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**Author(s):** Bergström, Tomi; Seikkula, Jaakko; Alakare, Birgitta; Mäki, Pirjo; Köngäs-Saviaro, Päivi; Taskila, Jyri J.; Tolvanen, Asko; Aaltonen, Jukka

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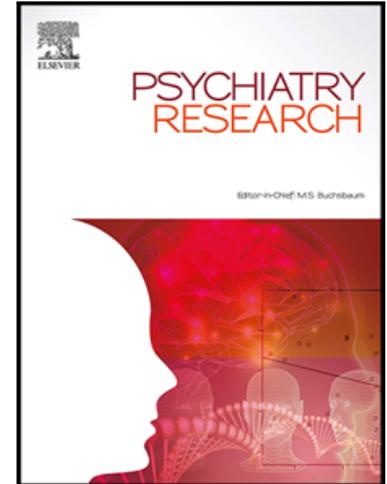
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## Accepted Manuscript

The family-oriented Open Dialogue approach in the treatment of first-episode psychosis: nineteen-year outcomes

Tomi Bergström , Jaakko Seikkula , Birgitta Alakare , Pirjo Mäki , Päivi Köngäs-Saviaro , Jyri J. Taskila , Asko Tolvanen , Jukka Aaltonen

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**Highlights:**

- The long-term outcomes of a network-based treatment of psychosis were studied.
- The approach was associated with a decreased need for treatment, and with better work capability.
- Over decades, the outcomes were more sustained than with other FEP treatments.
- The approach showed no significant difference in its ability to prevent suicides.

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**The family-oriented Open Dialogue approach in the treatment of first-episode psychosis:  
nineteen-year outcomes**

Tomi Bergström\*<sup>a</sup>, Jaakko Seikkula<sup>a</sup>, Birgitta Alakare<sup>b</sup>, Pirjo Mäki<sup>c,d</sup>, Päivi Köngäs-Saviaro<sup>b</sup>, Jyri J. Taskila<sup>b</sup>, Asko Tolvanen<sup>e</sup>, Jukka Aaltonen<sup>a</sup>

<sup>a</sup> Department of Psychology, University of Jyväskylä, Jyväskylä, Finland

<sup>b</sup> Department of Psychiatry, Länsi-Pohja healthcare district, Kemi, Finland

<sup>c</sup> Department of Psychiatry, Research Unit of Clinical Neuroscience, University of Oulu, Oulu, Finland

<sup>d</sup> Department of Psychiatry, Oulu University Hospital, Oulu, Finland

<sup>e</sup> The Methodology Center for Human Sciences, University of Jyväskylä, Jyväskylä, Finland

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\*Correspondence author:

phone: +358400 986486

Email: tomi.bergstrom@lpshp.fi

## The family-oriented Open Dialogue approach in the treatment of first-episode psychosis: nineteen-year outcomes

### Abstract:

*Open Dialogue* (OD) is a family-oriented early intervention approach which has demonstrated good outcomes in the treatment of first-episode psychosis (FEP). Nevertheless, more evidence is needed. In this register-based cohort study the long-term outcomes of OD were evaluated through a comparison with a control group over a period of approximately 19 years. We examined the mortality, the need for psychiatric treatment, and the granting of disability allowances. Data were obtained from Finnish national registers regarding all OD patients whose treatment for FEP commenced within the time of the original interventions (total  $N=108$ ). The control group consisted of all Finnish FEP patients who had a follow-up of 19–20 years and who were guided to other Finnish specialized mental healthcare facilities ( $N=1763$ ). No difference between the samples was found regarding the annual incidence of FEP, the diagnosis, and suicide rates. Over the entire follow-up, the figures for durations of hospital treatment, disability allowances, and the need for neuroleptics remained significantly lower with OD group. Findings indicated that many positive outcomes of OD are sustained over a long time period. Due to the observational nature of the study, controlled trials are still needed to provide more information on effectiveness of approach.

**Keywords:** schizophrenia; family therapy; long-term follow-up; mortality; hospital admission; disability pension; work capability, antipsychotics

### 1. Introduction

Schizophrenia and other psychoses represent a complex phenomenon, characterized by a wide variety of phenotypic expressions, courses, and outcomes. The heterogeneous nature of psychoses has challenged the development of optimal treatment strategies (Alanen, 2009). In response to this challenge, recent decades have witnessed more studies on preventive early intervention and integrative treatment practices (Bird et al., 2010). One example of such practices is the psychotherapeutically-oriented *needs-adapted approach* (NAA), developed in the context of the Finnish *Turku project* and *National Schizophrenia project* (Alanen et al., 1991). In these projects, the treatment of schizophrenia group psychoses was seen as a continuous process in which different treating methods are combined to meet the therapeutic needs of each individual patients as well as their social networks (Alanen, 2009).

NAA has since been applied and studied in several multi-center programs, including the national *Acute Psychosis Integrated Treatment* project (API), conducted in six Finnish psychiatric catchment areas in the early 1990s (Lehtinen et al., 2000). In one catchment area, consisting of the western parts of Finnish Lapland, the NAA was further modified. Constant on-the-job psychotherapy training was included within it; moreover, there were several research programs which had commenced before API (Keränen, 1992; Seikkula, 1991), and which continued locally thereafter, namely the *Open Dialogue in Acute Psychosis* (ODAP I and ODAP II) projects (see Seikkula et al., 2011). By the mid-1990s, a process of gradual development had led to a new way to organize the entire psychiatric treatment system within the area, based on seven principles (Figure 1). The model is hereafter referred to as the *Open Dialogue* approach (OD) (Aaltonen et al., 2011; Seikkula et al., 2011).

[Insert figure 1 here]

The primary goal in the NAA and OD programs has been to create a comprehensive, psychotherapeutically-oriented model of treatment within the psychiatric public health sector, to address the real and changing needs of (in particular) first-contact schizophrenia patients, plus their families (Aaltonen et al., 2011). In Western Lapland, attempts have also been made to apply the NAA and the principles of OD in all psychiatric treatment conducted in the region, regardless of the diagnosis. The primary aim has been to create low-threshold- and family-oriented treatment system which promotes the reciprocal open dialogues between patients, the persons in their closest networks, and mental health workers, seeking thus to ease the accessibility of mental health services and to create a shared understanding of each situation (Seikkula et al., 2006).

Outcome studies on both OD (Seikkula et al., 2006; Gordon et al., 2016) and NAA (Lehtinen et al., 2000) indicate that with low-threshold- and integrative family-oriented treatment of first-episode psychosis, the total recovery rates are often better than those with treatment-as-usual. For example, two- and five-year non-randomized follow-up studies conducted in Western Lapland showed that with OD there is a decrease in both the overall need for psychiatric treatment and the incidence of residual psychotic symptoms (Seikkula et al., 2011). In addition, after two years from onset, only 33% of the patients were using neuroleptics, and 84% had returned to full-time employment or studies (Seikkula et al., 2006).

However, in the absence of controlled trials, it remains unclear which aspects of the intervention are significant, given that OD integrates diverse elements that have been proven to be potentially beneficial in the treatment of psychosis (Pavlovic et al., 2016). These include, for example, early-stage family interventions (Marshall and Rathbone, 2011), with a shortened duration of untreated psychosis (Farooq et al., 2009), and increased therapeutic alliance (Laska and Gurman, 2014). Improved treatment outcomes have also been observed in other early and comprehensive intervention systems (Cullberg et al., 2006;

Kane et al., 2015; Granö et al., 2016). Nevertheless, regarding the *long-term outcomes* of early intervention practices in the treatment of psychoses, research has been limited, and contradictory results obtained. For example in the Danish *OPUS* trial (Secher et al., 2015), and in the *Lambeth Early Onset* study (Gafoor et al., 2010), the improved treatment and symptom outcomes were not found to be sustained at five years from onset.

In the present register-based cohort study, the aim was to evaluate the stability of OD outcomes in the treatment of first-episode non-affective psychosis (FEP), at an average of 19 years from onset. The more specific aims were: (i) to compare mortality rates and causes of deaths between the Western Lapland research cohort (Open Dialogue group (OD)) and a control group (CG), the latter being formed from patients whose treatment commenced in all other public sector psychiatric catchment areas; (ii) to compare the use of psychiatric services and disability allowances granted from the times of onset to the end of the follow-up; and (iii) to compare and evaluate OD and CG with regard to temporal changes in the need for hospital treatment and disability allowances over the entire follow-up period.

## 2. Methods and material

### 2.1. Design and context

The research data for this study were collected as part of the project called *Open Dialogue long-term outcomes in a naturalistic setting (ODLONG)*. The primary aim in the project was to evaluate the long-term outcomes of OD treatment with reference to Finnish national registers. Finland is a northern European country with a population of 5.5 million in 2017. The population has been considered to be both culturally and ethnically homogeneous (see Hovatta et al., 1997). During the 1990s roughly 90% of the population were Finnish-speaking Lutheran Finns. The figures were similar within the Western Lapland catchment area.

#### 2.1.1. The Finnish healthcare system

The healthcare system in Finland is publicly funded, and municipalities throughout the country are responsible for providing healthcare to all residents. Patients with severe mental health problems, including psychosis, are usually guided from primary care to a more specialized secondary healthcare system provided by 21 regional hospital districts. Hence, acute psychosis is usually treated in a hospital setting, with neuroleptics as the cornerstone of treatment in both acute and maintenance treatment (Kiviniemi, 2014).

Even though there have been attempts to integrate family therapeutic interventions with the Finnish public healthcare system, it appears that in the mid-1990s there were no other centers implementing an OD-like network-based treatment model, with 24-hour low-threshold mobile crisis intervention teams, and

guaranteed continuity of treatment between in- and outpatient clinics, covering the entire regional public healthcare system. Note also that the dialogical stance in treatment meetings has been viewed as a more collaborative way of working than that which would occur in most clinician-patient interactions (Razzaque and Stockmann, 2016). It should nevertheless be borne in mind that there could have been both resource- and culture-related differences in treatment practices between and within Finnish hospital districts (see Pirkola et al., 2009); hence, the control group in this study represents on merely a general level how treatment was initiated outside the Western Lapland catchment area.

### 2.1.2 Western Lapland catchment area

The Western Lapland catchment area consists of the south western part of Finnish Lapland. The population of the area has fallen from 72 000 in 1995 to 63 000 in 2016, reflecting the national trend whereby education and job opportunities have been centered in the larger cities. The hospital district in the area consists of five municipal outpatient clinics and one psychiatric hospital (Keropudas hospital), which is in charge of all psychiatric inpatient treatment in area. At the time of the original implementation of OD in the 1990s, all mental health units in the area participated in the development of treatment by setting up case-specific mobile crisis intervention teams. In addition, 75% of the staff in the area participated in three-year on-the-job training in family therapy, or in psychodynamic individual psychotherapy.

Since then, the figure has fallen, due to generational shifts and changes in the Finnish psychotherapist training system. In addition, during the 2000s most of the outpatient clinics in the area were separated from the hospital district, operating now under the municipalities, which has decentralized the regional treatment system. Since these changes might have challenged the maintenance of a comprehensive treatment system over the whole region, this paper focuses only on the long-term outcomes of psychosis treatment that commenced under OD at the time of its original implementation.

### 2.2. Cohorts and data sources

The *Western Lapland research cohorts* used in this study consisted of FEP patients who were guided to in- and outpatient specialized mental healthcare units operating in the Western Lapland healthcare district within two specific research inclusion periods. The projects in question were *API* (from January 1<sup>st</sup>, 1992 until March 31<sup>st</sup>, 1993), and *ODAP I* (from January 1<sup>st</sup>, 1994 until March 31<sup>st</sup>, 1997). In forming the *control group*, the aim was to include all Finnish non-affective FEP patients with a similar follow-up of 19–20 years, whose first psychiatric treatment commenced outside the OD catchment area (meaning that the FEP treatment commenced outside the area within which a family-oriented Open Dialogue approach has been systematically developed and extensively applied).

Because psychosis is a rare problem and the Western Lapland catchment area is small, movement of even a single patient between categories may affect statistical significance. In order to increase the statistical power and reliability of the analyses, the Western Lapland research cohort was supplemented by data from a third research inclusion period with a shorter follow-up (ODAP-II: from February 1<sup>st</sup>, 2003 until December 31<sup>st</sup>, 2005 ( $N=27$ )).

The information was obtained from the following data sources:

1. The Finnish *Care Register of Health Care* (CRHC), and the *Register of Primary Health Care Visits* (RPHCV) provided by the *National Institute for Health and Welfare, Finland* (THL). The first of these (the formerly Finnish Hospital Discharge Register) consists of information on all hospital admissions since 1969, plus outpatient treatment conducted in Finnish specialized healthcare units since 1998. The second provides information on all treatment given in the primary healthcare system since 2011, including municipal mental healthcare units.
2. *The register of disability pensions and reimbursed medicines*, provided by the *Social Insurance Institution of Finland* (SII). This register contains information on all disability allowances (full or partial disability pensions, and cash rehabilitation benefits granted due to decreased work capacity caused by schizophrenia and/or other psychoses); it also states all purchases for reimbursed medicines (based on Anatomical Therapeutic Chemical (ATC) classification).
3. *The national cause-of-death register* provided by *Statistics Finland* (SF). This register contains information obtained from the death certificates issued by physicians, including the time and specific cause of death.
4. *Local medical records* (LMR). This information can be obtained from the specialized healthcare units of Western Lapland healthcare districts, and from the five municipal mental healthcare outpatient clinics operating in the area. They contain everyday clinical notes and case histories, including specific information on all treatment conducted in the Western Lapland catchment area, from baseline to 2015.

The study design was reviewed and approved by the ethical committee of the North Ostrobothnia hospital district. Further permissions were granted by Länsi-Pohja healthcare district (including five municipalities), Finnish National Institute for Health and Welfare, The Social Insurance Institution and Statistics Finland. All identification information was replaced with personal identification numbers, which were also used to link data across registers. Note that more comprehensive and detailed descriptions concerning the OD and the interventions applied to cohorts are presented elsewhere (Aaltonen et al., 2011; Seikkula et al., 2011).

## 2.3. Samples and inclusion criteria

### 2.3.1. The experimental group (OD)

The experimental group (OD) for this study was formed from research cohorts of the *Western Lapland catchment area*. The following inclusion criteria were applied:

- (i) The first treatment contact in the area with non-affective psychosis diagnosis (ICD-9-codes=295–295.9 and 297–298.9; ICD-10-codes=F20–29.1), occurred during the three inclusion periods (1992–1993, 1994–1997, 2003–2005), within which OD principles were reported as having been applied in the treatment, as part of the original intervention studies.
- (ii) The individuals had not received any mental health treatment prior to the inclusion period in question.
- (iii) The individuals were aged 16–50 at onset.

From the original research cohort of 116 people, three individuals were excluded from this study because they had received psychiatric treatment before the inclusion period; furthermore, the identification numbers for five individuals were unobtainable. Thus, the experimental group for this study was formed from a total of 108 people from the Western Lapland research cohorts. The observational period (onset to 2015) was from 10 to 12 years for people whose first onset occurred in 2003–2005 (20%), and from 18 to 23 years for people whose first onset occurred in 1992–1997 (80%). The average follow-up time was 19 years (MD=20, SD=4).

After identification of the persons to be included in the study, their residential history and mortality rates were obtained from the *Finnish Population Register Center* databases. The information concerning psychiatric treatment was obtained from LMR for people who had lived continuously in the area of Western Lapland ( $N=60$ ), and from CRHC and RPHCV for people who had moved away ( $N=37$ ), or who had died ( $N=11$ ) within the follow-up period (1992–2015). Information concerning disability allowances, medication purchases, and cause of death was obtained from SII and from cause-of-death-registers for the entire experimental group ( $N=108$ ).

### 2.3.2. The control group (CG)

The control group (CG) for this study was formed from the registers mentioned above, on the basis of the following inclusion criteria:

- (i) The first treatment contact in the Finnish public specialized healthcare system with non-affective psychosis diagnosis (ICD-9 codes=295–295.9 and 297–298.9; ICD-10 codes=F20–29.1), occurred between January 1, 1995 and December 31, 1996.
- (ii) The individuals had not received any psychiatric specialized healthcare and medical treatment or disability allowances for a mental health disorder prior to 1995.
- (iii) The treatment was initiated and conducted *outside* the Western Lapland healthcare district area.
- (iv) The individuals were aged 16–50 at onset.

There were 1763 people who had received treatment for first-episode psychosis in the period 1995–1996, and who fulfilled the other inclusion criteria. After identification of persons for the CG, information from the CRHC register was obtained concerning their demographic and diagnostic characteristics, and their use of psychiatric services, from the start of 1995 to the end of 2015. Information was obtainable on the outpatient treatment conducted in primary healthcare centers only from 2011 to the end of 2015 (RPHCV, see above). Information on disability allowances, medication purchases, and cause of death for the period 1995–2015 was obtained from the SII and cause-of-death registers.

## 2.4. Outcome variables

### 2.4.1. Demographics

Gender, age at onset, and GAS (*Global Assessment Scale*) scores were obtained from CRHC for CG, and from LMR for OD. GAS scores were rated and registered at onset by a member of the treatment staff, following a standard procedure used in Finnish healthcare units. Diagnostic information was obtained from the CRHC, SII, and LMR registers. For comparative purposes, the diagnosis was determined to be schizophrenia (i.e. prolonged and more severe psychosis), if the individual was noted as having one or more entries with a schizophrenic psychosis (ICD-9 codes: 295–295.9; ICD-10 codes: F20–20.9) within the first year from onset. The diagnoses were set (as a standard procedure by physicians in their everyday clinical practice) on the basis of the ICD-9 criteria prior to the year 1996. Thereafter, the ICD-10 criteria were applied. In the API and ODAP I projects, the reliability of the diagnosis was further evaluated by an independent psychiatrist ( $K=.453, p=.002$ ).

### 2.4.2. Clinical characteristics

The clinical characteristics in the two samples, from onset to 2015, were analyzed by combining information from all the registers. The following outcome variables were formed:

1. *>30 hospital days* (According to the CRHC and LMR registers, the total time spent in hospital within the follow-up was over one month.)
2. *Re-admissions* (*yes*=two or more hospital admissions within the entire follow-up, according to the CRHC and LMR registers. The total number of hospital admissions that occurred within the follow-up period, and the length of each admission, were obtained from either the CRHC or the LMR register. New entries caused by hospital transfers were combined with the initial admission.
3. *Treatment contact at the end of follow-up* (*yes*=one or more outpatient visits in 2015 to a specialized or primary mental healthcare clinic, or one or more hospital days in 2015, according to the CRHC, RPHCV, and LMR registers).

4. *Neuroleptics at (a) onset, (b) at some point, (c) at the end of follow-up* (yes=one or more purchased neuroleptics according to SII, or neuroleptics used during hospital treatment, according to the CRHC and LMR registers (a) within the first month from onset, (b) at some point, (c) in 2015).

5. *Disability allowance at (a) some point, and (b) at the end of follow-up* (yes=according to SII, one or more days spent on a partial or full-time disability allowance granted due to decreased work capability caused by mental health problems, (a) at some point, (b) in 2015. From SII we obtained the start and end dates for each disability allowance (a full or partial disability pension, or a cash rehabilitation allowance) granted within the follow-up for mental health problems (meaning that according to the medical certificate the individual's work capacity was determined to be partially or fully decreased due a diagnosed mental health disorder). The total time spent on disability allowances within the observation period was calculated by summing the differences between the start and end date for each entry.

To evaluate the temporal changes in the use of psychiatric services and in disability allowances from onset to 2015, hospital admissions ( $N$ ), hospital days, and the duration of the disability allowance (years) were each compressed to four sum variables matched with specific time frames (the first five years from onset, years 6–10, years 11–15, and after 15 years from onset).

## 2.5. Statistical analysis

The differences in mortality rates and causes of death between the groups were analyzed via Pearson's chi-square test, and by calculating the standardized mortality ratios (SMRs) for each group against the age and gender-specific risk ratios of death among the general Finnish population (obtained from the SF public register). The group differences in categorical variables between OD and CG were analyzed using cross-tabulation and Pearson's chi-square test. Temporal changes in hospital admissions, hospital days, and the duration of disability allowances were analyzed using the nonparametric Friedman test (the data were positively skewed). The Mann Whitney  $U$ -test was then applied in order to analyze the differences between OD and CG. Prior to the analyses, outliers were detected using Tukey's method; hence, all values higher than  $Q3+1.5(Q3-Q1)$  (where  $Q3$ =upper quartile,  $Q1$ =lower quartile) were excluded from the statistical analyses (see Table 3). The level of statistical significance was defined as a  $P$  value equal to or less than 0.05.

## 3. Results

### 3.1. Demographic characteristics and group differences at onset

The annual crude incidence rate\* of FEP which required specialized public healthcare treatment, and which met the other inclusion criteria averaged 17.9/100 000 persons for OD and 17.5/100 000 persons for CG.

There were no significant differences in gender, diagnoses (schizophrenia vs. other psychoses), and GAS scores at onset (Table 1). In this regard, the two groups can be considered comparable with each other.

[insert Table 1 here]

However, there were statistically significant differences in age, and in the way in which the patients were guided to treatment. Thus, the patients in the CG were older and more likely to have undergone involuntary admission at onset than those in OD (see Table 1). Another issue was that basically all the patients in the CG were admitted to hospital at least once, whereas in the OD, 30% underwent all treatment in an outpatient setting. This possible selection bias was associated with the data sources: concerning outpatient treatment, there are no reliable national registers in Finland prior to the year 2011. This means that the CG data were obtainable only from FEP patients with one or more admissions, in which case overall symptom severity at onset might have been higher in CG than in OD.

It was recognized that these differences – as well as the variations in the length of follow-up – might cause statistical bias. To address these issues, additional analyses were conducted via demographically (samples matched randomly with age- and the length of follow-up) and clinically (only persons with a schizophrenia diagnosis, and one or more hospital admissions included) matched samples. The potential effect of confounding variables was further evaluated via logistic regression analysis.

Because the results from the additional analyses did not differ from the results obtained from the samples as a whole (see online data supplements), and because all of these aspects (i.e. a lower threshold, earlier detection of psychosis, and emphasis on outpatient treatment) might in part be a consequence of the early-intervention practice itself, in the following paragraphs the outcomes are reported with reference to the complete CG and complete OD samples.

\**N* of new cases/year divided by the population of Western Lapland in 1992–2005 (*N*=72 000–65 000) for OD and population of rest of Finland in 1995–1996 (*N*=5 044 826–5 060 320) for CG

### 3.2. Mortality

296 (16.8%) patients from CG, and 11 (10.2%) patients from OD died within the follow-up period. The difference in mortality was not statistically significant (Table 2), although when calculated against the Finnish standard population, the SMR was slightly higher in CG than in OD (3.4 vs. 2.9). In the entire sample (OD+CG), most of the deaths (55%) occurred within ten years from onset, with suicide emerging as the most common cause (31.4% of all deaths). In CG, accidents comprised the second most common cause of death (16.7%), followed by cardiovascular diseases (14%), and cancers (12%). In OD, cancer was the second most common cause of death (18% of all deaths). No significant difference was observed in the total suicide rates between the two groups (Table 2). In CG, more people died from natural causes (illness and/or

another internal malfunction of the body) compared to OD, though when adjusted for age, the finding was not statistically significant (see online data supplements).

[insert Table 2 here]

### 3.3. Clinical characteristics from onset to the end of the follow-up

[insert Table 3 here]

Significantly more people from CG received neuroleptic medication at onset and spent over one month in a hospital over the entire follow-up (Table 3). Almost all the patients in the CG group (97.3%) received neuroleptics at some point in their treatment. By contrast, in the OD group, 46% were treated completely without neuroleptics, with 36% on medication at the end of the follow-up as compared to 81% in CG. At the end of follow-up, more patients from CG than from OD were still receiving psychiatric hospital or outpatient treatment, and also disability allowances due to mental health disorders. In addition, the CG group showed higher re-admission rates from baseline to the end of follow-up. Further statistical modeling indicated that initial administration of treatment *outside* the OD significantly predicted ongoing treatment (adjusted odds ratio (OR)=2.2; 95% CI=1.3–3.7), neuroleptic medication (OR=7.1; 4.3–11.8), and disability allowances (OR=2.6; 1.6–4.3) at the end of follow-up. The results remained statistically significant when potential confounders were adjusted (see online data supplements).

### 3.4. Temporal changes in hospital treatment and disability allowances, from baseline to the end of follow-up

[insert Table 4 here]

In both groups, there was a significant decrease in hospital admission rates ( $\chi^2=2341$ ,  $p<.001$ ) and in hospital days ( $\chi^2=2469$ ,  $p<.001$ ) over the four time periods (Table 4). By contrast, in both groups there was a significant increase in the average duration of disability allowances ( $\chi^2=760.6$ ,  $p<.001$ ). The admission rates ( $U=44140$ ,  $p<.001$ ), time spent in hospital ( $U=24538$ ,  $p<.001$ ), and the durations of disability allowances ( $U=46849$ ,  $p<.001$ ) were significantly lower in OD than in CG for all the time periods.

## 4. Discussion

The aim of this cohort study was to evaluate the long-term outcomes of the family-oriented Open-Dialogue approach (OD) in the treatment of first-episode non-affective psychosis. This was done by comparing OD treatment's outcomes with first-episode psychosis treatment initiated outside the OD catchment area 19–20 years ago, with reference to mortality rates, and the need for psychiatric services and disability allowances. The results indicated that with treatment commenced under OD as compared to controls, the overall need for hospital and neuroleptic treatment, and also the time spent on disability allowances, was

significantly lower in a follow-up of approximately nineteen years. These findings are in line with earlier studies on OD (Seikkula et al., 2006; 2011), and also with another register-based study with 5-year follow-up, which included all Finnish first-onset schizophrenia patients between 1995 and 2003 (Kiviniemi, 2014). In that study the Western Lapland catchment area presented the lowest figures for the durations of hospital treatment and disability pensions when compared to other Finnish healthcare districts.

As both groups showed a reduction in hospital treatment and an increase in the average time spent on disability allowances, it is important to note that within the OD cohorts, too, some people needed more psychiatric treatment than others. In a previous study it was observed that when more threatening behavior occurred, there could be difficulties in maintaining the dialogical approach and in applying the OD treatment principles favoring outpatient treatment and the selective use of neuroleptics (Bergström et al., 2017). The association between poorer outcomes and difficulties in organizing OD treatment has been reported previously (Seikkula et al., 2001). Note that since OD implementation took place in everyday clinical practice, it is possible that in some cases, difficulties in applying and maintaining the open dialogue occurred independently of patient-related factors.

Another issue concerns suicide rates, which were high in both groups. Overall, the results indicated that the suicide rate under the OD condition remained at a high level; in fact, it was the only variable in which no favorable change occurred when compared to controls. This was also observed in another Finnish study where the suicide rates of schizophrenia patients in Western Lapland whose treatment commenced in 1995 were above the median, while total mortality remained below the median (Kiviniemi, 2014). Then again, in one study it seemed that overall suicide rates in area remained below the median when compared to other parts of Finnish Lapland (Pirkola et al., 2009). Nevertheless, the figures underline the importance of developing treatment systems in such a way as to guarantee a safe environment.

Even though the treatment outcomes were not always clear-cut, there are some indications that long-term outcomes were more favorable with OD. Due to the observational nature of the study, it is not possible to directly evaluate the causal relations, or the specific elements in the OD treatment that might have brought about more favorable outcomes. Nevertheless, some possible factors deserve mention. In the first place, it is possible that the systematic provision of immediate help in psychotic crises, plus the guaranteed continuity of treatment between in- and outpatient settings, are beneficial in dealing with life-crises and other acute stress factors. The measures taken in OD could ease the difficulties that occur when there are breaks in treatment contact and in decision making, or when the treatment is restarted with staff who are unfamiliar with the patient's specific situation. The results here are in line with other studies, in which better treatment outcomes have been observed in integrative early-intervention systems for acute psychosis (Lehtinen et al., 2000; Cullberg et al., 2006; Granö et al., 2016).

Secondly, the OD principles concerning the tolerance of uncertainty, and of having open dialogues (see Figure 1) between staff, patients, and their close networks, could tend to break down the traditional expertise hierarchy, within which mental health professionals are led to provide treatment in an objectifying manner. In this way, OD could hypothetically shift the entire treatment process onto a more equal footing, with an emphasis on the patient's own agency and subjective expertise regarding the situation. In some cases this could encompass possibilities to approach psychotic crises in a more empathic and respectful manner – which has been proposed as one of the common factors in all psychotherapeutic processes (Laska et al., 2014). In addition, the shift from a traditional one-way type of interaction to more open dialogues gives opportunities for the creation of a new kind of understanding between staff, patients, and their close networks concerning the current situation. This makes it possible to plan the treatment in such a way as to meet the case-specific needs of each patient, and may itself reduce psychotic symptoms by increasing mutual trust (Aaltonen et al., 2011), and by offering a shared language and meanings for difficult experiences within the patient's natural networks and environments (Holma and Aaltonen, 1998; France and Uhlin, 2006).

Thirdly, in recent decades, traditional views of psychosis as a symptom of underlying or progressive brain disease have been questioned (Cooke et al., 2014), with new evaluations of the role of psychosis in wider social contexts and in a variety of life crises (Beard et al., 2013; Lindgren et al., 2017; Mansueto and Faravelli, 2017). Viewed in this light, many psychotic states can be interpreted as reactions to difficult life situations and/or traumatic events rather than as symptoms of biological disorders (Holma and Aaltonen, 1998; Read et al., 2005). In line with this, some authors have proposed that in certain cases neuroleptic medication could block psychological mechanisms that are essential for remission (Whitaker, 2004). In OD, the more selective use, and possible postponement of neuroleptic medication may give opportunities for the psychotic crises to progress along a more natural trajectory with an adequate sense of mutual trust and security, and this might have a favorable impact on the outcome. Our results are in line with other follow-ups, in which it was found that long-term treatment outcomes for the schizophrenia-spectrum population were more favorable with samples receiving less medication (Joukamaa et al., 2006; Wunderink et al., 2013; Harrow et al., 2014; Nykänen et al., 2016; Harrow et al., 2017).

Finally some limitations in the study should be addressed. First of all, the residual psychotic symptoms, the use of medication and the patients' current ability to function could not be directly evaluated, since the registers formed the only source of data. Moreover, both samples covered mainly non-affective psychoses, occurring among persons who were guided to the specialized healthcare system. On a more general level, the issues here apply to observational and naturalistic study designs as a whole. It is possible that selection bias could have existed, and/or that there could have been other unreachable variables affecting the course of psychosis, and the need for psychiatric services. Moreover, the lack of the kind of standardization

(in for example the diagnosis) that one would find in more experimental settings has implications for comparability. It should be noted that even though register-based cohort studies can in some cases offer more generalizable information concerning real-world outcomes (Saturni et al., 2014), standardized and randomized trials are still needed to evaluate the causalities and effectiveness of a given practice.

In the present study, the fact that there were two groups coming from different regions of Finland, with possible regional differences could have impacted the findings. It can be argued that this was compensated by the long follow-up time, with minimal loss. On a general level the long follow-up of the same individuals reduce the probability that observed differences are consequence of cultural-, regional- or time-related factors. Furthermore the use of national registers made it possible to gather information even when individual had moved away from OD catchment area within the follow-up, which potentially have reduced the bias followed by the regional differences. It has also been noted that in Finland the variations in racial and socio-economic status are very small, and it is therefore unlikely that these factors will cause significant bias to this kind of a register studies (Kiviniemi, 2014).

Some of the limitations were compensated by the inclusivity of the samples. As implementation of OD covered the whole regional area and thus all people with first-onset psychosis, the aim was to include *all* non-affective FEP patients who were guided to treatment in Finland within a specific time frame in order to reduce the non-randomization bias. The results indicated that this goal was at least partly achieved: there were no significant differences between the samples regarding the annual incidence of FEP, or in demographic and clinical baseline characteristics including both the diagnoses and the social, occupational, and psychological functioning evaluated with GAS. Exception to this was age and the way in which patient were guided to treatment at onset, both of which might have been due to the earlier detection of FEP, as is typical in OD-like early-intervention systems where goal is to provide low-threshold and mobile treatment in order to ease the accessibility of health services and decrease the need of hospitalization. As these differences, and especially the over-representation of hospitalized patients in the CG might still cause statistical bias, additional analyses were conducted with matched samples and with stronger control of confounding variables.

Overall, the results gave some indications that by investing in long-term and gradual developmental efforts, in conjunction with integrative and psychotherapeutically-oriented interventions for first-episode psychoses, it is possible in some cases to achieve a long-lasting and stable reduction in hospital admissions and in medical treatment, in addition to better preserved work capability. Nevertheless, due the naturalistic study design, the specific ingredients that might have led to more favorable outcomes could not be determined with certainty. Furthermore, the present study does not indicate how far the treatment culture has been preserved in the area since the original interventions – the point here being that one

cannot know how the research projects (conducted in the 1990s and early 2000s) themselves led to more favorable outcomes. It is possible that the research conducted in everyday clinical settings encouraged staff to observe their own work more closely, and there could have been benefits from greater treatment efforts, on-the-job psychotherapy training programs, and constant supervision activities. In the future, the aim would be to have better standardization of the different intervention and treatment variables, with more precise evaluations of outcomes.

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### **Declaration of interests**

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**1. Immediate help.** The first meeting will be arranged within 24 hours of the first contact; the aim is to integrate outpatient treatment as soon as possible with the patient's everyday life, and to prevent hospitalization if possible. In addition to this, a 24-hour crisis service will be set up.

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**2. A social network perspective.** Family members and other relevant members of the patient's social network will always be invited to the meeting, in order to mobilize support for the patient and the family. In addition to families, key members of the patient's social network can include other authorities, fellow workers, neighbors, or friends.

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**3. Flexibility and mobility.** The aim is to adapt the therapeutic response to the specific needs of each person, using the therapeutic methods that best suit each situation. The first meeting will often be organized at the patient's home.

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**4. Responsibility.** Whoever among the staff is first contacted will become responsible for organizing the first network treatment meeting, within which decisions will be made on the continuation of treatment and on the case-specific team responsible. The team will take charge of the entire treatment process.

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**5. Psychological continuity.** The team will be responsible for treatment for as long as necessary, in both the outpatient and the inpatient setting.

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**6. Tolerance of uncertainty.** In addressing psychotic crises, meetings will be arranged in as quick succession as possible, in order to generate an adequate sense of security for the joint process. It is imperative that decisions on treatment and premature conclusions should be avoided at the crisis phase;

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also that neuroleptic medication should not be introduced at the initial meeting, and should only be started if other efforts prove insufficient. In psychotic crises, efforts should be made to arrange meetings every day, at least for the first 10–12 days, in order to avoid premature conclusions and treatment decisions.

**7. Dialogue.** The focus in the treatment should be on promoting an equal dialogue between the patient, his/her close networks, and treatment staff. The aim within the dialogue is primarily for patients and families to increase their sense of agency in their own lives, and secondarily, to induce change in the patient or in the family. A shared understanding of the situation can thus be constructed between the participants within an open dialogue. All issues should be discussed openly, in the presence of all persons.

Figure 1. The seven treatment principles of Open Dialogue approach (OD)

Table 1. Demographic and clinical characteristics at onset

	OD <sup>a</sup> (N=108)	CG <sup>b</sup> (N=1763)	Statistics	<i>p</i>
Age (years)			<i>U</i> =57812	<b>0.00</b>
M	25.3	30.5		
MD	25	30		
SD	7.1	8.8		
GAS scores			<i>U</i> =75920	0.75
M	35.09	35.04 <sup>c</sup>		
MD	35	35		
SD	11.5	12.1		
Gender			$\chi^2=.001$	0.98
Male	57.4%	57.6%		
Diagnosis			$\chi^2=.001$	0.92
Schizophrenia	52.8%	53.3%		
Start of treatment			$\chi^2=23.4$	<b>0.00</b>
Involuntary <sup>d</sup>	26%	50%		

<sup>a</sup>Open Dialogue -group

<sup>b</sup>Control group<sup>c</sup>Missing *N*=162<sup>d</sup>Treatment commencing as involuntary was based on involuntary referral (by a doctor independent of the hospital).

Table 2. Mortality

	OD <sup>a</sup>	CG <sup>b</sup>	Statistics	
	( <i>N</i> =108)	( <i>N</i> =1763)	$\chi^2$	<i>P</i>
	%	%		
Deaths (Total)	10.2	16.8	3.24	0.07
Suicides	7.4	4.8	1.44	0.23
Natural causes	2.8	9.2	5.3	<b>0.02</b>

<sup>a</sup>Open Dialogue -group<sup>b</sup>Control group

Table 3. Clinical characteristics from onset to the end of the follow-up

	ODtotal <sup>a</sup>	ODhospital <sup>b</sup>	CG <sup>c</sup>	Statistics <sup>d</sup>	
	( <i>N</i> =108)	( <i>N</i> =75)	( <i>N</i> =1763)	$\chi^2$	<i>p</i>
	(%)	(%)	(%)		
Treatment patterns					
>30 hospital days	18.5	54.5	94.4	32.4	0.00
Re-admission(s)	45.4	63.6	90.5	201.4	0.00
Treatment contact at the end of follow-up <sup>e</sup>	27.8	35.3	49.2	5.1	0.02
Neuroleptics					
At onset	20.4	25	70.1	305.1	0.00
At some point	54.6	63.6	97.3	217.8	0.00
At the end of follow-up <sup>e</sup>	36.1	47.1	81.1	47.8	0.00
Disability allowances					
At some point	41.7	53.2	78.8	28.5	0.00

At the end of follow-up<sup>e</sup>                      33                      44.1                      61                      6.7                      0.01

<sup>a</sup>Open Dialogue –group, includes all persons from the OD cohort

<sup>b</sup>Includes only persons from the OD cohorts with one or more admissions

<sup>c</sup>Control group

<sup>d</sup>Comparison: OD(hospital) and CG

<sup>e</sup>Only people still alive in 2015 included ( $N=1564$ )

Table 4. Temporal changes in hospital treatment and disability allowances

Years from onset	0-5 $N=1775^a$	6-10 $N=1703^b$	11-15 $N=1622^c$	16-20 $N=1544^d$	Total $N=1871^e$
	$M(SD)$	$M(SD)$	$M(SD)$	$M(SD)$	$M(SD)$
Hospital admissions ( $N^f$ )					
Open Dialogue	1.9(3.2)	0.9(1.9)	0.3(1.2)	0.2(1.2)	3.2(4.7)
Control	3.8(3.1)	1.9(2.9)	1.1(2.4)	0.8(1.9)	7(6.5)
Hospital days <sup>g</sup>					
Open Dialogue	27.4(49)	36.9(123.2)	11(64)	6.1(40.9)	63.1(131)
Control	202.1(231)	69.2(136)	48(112)	33.7(100)	340.4 (359)
Disability allowance (years) <sup>h</sup>					
Open Dialogue	0.5(1.2)	0.8(1.7)	1(1.5)	1.4(2.4)	3.4(5.5)
Control	1.7(1.8)	2.5(2.3)	2.7(2.4)	3(2.1)	9.7(8.1)

<sup>a</sup>Excludes persons dead within years 0–5 ( $N=96$ )

<sup>b</sup>Excludes persons dead within years 0–10 ( $N=168$ )

<sup>c</sup>Excludes persons dead within years 0–15 ( $N=229$ ), and from the OD group persons with first onset in 2002–2005 ( $N=20$ )

<sup>d</sup>Excludes persons dead within years 0–20 ( $N=307$ ), and from the OD group persons with first onset in 2002–2005 ( $N=20$ )

<sup>e</sup>Includes all persons

<sup>f</sup>Excludes outliers= $N>38$  (hence  $N=52$  from CG and  $N=1$  from OD are excluded)

<sup>g</sup>Excludes outliers= $N>1800$  (hence  $N=64$  from CG are excluded)

<sup>h</sup>Average time spent on full or partial disability allowances granted due to decreased work capability caused by mental health problems; no outliers detected