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The Effectiveness of a Patient-Centred Assessment with a Solution-Focused Approach (DIALOG+) for Patients with Psychosis: A Pragmatic Cluster-Randomised Controlled Trial in Community Care

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Key Words

Computer mediation · Psychiatric treatment · Quality of life · Schizophrenia · Treatment outcomes

Abstract

Background: DIALOG+ was developed as a computer-mediated intervention, consisting of a structured assessment of patients' concerns combined with a solution-focused approach to initiate change. This study tested the effectiveness of DIALOG+ in the community treatment of patients with psychosis. ***Method:*** This was a pragmatic, exploratory, parallel-group, cluster-randomised controlled trial. Clinicians within community teams – along with patients with psychosis under their care – were randomised to use DIALOG+ once per month for 6 months or an active control. The primary outcome (subjective quality of life, SQOL) and secondary outcomes were assessed after 3, 6 and 12 months by blinded assessors and analysed using mixed-effect models. ***Results:*** A total of 49 clinicians and 179 patients were randomised. Implementation of DIALOG+ was variable, with an average of 1.8 sessions (SD = 1.6) in the first 3 months and 1.1 (SD = 1.2) in the following 3 months. Patients in the DIALOG+ arm had better SQOL at 3, 6 and 12 months ($p = 0.035$, 0.058 and 0.014, respectively; Cohen's $d = 0.29$–0.34). They also had significantly fewer unmet needs at 3 and 6 months, fewer general psychopathological symptoms at all time points and better objective social outcomes at 12 months, with no significant differences in other outcomes. Overall care costs were lower in the intervention group. ***Conclusion:*** Despite variable implementation, DIALOG+ is a beneficial intervention for community patients with psychosis. As a non-expensive and potentially cost-saving, generic intervention, DIALOG+ may be widely used and may improve the effectiveness of community treatment. Further trials should test DIALOG+ in different patient groups and contexts.

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Introduction

Routine meetings between patients and clinicians are central to community mental health care. There is little research evidence on how these meetings should be conducted in order to be therapeutically effective, and there has been no evidence-based therapeutic intervention specifically developed for this context [1]. The meetings should assess all relevant information but also help patients to initiate change and improve their situation. Interventions for inducing change should be based on a therapeutic model [2]. Given the variety of problems and concerns of patients with psychosis in the community, a model that strengthens and utilises the resources of patients rather than addresses specific deficits might be useful. Several such resource-oriented and generic models have been suggested in the literature. One such model is solution-focused therapy (SFT) [3]. It may be particularly useful to underpin practice in community treatment as it can be very brief, is flexible with regard to setting and format and provides guidance for individual problem solving.

Previous interventions to improve community mental health care have attempted to feed back regular patient outcome data to clinicians in order to inform their practice [4–6]. These interventions have been found to have little effect on patient outcomes, possibly because they fail to influence clinician behaviour within meetings. To address this issue, a computer-mediated intervention (DIALOG) was developed in which patients rate their satisfaction and needs for care on 8 life domains and 3 treatment aspects within the routine meetings [7]. This assessment provides a structure to the meetings and aims to make them patient centred and focused on change. DIALOG was tested in a cluster-randomised controlled trial with community patients with psychosis in six European countries over 1 year. Patients receiving DIALOG had significantly better subjective quality of life (SQOL), fewer unmet treatment needs and higher treatment satisfaction [7].

Though the DIALOG intervention implements a structured patient assessment, it does not provide any guide for clinicians on how to respond to patients' ratings. To address this, a brief psychological intervention informed by the principles of SFT has been developed. It is based on the following: (1) experiences with DIALOG in practice; (2) consultations with clinicians in community mental health teams and leading practitioners in SFT, and (3) focus groups with patients. A 4-step approach provides a guide for dealing with the specific concerns raised by the patient and equips the clinician, as well as the patient, with a method to explore and address the identified problems and wishes. The new intervention 'DIALOG+' combines the original computer-mediated DIALOG assessment with this 4-step approach. The intention is to structure the patient-clinician communication so that there is a patient-centred and comprehensive assessment of patients' views and concerns followed by a discussion that leads to solutions and helps patients to adopt a model of problem solving. The hypothesis is that such interventions will initiate and monitor change.

The aim of this pragmatic trial was to investigate whether the DIALOG+ intervention, used about once a month over 6 months with patients with psychosis in routine community mental health meetings, is associated with positive changes in patients' quality of life and other favourable outcomes compared with an active control condition. The active control administered the same computer-mediated ratings but at the end of the meeting and without any further discussion. This was to control for the novelty of using an electronic device in the clinical setting, the addition of a regular assessment to routine meetings and the same repeated ratings of satisfaction.

Method

Study Design

The study was a pragmatic, parallel-group, cluster-randomised controlled trial. A detailed description of the methodology can be found in the protocol (Current Controlled Trials No. ISRCTN34757603) [8].

Clusters were clinicians working in community mental health teams in London, UK. Clinicians were randomly assigned to either the DIALOG+ intervention or the control condition, with an allocation ratio of 1:1. A cluster-randomisation design was used to avoid potential contamination of the practice of clinicians when treating patients in both groups.

Participants and Settings

The study was conducted in seven community mental health teams across East London. All teams were multidisciplinary and provided care for people with severe mental illnesses of working age. In these teams every patient has a dedicated clinician responsible for care coordination, with whom they meet at least once a month. These clinicians are qualified mental health professionals, mostly psychiatric nurses, often referred to as care coordinators or keyworkers. They are the main contacts for patients and may arrange further input of other clinicians if and as required.

To reflect the pragmatic approach of the trial, teams and participating clinicians within teams were identified by the management of the provider organisation (East London NHS Foundation Trust). Clinicians were eligible if they had a professional qualification, more than 6 months' experience of working in community mental health care and no plans to leave their post within the study period.

The caseloads of participating clinicians were screened to identify eligible patients. Inclusion criteria for patients were as follows:

age 18–65 years; treatment in the community team for at least 1 month; no planned discharge for the next 6 months; a clinical diagnosis of schizophrenia or a related disorder (ICD-10 F20–29), and capacity to give informed consent. Patients were excluded if they had a mean score of 5 or higher on the Manchester Short Assessment of Quality of Life (MANSA) [9], reflecting an average rating of at least 'mostly satisfied' with all life domains, and if they had insufficient command of English for conducting meetings in English. Initially, a random sample of 7 eligible patients from each clinician was approached. If less than 5 consented, additional eligible patients were approached in a predefined random order. Recruitment took place between October 2012 and September 2013.

Written informed consent was obtained from all clinicians and patients. The study received a favourable opinion from the Research Ethics Committee (Stanmore; 12/LO/1145).

Interventions

Experimental Condition

In the experimental group, clinicians and patients were instructed to use DIALOG+ once per month over a 6-month period, as clinicians are expected to meet patients at least once a month in these services. However, it was acknowledged that this could vary in practice. After 6 months, clinicians and patients could continue the intervention if they wished. DIALOG+ was delivered using a tablet computer, which could be shared between clinician and patient throughout the conversation (for screenshots, see online suppl. 1; see www.karger.com/doi/10.1159/000430991 for all online suppl. material).

Each DIALOG+ session begins with the same assessment of topics as in the original DIALOG intervention, whereby patients are asked to rate their satisfaction with 8 life domains (mental health, physical health, job situation, accommodation, leisure activities, friendships, relationship with family/partner, personal safety) and 3 treatment aspects (medication, practical help, meetings with professionals). Each satisfaction item is rated on a scale from 1 ('totally dissatisfied') to 7 ('totally satisfied') and followed by a question on whether the patient wants additional help in the given domain. The ratings are then summarised on the screen, allowing for comparisons with previous ratings. Clinicians are instructed to offer positive feedback on any improving or high-scoring domains. The summary is then used to inform a joint decision about which domains should be discussed in greater depth.

Each of the domains chosen for further discussion are addressed in a 4-step approach informed by the principles of SFT: (1) understanding the patient's concerns and previous effective coping strategies; (2) identifying best-case scenarios and smallest steps for improvement; (3) exploring options available to the patient, including the patient's own resources, the clinician's and those of others in the patient's life, and finally, (4) agreeing on actions to address the identified concerns. Agreed actions are later reviewed at the start of the following meeting.

All clinicians in the experimental group received a half-day one-to-one training. The first and 1 subsequent DIALOG+ session for each patient were audio-recorded and feedback provided. The manual is available from the authors on request.

Control Condition

In the control condition, patients conducted the same ratings using the devices and software but at the end of the meetings, independently rather than collaboratively, and without further discussion. This was to control for the novelty factor and to ensure that potential effects on SQOL were not influenced by more frequent ratings in the intervention group.

Outcomes

All outcomes were prespecified and measured at baseline and at the 3-, 6- and 12-month follow-ups.

Baseline Characteristics

Information on the gender, ethnicity, age, marital status, education level, admission history, length of relationship with clinician, and primary diagnosis was collected at baseline. The primary diagnosis was obtained from the electronic patient record system and was based on the latest psychiatric assessment.

Primary Outcome

The primary outcome was SQOL, which was measured as the mean score on the MANSA [9, 10]. On 12 Likert-type scales, patients rate their satisfaction with different life domains from 1 (could not be worse) to 7 (could not be better). This has been widely used in research with community patients [11].

Secondary Outcomes

The number of unmet needs was self-assessed on the Camberwell Assessment of Need Short Appraisal Schedule (CANSAS) [12, 13], with ratings in 22 domains. Treatment satisfaction was self-rated on the Client Satisfaction Questionnaire (CSQ-8) [14, 15], with 8 items and higher scores indicating greater satisfaction. Self-efficacy was self-rated on the 10-item General Self-efficacy Scale (GSS) [16, 17], with higher scores reflecting higher self-efficacy. Mental well-being was self-assessed on the 14-item Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) [18, 19], with higher scores indicating better well-being. Psychopathological symptoms were observer rated using the 30-item Positive and Negative Syndrome Scale (PANSS) [20, 21], which provides scores for positive symptoms (ranging from 7 to 49), negative symptoms (from 7 to 49) and general symptoms (from 16 to 112). The therapeutic relationship was assessed on the Scale for Assessing Therapeutic Relationships in Community Mental Health Care, patient version (STAR-P) and clinician version (STAR-C) [22]. Both scales have 12 items, with higher scores indicating a stronger relationship. Social outcomes were assessed using the Objective Social Outcomes Index (SIX) [23], which obtains objective data on employment status, accommodation status, living situation, and social contacts and provides a total score from 0 to 6 (higher scores reflect a more positive social outcome).

All outcomes were collected in one-to-one meetings between a researcher and a patient, with researchers guiding patients through self-report measures and using structured interviews for the PANSS. The only exception was the STAR-C, which was independently self-rated by clinicians. A total of 6 researchers were involved in the assessment of outcomes. Interrater reliability for the PANSS between the 6 researchers was good (intraclass correlation coefficient = 0.828).

Cost-Effectiveness Outcomes

The costs of care were recorded using the Client Service Receipt Inventory (CSRI) [24], which records patients' use of health and social care services, including hospital services, community and outpatient services, and medication. These data were collected ret-

rospectively for the 3 months prior to each time point (baseline and 3, 6 and 12 months). The data were collected through patient self-report supplemented by the clinical notes from the patient electronic record system to improve accuracy.

Sample Size

We aimed to recruit 36 clinicians and 180 patients, with 18 clinicians and 90 patients in each condition (5 patients per clinician). We anticipated the loss of 6 clinicians and 30 of their patients due to unexpected job changes. With a patient dropout rate of less than 10%, we would end with a sample of 136 patients. Assuming a practically negligible cluster effect (as in the original DIALOG trial), the sample size would be sufficient to detect a medium effect size with 80% power at the 5% significance level.

During the recruitment phase, the sample size as described in the protocol was increased from 36 clinicians to 49, as a lower number of patients per clinician were being recruited than expected. This did not change the target sample size of patients.

Randomisation

An independent statistician allocated clinicians to the experimental or control conditions according to a computer-generated randomisation list. The randomisation sequence was created using random block sizes of 4 and 6. Randomisation was not stratified, as all clusters (clinicians) had similar experience and patient caseloads.

To minimise selection bias within clusters, clinicians were randomised once all patients from their caseload had been recruited and all baseline assessments were completed. The allocation of clusters was concealed from outcome assessors, and clinicians were asked to keep their treatment allocation concealed from their colleagues and managers.

Blinding

The principal investigator, all 6 outcome assessors and the data analysts were blinded to the clinicians' and patients' allocations. Although it was not possible to blind patients to the treatment allocation, those in the control group were still required to complete the same assessments on a tablet computer, and it was not made explicit whether they were receiving the experimental intervention or not. If blinding was compromised during the interviews, a different researcher conducted the next follow-up assessment.

Statistical Analysis

An analysis plan was drafted and signed off prior to any unblinding and analysis taking place. All analyses were conducted two sided and significance interpreted at the 5% level.

Available Case Analysis

The main analysis was conducted at the level of the individual and based on available cases, following intention-to-treat principles. The analysis of continuous outcomes was conducted using a generalised linear model, with a fixed effect for treatment and the associated baseline value of the outcome and a random effect for clinician to account for clustering. Cohen's d was derived from raw data and calculated for significant results of continuous variables as a standardised effect size measure. The number of unmet needs (CANSAS) was analysed using a Poisson regression, with treatment and baseline unmet needs fitted as fixed effects and clinician fitted as a random effect. The analysis of objective social outcomes (SIX) was conducted using a proportional odds model with random intercept, with treatment fitted as a fixed effect and clinician fitted as a random effect. The software used was Stata version 12.1.

Further Analyses

Two further analyses were conducted on the primary outcome. To address the potential bias of the available case analysis due to attrition, a linear mixed effects model was conducted with MANSA scores at all time points as the dependent variable. The model included a random effect of cluster and, within clusters, cross-classified random effects of time and patient. A likelihood-based analysis of this kind provides an unbiased estimate of the treatment effect under the assumption that data are missing at random conditional on the included data.

A per protocol analysis was also carried out on MANSA scores, using the same methods as the available case analysis but including only those patients who received 2 or more DIALOG+ sessions or control sessions, respectively. At least 1 repeat session was considered essential to capture the key elements of the intervention.

Cost-Effectiveness Analysis

The extra intervention costs of DIALOG+ included specific training of staff and the tablet computer (GBP 109 per patient). The cost of the tablet computer in the control group was not included as it was designed to control for non-specific effects. Service use as measured on the CSRI was combined with the relevant unit costs [25, 26]. The total costs over 12 months were then calculated based on the CSRI at 3, 6 and 12 months, plus an average of the 6- and 12-month costs (as no 9-month follow-up was conducted).

The total costs of the two groups were compared using a bootstrapped regression model (to account for a non-normal distribution) and controlling for baseline costs. Cost-effectiveness was assessed by combining the total costs with the MANSA change scores. Uncertainty around the point estimates was addressed by generating 1,000 incremental cost-outcome combinations using bootstrapping methods and plotting these onto a cost-effectiveness plane. This allowed for a calculation of the probabilities of the intervention saving or increasing costs and improving or worsening outcomes.

Results

Participant Flow

The CONSORT diagram summarising the flow of participants throughout the study and the reasons for excluding clinicians and patients is contained in online supplement 2.

A total of 59 clinicians and 709 of their patients were assessed for eligibility. Following baseline assessments, the 49 eligible clinicians and their 188 patients were randomly assigned to the DIALOG+ or control condition. Of the 188 participating patients, 9 either withdrew from the study or were discharged from the clinician's caseload prerandomisation, though the research team did not learn of this until after the randomisation had taken place. As a

Table 1. Baseline characteristics of patients

Characteristics	Intervention group (n = 94)	Control group (n = 85)	Total (n = 179)
Gender			
Female	28 (30)	28 (33)	56 (31)
Male	66 (70)	57 (67)	123 (69)
Ethnicity			
White	23 (25)	23 (27)	46 (26)
Black	38 (40)	32 (38)	70 (39)
Asian	28 (30)	21 (25)	49 (27)
Mixed/other	5 (5)	9 (11)	14 (8)
Age, years	41.5±10.7	41.7±9.3	41.6±10.1
Marital status			
Single	75 (80)	71 (84)	146 (82)
Married	19 (20)	14 (17)	33 (18)
Highest level of education			
None (left prior to compulsory education)	26 (28)	22 (26)	48 (27)
Compulsory education (age 16)	27 (29)	25 (29)	52 (29)
Postcompulsory education	40 (43)	38 (45)	78 (44)
Number of previous psychiatric admissions[1]	2.0 (1–4)	2.0 (1–5)	2.0 (1–4)
Length of relationship with keyworker (years)	1.0 (0–2)	1.5 (1–2)	1.3 (1–2)
Length of contact with services (years)	11.5 (7–19)	12.0 (7–19)	12.0 (719)
Primary diagnosis (ICD-10)			
Schizophrenia (F20)	76 (81)	65 (76)	141 (79)
Delusional disorders (F22)	0	2 (2)	2 (1)
Schizoaffective disorders (F25)	14 (15)	10 (12)	24 (13)
Unspecified non-organic psychosis (F29)	4 (4)	0	4 (2)
Bipolar disorder (F31)[2]	0	4 (5)	4 (2)
Major depressive episode (F32, F33)[2]	0	4 (5)	4 (2)

Values are n (%), mean ± SD or median (with interquartile range), as appropriate.
[1] All admissions to psychiatric hospitals for longer than 24 h.
[2] The primary diagnosis for 8 patients changed after eligibility screening. However, this information was not identified until after randomization, so they remained in the trial and were included in the analysis.

result they were deemed as 'randomised in error' and excluded from the analysis. Thus, 49 eligible clinicians and 179 patients were correctly assigned to the DIALOG+ intervention (clinicians: n = 25; patients: n = 94) or the control condition (clinicians: n = 24; patients: n = 85).

Overall, 4 clinicians (3 experimental; 1 control) withdrew from the study, and their patients (11 experimental; 3 control) did not receive the allocated intervention. In the DIALOG+ intervention group, 1 further clinician withdrew from the study; however, the patients (n = 2) received the intervention from another included clinician. The primary outcome was assessed in 120/179 patients at 3 months (67%; 61 experimental, 59 control), 147/179 at 6 months (82.1%; 73 experimental, 74 control) and 129/179 at 12 months (72.1%; 61 experimental, 68 control).

Implementation

The implementation of the DIALOG+ intervention was variable. Data on the number of sessions delivered were obtained for 80 patients (data were missing for 14). Of these, 24 (30%) did not have any DIALOG+ sessions with their clinician. This was because the clinician withdrew from the study (n = 11), the patient withdrew from the study (n = 7) or no DIALOG+ sessions took place within the intervention period (n = 6). Overall, patients allocated to the DIALOG+ arm had on average of 1.8 sessions (SD = 1.6) in the first 3 months and 1.1 (SD = 1.2) in the second 3-month period. Of the patients who received at least 1 DIALOG+ session, the intervention was delivered on average 2.6 times (SD = 1.3) in the first 3 months and 1.5 times (SD = 1.1) in the second 3 months, with a total mean number of 4.1 sessions

(SD = 1.9). Only 6 patients continued to use the DIALOG+ intervention with their clinician after the 6-month follow-up, with an average of 1.2 (SD = 0.4) additional sessions.

Out of the 85 patients in the control group, 7 did not complete any ratings (8%). This was because the clinician went on sabbatical (n = 3), the clinician did not deliver the control intervention (n = 3) or the patient withdrew from the study (n = 1). Those who completed at least one rating had on average 4.2 (SD = 1.8) ratings overall, with 2.6 (SD = 1.1) in the first 3 months and 1.7 (SD = 1.3) in the second 3 months.

Baseline Characteristics of Participants

The clinical and sociodemographic characteristics of the patients are shown in table 1. Patients were predominantly male and single, from a wide range of ethnicities. In 8 patients in the control group, the primary clinical diagnosis changed before randomisation. However, the research team did not learn of this until after randomisation and, therefore, they were included in the analysis. A total of 14 clinicians (56%) in the experimental group and 15 (63%) in the control group were female.

Blinding

Blinding was compromised for 2 interviewers in a total of 3 cases, where the interviewer identified the allocation of a patient (1 at the 3-month follow-up, 2 at 6 months and none at the 12-month follow-up).

Primary Outcome

The results for all outcomes are summarised in table 2. At the 3-month follow-up, SQOL (MANSA) was significantly higher in the experimental group (effect size: Cohen's d = 0.34). At the 6-month follow-up, there was a trend towards higher SQOL in the experimental group (d = 0.29). This effect remained significant at the 12-month follow-up (d = 0.34).

Further Analyses

The further analyses provided similar results. The linear mixed effects model, with MANSA scores at all time points as the dependent variable, showed slightly lower adjusted mean differences, i.e. 0.24, 0.26 and 0.26 after 3, 6 and 12 months (p = 0.059, 0.028 and 0.034, respectively) versus 0.30, 0.26 and 0.32 in the available case analysis. The adjusted mean differences in the per protocol analysis were also similar, i.e. 0.25, 0.32 and 0.32 after 3, 6 and 12 months (p = 0.178, 0.030 and 0.034, respectively).

Secondary Outcomes

There were significantly fewer unmet needs (CANSAS) in the experimental group at 3 and at 6 months. The effect reflects an absolute difference of 1.0 need at 3 months and 1.1 needs at 6 months. The level of general psychopathological symptoms was significantly lower in the experimental group at 3 months (effect size: d = 0.55), 6 months (d = 0.54) and 12 months (d = 0.65).

There was no significant difference on objective social outcomes (SIX) at 3 months (d = 0.21) and 6 months (d = 0.30). However, patients in the experimental group had significantly better objective social outcomes at the 12-month follow-up (d = 0.50). No statistically significant differences between the treatment groups were found in any of the other secondary outcomes at any time point.

Cost-Effectiveness

The mean total costs over 12 months were lower in the experimental group (GBP 3,279) than the control group (GBP 4,624). This amounted to a cost saving of GBP 1,288 after controlling for baseline costs (bootstrapped 95% confidence interval: GBP –1,318 to GBP 5,633). There is a 72.4% probability of the intervention both improving outcomes and saving costs. The probability of the intervention being more effective at a higher cost is 26.5%.

Discussion

Main Findings

DIALOG+ had a positive effect in the community treatment of patients with psychosis. SQOL was already improved after 3 months. The effect was still apparent at 12 months (6 months after, all but 6 patients had stopped the intervention). Different types of analyses provided similar results. The number of unmet needs was significantly reduced after 3 months and at 6 months. This is in line with the intention of DIALOG+ to identify and address the concerns and unmet needs of patients. There were also significant benefits on general psychopathological symptoms and objective social outcomes after 12 months only, and the intervention is likely to be cost saving. There was no effect on other secondary outcomes.

Strengths and Limitations

A key strength is the pragmatic nature of the trial. The intervention was implemented in routine services as it would be rolled out in practice, and the results are therefore likely to be generalisable to other routine services.

Table 2. Primary and secondary outcomes at baseline and at 3, 6 and 12 months

Outcome	Intervention group		Control group		β coefficient	95% CI	p value	ICC
	n	mean ± SD	n	mean ± SD				
Quality of life (MANSA)								
Baseline	94	4.0 ± 0.9	85	3.8 ± 0.9				
3 months	61	4.4 ± 0.9	59	4.1 ± 0.9	0.299	0.021 to 0.578	0.035	<0.001
6 months	73	4.3 ± 1.0	74	4.0 ± 1.0	0.257	−0.009 to 0.524	0.058	<0.001
12 months	61	4.4 ± 0.9	68	4.1 ± 0.9	0.319	0.063 to 0.575	0.014	<0.001
Treatment satisfaction (CSQ-8)								
Baseline	93	24.0 ± 4.8	85	23.9 ± 5.5				
3 months	61	23.4 ± 5.1	58	24.2 ± 5.3	−0.860	−2.325 to 0.606	0.25	0.037
6 months	73	24.2 ± 5.4	71	23.8 ± 6.0	0.436	−0.956 to 1.827	0.54	<0.001
12 months	61	24.4 ± 5.0	65	23.6 ± 6.0	0.730	−0.800 to 2.260	0.350	<0.001
Self-Efficacy (GSS)								
Baseline	91	25.6 ± 7.4	85	25.9 ± 6.6				
3 months	61	25.8 ± 6.9	57	26.9 ± 6.6	−1.458	−3.347 to 0.432	0.131	<0.001
6 months	73	26.5 ± 6.6	73	26.5 ± 6.2	−0.162	−1.848 to 1.525	0.851	<0.001
12 months	60	27.0 ± 7.0	65	27.1 ± 6.1	0.231	−1.604 to 2.065	0.805	<0.001
Well-being (WEMWBS)								
Baseline	93	43.0 ± 10.6	84	41.7 ± 9.9				
3 months	61	43.4 ± 10.9	59	42.5 ± 10.6	0.025	−0.165 to 0.214	0.799	<0.001
6 months	73	43.8 ± 11.5	73	42.8 ± 10.0	0.030	−0.157 to 0.217	0.753	<0.001
12 months	61	45.8 ± 11.2	65	43.8 ± 10.4	2.005	−0.802 to 4.811	0.162	<0.001
Positive symptoms (PANSS-positive)								
Baseline	93	14.8 ± 5.7	84	15.1 ± 6.4				
3 months	61	14.1 ± 5.6	58	14.0 ± 5.3	0.206	−1.102 to 1.514	0.757	<0.001
6 months	73	13.2 ± 5.2	73	14.4 ± 5.7	−0.927	−2.432 to 0.579	0.228	0.065
12 months	60	12.8 ± 5.3	65	14.3 ± 5.3	−1.459	−3.003 to 0.086	0.064	<0.001
Negative symptoms (PANSS-negative)								
Baseline	94	17.1 ± 6.4	84	18.0 ± 7.8				
3 months	61	15.2 ± 5.7	58	16.9 ± 6.6	−0.923	−2.692 to 0.846	0.306	<0.001
6 months	73	15.1 ± 5.8	73	15.7 ± 6.1	0.037	−1.591 to 1.665	0.965	<0.001
12 months	60	13.3 ± 5.1	65	15.3 ± 6.3	−1.470	−3.364 to 0.423	0.128	0.208
General symptoms (PANSS-general)								
Baseline	93	32.9 ± 8.3	84	34.6 ± 10.1				
3 months	61	29.2 ± 8.8	58	34.2 ± 9.2	−3.415	−6.335 to −0.495	0.022	0.189
6 months	73	28.0 ± 9.2	73	32.8 ± 8.9	−4.041	−6.82 to −1.263	0.004	0.079
12 months	60	26.4 ± 7.7	65	31.3 ± 7.3	−4.271	−6.712 to −1.829	0.001	0.067
Therapeutic relationship (STAR-P)								
Baseline	93	33.2 ± 8.0	85	34.4 ± 8.2				
3 months	56	34.2 ± 8.0	59	33.3 ± 8.8	1.219	−1.102 to 3.539	0.303	<0.001
6 months	66	33.9 ± 8.7	70	32.2 ± 10.4	2.114	−0.67 to 4.897	0.137	0.113
12 months	48	33.0 ± 9.7	56	32.8 ± 9.3	0.448	−2.712 to 3.607	0.781	<0.001
Therapeutic relationship (STAR-C)								
Baseline	77	40.8 ± 5.2	83	41.3 ± 4.4				
3 months	52	39.8 ± 4.8	54	40.6 ± 4.7	−0.033	−2.341 to 2.276	0.978	0.557
6 months	66	40.8 ± 4.7	66	41.7 ± 5.2	−0.971	−3.203 to 1.262	0.394	0.41
12 months	39	40.2 ± 4.4	47	41.8 ± 4.9	−2.454	−5.108 to 0.200	0.070	0.536
Unmet needs (CANSAS)								
Baseline	94	3.5 ± 3.1	85	3.9 ± 2.9				
3 months	61	2.2 ± 2.2	59	3.2 ± 3.1	0.679	0.485 to 0.951	0.024	0.018
6 months	73	2.0 ± 2.9	73	3.1 ± 3.0	0.607	0.412 to 0.895	0.012	0.033
12 months	61	2.0 ± 2.3	66	2.7 ± 2.9	0.732	0.480 to 1.115	0.146	0.045
Social outcomes (SIX)								
Baseline	93	2.8 ± 1.0	85	2.6 ± 0.9				
3 months	61	2.9 ± 1.3	59	2.7 ± 0.8	0.97	0.39 to 2.44	0.95	<0.001
6 months	73	2.9 ± 1.1	74	2.6 ± 0.9	1.34	0.72 to 2.49	0.358	<0.001
12 months	61	3.1 ± 1.0	68	2.6 ± 0.9	2.91	1.225 to 6.911	0.016	0.149

Outcome: all outcomes were analysed using random effects linear regression, with treatment and baseline score fitted as fixed effects and clinician fitted as a random effect. Unmet needs (CANSAS): assessed using a Poisson regression, with treatment and baseline unmet needs fitted as fixed effects and clinician fitted as a random effect (incidence rate ratio used instead of β coefficient). SIX score: analysed using a proportional odds model, with treatment fitted as fixed effects and clinician fitted as a random effect (proportional odds ratio used instead of β coefficient). Reported intracluster coefficient is on the logistic scale. CANSAS: patient-rated version. ICC = Intracluster coefficient.

However, the pragmatic approach also contributed to the variable implementation. A total of 30% of patients in the experimental group never received an intervention at all.

Further strengths are that the inclusion criteria for patients were wide, the trial had an active control condition, the control intervention was delivered with a similar frequency to the experimental one, and outcome assessors were blinded towards the allocation of patients.

The study also has several limitations beyond the inconsistent implementation of the intervention. Clinicians could not be blinded towards their own allocation, which raises the possibility of performance bias. The study also excluded patients who had an insufficient command of English, already had a high SQOL at baseline or were deemed too unwell to provide informed consent. If the intervention is to be rolled out in routine care, such patients will have to be included, and it remains unclear as to what extent the findings of this study would apply to the excluded groups. The primary diagnosis was also assessed based on clinical notes. Structured interviews may have been more reliable, although the intervention is not diagnosis specific. The dropout rate was higher than expected [8]. Finally, the sample size was too small to detect small effect sizes with sufficient power, although such effects may still be relevant.

Interpretation of the Results

The findings are consistent and expand the results of the original DIALOG trial [7]. What is common to the original DIALOG assessment and the extended DIALOG+ intervention is that they provide a structured, comprehensive assessment in routine meetings that is patient centred and explores wishes for change. Indeed, a positive change to patients' self-reported needs has been found to be a stronger predictor of improved SQOL than clinician-perceived needs [27], which highlights the importance of a patient-centred assessment in routine meetings.

DIALOG+ is intended to be more intensive and improve treatment outcomes even if patients do not stay in care for a year or more as in the original DIALOG trial. Whilst in the original DIALOG intervention clinicians were expected to respond to patients' concerns, there were no instructions on how to do this. DIALOG+ provides such instructions and goes beyond facilitating a mere assessment. It guides clinicians in their response to the concerns of patients, helping to reach agreements on actions in a shared discussion. The 4-step approach in DIALOG+ is based on principles of SFT, which has been found to be effective in treating a wide range of disorders [28, 29], requires a shorter time span than alternative models [28] and utilises the patient's personal and social resources rather than being deficit focused [3, 30].

This study did not find a benefit on treatment satisfaction and failed to demonstrate significant effects on further patient-reported outcomes such as mental well-being and self-efficacy. Whilst this may be seen as disappointing, it clarifies that the positive impact on SQOL and self-rated unmet needs is not just a generalised more positive appraisal across all patient-rated outcomes [31]. The effect seems to be more specific and is not primarily linked to a non-specific effect of the therapeutic relationship either. In fact, the quality of the therapeutic relationships did not significantly differ between the experimental and control groups.

The intervention did improve general psychopathological symptoms, which may be more closely associated with immediate problems and concerns than are positive or negative symptoms, on which there was no effect. The positive effect on SQOL and general symptoms remained at 12 months (6 months after all, but 6 patients had stopped using the intervention), suggesting long-term benefits for patients. Furthermore, patients in the DIALOG+ arm had significantly better objective social outcomes at the 12-month follow-up. Such outcomes, which include employment and housing situation, take much longer periods of time to improve. This further supports the specific effect of DIALOG+ in initiating real change in the patient's life.

After 3 months and on average 2–3 meetings DIALOG+ already had an effect. One may assume that the intervention effectively helps patients and clinicians to identify concerns as well as possible solutions and actions during the initial 2 or 3 sessions, producing a visible benefit after a short period of time. Once this has happened, mere repetitions within the subsequent months may not be of much further benefit. Thus, DIALOG+ is likely to be a generic short-term intervention – with a lasting effect, however. Rather than being frequently applied in regular short intervals, it might be used more flexibly and repeated once the situation of the patient has changed or new problems have arisen.

The effect size on SQOL is equivalent to more positive quality of life ratings in at least 3 out of 12 life domains on the MANSA, which should be regarded as a clinically significant improvement. The effect is greater than in the original DIALOG trial (adjusted mean difference on the MANSA of 0.30 vs. 0.12), which provided the assessment without the 'plus' part of DIALOG+, assessed outcomes after 1 year, had no active control, and used unblinded assessors of outcomes. The effect size is similar to those re-

ported for much more extensive and costly psychological treatments such as cognitive behaviour therapy [32–34]. One can only speculate as to why DIALOG+ as such a brief intervention has a similar effect to more time-consuming and cost-intensive therapies. Unlike other therapies, DIALOG+ does not require the referral of a patient to a different clinician or service. It is used within the existing patient-clinician relationship. This may facilitate mutual trust and credibility and support the delivery of the agreed actions. Another potential advantage is that clinician and patient address practical issues as well as psychological ones, which may have a tangible impact on the patient's life. This may in turn help to alleviate general psychopathological symptoms, on which the intervention showed a medium-sized beneficial effect, and lead to longer-term improvement on objective social outcomes.

Implications and Future Directions

Given that this is a low-cost, potentially cost-saving and generic intervention which requires limited training and no service reorganisation, it is easy to carry out. When it is used on a larger scale, small effect sizes in individual patients would add up to substantial public health gains. Using the intervention in practice will also deliver, quasi as a side effect, patient-reported outcome measures. The scores of the scale in DIALOG and DIALOG+ have been shown to be valid indicators of SQOL and treatment satisfaction [35]. Obtaining such outcomes in a clinically meaningful procedure may be more economical and provide better response rates than separate assessments purely for evaluation purposes.

The findings from this pragmatic trial suggest that DIALOG+ may be used widely in community care. The results may also encourage further attempts to use psychological models for making routine meetings in community mental health care therapeutically more effective [2]. Computer technology like that in DIALOG+ may support such attempts but is not the essence of the intervention, as demonstrated by the active control. At the heart of the effective intervention is a structured patient-clinician communication which identifies patients' concerns, analyses them, finds appropriate solutions in a collaborative way, and, hence, initiates change.

Further research should test DIALOG+ outside London and in different clinical settings and with different patient groups. If used in different contexts, the intervention might be further adapted and refined.

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Disclosure Statement

The authors declare no conflicts of interest.

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