

**What works for whom in a computer mediated communication intervention in
community psychiatry?**

Moderators of outcome in a cluster randomised trial

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ABSTRACT

Introduction: An intervention aimed to structure patient-key worker communication has been tested in a RCT. The aim of this paper is to investigate effectiveness of the intervention in terms of moderators of effectiveness.

Methods: 507 patients with schizophrenia were included. Moderators of effectiveness were investigated by two-way ANOVA:s.

Results: Patients with a better relationship with their key worker and shorter duration of illness benefited more from the intervention in terms of quality of life. Patients in the intervention group with competitive employment or shorter illness duration showed greater reduction of unmet needs. Older patients receiving the intervention had better treatment satisfaction.

Conclusions: Outcome of the intervention was moderated by patient characteristics. Research in moderators is very limited, which would call for further research addressing moderators of importance for implementation of interventions.

Significant outcomes

There was a main effect of the intervention.

The intervention effects were differential with regard to quality of the therapeutic relationship, duration of illness, employment situation and age.

Limitations The lack of research on moderators of psychosocial interventions in community-based mental health limits the conclusions from the present study.

The design of the study unable analyses whether specific elements of the intervention were related to the moderator effects

INTRODUCTION

People with schizophrenia living in the community is a vulnerable group, often characterised by complex needs and disabilities in several life domains. Treatment in community-based services is mostly performed by multi-professional teams with a designated key worker responsible for planning and implementation of care interventions. We have also seen the development of a number of evidence-based psycho-social interventions intended to support and increase effectiveness of community-based care (1-4). Furthermore, the therapeutic relationship between patient and clinician has been considered pivotal for care delivery in community-based mental health services, and qualities of this relationship have been found to predict both compliance and treatment outcome across different patient groups and service settings (5).

Although the regular meetings between a patient and his key worker seem to be of vital importance for the process and outcome of community mental health care, the content and communication of these routine contact has been the subject of little systematic research, and no evidence-based method to structure these meetings in order to improve treatment outcome exists. Recently, a novel intervention structuring communication between patients and key workers in routine meetings by means of a regular, two-monthly assessment of satisfaction with various life domains and aspects of current treatment was implemented, the DIALOG intervention. The intervention was supported by computer mediated technology and intended to ensure that a range of life domains and treatment aspects were consistently addressed and patients' perspectives always elicited. The results of the interview were fed back immediately to the patient and aimed to feed into patient-key worker discussions and have an impact on subsequent care and the therapeutic relationship. This new intervention has in a cluster randomised trial been shown to have a positive significant effect after one year on subjective quality of life (ES= .20), treatment satisfaction (ES=.27) and prevalence of unmet needs

(ES=.22) (6). These results raised the question whether this intervention was moderated by baseline characteristics of the patients, and thus more or less effective in subgroups of patients compared to treatment as usual. Moderators are variables preceding assignment to treatment which interact with the treatment variable in affecting outcome. The aim of this paper is to further investigate the effectiveness of the DIALOG intervention in terms of differential effects in subgroups of patients with regard to patient sociodemographic, clinical and social characteristics at baseline, i.e. to explore the interaction between baseline moderator variables and the DIALOG intervention.

METHOD

Design

The study used a cluster randomised controlled trial design. Key workers were randomly assigned to either the experimental intervention or treatment as usual (TAU), with a pre-post design over a one-year period. Cluster randomisation was used in order to avoid potential contamination between the interventions in the two groups. Collection of baseline data began in December 2002, and 1-year follow-up data collection ended in May 2005. At both time points key workers and patients were interviewed by researchers who had no involvement in the patients' care. For more detailed information concerning design and randomisation procedures see Priebe et al (6).

Settings and participants

The study was conducted in community mental health services in Granada (Spain), Groningen (The Netherlands), London (United Kingdom), Lund (Sweden), Mannheim (Germany), and Zurich (Switzerland). The participating teams were multidisciplinary and provided comprehensive care programmes for people with severe and enduring mental illnesses. They operated a key worker system in which every patient had a designated member of the staff

with a lead responsibility for care co-ordination and delivery. Referrals were determined by geographical area and age limits.

Eligibility criteria for participating key workers were a professional qualification in mental health and/or a minimum of one-year professional experience in an outpatient setting, and an active case load as key worker. The caseloads of participating key workers were screened to identify suitable patients meeting the following inclusion criteria: living in the community (not 24 hour supported accommodation) and treated as outpatients by community psychiatric teams; at least 3 months of continuous care in the current service; capable of giving informed consent; having sufficient knowledge of the language of the host country; having a primary diagnosis of schizophrenia or related psychotic disorder (ICD-10 = F20-F29); aged between 18 and 65 years of age; having routinely at least one meeting with their key worker every two months with the expectation that they would continue with the service for the next 12 months; and having no severe organic psychiatric illness or primary substance abuse. Patients were first informed about the study by the key workers and then – if they agreed – approached by a researcher for consent. The study was approved by the relevant research ethics committees in the six countries, and written informed consent was obtained from all key workers and patients in the study.

Intervention

Key workers in the control group continued with standard treatment with their participating patients. In addition to standard treatment key workers in the intervention group implemented a new manualised intervention. Key workers in the intervention group used a computer mediated procedure to discuss a number of defined issues with their patients. They asked patients to rate their satisfaction with 8 life domains (mental health, physical health, accommodation, job situation, leisure activities, friendships, relationship with family/partner,

personal safety) and 3 aspects of treatment (practical help, psychological help and medication). Satisfaction was in each area rated on a 7-point rating scale, ranging from couldn't be worse to couldn't be better, and followed by a question on whether the patient wanted any additional or different help in the specific domain. The intervention was to be applied every two months in meetings that had been arranged as part of routine care.

Data collection

Outcome in the two groups was compared in a pre-post design at baseline and 12-month follow-up. Subjective quality of life was the primary outcome measure and rated on the Manchester Short Assessment of Quality of Life (7). MANSA contains 16 items of which 12 assess satisfaction with life in general and in different life domains using a 7-point response scale ranging from couldn't be worse to couldn't be better. The mean score of all 12 satisfaction ratings is taken as the indicator of overall subjective quality of life.

Secondary outcomes were number of unmet needs and satisfaction with treatment. Needs were measured using the Camberwell Assessment of Need Short Appraisal Schedule, patient rated version (CANSAS) (8), which assesses health and social needs across 22 domains. For each domain it distinguishes between 'no need', 'met need' and 'unmet need'. Patients' satisfaction with treatment was assessed on the 8-item Client Satisfaction Questionnaire (CSQ-8) (9). Helping Alliance was measured by a 6-item self-report questionnaire Helping Alliance Scale (HAS), developed by Priebe and Gruyters (10). Interviewers assessed patients' symptoms on the Positive and Negative Syndrome Scale (PANSS) (11). Socio-demographic and clinical characteristics of patients were obtained at baseline. The psychiatric diagnosis was obtained through a standardised and computer based method using operationalised criteria (OPCRIT) (12).

Statistical analysis

Descriptive statistics are presented with frequency and percentage distributions for categorical data and means and standard deviations for continuous data. In order to investigate predictors of outcome regarding quality of life, needs and treatment satisfaction, a number of patient baseline characteristics were included in a series of two-way ANOVAs (13). Having shown a main intervention effect of the three outcome measures in an earlier paper, the main effects of a number of moderator variables and the interaction between these and the intervention were investigated. Interaction effects were analysed in order to explore whether any patient baseline characteristics were moderators of the intervention effect. Change scores over the 12-month follow-up period of unmet needs and quality of life, and follow-up scores of treatment satisfaction were used as dependent variables. The patient characteristics included were sex, age (median cut), marital situation (married/not married), employment situation (employment/no employment), living situation (independent living/dependent living), duration of illness (median cut) and number of psychiatric hospital admissions (median cut), baseline assessments on symptoms (median cut) and patient ratings of helping alliance, (median cut). The statistical software used was SPSS 14.0.

RESULTS

From the key workers caseloads, 507 eligible patients agreed to take part, with 236 patients in TAU and 271 in the intervention group. At 12 months, 451 patients (243 intervention, 208 TAU) were re-interviewed, a follow-up rate of 88.9%. Social and clinical background characteristics of the patient sample divided in intervention groups are given in Table 1. There were no significant differences between the two groups.

Insert Table 1 here.

In an earlier paper we demonstrated significant intervention effects in favour of the DIALOG intervention, in three areas: subjective quality of life, unmet needs and treatment satisfaction. Table 2 displays the results from the moderator analyses. Regarding quality of life there was a main effect for symptoms; patients with more severe negative symptoms at baseline improved more regarding quality of life. There were also two moderator variable effects insofar as patients with a better initial helping alliance or shorter duration of illness receiving the DIALOG intervention perceived a greater improvement in subjective quality of life.

Insert table 2 here.

The results regarding unmet needs showed a main effect on reduction of unmet needs for patients with a more severe initial psychopathology. There were two moderator effects, a greater reduction of unmet needs were shown for patients with a competitive employment or shorter duration of illness receiving treatment in the DIALOG group.

A better treatment satisfaction was related to a better initial helping alliance, a less severe initial psychopathology and not having an independent accommodation. Only one interaction effect was detected; treatment satisfaction for older people was moderated by treatment condition, older patients in the DIALOG group having a better satisfaction with treatment.

DISCUSSION

The main purpose of the DIALOG study was to test the effectiveness of a novel intervention in community care for patients with schizophrenia and related psychotic disorders. To our knowledge this is the first study to investigate an intervention aimed at restructuring patient-key worker interaction in community mental health care across a range of healthcare systems,

and to test its effectiveness in a 12-month perspective (6). After 12 months, the intervention had a significant positive effect in three essential outcomes domains, i.e. quality of life, unmet needs, and treatment satisfaction.

In the present paper we investigated moderators of intervention effects, exploring whether treatment effects were differing in subgroups of patients, in terms of social and clinical baseline characteristics of the participating patients. Research on moderators of effectiveness of psychosocial or communication interventions in community-based mental health care is very limited. A few earlier studies have explored moderators of outcome in the context of case management studies (14-15), mainly focusing on treatment satisfaction and psychiatric symptoms. There is an obvious need to further develop more refined conceptual models for the investigation of moderators. Within the field of psychotherapy research the influence of client variables on psychotherapy outcome has been extensively researched, mostly using ad hoc hypotheses and frequently showing main effects of patient characteristics but rarely any moderating treatment by patient characteristics interaction effects (16).

The main results from the present analyses of moderators were that patients with a shorter duration of illness and a better baseline perceived helping alliance, receiving the DIALOG intervention, improved more regarding subjective quality of life. Variables moderating effectiveness regarding changes in unmet needs were employment and duration of illness, insofar as patients with a competitive employment and a shorter duration of illness benefited more from the DIALOG intervention in this respect. Treatment satisfaction at follow-up was moderated by age; older patients in the DIALOG intervention group had a better treatment satisfaction.

In addition a number of main effects were revealed indicating that, irrespective of type of intervention, certain subgroups benefited more from community-based care. Patients with more severe baseline negative symptoms improved more regarding quality of life, patients with a more severe baseline overall symptom level improved more as to unmet needs, and patients with a baseline supported housing situation, less severe psychopathology and a better helping alliance had a superior satisfaction with treatment at follow-up.

In view of the general lack of research on moderators of psychosocial interventions in community-based mental health care, the conclusions from the present results, referring to a primal investigation of a novel intervention, are limited. Tentatively, patients with a shorter duration of illness, a better relationship with their key worker and a better social situation in terms of competitive employment seem to benefit more, in terms of clinical outcome, from the structuring of the communication between patient and key worker which is at the heart of the intentions of the DIALOG intervention. This would indicate that the DIALOG intervention would make most difference in subgroups of patients in a more acute phase of illness, with a better integration in society, and entering the intervention with a more positive relationship with their key worker. The latter is in line with results from an observational study by Little et al (17) showing a relationship between outcome and patients' perceptions of the provider having a patient centred and positive approach. These results may also indicate that for patients with a more chronic and longstanding illness it might be harder to change communication patterns.

The design of the study unable analyses whether specific elements of the intervention are related to these moderator effects, since the intervention was delivered as a package. We have proposed that the distinct elements of the DIALOG intervention are: a) the structuring of the patient-key worker meeting ensuring that important areas of needs and treatment are always

covered; b) the focus on patient views of treatment process and outcome in every 2 month meeting, and c) the specific computer mediated option to feed back by comparisons on a computer screen of current ratings with previous ones across the different life domains assessed.

A limitation of the present study is that the analyses of moderators of outcome were performed post-hoc in order to support and further explore the main findings of the study. This means that the inclusion of moderator variables in the data collection were not derived from any theoretical considerations or the hypothetical influence of certain moderators, based on earlier research. On the other hand there is almost no empirical research, or evidence from existing intervention research in the mental health research area, which would indicate that specific moderator variables of outcome would be of interest to investigate.

In conclusion, treatment outcome over a one year period of a computer mediated procedure aimed to structure routine communication between patient and key worker was moderated by specific patient characteristics. Although of potential importance for the implementation and use of such interventions, research in moderators of the effectiveness of community-based psychosocial interventions is very limited. This would call for further intervention research specifically addressing the issue of moderators, and mediators, of effectiveness.

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Table 1. Baseline Demographic and Clinical Characteristics of Patients

Characteristic	Treatment as Usual (N=236)	Intervention (N=271)
Age (yr)	41.8 \pm 11.6	42.5 \pm 11.3
Gender (% female)	35.2	32.5
Marital status (% single)	83.9	89.3
Unemployed (%)	36.9	35.2
Independent living situation (%)	66.5	67.5
Duration of illness (yr)	15.2 \pm 9.9	16.6 \pm 10.5
Number of hospital admissions	4.5 \pm 6.9	5.8 \pm 7.6
MANSA (QoL)	4.7 \pm 0.8	4.7 \pm 0.8
CSQ (satisfaction with treatment)	25.7 \pm 4.2	25.7 \pm 4.1
CANSAS (unmet needs)	3.0 \pm 3.1	2.7 \pm 2.7
PANSS (symptoms total score)	62.2 \pm 17.4	64.8 \pm 19.8
HAS (helping alliance)	8.1 \pm 1.6	8.0 \pm 1.7

Table 2. Moderator variable analyses for unmet needs, quality of life and treatment satisfaction*

Effect	Quality of life		Unmet needs		Treatment satisfaction	
	F	p	F	p	F	p
Gender	0.94	.334	0.24	.876	3.68	.058
Gender x intervention	0.24	.622	0.06	.814	0.32	.572
Age	1.13	.287	1.32	.251	1.96	.162
Age x intervention	0.01	.924	1.21	.272	8.22	.004
Living situation	0.04	.840	3.49	.063	14.11	.001
Living situation x intervention	0.54	.463	0.04	.842	0.27	.607
Marital status	2.43	.120	0.01	.995	0.22	.638
Marital status x intervention	0.26	.608	2.75	.098	0.24	.625
Employment	0.007	.934	1.04	.309	1.30	.256
Employment x intervention	0.78	.379	3.99	.047	1.28	.258
Duration of illness	2.32	.129	0.10	.757	0.68	.412
Duration of illness x intervention	4.26	.040	10.14	.002	0.01	.994
Psychiatric hospital admissions	0.07	.791	0.90	.341	1.15	.284
Psychiatric hospital admissions x intervention	0.03	.857	0.10	.927	135	.247
Negative symptoms	5.26	.022	2.73	.099	3.43	.065
Negative symptoms x intervention	2.61	.107	0.38	.539	1.17	.280
Total symptoms	0.83	.363	16.28	.001	14.95	.001
Total symptoms x intervention	1.04	.308	0.31	.578	0.09	.771
Helping alliance	1.20	.274	2.04	.154	71.31	.001
Helping alliance x intervention	8.40	.004	2.571	.110	0.12	.730

* Two-way ANOVA, significant p-values in bold text