


Effects of the Two-Way Communication Checklist (2-COM): A one-year cluster randomized study in a group of severely mentally ill persons

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Abstract

Background: In a health-care service with the emphasis on improvement related to functioning and well-being, the communication process between patient and professionals is essential. There is a lack of research on this matter.

Aim: The aim was to investigate, in a group of severely mentally ill persons, whether the use of a simple communication tool could influence the sense of empowerment, satisfaction with care, therapeutic alliance and unmet needs.

Method: The study had a cluster randomized design. The intervention was a communication tool (2-COM) applied in two teams during one year. In a comparison group of two other teams, the treatment was as usual. At baseline, after six months, and after one year, assessments were made.

Results: After one year the 2-COM groups seemed to have a larger reduction in unmet needs compared to the treatment-as-usual group. However, there were large problems with attrition in the study, and it was not possible to draw relevant conclusions.

Conclusions: The methodological problems were substantial, and the study may be considered as a pilot study. In a main study the researchers ought to take control over the selection of patients on the basis of the experiences from this study.

Keywords

Communication, intervention, needs, cluster randomized study, severely mentally ill

Introduction

In the care of severely mentally ill persons, there seem to be large differences in the way that patients describe themselves and how professionals perceive them (Biancosino et al., 2007; Lasalvia, Bonetto, Tansella, Stefani & Ruggeri, 2008). There are many reasons for these differences, and they cause problems in treatment planning and outcome. Efforts should be made by services to implement strategies aiming to increase the consensus concerning staff and patients (Lasalvia et al., 2008). In a health-care service with the emphasis on improvement related to functioning and well-being as well as symptom reduction (Fleischhacker, Rabinowitz, Kemmler, Eerdekens & Mehnert, 2005; Nasrallah, Targum, Tandon, McCombs & Ross, 2005), the communication process between patient and professionals is essential.

The concept of empowerment has evolved as an expression of efforts to strengthen the patient's own control over his/her own life and the control and influence of the care and support situation (Hansson & Björkman, 2005). In 1997, the World Health Organization (WHO) adopted

empowerment as a guiding principle for health care (Kilian et al., 2003). Shared decision-making seems to be one way for the severely mentally ill person to influence his/her care. An iterative administration of a decision aid may influence the long-term outcome (Hamann, Cohen, Leucht, Busch & Kissling, 2007). However, it needs to be clarified how patients diagnosed with schizophrenia could be empowered and educated to share important treatment decisions (Hamann et al., 2009).

The patient's perspective must be elicited in the meeting between the patient and the professional when the outcome

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concerns subjective needs, satisfaction with care, or empowerment. However, patient–professional communication is central in mental health care but neglected in research (van Os et al., 2004; Priebe et al., 2007).

One way to strengthen the patient's influence on the professional meeting is to use a communication tool developed for this particular aim. In one study, Priebe et al. (2007) used a computer-mediated procedure to structure the patient–professional meeting. The one-year outcome for the patients using this tool was a better quality of life, fewer unmet needs and higher treatment satisfaction. Another tool for communication is the 2-COM (van Os et al., 2002). The 2-COM is a checklist designed to help patients and staff to verbalize and identify problem areas. It consists of 20 common problems or needs for the patient to consider before the meeting with the key worker. It is designed to make sure that the patient's problems and needs are identified and discussed in the meeting with the patient, in order to decide how to handle identified problems, and follow up the effects of the efforts made. Another aim with the 2-COM is to give the patient the opportunity to speak openly about experiences of the illness, the treatment, and how the illness influences everyday life (van Os et al., 2002). The 2-COM could be seen as a tool for shared decision-making, increasing the possibility of compliance and a better long-term outcome. However, it could also be regarded as a mean for the severely mentally ill person to achieve empowerment.

The 2-COM has acceptable test-retest reliability (van Os et al., 2002). The use of a checklist has resulted in improved communication and changes in management (van Os et al., 2004; Robert et al., 2007). Furthermore, one study showed that disagreement between the patient and the professional concerning the identification of needs has a negative impact on the six-month outcome (van Os & Triffaux, 2008).

To our knowledge, studies of the 2-COM with an outcome longer than six months are lacking, as well as outcome studies with instruments measuring more aspects than those included in the 2-COM. One important aim of the instrument is to achieve a change in clinical decision-making and consequently sometimes also a change in treatment. However, the main aim of this study was to investigate, in a group of severely mentally ill persons, if the use of a tool developed to improve communication between patient and key worker could influence the patient's sense of empowerment, satisfaction with care or opinion of the therapeutic alliance, and his/her own estimation of unmet needs. The hypotheses were that using the 2-COM would strengthen the patient's sense of empowerment and satisfaction with care, as well as his/her view of the therapeutic alliance. Furthermore, it was hypothesized that using the 2-COM would result in fewer patient-rated unmet needs.

Method

The intervention

The intervention involved using the dialogue-based instrument 2-COM (van Os et al., 2002). The original version consists of 20 common problems or needs for the patient to consider. As far as we know, this was the first time that the instrument was used in Sweden. The problem areas in the checklist were somewhat changed compared to the original English version. The Swedish checklist consisted of 19 areas, of which 15 were identical to those in the original English version. Four areas were adjusted to a Swedish context.

Measurements

Therapeutic alliance. The Helping Alliance Scale (HAS; Priebe & Gruyters, 1993) was used to assess the therapeutic alliance. The scale consists of six items for the patient to consider. One example is: 'How much is your key worker committed to and actively involved in the treatment?' The ratings are made on a 10-point Likert scale. Summary scores were used. The reliability of the HAS is acceptable (McCabe & Priebe, 2004).

Needs. The Camberwell Assessment of Need (CAN; Phelan et al., 1995) is a widely used instrument to measure the needs of severely mentally ill persons. It includes the views of the patient and staff. The CAN has a short form (CANSAS; Slade, Beck, Bindman & Thornicroft, 1999), which was used in the present study. The CAN and CANSAS assess needs in 22 different domains, each of which is assessed by patient and staff, considering the existence of a need. The needs are rated on a three-point scale: 0 = no serious problem (no need); 1 = no problem or just a moderate problem because of help given (met need); 2 = serious, regardless of any help given (unmet need). Test-retest and inter-rater reliability of the assessment of needs (CAN) was investigated by Phelan et al. (1995) and inter-rater reliability by Andresen, Caputi and Oades (2000) (CANSAS). The inter-rater reliability of a Swedish version of the CAN has been tested by Hansson, Björkman and Svensson (1995) and the test-retest reliability by Arvidsson (2003), both with acceptable results. The sum of the patient's ratings of unmet needs was used in this study.

Satisfaction with services. A Swedish translation of the eight-question Client Satisfaction Questionnaire (CSQ) was used (Attkisson & Zwick, 1982). The questions concern the client's evaluation of services and are answered on a four-point Likert scale. One example is: 'How would you rate the quality of the service you have received?' A sum value is calculated. The scale has high internal consistency, and its construct validity has been investigated (Attkisson & Zwick, 1982; Nguyen, Attkisson & Stegner, 1983).

Empowerment. Empowerment was assessed using a Swedish version of the Making Decisions Scale (EMP; Rogers, Chamberlin, Ellison & Crean, 1997). The EMP consists of 28 statements, for example: 'I am often able to overcome barriers.' The statements are rated on a four-point Likert scale, and a summary score is calculated. The Swedish scale has been tested for reliability and validity with satisfactory results (Hansson & Björkman, 2005).

Implementation

The basis of this study was one outpatient unit of care for persons with severe mental illness in Gothenburg, Sweden. The unit was composed of four different multi-professional teams and the matching between patient and team depended on the patient's address. Each team included a psychiatrist, a trained nurse, a mental keeper, a social worker, a psychologist, an occupational therapist and a physiotherapist.

Contact was established with the manager at the psychiatric outpatient clinic to discuss the possibility of implementing the 2-COM. The manager and most of the staff were positive to participate. The manager, together with the researchers, held meetings to motivate those who were sceptical, and a decision was made to perform the planned study.

In an early phase, two teams were randomized to apply the implementation (the 2-COM group), and two teams were randomized to a comparison group where the treatment was as usual (the treatment-as-usual group). Randomization was used in order to achieve equation between the groups for observed and unobserved variables. Moreover, randomization was used to facilitate the possibility to define a causal relationship between the intervention and the outcome (Shadish & Cook, 2009).

After the team randomization, all information meetings were held separately with the two groups to avoid affecting the treatment in the comparison group. However, it may be assumed that there were some nesting effects, since the intervention and the comparison groups were located at the same clinic.

The information phase regarding the 2-COM instrument seemed extensive. The intervention group received oral information on two occasions as well as written instructions about how the care provider, and the patient, should use the 2-COM. During a third information meeting, both groups received oral and written information regarding the data collection procedure for the self-rating forms. This was done to assure that both groups received identical information. All care providers received information sheets directed to the patients. The information sheet was provided in two versions depending on the group to which the staff/patients belonged. On several occasions during one year, the staff was given oral information at staff meetings. One of the authors was regularly available at the outpatient unit to answer questions from staff as well as from patients.

The recruiting phase

The patient recruitment was designed so that all care providers asked their patients if they were willing to take part in a research project. However, the staff were instructed to exclude patients with organic psychoses and those with an active substance abuse. Nor were patients whom staff considered too ill to participate asked. Out of a total of 191 patients, 130 were asked. Out of these 130 patients, 49 accepted to participate in the study (Figure 1).

Twenty people agreed to take part in the intervention (the 2-COM group) and 29 in the comparison group (the treatment-as-usual group) (Figure 1). Those 49 people were aged between 23 and 75 years ($M = 45.0$, $SD = 12.7$); 17 were female and 32 male. Out of the 49 patients, 21 were given a diagnosis of schizophrenia (F20; WHO, 2010) or schizoaffective syndromes (F25), and 28 were given other diagnoses, most of them other psychoses or bipolar syndromes. Twenty-one patients were born in Sweden, 10 in other countries in Europe, and 18 were born outside Europe. Considering age, gender, diagnoses and country of birth, no significant differences between the 2-COM group and the treatment-as-usual group were found. For some characteristics of the groups, see Table 1.

Procedure

Self-rating forms. If the patient, regardless of group belonging, accepted to participate in the research project, an appointment was made with one of the authors. During this appointment, the patient received further information about the research project, as well as oral and written information about anonymity, and about participation being voluntary. For patients who gave their written consent, the self-rating forms (EMP, CANSAS, HAS and CSQ) were filled in under supervision of one of the authors. After six months and also after one year the procedure was repeated (Table 2).

2-COM. Patients and their key care provider filled in the 2-COM separately before the meeting. The patient's 2-COM version was then used as a guide for discussions during the treatment session. The aim was that this process should be repeated every other month during one year (Table 2).

Statistics

The differences between the assessment at baseline and the assessments six months later and one year later, respectively, were calculated concerning the summary scores in the HAS, EMP and CSQ, and concerning the number of each patient's ratings of unmet needs in the CANSAS. These differences were compared between the 2-COM group and the treatment-as-usual group with the Mann-Whitney U-test, which was used in regard to the skewed

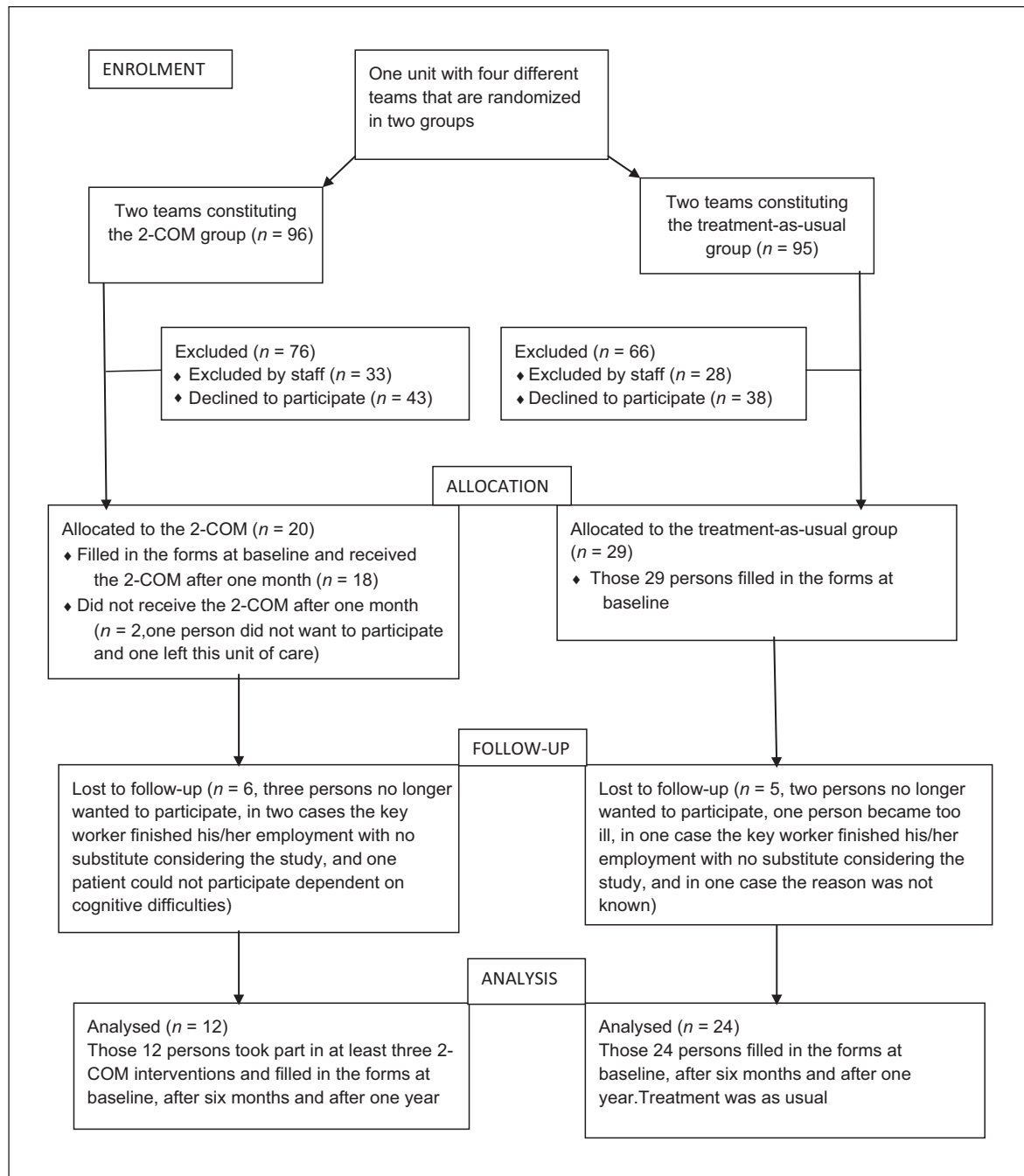


Figure 1. A CONSORT diagram.

Table 1. Some characteristics of the persons in the 2-COM group and in the treatment-as-usual group who took part in the study and of those who did not.

Variable	2-Com group (n = 20)		Treatment as usual (n = 29)	
	Took part (n = 12)	Attrition (n = 8)	Took part (n = 24)	Attrition (n = 5)
Age >45 years	6 (50%)	4 (50%)	12 (50%)	2 (40%)
Born in Sweden	7 (58%)	4 (50%)	8 (33%)	2 (40%)
Female	4 (33%)	2 (25%)	8 (33%)	3 (60%)
Diagnosis F20 or F25	6 (50%)	5 (63%)	7 (29%)	3 (60%)

Table 2. Research design.

Researcher/patient										
Intervention group										
Comparison group										
	Baseline	Month I	Month3	Month5	Month6	Month7	Month9	Month I I	Month12	
EMP	X				X					X
CANSAS	X				X					X
HAS	X				X					X
CSQ	X				X					X
Key worker/Patient										
Intervention group										
2-COM		X	X	X		X	X	X		

Table 3. Mean and median values at baseline and six month later in the 2-COM group and the treatment-as-usual group concerning outcome variables. Comparison between the two groups concerning differences between assessment on baseline and six months later.

Variable	2-COM (<i>n</i> = 12)				Treatment as usual (<i>n</i> = 24)				<i>p</i> (Mann-Whitney) (two-tailed)
	Baseline		After six months		Baseline		After six months		
	<i>M</i>	Med	<i>M</i>	Med	<i>M</i>	Med	<i>M</i>	Med	
EMP	2.78	2.82	2.81	2.89	2.66	2.71	2.69	2.73	.980
HAS	8.35	9.20	9.00	9.50	8.05	8.00	8.35	8.00	.560
CSQ	26.83	27.00	29.18	30.00	25.13	25.50	25.41	25.50	.218
CANSAS	3.17	1.50	.75	0.00	2.30	1.00	2.19	1.00	.055
Unmet need									

Table 4. Mean and median values at baseline and one year later in the 2-COM group and the treatment-as-usual group concerning outcome variables. Comparison between the two groups concerning differences between assessment on baseline and one year later.

Variable	2-COM (n = 12)				Treatment as usual (n = 24)				p (Mann-Whitney) (two-tailed)
	Baseline		After one year		Baseline		After one year		
	M	Med	M	Med	M	Med	M	Med	
EMP	2.78	2.82	2.84	2.89	2.66	2.71	2.72	2.64	.869
HAS	8.35	9.20	8.54	9.20	8.05	8.00	8.72	9.20	.553
CSQ	26.83	27.00	27.58	26.50	25.13	25.50	26.48	27.00	.599
CANSAS	3.17	1.50	1.00	0.00	2.30	1.00	2.08	1.00	.018*
Unmet need									

*p < .05.

distribution of values. According to the hypotheses, there should be larger negative differences in the 2-COM group compared to the treatment-as-usual group concerning HAS, EMP and CSQ, and larger positive differences in the 2-COM

group compared to the treatment-as-usual group concerning the number of unmet needs (CANSAS). The differences between the 2-COM group and the treatment-as-usual group were considered significant if $p < .05$ (two-tailed).

The Wilcoxon sign rank test was used to study the drop of unmet needs in the 2-COM group and in the treatment-as-usual group separately.

The software used was PASW Statistics 18.

Results

Attrition

There were different kinds of attrition at different phases in the study, as described in a consort diagram (Figure 1). Of a total of 191 patients, 49 agreed to participate. Out of the 20 persons who agreed to participate in the 2-COM group, two dropped out before the first 2-COM intervention. Of the 18 persons remaining, 12 did participate on all three assessment occasions (at baseline, after six months, and after one year). Out of the 29 persons in the treatment-as-usual group, 24 participated on all three assessment occasions. The distribution of persons in these groups concerning gender, age, diagnosis and country of birth is shown in Table 1.

According to the design of the study, the 2-COM intervention was to be repeated every two months during one year; consequently, each patient should have used the 2-COM six times. However, the compliance with this guideline was incomplete. In reality, the 2-COM intervention was performed between two and six times per patient ($M = 4.0$, $SD = 1.7$).

The 2-COM group and the treatment-as-usual group

After six months, no significant differences could be found between the 2-COM group and the treatment-as-usual group (Table 3). However, there was a decrease in the number of unmet needs concerning the 2-COM group (Wilcoxon, $z = 2.144$, $p = .032$). There was no such decrease in the treatment-as-usual group.

After one year, a significant difference in the expected direction was found with regard to the number of unmet needs (Table 4) (Mann-Whitney, $U = 75.5$, $z = 2.359$, $p = .018$). It seemed as if the drop in unmet needs in the 2-COM group appeared during the first six months and was still remaining after one year (Tables 3 and 4).

The attrition groups were large. In order to make the statistical conclusions more conservative, comparisons between the 2-COM group and the treatment-as-usual group were also performed, hypothesizing that none of the persons in the attrition groups would assess any differences between the assessment at baseline and the one made one year later, considering the number of unmet needs (CANSAS). When assuming that the persons in one kind of attrition group (Figure 1; Allocation and Follow-up, $n = 20$ in the 2-COM group and $n = 29$ in the treatment-as-usual group) would have no differences between the assessments

at baseline and one year later, the corresponding p -value was $p = .041$ (Mann-Whitney, $U = 197.5$, $z = 2.042$). If, however, we assumed that the study had comprised all the enrolled individuals, including the attrition groups, and that none of the individuals in the latter groups had shown any difference between the baseline and the one-year follow-up assessments, then the p -value would not be significant (Figure 1; Allocation and Follow-up, $n = 96$ in the 2-COM group and $n = 95$ in the treatment-as-usual group; Mann-Whitney, $U = 4165.5$, $z = 1.827$, $p = .068$).

No significant differences were found concerning empowerment (EMP), satisfaction with care (CSQ) and the therapeutic alliance (HAS) (Tables 3 and 4).

Discussion

The main aim of this study was to investigate, in a group of severely mentally ill persons, if the use of a tool developed to improve communication between patient and staff could influence the patient's sense of empowerment, his/her satisfaction with the care, or opinion of the therapeutic alliance, as well as his/her own estimation of unmet needs. No differences between the groups were found concerning the patients' sense of general empowerment, satisfaction with care, or their view of the therapeutic alliance. The reported degree of empowerment had not increased more in the 2-COM group compared to the treatment-as-usual group. This was the case between the baseline and the six-month follow-up as well as between the baseline and the one-year follow-up. In the same way, there were no differences between the changes concerning the view of the therapeutic alliance or satisfaction with care.

However, there seemed to be a larger decrease in patient-rated unmet needs in the 2-COM group compared to the treatment-as-usual group. The differences occurred in the expected direction. Some of the impact of the 2-COM intervention on unmet needs may be explained by the fact that the problem areas in the 2-COM are partly selected from the CAN (van Os et al., 2002). Furthermore, the 2-COM could be seen as a tool for shared decision-making, resulting in changes in treatment and a better long-term outcome. However, changes in treatment and long-term outcome were not the main aim of this study. Nevertheless, a drop in unmet needs seems important in this respect, as unmet needs have been found to be related to other outcome variables (Joska & Flisher, 2005). Wiersma et al. (2009) discuss the sensitivity and suitability of unmet needs as an outcome criterion of interventions. These authors concluded that studies of repeated measures, like the present, are important in order to assess whether the CAN is sensitive to change or not. A drop in patient-rated unmet needs has also been reported when using a computer-mediated procedure to structure the patient-staff meeting (Priebe et al., 2007).

Limitations

There were serious limitations in this study. The most important concerned attrition. Out of the 96 persons originally constituting the 2-COM group, only 12 completed the intervention and the answering of the self-report instruments (13%). Out of 95 persons constituting the treatment-as-usual group, only 24 (25%) completed the self-report instruments. Serious questions must therefore be raised about the representativeness of the sample.

One reason for the high attrition rates seems to be how the patients were approached. The key worker had the main responsibility when estimating if the patient was too ill to participate and was also responsible for asking the patient if he/she was willing to participate. It could be complicated for staff to be both responsible for treatment and also for asking patients to take part in a study. If the staff only ask patients whom they find appropriate for participation, there is a risk of selection bias (Shadish, Cook & Campbell, 2002). There is often an overall protective atmosphere towards severely mental ill persons as a group, which is natural because of their vulnerable mental health but also because assumptions made of what is appropriate for the patient. Unfortunately, participation in a research project does not seem to be regarded as appropriate. To sum up, the recruiting phase in this intervention work could be described as 'a complicated process' with difficulties of recruiting participants, partly due to resistance among staff to asking patients to participate, partly because of the psychological difficulties that characterize this group of patients. In future studies, our conclusion is that the role of the staff as gatekeepers cannot be underestimated and that huge efforts must be made, partly to inform and educate staff and partly to work with possible resistance in different settings.

The selection bias could be assumed to affect the study in the way that the patients who participated were not entirely representative of the group as a whole. We had little control over how the selection was made by the staff and we could not assume that patients who accepted to participate were representative of those who refused. Furthermore, it seems as if the amount of attrition was larger in the 2-COM group than in the treatment-as-usual group. This difference further decreases the possibility of drawing conclusions (Shadish & Cook, 2009). To prevent attrition, Shadish et al. (2002) have given some advice, which was followed in the study at least to a certain degree. However, this work did not seem to be sufficient.

The study was randomized at a team level. Two teams were randomized to the 2-COM group and two teams to the treatment-as-usual group. The study had a cluster sample, chosen from an already existing unit, and the results might not be representative for other units. Another limitation concerns the compliance with the research design. The

2-COM intervention was only performed four times on average in the 2-COM group. The optimal procedure would have been to perform it six times. This lack of compliance from the staff could be due to the psychodynamic tradition that characterized this health-care unit, implying a resistance to work with manual-based instruments during treatment.

Conclusions

It seemed that using the 2-COM invention could have consequences in reducing the number of unmet needs. There were no such signs concerning an increased sense of empowerment, a better helping alliance, or a better satisfaction with care. The reduction of unmet needs could be seen as one promising result among others concerning interventions to improve how patients and staff communicate. However, the problem in this study with its large attrition was substantial, and maybe it would be relevant to view this study more as a pilot study than a main study. In a future main study the researchers ought to have better control of the implementation process and of the selection of patients on the basis of the experiences from this study. A main study should also include a study of the effects of using the 2-COM for changes in treatment.

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