Crisis Dialogue for acute psychotic state, and ethical difficulties: What do you do when trials are interrupted because clinicians find the intervention too effective?

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Abstract:

Clinical studies carry with them a paradox: The more obviously efficient an intervention is, the more ethical problems its trials pose. This article discusses the ethical problem of breached equipoise principle, due to the perceived effectiveness of a non-blindable verbal technique, Crisis Dialogue (CD). CD is designed to help establish a therapeutic relationship with persons in a suspected psychotic state. In a pilot randomized controlled study in Yverdon, Switzerland (usual treatment versus usual treatment + CD), after inclusion of 30 patients, clinicians expressed a consensual opinion that CD was effective in most cases. Following their opinion, the joint clinical and research team decided that the study had to be discontinued and that CD should be tried with all patients for ethical reasons. This poses an ethical problem with potential far-reaching consequences: In this interrupted study, differences between groups in terms of clinical outcome (BPRS, CGI), therapeutic alliance (WAI, DDPR) and patient satisfaction, were consistent in favouring CD, but these differences did not reach statistical significance in most measurements. The early interruption of the study due to perceived effectiveness of the intervention can be seen as unethical as well, because chances were high that a larger sample would have shown more conclusive results, allowing for faster introduction of CD in various clinical settings, with corresponding improvement of patient care. (218 words)

Key words: Emergency Psychiatry; Controlled Clinical Trial; Pilot Study Clinical Trials; Methods; Psychotic Disorders; Nurse-Patient Relations; Physician-Patient Relations; Emergency Care.

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The rationale for focusing on a verbal technique in emergency psychiatry is that communication is particularly challenging with acute psychotic patients during the first days of care; it can be frightening and finding a common language with a delirious counterpart is often difficult. "Positive patient-therapist relationship has been found to be the most significant factor correlated closely with the treatment outcome », declared Lee more than thirty years ago (Lee, 1979). The importance of the therapeutic alliance, first recognized in psychotherapeutic theory and research, has been also increasingly studied in psychiatry (Catty, 2004). A strong alliance appears associated with positive treatment outcome among psychotic patients (Melau et al., 2015). During the first days of treatment for acute psychosis, one of the most stressful of all care situations, patients could benefit from a range of improvements in conceptual models, interventions and specific training in communication (McCabe & Priebe, 2008). Better communication especially during the first days of care could improve not only patient satisfaction but also long-term outcomes (priebe, 2009) & 2011). It could decrease undesirable late consequences of a psychotic episode, such as post-traumatic stress disorder, which affects as many as 30-40% of the cases (McGorry et al., 1991). Most of the research on the importance of clinician-patient communication in acute psychosis has been conducted on psychological interventions which starting after several weeks of care, once the most acute phase is over. A notable exception is the Scandinavian *Open dialogue*; the terms covers a whole programme of care, much broader than the Crisis dialogue described here, see below), with family and/or individual meetings in the community as soon as possible (Seikkula & Olson, 2003). The verbal technique called the Crisis Dialogue (CD) interested us because, from preliminary clinical experience, it seemed to address the need for an improved link with patients during the acute phase and at the onset of emergency care.

Conducting a randomised clinical trial (RCT) in emergency psychiatry presents special ethical and related methodological challenges. In emergency situations when clinicians have the impression that patients have impaired decision-making capacity, it can be considered impossible to elicit informed consent before starting the intervention (Lecouturier et al., 2008). A second challenge, perhaps less obvious, is related to blinding. If the assessed intervention is a verbal technique, blinding is impossible; and users can comment early on its perceived effects. If they perceive the intervention as detrimental, they can make an ethical case for a trial interruption. If on the other hand they perceive the intervention as beneficial, this also becomes a case for interruption, as the experience reported here will show. In this latter situation, further research on the same intervention becomes problematic and an original way should be found out of the dilemma, if one wants to continue to assess the intervention.

This article describes the experience of trying to document the effects of a verbal technique through a comparative study in emergency conditions. Such conditions create exactly those ethical and methodological problems described above. We will discuss them and propose possible solutions.

Subjects and Method

Patients consecutively admitted to Yverdon psychiatric hospital (Switzerland) from February 2009 to April 2010 were included according to the following eligibility criteria:

Aged 18 and over, admitted with a diagnosis (according to the first clinical impression during admission) of acute psychotic syndrome (first episode or relapse after free interval of >=6months).

Patients were excluded in cases of apparent of persistent systematised delirium (detailed mission, perception of a defined plot, etc.) or a major medical problem requiring rapid referral to another hospital.

All patient admitted to the hospital and meeting the criteria for inclusion were recruited and randomised (by the team, using sealed envelopes with random allocation based on a computer-generated random-numbers' table) at the time of their arrival in the hospital (see below for explanations concerning delayed consent in emergency situations). Patients could be exposed to CD the very first day of their arrival. Then, once they had retrieved the ability to decide with their free and informed consent, they would receive full information about the study and be asked whether they wanted to be part of it (see below under "ethical approval" for details).

The expected sample size was supposed to be 120 (60 cases and 60 controls) in order to detect risk difference of 1.52, or a difference in proportion of 26% (50% versus 76%) for any of the planned measurements and scores, this with confidence interval 95% (1-alpha) and power 80% (1-beta) (Epi-info version 6).

The intervention : a verbal technique:

Here is a composite example of using the Crisis Dialogue (CD):

A young woman (let's call her Alice) is brought to the emergency ward in a very agitated state. Alice, grumbles in a low voice:

-The Devil has taken everything from me. He took my friend, he is going to take everything. I beg you, call the angels to protect me.

The clinician says:

-Sorry, Madam, may I ask you a question? Are you somehow the centre of the world, …in contact with everybody?

The clinician has been using the exact words of the first sentence of the CD "Memo card" see Figure 1). The main novelty is for him to say "are you..." rather than "do you feel..." or "do you believe...").

Alice nods, her voice becomes clearer:

-Yes, that's it, exactly.

She listens to the rest of what the clinician wants to tell her at this moment, verbatim from the Memo card because the clinician has his first experience with CD today and also in order to test a definite verbal intervention in the research process. Alice interjects only brief "umh" and "yeah", then declares:

-Finally someone understands me.

She repeats this several times and asks to be left alone for a while because now she feels better.

Another example is a patient admitted for a cataleptic state, who had not spoken a word for the past two weeks. With CD the patient started immediately to speak again and a therapeutic alliance built up in the next few days. The two examples given above were the types of promising experiences that prompted us to continue in experimenting with CD use in emergency situations.

The Crisis dialogue (CD) is a verbal technique which takes about 3 minutes of the consultation time, once or twice a day, over a period of 3 to 7 consecutive days according to clinical progress and is meant as a **complement to usual care** (Bangerter, 2011). **Usual care** was, in the study settings, a psychiatric examination at admission aimed at welcoming and reassuring the patient, eliciting personal, familial and social history, observing mental status in order to prescribe subsequent treatment orientation including drugs, surveillance and sometime contention in a closed room. Clinicians providing care were a composite group of male and female nurses of all ages, junior and senior psychiatrists, and psychologists. Demographic data of clinicians were unfortunately not collected; it was felt unimportant because they served as their own control, providing usual care with / without CD. Such a design has the advantage of between-groups homogeneity of providers, but also entails a risk of spill-over (see limitations in the Discussion section).

CD can be tried with any patient who seems to be in a psychotic state and has sufficient cognitive capabilities (i.e. as practical rule: a patient who has finished elementary school).
CD was based on clinical observations during 10 years in the emergency psychiatry Services of Hotel-Dieu Hospital in Paris (Grivois, 2007) & (Grivois, 2012). With the help of H. Grivois, a team in Lausanne, Switzerland, including psychiatric nurses, professors at the school of nursing, psychologists and psychiatrists, designed a condensed verbal technique which could be taught to emergency teams (Graz, 2006).
CD focuses on the present experience of an acute psychotic state or proposes to recall the beginning of the episode; it provides tools and an underlying theory to help de-construct the delusions. Although the name might imply similarity, it is different from the Scandinavian "Open dialogue" which refers to a range of various therapeutic activities (family and/or individual therapy) (Seikkula & Olson, 2003). It also differs from the crisis model by De Coulon (1993), although it can shares the aim of improvement of the therapeutic alliance during an acute psychotic episode, especially relevant because the patient will often require a long term treatment program (De Coulon & Von Overbeck, 1993).

Patients in a psychotic state undergo a fundamental transformation of the structure of subjectivity and inter-subjectivity (Bovet & Gamma, 2002). By "subjectivity" , we refer here to the unique experiences a person makes of the world and of his/herself; by "inter-subjectivity", we refer to the confrontation of several persons' experiences with a commun focus. If the clinician (nurse, psychologist, physician or other) can find a language that matches the patient's experience, then the gap of inter-subjectivity may be narrowed, thereby establishing a relationship with better mutual understanding. This means that, at least for a part of the consultation, the clinician must use a language fitted not to his/her own reality (or, more precisely: experience and conception of the reality), but to the patient's present reality. We actually try to do this with any treatment, from

migraine to stomach ache, endeavouring to find a common language with our patient when explaining possible causes and ways to deal with the problem, but many of us tend to have difficulties achieving this with psychotic patients.

Some features of the patient's experience, especially at the onset of an episode, are common to most people experiencing psychosis (Salvador, 2008), (Grivois, 1999). These common features (« 3 invariants ») are, briefly stated:

1.Dys-mimetism: Normally, mimetism (a fundamental ability to learn and to coordinate inter-personal relationships) remains largely unconscious. In a psychotic state, mimetism becomes conscious and dys-functional, leading to un-differentiation of the self: *2.Un-differentiation of the self*: Patients have the experience – usually traumatic but sometime thrilling – of having no autonomous authorship of their acts and ideas. It becomes impossible to know who, oneself or others, initiates acts and thoughts: the differentiation of the subjective self-vanishes.

3.Generalised concern: Whilst being invaded by the experience of the universal nature of mimetism in the human species, the patient senses that all other human beings are in some relation with him/her; he/she has become the focus of attention, the "centre of the world", influenced by or influencing all others. At this stage, signals are spotted and interpreted as reinforcing this new view, often with delusional interpretations including an exceptional and unique destiny.

Drawing on the common features described above, an account of patients' experience is proposed (**Figure 1**, "first contact" and "explain"). The main idea is to suggest to the delusional patient an alternative meaning to his/her psychotic experience, a meaning that is closer to the inaugural event, descriptive and reassuring. The CD is designed to fit various kinds of clinical manifestations (e.g. exalted or persecuted patients).

Feasibility study:

A feasibility study was first organised in the psychiatric hospital of Yverdon (Switzerland): observations of 17 patients (9 before, 8 after teaching CD, mean age 29, 6 female, 11 male) with the same outcomes measurements as the one used for the later pilot RCT (see below).

"Before – after" study

In another institutional setting (Geneva, Switzerland – Belle-Idée Psychiatric Hospital, JADE project) length of stay was compared with 34 patients before, 17 after introduction of CD. Duration of hospital stay was shorter once CD had been introduced: a median of 46 days with CD, as compared to 61 days without CD, (P = 0.01 – unpublished). This however is an association without possibility of implying a causal link with high probability.

Implementation

The CD was taught by members of the group who had designed it to clinicians (all physicians, nurses and psychologists on the ward). The allotted time was a 2-hour session plus 12 hours coaching. Clinicians were instructed to begin by using ready-made sentences as displayed on a memo card (Fig 1), and then apply the underlying theory as a working hypothesis with increasing flexibility. They were encouraged to read provided books and an article on CD's underlying theory (Grivois, 2007, 2012; Salvador, 2008). The time for teaching CD to the whole team was two hours, followed by individual coaching on the ward during weekly half-day visit during 1 month.

Measurements:

The outcomes measurements were derived from the conceptual background and observation of clinician-patient encounters in Henri Grivois' clinic. Two types of measurements were recorded, one by patients and one by clinicians:

By clinicians:

Clinical Global Impression (CGI) (time: day 0, 3, 7, discharge), Brief Psychiatric Rating Scale (Leucht, 2006) from which a shorter version ("remission items" prepared in the Geneva psychiatric hospital - unpublished) (time: day 0, 3, 7, discharge), Difficult Doctor-Patient Relationship (DDPR) (Hahn, Thompson, Stern, Budner, & Wills, 1990) clinicians' ease/difficulty with the clinical encounter and subjective quality of the therapeutic relationship, (time. day 3, at discharge)

By patients:

Patients were interviewed at the time of deferred informed consent (when patients had, according to the ward's team consensus, retrieved their ability to decide upon their free and informed consent) and at discharge. Measurements were: Working Alliance Inventory – WAI short form (Hatcher & Gillaspy, 2006) and Patient satisfaction (questionnaire in use in Geneva hospital, Ferrero et al., unpublished). In addition we have been trying to recontact patients 3 months after discharge in order to ask them about their hospital experience, but were able to contact only a very small proportion (3/30, 10%) of them (results not shown).

Organisation of the pilot RCT

For the randomisation, sealed envelopes were prepared with computer-generated random numbers and opened after inclusion, dividing patients into two groups, treated or not treated with the new technique. The clinicians were asked to refrain from using the CD with patients in the control group. Although this entails a risk of spill-over (of aspects of the CD in the control group), it also produces a better balance of clinicians and their personal characteristics across both group, as seemed more important in this context.

The stopping rule was the observation of a lasting (>=3 months) statistically and clinically significant difference between groups, so interim analyses were planned every 3 months. Another stopping rule was the deadline for completing the study (after 2 years), even if the expected number of enrolled patients was not reached.

Investigators were in principle not aware of the treatment allocation when evaluating the patient. However, for practical reasons (week-ends, holidays), about one tenth of data were collected by members of the clinical staff, thus potentially aware of the treatment allocation.

Ethical approval

The local ethics committee (Canton of Vaud and CHUV) approved the trial. It was based on the following rational: The trial was about an intervention provided from the very first day of arrival to a vulnerable population. According to recommendations of Swissethics 2006 (http: //www.swissethics.ch) :

« Exceptionally, clinical trials can be conducted in a medical emergency if a procedure approved by the ethics committee will in time:

1. Get the consent of the legal representative of the minor or prohibited persons.

2. Establish the willingness of each participant in the research, including consultation with their family.

The procedure, accepted by the ethical committee, was as follows: Since preliminary tests had showen that CD was apparently not dangerous and probably beneficial, patients could receive CD the very first day of their arrival. Then once they had retrieved their ability to decide upon their free and informed consent (once the registrar in charge considered them able to make an independent decision), they would be asked whether they wanted to be part of the study. At this time, patients were provided with written and oral information on the study; they had time to decide and, if they wanted, sign the authorisation to use recorded data in an anonymous fashion. At any time they could remove their consent and quit the study (see Discussion section for comments on ethical problems).

Analysis:

RCT data were analysed according to "intention to treat" with SPSS and Stata software, with a first exploration of correlations between indicators and the type of treatment (with or without CD), using the test NP-Chi2 for trend, the sign test (Willcoxon) (for numerical variables in the shape of scores of less than 5 possible values), then with the search for a model describing the most characteristic effects of CD. This was performed with a logistic regression model, using a maximum of 3 variables (indicators) at a time in order to reduce the risk of error due to multiple testing. The threshold of significance was set at 0.1 / 90% confidence interval, because of the pilot nature of the trial.

Results

Implementation

Two to three teaching or learning sessions were necessary to reach all of the staff, due to rotations. Some clinicians were able to use the CD after a single teaching or learning session. Others required repeated demonstrations and encouragement to feel at ease with the new tool.

It was explained that the ready-made sentences ("Memo card" - Figure 1) were only a help for beginners. Clinicians were encouraged to read provided books and an article on CD's underlying theory, so that, once the theory was appropriately understood, at least as a working hypothesis for the trial, they could use CD in a more flexible way, adapt it to each individual encounter. However, the proportion of clinicians who actually read provided material was low, 1/20, so most of them continued reading the CD Memo card verbatim.

RCT discontinuation

However, after the inclusion of the first 30 eligible patients to the study (Table 2), clinicians expressed their experience that CD improved their relationship with patients and that patient progress toward "return to normality" was eased in most cases.

The participating clinicians dod not want to further randomize the sample. They did not want to include further patients in the "treatment as usual" or control group, was motivated by their opinion that it would be unethical not to offer CD to all patients, since their clinical experience had led to their being certain of the CD's clinical effectiveness.

As a consequence a much smaller sample than initially expected was analysed. The reduced sample only allowed for the detection of a large difference of 45% (40% vs 85% of patients with a certain outcome) or a risk ratio of 0.47, with the confidence interval set at 90% (because of the pilot nature of the trial) and the power still at 80%.

Results from interrupted RCT

Baseline characteristics are shown in Table 1. Patients allocated to "usual care + CD" had a more severe psychotic state at admission than those receiving usual care, in terms of BPRS ("remission items") score. The array of diagnoses was within the schizophrenia spectrum disorders, with no significant difference between groups (detailed diagnoses at discharge unfortunately not available) . Only one patient refused to give consent (reason not given) (Table 2).

Among measured indicators, the one with the strongest correlation was DDPR; trends with other indicators were all either equal or more favourable with CD, but without reaching statistical significance (Table 3). We did not perform covariate adjustment analysis in order to remain conservative with the claims about CD, because the group with CD had more severe Score BPRS (4.7-5.6 vs 3.6 - 4.6), and was expected to have worse outcome (all other things being equal). In logistic regression, the most discriminating model was constituted with the patient item "feeling reassured" , Wai-task and DDPR-Nurse ($p= 0.018$), as well as the patient item "feeling reassured" and DDPR-physician ($p=0.007$) (Table 4).

Discussion

This research on a verbal technique in emergency psychiatry was conducted in conditions generating two ethical challenges: patients were unable to give informed consent at the time of inclusion; the assessed intervention could not be blinded and clinicians had the impression that equipoise was not maintained.

Equipoise is a central ethical principle in clinical study; it states that a subject may be enrolled in a RCT only if there is true uncertainty about which of the trial arms is most likely to benefit the patient (Fries & Krishnan, 2004). As a result, a comparative trial is impossible for an intervention with marked effects due to the lack of equipoise. This gives rise to the "Philips' paradox" (Howick, 2011) which states that the more potent an intervention, the less likely the effectiveness can be proven in a double-blind study, therefor the most evidently effective treatments cannot be properly assessed. A Cochrane review on psychotherapy for psychosis (among others) concluded that there are many forms of therapy that are not suited to be evaluated sufficiently by RCT (Jung & Newton, 2009). The study described here was interrupted after inclusion of 30 patients because we were facing a case of lack of equipoise. However, interim analysis and the whole experience were presented because today it is recommended to also report from interrupted trials (Kasenda et al., 2014) and because the lessons learnt from the interruption might be useful for others. Interrupted trials are an important part of all research: 25% of RCT accepted by ethical committees are discontinued (22 % among industry's funded RCT; 38% among investigator's funded), for numerous reasons among which the apparition of an ethical problem.

A trial interrupted because of observed (or "felt") effectiveness stimulates questioning on research ethics and methodology. We have here a case where the lack of blinding made it possible early on to realise that a basic principle of randomised trials was lacking. Clinicians' impressions were expressed during a research meeting after inclusion of less than 3 dozen consecutive admissions of patients in an acute psychotic state. Clinicians said that there was no *true uncertainty* (cf definition of equipoise) about which intervention was better. A rather surprising result from such an attitude to research on non-blindable verbal techniques could be that we must, in the end, rely more on clinicians' impressions than on RCT. Is this wrong? On the one hand, it may seem foolish to stop a study when the sample is incomplete and interim analysis inconclusive; on the other hand, it is impossible to continue a study when clinicians declare it unethical. This reasoning remains robust even if the ethical problem is not an unexpected, undesired effect, but *lack of equipoise* due to the perceived effectiveness of the intervention.

The other ethical problem with this research was obtaining consent. In a very comprehensive paper (Brown, 2006), the situation of research without consent is summarised as follows (p. 73):

- Individual institutional review boards show great variation in their requirements for consent.
- The definition of who has the capacity to give consent varies widely. Informed consent is often part of a research plan even when the likelihood of meaningful competence is minimal.
- There is little agreement on the definition of risk, as applied to patient participation in psychiatric studies.

Informed consent was obtained at inclusion in some studies in emergency psychiatry, as in the Scandinavian Open dialogue experience (Seikkula et al., 2006). Browns also notices (p.73)that

> during the last decade or so, legal requirements have made this type of research even more challenging. Some may applaud the wide variation in approaches to requiring and obtaining informed consent as an example of local oversight in action. Others may view the same variation as proof that standards vary so widely as to be non-existent, which must result in concern on the part of regulators. If informed consent is being unreasonably demanded in situations, whether those situations are the treatment of acute agitation or an acute myocardial infarction, then such a demand needs urgent reassessment. The goal, after all, is to protect the true interests of patients.

The need for research in emergency psychiatry still seems immense. In the Scandinavian experience, the important investment in crisis communication led to encouraging results, with fewer psychiatric crises developing into schizophrenia (Seikkula & Olson, 2003) . Future studies could explore whether a specific tool like CD could help optimise such results. Although all indicators were as good as or better with CD, many differences did not reach statistical significance; this could be related to the fact that the study groups were much smaller than expected.

Some clinicians described the use of CD as straightforward, others had difficulties with the new technique, including a first experience with ready-made sentences. They expressed feeling a "lack of authenticity". This may actually be a correct description of the tool, because it is not meant to focus on individual feelings, but to transmit a message designed to help psychotic patients whatever voice or tone is used. The seven predetermined sentences of the "Memo card" (Figure 1), meant to help

beginners with limited knowledge of the underlying theory, can be read or learnt by heart. This can be seen as based on an underlying assumption that words do have an impact by their meaning only. Most clinicians did not read supplied material on the underlying theory. Rather than a lack of interest for the theory, this might be related to clinicians' heavy work load and their impression that the ready-made sentences were sufficient to reach the desired effect.

Limitations of this study must include at least the following: The number of patients is small, related to the early interruption of the trial. The RCT could not be blinded. Because of the exploratory nature of this study, a large number of indicators were assessed, so a multiple test bias cannot be excluded despite the precautions taken in the logistic regression, to include a maximum of 3 variables at a time in the model. The patients allocated to CD had more severe psychotic symptoms so that similar outcomes in absolute terms between groups may represent larger improvement in the CD group; no adjustment was performed for this baseline difference, in order to remain conservative about any claim. There could be a "spill-over" effect, i.e. a progressive change in clinicians' attitudes towards acute psychotic patients, also when they were supposed to work without CD, in the control group of the RCT. Groups were, however, too small to test this hypothesis. Regarding observed differences between groups during follow-up, one should remember that alliance, while correlated with clinical outcome, is not the same, and satisfaction questionnaires are not equivalent to valid alliance measures. The measurement of patient reassurance was a subscale and the patient satisfaction was measured with an unpublished questionnaire.

In order to create adequate study conditions of a verbal technique, a solution might be to organise research in several settings where CD is desired by clinicians and about to be taught. When, for logistical constraints, CD can be implemented in only one setting at a time, the idea to randomise the settings where CD is implemented first, second, third, etc. Settings waiting for CD implementation already include patients and do all the measurements; as such, they provide clusters of controls. This type of randomised cluster trial is referred to as « stepped wedge design » and, to our knowledge has not yet been used for assessing new verbal techniques in psychiatry (Woertman et al., 2013). Stepped wedge design is cluster randomised trial where clusters are settings that switch from control to intervention one at a time, with the time of switch for each setting being randomised. Such design offers solutions to the problems encountered in the study described here. The stepped wedge design allows for a comparative study that is ethically acceptable. The main limitation could however be a "spill over" effect if the "controls" change their usual care before formal implementation.

From the researchers' point of view, no claim can safely be made after this attempt at assessing the Crisis Dialogue. Differences between groups in terms of clinical outcome (BPRS, CGI), therapeutic alliance (WAI, DDPR) and patient satisfaction, were consistent in favouring CD, but these differences did not reach statistical significance in most measurements (Table 3). Such results suggest that the study did not reach statistical significance because of a lack of power due to early interruption resulting in a too small sample. One can argue that, on the scale of psychiatry in general, , the early interruption can be seen as unethical, because the chances are high that a larger sample would have shown more conclusive results, allowing for faster introduction of CD in various clinical

settings, with corresponding improvement of patient care. In short, both continuation and un-continuation can be seen as unethical: that is the dilemma.

A crucial question remains: are clinicians more sensitive than statistical tests and can their judgment prevail over classical clinical studies in choosing strategies of care which include a verbal component? There are arguments in favour of an assessment: to challenge clinician's impression and refine indications. An assessment could be conducted during further CD implementation – and this would require a special method, such as the stepped wedge design, in order to overcome the problem of lack of equipoise.

Conclusion

This study of "Crisis dialogue" presents an opportunity to reflect on ethical problems in mental health research. As researchers, we must keep a clear distinction between clinicians' perceptions of effectiveness and scientifically proven effectiveness. In the example shown here, there was an early disagreement during the trial, related to the non-blindable nature of the intervention. This study raised the ethical problem of lack of equipoise in the assessment of a verbal technique: Since clinicians perceived the intervention as effective, it was considered unethical not to offer it to all patients. As a result, an early interruption of the trial was decided, the final sample was small and no scientific claim could safely be made.
Further assessment of "Crisis Dialogue" – as for any verbal technique implemented in emergency psychiatry -- would still be useful. In order to remain rigorous and take into account the specific ethical problems, a solution could be to use a special research method such as the cluster randomised trial with stepped wedge design.

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Conflict of interest: None

Figures and Tables

Figure 1: *The assessed verbal technique: Brief instruction ("Memo card") for the use of "Crisis Dialogue"--Talking to patients with acute psychosis.*

the "CRISIS DIALOGUE" Markers:	Recommendations
First contact: --"*Are you somehow the centre of the world, in contact with everybody?*" If the answer is a clear « No », or of the type « I am not at that point … », you may stop and re-assess later. Validate : -"*In your place, I would feel the same way*." - "*Your experience is real and important.*" Explain : - "*We are all in touch with each other, whether we notice it or not. Sometimes we don't know who imitates whom, who influences whom.*" Encourage : -"*I do'nt think that anything important is going to happen.*" -"*Remember : it hasn't always been like this*."	- Use CD as soon as possible, after having introduced yourself (e.g.: "May I ask you a question?" – then start) - Read the exact sentences until you know the underlying theory and can adapt CD to each individual. Try to go through the whole CD at a time. Avoid any sentence like "do you have the impression that ... ". "do you believe that...". - Repeat CD 1-3 times a day, 3 days or more, always shortly after the beginning of the encounter. - If a patient is logorrhoeic, do not hesitate in interrupting him/her. - If a patient is mutic, go through the CD anyway. It is sometime more appropriate to use CD in the **past tense** ("*when all that began, were you somehow the centre of the world...*") - Towards the end of the crisis CD can be used less frequently and in parts (Prepared by Antenna/mental health-Geneva, JADE/HUG; Hecvsanté & HEdS la Source, Lausanne, 2008-2012)

Table 1 : Baseline data at inclusion (admission)

	Without "Crisis Dialogue"	With "Crisis Dialogue"	Statistical significance
Female/male	4 /12	3/ 11	NS
Treated with /without Antipsychotic	16/0	13/1	NS
Mean age	33	35	NS
Voluntary/unvoluntary	4/12	2/12	NS
Score BPRS Scale 1-7	4.11	5.16	CI90: 3.6 - 4.6 (without CD)/ 4.7-5.6 (with CD)
Score CGI: Moderately ill/ Seriously ill	1/15	0/14	NS

NS : non significant, CI90: Confidence interval 90%; BPRS : Brief psychiatric rating scale (the higher the more severe), CGI: clinical global impression. CD: Crisis Dialogue

Table 2: Flow Diagram of the randomised controlled trial

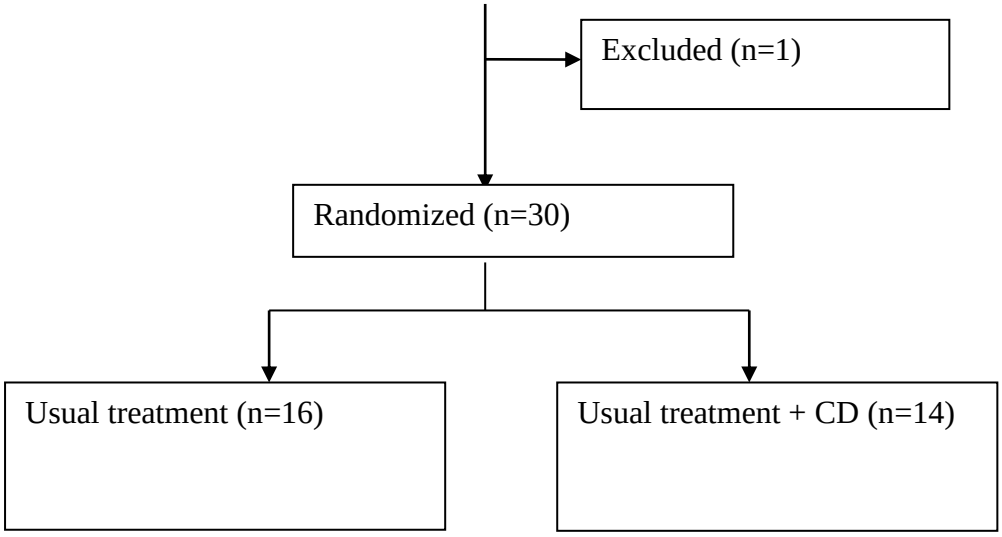

Table 3: Outcome, with and without Crisis dialogue (n=30)

	Without "Crisis Dialogue"	With "Crisis Dialogue"	Statistical significance, Trend and P value
DDPR Nurse, 3rd day after admission	2.92	3.05	+; NS
DDPR Physician, 3rd day	2.96	3.01	+; NS
DDPR Nurse, at discharge	2.75	3.17	+ ; P =0.04
DDPR Physician, at discharge	2.76	3.7	+ ; P =0.06
WAI	4.38	4.77	+ ; NS
Patient satisfaction: --Recommends the plan of care	2.71	3.00	+ ; NS
--Quality of care received	3.00	3.00	=
Patient's experience in communication: -- Had a good discussion	3.31	3.31	=
-- Felt reassured	2.77	3.13	+ ; NS
-- Caregivers have understood me in my head	2.81	3.62	+ ; NS
BPRS-remission items at discharge	3.92	3.67	+; NS
CGI at discharge	3.36	3.10	+; NS

+ Means trend in favour of CD; NS = no statistically significant difference); DDPR: Doctor-Patient Relationship, 1= most difficult/ 6= easiest; WAI = WorkiWorkng Alliance Inventory (higher = better); . Patient Satisfaction (1= poor/ 5= excellent); Patient's experience in communication (1= not agree / 5= completely agree).; BPRS=Brief psychiatric rating scale: 1-7, lower= less psychotic symptoms; CGI= Clinical global impression : 1= best / 5= worst.

Table 4: Statistical model including patients' feeling reassured and nurses' or physicians opinion that therapeutic relationship is improved (DDPR, WAI-task) with Crisis dialogue.

CD/no-CD	Odds Ratio	Std. Err.	z	P>|z|	[95% Conf.	Interval]
Patient reassured	**.3677034**	**.1921928**	**-1.91**	**0.056**	**.1320042**	**1.024253**
Physician-DDPR	**.255449**	**.2572216**	**-1.36**	**0.175**	**.0354974**	**1.838283**

Logistic regression : Prob > chi2 = 0.0073

CD/no-CD	Odds Ratio	Std. Err.	z	P>|z|	[95% Conf.	Interval]
Patient reassured	.4265383	.1944783	-1.87	0.062	.1745244	1.042461
Nurse-DDPR	.1202518	.1499568	-1.70	0.089	.0104382	1.385351
WAI-task	.6821304	.2923276	-0.89	0.372	.2944992	1.579977

Logistic regression : Prob > chi2 = 0.0175

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