

treatments. But some proponents of psychotherapeutic medicine claim that the methodology of controlled clinical trials is generally inadequate for their subject. Moreover, such trials seem to create a selection bias, i.e., the resulting sample of patients will differ profoundly from the population of patients in the community. The central question is that of generalizability or external validity. Therefore, a precise analysis of the selection process is warranted. In a study of cognitive-behavioural treatment of people with schizophrenia (funded by the German Society of Research, DFG) we recruited patients according to the following criteria. Inclusion criteria: diagnosis of schizophrenic or schizo-affective psychosis; exclusion criteria: substance dependence or abuse, intellectual deficit, not German speaking. The most critical stage of selection represents the possible rejection of the study by patients and/or relatives. The reasons for rejection were documented. Treatment takers and non-treatment takers were compared according to their socio-demographic and psychopathological characteristics. Preliminary findings show that a great proportion of patients without any insight in psychosis reject their inclusion into the study. Men with little drug compliance are under-represented as compared to women. There is no difference according to psychopathology. These and further results will be discussed. There seem to be some limitations of the study concerning its generalizability, but these are only of minor relevance and have to be taken into consideration when interpreting the final results. Thus, there is no justification for any further generalizability problem in this study. The results of this study will be compared to the generalizability results of other studies in schizophrenia research (Schooler et al., Pietzcker et al., Wiedemann et al.).

## P02.246

### THE EFFECTS OF RESTRICTIVE DIET IN GLUTEN KASEIN SENSITIVE AUTISTIC PERSONS – (PILOT STUDY)

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A starting base for this research is found in the results of the research of Reichelt et al. (1997, 1998, 1999) which showed that a great number of autistic persons suffer hyperpeptiduria (casomorphin, glutomorphin and glyadinic peptidfraction) which is a reflection of hyperpeptidemia displaying exorphine activity affecting clinical expression in autism. This actually formed a theoretical frame for the existence of gluten-kasein sensitive autism. Consequently, the "appropriate" therapeutic approach (regardless of the mechanisms of the origin of hyperpeptidemia) would be a restrictive diet.

The authors present the results of the prospective (six months) pilot study, of following the effects of the restrictive diet in the group of 15 verified (Prof. Reichelt) gluten-kasein sensitive autistic patients. The follow (monitoring) was carried out by (especially devised scale for this research) scales for estimation of the behaviour communication of sociability, together with the standard clinical-standard research. The authors discuss the results obtained in the context of their efficiency (as regards the age, the duration of the diet, the autistic profile).

## P02.247

### QUALITY OF LIFE IN A DANISH SAMPLE OF SCHIZOPHRENIC INPATIENTS

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**Background:** We translated Lehman's Quality of Life Interview (QoLI) and the questionnaire TL-30 into Danish, and tested the

two instruments in a pilot study. Then we carried out the present study, in which the objectives were to measure quality of life in schizophrenic patients by different instruments.

**Design:** Schizophrenic inpatients (ICD-10 F20) were invited to participate. All patients were interviewed with Lehman QoLI and rated with BPRS. All patients were asked to complete quality of life questionnaires, namely the TL-30, the SF-36, and the WHOQOL-BREF, furthermore the Major Depression Inventory, MDI was used.

**Results:** In total 56 patients (23 females, mean age 39.8 (11.7) & 33 males, mean age 38.5 (10.4)) were included; 29 patients (13 females) refused to participate; 40 patients (18 females) were able to complete questionnaires. Significant correlation ( $p < 0.001$ ) were found between interview (QoLI) and questionnaire (TL-30) mean score for satisfaction with certain life domains. Mean score showed no differences between males and females in those life domains. Mean score in the SF-36 subscales showed no differences between males and females. Mean score were below the population norm in all subscales except 'physical function'. Quality of life BREF total score were low compared to the Danish population. Female patients 44 (15) (norm 72 (14)) and male patients 54 (21) (norm 74 (13)).

**Conclusion:** Schizophrenic patients reports relatively high satisfaction with subjective life domains. They reported fairly high health status except for vitality and role emotion. Compared to the Danish population these patients have low quality of life.

## P02.248

### MAJOR DEPRESSION AND PSYCHOLOGICAL WELL-BEING IN THE GENERAL DANISH POPULATION

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**Background:** The newly developed questionnaire Major Depression Inventory (MDI) based on both DSM-IV and ICD-10 criteria was used. MDI has shown acceptable validity using SCAN-interview as golden standard. The questionnaire Psychological General Well-Being (PGWB) was used to measure negative versus positive well-being.

**Methods:** Questionnaires were distributed to an age- and gender-stratified sample of 3,200 persons randomly selected from The Civil Register System. All participants received MDI, 1600 of the participants received PGWB.

**Results:** 2,139 completed MDI, i.e. a responding rate of 66.8%. Of these subjects 3.7% (males: 3.1%, females: 4.3%) fulfilled the criteria for major depression (DSM-IV), 2.9% (males: 2.3%, females 3.4%) fulfilled the criteria for moderate to severe depression (ICD-10). In total 1040 subjects completed both MDI and PGWB, i.e. a responding rate of 65.0%. Concerning positive well-being the five items WHO subscale was used, those having major depression had a mean score of 28.0 while people without major depression had a mean score of 69.6. This difference was significant ( $p < 0.0001$ ). Concerning negative well-being we focused on generalised anxiety, a high score meaning high degree of symptomatology. Those having major depression had a mean anxiety score of 58.4 while those without major depression had a mean anxiety score of 17.4, a significant difference ( $p < 0.0001$ ).

**Conclusion:** The prevalence of major depression is comparable to other studies, though the gender difference was not statistically significant. Major depression markedly influence on positive as well as negative well-being. The comorbidity between depression and generalised anxiety was demonstrated.