"Crisis Dialogue" : fostering relationships with persons in psychotic crisis.
Ethical and methodological difficulties in assessing a verbal technique.

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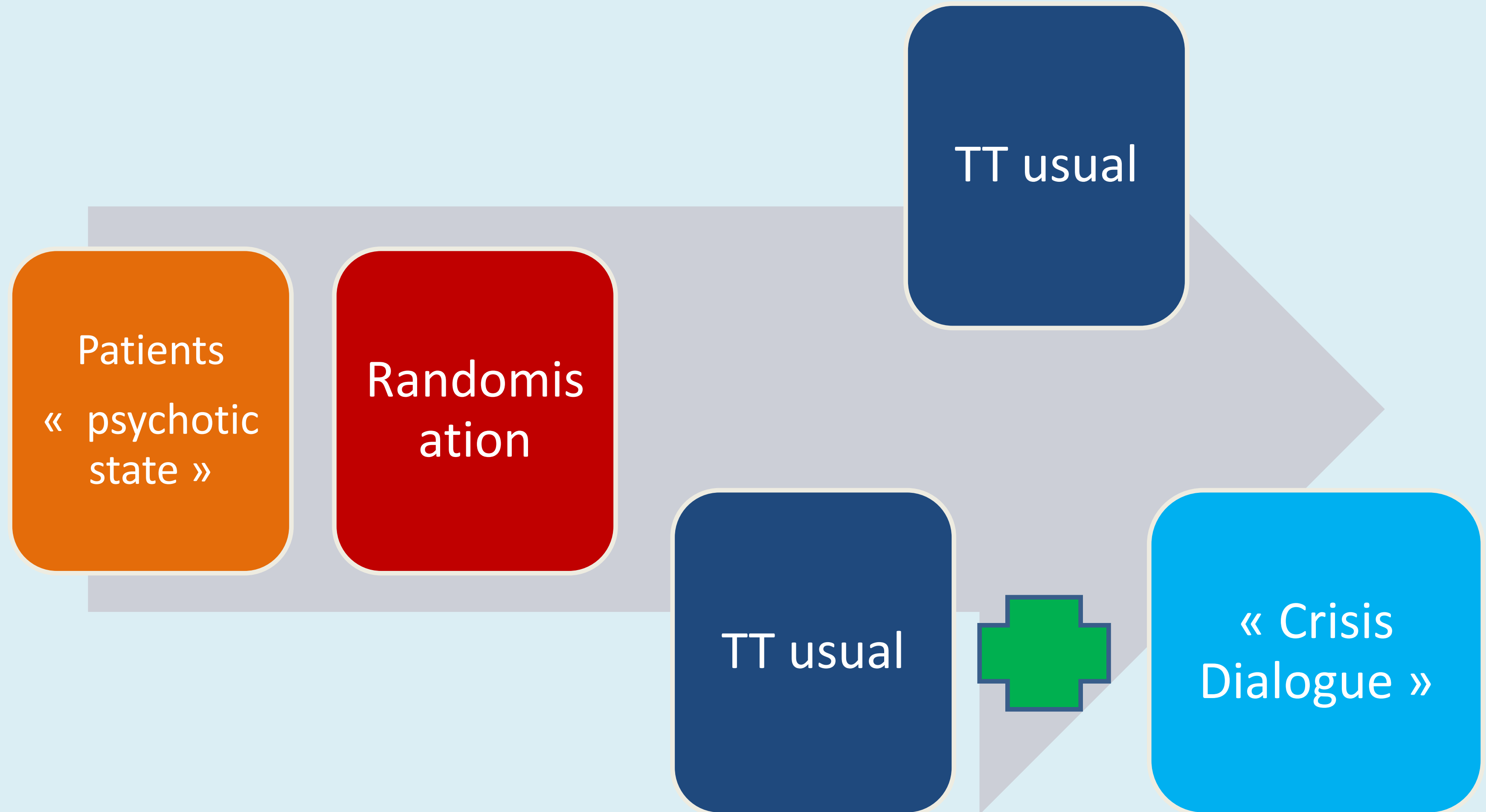
content

- A randomised controlled trial (RCT) of a verbal technique in emergency psychiatry
- Premature ending of the trial because of «perceived effectiveness»
- equipoise & « phillips'paradox »
- possible solution?

The Study

- Intervention : the teaching of **verbal technique** designed to help building therapeutic relationship during the first days of care for psychotic episode: “Crisis Dialogue” (CD)

Pragmatic trial: Usual TT VS (Usual + CD)



CD RCT -- Measurements

Pilot => many indicators

Brief Psychiatric Rating Scale

Clinical Global Impression (CGI)

Working Alliance Inventory – WAI

Difficult Doctor-Patient Relationship

Patient satisfaction (questionnaire in use in Geneva cantonal hospital)

The RCT

Expected N: 120 (60 “usual” & 60 “usual + CD”)

Discontinuation of the RCT!

After including 30 patients,

clinicians felt that it would be **unethical not to offer** the new intervention (CD) to all, because of **perceived effectiveness** with several patients

i.e. lack of equipoise…

‘**equipoise**’,a central ethical principle:

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 J & Krishnan E: Arth Res & Ther 2004

RCT discontinuation because of Clinicians impression of lack of equipoise

If clinicians « feel » that an intervention is effective

(=> do not want to randomise anymore patients to intervention or « no-intervention »)

One possibility is that *they are wrong*…

…an other possibility is that *clinicians have more sensitivity than (inconclusive at this point) statistical tests!*

Discussion:
Discontinuation of RCT
is a common problem!

25% of RCT accepted by ethical Committee are discontinued (many reasons)

Kasenda B, Von Elm A, al. JAMA, 2014.

What to do?
-- Analyse available data

30 patients (instead of the expected 120): trend toward better outcomes...

How can we go forward?

How to get out of the "Phillip's paradox"?

"a comparative trial is impossible for an intervention with marked effects"

(due to the lack of equipoise)

Fries J & Krishnan E (opus cit.)

CD *is being* implemented – can it still be assessed?

Several settings where CD is desired by clinicians

Logistics constraints: **one setting at a time**

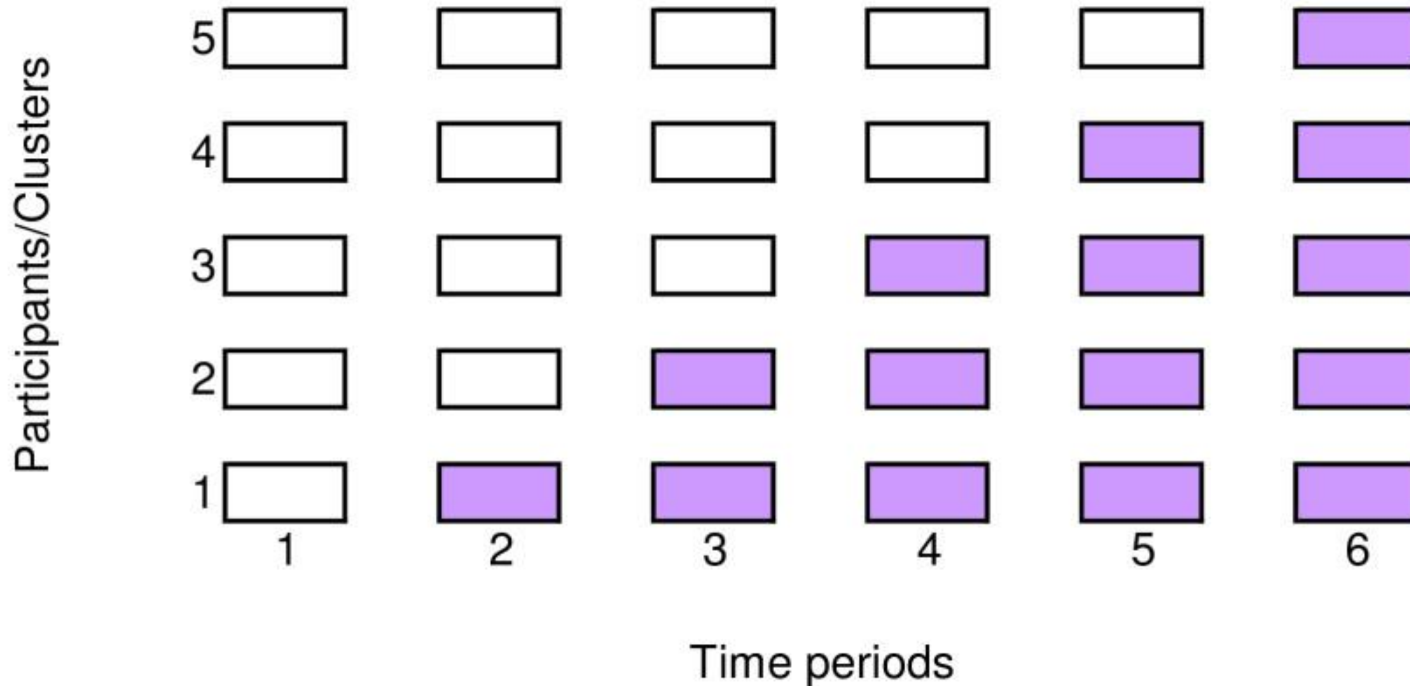
=> *idea:* **Randomise order** of implementation

Waiting list = controls

= « **stepped wedge design** »

Woertman W et al, J Clin Epidemiol 2013

Stepped wedge design



Brown and Lilford, *BMC Med Res Method* 2006

Conclusion

Even if clinicians feel that « Crisis dialogue » is usually effective with acute psychotic patients,

it might still be usefull to study its effects

(e.g. to determine more precise indications

and generate hypotheses about its mechanism of action)

Conclusion:

To **assess a verbal technique** in psychiatry, if it might be « perceived as effective » (problem with equipoise), we may **need a special method**,

e.g. a « stepped wedge design».

Thank you for your attention!

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Additional slides

The RCT

Expected N: 120 (60 “usual” & 60 “usual + CD”)

=> detect difference of >1.5 (risk) (e.g. 50% versus 76%) for any of the planned measurements and scores

with CI 95% (1-alpha) and power 80% (1-beta)

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