Open Dialogue versus treatment as usual for adults presenting in crisis to mental health services in England (the ODDESSI Trial): a multisite cluster-randomised trial

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Summary

Background Open Dialogue is a person-centred, transdiagnostic model of mental health care that emphasises continuity, therapeutic relationships, and collaboration with the service user's social network. Open Dialogue is a service-wide approach to care involving network meetings with the service user, members of their social network, and usually two practitioners who support the network throughout the duration of care. In this cluster-randomised trial, we aimed to evaluate the clinical effectiveness of Open Dialogue versus treatment as usual for adults presenting in crisis to community mental health services in England.

Methods This multicentre, parallel two-arm, cluster-randomised, controlled superiority trial was conducted in mental health services in five National Health Service trusts in London and the South of England. Clusters were defined at the level of primary care practices within service catchment areas. Participants were adults aged 18 years or older presenting in crisis to mental health services and registered with a practice within trial clusters. Randomisation was done at the cluster level (1:1), stratified by catchment area, and balanced on average general practice (GP) list size and Index of Multiple Deprivation (2015). The chief investigator, senior statistician, and assessors of the primary outcome were masked in the study. Participants either received Open Dialogue or treatment as usual, which refers to the functional team model currently implemented throughout English mental health services. The primary outcome was time (days) to first relapse following initial recovery from the index crisis censored at the end of the 2-year follow-up period. Participant-reported secondary outcomes were EuroQol Visual Analogue Scale, Social Provisions Scale, Lubben Social Network Scale, Questionnaire about the Process of Recovery, and the Client Satisfaction Questionnaire, measured at five timepoints over 2 years, and clinical measures were extracted from electronic health records. People with relevant lived experience were involved in the design and execution of the study. Fidelity to the model of care in Open Dialogue and treatment as usual, and adherence to the delivery of Open Dialogue, were measured prior to each site starting participant recruitment, then every 6 months thereafter until the final participant follow-up in that site. The trial was retrospectively registered (ISRCTN52653325) and is complete.

Findings 185 general practices associated with six mental health Trusts across England were identified for screening. 105 practices were excluded, and 80 were included in cluster formation, forming 32 clusters that were randomly assigned (16 to treatment as usual and 16 to the Open Dialogue intervention). One mental health trust (two clusters) withdrew, resulting in five mental health trusts (30 clusters) participating in the trial. Between June 25, 2019, and Dec 9, 2021, 494 participants (266 [54%] female gender, 221 [45%] male gender, 341 [69%] White British) with a mean age of 38·1 years (SD 13·4) provided consent for study inclusion (223 in the treatment as usual group and 271 in the Open Dialogue group). Of these, 174 (78%) in the treatment as usual group and 225 (83%) in the Open Dialogue group recovered and had data enabling relapse determination; there was no significant difference between groups on the primary outcome of time to relapse following initial recovery (marginal hazard ratio 0·95 [95% CI 0·67–1·32]). For secondary outcomes, Open Dialogue was associated with significantly lower probabilities of psychiatric inpatient admission and re-referral to crisis care or secondary mental health services, and with improvements in self-rated recovery, health-related quality of life, and satisfaction with services. There were no significant differences in social network quality or size. There were 386 serious adverse events (281 in the treatment as usual group and 105 in the Open Dialogue group); 376 (97%) were deemed to be unrelated to the intervention.

Interpretation Open Dialogue did not reduce time to first relapse compared with treatment as usual, the primary outcome, but it reduced acute inpatient bed use, improved service user reported outcomes and experience, and there were no significant safety concerns. Further investigation is required to determine whether Open Dialogue can enhance the effectiveness and acceptability of crisis care and continuing care in community mental health services.

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Introduction

For many people with severe mental illness, the first contact with services is via referral to a mental health crisis service or a hospital emergency department.[1] A mental health crisis is a mental health emergency—arising from risk of harm to self or others or a rapid increase in symptoms of psychosis or other psychiatric disorders—that substantially impairs personal or social functioning and requires urgent intervention.[2] In the English National Health Service (NHS), care during a crisis can be provided in inpatient settings or in the community through functionally distinct teams, referred to here as the functional team model,[3] which include Crisis Response and Home Treatment Teams (CRHTT), Early Intervention Services, Assertive Outreach Teams, Community Mental Health Teams, and Psychiatric Liaison Teams based in emergency departments. CRHTTs aim to reduce hospital admissions by providing intensive support to enable people to remain in the community.[3,4] Studies from several European countries suggest that crisis teams can reduce hospital admissions, although uncertainty remains about the active components of such services.[5,6]

The complexity of delivering effective care within the functional team model has been criticised,[2] and service users report dissatisfaction with the quality of care received, including moving between teams which can be disturbing for individuals, families, and carers,[7,8] and can lead to poorer mental health outcomes.[9]

Open Dialogue, developed in Western Lapland, Finland, with an initial focus on psychosis,[10] is a person-centred, social network model for the delivery of crisis and continuing care services in which continuity of care is a key organisational principle alongside a focus on therapeutic relationships. Open Dialogue is both a therapeutic practice and a way of organising mental health services[11] and is underpinned by seven principles: immediate help; a social network perspective; flexibility and mobility; responsibility; psychological continuity; tolerance of uncertainty; and dialogue and polyphony.[10] Open Dialogue is delivered through network meetings, where the service user, their social network (including family, informal or formal carers, and friends) meet with two Open Dialogue practitioners. The practitioners remain with the network throughout an episode of care and maintain links with inpatient services. Discussions focus on developing a shared understanding of presenting problems and on decisions about pharmacological, psychological, and social interventions.[11] The

Research in context

Evidence before this study

A systematic review of Open Dialogue was undertaken in preparation for this randomised controlled trial. We searched PubMed, CINAHL, Scopus, Web of Science, and PsycINFO for studies published up to Jan 31, 2018 using the search term "Open Dialogue" and identified 23 studies using mixed methods, qualitative, quantitative, and case study designs. Unpublished studies and studies that were not in English were excluded. We did not identify any randomised controlled trials. Quantitative and qualitative studies generally lacked methodological rigour and were judged at high risk of bias. The strongest evidence came from long-term follow-up studies suggesting possible benefits, primarily for people with psychosis. Despite limited evidence, international interest in Open Dialogue has continued, with services developing in the Americas, Europe, and Australia. A review confirmed this growing interest among practitioners and, in particular, among service users and families; it identified 53 studies, including several implementation studies of Open Dialogue, but again found no strong evidence of effectiveness. We also undertook a qualitative study of service users and clinicians who received or provided Open Dialogue. This work informed refinement of the Open Dialogue model used in this trial and the design of fidelity and adherence measures.

Added value of this study

To our knowledge, this study is the first randomised controlled trial of Open Dialogue. Open Dialogue produced recovery and relapse outcomes comparable to, but no better than treatment as usual, in the English mental health care system. However, the study demonstrated that Open Dialogue was significantly more effective than treatment as usual in reducing hospital admissions and re-referrals to crisis care. Open Dialogue was also associated with higher self-rated recovery, greater satisfaction with services, and better self-rated overall health state than treatment as usual.

Implications of all the available evidence

Open Dialogue integrated with existing community mental health services compared with treatment as usual had a positive effect on a number of important outcomes, including psychiatric hospital admissions but not on the primary outcome of the time to relapse. In light of these findings, consideration should be given to further research to assess the effectiveness of the integration of Open Dialogue into crisis and community mental health service and an increased provision of psychological interventions such as family interventions and individual psychological therapies. Family interventions are routinely provided as part of Open Dialogue in Finland where Open Dialogue was originally developed and has shown benefit in non-randomised studies. Routine outcome monitoring should also be established across all community mental health services to support service wide evaluation. Research is needed to determine whether refinement of the service delivery model of Open Dialogue can establish its clinical effectiveness.

approach aims to increase personal agency and the capacity to develop and maintain mutually supportive relationships.[11] Non-randomised studies have reported promising outcomes with some evidence of reduced hospital admission.[11–14] However, there is an absence of high-quality evidence from randomised controlled trials investigating the effectiveness of Open Dialogue compared with usual care.[15]

The primary aim of this study[2] was to determine whether Open Dialogue was more clinically effective than treatment as usual in the England NHS. Treatment as usual refers to the aforementioned functional team model. For Open Dialogue, specific service-related adaptations and additional core features in line with the Finnish model of Open Diaglogue[10] were introduced for implementation in the NHS. These included an integrated team approach, covering both crisis and continuing care; the provision of network meetings, augmenting existing multidisciplinary teams to provide a structured reflective space; and incorporating peer workers (people with lived experience of mental health challenges) into the multidisciplinary team.[2] Additionally, we adopted a so-called open door discharge policy, allowing patient or carer rereferral to the same team and clinicians, and team-based development activities.[2]

Methods

Study design and participants

This was a multicentre, cluster-randomised, parallel-group superiority trial comparing Open Dialogue with treatment as usual; full details are reported in the protocol (appendix p 74).[2] The study took place in England across five mental health trusts (Barnet, Enfield and Haringey NHS Trust, Camden and Islington NHS Foundation Trust [now merged and named North London Foundation Trust], Devon Partnership Trust, Kent and Medway Partnership Trust [now renamed to Kent and Medway Mental Health NHS Trust], and North-East London Foundation Trust), and their Open Dialogue and community mental health services. General Practitioner (GP) primary care services within these catchment areas—the primary referral route into mental health care—were grouped into clusters for randomisation.

Participants were adults aged 18 years or older, presenting in crisis to mental health services, with sufficient English to participate in research, and registered with a GP within trial clusters. Exclusion criteria were dementia or acquired cognitive impairment; a primary diagnosis of substance misuse (ICD-10, F10–19) or learning disability (ICD-10, F70–79); no fixed abode; care under forensic mental health services; previous receipt of Open Dialogue; concurrent participation in another research project; or any circumstance in which recruitment could pose a risk of harm to the participant, clinicians, or researchers.

Gender and ethnicity data were collected via self-report during the first research interview. Options for gender were female, male, gender identity not listed, or prefer not to say. Options for ethnicity were White; mixed or multiple ethnic groups; Asian or Asian British; Black, African, Caribbean, or Black British; and other ethnic group. People with lived experience were involved in the design, delivery, oversight, and interpretation of the study.

A feasibility study was completed before the main trial and details of cluster formation and GP inclusion criteria are provided in a preprint.[16] The trial received ethical approval from Wales 5-Research Ethics Committee on March 26, 2019 (19/WA/0096). Researchers checked eligibility, provided participant information sheets, gave potential participants the chance to ask questions and consider their involvement. Following this, participants signed a written consent form (or audio-recording of consent with corresponding written record following a COVID-19 amendment). For a potential participant who lacked capacity, a personal or nominated consultee unrelated to the study was consulted to assess the participants interests and capacity for participation. The study was registered retrospectively (ISRCTN52653325) and is complete. Reason for retrospective registration is in the appendix (p 2). The statistical analysis plan is presented in the appendix (p 40).

Amendment logs are presented in the appendix (p 10), describing two important changes during trial delivery that were made due to the COVID-19 pandemic. First, we adjusted the protocol to collect additional data on mode of intervention delivery and provided additional guidance on the use of video platforms for remote delivery of the intervention. Secondly, when agreeing the planned end date of the study following delays due to pausing participant recruitment in the pandemic, the sample size calculation was revised to reflect more accurate planning parameters. This was agreed with the Programme Steering Committee, Data Monitoring Committee (and sponsor and funder). We added a sensitivity analysis to explore the effect of the pandemic on the primary outcome.

See Online for appendix

Randomisation and masking

Randomisation was done at the cluster level (1:1), stratified by catchment area and balanced on average GP list size and Index of Multiple Deprivation (2015); the restricted randomisation approach is detailed in the feasibility paper.[16] The Chief Investigator (SP), Senior Statistician (SL), and assessors of recovery and relapse (the primary outcome) were masked to allocation. The trial statisticians (KJ and PC) remained masked until approval of the statistical analysis plan (appendix p 40). The trial manager and research assistants who liaised with mental health staff and compiled medical record data could not be masked. Participants were not masked; secondary outcomes from questionnaires were self-reported. The

trial was reported in line with the CONSORT recommendations for reporting of cluster randomised trials (appendix p 2).[17]

Procedures

Local researchers screened daily mental health crisis referrals to identify potentially eligible participants. Written consent was sought where possible. To include people who were unable to consent at the time, consent was temporarily sought from a consultee, and involvement was then reviewed and fully informed consent obtained when capacity was regained. We prioritised seeking consent from a personal consultee (relative or friend), or if not possible, from a nominated consultee (a local senior clinical professional with no other involvement in the trial) in accordance with the Mental Capacity Act.[18,19]

For participants in Open Dialogue clusters, care was provided from referral to discharge from the service through network meetings involving the service user, key network members such as family, and typically two Open Dialogue practitioners. Open Dialogue practitioners maintained close contact with participants if admitted to hospital. Inpatient staff did not receive Open Dialogue training but were aware of the objectives of the Open Dialogue team. Each team had a minimum of one peer practitioner who attended the same training as clinical staff and was supported by a trial-wide peer practitioner development group. Participants in the treatment as usual clusters received crisis care and continuing community mental health care as delivered by mental health services in England. All participants could receive any intervention ordinarily available in secondary care, including psychological and pharmacological treatments and social or housing support. Duration of contact was based on clinical need and agreed by each team in collaboration with the service user and their carers.

Participants received either Open Dialogue or treatment as usual according to their cluster's initial allocation, regardless of any clinical events that occurred, such as relapse. We monitored intervention delivery to ensure Open Dialogue and treatment as usual were delivered to an acceptable standard. Two measures were developed to support this. First, the Community Mental Health Team Fidelity Scale[20] operationalised key components of Open Dialogue and treatment as usual and assessed fidelity. Researchers collected data from each site before participant recruitment and every 6 months thereafter (until final participant follow-up in that site was complete) via interviews with service managers and practitioners and reviewed relevant operational and clinical policies and procedures. Second, an adherence measure[21] assessed alignment with core Open Dialogue practice by rating of audio recorded Open Dialogue network meetings. If adherence (Open Dialogue) or fidelity (Open Dialogue or treatment as usual) fell below a pre-specified threshold, remedial action was taken. If thresholds could not be restored, recruitment from that service was suspended until fidelity or adherence returned to the required level. No suspension of recruitment occurred.

Outcomes

The primary outcome was time (days) to first relapse following initial recovery from the index crisis in the sub-population of participants who recovered from the index crisis.[22] This was administratively censored at the end of the 2-year follow-up period. Electronic medical records over the 2-year follow-up were used to generate masked summaries for trained reviewers to determine recovery (absence of significant symptoms and adequate social functioning) and relapse (the return of significant symptoms and deterioration of social functioning) status; full details are presented in the appendix (p 95) and the protocol.[2]

Secondary outcomes—time from index crisis to initial recovery and total days in recovery during follow up—were derived from the same panel assessments. Electronic medical records were used to determine the number of days as a psychiatric inpatient and re-referral to crisis care or other secondary mental health services. For these secondary outcomes, observation started (ie, time zero) from the date of index crisis. Total days in recovery was defined only for participants who recovered from the index crisis. Days spent as a psychiatric inpatient was considered as two outcomes: (1) presence of any psychiatric inpatient admission; and (2) count of days as a psychiatric inpatient for those who were admitted. Participant-reported secondary outcomes were EuroQol Visual Analogue Scale (EQ VAS),[23] Social Provisions Scale (SPS),[24] Lubben Social Network Scale (LSN-6),[25] Questionnaire about the Process of Recovery (QPR-15),[26] and the Client Satisfaction Questionnaire (CSQ-8).[27] Details of score ranges and rating interpretations are available in the appendix (pp 69–70). These participant questionnaire outcomes were measured at first research interview and months 3, 6, 12, and 24, with the endpoint of interest being 24 months, except for the CSQ which was only measured at 3, 6, and 24 months, and the timepoint of interest being 3 months. The Modified OPTION shared decision-making questionnaire was a planned secondary outcome but had a high level of missingness at 24-months so could not be analysed.

Assessment and reporting of serious adverse events was agreed in accordance with our Sponsor's Standard Operating Procedures. For this trial, this did not include any protocol specific serious adverse events, nor a requirement to report all adverse events. All reports were reviewed by the local Principal Investigator and by the chair of Data Monitoring and Ethics Committee.

Statistical analysis

The original sample size calculation assumed recruitment of 28 clusters and 15% attrition. After recruitment was paused due to the COVID-19 pandemic

in 2020, the sample size calculation was revised to reflect more accurate planning parameters: 30 clusters recruited and a lower 5% attrition rate. All other parameters remained as per the original calculation. In an individually randomised trial targeting 58% relapse rate for treatment as usual and 40% for Open Dialogue, a logrank test following Freedman's formula assuming 90% power and 5% significance required 157 participants to relapse during the 24-month observation period. To account for clustering with an observable 18 participants per cluster, we inflated this number by a design effect calculated using the formula from Rutterford and colleagues[28] and an intra-class correlation coefficient (ICC) of 0·04 typical of cluster randomised trials: design effect=1+(cluster members per cluster−1)×ICC=1·68.[29] This requires 264 participants (157×1·68) to relapse during the observation period. An average relapse rate of 49% (average of target treatment as usual and Open Dialogue rates), meant recruiting 540 participants and accounting for 5% attrition per cluster resulted in a recruitment target of 570 participants (19 per cluster).

Analyses followed the statistical analysis plan sign-off by the Programme Steering Committee Chair, Chief Investigator, and Senior Statistician (Feb 12, 2024; appendix p 40), before database lock and final data extraction (Nov 29, 2024). A treatment policy strategy was followed (ie, among participants who recovered from the index crisis the estimate was the hazard ratio [HR] of relapse comparing participants seen by teams allocated to deliver Open Dialogue versus treatment as usual, regardless of treatment length or changes). All tests were two-sided with a 5% significance level. p values for secondary effect measures are reported without correction for multiple testing.

Time-to-event outcomes were analysed using Cox regression with fixed effects for trial arm, catchment area, GP list size, index of multiple deprivation (IMD), and baseline predictors of 24-month medical record status (appendix p 8). Marginalised HRs and percentile bootstrapped 95% CIs were generated using the procedures detailed by Daniel and colleagues.[30] Count outcomes derived from medical record data were analysed using negative binomial regression with exposure time defined as the interval from index crisis to the date of last record review, and fixed effects for trial arm, catchment area, list size, and IMD. For cases in which excess zeros were observed, zero-inflated negative binomial models were considered, with excess zeros modelled using logistic regression with the same fixed effects. Incidence rate ratios (IRRs) with corresponding 95% CIs were reported. Odds of re-referral (to crisis care or external secondary mental health services) were analysed using logistic regression with the same fixed effects; a marginalised odds ratio (OR) and percentile bootstrapped 95% CI based on 2000 replications were reported. Continuous questionnaire outcomes were analysed using linear mixed effects models. Scores at all follow-up timepoints (first research interview and at months 3, 6, 12, and 24 where collected) were modelled jointly with fixed effects for trial arm, timepoint (categorical), arm×timepoint, catchment area, list size, IMD, and baseline predictors of 24-month questionnaire status (appendix p 8). To account for within-participant correlation, models included participant-specific random intercepts and random slopes for continuous time, with the two random effects allowed to correlate. Mean differences between arms with 95% CIs were reported at 24 months (and at 3 months for CSQ-8).

Analyses were valid under respective missing at random assumptions. All models contained fixed effect parameters to model effects of cluster-level variables (number of catchment areas and balancing variables GP list size and IMD). We tried to include cluster-level varying intercepts to account for any residual variability between clusters, but models including such cluster-level random intercepts did not converge for any of the outcome variables. We attribute this non-convergence to negligible residual variability and did not include cluster-level random intercepts in the final models. Other planned robustness checks, causal mediation analyses of Open Dialogue effects on relapse, and analyses of carer data are described in the appendix (p 8). Analyses were at the individual level and performed using Stata version 18 or later and R version 4.4.0 or later. A separate health economic analysis will be undertaken and reported elsewhere.

Role of the funding source

The funder had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

185 general practices associated with six mental health trusts were identified for screening: 105 were excluded (43 did not meet criteria and 62 were not required as we had formed enough clusters to meet targets) and 80 were included in 32 clusters that were randomly assigned (16 allocated to the Open Dialogue intervention and 16 allocated to treatment as usual). Two clusters (one trust) withdrew after randomisation and enrolled no participants, leaving 30 clusters (five trusts) included in the study (figure 1). Recruitment took place between June 25, 2019, and Dec 9, 2021, 494 participants consented (271 for Open Dialogue and 223 for treatment as usual).

Summaries of cluster characteristics are reported in the appendix (p 15) and indicate successful randomisation, balancing catchment areas and cluster-level variables, including IMD and GP list size, across groups. Participant demographics and clinical characteristics at index referral were balanced between groups (table 1). In total, 266 (54%) of 494 participants were female, 221 (45%) were male, four (1%) did not have a gender identity listed, and three (1%) preferred not to say. The mean age at consent was 38·1 years (SD 13·4). Regarding ethnicity, 341 (69%)

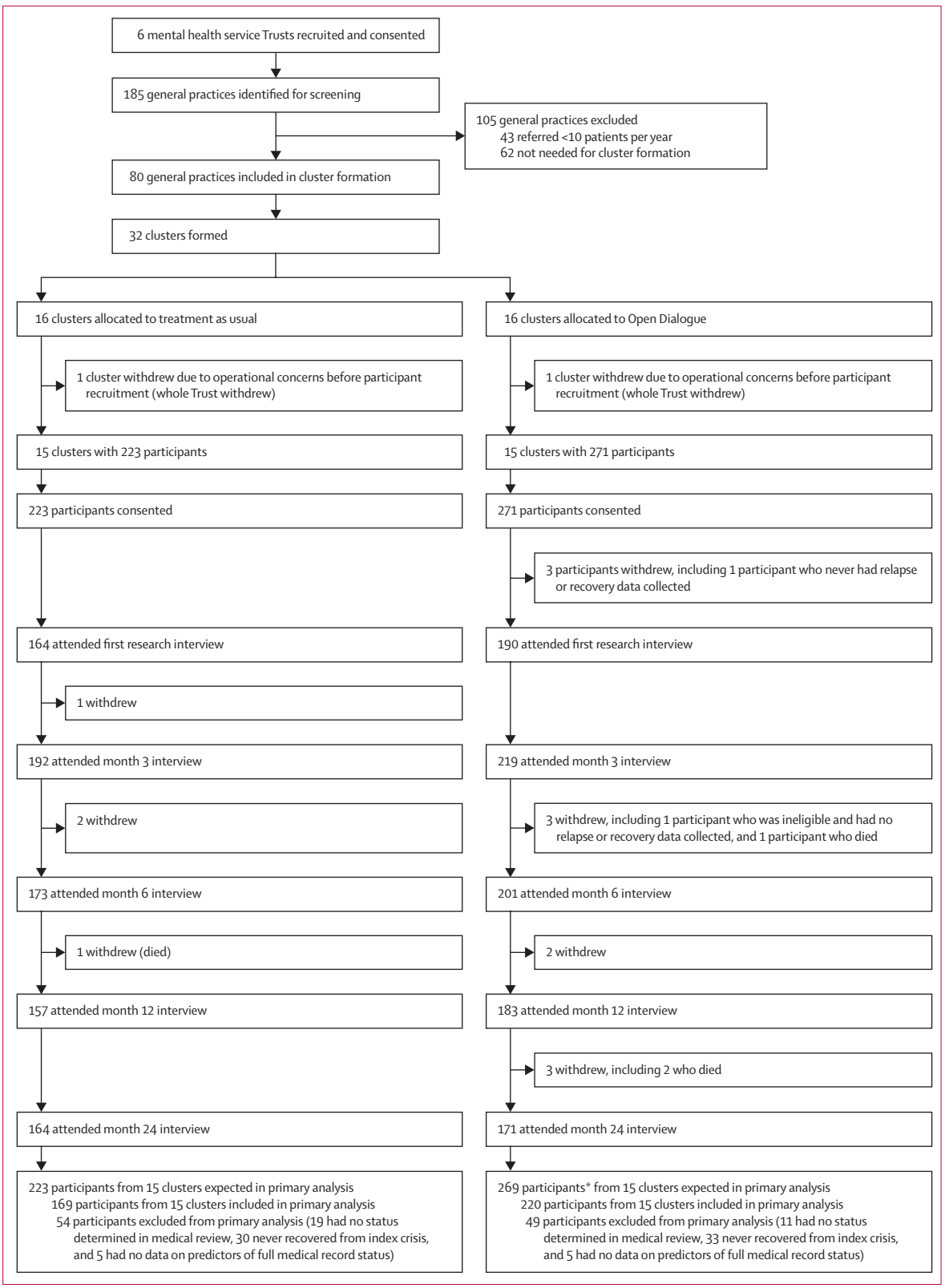

Figure 1: **Trial profile**
*Two participants from the 271 who consented had no relapse or recovery data collected.

	Treatment as usual (n=223)	Open Dialogue (n=271)	Overall (N=494)
Age at consent (years)	37·3 (13·4)	38·8 (13·4)	38·1 (13·4)
Brief Psychiatric Rating Scale score*	37·0 (10·5)	36·0 (8·4)	36·5 (9·4)
Gender			
Female	116 (52%)	150 (55%)	266 (54%)
Male	102 (46%)	119 (44%)	221 (45%)
Gender identity not listed	2 (1%)	2 (1%)	4 (1%)
Prefer not to say	3 (1%)	0	3 (1%)
Sexual orientation			
Heterosexual or straight	176 (79%)	224 (83%)	400 (81%)
Gay or lesbian	11 (5%)	11 (4%)	22 (4%)
Bisexual	13 (6%)	12 (4%)	25 (5%)
Sexual orientation not listed	5 (2%)	5 (2%)	10 (2%)
Prefer not to say	11 (5%)	9 (3%)	20 (4%)
Missing	7 (3%)	10 (4%)	17 (3%)
Race or ethnicity			
White British	159 (71%)	182 (67%)	341 (69%)
White other	13 (6%)	13 (5%)	26 (5%)
Mixed or of multiple ethnicity	14 (6%)	23 (8%)	37 (7%)
Asian or Asian British	14 (6%)	12 (4%)	26 (5%)
Black or Black British	14 (6%)	27 (10%)	41 (8%)
Any other ethnic group	5 (2%)	9 (3%)	14 (3%)
Missing	4 (2%)	5 (2%)	9 (2%)
Highest education level completed			
Primary education or less	14 (6%)	8 (3%)	22 (4%)
Secondary education to age 16 years	45 (20%)	72 (27%)	117 (24%)
Secondary education to age 18 years	52 (23%)	76 (28%)	128 (26%)
Tertiary or further education	87 (39%)	88 (32%)	175 (35%)
Other	7 (3%)	9 (3%)	16 (3%)
Missing	18 (8%)	18 (7%)	36 (7%)
Currently unemployed			
No	162 (73%)	191 (70%)	353 (71%)
Yes	56 (25%)	73 (27%)	129 (26%)
Missing	5 (2%)	7 (3%)	12 (2%)
Currently retired			
No	210 (94%)	258 (95%)	468 (95%)
Yes	6 (3%)	5 (2%)	11 (2%)
Missing	7 (3%)	8 (3%)	15 (3%)
Marital status			
Single	155 (70%)	172 (63%)	327 (66%)
Married or civil partnership	25 (11%)	50 (18%)	75 (15%)
Cohabiting	16 (7%)	15 (6%)	31 (6%)
Separated	10 (4%)	11 (4%)	21 (4%)
Divorced	8 (4%)	15 (6%)	23 (5%)
Widowed	3 (1%)	1 (<1%)	4 (1%)
Missing	6 (3%)	7 (3%)	13 (3%)
Housing			
Stable	207 (93%)	259 (96%)	466 (94%)
Other	11 (5%)	3 (1%)	14 (3%)
Missing	5 (2%)	9 (3%)	14 (3%)
Record of alcohol or drug misuse			
No	155 (70%)	219 (81%)	374 (76%)
Yes	66 (30%)	49 (18%)	115 (23%)
Missing	2 (1%)	3 (1%)	5 (1%)
Contact with secondary care mental health services in the 6 months before index crisis referral			
No	72 (32%)	156 (58%)	228 (46%)
Yes (one or more contacts)	151 (68%)	114 (42%)	265 (54%)
Missing	0	1 (<1%)	1 (<1%)
Offered intervention or taken onto caseload†			
No	33/151 (22%)	40/114 (35%)	73/265 (28%)
Yes	118/151 (78%)	74/114 (65%)	192/265 (73%)
Primary diagnosis at point of index crisis referral			
Psychotic disorder (psychosis, schizophrenia, or schizoaffective disorder)	46 (21%)	31 (11%)	77 (16%)
Bipolar disorder	21 (9%)	30 (11%)	51 (10%)
Personality disorder	42 (19%)	36 (13%)	78 (16%)
Depressive disorder	50 (22%)	77 (28%)	127 (26%)
Anxiety disorders (including post-traumatic stress disorder)	22 (10%)	35 (13%)	57 (12%)
Eating disorders	0	0	0
Other	23 (10%)	22 (8%)	45 (9%)
Missing	19 (9%)	40 (15%)	59 (12%)
Any current long-term physical health problems			
No	118 (53%)	167 (62%)	285 (58%)
Yes	105 (47%)	102 (38%)	207 (42%)
Missing	0 (0%)	2 (1%)	2 (<1%)

Data are n (%), n/N (%), or mean (SD). *Collected at first research interview. †If participant had any contact with secondary care mental health services in the 6 months before index crisis referral.

Table 1: **Baseline characteristics**

of 494 were White British, 26 (5%) were White other, 37 (7%) were mixed or of multiple ethnicities, 26 (5%) were Asian or Asian British, 41 (8%) were Black or Black British, and 14 (3%) were classified as any other ethnic group. The most common primary diagnosis at index crisis referral was depressive disorder (127 [26%] of 494); fewer than a quarter had a primary psychotic disorder (77 [16%] of 494), of whom 10% (51 of 494) had a diagnosis of bipolar disorder (table 1).

Review of fidelity scores for Open Dialogue and treatment as usual and Open Dialogue adherence supported delivery to an acceptable standard (appendix

p 17). Characteristics of clinical meetings are also reported in the appendix (p 18).

Summaries of raw data from electronic medical records are provided in the appendix (p 21). 63 (13%) of 494 participants never recovered from the index crisis and 32 (7%) had either no relapse or recovery status indicated or data were not available. 174 (78%) in the treatment as usual group and 225 (83%) in the Open Dialogue group had adequate data for the rating of relapse. If participants recovered from the index crisis, median days in recovery were similar between groups. The Kaplan–Meier curve for time to recovery is shown in the appendix (p 23). 487 participants had data on psychiatric inpatient hospitalisations and crisis re-referrals. A higher proportion of participants in the treatment as usual group (97 [44%] of 221) had any psychiatric inpatient days reported than in the Open Dialogue group (55 [21%] of 266). The proportion re-referred to crisis and community services was also higher in the treatment as usual group: 133 (60%) of 223 compared with 108 (40%) of 271 in the Open Dialogue group. Summaries of secondary questionnaire outcomes are presented in the appendix (p 24). Hospital admission for the index crisis (admission within 14 days of the index crisis) occurred in 71 (32%) of 223 participants in the treatment as usual group and 43 (16%) of 269 participants in the Open Dialogue group; data were unavailable for two participants in the Open Dialogue group.

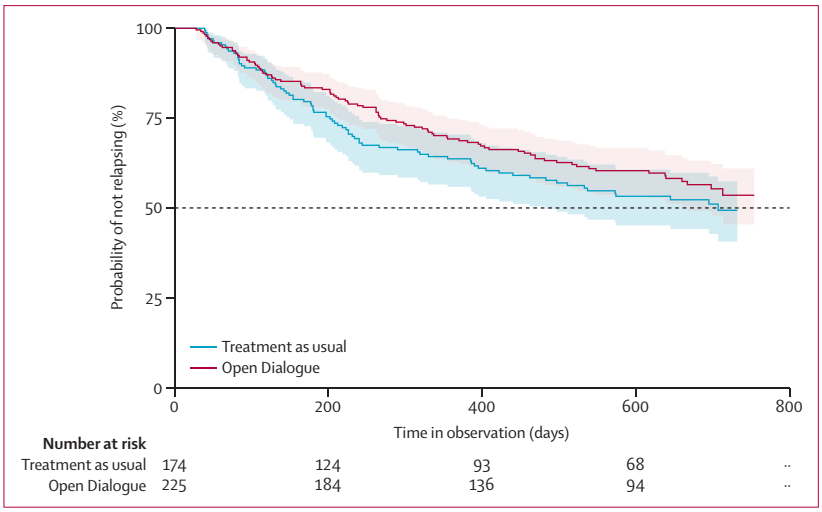

Figure 2: **Kaplan–Meier plot of time-to-relapse**
Data show time to relapse after initial recovery for ODDESSI trial participants.

	Number of participants in analysis	Estimated Open Dialogue effect (95% CI)	p value
Primary outcome			
Time to relapse after initial recovery (conditional HR)	221 (57%) of 389 (censored at end of 2-year follow-up)	0·92 (0·66 to 1·28)	0·62
Time to relapse after initial recovery (marginal HR)	..	0·95 (0·67 to 1·32)	NA
Secondary outcomes derived from medical data			
Time to initial recovery (conditional HR)	489 (99% of 494)	1·16 (0·94 to 1·42)	0·17
Time to initial recovery (marginal HR)	..	1·11 (0·91 to 1·44)	NA
Total days in recovery if ever recovered from initial crisis (conditional IRR)	398 (99% of 399)	1·00 (0·91 to 1·11)	0·94
Total days in recovery if ever recovered from initial crisis (marginal IRR)	..	1·00 (0·93 to 1·08)	NA
Total days as psychiatric inpatient	484 (98% of 494)	..	..
Odds of having no admissions (conditional OR)	..	3·75 (2·34 to 6·00)	<0·0001
Odds of having no admissions (marginal OR)	..	3·30 (2·18 to 5·22)	NA
If ever admitted, total days as psychiatric inpatient (conditional IRR)	151 with any admission	0·87 (0·53 to 1·43)	0·59
If ever admitted, total days as psychiatric inpatient (marginal IRR)	..	0·86 (0·47 to 1·39)	NA
Re-referral to crisis care or external secondary mental health services (conditional OR)	487 (99% of 494)	0·44 (0·30 to 0·64)	<0·0001
Re-referral to crisis care or external secondary mental health services (marginal OR)	..	0·44 (0·30 to 0·64)	NA
Secondary outcomes from participant questionnaires			
EQ VAS*	419 (85% of 494)†	6·65 (1·82 to 11·48)	0·0070
SPS*	419 (85% of 494)†	2·61 (–0·12 to 5·34)	0·061
LSN-6*	419 (85% of 494)†	0·03 (–1·19 to 1·26)	0·96
QPR-15*	418 (85% of 494)†	3·99 (1·15 to 6·82)	0·0058
CSQ-8*	417 (84% of 494)†	4·85 (3·59 to 6·11)	<0·0001

For the primary time to relapse after recovery outcome, a HR of less than 1 indicates benefit whereas for the secondary time to recovery outcome, a HR or more than 1 indicates benefit. HR=hazard ratio. IRR=incidence rate ratio. OR=odds ratio. EQ VAS=EuroQol Visual Analogue Scale. SPS=Social Provisions Scale. LSN-6=Lubben Social Network Scale. QPR-15=Questionnaire about the Process of Recovery. CSQ-8=Client Satisfaction Questionnaire. NA=not applicable. *Data are presented as mean difference at 24 months except for the CSQ which is presented as mean difference at 3 months. †Numbers are the number of participants contributing to repeated measures analyses and the corresponding proportion of the 494 randomised; actual numbers of observations at each timepoint are summarised in the appendix (p 24).

Table 2: **Results from formal analyses of primary and secondary trial outcomes**

At 24 months post initial recovery, the estimated probability of not relapsing was 49% (95% CI 41–58) in the treatment as usual group and 54% (45–61) in the Open Dialogue group (figure 2). Kaplan5–Meier curves by gender categories are displayed in the appendix (p 26). Of the 399 participants who achieved initial recovery from the index crisis and had data available, the majority 228 (57%) did not relapse and relapse times were censored at the date of last medical record review. Therefore, to support the non-informative censoring assumption, baseline predictors of full medical record status identified from the data (housing status; previous contact with secondary mental health services) were included in the primary analysis model (appendix p 27). Ten participants had missing values for these predictors, leaving 389 participants contributing to the primary outcome analysis (table 2). There was no statistically significant difference in the hazard of relapse (Open Dialogue marginal HR 0·95; p=0·62). Visual diagnostics indicated no departures from the proportional hazards assumption for relapse times.

For formal analyses of secondary outcomes derived from medical records, nearly all potential observations for medical record outcomes were available; therefore, predictors of missingness were not considered. The Modified OPTION shared decision-making responses from the participant-reported questionnaires were not formally analysed, and descriptive data are presented in the appendix (p 24). The chance of recovery was not significantly different between Open Dialogue and treatment as usual (marginal HR 1·11 [95% CI 0·91–1·44]; p=0·17). Total days in recovery among those who recovered were similar between groups (p=0·94). Open Dialogue was associated with reduced acute service use (hospitalisation and crisis teams): participants in Open Dialogue clusters had more than three-times higher odds of never being admitted to psychiatric inpatient care (marginal OR 3·30 [95% CI 2·18–5·22]; p<0·0001) and lower odds of re-referral to crisis care or external secondary mental health services over 2 years (marginal OR 0·44 [0·30–0·64]; p<0·0001). Among those ever admitted to psychiatric inpatient care with known observation periods (151 [31%] of 484), total inpatient days were similar between groups (p=0·59; appendix p 29).

To support missing at random assumptions, baseline variables predictive of missingness at 24 months (long-term endocrine problems, highest education level completed, and housing status) were included as additional covariates in analysis models (appendix p 27). At 24 months post index crisis referral, participants in Open Dialogue clusters reported better general health on EQ VAS (adjusted mean difference 6·65 points [95% CI 1·82–11·48]; p=0·0070; table 2). Participants in Open Dialogue also reported better self-rated recovery on QPR-15 (adjusted mean difference 3·99 points [95% CI 1·15–6·82]; p=0·0058), and higher service satisfaction on CSQ-8 at 3 months post index crisis (adjusted mean difference 4·85 points [3·59–6·11]; p<0·0001). LSN-6 scores were similar between groups (p=0·96), as were improvements on SPS (p=0·061). Overall, participant-reported effects favoured Open Dialogue (appendix p 30). Results of planned sensitivity analyses, mediation analyses, and descriptive summaries of carer measures are provided in the appendix (pp 31–32, 34) and none altered the substantive findings.

Only data on serious adverse events were collected. In total, 386 serious adverse events were reported (281 events in the treatment as usual group and 105 in the Open Dialogue group; 263 events were in females; table 3). Most events (376 [97%] of 386) were deemed unrelated to the study intervention. A full breakdown of serious adverse events by gender is presented in the appendix (p 36). There were 15 withdrawals in total (four in the treatment as usual group and 11 in the Open Dialogue group); reasons are summarised in the appendix (p 39).

	Treatment as usual (n=281 events)	Open Dialogue (n=105 events)	Overall (n=386 events)
Body system affected			
Cardiovascular	3 (3)	4 (3)	7 (6)
Respiratory	5 (3)	0 (0)	5 (3)
Hepatic or gastrointestinal	6 (4)	3 (2)	9 (6)
Genito-urinary and renal	7 (3)	2 (2)	9 (5)
Endocrine	1 (1)	1 (1)	2 (2)
Haematological	0 (0)	1 (1)	1 (1)
Musculo-skeletal	4 (4)	2 (2)	6 (6)
Neoplasia	1 (1)	0 (0)	1 (1)
Neurological	3 (3)	2 (2)	5 (5)
Psychological	234 (71)	73 (43)	307 (114)
Immunological	0 (0)	0 (0)	0 (0)
Dermatological	0 (0)	0 (0)	0 (0)
Allergies	0 (0)	1 (1)	1 (1)
Eyes, ear, nose, or throat	1 (1)	0 (0)	1 (1)
Other	16 (10)	16 (14)	32 (24)
Severity			
Moderate	1 (<1%)	0	1 (<1%)
Severe	280 (>99%)	105 (100%)	385 (>99%)
Relationship to study intervention			
Possible	0	1 (1%)	1 (<1%)
Remotely	6 (2%)	3 (3%)	9 (2%)
Not related	275 (98%)	101 (96%)	376 (97%)
Seriousness			
Yes, resulted in death	1 (<1%)	3 (3%)	4 (1%)
Yes, was life-threatening	18 (6%)	4 (4%)	22 (6%)
Yes, required hospital admission or prolongation	262 (93%)	98 (93%)	360 (93%)

Data are number of events with number of participants reporting the event in parenthesis, or n (%).

Table 3: **Serious adverse events reported by group and overall**

Discussion

In this trial, Open Dialogue did not have a beneficial effect on the primary outcome of time to relapse after recovery compared with treatment as usual care. However, Open Dialogue was associated with marked reductions in psychiatric hospital admissions and re-referrals to crisis teams. Additionally, Open Dialogue was associated with improvements over the 2-year follow-up in self-rated overall health, self-rated recovery, and satisfaction with care.

The improvements on some secondary outcome measures associated with Open Dialogue might be a result of improved team functioning, including an emphasis on reflective practice, shared decision making, risk management, and continuity of care. A good standard of care, as indicated by the fidelity measure, was maintained in both groups, including during the COVID-19 pandemic, as was adherence to Open Dialogue. As fidelity to Open Dialogue and to treatment as usual and adherence to Open Dialogue delivery were maintained during the trial, we can be confident that the whole team approach to Open Dialogue developed in Western Lapland, Finland was replicated in this study. This suggests that the lack of an effect on the primary outcome does not reflect a broader implementation failure.

This study had some important limitations. First, participants could not be masked to the intervention. Second, the relapse measure was originally developed for the evaluation of first-episode psychosis services[22] and the measure might have lacked sensitivity to the nature of relapse and recovery for other diagnoses. Fewer than 30% of participants had a diagnosis of psychosis or bipolar disorder, in contrast with those in other evaluations of English crisis services[31,32] where more than 40% of participants had a psychotic disorder and greater social disadvantage; for example, in the Islington crisis study[31,32] participants had an unemployment rate of 82·5% compared with 26·0% in the current study. Third, observed differences between groups, such as primary diagnosis, drug and alcohol misuse, and education attainment, can arise by chance but might have affected outcomes.

Fourth, previous Open Dialogue studies had systemic family interventions as routine components of Open Dialogue,[13,14] but in this study, formal psychological interventions, including family, cognitive behavioural, and mentalisation-based interventions, were not routinely provided in either group.

Fifth, despite the ratings of adherence and fidelity remaining at acceptable levels throughout the study, the number of adherence tapes that teams provided was lower than planned, and the fidelity measure focused on whole team function and structure, not the experience of individual participants. Network meetings with family members present were not the majority of interactions within the Open Dialogue group.

The positive effect of Open Dialogue on a number of secondary outcomes measures (eg, inpatient bed usage) together with the absence of an effect on measures of social network size or quality, raises questions about the potential mechanisms of Open Dialogue.[11,13] The developers of the Open Dialogue approach[10] emphasise social network involvement as a central mechanism in the effectiveness of the intervention, but this study included more limited network involvement than intended. Improved team functioning and the greater continuity of care associated with the single team approach of Open Dialogue might have contributed to the effect on hospitalisation and self-reported quality of life.

This cluster-randomised trial with adults presenting in crisis to community mental health services in England showed that Open Dialogue did not reduce time to first relapse compared with treatment as usual, the primary outcome, but it reduced acute inpatient bed use, improved service user reported outcomes and experience, and there were no significant safety concerns. Further large-scale studies are required to determine whether Open Dialogue is associated with improved patient outcomes, and reduced health service utilisation. Future evaluations of the intervention should seek to understand the mechanisms associated with the potential effectiveness of Open Dialogue.

Contributors

SP contributed to study conceptualisation, investigation, project administration, writing of the original draft, supervision, and securing funding for the study. JS, SL, RR, MG, KC, TCr, SJ, DZ, TW, TCa, JT, MH, GJ, CH, SC, VC, JC, CK, and YI contributed to study conceptualisation, project delivery, and administration. DZ, RR, TCr, TW, CH, MH, CK, JT, MG, SL, and SJ contributed to securing funding for the study. KC was responsible for strategic oversight and coordination as trial programme manager. RR, AJ, GJ, JO, VC, and JC provided clinical leadership for participating sites, and contributed to protocol adherence, service delivery, and supervision. SC and CH were responsible for lived-experience involvement as patient and public involvement leads. KC, EM, SNoo, SNou, GP, JK, and DS contributed to data curation and collection, and project administration and investigation. TCr led the panel of psychiatrists who rated the primary outcome measure and SNou was responsible for coordinating and facilitating these panels. SL was responsible for the statistical design and analysis of the trial, and reporting of the results. The trial statisticians, KJ and PC, supported all statistical aspects throughout the duration of the study, developed the statistical analysis plan, conducted all analyses, and provided the statistical report on which the paper is based. SP, TCr, MG, KC, KJ, PC, JW, EM, NSCC , SL, and RR were involved in interpretation of data and the writing and revision of the original draft of the manuscript. SP, KC, SL, PC, KJ, EM, MG, and JW directly accessed and verified underlying data reported in this manuscript. All authors critically reviewed and approved the final version of the manuscript and agree to be accountable for all aspects of the work.

Declaration of interests

SP is a Consultant Clinical Advisor on Mental Health to the National Institute of Health and Care Excellence. MH, JS, and YI are accredited Open Dialogue trainers who routinely provide Open Dialogue training for which they are funded. CH delivers Open Dialogue training as a guest lecturer and guest trainer. DZ is on the International Advisory Board in HopenDialogue (Italy). SL was a co-applicant on the now completed PGfAR funded research project "Evaluation of the

effectiveness of Intensive Community Care Services for Adolescents with Acute Psychiatric Emergencies (IVY)". All other authors declare no competing interests.

Data sharing

The anonymised datasets will be available, subject to review, by contacting the corresponding author.

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