did not refer to the Soteria paradigm.
[b]The cited article, although referring to the Soteria paradigm, was either not peer reviewed or did not contain any new data relevant to an evaluation of efficacy, or both.

size calculation to see if the combined studies are adequately powered.

At first sight, having reinterpreted the data, the results look relatively unimpressive. Only one outcome—living alone or with peers—showed a significant difference using endpoint analysis. Only one outcome, global psychopathology, was significant based on completer data. Three outcomes—composite outcome, global psychopathology, and number of readmissions—were significant for completers after adjusting for attrition bias.

Soteria Berne: Ciompi et al (1992); Ciompi (1997); Ciompi and Bernascomi (1986); Ciompi et al (1991); Ciompi et al (1993); Ciompi and Hoffman (2004); Reference Nos.[10,26–34,88] This was a small study wherein 2-year outcome comparisons were made between 22 people diagnosed with schizophrenia or schizophreniform disorder using *DSM-III-R* criteria, and an equal number of control cases matched on age, sex, education, psychopathology, and duration since onset. Allocation was by randomization constrained by bed availability, which the authors concede may have resulted in biases. They found significant differences only for mean daily dose and total dose between the 2 groups, replicating the limited differences found in the American studies.

Full details of all included studies are shown in tables 1–3 below.

Discussion

Both the research in the United States and Switzerland showed only modest differences between the Soteria paradigm and standard treatment, with only 5 of the Soteria USA, and 2 of the Soteria Berne comparisons attaining

significance at the .05 level. However, in the case of the American experiments, the direction of effects for the remaining comparisons, while not reaching statistical significance, did favor the Soteria treatment.[23] This is an important, though subtle, finding because in a truly ineffective treatment (ie, no differences between the intervention and control), one would expect an equal number of comparisons to favor each treatment. Hence, the evidence does not appear to indicate that the Soteria paradigm was ineffective; rather it suggests that it seemed to be at least as effective as traditional hospital-based treatment, with this being achieved without the use of antipsychotic medication as the primary treatment.

Limitations

Critical to the success of our search strategy was the concept of the Soteria paradigm, ie, the existence of a therapeutic regimen with ingredients sufficiently specific to demarcate said project from other minimal medication approaches to the treatment of schizophrenia. The seminal review by Bola[89] of medication-free research in early-episode schizophrenia briefly outlines the components of the different treatments used by 8 minimal medication comparative studies (including those cleaving to the Soteria paradigm covered by the present study). We interpret Bola as appearing to suggest that there were specific differences with regard to the constituents of the nonmedication intervention treatments between the 2 studies cleaving to the Soteria paradigm, and the remaining studies, thereby implying that the Soteria paradigm is specifically different, in terms of its constituent features (though not necessarily its effects) from all other minimal medication approaches to the treatment of early-episode schizophrenia. This, together with the existence of the Soteria critical elements supports our assertion that the Soteria paradigm constitutes a specific treatment format, though this issue may be open to further debate. Despite this we may have inadvertently included studies wherein the term Soteria was used in an unrelated sense, or where some, but not all, of the Soteria critical elements were incorporated into traditional general psychiatric hospital wards; a problem that has been discussed elsewhere.[90] Our inclusion criteria were designed to circumvent this problem by filtering out said anomalies (with 2 of the former and 4 of the latter being among the excluded articles). Hence, it is likely that our review encompasses only those peer-reviewed, controlled studies that have assessed the efficacy of the Soteria paradigm proper. The exclusion of data derived from books and book contributions from our review could conceivably have resulted in our omitting information relating to the problems of medication, qualitative aspects, and possible explanations for the therapeutic effects of the Soteria paradigm. However, the explicit aim of this systematic review was to assess the best possible empirical evidence relating to the evaluation of the *efficacy* of the Soteria paradigm as a therapeutic intervention, hence our a priori inclusion criteria. With this in mind, we focused on peer-reviewed comparative efficacy studies, but as an additional, though *a posteriori*, quality assurance check, we scrutinized all the relevant excluded book contributions. We were unable to identify any further efficacy data in addition to that already included in the review.

Despite a relatively large body of published literature, there was only a very modest amount of data. It is noteworthy that the same data from the American project were published several times in different journals, though, in fairness, the authors did not attempt to conceal their previous publications. The quality of the research was variable, with some lapses excusable within the context of the era when the projects were carried out (pseudorandomization), and others less so (statistical presentation). Soteria USA included both first- and second-episode patients, while Soteria Berne included only individuals experiencing their first episode of schizophrenia. Hence, any conclusions regarding the efficacy or otherwise of the Soteria paradigm may only be applicable to those people diagnosed with early-onset schizophrenia and cannot necessarily be applied to people diagnosed with longer term forms of the disorder.

In addition, the American study employed *DSM-II*[91] criteria to diagnose schizophrenia, while Soteria Berne used *DSM-III-R*. The primary change from *DSM-II* to *DSM-III* (and hence *DSM-IV*) was the addition of the 6-month length of symptom criterion, thus, in the era of *DSM-IV*, the validity and generalizability of the findings should be questioned. However, rediagnosis of the American cohort, using *DSM-IV* criteria, showed that although 58% of those individuals diagnosed with schizophrenia at study inception were subsequently rediagnosed with schizophreniform disorder, 68% of these were rehospitalized within the 2-year follow-up period and would likely have met *DSM-IV* criteria for schizophrenia.[24] This finding actually serves to increase the validity of the results, given that the 6-month *DSM-IV* duration criterion is particularly conservative. There was also a paucity of economic data, though Soteria USA was described as slightly cheaper, and Soteria Berne as initially more expensive, than standard treatment. However, a subsequent economic reevaluation of Soteria Berne revealed that, by transferring social and vocational rehabilitation to specialized local community-based settings (rather than providing same within the project itself), the project could be run at 10%–20% lower costs than comparable local units.[88]

The Wider Context

These limitations notwithstanding the data do, nevertheless, suggest that, despite the absence of evidence for any wide-ranging advantages for the Soteria paradigm over

standard treatment, there are a number of compelling reasons to reconsider the Soteria paradigm in the context of the changing landscape of mental health services and policy. For example, it is interesting to compare the results from the Soteria paradigm with those from the international studies of schizophrenia conducted by the World Health Organization[92,93] which demonstrated superior outcomes for individuals diagnosed with the disorder in developing countries. Although a truly compelling explanation for this finding is still awaited, it must be remembered that the authors of the original report concluded that differences in sociocultural factors had the greatest explanatory power for the differences in outcome for schizophrenia between the developing and developed worlds.[93] Taken at, albeit speculative, face value, the Soteria paradigm seems more likely than standard treatment to approximate the supportive and collectivist sociocultural mechanisms often suggested as responsible for better developing country outcomes.[25]

The Question of Medication

Conventional medical treatment of people diagnosed with schizophrenia continues to rely almost entirely on the (sometimes involuntarily) use of antipsychotic medication. The Soteria paradigm is noteworthy in that, while not adopting a dogmatically "antimedication" position, it seeks to marginalize the use of medication and treat it as something to be taken voluntarily from a position of informed choice, without the overt or tacit compulsion encountered in standard treatment settings. In the original study,[13] only 24% of the experimental group received any medication during the initial 6 weeks of treatment (as opposed to 100% of the hospitalized control group), with only 16% of these receiving "substantial" drug treatment, ie, $>$ 7 days.[71] At 2-year follow-up, the percentage of experimental subjects who had taken antipsychotic medication had risen to 57%, as opposed to 97% of the control group.[25] At Soteria Berne, 73% of the experimental group had taken antipsychotics at two-year follow-up, compared with 95% of controls, and the total 2-year doses of antipsychotics were 56% lower in the experimental group.[88]

Such an approach clearly risks garnering opprobrium, given that there is a wealth of quantitative empirical evidence, suggesting that antipsychotic medication produces statistically significant improvements in schizophrenia symptoms,[94] prevents relapse,[95] and obviates the problems of a long duration of untreated psychosis (DUP)[96] (though, some have argued that an aversion to engaging with conventional, medication-oriented psychiatric services actually prolongs DUP[97]). However, the consistency of these research results and the nature and sustainability of longer-term outcomes have been questioned.[98,99] For example, the relapse rate among patients with a diagnosis of schizophrenia on medication remains high and noncompliance with treatment is frequently seen as a problem.[100] In addition, some people do not respond to antipsychotic medication at all,[72] and research has suggested that the only real advantage of the atypical antipsychotics, compared with first-generation antipsychotics, is the reduced risk of extrapyramidal symptoms such as Parkinsonism, acute dystonia, and akathisia,[101] though even these "negative benefits" have been challenged in recent years.[102,103] Indeed, recent research continues to point to high levels of morbidity and lower life expectancy for people taking atypical antipsychotic medication on a long-term basis,[104] with this risk operating via an increased incidence of fatal cardiac arrhythmias and obesity.[105]

Service users themselves have questioned the overreliance on medication.[106] They have complained that other side effects, which are not obviated by atypical antipsychotics, such as loss of motivation, sexual dysfunction, weight gain,[96] drowsiness, and restlessness[108] are actually more troubling for them than the extrapyramidal effects.[107] Partly because of these concerns, there has been ongoing interest in creating alternatives to traditional inpatient treatment with medication.[108–110] For all these reasons, it is important to investigate the option of therapeutic alternatives, particularly given the rise of notions of patients or consumer "choice" and the growing interest in advanced directives as ways to increase patient choice and autonomy in periods of acute mental health crisis when capacity may be hindered.[111–113]

Choice and Capacity in the United Kingdom

Patient choice sits at the center of current UK governmental health reforms,[114] has been cited as a vital component of an evidence-based and patient-centered mental health care system,[115–117] and is also an important component of the influential medical risk-benefit framework for evaluating competing interventions.[118] The current National Institute for Clinical Excellence guidelines for the management of schizophrenia state that "during an acute episode, antipsychotic drugs are necessary,"(p11) a mandate not extended to psychological interventions. Patient choice in this context is reduced to having some say over which antipsychotic is prescribed. The concept of choice underpins informed consent, in that consent can only be said to be informed if a person appreciates that there are other choices available to them. It is interesting to consider how the concept of informed consent sits within a system that treats of one intervention as mandatory and all other treatment modalities as inherently subsidiary.

Good practice also dictates that doctors should work on the presumption that every adult has the capacity to decide whether to consent to, or refuse, proposed medical intervention, unless it is shown that they cannot understand information presented in a clear way.[119] Yet the

Mental Health Act 1983 in England and Wales attributes little significance to the patient's capacity to consent, a state of affairs replicated in the, now defunct, Draft Mental Health Bill. In the context of involuntary detention perhaps absence of capacity is presumed, but this may not be justifiable: past research has suggested that approximately 75% of people diagnosed with schizophrenia understand information and make decisions similar to comparison groups around issues of consent.[120] More recent work, employing a global assessment of capacity, showed that 56% of patients admitted to an acute general adult psychiatric ward retained treatment-related decisional capacity,[121] with mania and the presence of delusions, not involuntary detention, being the best predictors of incapacity. Although syndromal diagnoses were not generated, making it very difficult to draw conclusions about specific diagnostic categories, this suggests that, at the very least, the majority of people admitted to general adult psychiatric wards may retain treatment-related decisional capacity.[122] In theory, these individuals could make an informed choice regarding their treatment preference, yet at the present time, the only universally accessible treatment option is medication, with or without psychosocial interventions as circumstances dictate.

Future Research and Ethical Considerations

The Soteria paradigm remains an intriguing example of medical parsimony in the treatment of schizophrenia, via its use of significant numbers of nonmedically indoctrinated staff and minimal use of medication. The studies included in this review suggest that the Soteria paradigm yields equal (and in certain specific areas, better) results in the treatment of schizophrenia when compared with conventional, medication-based approaches. This review complements the results of the meta-analysis by Bola[90] which showed a small to medium, statistically nonsignificant long-term advantage for the Soteria paradigm over conventional treatment. How exactly these effects are achieved remains moot, though explanatory models have focused on the importance of a consistent, emotionally relaxing therapeutic environment,[89] a hypothesis given strong empirical support by extant research on outcome in schizophrenia.[123,124] Importantly, the Soteria paradigm appears to achieve its effects using considerably less antipsychotic medication and at a lower overall cost.

Other researchers have minimized the use of antipsychotic medication within more orthodox medical regimens employing intensive psychotherapeutically oriented support.[125–127] These studies have, like the Soteria paradigm, found few advantages, yet no disadvantages, for people adhering to their minimal medication regimens. Hence, there appears to be some, albeit limited, evidence supporting the minimal medication approach adopted within the Soteria paradigm. However, none of these studies adopted a rigorous randomized controlled methodology. Although the evidence used to support evidence-based patient choice should arguably be based as much as possible on systematic reviews of RCTs, the results of observational studies, including qualitative research, should also be given due weight and influence.[117] The paucity of RCT data for the Soteria paradigm and the other minimal medication approaches outlined above can only be ameliorated by further research employing rigorous trial methodologies, in-depth qualitative research utilizing user-centered outcomes, and long-term follow-up to evaluate the paradigm's longitudinal effects. It would also be important to give due consideration to appropriate subgroup analyses in order to try and identify those people (eg, those diagnosed with true schizophreniform disorder), who might garner particular benefit from the paradigm. This, of course, can only happen if further Soteria or Soteria-like projects are established: such research would necessitate the use of medication-free, or minimal medication protocols, a potential cause for concern, but one which has been extensively debated.[89,128–133] The current consensus would appear to be that such research is not associated with widespread problems of informed consent or adverse consequences to patients and is ethically justifiable in the search to identify new treatments.[128]

Conclusion

The lack of both quantity and quality of the evidence base to date mean that we cannot yet recommend the Soteria paradigm as a standard treatment. However, there is also an absence of evidence that the regimen did harm, and indeed, evidence to suggest specific advantages for the paradigm over conventional treatment (with particular regard to antipsychotic load and overall cost). In the somewhat convoluted mantra of evidence-based medicine "an absence of evidence is not evidence of an absence of effect," and it must be said that many treatments, including the formal psychotherapies for psychosis, also lack a substantial evidence base. Recent research has again indicated that service users highly value the absence of side effects[134,135] and the vast majority of service users and providers support the idea of residential crisis services as an alternative to acute inpatient treatment.[136] This suggests that the minimal medication approach offered by the Soteria paradigm may be more responsive to patients' priorities.

In terms of formal research evidence, the Soteria paradigm remains very much what it has always been, an intriguing, but in many ways still experimental approach to the treatment of people diagnosed with schizophrenia. However, the paradigm has been in existence for over 30 years, and it appears that there is a wealth of clinical experience in its implementation which is at present only available to a small number of people in a handful

of European countries.[88] Further research using more rigorous quantitative and qualitative methodologies is urgently required to help clarify its effects, both positive and negative, over both the short and longer term. Given that interest in this approach is growing internationally, perhaps the time for this reassessment is approaching.

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