INSERM Clinical and Public Health Network

Coordinators: Bruno FALISSARD and Jean-Michel THURIN

PRACTICE-BASED RESEARCH NETWORK IN PSYCHOTHERAPY

PROGRESS REPORT at 4 years

AUTISM Section – March 2013

Practice-based research network in psychotherapy

Coordinators: Jean-Michel Thurin and Bruno Falissard

Institutions: INSERM Unit U669 and the French Federation of Psychiatry

Financial support: INSERM, Direction Générale de la Santé and Fondation de France

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Methodology and data analysis: Bruno Falissard, Jean-Michel Thurin, Monique Thurin, Tiba Baroukh, Fadia Dib (U669)

http://www.techniques-psychotherapiquesorg/Reseau/

III REVIEW OF OUR NETWORK'S OBJECTIVES

The general objectives of the network, selected from a call for projects (INSERM CFP 2007: Networks for clinical research and population health) are described in detail in the French journal <u>Pour la recherche 55</u>. They are:

- to learn more about psychotherapeutic practices in their different conditions and contexts;
- to develop the assessment of various types of psychotherapy in natural conditions and to deepen our knowledge of the configurations and mechanisms of change during the psychotherapeutic process.

Three priority disorders were selected for network studies: ASD, borderline personality disorder, and Alzheimer disease and its related disorders.

This report is devoted to the studies by the ASD section, which has focused on the study of progress and skills in the process of the development of children with during various kinds of therapy (exchange and development therapy, psychodynamic psychotherapies, and others).

IV METHODOLOGICAL CHOICES OF THE NETWORK IN THE INTERNATIONAL CONTEXT OF PSYCHOTHERAPY RESEARCH AND EVIDENCE-BASED PRACTICE

The network's methodology takes full advantage of the general developments in research in psychotherapy since the turn of the century, described simultaneously in several reports by the NIMH, the American Psychological Association, and in European research.

The stakes related to these developments are:

- a reduction in the gap between research and practice (NIMH Rush AJ 1998¹⁵; Insel 2006¹⁶; American Psychological Association 2006¹⁷), especially by developing studies of what works successfully in practice;
- consideration of the limitations of first-generation randomized controlled trials (RCTs, for efficacy research¹⁸), which include excessively specific samples, too few indicators, a limited study period, and failure to consider individual context all of which reduce the applicability of their results;
- increase in the frequency of research concerning the real world, that is, of effectiveness studies under natural conditions that respond to questions asked by patients, clinicians, health-care facilities, and insurers. Such research should also work towards decompartimentalizing different research projects and the people involved with them.

Concretely, this involves:

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¹⁵ Rush, A. J. (1998). Bridging science and service. The National Advisory Mental Health Council's Clinical Treatment and Services Research Workgroup report. *National Institute of Mental Health*.

¹⁶ Insel, T. R. (2006). Beyond Efficacy: The STAR*D Trial. *Am J Psychiatry, 163*(1), 5-7.

¹⁷ American Psychological Association. (2006). Evidence-based practice in psychology. APA Presidential Task Force on Evidence-Based Practice. *Am Psychol, 61*(4), 271-285. doi: 10.1037/0003-066X.61.4.271

¹⁸ American Psychological Association. (2002). Criteria for evaluating treatment guidelines. *American Psychologist*, *57*(12), 1052-1059. doi: 10.1037//0003-066x.57.12.1052

- development of second-generation clinical studies that seek to involve more patients, follow them
 for longer periods, and take into account diagnostic complexities (i.e., patients' comorbidity,
 chronicity, subtypes, and particularities); expansion of result indicators to include functional
 normalization; consideration and comparison of interventions that are actually implemented in
 practice and their effects on the course of the treatment; consideration of rehabilitation as a strong
 form of intervention and comparison of interventions in isolation and in combination;
- multisite studies that taken into account different contexts of organization of care and the existence of particular treatment configurations in the variations of results.

Beyond the general developments presented above, which both clinicians and researchers have been awaiting eagerly, one major change in psychotherapy research in recent years has been to abandon the global viewpoint of outcome studies in relation to "brand names" to look specifically — both generally and in particular situation — at individual and general factors of change (and immobility), at the concrete form of their intervention in the psychotherapy process (*mediators*), and at their association with the mechanisms of change.

The general theme of research in psychotherapy has thus moved from "Does psychotherapy work?" and "What are the general psychotherapeutic approaches that work in different disorders?" to "How does a particular course of psychotherapy work and in what conditions?" (Kraemer et al. 2001¹⁹, NIMH Seminar 2002, Kazdin & Nock 2003²⁰), and "What are the factors that will contribute to positive results in each type of therapy, in different therapies, and across therapies" (Barber 2007²¹).

This general change has resulted in refocusing research on practices, intensive case studies, and on the joint work of clinicians and researchers. This development has been expressed in the themes of international conferences of the Society for Psychotherapy Research (SPR) and of the Society for the Exploration of Psychotherapy Integration (SEPI) since 2010.

These methodological principles explain the importance attributed in the network:

- to intensive studies of individual cases and to the qualitative and quantitative analysis that accompany them; that is, only from very extensive data can we apprehend the mediators and mechanisms of change;
- to the initial clinical expert assessment (through the case formulation), especially the psychopathology diagnosis (which pays particular attention to clinical subtypes and to the specific dysfunctions that accompany them, as well as to the points of support), in order to design the initial treatment strategy. This strategy and the objectives accompanying it also take into account specific variables (e.g., disease severity) and situations (social isolation), which are moderators;

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¹⁹ Kraemer, H. C., Stice, E., Kazdin, A. E., Offord, D., & Kupfer, D. (2001). How Do Risk Factors Work Together? Mediators, Moderators, and Independent, Overlapping, and Proxy Risk Factors. *Am J Psychiatry*, *158*, 848-856.

²⁰ Kazdin, A. E., & Nock, M. K. (2003). Delineating mechanisms of change in child and adolescent therapy: methodological issues and research recommendations. *Journal of Child Psychology and Psychiatry, 44*(8), 1116-1129.

- to the variables concerning the process (the patient, the therapist, and her technique²², and their interactions), which initially play a role in the therapeutic alliance (a major factor in the result) and the course of the therapy, especially in the choices of specific interventions.
- to the fact that these case studies come from "real-world" practices and that they can be pooled for analysis, because no therapist or even any institution could conduct alone the research work that this program requires.

They also explain the choice of the network's organizational structure.

V SETTING UP THE NETWORK AND ITS METHODS OF WORK

1. Preparation for organization and operation of the network

In the very extensive literature review that preceded the network's establishment, 2 articles helped us enormously because they presented the authors' thoughts and recommendations based on their experience in this domain. These were the article by Borkovec et *al.*²³ from 2001 about the beginning of the *Pennsylvania Practice Research Network* and that by Kutner et *al.*²⁴ on research about end-of-life care. Reading them over showed that the objectives, central questions, obstacles encountered, and ways of solving them presented there remain very current and interdisciplinary in terms of their principles and working methods.

2. Presentation of the network and calls for study participation

A general call for participation in these studies was launched at the time that the article in <u>Pour la Recherche 55</u> was published describing the network methodology and conditions for participation. The first meeting to present and discuss the network took place on April 25, 2008, at Sainte Anne Hospital in Paris. A report about the meeting ran in <u>Pour la Recherche 56</u>, and all the presentations, including questions from the audience and the speakers' response, were posted on the network's <u>website</u>. This call for participation was widely relayed by the institutions and departments concerned and at subsequent scientific events. Three other meetings to call for participants took place the same year and covered all 3 sections of the network: borderline personality disorder, ASD, and Alzheimer disease.

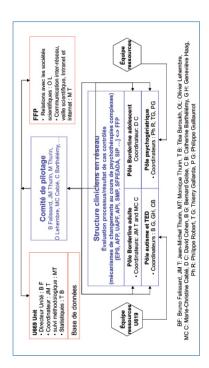
A brochure presenting the network was designed and printed; it is distributed regularly at relevant scientific events.

²² To avoid language bias, the reptitive and turgid use of he/she, the use of the plural when discussing individual therapists and children, and especially pronoun confusion, individual patients here will be referred to as he/him, and individual therapists as she/her.

²³ Borkovec, T. D., Echemendia, R. J., Ragusea, S. A., & Ruiz, M. (2001). The Pennsylvania Practice Research Network and future possibilities for clinically meaningful and scientifically rigorous psychotherapy research. *Clinical Psychology: Science and Practice, 8,* 155-168.

Kutner, J. S., & Westfall, J. M. (2005). The Practice-Based Research Network as a Model for End-of-Life Care Research: Challenges and Opportunities. *Cancer Control*, *12*(3), 186-195.

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- Monique Thurin, Tiba Baroukh, Fadia Dib, Bruno Falissard (U669)



How to Join :

- ◆ Send an e-mail (mthurin@techniques-psychotherapiques.org) asking to become a member of one of the network sections (borderline personality, autism spectrum disorders, and Alzheimer disease and related disorders).
- ◆ The clinician will assess the psychotherapeutic treatment of one of his patients as part of a peer group (with other two clinicians).
- ◆ A clinician interesting in participating in these studies can consult the website, asks questions, and participate in the network's regular meetings. A calendar and agenda of meetings is available on the website, at the following URL:

http://www.techniques-psychotherapiques.org/Reseau/













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Psychotherapy Practice-Based Research Network





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What is the Network of Practice-Based Research in Psychotherapy (RRFPP)?

- This network is an innovative framework for clinical research in psychiatry intended to answer the questions clinicians ask in their daily practice. It is coordinated par B. Falissard (U669) and JM. Thurin (FFP & U669). The research focuses on psychotherapy, a major treatment in psychiatry and mental health.
- ◆ The methodology developed makes it possible to conduct rigorous studies in real conditions. It opens very promising perspectives for knowledge and for practices.
 - Currently, nearly 200 clinicians are participating in studies. Dynamic international collaborations are already underway.
- ◆ Selected by INSERM in a highly competition process, this research is also supported by the Directorate-General of Health and the Fondation de France.

How is this network innovative?

- Its methodology is based on third-generation (pragmatic) case studies and the organization of work in a network.
- ◆It combines qualitative and quantitative approaches. It makes it possible to describe the processes of treatment approaches that were previously kept out of the game of empirical research because of their complexity (for example, play therapy, psychodynamic psychotherapy, and psychoanalytic therapy).
- Each study respects the natural process of psychotherapy, takes individual differences into account, and integrates the best standards of evidence.
- Each case begins with an initial psychopathologic case formulation accompanied by objectives and an initial strategy for attaining them; longitudinal observation follows to assess its visible changes (symptoms, behavior, and functioning) and the internal processes of the psychotherapy that underlies them. A systematic and multidimensional vision of the processes of change results, opening up an understanding of its causes and mechanisms.
- Research in a network makes it possible to pool similar cases and examine the differences and common features involved in their course.
 The individual or more general nature of the results is taken into account.
- Clinicians and researchers work closely together on a common objective and reduce the gap that previously characterized their respective approaches
- The network makes full use of the new communication technologies.

How does it work?

- ◆ 3 clinicians meet in peer groups.
- Clinicians follows one of their own cases for a year, using data collected during the first 3 interviews, and then during 2 interviews at 3 months, and again at 6 and 12 months. Assessments are then performed individually by each member of the peer group, based on these data. They then compare their scores and discuss them until they reach a consensus.
- ◆ Training to conduct research is based on:
- Presentations of the methodology and the instruments on the network's website: www.techniques-psychotherapiques.org/reseau;
- Targeted training; operational feedback meetings;
- E-mail and when necessary telephone support for the peer groups.
- Clinicians receive the analysis of the data from their cases.

What does the network offer to the clinicians who participate?

- A reduction of their isolation, the possibility of sharing clinical and theoretical questions, and a solid methodology to answer them.
- Knowledge about the effectiveness of the therapy they provide, both in general and in its various dimensions.
- Enrichment of their tools for clinical observation and of their understanding of the fundamental processes of the therapeutic interaction.
- ◆ The possibility of describing their approach, the principal therapeutic actions used, and their evolution during the psychotherapeutic process.
- Training in research and validation of requirements for continuing professional education and evaluation.

What are its initial results?

- Practices do not correspond to the stereotypes. Therapists adopt an empathetic attitude and accommodate their approach to their patients' baseline condition and to their changes as they occur.
- ◆ Moderators (severity of disorder, family support, etc.) play a role in the results.
- The therapeutic alliance is an essential, factor with convergences and catching-up between the patient and the therapist.
- Other factors, such as insight and improved interpersonal relationships, are also important in the patient's progress.

3. Compliance with ethics rules, including related to data collection, scoring, and management

a) Information and consent by patient

In April, 2008, JC Thalabard presented the general ethical rules concerning observational studies such as those conducted in our network (online slide show).

The initial request to the Comité consultatif sur le traitement de l'information en matière de recherche dans le domaine de la santé (committee on data treatment in health research) was approved; the CNIL (the National Data Protection Authority, Commission nationale de l'informatique et des libertés) also approved our plan, on the following conditions:

- Each physician participating in the network study who wants to include a patient must inform the patient's family (the patient's legal representative for the purpose of the study.
- If the family agrees in principle, the therapist gives the parent the <u>Informed Consent Form</u> for participation in research to assess psychotherapies, including information about their right to access and correct the information, in compliance with the law on information technology and freedom, dated 6 January, 1978.
- The therapist, after receiving the written consent of the patient's representative, contacts Monique Thurin (MT), clinical psychologist (and the person responsible for all identification data), to obtain a patient code. If the patient is the therapist's first in the study, she too receives a code. To be able to participate in the study, she must also designate 2 peers who will assess the psychotherapy of her patient with the same tools.
- The *therapist code* is a 3-digit sequential identifier, issued in order by MT as therapists include their first patient in the study: 001, 002, ... The number attributed to the therapist is unique. It is recorded on a notebook reserved specifically for this purpose, with each therapist's full name (first name and last name). This code serves as her identifier throughout the study and allows her to remain anonymous. Similarly, the *patient codes* are issued sequentially, as patients are included. To be able to distinguish the patient and therapist codes easily, the patients' codes are defined as follows: X, followed by a 3-digit sequential identifier, as each girl is included: X001, X002 ...; Y, followed by a 3-digit sequential identifier, as each boy is included: Y001, Y002... . For the Italian patients, an i- is included in the code, as Xi01, Xi02

b) Case report file

- Once the patient code has been attributed, his therapist receives an <u>assessment booklet</u> related to the disease; it is anonymized and in rtf format, for use with *Word*. This booklet allows the clinician to collect in one place all data associated with the study of the patient's psychotherapy for the 1-year study period. The delivery of the therapist and patient codes and of the empty (except for section information) assessment booklet follows the therapist's email request to MT.
- On receipt of the assessment booklet, the therapist adds the patient code and age, the treatment start date, the therapist code, and the codes for the 2 peers. During the first 3 clinical interviews, she drafts a qualitative assessment of the patient, diagnosis, objective, and strategy, according to the case formulation method, as well as a quantitative pathology assessment, using the questionnaires specific to ASD. The notes of each clinical interview and any recordings are also examined by the 2 peers (as detailed below), and the questionnaire scores by all 3 therapists are compared to reach a global validation of the diagnosis. The 3 peers in each group communicate by secure e-mails, by telephone, or during meetings, either in person or by Internet.

- At the conclusion of this stage, the therapist transmits the initial assessment (case formulation) in the first part of the booklet, identified by the patient code and validated by the peer group, by secure e-mail to MT. If preliminary tests were conducted, the clinician reports them in addition to the case formulation.

c) Data collection and analysis

The data are based on extensive notes taken by the clinician during or immediately after each session. When possible, they are accompanied by video recordings of the first 3 sessions, and then of 2 sessions at 2, 6, and 12 months. These too are as complete as possible and contain what the patient said and did (behavior), his physical attitudes, the therapist's interventions, what the therapist thought during the session, and the atmosphere of the session, in chronological order.

These data are transmitted electronically to the 2 other members of the peer group (not present during the session). Each clinician individually scores the child on each of the instruments used in the study. A peer group meeting then follows (generally by videoconference) and allows a consensus to be reached on the definitive score after discussion of the initial differences and the data on which they are based.

We paid special attention to the question of inter-rater reliability, central here in view of the multicenter nature of the study. The procedure for inter-rater agreement took place in 3 stages. In the first stage, each judge scores each of the data items from the validated instruments. The second stage is a meeting of the peer group to analyze the results and enable convergence toward an overall group score. This method was chosen to improve the reliability of scores for data from instruments that may require a period of adaptation for clinicians who work alone and do not know them perfectly, especially to enable them to identify the potential biases of the scoring and to define rational causes of divergences. The overall score is never obtained by averaging the 3 scores, but by discussion of the data. The scores from each stage are recorded and saved.

In addition to these 2 stages for each case, regular meetings are held for operational feedback, at which time is systematically devoted to potential scoring difficulties. Details, generally from the scoring manuals, are provided orally to participants in those meetings. Whenever necessary, additional instructions are developed and posted on the network website.

d) Data receipt, verification, and storage

Once the instruments are scored and a consensus obtained for each, these data are transmitted to MT for entry and storage in the databases.

- On receipt of the assessments, MT (the data identification supervisor) informs both the statistics technician and Jean-Michel THURIN (psychiatrist and network director) that the data are available.
 The qualitative data (text) are stored on a Mac OS X Server v 10.5, and the quantitative data on a second Mac OS X Server v 10.5 located at INSERM's P Broca Centre. They are then entered into the network database, managed by FileMaker Pro file management software.
- MT verifies that the patient follow-up procedure began correctly, in compliance with the study methodology, and in particular, that the different rubrics are correctly completed. She then verifies the content and consistency of the quantitative data. Remote access to the 2 Mac OS X Servers is secured with the FileMaker Pro Server software, the file sharing protocol used by Apple (AFP, *Apple Filing Protocol*).
- The File Maker Pro Server enables (through secure SSL) encryption of all communications between the clients equipped with FileMaker Pro and the Mac OS X Server v 10.5. It is thus possible to

designate a set of users with POSIX permissions (inspired by the system of UNIX user lists) and to monitor them in real time with the Admin Console. The list of users in this study is very small: Monique and Jean-Michel THURIN, and the statistics technician.

In cases of incomplete or anomalous data, MT informs the therapist by e-mail and requests that the data be completed or reexamined.

The date of receipt of the case formulation opens a 2-month period at the end of which the therapist should have submitted her essentially quantitative assessment (questionnaire scores), validated by her peer group, following the second stage of the procedure described above. If MT does not receive it, she e-mails the clinician to request that it be sent.

The procedures at 6 months, 9 months (if possible), and at 12 months are similar: the therapist transmits her assessment, MT receives it and verifies its content and consistency before entering it in the database.

The 12-month assessment again includes a diagnosis and a case formulation, validated by the peer group. The data are transmitted one last time to MT. After final validation, the case file is closed and cannot be modified.

e) Organization of databases

Filemaker Pro software is used to organize the data into 12 databases, focused on the individual cases, the result indicators, the process indicators, and the pooled cases.

A diagram of their organization is presented below. The data access and their presentation in forms that already enable classification and extraction in various formats from the case to the pooled cases allow a direct approach and rapid glimpses that are consolidated with statistical tools.

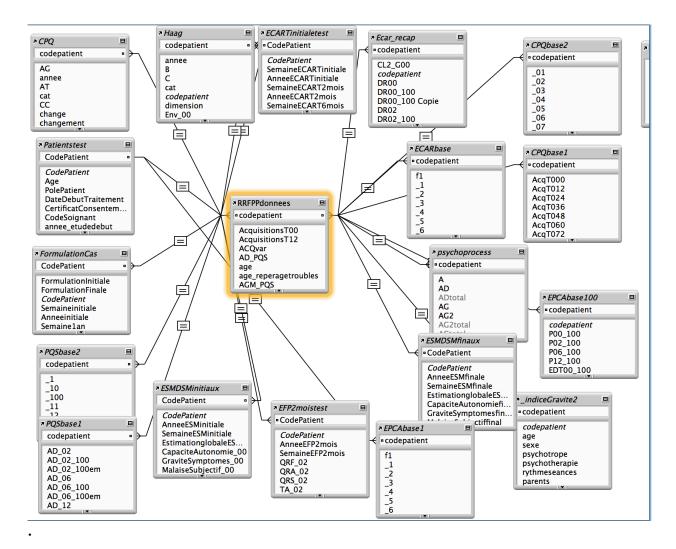


Diagram of databases and their organization

4. Network operations for the clinicians participating in studies

The support of network members is of major importance. It is one of the aspects that Kutner et al. stressed most, based on their extensive experience in this domain.

In our network, support for the therapists to aid them to participate, understand the methodology, and use the necessary tools has been organized around 6 forms of communication: meetings for information, training, and operational feedback; written documents; the network website; exchanges by e-mail and by telephone; and recognition of their work.

a) Meetings for information, training, and operational feedback

- There are 2 principal types of meetings:
 - meetings (Journées), which bring together all the clinicians from each of the network's 3 sections and interested members of the public
 - o *seminars*, devoted to each separate section and covering the therapists' work and results.

b) Written documents

- The assessment booklet, specific to each disease group
 - It is sent to all clinicians when they join the network. It reviews the methodology step-by-step, with the assessment forms.
- Publications in Pour la Recherche
 - Several issues have described the general methodology, the methods for each section, and summaries of the operational feedback.
- The network progress reports and their discussion.
 - c) The Network website <u>www.techniques-psychotherapiques.org/Reseau/</u>

It includes

- General information of the conditions for becoming a member: http://www.techniques-psychotherapiques.org/Reseau/Candidatures.html
- A toolbox for network members: http://www.techniques-psychotherapiques.org/Reseau/BoiteO utils.html
 - This link goes to a page where the clinician can consult all components of the network's general methodology as text and in power-point presentations.
 - They can then easily download the computer tools useful for playing the videos (Quicktime) or for peer group remote communication (Skype)?
 - the steps to take to begin a study
 - This page also has links for information for each section: a general description of the tools and a link for the specific methodology for each.
 - From this page, the clinicians participating in one of the sections can obtain training for the instruments, and practice completing them online.
- The network's calendar of activities http://www.techniques-psychotherapiques.org/Reseau/Calendrier.html
 - The calendar is very useful for clinicians, who can check the dates of meetings but can also find the minutes of earlier meetings (slide shows and videos).
- Literature watch for priority research themes http://www.psydoc-fra nce.fr/Phorum5/list.php?10
 - Members can consult summaries of recently published research on network themes.
- The site: http://www.techniques-psychotherapiques.org/
 - An excellent source of documents about assessment of psychotherapy

d) E-mail exchanges with clinicians

Initial contact: joining the network

E-mail exchanges begin with the clinician's request for participation. She receives in return a form to complete: name, work address, whether she sees patients privately or in an institutional or other setting, and theoretical approach (psychodynamic, CBT, family, psychomotor). On this occasion, the therapist is also asked the age and sex of the patient she plans to include in the study and the date of the first psychotherapy session (date from which the assessment will start). On returning this information, the clinician receives a code for herself, a code for the patient (to enable anonymization of the clinical data), and the assessment booklet for the section she is joining.

- Help with the methodology

• After these preliminaries, numerous discussions follow to answer the therapist's questions, to clarify methodological points, or to help complete the instruments.

Assessments

- The completed assessment forms for the various instruments are sent by e-mail to only 1 person (MT), who verifies them. When appropriate, she asks for additional details or suggests that unclear or unspecified points be reviewed by the peer group. The definitive assessment for each case includes 23 files: 9 contain the basic data (exhaustive session notes), 2 the case formulations from the beginning of the therapy and at 12 months, which include a diagnosis of the child and a description of his problems and his strengths, 1 the moderators, and the other 11 files the assessments performed with the different tools assessing: 1. symptoms and behaviors, 2. development and 3. the internal process of the psychotherapy.
- The situation is reviewed regularly with the peer groups, to allow us to verify that the data have indeed arrived and to stimulate their work.

e) Telephone conversations

- Therapists can call every Monday from 9-10 pm. Telephone appointments can also be made individually to discuss methodology or other difficulties to be resolved.

f) Recognition of the therapists' work

As Kutner proposed, this recognition takes the form of references to their work in presentations, articles, and conferences. The Italian group asked for certificates to be issued at one of their meetings, and this was done.