

A randomised clinical trial of the effect of five-years versus two-years specialised assertive intervention for first episode psychosis – the OPUS-II trial

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Previous finding

- The effects of OPUS treatment were clearly better than standard treatment (Petersen et al, 2005) 😊
- Five-years follow up show that many of the encouraging finding where not sustainable three-years after the patient ended the OPUS treatment (Bertelsen et al, 2008) ☹️
- - except that the patients who received OPUS treatment where able to maintain indepedended living (Bertelsen et al, 2008) 😊

A question to ask:

- Is it possible that extending the specialised assertive intervention service (OPUS) will allow the beneficial effects to continue, through consolidation of improved social and functional outcomes?

Duration of the OPUS treatment?

- The evidence for the duration of specialised treatment is lacking, and it is likely that two years of treatment is too short.

The critical period

It has been hypothesized that there is a critical period up to five years after onset of illness, where a long time course can be influenced – a window of opportunity.

(Birchwood et al, 1998).

Aim of the OPUS II - trial

To compare the effect of five-years versus two-years OPUS treatment.

Hypothesis

- It is possible to maintain the positive result of the intensive two-years OPUS treatment in another three years for those who keep receiving the specialized assertive intervention program (OPUS).

Design of the OPUS II trial

Randomised controlled clinical trial

- Comparing the effect of five versus two years of OPUS treatment
- Inclusion criteria:
- patients aged 18 – 37 years,
- First episode psychosis
- treated for at least 1½ year in the five OPUS teams in the Capital Region and
- the OPUS teams in Region Midt

Assessments

- SCAN (Schedule for Clinical Assessment in Neuropsychiatry)
- SAPS (Schedule for Assessment of Positive Symptoms)
- SANS (Schedule for Assessment of Negative Symptoms)
- Side effects and adherence to medications
- GAF + PSP (social function)
- WHO Quality of life Scale
- Client Satisfaction Questionnaire
- Life Chart Schedule
- Cognitive test (BACS)
- Working Alliance Inventory (WAI-c)
- Demographic data including educational, employment and housing status

Outcome measures

Primary outcome measure

- Simultaneous remission of psychotic and negative symptoms

Secondary outcome measure

- Psychotic symptoms
- Negative symptoms
- Substance abuse
- Users satisfaction
- Adherence to treatment
- Compliance with medication
- Suicidal behaviour
- Use of bed days
- Living independently
- Labour market affiliation

The criteria for remission

(level of symptoms sustained for three months)

Psychotic and negative symptoms:

None of the global measures of severity in SAPS (global scale for hallucinations, delusions, bizarre behaviour or thought disorder) and SANS (global scale for anhedonia, avolition, alogia and affective blunting) exceeds a value of 2 (2 = mild symptoms).

Design

The trial is pragmatic, all patients in the study are receiving OPUS treatment up to the randomization

The OPUS treatment:

- Multidisciplinary team,
- primary team member, caseload 1:10
- Flexible frequency of contact (weekly), home visits
- Psychoeducational multi family groups, social skills training
- Group interventions to aid with recovery
- Early warning signs monitoring relapse prevention and crisis plan
- Coordinate different institutions involved in the treatment of the patient. GP, somatic department, creditors and social services.

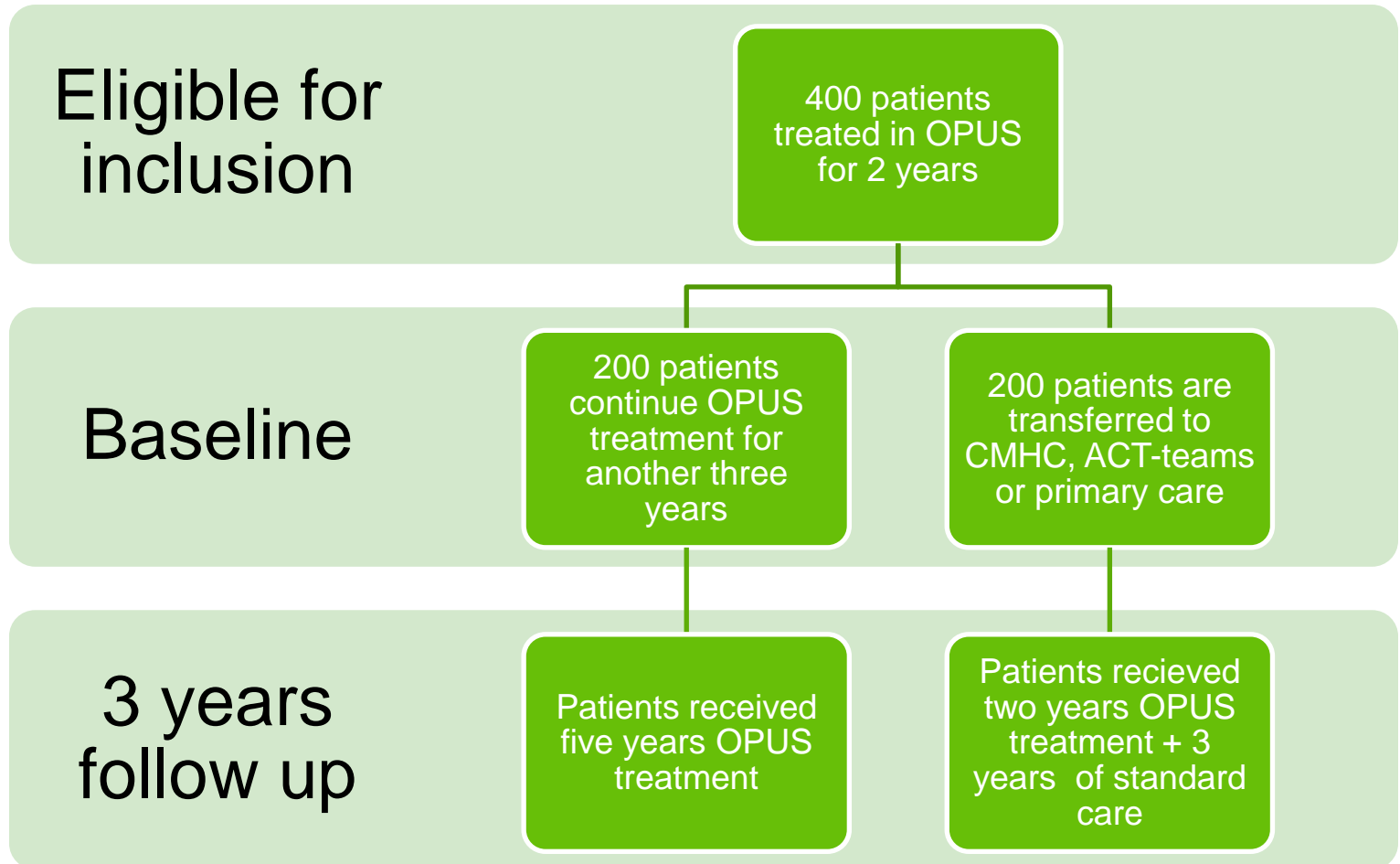
Intervention in the extension period

- **No change in primary team member** , caseload 1:15
- Still OPUS treatment tailored to meet the patients individual needs, incl. all group programmes available when indicated
- Minimum **one face to face contact each month** with their primary team member, and **at least one other contact** (e.g., telephone, mail).
- **Booster family psycho-education**
- No upper limits for the amount of treatment the individual patient and family may obtain.
- Staff will be employed to meet the extra needs for primary team members in the five years trial period

Control group

- The patients in control group are **transferred to standard treatment** after the ordinary two years of OPUS treatment
- The transition will be carried out **gradually** and **as gentle as possible**
- **Standard care** are usually treatment at a **community mental health centre**, where home visits are possible but office visits is the general rule.
- The caseload of staff members varies between 1:20 and 1:30 or more.

The extension OPUS II-trial flow chart



The patients experience of the core elements in the OPUS treatments?

- We want to explore the patients view on the OPUS treatment in general and particularly in relation to the alliance to the primary team member and to which elements in the treatment facilitating their motivation
- A questionnaire, WAI (n=400) and a semi-structured qualitative interview study (n=20) will be incorporated in this trial

The working alliance between the patients and their primary team member

- The patients are offered different kind of OPUS treatment to match their individuality
- They all got a primary team member as a minimum
- Primary team member has a key position
- The patients perspective on their relation to the primary team member and their working alliance might influence patients motivation to stay in treatment

Working Alliance Inventory, short form (WAI - C)

(A. O. Horvath, L. S. Greenberg, 1989)

- WAI-C is a self-report instrument for measuring the quality of alliance, patients perspective.
- 12 items, 3 sub-scales:
 1. Therapeutic bond
 2. Agreement on task
 3. Agreement about goals

Working Alliance Inventory - scale

The measure is based on E. Bordin's (1980) definition of alliance, consisting of three related components:

- Client and therapist agreement on goals of treatment
- Client and therapist agreements of how to achieve the goals (task agreement)
- Development of a personal bond between the therapist and client

Funding

- The Capitol Region and Region Midt, have offered to fund the inventions part of the trial, with 21 millions DKK during the five years the eksperimental part of the interventions last.
- The Danish Medical Research Council support the trial with 1.443.400 DKK, and
- The Ministry of Social Welfare contribute with 900.000 DKK to the investigating part of the trial



International collaboration

- The five OPUS teams in the Capital Region
 - The OPUS team i Central Denmark Region
 - Professor Ashok Malla, PEPP – project in Montreal, Canada
- and hopefully EPPIC, Australia – will join the extension trial collaboration

