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ORIGINAL PAPER

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Recent approaches to psychological interventions for people at risk of psychosis

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Abstract With the emerging global focus on early psychosis, indicated prevention in schizophrenia has increasingly become a focus of psychiatric research interests. It has been argued that CBT may have some advantages compared with antipsychotics regarding this issue. According to MEDLINE, EMBASE and Psycinfo two completed randomised controlled trials (RCTs; PACE, Melbourne, Australia; EDIE, Manchester, United Kingdom) and one ongoing RCT with only preliminary results published so far (FETZ, Cologne/Bonn, Germany) on indicated prevention in schizophrenia including manualised and standardised psychological treatment can be identified. The aims of the present paper are to present and discuss the three approaches with regard to (I) inclusion, exclusion and exit criteria, (II) characteristics of interventions and (III) evaluations. All interventions use intake, exclusion and exit criteria, which have been evaluated in prospective follow-along studies. The approaches are based on the general structure and principles of cognitive behavioural therapy which have been developed, applied and evaluated in a wide range of mental health problems. Despite several methodological limitations, the first evaluations indicate some effects with regard to three possible aims of early intervention: (1) improvement of present possible pre-psychotic symptoms, (2) prevention of social decline/stagnation and (3) prevention or delay of progression to psychosis. Even though the first results are promising, we conclude that several ethical issues have to be taken into consideration and further predictive and therapeutic research is needed to judge whether psychological intervention is a realistic option for the treatment of people at risk of psychosis.

Key words schizophrenia · prodrome · early intervention · psychological treatment · cognitive behavioural therapy

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Introduction

Schizophrenia is a chronic disease with devastating consequences for individuals, families and society. It has a lifetime risk of approximately 1 %, and usually presents during early adulthood (APA 1997). Post-onset interventions generally have unfavourable outcomes: Schizophrenia is one of the ten illnesses causing the main contribution to the global burden of disease, the disorder going along with most lost years of life or years lived with disability (WHO 2001), and its costs for German society alone were estimated at € 9 billion per year (Kissling et al. 1999).

A number of recent clinical findings and hypotheses have shifted research interests towards prevention of schizophrenia and have stimulated researchers to formulate the "early intervention hypothesis" (McGlashan and Johannessen 1996) saying that the course of the illness may be improved when the disorder is detected and treated early. These findings and hypotheses are (a) schizophrenia goes untreated for 5 years in 75 % of the cases with non-psychotic prodromal symptoms (anxiety, depression, cognitive disturbances, negative symptoms) (Häfner et al. 1992), (b) social decline starts prior to the onset of positive symptoms (Häfner et al. 1995), (c) delayed treatment correlates with an unfavourable outcome (e. g. Norman and Malla 2001), (d) psychotic

episodes itself to may have neurotoxic effects (e. g. Copolov et al. 2000; Pantelis et al. 2003), (e) criteria have been developed, which enable prediction of the onset of psychosis in prospective follow-along studies in 35–54 % of the cases in a help-seeking population within 12 months [ultra-high risk (UHR) (Miller et al. 2002, 2003a; Yung et al. 2003, 2004a)] and in 65 % of the cases within 5.4 years on average [basic symptoms (Klosterkötter et al. 2001)]. (f) Clients fulfilling at-risk criteria are suffering from relevant clinical symptoms, are substantially compromised in psychosocial functioning, as well as in quality of life and make an odyssey through the health system before they receive substantial support (e. g. Preda et al. 2002; Miller et al. 2003b; Köhn et al. 2004; Bechdolf et al. 2005c). (g) In addition to a wide range of other mental health problems a cognitive behavioural therapy (CBT) of schizophrenia was developed (Kingdon and Turkington 1994; Fowler et al. 1995; Chadwick et al. 1996), which directly addresses psychotic symptoms and showed encouraging evidence (reviews by Gould et al. 2001; Rector and Beck 2001; Pilling et al. 2002; Cormac et al. 2003). (h) Atypical antipsychotics were introduced with reduced side effects.

At this stage of etiological research on schizophrenia an "indicated prevention", although still controversial (for an overview especially of the ethical discussion see issue 51 of Schizophrenia Research, 2001), is judged to have the best prospects of success at present (Mrazek and Haggerty 1994; Yung et al. 1998, 2003, 2004a; McGorry et al. 2002). It targets persons who already show signs and symptoms associated with a relatively high risk of transition to psychosis and schizophrenia, but who do not (yet) fulfil diagnostic criteria of schizophrenia.

It has been argued that CBT may have some advantages compared with antipsychotics for indicated prevention in persons at risk of psychosis (e. g. Bentall and Morrison 2002): (a) more acceptable, tolerable and less stigmatising to clients (e. g. Angermeyer and Matschinger 1996; Lauber et al. 2001), (b) no risk of exposing false positives to pharmacological side effects, (c) effective treatment for false positives (depression, anxiety disorders; (APA 1998, 2000)), (d) some treatment effects in patients with schizophrenia (e. g. Pilling et al. 2002; Cormac et al. 2003). Therefore the present paper will focus on recent psychological approaches for people at risk of developing psychosis.

Because indicated prevention in schizophrenia is a newly emerging research area, according to MEDLINE, EMBASE and Psycinfo (search until 05/2005; using the phrases "prevention", "intervention", "first episode psychosis", "pre-psychotic-phase", "schizophrenia", "subthreshold symptoms", "psychotherapy", "cognitive-behavioural-therapy" and their combinations) only two completed randomised controlled trials (RCTs) and one ongoing RCT with only preliminary results published so far on indicated prevention in schizophrenia including manualised and standardised psychological treatment can be identified. These are the approaches of the Personal Assessment and Crisis Evaluation Service – PACE – in Melbourne, Australia (principal investigators: P. D. McGorry; A. R. Yung; L. J. Phillips; McGorry et al. 2002), the Early Detection and Intervention Evaluation – EDIE – in Manchester, United Kingdom (principal investigators: A. P. Morrison; R. Bentall; S. Lewis; Morrison et al. 2004) and the Early Recognition and Intervention Centre for mental crises (Früh-Erkennungs und Therapie Zentrum) – FETZ – in Cologne, Germany, in close collaboration with the Early Recognition and Intervention Centre in Bonn, Germany (principal investigators: J. Klosterkötter; A. Bechdolf; M. Wagner; Häfner et al. 2004; Ruhrmann et al. 2003).

The aim of the present paper is to provide the reader with a comprehensive overview on the actual state of research in this evolving area. Therefore we present and discuss the three approaches with regard to the three major issues of psychological interventions in people at risk of psychosis: (I) definitions of persons at risk [inclusion, exclusion and exit criteria (conceptual, frame work, criteria used, evaluation cohorts, transition rates, scales used, reliability measures)], (II) characteristics of interventions (rationales, models used, aims of intervention, setting, duration of treatment, number of sessions, content of intervention) and (III) evaluations (number and age of participants, design of study, experimental control condition, duration of treatment, follow-up after treatment, quality control and results of each trial).

I. Inclusion, exclusion and exit criteria

Personal Assessment and Crisis Evaluation (PACE)

The at-risk criteria developed by PACE underpin early detection and intervention studies and differ significantly from the traditional genetic high-risk criteria. Only a low proportion of cases identified by a crude measure of genetic risk eventually develop schizophrenia and the latent period is long (e. g. Erlenmeyer-Kimling et al. 1995, 1997; Johnstone et al. 2001). McGorry and colleagues aimed at identifying persons at risk who have manifest symptoms, an impaired functioning and demonstrate a substantially increased risk of psychosis onset and thereby represent a population, in which early intervention appears to be more indicated. For this purpose they used the "close-in" strategy as suggested by Bell (1992) which allows putting together a number of primarily symptom and family history measures to concentrate the level of risk and at the same time reduces the number of false positives. After being initiated in Melbourne, Australia (Phillips et al. 2000; Young et al. 1998), it has been adopted widely (e. g. Häfner et al. 2004; Miller et al. 2002, 2003a; Morrison et al. 2004). These criteria identify young people who are in the age range of peak incidence of onset of a psychotic disorder (late adolescence/early adulthood) who additionally describe mental state changes that are suggestive of an emerging

psychotic process, or who may have a strong family history of psychosis [ultra-high risk (UHR) group, see Table 1 for details].

The exit criteria of the intervention trial have been developed to define the onset of psychosis in the at-risk group (Table 1). These criteria are not identical to DSM-IV psychosis or schizophrenia criteria, but aim to define the minimal point at which neuroleptic treatment is indicated. Although the definition may be somewhat arbitrary, it does, at least, have clear treatment implications and applies equally well to substance-related symptoms, symptoms that have a mood component – either depression or mania – and schizophrenia spectrum disorders.

The PACE inclusion, exclusion and exit criteria (Phillips et al. 2002; Yung et al. 2003) were prospectively validated in a cohort of 49 young people meeting those criteria. By the end of the 12-month follow-up, 41 % of the cohort fulfilled exit criteria to psychosis and had been started on appropriate neuroleptic treatment (Yung et al. 1998, 2003). This occurred despite the provision of minimal supportive counselling, case management and antidepressant medication if required. 13 persons (65 %) of the group who became psychotic (n = 20) developed schizophrenia according to DSM IV. 3 persons (15 %) were diagnosed with a schizoaffective disorder. 10 % (n = 2) developed a major depression with psychotic features and another 10 % (n = 2) a psychotic episode not other specified. A subsequent report (Yung et al. 2004a) on an expansion of the same sample (n = 104) indicated a transition rate of 35 % (n = 36) at month 12. Of these 20 subjects (55.6 %) developed schizophrenia. The PRIME group based at Yale University in the United States reported transitions to "schizophrenic psychosis" in 7 of 13 persons (54 %) and 14 of 34 (41 %) fulfilling similar at-risk criteria (Miller et al. 2002, 2003a).

The PACE criteria were initially operationalised as scores on the Brief Psychiatric Rating Scale (BPRS: Overall and Gorham 1962) as shown in Table 1. More recently a measure has been developed at PACE that specifically assesses putative pre-psychotic symptomatology. This is the Comprehensive Assessment of At-risk Mental States – CAARMS (Yung et al. 2004b).

The inter-rater reliability of clinicians and research staff in relation to assessing whether potential subjects met inclusion or exit criteria was assessed in a separate study (n = 21). The pair wise kappa values for inclusion criteria were 0.81–1.0 and for exit criteria 0.77–1.0 (McGorry et al. 2002; Yung et al. 2003).

Early Detection and Intervention Evaluation (EDIE)

The inclusion, exclusion and exit criteria were directly derived from the PACE criteria outlined above. However, assessment instruments and opertionalisations of the concepts differ between PACE and EDIE [e.g. PANSS rather than BPRS, using the the GHQ (Goldberg and Hillier 1979) to define the state/trait criterion].

The inter-rater reliability regarding the PANSS scores is regarded as good, although exact numbers are not available (Morrison et al. 2004).

Cologne Early Recognition and Intervention Centre for mental crisis (FETZ)

Within the German Research network on schizophrenia a differential approach to the initial pre-psychotic phase of psychosis is evaluated based on the concept of two distinct at-risk mental states (Ruhrmann et al. 2003; Häfner et al. 2004; Bechdolf et al. 2005b). The early initial prodromal state (EIPS) is defined by the presence of certain self-experienced cognitive thought and perception deficits ("basic symptoms" according to Huber and Gross 1989), which were found to be predictive for transition to psychosis in 70 % of the cases within five years (Klosterkötter et al. 2001) and/or by a state trait risk factor group similar to the one defined by Yung et al. (1998). By defining an EIPS we aimed at identifying an especially early stage of the illness as compared to UHR criteria, because according to the early intervention hypothesis (McGlashan and Johanessen 1996) intervening particularly early in the course of the illness is supposed to be especially effective. Estimating benefits and risks of intervening in the EIPS, a pharmacological intervention with antipsychotics appeared to be unjustified. Instead the effects of a specially designed psychological intervention are evaluated. The late initial prodromal state (LIPS) is defined similar to the APS and BLIPS criteria used by PACE and EDIE (Phillips et al. 2002; Yung et al. 2003; Morrison et al. 2004). In the LIPS group the atypical antipsychotic amilsulpride is evaluated (Häfner et al. 2004; Ruhrmann et al. 2003). In this paper we only refer to the psychological intervention in the EIPS, because only in this state is a manualised and standardised psychological treatment applied.

The EIPS inclusion criteria are mainly based on the basic-symptom concept, which was introduced by Gerd Huber (1989). It describes subtle, often only self-experienced, very early sub-clinical symptoms. In the Cologne Early Recognition (CER) study (Klosterkötter et al. 2001) from a study sample of 385 subjects who were referred to specialised outpatient departments for diagnostic clarification of a possible incipient schizophrenic disorder, a cohort of 160 patients presenting with these symptoms, but not with any psychotic symptom, was prospectively investigated over a mean follow-up period of 9.6 years. 70 % of the patients presented with at least one of the basic symptoms shown in Table 1 (EIPS criteria) developed schizophrenia within an average of 5.4 years. The transition rates of these subjects in the CER study were 19.2 % within the first 12 months and additional 17 % in the second 12 months. In another independent sample (n = 147) 17 % of those persons who fulfilled EIPS basic symptoms developed psychosis within 12 months on average (Schultze-Lutter et al. 2004).

These schizophrenia predictive EIPS basic symptoms serve as inclusion criteria for the FETZ psychological intervention trial. The second group of inclusion criteria

Table 1 Inclusion, exclusion and exit criteria

	Inclusion criteria	Exclusion criteria	Exit criteria
PACE	ultra high-risk group (UHR): Belong to one (or more) of the following groups: *group 1: attenuated psychotic symptoms (APS):* ideas of reference, magical thinking, perceptual disturbances, paranoid ideation, odd speech (2–3 on unusual thought content scale, 1–2 on hallucinations scale, 3 on suspiciousness scale, 1–3 on conceptional disorganisation scale of BPRS (Overall, Gorham 1961); frequency of symptoms several times a week; change in mental state present during the past year for not more than five years or *group 2: brief limited intermittent psychotic symptoms (BLIPS):* ideas of reference, magical thinking, perceptual disturbances, paranoid ideation, odd speech (≥4 on unusual thought content scale, ≥3 on hallucinations scale, ≥4 on suspiciousness scale, ≥4 on conceptional disorganisation scale of BPRS); duration less than 1 week; symptoms resolve spontaneously or *group 3: trait state risk factors:* first degree relative with a psychotic disorder or individual has schizotypal personality disorder; significant decrease in mental state or functioning-maintained for at least a month (reduction in Global Assessment of Functioning Score scale (DSM IV) of 30 points from pre-morbid level); decrease in functioning occurred within the past year	aged below 14 and above 30 years, intellectual disability, lack of fluency in English, presence of a known organic brain disorder, and a history of a prior psychotic episode- either treated or untreated	*transition to psychosis:* ≥4 on unusual thought content scale, ≥3 on hallucinations scale, ≥4 on conceptional disorganisation scale of BPRS, duration of mental state longer than 1 week
EDIE	ultra high-risk group (UHR): Belong to one (or more) of the following groups: *group 1: attenuated psychotic symptoms (APS):* ideas of reference, magical thinking, perceptual disturbances, paranoid ideation, odd speech (2–3 on hallucinations scale, 3 on delusions, 3–4 on suspiciousness scale, 3–4 on conceptional disorganisation scale of PANSS (Kay, Opler 1987); frequency of symptoms several times a week; change in mental state present for one week or *group 2: brief limited intermittent psychotic symptoms (BLIPS):* ideas of reference, magical thinking, perceptual disturbances, paranoid ideation, odd speech (≥4 on hallucinations scale, ≥5 on suspiciousness scale, ≥5 on suspiciousness scale of PANSS); duration less than 1 week prior to spontaneous resolution or *group 3: trait state risk factors:* first degree relative with history of psychosis or client meet criteria for schizotypal personality disorder (DSM IV) and caseness on the General Health Questionnaire (Goldberg, Hilier 1979) or loss of 30 points or more on the GAF (DSM IV)	aged below 16 and above 36 years; current or past receipt of antipsychotic medication	*transition to psychosis:* ≥4 on hallucinations scale, ≥4 on delusions, ≥5 on conceptional disorganisation scale of PANSS, at least several times a week, duration longer than 1 week
FETZ	early initial prodromal state (EIPS): Belong to one (or more) of the following groups: *group 1: Self-experienced cognitive thought and perception deficits (basic symptoms):* (one or more of the following basic symptoms in the last 3 months several times a week) as measured by ERI (Maurer et al. 2000): thought interferences, thought perseveration, thought pressure, thought blockages, disturbances of receptive language, either heard or read, decreased ability to discriminate between ideas and perception, fantasy and true memories, unstable ideas of reference (subject-centrism), derealisation, visual perception disturbances (blurred vision, transitory blindness, partial sight, hypersensitivity to light, etc.), acoustic perception disturbances (hypersensitivity to sounds or noise, acoasms, etc.) or *group 2: trait state risk factors:* reduction in the GAF (DSM IV) of at least 30 points (within the past year) and at least one of the following risk factors: first-degree relative with a lifetime-diagnosis of schizophrenia or a schizophrenia spectrum disorder, pre- or perinatal complications	aged below 18 and above 36 years; present or past diagnosis of a schizophrenic, schizophreniform, schizoaffective, delusional or bipolar disorder according to DSM IV; present or past diagnosis of a brief psychotic disorder according to DSM IV with a duration equal to or of more than one week or within the last 4 weeks regardless of its duration; diagnosis of delirium, dementia, amnestic or other cognitive disorder, mental retardation, psychiatric disorders due to a somatic factor or related to psychotropic substances according to DSM IV; alcohol- or drug abuse within the last three months prior to inclusion according to DSM IV; organic diseases of the central nervous system	*(1) transition to late initial prodromal state (LIPS): attenuated psychotic symptoms (APS):* 2–3 on hallucinations scale, 3 on delusions, 3–4 on suspiciousness scale, 3–4 on conceptional disorganisation scale of PANSS; frequency of symptoms several times a week; change in mental state present for one week or *brief limited intermittent psychotic symptoms (BLIPS):* ≥4 on hallucinations scale, ≥4 on delusions scale, ≥5 on conceptual disorganisation of PANSS); duration less than 1 week prior to spontaneous resolution or *(2) transition to psychosis:* ≥4 on hallucinations scale, ≥4 on delusions, ≥5 on conceptional disorganisation scale of PANSS, duration longer than 1 week

represents a slightly modified version of the PACE "state and trait risk factors" criterion (Yung et al. 1998), by adding the well-established risk factor "pre- or perinatal complications".

For details of exclusion criteria see Table 2. Exit criteria from the trial are defined analogous to the criteria of PACE and EDIE as presence of at least one psychotic symptom for longer than six days. In accordance with

Table 2 Characteristics of interventions (all interventions are delivered as outpatient treatments)

Service	Rationale	Setting	Sessions	Content	Applied strategies	Duration
PACE	vulnerability-stress-coping model (Zubin, Spring 1977); Cognitive models of psychosis (Frith 1992; Garety and Helmsley 1994; Garety et al. 2001)	individual	ca. 15	*phases:* assessment/ engagement, treatment, termination *modules:* stress-management, depression/negative symptoms, positive symptoms, other comorbidity	offering practical help, formulation; collaborative goal setting, provision of information and education about stress, positive and negative symptoms, depression, anxiety, substance abuse; stress-monitoring, relaxation-, meditation-, distraction-techniques; thought monitoring, cognitive restructuring, positive coping, positive reframing and challenging, goal setting and time management; assertiveness training, verbal challenge and reality testing of delusional thoughts and hallucinations, coping enhancement techniques, normalizing psychotic experiences, self-monitoring of symptoms, scheduling and monitoring of mastery and pleasure activities, problem solving, social-skills training; cognitive restructuring of negative and self-defeating cognitions, exposure techniques, behavioural strategies such as thought stopping, distraction, activity scheduling	6 months
EDIE	cognitive model of psychosis (Morrison 2001)	individual	max. 26	engagement, assessment, formulation, a number of individually applied change strategies, relapse prevention no formal treatment phases or modules	offering practical help, formulation; collaborative goal setting, provision of a cognitive model of psychosis; self-monitoring of symptoms, normalising (attenuated) psychotic experiences, generating and evaluating alternative explanations, behavioural experiments and activity scheduling to reduce safety behaviours; evaluating evidence, generating alternative explanations, behavioural experiments, considering advantages and disadvantages to challenge negative metacognitions cognitive restructuring of negative and self-defeating core beliefs	6 months
FETZ	vulnerability-stress-coping model (Zubin, Spring 1977) specific cognitive model of the early initial prodromal state (Larsen et al. 2003)	individual group cognitive training Information and councelling of keypersons	max. 30 15 max. 12 3	individual: *phases:* assessment/ engagement, treatment, termination *modules:* psychoeducation, stress-, symptom (basic symptoms; depression, anxiety, negative symptoms), crisis-management group: positive mood/enjoying social skills training problem solving training	offering practical help; formulation; collaborative goal setting; provision of information and education about stress; basic and negative symptoms, depression, anxiety; stress-monitoring, relaxation-, distraction-techniques; self-monitoring of symptoms, thought monitoring, cognitive restructuring, positive coping, positive reframing and challenging, goal setting and time management; coping enhancement techniques, normalizing self-experience of neuropsychological deficits, behavioural strategies such as thought stopping, distraction, activity scheduling; exposure techniques; cognitive restructuring of negative and self-defeating cognitions; relapse prevention; scheduling and monitoring of mastery and pleasure activities, keeping well strategies, assertiveness and social-skills training; problem solving; computer-based training of concentration, attention, vigilance and memory; psychoeducation of keypersons	12 months

the differential intervention concept, the presence of APS and BLIPS served as additional exclusion criteria from the EIPS intervention trial (and as inclusion criteria for the LIPS study, see Table 1 for details).

Symptom assessments of inclusion and exit criteria were performed observer rated with the symptom list of the Early Recognition Inventory and Interview for the Retrospective Assessment of the Onset of Schizophrenia – ERIraos (Maurer et al. 2000). This instrument was specially designed for the assessment of prodromal symptoms and consists of 110 items covering 12 categories. Because the instrument is still subject of an evaluation study, where possible, corresponding PANSS scores (Kay and Opler 1987) were given in Table 1. Kappas for "symptoms present in the year before interview" of the ERIraos range between 0.41 and 0.87 (Maurer et al. 2004).

II. Interventions

All presented approaches exclusively study help-seeking persons presenting with possible pre-psychotic symptoms who worry about their symptoms and wish to receive treatment. For this purpose, all centres funded specially designed clinical outpatient services which aim to provide a non-stigmatising, low-threshold setting for young persons presenting with signs and symptoms assumed to be associated with a relatively high risk of transition to psychosis and schizophrenia.

Personal Assessment and Crisis Evaluation (PACE)

The stress-vulnerability model of psychosis underpins the PACE treatment (Zubin and Spring 1977). It acknowledges biological factors, psychological and social factors in the development of psychosis. An underlying assumption of the stress-vulnerability model is that ambient/environmental stressors (such as relationship issues, substance use, lifestyle factors) are key factors in the development of psychosis. Moreover, such a model implies that the implementation of appropriate coping strategies may ameliorate the impact of vulnerability factors (Boeker et al. 1989). As a result, strategies addressing the experience of stressors and the individual's response are a core component of the therapy offered at PACE. The PACE psychological treatment also draws on cognitive-behavioural models and techniques targeting psychotic symptoms. These models propose that the core symptoms of psychosis are derived from fundamental disturbances in information processing which results in perceptual abnormalities and disturbed experience of the self. Cognitive biases, inaccurate appraisals and core self-schema contribute further to unusual beliefs (Frith 1992; Garety and Helmsley 1994; Garety et al. 2001). Like all people, those at risk of psychosis attempt to make sense of their experiences in the light of their earlier development and the meaning they attach to events will influence symptoms, emotional responses and behaviour.

The aims of therapy, therefore, are to reduce stress, to improve coping resources and thereby reduce the likelihood of transition to psychosis. Moreover, the therapy assists people to develop an understanding of the cognitive processes that influence their thoughts and emotions, and to develop more realistic and positive views of themselves.

The psychotherapy incorporated in an early intervention trial at the PACE Clinic comprises of approximately 15 individual sessions over a 6 month period, with the frequency of sessions depending on arrangements made between individual clients and therapists as well as on the mental state of individual clients. The psychotherapist who implements therapy is also responsible for the provision of regular case management, including addressing more practical issues such as finding housing, arranging social security payments, enrolling in school, applying for employment and so forth. There are three phases of treatment (assessment/engagement, therapy, termination). Although stress management forms the backbone of this therapy, specific symptoms experienced by clients are also targeted. As the symptoms reported by UHR clients vary widely, a number of treatment modules have been developed within the cognitive therapy – Stress management, Depression/negative symptoms, Positive symptoms and Other comorbidity. The selection of modules to be implemented during the course of therapy with an individual client is informed by an assessment of the presenting problem(s) and the clients' own perception of their functioning. The content of these modules draws extensively on stress management and cognitive behavioural treatment techniques that have been developed and applied to a wide range of mental health problems (see Table 2 for details of the cognitive-behavioural strategies which are applied). The CBT approach is presented in more detail and with case examples in Phillips and Francey (2004).

Early Detection and Intervention Evaluation (EDIE)

The intervention provided in the EDIE study is CBT that is based on a recent cognitive model of the development and maintenance of psychosis (Morrison 2001). The model suggests that it is the culturally unacceptable interpretations of events that determines whether someone is viewed as psychotic or not and highlights maintenance processes that were initially identified in models of emotional disorders (Clark 1986; Salkovskis et al. 1999; Wells and Matthews 1994). These processes include selective attention, safety behaviours designed to prevent feared outcomes, thought control strategies and avoidance. The model also highlights the importance of beliefs about the self, world and others, as well as metacognitive beliefs including positive beliefs about psychotic experiences. The aim of intervention is the reduction of distress and increasing quality of life, rather than the reduction of psychotic experiences.

CBT at EDIE lasts for up to 26 sessions over a six-month period, and is based on the general structure and principles of cognitive therapy, such as involving agenda setting and homework tasks, being time-limited, problem-orientated and involving collaborative empiricism and Socratic questioning (Beck 1976). The psychotherapist who implements therapy is also responsible for the provision of regular case management. The intervention is personalised for each patient, and is based on an idiosyncratic case conceptualisation that is derived from the model. This formulation is collaboratively developed with the patient in the early stages of therapy and is used as a working hypothesis to guide the selection of treatment strategies. The clinical assessment focuses on current problems and life history with the aim of gathering the information required to develop a case conceptualisation and eliciting information regarding cognitive, behavioural, emotional, physiological and environmental factors. A shared list of problems and goals is also generated early in therapy. The treatment is, therefore, de-

termined by a combination of the case conceptualisation and the priorities identified on the problem list. Typically, patients will prioritise problems that are not directly related to psychotic experiences, such as relationship issues, anxiety and mood disorders, fears regarding the onset of madness and a lack of structure or meaningful activity in daily living. Where appropriate, specific cognitive models of anxiety or mood disorders are utilised to inform the conceptualisation and selection of intervention strategies. Common treatment strategies include consideration of the advantages and disadvantages of holding particular beliefs or having certain experiences, and, if appropriate, the generation of alternative explanations for distressing events and the examination of evidence for and against such interpretations. In addition, the examination of metacognitive beliefs about thoughts, beliefs and hallucinatory phenomena is commonly used, as are behavioural experiments to test out problematic beliefs. Normalisation of psychotic experiences is another very common aspect of treatment. Therapy finishes with the development of a relapse prevention plan and a therapeutic blueprint, which identifies the strategies the patient has found helpful and plans for the consolidation of treatment gains.

Sessions follow a detailed manual containing assessment, formulation and change strategies, examples of interventions and model responses for the therapist (French and Morrison 2004). Further details and case examples can be found elsewhere (French et al. 2001, 2003).

Early Recognition and Intervention Centre for mental crisis (FETZ)

The vulnerability stress coping model of schizophrenia (Zubin and Spring 1977; Nuechterlein and Dawson 1984) and the basic symptom concept (Huber and Gross 1989; Süllwold and Herrlich 1998), serve as the framework of the FETZ intervention. Thus, improving coping resources and stress-management are underlying strategies of the intervention. Arguing that there is some empirical evidence that cognitive thought and perception disorders might precede negative affective states, social withdrawal and social decline (Häfner et al. 1992; Klosterkötter et al. 2001), a specific cognitive model of the EIPS (Larsen et al. 2003) was developed as an extension of the vulnerability stress coping model based on recent cognitive models of psychosis (Kingdon and Turkington 1994; Fowler et al. 1995; Chadwick et al. 1996). In this model biological, psychological, social stress and vulnerability factors are presumed to interact to leave the person at a high risk for the subsequent development of prodromal symptoms. The prodromal symptoms become manifest on exposure to a range of additional stress, which again may be social, psychological, or biological. The occurrence of self-experienced cognitive thought and perception deficits ("basic symptoms") could then serve as triggering events for the appraisal of negative beliefs and assumptions. Self-experiencing basic symptoms may then result in emotional disturbances, like depression or anxiety, social withdrawal and social decline, which jointly contribute to the development and maintenance of symptoms and distress.

The aims of the intervention are: first, improvement of present prodromal symptoms; second, prevention of social decline or stagnation; third, prevention or delay of progression to psychosis.

The programme draws on strategies of the cognitive therapy for people with psychosis (Kingdon and Turkington 1994; Fowler et al. 1995; Chadwick et al. 1996) and considers empirical study results on effective strategies for first episode or recurrent schizophrenia and for clients with anxiety disorders or depressive symptoms (e. g. APA work group 1998; Liebowitz 1999; APA work group 2000; Bustillo et al. 2001). The intervention is delivered to clients for 12 months as an outpatient treatment. It consists of 30 sessions of individual therapy, 15 sessions of standardised group intervention, 12 sessions of cognitive training and 3 sessions of psychoeducational multifamily intervention. The psychotherapist who implements individual therapy also covers case management issues.

Individual therapy forms the central part of the early intervention programme. It is separated into assessment/engagement, treatment and termination phases. During these phases a combination of psychoeducation, symptom- (basic symptoms, depression, anxiety, negative symptoms), stress- and crisis-management modules are adapted to the specific needs of each client. The therapy begins with a period of building and establishing a collaborative, therapeutic relationship in which enabling the client to feel understood is of major importance. The primary aim is to ensure that the sessions are tolerable – always explicitly discussing this with the clients. Gradually the therapist moves from empathic listening to more structured assessment interviewing, in which the therapist attempts to clarify the particular life circumstances, events, and experiences that provided the context for the onset of prodromal symptoms and makes a detailed analysis of specific distressing symptoms and other problems. By the end of this period, some preliminary shared goals for the therapy should be developed. These must be relevant to the client and expressed in the client's own terms, while being compatible with what the therapy can hope to achieve. Although possible pre-psychotic symptoms serve as inclusion criteria for therapy, these goals often include problems other than pre-psychotic experiences, such as anxiety, depression, family or occupational problems.

Work on coping strategies follows directly from the assessment, in which current distressing symptoms and experiences have been identified, for example, episodes of thought blockages, derealisation or visual and acoustic perceptual deficits. A detailed assessment of existing strategies and of antecedents and consequences of current symptoms is carried out. The goal is to ma-

nipulate any factors that contribute to symptoms appearance and maintenance. Often situations which tend to overwhelm the individual's information processing resources have been found to precede self-perceived neuropsychological deficits, i. e. overload due to competing conversations being held in the same room, or tasks requiring long periods of high amounts of concentration. A range of cognitive and behavioural strategies, including attention switching, attention narrowing, reattribution, awareness training, de-arousing techniques, social engagement and disengagement are applied to reduce the occurrence or duration of such problems. Computerised cognitive training is provided as a tool to train cognitive thought and perception disorders directly. Developing an effective coping strategy can bring particular relief in cases where symptoms are experienced as overwhelming and uncontrollable, resulting in social withdrawal, depression and anxiety. The aim of these strategies is to foster feelings of control and hope and to provide practical help in the early stages of therapy. Apart from the treatment of the psychopathologic syndromes, psychosocial problems and providing stress management training, one major treatment aspect focuses on attributional styles that underpin the key problems. The therapy aims to establish a coherent understanding of the pre-psychotic state in clients, which enhances and protects self-esteem. To the experience of the researchers in the group, clients with cognitive thought and perception disorders are very much likely to link these experiences with threatening and traumatic events in earlier life. Usually these links are associated with negative self-evaluations and beliefs, which could lead to feelings of loss and demoralisation and further onto depression, social anxiety and social withdrawal. If negative evaluations have been identified, standard cognitive approaches are applied such as identifying automatic thoughts and dysfunctional assumptions, reviewing the history of the development of these ideas over the life span and re-evaluating the evidence and exploring alternative appraisals.

A group therapy is also offered to the clients, to encourage them to communicate about their problems and beliefs. This often results in relief and in a reduction of negative self-evaluations. In this group training social anxiety, social withdrawal and depression, which are often found in the initial prodromal state (Häfner et al. 1992), are also treated. At the beginning of the group intervention, positive activities and resources are focused on to reduce possible anxiety of the participants concerning the group therapy itself. Later on, standardised social perception, social skills and problem solving training are applied. Moreover, a short psychoeducational multifamily intervention to clients' key persons is offered, which is primarily didactic, introducing the vulnerability-stress-coping-model of the disorder and the rationale for early intervention.

The termination stage of therapy involves reviewing the work done and looking to the future. Usually a crisis management plan is developed, including helpful coping strategies and defining at which stage key persons and/or the early recognition and intervention centre should be contacted.

During the several stages and formats of therapy a variety of cognitive-behavioural strategies is applied (see Table 2 for details). Each session follows a detailed protocol containing the aims of the session, examples of interventions and model responses for the therapist (Bechdolf et al. 2002). Further details and case examples can be found elsewhere (Bechdolf et al. 2003; Larsen et al. 2003).

III. Evaluations

Personal Assessment and Crisis Evaluation (PACE)

The PACE psychological intervention has been evaluated in conjunction with low-dose anti-psychotic medication in a randomised controlled, parallel group trial (McGorry et al. 2002). In this study, clients were randomised to receive either CBT plus low-dose risperidone or a need based psychosocial intervention alone (both monitoring and CBT condition incorporated elements of case management). Treatment was provided for six months and research assessments took place at baseline, end of treatment (6 months) and 6-months after treatment ended (12 months after intake). 59 predominately male clients were randomised. Assessments were not blinded and no formal measures of treatment fidelity were carried out. Clients randomised in the experimental condition received a mean number of 11 CBT sessions (SD 8.4) and a mean dosage of 1.3 mg risperidone (SD 0.9). In addition 41.9 % of the participants were treated with sertraline. Clients in the control group received 5.9 sessions (SD 4.3) on average of a need based psychosocial intervention. In addition 60.7 % of the participants were treated with sertraline. Almost 50 % of the clients in the experimental group received less than 10 sessions of psychological therapy. Although some clients withdrew from treatment it is difficult to determine whether this was a reaction to the psychological treatment or the medication they were offered. It is noted that 6 participants ceased the antipsychotic medication but continued with the psychological treatment component. Analyses were by intention to treat. No participant was reported to have dropped out from treatment or to be lost to follow-up. A reduced transition rate according to the exit criteria (Table 1) was found in the experimental group compared with the control group after treatment (10 % vs. 36 %; $p = 0.026$). At follow-up (6 months after the cessation of treatment) this difference was no longer significant (20 % vs. 36 %; $p = 0.24$). When adherence to risperidone was incorporated in the analysis, the significant difference between the experimental and the control group was sustained through the follow-up period (7 % vs. 36 %). Although the use of sertraline was higher within the control group, the transition rate was not significantly different whether or not sertraline

Table 3 Evaluation

Service	Participants	Age (mean, years)	Design	Experimental condition	Control condition	Duration of treatment (months)	Follow-up after start of treatment (months)	Quality control	Results
PACE	n = 59 25 female 34 male	20 SD 4	randomised controlled, parallel group, open label	CBT (mean number of sessions: 11.3, SD 8.4) combined with risperidone (mean dosage 1.3 mg, SD 0.9), in addition 41.9 % of the participants were treated with sertaline	need based psychosocial intervention (mean number of sessions: 5.9, SD 4.3; in addition 60.7 % of the participants were treated with sertaline	6	6 12	regular supervision no formal measure of treatment fidelity	transition to psychosis: 6 months: exp.: 10 % vs. contr.: 36 %; p = 0.026; 12 months: exp.: 20 % vs. contr.: 36 %; p = 0.24; symptoms, social adjustment: no significant differences
EDIE	n = 60 (2 persons later excluded) 18 female 40 male	22 SD 4.5	stratified randomised assignment controlled, parallel group study, blindness of assessments intended	CT (mean number of sessions: 11) and monitoring (mean number of assessments: 8)	monitoring (mean number of assessments: 7)	6	6 12	regular supervision no formal measure of treatment fidelity	transition to psychosis: 12 months: exp.: 6 % vs. contr.: 22 %; p = 0.028; exp. condition significant improves symptoms; social adjustment: no significant differences
FETZ*	n = 123 (gave informed consent to participate at the RCT) 41 female 72 male	26 SD 6.3	block-randomised controlled, parallel group, blindness of assessments intended	comprehensive CBT program: individual (sessions: 30) group (sessions: 15) cognitive training (sessions: 12) Information and councelling of keypersons (sessions: 3)	clinical management (sessions: 21)	12	12 24 36 (subgroup)	regular supervision no formal measure of treatment fidelity	transition to LIPS or psychosis: exp.: 5 %., contr.: 15 %; pre-post-treatment effect sizes in exp. for symptoms and for social adjustment in an uncontrolled pilot sample (n = 12) d = 1.85–3.80

* interim description of ongoing trial

was prescribed. No significant differences between treatment groups with regard to psychopathological symptoms or social adjustment were observed.

Early Detection and Intervention Evaluation (EDIE)

The CBT approach was evaluated in a randomised controlled, parallel group trial in comparison to monthly monitoring (Morrison et al. 2004). Both monitoring and CBT conditions incorporated elements of case management. A total of 60 predominately male participants were randomised. Two patients were later excluded from further analyses because at the first post-randomisation assessment, they were assessed as meeting PANSS criteria for psychosis and also reported having concealed psychotic symptoms during the initial assessment. Assessors were intended to be blind to the condition the patient was allocated, but in practice this was difficult to achieve, because participants often divulged information about the therapist or used language that suggested they were receiving cognitive therapy. The experimental group received a mean number of 11 CBT sessions over a 6 month period in addition to a mean number of 11 monitoring sessions over 12 months. Drop out from therapy was reported at 14 %. Participants of the control condition were at mean monitored at seven assessments in the study period of 12 months. CBT sessions were regularly supervised, but no measure of treatment fidelity was employed. Medications other than neuroleptics were not assessed. Comparison of the two groups was by intention to treat. The exact number of missing data was not reported, but is was described that missing data were recorded as missing with the exception of transition status, which was assumed to be no transition if this data was not available. Moreover, 21 PANSS interviews were conducted over the telephone. At the 12-month follow-up (six months after the maximum duration of cognitive therapy) 6 % of the CBT treatment group and 22 % of the control group made the PANSS-defined transition to psychosis. In the primary logistic regression analysis using PANSS-defined transition to psychosis as the dependent variable, the main effect of CBT was significant (odds ratio = 0.04; 95 % confidence interval = 0.01–0.71; $p = 0.028$). In addition, CBT significantly reduced the likelihood of being prescribed antipsychotic medication (odds ratio = 0.06; 95 % confidence interval = 0.01–0.57; $p = 0.014$) and of meeting criteria for a DSM-IV diagnosis of a psychotic disorder (odds ratio = 0.04; 95 % confidence interval = 0.01–0.57; $p = 0.019$). Analysis of covariance showed that CBT also significantly improved positive symptoms of psychosis in this population over the 12-month period ($F(1,48) = 4.09$, $p = 0.049$). There were no significant differences between groups on Global Assessment of Functioning or General Health Questionnaire scores at 12 months.

Early Recognition and Intervention Centre for mental crisis (FETZ)

The intervention is evaluated in a randomised controlled, parallel group, multicentre trial, involving Early Recognition and Intervention Centres in Cologne, Bonn, Dusseldorf and Munich (Ruhrmann et al. 2003; Bechdolf et al. 2004a, b; Häfner et al. 2004). In the ongoing trial, clients are block-randomised to receive either a comprehensive CBT intervention (for details see intervention section) or 21 sessions of clinical management (CM) over a 12-month period (both treatment conditions incorporate elements of case management). Assessments take place at intake, post treatment, at month 24 and (for a subgroup) at month 36. From month 13 until month 36, monthly telephone interviews are carried out to check transition criteria. Blindness of assessments is intended. Treatment sessions are regularly supervised, but no measures of treatment fidelity are employed. Because the study is ongoing, data on treatment attendance or lost-to follow-rate are not available yet and analyses are preliminary.

A feasibility analysis was conducted for the first 12 participants, who were randomised to receive the CBT intervention (Bechdolf et al. 2004a). From the initial sample, 2 subjects (16.8 %) dropped out after one or more sessions and were lost to follow-up. Significant and large pre-post-treatment improvements were found in the completer group ($n = 10$). General psychopathology as measured by the PANSS (Kay and Opler 1987) and basic symptoms as measured by the ERIraos (Maurer et al. 2000) were significantly reduced by CBT ($p = 0.009$; $p = 0.008$). Depression as measured by the MADRS (Montgomery and Asberg 1979) and global functioning (GAF, APA 1997) were significantly improved ($p = 0.009$; $p = 0.005$). According to Cohen (1988), these results comprised large effect sizes ($d = 1.85–3.80$). A descriptive analysis of transition rates to LIPS and PANSS-defined psychosis based on all data for all clients who gave informed consent to participate at the trial until October 16, 2003 ($n = 123$), again as in the other trials predominately men, indicated transition rates of 5.3 % for the CBT group and 14.8 % for the control group (Häfner et al. 2004). Drawing conclusions from the findings is limited by differences of observation time between the two groups [CBT 16.3 months (SD 8.5), CM 9.2 months (SD 8.6)].

Discussion

It should be noted that the discussion of the three approaches with regard to inclusion, exclusion and exit criteria, interventions and evaluations can not be generalised beyond the help-seeking subset of people at risk. Despite the intensive awareness-raising and educational efforts at all centres, the majority of young people who were eligible for treatment in the putatively pre-psychotic phase were probably not involved in the presented interventions.

All approaches employ **inclusion, exclusion and exit criteria**, which have been evaluated in prospective, follow along studies (Yung et al. 1998, 2003, 2004a; Klosterkötter et al. 2001; Miller et al. 2002, 2003a). These criteria define a risk of developing psychosis of up to 54 % within 12 months, which is several thousand times higher than the annual risk in the general population (APA 1997). Although there is a finite false positive rate (45–65 % at 1 year; 30 % at year 3–5 depending on the criteria used) at present 4 persons at risk need to be treated to prevent 1 transition within 12 months (NNT = 4, McGorry et al. 2002), which is a far better rate than those which are accepted for, e. g., antihypertensive medication in mild hypertension to prevent one stroke (NNT = 167; McGorry et al. 2003). Taking into account the devastating consequences of post-onset interventions intervening in persons fulfilling these at-risk criteria with interventions like CBT presenting with a good benefit/risk ratio to us is justified, because (a) irrespective of whether transition ultimately occurs, help is needed to tackle serious problems of social withdrawal, impaired functioning and subjective distress in persons at risk, (b) engagement and trust is easier to develop in the pre-psychotic phase than in a psychotic phase and lays the foundation for later therapeutic interventions, (c) if psychosis develops, it can be detected rapidly and duration of untreated psychosis minimized, and (e) comorbidity, such as depression, anxiety and substance abuse can be effectively treated.

However, the predictive validity of the "at-risk mental state" concept still needs to be improved. There are a number of reasons for this: *(a) Heterogeneity of concepts:* PACE and EDIE used criteria which has been referred to as the "ultra-high risk" (UHR) approach (Yung et al. 1998, 2003, 2004a; Phillips et al. 2000). These criteria are associated with the highest rates of transitions to psychosis available to date between 35 % and 54 % within one year (Yung et al. 1998, 2003, 2004a; Miller et al. 2002, 2003a). Some limitations of the concept have been articulated: (i) Predictive validity could still be improved and needs to be more homogenous between different samples using similar criteria (e. g. Miller et al. 2002: Transition rate to psychosis: 54 %; Yung et al. 2004a: Transition rate to psychosis: 35 %). (ii) Significant impairment of social or vocational functioning may be already present (Häfner et al. 1992; Miller et al. 2003b). (iii) Stage might be "too late" for achieving effects on transition rates with intensive (especially non-pharmacological) interventions. (iv) The definition may appear somewhat arbitrary saying that certain individuals fulfilling criteria for DSM-IV Brief Psychotic Disorder are recognized as at risk (BLIPS), where others (duration of positive symptoms longer than 6 days) are labelled as already psychotic. In contrast to the UHR criteria, the FETZ EIPS criteria are meant to define an earlier initial prodromal state [prediction of transition into schizophrenia in 70 % of the cases within 5.4 years (Klosterkötter et al. 2001)]. Given that early intervention can prevent progression into first psychotic episodes, an intervention in an earlier stage of the illness should be particularly effective (McGlashan and Johannessen 1996). Moreover social decline associated with schizophrenia might not yet have taken place in this stage. However, this approach also carries several limitations: (i) Longer follow-ups are needed to evaluate the model and the intervention, which is difficult to achieve in a young urban population. (ii) Symptoms are less obvious and more difficult to assess than the ones from the UHR approach, which may lead to problems of reliability and validity. However, there is growing consensus in the field that the UHR and the FETZ EIPS approach complement one another by providing criteria allowing the detection of different at risk mental states (Klosterkötter et al. 2005). *(b) No established measures:* At all three centres by the time intervention studies were initiated, published assessment tools with sufficient reliability and validity to identify persons at risk were not available. There were two strategies to deal with this problem: FETZ used measures which were especially developed for identifying persons at risk and assessments were "translated" – where possible – into scores of established instruments for assessing symptoms of schizophrenia (PANSS). PACE or EDIE directly used the established instruments for schizophrenia symptomatology (BPRS, PANSS) to assess sub-threshold psychopathology and used a number of other measures to identify the "state-trait" UHR criterion. Both strategies, of course, reduce the reliability and validity of the findings and could lead to heterogenic results. However, when presented, the reliability for the "presence of symptoms" or "belonging to an at-risk mental state" were acceptable (PACE, FETZ) and validations of specific assessment instruments for people at risk of psychosis are in preparation or available meanwhile (Maurer et al. 2004; Miller et al. 2004; Schultze-Lutter et al. 2004; Yung et al. 2004b). *(c) Heterogenic operationalisation of inclusion and exclusion criteria:* Even though PACE and EDIE refer to the same at-risk cohort, the operationalisation and assessment of inclusion and exclusion criteria differ and thus could lead to heterogenic results between the two studies. EDIE did not exclude clients presenting with APS for more than 5 years like PACE did. Therefore, EDIE could have included persons fulfilling DSM IV schizotypal personality disorder criteria without reduction in social functioning, which are probably less likely to develop psychosis than persons fulfilling APS criteria within an acute or subacute timeframe. Regarding the "trait-state risk" criterion, EDIE was probably more strict than PACE having persons included which fulfil caseness on the General Health Questionnaire (Goldberg and Hillier 1979). With regard to exclusion criteria, persons with intellectual disability, presence of a known organic brain disorder or a history of a prior psychotic episode not treated with neuroleptics were not excluded from the EDIE study but were excluded from the PACE trial. Fulfilling inclusion criteria could be due to psychotropic substance abuse at PACE and EDIE but not at FETZ. *(d) Fulfilling exit criteria does not imply diagnosis of schizophrenia:* Even

though the definitions of exit criteria to psychosis are homogenous across the three centres, it has to be emphasised that these criteria are not identical to DSM-IV criteria of schizophrenia, but are designed on an ethical and pragmatical basis to define the minimal point at which neuroleptic treatment might be indicated (McGorry et al. 2002). Thus the definition is meant to have clear treatment implications and applies equally well to substance-related symptoms, symptoms that have a mood component – either depression or mania – and schizophrenia spectrum disorders. According to the naturalistic follow along study of Yung et al. (2003, 2004a, 2004b) only a subsample of around 56 % – 65 % of the persons fulfilling exit criteria later on developed schizophrenia (despite adequate neuroleptic and psychosocial treatment). In the FETZ trial drawing conclusions with regard to transition to psychosis or schizophrenia is further limited by the fact that APS and BLIPS serve as additional exit criteria and at the same time as inclusion criteria for a randomised pharmacological intervention trial. Because two interventions designed to reduce transition to psychosis are applied at the same persons one after another, the conclusions regarding the relative contribution of the CBT intervention to the reduction of the transition rate to psychosis or schizophrenia are limited further.

Concerning **interventions**, all recent approaches are based on the general structure and principles of cognitive behavioural therapy, which have been found to be effective in a variety of clinical and other problems (e. g. APA 1998, 2000). Consequently all approaches involve agenda setting and homework tasks, are time-limited, problem-orientated and use collaborative empiricism, Socratic questioning (Beck 1976) and other evaluated cognitive-behavioural treatment techniques. As the problems reported by the clients in the pre-psychotic phase vary widely, at all contemporary centres treatment is highly individualised and customised to the needs of each participant (at PACE and FETZ by developing a number treatment modules). As framework two of the three contemporary approaches (PACE, FETZ) refer to the vulnerability-stress-coping model of schizophrenia (Zubin, Spring 1977). In addition, all contemporary approaches use a cognitive model of the presenting problems (Morrison 2001; Larsen et al. 2003) and draw extensively on cognitive therapy approaches for people with psychosis (Frith 1992; Garety and Helmsley 1994; Kingdon and Turkington 1994; Fowler et al. 1995; Garety et al. 2001). Although treatment rationales, settings, contents, applied strategies and duration of treatment go along similar lines at PACE, EDIE and FETZ, there are also differences between the centres: PACE and EDIE treatments last for 6 months, FETZ treatment is designed to cover 12 months. EDIE offers individual CBT treatment alone, the FETZ programme consists of individual CBT sessions, a group therapy, cognitive remediation and a short psycho-educational group intervention for key-persons, whereas the specific PACE intervention involves individual CBT treatment and low-dose medication with an atypical neuroleptic. However, future research in this area should also involve strategies other than CBT, e. g. family interventions.

Regarding **evaluations** the low drop out and lost-to follow-up-rates in the first evaluations completed so far (PACE, EDIE) indicate that recent interventions for people at risk of developing psychosis which include CBT are feasible and acceptable to clients. Moreover, the first studies indicated at least some empirical evidence with regard to three possible aims of interventions for people at risk of psychosis: first, improvement of present possible pre-psychotic symptoms (Bechdolf et al. 2005a, 2005b; Morrison et al. 2004); second, prevention of social decline or stagnation (Bechdolf et al. 2005a, 2005b) and third, prevention or delay of progression to psychosis (McGorry et al. 2002; Häfner et al. 2004; Morrison et al. 2004). Even though these initial findings are encouraging, there are still several methodological limitations: (a) *Conclusions regarding the specific beneficial effect of CBT are limited* because (i) in all studies both experimental and control condition included elements of case management. Moreover, in the PACE trial additional antidepressant and benzodiazepine treatment was allowed. (ii) In all trials higher levels of attention can be observed for the experimental in comparison to the control condition. (iii) In the PACE study, treatment with CBT and anti-psychotics was combined, while in the FETZ trial psychoeducation and group therapy were combined with CBT in its narrow sense. (iv) No formal measure of treatment fidelity was employed in any of the trials. (v) As with most trials which include psychosocial interventions, it was difficult to achieve blindness of the ratings in all of the studies. (b) *Comparability between samples could be limited:* Although PACE and EDIE referred to the same concept of at-risk mental states, the transition rates in the respective control groups of the trials differed relevantly (PACE: 36 %, EDIE: 22 %). This could be due, in part, to the different operationalisations of the concept in the two centres (as mentioned above) or due to the lower non-consent rates in the EDIE trial as Morrison argued (2004). However, one has also to take into account that the EDIE sample may consist of less severely ill clients, which might be a consequence of, for example, the different pathways of referrals or of the fact that the different treatments offered attract different populations. (c) *Monitored cohorts were small:* Due to the comparably small number of participants in the trials, the transition of one or two individuals has strong impact on the overall transition rate within the study. In the EDIE trial, for example, the exclusion of two participants who, at the first post-randomisation assessment, reported having been psychotic at baseline. This results in highly relevant consequences, as the study would not have achieved significant results had they been included in the analyses. This shortcoming might be, in part, compensated in the FETZ trial (once completed), which aims at a comparably large sample size. But because there are lower transition rates expected in this population than in the other trials, this advantage will be probably

equalised. However, there is a need for methodologically stricter randomised trials in people at risk using larger sample sizes.

Conclusion

The first evaluations of recent psychological interventions for people at high risk of developing psychosis in RCTs are encouraging regarding the three possible aims of early intervention (improvement of present possible pre-psychotic symptoms, prevention of social decline or stagnation, prevention or delay of progression to psychosis). To date, however, due to various methodological problems, the empirical evidence supporting the presented approaches has to be qualified as preliminary. Although persons at risk are suffering from relevant clinical symptoms, are substantially compromised in psychosocial functioning as well as in quality of life, because the specificity of pre-psychotic syndromes is still ambiguous and the empirical evidence for intervening with at-risk populations is preliminary, caution must be taken to avoid unnecessary stigmatisation and false positives. Therefore, we believe that, to date, only clients who are help-seeking, worrying about their symptoms and wishing to receive treatment should be included in intervention efforts. These interventions should take place in a non-stigmatising and low threshold setting with special awareness of the needs of young people suffering from possible pre-psychotic symptoms. There are arguments to include CBT as a first line treatment in those intervention efforts. However, further predictive and therapeutic research is needed to judge whether psychological intervention is a realistic option for the treatment of people at risk of psychosis.

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