Are Day Hospitals Effective for Acutely Ill Psychiatric Patients? A European Multicenter Randomized Controlled Trial

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Objective: Acute psychiatric day care has been proposed as an alternative to conventional inpatient care, yet the evidence of its effectiveness is inconsistent and based only on single-site studies in 3 countries. The aim of this multicenter randomized controlled trial was to establish the effectiveness of acute day hospital care in a large sample across a range of mental health care systems.

Method: The trial was conducted from December 2000 to September 2003 in 5 European countries, with a sample of 1117 voluntarily admitted patients. Immediately before or very shortly after admission to the participating psychiatric facilities, patients were randomly allocated to treatment in a day hospital or an inpatient ward. Psychopathology, treatment satisfaction, subjective quality of life, and social disabilities were assessed at admission, at discharge, and 3 and 12 months after discharge. An intention-to-treat analysis was conducted using fixed-effects linear models with structured error covariance matrices and covariates.

Results: Day hospital care was as effective as conventional inpatient care with respect to psychopathologic symptoms, treatment satisfaction, and quality of life. It was more effective on social functioning at discharge and at the 3- and 12-month follow-up assessments.

Conclusion: This study, which has more than doubled the existing evidence base, has shown that day hospital care is as effective on clinical outcomes as conventional inpatient care and more effective on social outcomes.

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Acute day care, defined as a day hospital for acutely ill patients who would otherwise be treated on conventional inpatient wards, has been suggested as a viable alternative to conventional inpatient treatment. The evidence regarding its effectiveness, however, is limited. A recent Cochrane review[1] identified key methodological weaknesses of studies on day hospitals, including limited individual patient data, widely variable follow-up periods (from 2 to 24 months), and that the trials reviewed[2–10] were conducted in only 3 countries (United Kingdom, United States, and the Netherlands). In meta-analyses,[1,11] evidence on clinical effectiveness within a 6-month follow-up period is available on symptomatology for approximately 600 patients, social functioning for 300 patients, treatment satisfaction for 141 patients, and family burden for only 86 patients.

Although the breadth of the evidence base is not optimal, the results are promising. They indicate that acute day care is as effective as inpatient care with respect to symptoms, social functioning, and family burden (type 1 trials)[6,9,10] and is more effective with respect to both treatment satisfaction and speed of symptom reduction.[5] As the Cochrane review identified, however, a multicenter randomized controlled trial (RCT) with a large sample is needed to test the replicability of these findings across a wider range of health care services and settings.[1]

The European Day Hospital Evaluation (EDEN) Study implemented an RCT to compare acute day care with conventional inpatient treatment in 5 countries.[12,13] To overcome methodological shortcomings of previous studies,[1,14,15] the study used a clear definition of day hospital treatment and standardized scales to assess outcome, assessed quality of life as an outcome domain, and employed appropriate statistical techniques to analyze all of the available data rather than only data for patients for whom full follow-up data are available.

METHOD

In the following descriptions, *center* refers to the study site, and *setting* refers to the treatment setting, i.e., acute day hospital or inpatient ward.

Centers and Settings

The trial was conducted from December 2000 to September 2003 in 5 centers (Dresden, Germany; London, United Kingdom; Wrocław, Poland; Michalovce, Slovak Republic; and Prague, Czech Republic) covering both urban and rural areas (Table 1). Day hospitals provided between 15 and 35 places, with mean staff hours per week per treatment place ranging from 8.8 to 16.0. General clinical expertise with day hospital treatment was high in all centers. Day hospitals were established 5 to 7 years ago in Wrocław and Michalovce and 30 years ago in the German center. The acute day hospital in London opened in 1999. In the Czech center only, all wards had been providing integrated day care as an alternative to inpatient care for approximately 20 years. Implementation of the EDEN Study required the day hospitals in Dresden, Michalovce, and Wrocław to redefine their original variety of functions.

As International Classification of Mental Health Care assessments[16] indicated (interrater agreement $\kappa = .61$), day hospitals were similar across centers in both the type of interventions provided and their respective level of specialization. Differences across inpatient wards, attributed to staffing levels,[13] applied particularly to time-consuming activities designed to engage patients and retrain their basic skills.

Within centers, settings differed unsystematically in very few specific modalities of care. In the Dresden day hospital, the higher level of specialization referred to "establishing and maintaining relationships" and "interventions related to daily activities," stemming from a long tradition of outreach activities and vocational rehabilitation. This service also provided several psychological interventions requiring specific training. Due to well-staffed wards, the modalities of "psychopharmacological and somatic interventions" and "taking over activities of daily living" were provided with a higher standard in the inpatient setting. The only major difference in the London center concerned "psychological interventions." For inpatients, these were limited to supportive talks. In the day hospital, some theoretically well-founded interventions could be provided. In Wrocław, differences between the settings and the reasons for them were more or less similar to those reported for the German center. Because the day hospitals in Wrocław and Michalovce were not located in the same areas as the affiliated somatic hospitals, regular efforts of medical specialists were not available, leading to a low level of "general health care." In Prague, finally, no differences between the settings appeared. Treatment environment and methods were constant in all settings over the study duration.

Community-based treatment after discharge from index hospitalization was not standardized across centers, but did not systematically differ between the 2 groups at each center.

EDEN Study Design

Eligibility and inclusion criteria. All patients in need of acute admission to a psychiatric facility were eligible to participate. To be included, patients must have presented with a mental disorder with current symptoms that had either led to at least moderate disturbance in performance in more than 1 area of daily living or had jeopardized the residential, financial, or occupational status of the patient or his/her family. Treatments other than inpatient or day hospital care must have been inadequate or not sufficiently effective for the patient's current mental state. Main exclusion criteria (Figure 1) were temporary admission for diagnostic purposes or for other reasons; age under 18 or over 65 years; involuntary admission; one-way journey to hospital greater than 60 minutes; measures to restrict the patient's freedom, or one-on-one supervision, required or deemed probable; acute intoxication; main diagnosis of addictive disorder; presence of a somatic disorder requiring inpatient care; direct transfer from a different hospital; homelessness; need for constant pick-up and delivery service; and inability to give informed consent.

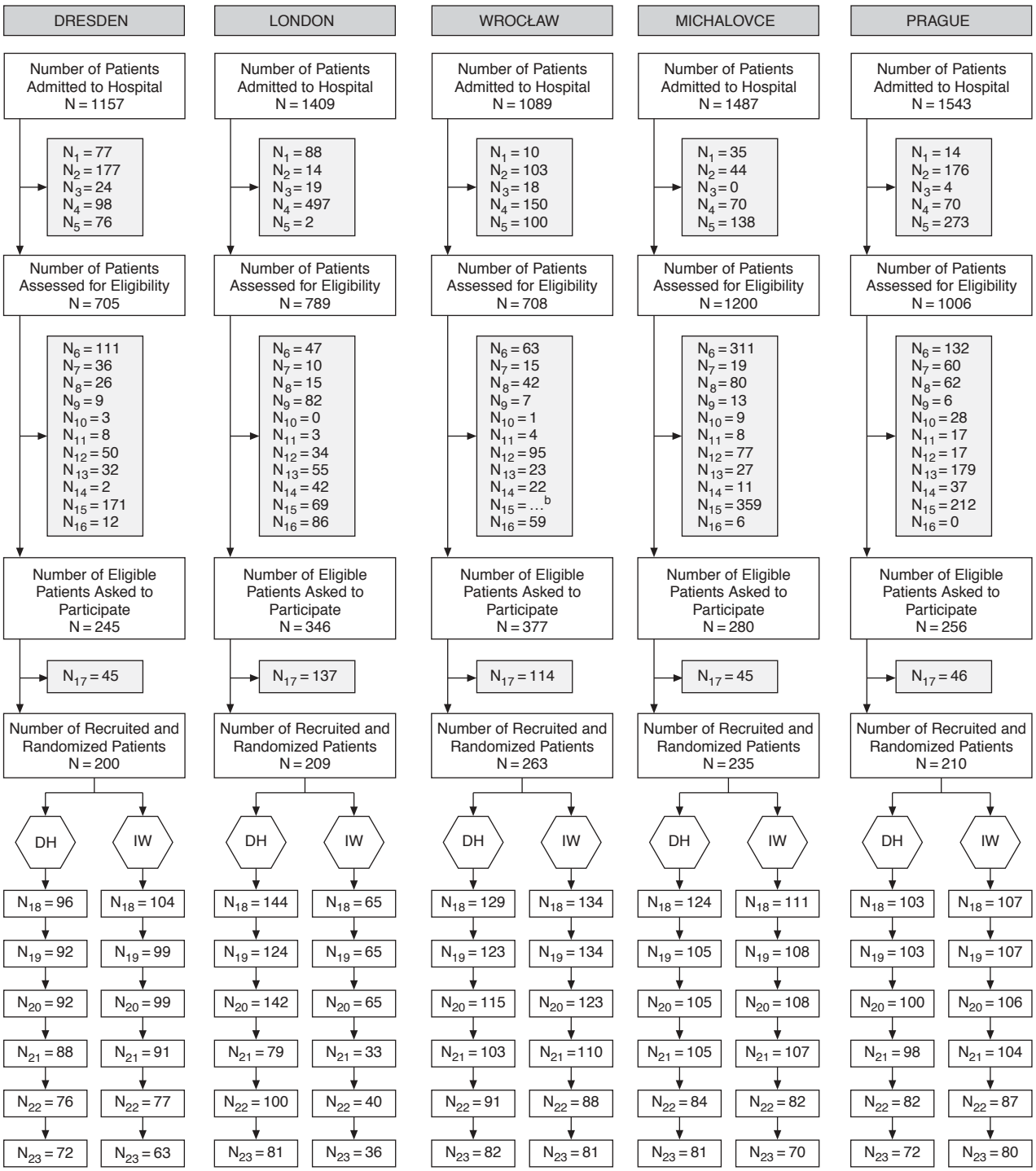
Randomization procedure. A simple randomization[14] procedure was used with a randomization ratio slightly in favor of inpatient care (i.e., 1:1.16), with the exception of London, where the day hospital was a completely new service and therefore used a ratio of 1:3 in favor of day

Table 1. Organizational Features and Process of Providing Care in the EDEN Day Hospital and Inpatient Settings[a]

	Dresden		London		Wrocław			Michalovce		Prague	
Organizational Feature	Day Hospital	Inpatient Wards	Day Hospital	Inpatient Wards	Day Hospital I	Day Hospital II	Inpatient Wards	Day Hospital	Inpatient Wards	Adolescent Day Care Unit[b]	Inpatient Wards
Fixed no. of treatment places	25	58	20	75	35	35	54	30	103	15	119[c]
Staff hours per week available per treatment place, mean	15.8	36.3–69.4	15.1	18.3–40.4	16.0	10.1	27.8–42.6	8.8	9.3–42.2	14.6	18.8–42.6
Form of organization[d]	1		2		4	5		1		3	
Original program function[e]	A, B, C, D		A		A, B, C, D			A, B, C, D		A, B,C, D	
ICMHC modalities of care[f]											
Establishing and maintaining relationships	3	1–2	2	1–2	2	2	2	2	1–2	2	1–2
Problem and functional assessment	3	2–3	3	2–3	3	2	2–3	2	2	2	2
Care coordination	2	1–2	2	2	3	1	2–3	2	1–2	2	2
General health care	2	2–3	2	2	1	1	2–3	1	2–3	2	2
Taking over activities or daily living	1	2–3	1	1	1	1	1–3	1	1–2	1	1
Psychopharmacologic and somatic interventions	2	3	2	2	2	2	2–3	2	2	3	3
Psychological interventions	3	1–2	2	1	2	2	2	2	1–2	2	2–3
Reeducating basic, interpersonal, and social skills	2	1–2	2	2	2	2	1–2	2	1–2	2	1–2
Interventions related to daily activities	3	2	2	2	2	2	1	2	2	2	1
Interventions aimed at family, relatives, and others	2	1–2	2	1–2	2	2	2	2	1–2	2	1–2

[a]All data in this table reflected the current situation in the EDEN institutions.
[b]For adolescents 14–21 years; opened in 2000.
[c]As an integrated day hospital, an unfixed number of further patients may be assigned to the wards, but treated as day hospital patients.
[d]Forms of organization: 1 = not free-standing, but organizationally independent and equipped with own units; 2 = free-standing on the grounds of a psychiatric hospital and organizationally independent; 3 = integrated in a psychiatric hospital with few own units; 4 = organizationally independent and free-standing with the administration of the psychiatric hospital located in the same building; 5 = free-standing in another district but organizationally dependent.
[e]Program functions: A = alternative to admission, B = shortening admission, C = rehabilitation and maintenance, D = enhancing outpatient treatment.
[f]Rating scale for level of specialization: 3 = high level of specialization, 2 = intermediate level of specialization, 1 = low level of specialization, 0 = not applicable to this module of care.
Abbreviations: EDEN = European Day Hospital Evaluation, ICMHC = International Classification of Mental Health Care.

Figure 1. Recruitment and Flow Through the Stages of the Randomized Controlled Trial[a]



[a]N_1–N_{16} indicate reasons for exclusion: N_1: admitted strictly for diagnostic purposes/other purposes than treatment, N_2: patients aged < 18 or > 65 years, N_3: already randomized patients, N_4: involuntary admissions/other legal restrictions, N_5: one-way journey to hospital > 60 minutes, N_6: main clinical diagnosis of addictive disorder, N_7: somatic disorder requiring inpatient care, N_8: direct transfer from another hospital, N_9: homelessness, N_{10}: needs constant pick-up and delivery, N_{11}: acute intoxication, N_{12}: unable to give informed consent, N_{13}: suicidal risk, N_{14}: risk to others, N_{15}: measures to restrict the patient's freedom, or one-on-one supervision, required or deemed probable, N_{16}: other reasons for exclusion; N_{17} indicates refusals; $N_{18–23}$ indicate disposition as follows: N_{18}: randomly allocated to treatment, N_{19}: received allocated treatment, N_{20}: assessed at admission, N_{21}: followed up at discharge, N_{22}: followed up 3 months after discharge, N_{23}: followed up 12 months after discharge.

[b]The N_{15} category was not used in the Wrocław site; alternatively, the patients were assigned to the category "unable to give informed consent" (N_{12}).

Abbreviations: DH = day hospital, IW = inpatient wards.

care. Prior to patient recruitment, a computerized random-number generator created an allocation sequence; the results were placed in identical, sequentially numbered, opaque, sealed envelopes.[1,14] Each center guaranteed a complete separation of the people involved in the generation (and storage) of the allocation list and the implementation of allocations. Quality assurance measures for the randomization process are reported elsewhere.[13,17]

Each center established detailed written protocols of local procedures and clinical responsibilities, approved by all local ethics committees. Treatment allocation (to day hospital or inpatient ward) was determined immediately before admission or, at the latest, before noon of the following workday (i.e., a maximum of 72 hours) following admission to an inpatient unit. During this period, patients were assessed individually to determine eligibility by researchers independent of the center's clinicians. The researcher provided a detailed explanation of the study to those invited to participate. Upon granting informed consent (which was reaffirmed in writing on a separate date on the following workday in which the admission assessment was performed), each patient was given an envelope to open containing the result of the random allocation sequence and was assigned to treatment accordingly. Random allocation was independent of availability of space in the treatment settings. A change in allocation was made, however, if no corresponding treatment place could be found within 24 hours, and the patient was then excluded from further participation in the study.

Outcome measures. Psychopathology, treatment satisfaction, subjective quality of life, and social disabilities were assessed at admission, at discharge, and at 3 and 12 months following discharge.

Sociodemographic and clinical characteristics were assessed using the Client Sociodemographic and Clinical History Schedule.[18]

Psychopathology was assessed with the 24-item version (4.0) of the Brief Psychiatric Rating Scale (BPRS).[19] Although researchers were independent from the treating clinicians, they were not blind to group allocation, as it was necessary to assess patients in their treatment setting. Translation and specific training procedures, along with results of a BPRS rater training (intraclass correlation coefficient [ICC] = .78), are reported elsewhere.[20]

Treatment satisfaction was assessed at admission and discharge using the Client Assessment of Treatment. The questionnaire comprises seven 11-point visual analogue rating scales assessing, for example, general satisfaction, medication, other therapeutic activities, and staff behavior.[21]

Quality of life was assessed with the Manchester Short Assessment of Quality of Life, a modified version of the Lancashire Quality of Life Profile[22] consisting of subjective ratings of satisfaction with life as a whole and with specific life domains (e.g., employment, family relationships) on a 7-point Likert scale. Several studies have demonstrated sufficient construct validity, and internal consistency.[23]

Social disability was assessed using the Groningen Social Disabilities Schedule, Second Revision (GSDS-II).[24] Ratings are assigned for 9 different social roles (overall ratings assess, for example, family, partner, citizen, or occupational role) and for each dimension of the role (dimensional ratings assess, for example, daily routine and performance in the occupational role). The sum score is based on overall role ratings. The rating period covered the previous 4 weeks; thus, social disabilities of patients whose index hospitalization lasted less than 6 weeks were not reassessed at discharge. Interrater reliability for the GSDS-II sum score of all overall role ratings was good (ICC = 0.77).[20]

Statistical Issues

Sample size estimation. For the primary outcome, the mean BPRS score at the 12-month follow-up, a result of $d = 0.60$ was judged to be the minimum relative effect size, i.e., a difference of approximately 0.2 points on the BPRS mean (or 5 points on the sum) score with expected standard deviation of 0.33 in the linear models. In analyses of variance with covariates, while defining $\alpha = \beta = 0.05$ and thus $1 - \beta = 0.95$, the necessary sample size in each setting at the 1-year follow-up is at least $N = 76$ in each center. Loss to follow-up of 20% in the day hospital and 30% in the inpatient setting was expected. Hence, assuming a balanced allocation, a recruitment target of approximately 200 was set for each center, distributed 95:105 for day hospital to inpatient setting. This distribution was modified in London to keep the day hospital operational. As the sample size was set to allow significant differences to be detected across settings within each center, the statistical power increases considerably for the total sample, allowing a relative effect of $d = 0.23$ to be detected (i.e., 0.08 points on the BPRS mean).

Methodological approach for analyses. Characteristics of the study groups were compared using χ^2 and t tests. The admission measurements of each outcome variable were analyzed in linear fixed-effects models. These contained the test factors "setting" and "setting-by-center interaction" and accounted for the hierarchical classification caused by the participating centers. Tests of the differences in means between both settings were Tukey-adjusted. Means of admission measurements were estimated by the corresponding model and thus adjusted to equal numbers of cases across sites.

The mean scale scores (BPRS, Client Assessment of Treatment, Manchester Short Assessment of Quality of Life) or sum scores (GSDS-II) of the outcome measures at the 3 follow-up timepoints were used in an intention-to-treat analysis.[14] A statistician who was blind to the service provision in the participating centers performed this

analysis. The analysis used data from all randomized patients, i.e., their original group assignment was not changed if they were transferred to the other setting during index hospitalization. Patients who were not reassessed were not excluded from the analysis. For this, missing values for their follow-up assessments were assumed to occur at random, and multiple imputations* (as control variant for the results presented in this article) did not indicate any counterarguments. Differences between acute day and inpatient care were compared in fixed-effects linear models with structured error covariance matrices.[25] The models contained the parameterized repeated-measures factor "timepoint," for which autoregressive first-order covariance structure was assumed†, as well as the test factors setting, center, setting-by-center, setting-by-timepoint, center-by-timepoint, and setting-by-center-by-timepoint interaction.[26] The models[14,27] included as covariates admission measurement, the duration of index hospitalization, and, because of its nonlinear degressive course, its logarithm. All group comparisons of means of outcome domains, again adjusted to equal numbers of cases across sites, were Tukey-adjusted.

The SAS Version 9[28] procedure MIXED used for analysis does not eliminate data sets with missing values during the course of the study but, independently from each other, statistically estimates correlation structure, effects, and derived marginal means.[15,29]

RESULTS

Exclusion, Refusal, and Follow-Up Rates

The number of excluded patients differed among centers because of specific contextual factors (Figure 1). For instance, the rate of patients admitted involuntarily was high in inner-city London; travel time to the hospital for many patients admitted to the Prague facilities was more than 60 minutes; and a relatively high number of patients with primary substance abuse disorders were admitted to the Michalovce hospital. From those patients assessed for eligibility, 46.8% (Wrocław) to 76.7% (Michalovce) met the exclusion criteria and were excluded from the study. The overall non-consent rate was 25.7%; refusal rates were similar in 3 centers (16.0%–18.4%) and higher in Wrocław (30.2%) and London (39.6%).

Because of the 2-step process of obtaining informed consent, not all patients meeting criteria for inclusion in the study could be assessed at admission. Some did not show up for the intended treatment, had been discharged already, or had not given their definite (written) consent; therefore, baseline data on these patients could not be recorded. The initial attrition rates from randomization to admission varied significantly among settings and centers, with rates for the total sample of 7.9% for those allocated to day hospitals and 1.5% for those allocated to inpatient settings (Figure 1).

Follow-up rates for the total sample assessed at admission were 87.0% at discharge, 76.5% 3 months after discharge, and 68.1% 12 months after discharge (Figure 1). Some significant differences between patients who were reassessed and those who were not appeared at discharge. Those not reassessed were younger ($p = .008$), were more likely to be unemployed ($p = .001$), were more likely to be living alone ($p < .000$), had more severe psychopathology ($p = .001$), and were less satisfied with treatment at admission ($p < .001$). At both the 3- and 12-month follow-ups, we found no significant differences on the baseline characteristics between patients who were reassessed and those who were not.

Characteristics of the Sample

Sociodemographic and clinical characteristics of the study groups are shown in Table 2. Some significant differences between the 2 groups were found at admission. Day hospital patients showed lower psychopathology on the basis of mean BPRS score ($p = .001$), were less frequently female ($p = .02$), were slightly younger ($p = .01$), and were less likely to have a diagnosis of affective disorder ($p = .03$), and a smaller number of them had ever been treated as an inpatient prior to the index episode ($p = .03$); those who had been treated as inpatients were retrospectively less satisfied with this treatment ($p = .006$).

Untoward Events, Transfer Rates, and Duration of Index Hospitalization

Three suicides occurred in the inpatient group, 1 each in Dresden, London, and Wrocław. The proportion of day hospital patients who had to be transferred to inpatient settings for clinical reasons (e.g., for sleep deprivation therapy or because of a significant exacerbation of psychotic symptoms) varied from 8% to 16%. Mean duration of treatment, assessed as the days between admission and discharge (i.e., including weekends and missed days in both settings), was significantly longer in the day hospital setting: 78 (SD = 73) days versus 46 (SD = 46) days in the wards ($p < .001$).

Effectiveness of Acute Day Care

In terms of the main effects on the outcome domains assessed, an overall effect according to treatment setting in favor of day care appeared only in the social disabilities model (Tables 3 and 4).

*In this, per imputation each missing value was replaced by the respective group mean plus a random term that contained the original variance. The whole process including analyses within the linear models was repeated 20 times, and means of the results of the statistical tests and estimations based on all imputations were calculated.

†In a formal assessment of different covariance structures (autoregressive, Toeplitz, and compound symmetry), slightly varying p values appeared that did not, however, result in different conclusions on the significance of the tested effects.

Table 2. Sociodemographic and Clinical Characteristics of the Study Groups

	Total Sample		Dresden		London		Wrocław		Michalovce		Prague	
Characteristic	Day Hospital	Inpatient Wards	Day Hospital	Inpatient Wards	Day Hospital	Inpatient Wards	Day Hospital	Inpatient Wards	Day Hospital	Inpatient Wards	Day Hospital	Inpatient Wards
No. of patients[a]	102–554	84–501	24–92	29–99	15–142	6–65	49–115	21–123	9–105	13–108	18–100	20–106
Gender, female, N (%)	313 (56)	318 (63)*	62 (67)	68 (69)	77 (54)	29 (45)	69 (60)	94 (76)†	50 (48)	57 (53)	55 (55)	70 (66)
Age, mean (SD), y	38 (12)	40 (11)*	36 (11)	39 (12)	37 (12)	36 (9)	42 (11)	42 (11)	38 (11)	41 (10)*	35 (15)	42 (13)‡
Married, N (%)	236 (43)	225 (45)	31 (34)	37 (37)	62 (44)	16 (25)†	46 (40)	71 (58)†	61 (58)	58 (54)	36 (36)	43 (41)
Living alone, N (%)	103 (19)	95 (19)	25 (27)	30 (31)	46 (32)	27 (42)	20 (18)	10 (8)*	3 (3)	8 (7)	9 (9)	20 (19)*
Employed, N (%)	164 (30)	142 (29)	46 (50)	34 (35)*	27 (19)	10 (15)	16 (14)	17 (14)	40 (38)	28 (26)	35 (36)	53 (51)*
Obtaining social/state benefits, N (%)	365 (69)	319 (67)	57 (63)	71 (72)	107 (76)	51 (78)	75 (66)	57 (48)†	81 (83)	94 (93)*	45 (51)	46 (51)
First manifestation of a mental disorder, N (%)	98 (20)	99 (21)	10 (11)	10 (10)	25 (21)	12 (23)	5 (4)	20 (17)†	24 (30)	28 (29)	34 (37)	29 (28)
No previous inpatient treatment, N (%)	98 (29)	65 (22)*	34 (45)	22 (27)*	19 (25)	2 (6)*	34 (31)	28 (30)	1 (4)	2 (6)	10 (21)	11 (18)
Satisfaction[b] with previous inpatient treatment episodes, mean (SD)	4.5 (1.9)	5.0 (1.7)†	4.2 (2.0)	4.8 (1.6)	4.0 (2.2)	4.0 (1.8)	4.6 (1.9)	5.2 (1.6)	4.7 (2.0)	5.6 (1.7)	4.9 (1.8)	4.9 (1.8)
No previous day-hospital treatment, N (%)	212 (66)	204 (71)	52 (68)	52 (64)	64 (90)	30 (97)	58 (53)	73 (78)‡	12 (48)	17 (61)	25 (61)	31 (61)
Satisfaction[b] with previous day-hospital treatment episodes, mean (SD)	5.5 (1.5)	5.1 (1.6)	5.5 (1.4)	4.9 (1.6)	…[c]	…[c]	5.4 (1.7)	5.3 (1.7)	6.3 (1.3)	5.4 (1.0)	5.4 (1.5)	5.3 (1.7)
Length of stay, mean (SD), d	78 (73)	46 (46)‡	88 (77)	68 (75)	62 (66)	30 (36)‡	150 (81)	58 (43)‡	48 (30)	28 (18)‡	39 (19)	39 (18)
Transfer between day hospital and inpatient ward, N (%)[d]	71 (13)	28 (6)‡	11 (12)	14 (14)	29 (21)	2 (3)‡	9 (8)	1 (1)†	17 (16)	5 (5)†	8 (8)	6 (6)
Main clinical ICD-10 discharge diagnosis, N (%)[e]												
F20–F29	140 (26)	118 (24)*	9 (10)	19 (19)	2 (19)	20 (32)	60 (53)	35 (28)‡	27 (27)	32 (30)	13 (13)	12 (12)
F30–F39	178 (33)	209 (42)	44 (48)	49 (49)	54 (48)	27 (44)	22 (19)	70 (57)	21 (21)	22 (21)	33 (34)	41 (39)
F40–F49	123 (23)	83 (17)	20 (22)	17 (17)	16 (14)	6 (10)	21 (18)	13 (11)	36 (36)	23 (22)	29 (30)	24 (23)
F60–F69	52 (10)	37 (7)	14 (15)	10 (10)	16 (14)	4 (6)	2 (2)	4 (3)	11 (11)	11 (10)	7 (7)	8 (8)

[a]Ranges of numbers of patients for whom data on the variables listed are presented.
[b]The satisfaction rating scale ranged (as for the Manchester Short Assessment of Quality of Life) from 1 (“could not be worse”) to 7 (“could not be better”).
[c]Because the day hospital was a new service in the London catchment area, very few patients had received previous day hospital treatment; therefore, these highly selected values are not reported.
[d]Cases with no retransfer to the initial treatment setting within 2 days.
[e]p Value footnotes are attached to data in the first line but refer to the full 2 × N table.
*.01 ≤ p < .05, day hospital group vs. inpatient group.
†.001 < p < .01, day hospital group vs. inpatient group.
‡p < .001, day hospital group vs. inpatient group.

Table 3. Mean Scores on the Outcome Domains

Measure	At Admission		At Discharge		At 3 Months		At 12 Months	
	Day Hospital	Inpatient Wards	Day Hospital	Inpatient Wards	Day Hospital	Inpatient Wards	Day Hospital	Inpatient Wards
BPRS[a]								
Mean (SE)*	1.94 (0.017)	2.02 (0.018)	1.51 (0.018)	1.52 (0.023)	1.57 (0.018)	1.62 (0.022)	1.52 (0.019)	1.57 (0.023)
Mean (SE)†	NA	NA	1.53 (0.017)	1.49 (0.022)	1.59 (0.017)	1.58 (0.021)	1.54 (0.018)	1.54 (0.023)
CAT[b]								
Mean (SE)*	7.55 (0.085)	7.33 (0.100)	8.12 (0.079)	8.06 (0.091)	NA	NA	NA	NA
Mean (SE)†	NA	NA	8.14 (0.073)	8.19 (0.091)	NA	NA	NA	NA
MANSA[c]								
Mean (SE)*	3.95 (0.040)	3.97 (0.042)	4.37 (0.045)	4.36 (0.052)	4.44 (0.045)	4.33 (0.050)	4.51 (0.047)	4.50 (0.053)
Mean (SE)†	NA	NA	4.39 (0.039)	4.37 (0.047)	4.47 (0.038)	4.35 (0.045)	4.54 (0.040)	4.51 (0.048)
GSDS-II[d]								
Mean (SE)*	1.21 (0.025)	1.25 (0.028)	0.90 (0.033)	1.24 (0.061)	0.82 (0.028)	0.92 (0.034)	0.77 (0.028)	0.88 (0.033)
Mean (SE)†	NA	NA	0.94 (0.033)	1.15 (0.058)	0.84 (0.028)	0.89 (0.035)	0.80 (0.029)	0.87 (0.037)

[a]The rating scale for each BPRS item ranged from 1 (“not present”) to 7 (“extremely severe”).
[b]The rating scale for each CAT item ranged from 0 (“not at all satisfied”) to 10 (“yes, entirely satisfied”). The CAT was administered at admission and discharge only.
[c]The rating scale for each item on the MANSA ranged from 1 (“could not be worse”) to 7 (“could not be better”).
[d]The rating scale for the GSDS-II sum score ranged from 0 (“no disability”) to 3 (“severe disability”).
*Adjusted for equal number of cases across sites.
†Adjusted for equal number of cases across sites, duration of hospitalization, $\log_{(\text{duration of hospitalization})}$, and admission measurement.
Abbreviations: BPRS = Brief Psychiatric Rating Scale, CAT = Client Assessment of Treatment, GSDS-II = Groningen Social Disabilities Schedule, Second Revision, MANSA = Manchester Short Assessment of Quality of Life.

Table 4. Tests of Fixed Effects on the Outcome Domains

Factor	Psychopathology (BPRS)			Satisfaction With Treatment (CAT)			Quality of Life (MANSA)			Social Disabilities (GSDS-II)		
	df	F	p	df	F	p	df	F	p	df	F	p
Setting	1,956	0.46	.498	1,786	0.15	.699	1,929	1.47	.225	1,808	8.30	.004
Timepoint	2,1375	13.37	.001	NA	NA	NA	2,1316	8.07	.001	2,973	15.87	< .001
Center	4,956	5.87	.001	4,786	3.92	.004	4,929	5.48	.001	4,808	2.30	.058
Setting × center	4,956	0.56	.695	4,786	7.31	.001	4,929	1.52	.193	4,808	1.08	.364
Setting × timepoint	2,1375	0.79	.454	NA	NA	NA	2,1316	1.99	.137	2,973	2.58	.076
Center × timepoint	8,1375	8.62	.001	NA	NA	NA	8,1316	2.93	.003	8,973	7.95	.001
Setting × center × timepoint	8,1375	4.73	.001	NA	NA	NA	8,1316	1.37	.206	8,973	3.03	.002
Duration of index hospitalization	1,956	5.51	.019	1,786	2.98	.085	1,929	0.26	.609	1,808	4.01	.046
Log(duration)	1,956	7.05	.008	1,786	3.15	.076	1,929	0.22	.639	1,808	5.10	.024
Admission measurement	1,956	287.20	.001	1,786	319.04	.001	1,929	695.99	.001	1,808	371.15	.001

Abbreviations: BPRS = Brief Psychiatric Rating Scale, CAT = Client Assessment of Treatment, GSDS-II = Groningen Social Disabilities Schedule, Second Revision, MANSA = Manchester Short Assessment of Quality of Life.

The timepoint effect shown in this model referred to an improvement of social functioning between discharge and the follow-up at 3 months ($p < .001$) and between discharge and the follow-up at 12 months ($p < .001$). Further timepoint effects appeared in the models for psychopathology and quality of life. Psychopathologic symptoms had increased from discharge to the follow-up at 3 months ($p < .001$) and had decreased at the 12-month follow-up ($p = .007$), reaching the discharge level again. Quality of life improved slightly from discharge to the 12-month follow-up ($p < .001$) and from the 3- to the 12-month follow-up ($p = .001$).

Center-specific effects (indicating different mean or sum scores for patients in both settings of 1 center at all timepoints) were demonstrated in the models for 3 outcome domains, but not for social disabilities.

In terms of interaction effects, only the model for treatment satisfaction showed significant setting-by-center effects (indicating center-specific differences of setting effectiveness), whereas the other domain models did not. Further center interaction effects seemed to be relevant for nearly all outcome domains.

Of the model covariates, admission measurement showed significant effects on all outcome domains, and the duration of index hospitalization showed effects on psychopathology and social disabilities.

DISCUSSION

This study found that acute day care was as effective as conventional inpatient care on psychopathology, treatment satisfaction, and subjective quality of life and was

more effective on social disabilities at discharge, as well as at the 3- and 12-month follow-up assessments. Detecting this effect for the first time was perhaps facilitated by the large sample size and may be explained by a core principle of day hospital treatment,[30] namely, that the patient remains rooted in his/her normal surroundings and social role during the acute crisis rather than being uprooted and staying day and night on an inpatient ward.

Evaluating acute day care in an international RCT presents several challenges, and this trial had its particular strengths and weaknesses. Standardized criteria for classifying a service as acute are still lacking, routine care varies widely even among so-called acute services, and the functions of services depend on the structure of the overarching mental health care system.[31] Some center-specific differences reflecting these issues may be explained by local variation in the precise delivery of day and inpatient care.[32–36]

The generalizability of these findings may be evaluated vis-à-vis the feasibility of treatment in acute day care and follow-up rates in the trial. Although exclusion and refusal rates varied significantly across centers in this study, the overall feasibility rate* was estimated[1,37] to be 23.3%, ranging from 16.6% (Michalovce) to 35.4% (Wrocław). This is comparable to other single-center studies that found that 23% to 39% of patients in need of acute treatment could be cared for in day hospitals.[1]

The follow-up rate in our study was 87% at discharge, 76% at 3 months, and 68% at 12 months. These rates compare favorably to those in similar studies and are slightly higher than the follow-up rates reported by Schene et al.[7] and Sledge et al.[10] Analyses of the patients' baseline characteristics showed that the results were biased by selective loss to follow-up only slightly at discharge, but not at the 3- and 12-month follow-up assessments (T. Eichler, M.Sc.; M.S.; S.P., et al., manuscript submitted). Furthermore, the chosen statistical approach might have minimized the influence of attrition bias in our study.[15,29]

The main strengths of this study include its large sample size and its implementation across different health care systems and social contexts.[31,38] The findings suggest that acute day hospitals are a viable and clinically effective alternative to inpatient admission for approximately one fifth of all acute admissions.

The significant setting-by-center interaction effect for treatment satisfaction indicates, however, that relative effects of acute day hospital care might depend on contextual factors. Thus, findings from the EDEN Study demonstrate that future mental health services research trials will face the task of reporting center and treatment characteristics in as much detail as possible.[38] This study also emphasizes that the evidence for specific treatment options is deficient unless confirmed in multicenter studies.

To judge the applicability of our results at the national service level in each country, we consulted survey findings on the characteristics of currently established day hospitals for general psychiatric patients for the 5 sites of the EDEN Study.[31] Because of the similarity of organizational features and of the patient populations in the EDEN centers, we could conclude, with caution, that the results of this RCT are relevant for 39% to 49% of day-hospital services in the 2 Western European countries. By contrast, in the 3 Central European countries, the results of the trial would apply for only 7% to 32% of the day hospitals.

Although this article does not present a methodologically difficult cross-national cost-effectiveness analysis, our results suggest that health economic research on day hospitals should not focus only on direct health care costs. While several single-site RCTs[5,6,9,39] have provided evidence that direct costs are 21% to 37% lower for day care than for inpatient care, only 1 trial[9] has assessed indirect costs, showing that they were greater for the day care group. Particularly the effectiveness on social disabilities demonstrated in our trial emphasizes the need for cost-effectiveness analyses based on total social costs using the net benefit approach.[40] Only such data would facilitate a robust conclusion that the increasing movement of acute day care saves society scarce resources.

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*The general formula used was (100 × number of patients engaging in day care) divided by (number assessed for eligibility × R), where R represents the randomization ratio for the trial (defined as number randomized to day hospital divided by number of patients randomized).

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