

## Efficacy of psychiatric day hospital treatment: Review of research findings and design of a European multi-centre study

T.W. Kallert<sup>1</sup>, M. Schützwohl<sup>1</sup>, A. Kiejna<sup>2</sup>, P. Nawka<sup>3</sup>,  
S. Priebe<sup>4</sup>, and J. Raboch<sup>5</sup>

<sup>1</sup>Dresden University of Technology, Faculty of Medicine,  
Department of Psychiatry and Psychotherapy, Dresden, Germany

<sup>2</sup>Wrocław University of Medicine, Department of Psychiatry, Wrocław, Poland

<sup>3</sup>Michalovce Psychiatric Hospital, Michalovce, Slovakia

<sup>4</sup>St. Bartholomew's and the Royal London School of Medicine and Dentistry,  
Department of Psychiatry, Unit for Social and Community Psychiatry, London, UK

<sup>5</sup>Charles University of Prague, First Medical Faculty,  
Department of Psychiatry, Prague, Czech Republic

*The paper presents a literature review of research findings on acute treatment in psychiatric day hospitals, and outlines the design of an ongoing multi-site study on the effectiveness of acute day hospital treatment. The review is based on relevant older publications and recent randomised controlled trials comparing day hospital treatment with inpatient care. The findings suggest that (a) a wide range of patient groups are cared for in day hospitals, (b) both patients and their relatives assess day hospital treatment favourably, (c) treatment in day hospitals is at least as effective as inpatient care, and (d) day hospital treatment may lead to significant cost savings as compared to in-patient care. There are, however, a number of important questions that cannot be answered on the basis of the existing literature, and further research on the topic is warranted. The EDEN-study (European Day Hospital Evaluation) is a randomised controlled trial comparing day hospital treatment with conventional in-patient care and following the same protocol in five European countries (Czech Republic, Germany, Poland, Slovakia, and United Kingdom). Aims and methods of the study are presented.*

*Key words:* Psychiatric day hospital, review, EDEN-study

### Introduction

The provision of treatment on a semi-inpatient basis at day hospitals has been an established component in the system of mental health care for over 60 years, constituting a central link between complete inpatient and community-based care. At least in the German-speaking and Eastern European countries, however, the importance and capacity of this mode of treatment is still underestimated [1, 2]. In view of the modern concepts of the aetiology and treatment of mental disorders, this fact is amazing given the following fundamental concept of this treatment setting: the pragmatic dimension

afforded by the insights into the social structure of the patient's life enriches the psychopathological and dynamic clinical view. The psychiatric/psychotherapeutic therapy offered is in no way inferior to that offered in a completely inpatient setting, and is combined with a daily test of the familial and social reality of the patient [3, 4, 5, 6].

The organisational structure of day hospitals exists in three different forms, namely a) an independent unit attached to a psychiatric hospital – the most common type in most countries, b) an autonomous day hospital (i.e. without association to a completely inpatient unit), and c) an integrated day hospital (i.e. treatment on a ward that also provides complete inpatient care to patients). The broad spectrum of different patient groups that exists in day hospital settings demonstrates the variety of its practical modes of operation. Connected with this, the “classical” distribution of day hospitals – mainly for rehabilitation, as alternatives to inpatient treatment, for crisis intervention or psychotherapy – can be viewed as outdated [7]. For the individual institution, usually with a capacity of 15–25 treatment places, differentiation and growing polymorphy, which is favourable in principle, creates an enormous problem regarding provision of needs-oriented psychiatric care [8]. An increasing number of day hospitals face the task of establishing a treatment programme that integrates somatic, psycho- and sociotherapeutic elements adhering to the professional standards for several main diagnostic groups of mental disorders. At the same time the complicated courses of the treated disorders require – in succession or in parallel – professional competencies which cover a spectrum from rehabilitation to crisis intervention and psychotherapy [9, 10].

Starting in the early 1980's, several main research focuses have been established in the practice of day hospital treatment. In general, research to date, including randomisation and control group design, conducted partially on a multi-site level, has been done almost exclusively in the Anglo-American language area [11, 12, 13, 14] and in the Netherlands [15, 16, 17], but not in the German-speaking and Eastern European countries [2].

Topics of published studies include sociodemographic features of day hospital patients [18, 19] as well as diagnoses, psychopathological syndromes and characteristics of the clinical course [20]. Furthermore, ward atmosphere, predictors and factors influencing treatment efficacy have constituted main research areas [21, 22, 23, 24]. Subjective needs for care [25], satisfaction with care [26] and quality of life [27] came to the fore of research interests in the last few years. Involvement of, as well as burden on relatives and therapists are addressed in some recent publications [28, 29]. Using different outcome-criteria and follow-up time-periods, the efficacy of treatment in this setting has also been compared to other modes of treatment [30]. The most recent area of research concerns the health economics of day hospital treatment [31].

This article seeks to give a survey of the research results concerning the clientele, evaluation, efficacy and possible cost-savings in this treatment setting. Furthermore, implications for further studies are discussed, and the design of an ongoing multi-site study of psychiatric day hospital treatment is presented.

The given review of the literature comprises the most important older publications as well as recent randomised, controlled studies comparing day hospital and inpatient

treatment. Search for these studies was done by a MEDLINE-search.<sup>1</sup> Table 1 shows those identified recent publications using satisfactory research methodology.

### **Sociodemographic and disorder-related features of the clientele in day hospitals**

Currently, day hospitals providing services do not exclude any specific patient group. Under the appropriate circumstances, forensic psychiatric [32], gerontopsychiatric [33], and addicted patients, as well as those suffering from neurotic, psychosomatic and personality disorders [34] are able to be treated in this setting. The traditional core group of patients - mostly with schizophrenic disorders, treated with a rehabilitative approach in a day hospital setting directly after inpatient treatment - has lost its significance [35; cf. 36]. The spectrum of diagnoses has widened as day hospitals have become an alternative to acute inpatient care [37].

To some extent, an international comparison can be made concerning the general differences of mental health services' organisation and of the concepts of treatment; recent publications identify the following features of the general psychiatric clientele in day hospitals: the patients' mean age is in the second half of the 4<sup>th</sup> decade [10, 15], and the majority of patients in day hospitals are women [10, 15, 38]. Depending on the respective distribution of age, sex and diagnoses, several studies [16] report that at least 40% of the patients do not have employment paying normally expected wages when starting their treatment in a day hospital. Schizophrenic and affective disorders (each up to 50%) are the main diagnoses, but neurotic and personality disorders are also of considerable frequency and importance, especially in those institutions not concentrated on the rehabilitation of chronic mental disorders [16, 39]. The frequency of addicted patients (up to 20% [15]) varies depending on the exclusion criteria for admission defined by the institutions.

Based on the features demonstrated so far, it is reasonable to assume that the day hospital clientele consists of patients with rather chronic mental disorders, mostly treated as inpatients several times before admission [10] and characterised by at least moderately severe psychopathological symptoms and disturbed social functioning [39].

Due to the different setting-specific therapeutic concepts and the additional structures/provisions of care in a mental health service system, length of day hospital treatment has such a broad range (from 2 weeks to longer than 1 year [38]) that a definite mean score cannot be derived from the literature published to date. The integration of socio-rehabilitative [40] and psychotherapeutic treatment elements often justifies a treatment period of 2 to 3 months [37].

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<sup>1</sup> The MEDLINE search was done using the following algorithm: («DAY HOSPITAL» or «DAY CLINIC» or «DAY TREATMENT» or «PARTIAL HOSPITALISATION») and (INPATIENT) and (MENTAL or PSYCHIATRIC) not (GERONTOPSYCHIATRIC or GERIATRIC or CHILDREN) and (PY GT 1990).



### **Patients' and relatives' evaluation of day hospital treatment**

Results from evaluative comparisons of different treatment settings performed from the patients' subjective perspective unequivocally show [41] that patients assess semi-inpatient and community-oriented settings more positively than inpatient and traditional modes of treatment. An assumed setting-specific significance can be derived from the patient's previous clinical experiences. This assumption can be based on the finding that, at the beginning of a subsequent treatment period, day hospital patients familiar with the clinical institution voiced an attitude significantly more positive to this institution than patients without similar personal knowledge or experience [42]. Especially high practical relevance can be attributed to the results demonstrating that the patients' initial global assessment is a considerable predictor of success of treatment (of schizophrenic patients), and psychopathological symptomatology still manifest at discharge from the day hospital [26]: patients with a positive attitude have a significantly better course of treatment than patients with an initially negative attitude.

Patients assess the following special therapeutic elements of day hospital treatment as most favourable for facilitating change: the programme of day-structuring activities and the level of interpersonal contacts which is characterised by acceptance, achieving group membership, companionship, sharing and support. Medication, psycho-educative and behaviour-modifying interventions are, from the patients' point of view, as important as mobilisation of family support, connection to community and the encouragement of patient autonomy [4, 25].

In accordance with the results of the patients' treatment assessment, the studies available to date demonstrate that day hospital patients, especially those with chronic mental disorders, rate their subjective quality of life, another well-established outcome criterion, higher than long-term inpatients [27, 43]. Contacts with the family and satisfaction with participating in normal social activities might contribute to the positive rating by day hospital patients.

Families with chronically mentally ill members experience an especially high practical, but also economic burden [19]. Against this background the low incidence of complaints and symptoms voiced in respective questionnaires and examinations [44; cf. 28] is quite surprising. This might be explained by the fact that a) the relatives do not want to place an additional burden on their mentally ill family member [45], who is sometimes taking important responsibilities for the whole family, b) that some relatives, hindered by feelings of shame and guilt, are unable to articulate their problems openly, or c) that they have adapted with resignation to the patient's disabled state [29]. The closer involvement of relatives into the treatment process established in a day hospital setting can also be viewed as an important factor in increasing relatives' acceptance of this mode of treatment [46].

### **Efficacy of day hospital treatment**

Until the early 1990's, no satisfactory research methodology [47] existed for identifying which categories of patients would benefit from a day hospital setting or how this treatment would affect psychosocial functioning levels [22]. Although at least nine

controlled studies had been carried out since the mid-'60s [14, 48, 49, 50, 51, 52, 53, 54, 55], due to the selection procedures employed, the definitions of various outcome criteria and the partially incomplete documentation of relevant socio-demographic data, their individual cohesiveness or comparability is too limited to derive any general conclusions [30].

In this respect, the following research from the 1990's is of particular value: in a randomised study of unselected patients [22] originally scheduled to receive inpatient treatment, treatment carried out in a day hospital setting was satisfactory for 40% of the experimental population, but was also unable to be carried out for another 40%. Moreover, no absolute contraindications for day hospital treatment could be identified. In a multiple regression analysis which explained 36% of the variance, four predictors of successful day hospital treatment were identified: a (rapidly decreasing) level of supervision during the first week of treatment, absence of physical illness, lack of previous preliminary treatment, and depressive syndromes as the reason for admission. Results from a 2-year follow-up study of this group of patients [15] with regard to psychopathology and level of social functioning are presented elsewhere. At first, no differences in conspicuous psychopathological behaviour and social functioning level were found between the two groups of patients, who had been assigned at random to treatment in either a day hospital or an inpatient setting. During the follow-up period, both groups improved with equal significance in regard to psychopathology and levels of psychological and social functioning; the capacity for self-care, however, had improved markedly among the group of patients treated in a day hospital setting. Over the 2-year period during which the patients suffered for an average of 11 months from a mental disorder defined according to operationalised criteria, 40% were assessed to be still in need of psychiatric treatment at the end of the observation period.

Other random-design studies have corroborated the efficacy of day hospital treatment. For example, in a group of severely ill, poor patients living in an urban region [39] no significant differences with regard to various outcome criteria could be assessed over a post-hospital release follow-up period of 10 months, compared to groups of patients randomly assigned to either inpatient ( $n = 104$ ) or day hospital treatment ( $n = 93$ ). Standardised research instruments were used to assess, among other things, the psychopathology, the self-assessment of symptoms, the global level of psychosocial functioning, the presence of a mental disorder, the level of social functioning, and the quality of life. A group comparison revealed that treatment in a day hospital setting had a somewhat more positive effect on the degree of severity of conspicuous psychopathological behaviour as well as on the levels of global and social functioning [cf. 56]. A study [31] among acute psychiatric patients randomly assigned to inpatient or day hospital treatment settings also revealed that, with regard to either the hospital or social outcome, no significant differences between the two groups could be found twelve months after admission. Nonetheless, the improvement dynamic among the patients treated as inpatients was significantly faster, while the stress upon relatives of the group initially treated in a day hospital setting had lessened significantly after twelve months.

All random studies thus unanimously agree that, with regard to any aspect of outcome, the efficacy of treatment in a day hospital setting is in no way inferior to that of treatment in an inpatient setting [57].

### **Does day hospital treatment reduce costs?**

To date, only a few scientific studies which meet the methodological criteria of health care economics [58] contain conclusive data on the costs of treatment in a day hospital setting. Older studies restricted to ascertaining the direct costs of treatment conclude that treatment in a day hospital setting generally costs 1/3rd to 2/3rds less than comparable inpatient treatment. These calculations, however, pay insufficient attention to the fact that day hospital treatment can prevent or reduce both the extent of necessary (inpatient) psychiatric care as well as the need for somatic therapy measures [14, 17, 48, 59, 60].

A differentiated analysis of the direct costs incurred by both patient groups [61] indicates a cost savings of 6.600 Euro per patient treated in a day hospital setting during the phase of hospitalisation, which corresponds to roughly 20% of the total direct costs of treatment. In a 10-month follow-up period, the study was unable to discover any differences between the two subgroups' use of medical services and its resulting costs. A diagnosis-guided analysis states that potential cost savings for non-psychotic patients are higher than for other groups of patients, but this patient group is not particularly representative of other day hospital institutions. Another study [31] includes indirect costs (such as those for patients and relatives) in its cost analysis and concludes that the cost reduction in the one-year study period amounts to slightly less than 3.030 Euro per patient treated with comparable treatment efficacy in a day hospital setting.

### **Implications for further studies**

While the review of the literature documents the general efficacy of psychiatric day hospital treatment, it also highlights the need for further research [57]. Small numbers of included patients, lack of randomisation, numerous drop-outs, and insufficient controls for diagnosis, socio-demographic features and previous modes of treatment limit the value of the published research results [50]. Therefore, these results prohibit differentiated statements regarding indication for day hospital treatment. This applies to clinical variables (e.g. diagnostic subgroups or degree of severity of disorders) as well as to social factors (e.g. special characteristics of the patient's living situation and family status). Neither can conclusions regarding the possible setting-specific effectiveness or efficacy of psychiatric and psychotherapeutic elements of treatment be deduced from the literature.

When designing a research project to evaluate the efficacy of psychiatric treatment in day hospital settings, several issues from this review and summary of the literature must be taken into consideration: First, modes of organisation, number and professional qualifications of the employees of participating institutions must be described in detail, as well as the therapeutic activities provided [4] and their course during the treatment period. This procedure ensures that the results will be comparable to other clinical institutions and can be related to previous research results [39, 61]. Second, this requirement also applies especially to the distribution of diagnoses, length of illness and previous treatment periods, the modes of treatment, age range and socio-demographic features of patients, as well as the social competencies of the clientele

treated in the day hospital setting.

## **Design and objectives of the EDEN-study**

### **Aims and objectives**

The EDEN-study aims to evaluate the efficacy of acute psychiatric treatment in a day hospital setting in five European centres: Dresden (D), London (UK), Wrocław (PL), Michalovce (SK) and Prague (CZ). The main hypothesis is that day hospital treatment for acute psychiatric patients is as effective as conventional inpatient hospital care. The main objectives of the study are as follows: a) to evaluate the viability and effectiveness of day hospitals for acute psychiatric treatment; b) to identify subgroups of patients with a more or less favourable outcome so that the treatment setting might be specifically applied; and c) to ascertain the cost-effectiveness of day hospital treatment compared to conventional inpatient treatment.

### **The Consortium**

The consortium is composed of the following centres:

1. The Clinic and Policlinic for Psychiatry and Psychotherapy at the University Hospital of the Dresden University of Technology has offered treatment at the day hospital for over 30 years and is thus one of the oldest in the entire German-speaking area. The clinic has 58 full inpatient treatment places, the day hospital offers 25 places in separate facilities.
2. The Department of Psychiatry at Wrocław Medical University is an educational and scientific institution sited in the Psychiatric Health Care Centre with an inpatient ward (30 beds) and a day hospital (35 places).
3. The Unit for Social and Community Psychiatry is part of the Department of Psychiatry at St. Bartholomew's and the Royal London School of Medicine and Dentistry (Queen Mary and Westfield College), University of London. It was established in 1997. In 1999, a new acute day hospital with 20 places was opened. The day hospital is intended to be an alternative to acute in-patient care.
4. The Psychiatric Hospital in Michalovce (SK) was opened in 1990. It has 260 inpatient-beds and 25 places at the day hospital, which was opened in 1993. As a model-institution, the Hospital is organised according to the community-oriented intentions of the Slovakian psychiatry-reform.
5. The Psychiatric Clinic of the General Faculty Hospital in Prague is the oldest psychiatric hospital in the Czech Republic. There are six inpatient wards with a total capacity of 140 beds and 20 places in day care; a new day care centre for adolescent patients was opened in 1999.

The institution in Prague contributes its model of integrated day hospital treatment (i.e. day hospital treatment on a ward that also provides complete inpatient care for the patients), while the other centres work with day hospital treatment models that are institutions completely separate from the fully inpatient care wards of the hospital but which are nonetheless affiliated with them.



## Design and assessment instruments

The evaluation of the day hospital utilises a Randomised Controlled Trial (RCT) design with repeated measures at a maximum of six time points: at admission and three days after admission ( $t_1$ ), one week after admission ( $t_2$ ), four weeks after admission ( $t_3$ ), discharge ( $t_4$ ), three months after discharge ( $t_5$ ), and 12 months after discharge ( $t_6$ ).<sup>2</sup>

A combination of well-established standardised assessment instruments and open questions is used. Table 2 lists the constructs that will have to be assessed according to the study's questions, the chosen assessment instruments, and the time point of assessment:

The instruments are chosen with respect to their objectives and quality. All are available in Polish, German, English, Czech and Slovak.

1. Schedules for Clinical Assessment in Neuropsychiatry SCAN 2.1 [62]. SCAN is a set of instruments designed to assess, measure and classify the psychopathology and behaviour associated with the major psychiatric syndromes of adult life. It encompasses both a Glossary of differential definitions and a set of computer programs (e.g. I-Shell) for processing SCAN data and providing a range of outputs.

Table 2

Assessment instruments and design

Construct/criteria	Assessment instruments	t <sub>1</sub>	t <sub>2</sub>	t <sub>3</sub>	t <sub>4</sub>	t <sub>5</sub>	t <sub>6</sub>
Diagnoses	SCAN 2.1	+					
Psychopathology	BPRS- Expanded Version 4.0	+	+	+	1	+	+
Needs for Care - Self-rating	BeB I for Clients	+				+	+
Needs for Care - Professionals rating	BeB I for Carers	1				+	+
Health Service Utilization/ Treatment Costs	CSS RI	+			1	+	+
Social Disability	GSDS-II	+			1	+	+
Quality of life	MANSA	+			+	+	+
Patient Satisfaction	CAT	1	+	+	+		
Helping Alliance	HAS					+	+
Caregivers' Involvement	IEL	+		+		+	+

Notes: t<sub>1</sub>: at admission; t<sub>2</sub>: one week after admission; t<sub>3</sub>: four weeks after admission;

t<sub>4</sub>: at discharge; t<sub>5</sub>: three months after discharge; t<sub>6</sub>: 12 months after discharge

1 only if t<sub>3</sub>-t<sub>4</sub> > 1 week; 2 within five days after admission; 3 concerning the treatment period

4 only if t<sub>1</sub>-t<sub>4</sub> > six weeks; 5 3rd day after admission

<sup>2</sup> In cases in which the treatment period does not last for four weeks or more (i.e.  $t_1-t_4 < 4$  weeks), t<sub>3</sub> will be dropped.

2. Brief Psychiatric Rating Scale - Expanded version 4.0 (BPRS; [63]). Describing major psychiatric symptom characteristics, the BPRS is a 24-item scale that provides a rapid evaluation procedure for assessing symptom change in psychiatric patients.
3. Berliner Bedürfnisinventar for Clients [64]. The BeBI questionnaire for clients assesses the patient's needs for care. The 16 subjective items on this instrument ask the client whether he or she needs help and/or support in various areas of his or her life. If support is not needed in any of the 16 areas listed on the questionnaire, the client is then asked about support received from friends or relatives and social / health care services. Any help received is recorded as low, moderate or high. This questionnaire has been published in many papers and used across research settings.
4. Berliner Bedürfnisinventar for Carer [64]. The BeBI questionnaire for carers assesses the client's needs for care from his or her professional carers' perspective. This objective, 16 item instrument asks the carer whether the client needs help / support in various areas of life and whether the carer's service provides this support. This measure has been used across research settings.
5. The Client Sociodemographic and Service Receipt Inventory (CSSRI-EU, [65]) is used to assess health service utilisation and health care costs. The instrument was developed within an international European Commission-funded study and is currently widely used. Within the EDEN study, a detailed assessment of the time during which an individual client has been treated complements the CSRI.
6. The CSSRI allows for the assessment of socio-demographic data as well. In addition to this questionnaire, socio-demographic and clinical data are assessed using a questionnaire developed prior to the study (Client Sociodemographic and Clinical History Schedule CSCHI; [66]).
7. Groningen Social Disability Schedule (GSDS; [67]). The GSDS is a semi-structured interview for assessing social functioning in eight different social roles (e.g. occupational role). It was developed for application in scientific research and has been used in many different languages.
8. Manchester Short Assessment of Quality of Life (MANSA; [68]). Developed from a brief, modified version of the Lancashire Quality of Life Profile (LQLP) the MANSA consists largely of subjective ratings of satisfaction with life as a whole and with specific life domains (e.g. employment, family relationships etc.). Objective questions assess relationships with close friends, and the client's exposure to physical violence and accusations of crime. Concurrent validity was demonstrated with high correlation between the MANSA and LQLP scores, in addition to face and construct validity. Internal consistency was acceptable.
9. Client Assessment of Treatment (CAT; [69]). The CAT measures the client's satisfaction with the treatment currently being received. The questionnaire consists of seven rating scales and four open standardised questions. Results have been shown to have predictive validity for outcomes of both short and long term treatment.
10. The Helping Alliance Scale (HAS; [70]). This six item subjective instrument measures the therapeutic relationship between the client and his or her key therapist. It

assesses the client's experience of the therapist's personal qualities and attitudes towards the client, as well as the client's views of the therapist's professional competence, the appropriateness of treatment, and the general effect of a therapeutic session on the person. An additional item has been added to ask post-discharge patients which treatment site (day hospital or inpatient ward) they would prefer if acute treatment were needed in the future.

11. Involvement Evaluation Questionnaire (IEQ; [71]). The IEQ is a 31-item questionnaire completed by the patient's closest reference person. The items relate to the encouragement and care given by the reference person to the patient, to personal problems between patient and reference person, and to the reference person's worries, ability to cope, and subjective burden. As in other studies, [71], the EDEN study extends the IEQ with a) 15 socio-demographic and contact variables, b) eight items on extra financial expenses incurred on behalf of the patient, c) three items about the reference person's use of professional help, d) 11 items concerning the consequences for the patient's children, e) one open question for comments and additions, and f) the 28-item version of the General Health Questionnaire (GHQ-28; [72]), which is used to assess the reference person's general health status. Both the IEQ and the GHQ-28 have been shown to have at least satisfactory reliability and validity.

In addition to these participants-administered questionnaires, some further assessment instruments are used:

12. The specific characteristics of the index-treatment are recorded using a documentation system developed for the purposes of this study. Furthermore, the services under study are described using the International Classification of Mental Health Care (ICMHC; [73])
13. European Service Mapping Schedule (ESMS; [74]). The ESMS allows the following tasks to be carried out in a standardised fashion: a) compilation of an inventory of the mental health services serving the adult mentally ill population of a particular catchment area, b) delineation and comparison of the structure and range of mental health services among catchment areas, and c) measurement and comparison of the levels of provision of the major types of mental health services among catchment areas.
14. A sheet originally designed for another EU-study was used to assess information on the socio-demographic characteristics of the catchment areas of the five participating centres [75].

All the instruments, previously available in English and German, have been translated and back-translated by the institutions in Wroclaw, Prague, and Michalovce prior to the study.

### Sample Recruitment and Randomisation

All patients admitted to acute psychiatric services who do not meet the exclusion criteria and fulfil the inclusion criteria are eligible to take part in the study. The exclusion criteria are as follows:

- under 18 or over 65 years of age;
- admission to the psychiatric hospital without consent of the patient (according to the legal regulations of the respective countries);
- degree of severity of the disorder requires measures restrictive of the patient's freedom on the day of admission, or a 1:1 supervision, or deems such probable;
- acute intoxication;
- presence of a somatic disorder requiring complete inpatient care;
- direct transfer from a different hospital;
- homelessness;
- one-way journey to hospital longer than 60 minutes;
- requires constant pick-up and delivery service to manage the journey to and from the hospital (for example due to limited mobility);
- inability to give informed consent;
- admission for diagnostic reasons only (e.g. PET);

After application of the exclusion criteria, the following inclusion criteria must be fulfilled:

- Presence of a mental disorder with current symptoms whose degree of severity is sufficient to provoke a moderate disturbance in role performance in more than one area of daily living or which endangers the residential or financial status of the patient, or whose degree of severity implies a danger to the patient himself or to others;
- Available external (non-inpatient) treatment was not sufficiently effective (or – if not attempted - is assessed as unsuitable for the current mental state of the patient) to prevent a deterioration of the mental state;
- No hospital treatment other than at the participating hospital is available to the patient;

Patients who fail to meet the exclusion criteria while at the same time fulfilling the inclusion criteria receive an explanation of the study; those who consent to participate are randomly assigned to the day hospital or to in-patient services. The allocation sequence is computer generated and concealed in sequentially numbered, opaque, sealed envelopes. The assignment happens prior to admission or shortly thereafter.

Random allocation is independent of availability of space in the treatment setting. A change in allocation is made, however, if no corresponding treatment place can be found within 24 hours. If no treatment place is available within this treatment setting either, the patient is then switched to a treatment setting in which a space is available, regardless of the random distribution.

Patients who were treated for at least 6 days in a treatment setting following assignment are regarded throughout the entire course of the study as having been assigned to this treatment setting, regardless of any switch to a different treatment setting later in the course of the study.

In light of recent patient numbers treated at each of the five study sites, it can be assumed that the study groups that will have been recruited 12 months after starting the study will comprise at least 100 patients at  $t_6$  in each setting. This is a sample size

large enough to show differences in treatment efficiency in each of the five centres, using  $\alpha=0.05$  and thus  $1-\beta=0.95$ . This takes into account that a) about 60% of the admitted patients will meet the criteria for exclusion, b) approximately 15% of the remaining 40% will fail to meet the inclusion criteria, c) approximately 15% of the remaining patient population will refuse to participate, and finally d) the drop-out rate will be roughly 20%-30%.

### Quality Management

Within the EDEN-study, quality management contains the following specific elements:

1. Internal quality assurance. Inter-rater reliability for the instruments is calculated from joint rating exercises using written materials and video recordings. Case vignettes sent monthly are rated by each member of the European teams using the GSDS. Video recordings of interviews are also rated for symptomatology using the BPRS. The inter-rater reliability is assessed every 3 months until all  $t_1$  interviews are completed, and then every 6 months.
2. Monthly internal reports. All participating centres submit a monthly written report detailing the number of persons, their qualifications, and the amount of working hours each centre provides for the study. In addition, data on the number of patients recruited and interviewed at each time point, and the number of complete sets of data collected are provided by each centre. Problems encountered by the projects in the administration of the measures are recorded in these reports and discussed via e-mail, and at the regular EDEN meetings.
3. EDEN meetings. Until the completion of recruitment for  $t_1$ , the European centres will meet every 3 months. The meetings cover issues raised in the administration of the measures and the development of increasingly precise definitions within the glossaries of the survey instruments. Reports on organisational issues from each centre, development of strategies for analysis and dissemination, and other corresponding activities are also part of the proceedings of the EDEN meetings. Once all  $t_1$  interviews have been completed, EDEN meetings will take place every 6 months.

### Concluding remarks

If the findings from this evaluation confirm results from prior studies, reflecting positively on the efficacy of day hospital treatment, some practical consequences for the provision of this special mental health service could be inevitable:

- At a mental health policy level, these results could lead to an increase in the capacity of day hospitals; the current policy of establishing 0.15 day hospital places for 1.000 residents in Germany and Poland [2], could define the minimum number

needed.

- Clinical departments could be forced to redefine their concepts of care to consider the economic perspective.
- An improved scientific knowledge of this special setting could also lead to binding regulations that professional training/education of psychiatrists and psychiatric nurses must include day hospital experience that provides information about the special indications and elements of treatment in this setting.

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**Acknowledgement:** This publication was supported by the European Commission (Quality of Live and Management of Living Resources Programme, contract no. QL4-CT-2000-01700). We gratefully acknowledge the assistance in translation by Charlene Reiss.

Author's address:

PD Dr. med. Thomas W. Kallert, TU Dresden,  
Universitätsklinikum C.G. Carus, Klinik und Poliklinik für Psychiatrie  
und Psychotherapie, Fetscherstr. 74, D - 01307 Dresden, Germany  
Phone (+49) 351 458 5903, Fax (+49) 351 458 5380;  
e-mail: [Thomas.Kallert@mailbox.tu-dresden.de](mailto:Thomas.Kallert@mailbox.tu-dresden.de)

