

PSYCHOTHERAPIES FOR ANXIETY AND DEPRESSION: BENEFITS AND COSTS

Scientific Committee of Conference "Psychotherapies for Anxiety and Depression: benefits and costs", 6-7 November 2016, Padua, Italy

Anxiety and mood disorders have a very high prevalence in the general adult population. According to epidemiological research carried forward across countries, the prevalence of Major Depression in general population is around 7% and a similar prevalence has been shown for Social Anxiety Disorder. Panic Disorder and Generalized Anxiety Disorder seem to be less prevalent, although the occurrence in general population is still relevant (2-3% and 0.4-3.6% respectively). Despite the differences among countries these prevalence rates portrait a wide and worrying phenomenon: in Italy, for instance, millions of persons are affected by this type of conditions. Typically, however, the great part of the resources for mental health is devoted to treatment and rehabilitation of psychotic disorders, which have a prevalence around 1% in the general population. Therefore, it is unquestionable that Depressive and Anxiety Disorders need a more tuned and solid attention.

A 2011 survey claimed that 4% of the entire European Population has taken antidepressants for at least four weeks in the previous year. The World Health Organization (WHO) has listed Depression in the public health priorities given the fact that it is the second most important cause of disability in western countries. WHO estimation, moreover, forecasts that it will become the first cause of mortality and morbidity in western countries by 2030.

The dimension of the problem is even bigger than one can say from the above-mentioned prevalence data: for anxiety disorders and even more for depressive ones we have to consider sub-threshold conditions along with pediatric and adolescent onsets. Despite the fact that these conditions were not considered when the adult population prevalence is computed, they have a strong impact on quality of life, welfare and, more widely, on society itself.

Depression and Anxiety Disorders are responsible for a huge number of consultations with the general practitioner and of help-seeking in pharmacies (asking both for over-the-counter or prescription drugs). They are also responsible for a lot of working day lost, early retiring and, more in general, for a weakening of the productive system.

Finally, Anxiety and Depression have related also to physical health conditions: as an example, Depression is a well-known risk factor for heart ischemic conditions and the presence of Depression in cardiac patients is associated with a three folded risk of mortality and hospitalization as compared to patients without depression.

Given this précis the conference was aimed at:

1. Describe the Italian situation both in terms of 'state-of-the-art' of the epidemiological research in our Country and in terms of public health and welfare resources devoted to Anxiety and Depression.
2. Start a discussion on possible models to exploit evidence-based psychological treatments for Anxiety and Depression to the widest possible number of patients.

Psychological treatments for Anxiety and Depression have the same scientific validity and similar efficacy as compared to biological ones.

A prejudice as much diffuse as wrong stated that psychological treatments are just a matter of emotional support, not particularly different from the one a relative or a close friend could give. Despite the relevance and the value of this type of emotional support, it is relevant to underline how psychology is an empirical science, and, as such, it has its own rules, researches, methods and discoveries. In this sense, psychological treatments (including not only psychotherapies, but also first level psychological interventions – such as the so-called ‘low-intensity interventions’) cannot be considered just a form of emotional support, but a relative complex set of procedures involving several aspects. Each of these aspects has been identified and studied through scientific procedures, which, in turn, have been refined and have evolved through a continuous development during the last 50 years.

When research on the theoretical level of efficacy of psychological treatments is concerned the simplest analogy is with the research on biological therapies. Research on efficacy implies the use of control groups to disentangle the improvements specifically related to the treatment from those related to the mere natural evolution of the disorder, the effect of the human supportive and empathic interaction with a clinician, and to the positive expectations. Psychological research refers to such aspects as the placebo effect and as common (as opposed to specific) factors of psychotherapy efficacy. Other options for control groups are typically those in which patients undergo treatments with one or more drugs (with an already established efficacy) and those where a combination of psychological and biological treatments is involved. As in other research fields, the groups are formed to be equivalent for all the variables but the experimental one (i.e., the type of treatment) and the allocation to each group is based on a rigid randomization procedure. This is why this type of studies is known as Randomized Control Trials (RCT)¹.

Again, as it happens, in other research fields, also in the evaluation of psychological treatments, outcomes are assessed longitudinally, by qualified experts in a blind fashion (i.e., the evaluator is not aware of which treatment the subject is following and, sometimes, not even of the purpose of the study). Moreover, the outcomes are typical, multidimensional with a definite clinical meaning (other than a mere statistical significance). In the case of anxiety and depression, the results cannot be limited to a pre vs. post analysis (or to a comparison between the intervention and the control groups) because outcomes such as remission stability and risk of relapse are as much important as the outcomes measured right after the treatment. Finally, positive results should be replicated and confirmed by several independent researchers and institutions in

¹ Despite the fact that RCT methodology is still the most rigorous and applied approach for clinical research, few other methods have been developed in the last decades. Most of these methods were aimed to test the efficacy of psychological interventions in *real* and more naturalistic clinical settings. Such studies provided significant results both for patients and for all the individuals (e.g., relatives, physicians) and institutions (e.g., health care agencies, patients associations, national health care systems) involved in the care processes. Moreover, meta-analytic techniques, pooling data together, provided a scientific validation for longitudinal studies and case series and proved they have a sufficient validity to test the effectiveness of psychological treatments.

order to prove the generalizability of the findings. Positive results should be attributed to the specific elements of the treatment rather than to the excellence of the clinical research team performing the RCT. Such results should be described, transmitted and taught in *ad-hoc* manuals in order to become general practice as well.

When a treatment has been proved efficient the next problem is to evaluate its clinical efficiency in *real* clinical settings (the so-called effectiveness). Is a given efficient therapy exploitable in clinical practice, for instance in the facilities of our National Health Care System? Or, on the contrary, does it have some peculiarities that make it only applicable in few highly specialized structures or exploitable only in private practice? In the field of psychological treatments for anxiety and depression, some limits seem to be easily bridgeable. These include the due for an adequate training and continuous update of the psychologists working in the health care system and the necessity: to overcome the typical inertia toward the implementation of efficacy and efficiency evaluations; to fight the negative stigma toward mental disorders which is often extended to psychological treatments; to contrast the lack of correct information about such treatments widely spreading across some physicians. Finally, another huge, but bridgeable problem is the difficulty in organizing an intervention program grounded on evidence-based psychological treatment within the mental health services of our National Health Care System.

We would like to emphasize that we use the term evidence-based psychological treatments instead of psychotherapies. This because we are not promoting psychotherapies *tout court* (as there are several psychotherapies which are not evidence-based). On the contrary we promote and sustain the right of patients to have access to specific treatments (psychological or psychotherapeutic) with the highest evidence-based efficacy.

The English Experience: Improving Access to Psychological Therapies (IAPT)

Is relevant to note that the so-called IAPT program has been developed far away from the psychological or, more in general, mental health context. It has been thought in a Business and Economic context, particularly at the London School of Economics and Political Science. The last decade was dominated by a worldwide economic crisis and the European governments (including the British one) raised as priorities: cut the expenses (as requested by the spending review procedures), make the productive system regain competitiveness, and increase the Gross National Product (GNP). Among other suggestions, the advisors of the British Government (first headed by Tony Blair and then by Gordon Brown) focus their attention to target depressive disorders. ‘The Depression Report’ a document signed by Lord Richard Layard of the London School of Economics and Political Science pointed out that Depression and psychopathological disorders have a highly negative impact on economy with relevant social costs which were quantified in 12 billions of Pounds. A more detailed analysis highlighted that 15% of the general population suffered from Anxiety or Depressive symptoms accounting for the 23% of the entire burden of the National Health Care System. Looking at the working population Depression and Anxiety Disorders were considered responsible for up to 40-50% of all the absences from work. Considering that this problem interested about 6 millions of patients, the only way to cut the associated costs was to develop a more efficient program of intervention. To do so, rather than change or update the available mental-health services, something new was created. In that period only 5% of English patients had

the opportunity to access to an adequate psychological intervention. In contrast the number of patients preferring a psychological intervention is two-fold the number of those who prefer a pharmacological one. The National Institute for Health and Care Excellence (NICE) guidelines that inspires the English Health Care System indicates the psychological treatments as first line for the therapy of Anxiety and Depression and suggests the use of pharmacological treatments as a first choice only for severe Depression or for psychotic disorders.

The economical difficulties of the period were not considered an issue but, on the contrary, an urge to act with celerity: if it is true that a psychological treatment cost about 1000 €, it is also true that it allowed for a save of 4800 € in terms of social and productive costs. This means that the treatment would eventually, not only repay by itself, but produce a save for the Health Care System even in the short-medium term.

In 2008 the IAPT program has been founded with 372 billions of Euros for three years. The program received further 500 billions of Euros for the period 2011-2015. Finally, in the 2010 a similar program has been launched for developmental mental health changing the existing Children and Adolescent Mental Health Services (CAMHS) into a new type of clinical services providing evidence-based treatments and conducting a meticulous monitoring of the outcomes.

The IAPT model

The IAPT model was summarized by David Clark and Richard Layard in six points:

1. Provide treatments based of the highest level of efficacy evidence only. The level of efficacy is based on the NICE guidelines. As far as Depression and Anxiety Disorders are concerned, the treatments that have such level of efficacy are Cognitive Behavioral Therapy based interventions, Interpersonal Therapy based interventions and Brief Dynamic Psychotherapy based interventions.
2. Treatments should be conveyed only by psychotherapists who are full-trained in one of the above-mentioned intervention protocols. This required an intense and huge training campaign because of the vast number of therapists to train and because of the huge amount of time devoted to training. The number of specialists to be trained was estimated in 800/1000 per year. Those therapists, who have previously done clinical practice, were asked to spend an year in further training with a schedule of two days a week devoted to theoretical training and three days a week devoted to clinical practice under supervision.
3. Outcome measures after each treatment session have to be collected. This may sound excessively punctilious, but it appears to be the only way to evaluate the effectiveness of the program, to compare it with traditional and routine interventions (treatment as usual) and to monitor the progress and the diffusion of the program across the Country.
4. The necessity to adopt a “stepped-care” model: after the initial assessment patients are assigned to one of the two types of treatment (low or high intensity) on the basis of diagnosis and clinical severity. The two types of treatment are different both for characteristics of the intervention and for the number of therapeutic sessions. The idea is that the earlier will be the diagnosis the lower number of patients will need the high intensity treatment.
5. Each of the therapists involved in the program have to participate a weekly-based session of supervision.
6. Patients can access the program whether they decide, without the necessity of

a preliminary visit with the general practitioner or any other type of physician.

Above all, it is fundamental to highlight the economic and organizational autonomy of the program. This autonomy is considered crucial for the project success by its very developers: “But *one thing is sure: IAPT would never have been so successful if it had not been an autonomous service, able to develop an ethos and standards of its own*” (Layard e Clark, 2014, p.204).

The Italian Situation

Italy has a long-lasting tradition in public welfare and healthcare systems. Particularly, in the field of mental health Italy has been a pioneer in terms of legislative actions, network of mental health services and efficiency of interventions for the last thirty years. Also for these reasons we believe that Italy has to join the experience of the most advanced European programs for psychological treatments of Anxiety and Depression and apply them in its National Health Care System. As a matter of fact, at the moment the possibility to access to psychological interventions in the public healthcare system is highly limited by the lack of structures that convey this type of treatment. Moreover, when this is possible, the treatments are often not first line, elective treatments (i.e., they are not evidence-based treatments). This situation affects a high percentage of potential users of the National Health Care System and is a limitation to the Right for healthcare and to the right of undergoing to the preferred treatment, among the efficient ones. The situation is similar, and maybe worse, in private practice. Only a small amount of psychotherapists has a valid, solid and optimal training to treat Anxiety and Depression. Indeed, as mentioned before, not all the available psychological interventions are efficient and feasible to treat Anxiety and Depression. When a non-feasible treatment is used, it is not only a matter of creating or maintaining patient’s psychological sorrow during an excessive long-lasting or inefficient psychotherapy. Indeed, some interventions may even harm: the so-called “deterioration effect” has been known for several years and it refers to the worsening of symptoms during a psychotherapy. This issue is particularly present and marked when an incongruent, inadequate therapy, based on obsolete models, is conveyed. As it happened in England, also in Italy adequate training and updates are needed. In Italy, however, some pilot initiatives have been developed within the National Healthcare System, the Universities and even in the private practice settings. These initiatives were aimed not only to adult population, but also to developing age and ageing populations and also involved patients with Depression and Anxiety in comorbidity with severe somatic disorders. Given these premises we think that the Italian background is better than the one present in England when IAPT begun. It is also relevant to note that during these years the IAPT program recruited around 1000-1500 young Italian psychologists, part of which may be interested in coming back to Italy.

Conclusive remarks

1. We request the same attention and the same allocation of resources for evidence-based psychological treatments of Depression and Anxiety of those devoted to biological treatments. This because, scientific research has shown that psychological treatments are usually as effective as (or even more effective than), pharmacological ones. Psychological treatments also have more long-lasting effects, are more effective in reduce the risk of relapses and may induce benefits that overcome the simple remission achievement. Finally, psychological treatments are often preferred by patients.

2. In professional consultation regarding Anxiety and Depression, healthcare personnel is deontologically due to give complete information about any evidence-based available treatment, therefore including psychological evidence-based treatments. This information should include clinical efficacy and effectiveness, risk of relapses, possible side effects or contra-indications. Given, the availability of highly efficient and effective treatments, the use and the maintenance in time of therapeutic options with no or low evidence-based efficacy, especially in absence of any improvement in symptomatology, is unacceptable. For these reasons we ask for a more careful attention from the professional associations and boards. Moreover, we ask for a triage evaluation of Depression and Anxiety in the National Health Care System. Triage should be performed by trained personnel and on the bases of the internationally accepted evaluation criteria. The triage would guarantee an equal and transparent access to psychological treatments with waiting lists and waiting list priorities just as it happens for access to consultations and treatments for somatic disorders.
3. We demand the Agencies and Institutions devoted to the development of Guide-lines for Anxiety and Depressive Disorders, for National Guidelines both for adults and developing age, based on a multidimensional approach. As a *pro tempore* solution we suggest the adoption of rigorous international guidelines already developed and issued in other European Countries.
4. Given the relevance of these topics we demand for the necessary attention of traditional and new media in order to increase the knowledge and the awareness about mental disorders and about their psychological treatments. A discussion should be set and maintained among researchers, clinicians and scientific journals of the field.
5. We pointed out to IAPT as a successful example that should be more widely known, discussed and analyzed in order to create similar programs in Italy. Indeed, at the end of this stage of discussions and deepening we recommend to the Italian Institutions (including the Government, the Parliament and the Regions) to start such type of programs.
6. We agree with the IAPT view stating that evidence-base psychological treatments pay for themselves since they allow a reduction of the sanitary expenses and of the social costs, which are directly or indirectly related to Depression and Anxiety.
7. Within the Universities we remark the importance on teaching psychological treatments in Master Courses of psychology. Particularly, we consider useful an increased number of teaching programs on first level psychological treatments (e.g., the so-called structured brief interventions), and on interventions based on emotional expression and recognition of dysfunctional thoughts, patterns and themes. In this sense we consider fundamental a tighter collaboration, within a common Strategic Panel, with the Board of Psychologists, the Italian Psychological Association (Associazione Italiana di Psicologia –AIP) and the Academic Psychology Conference (Conferenza della Psicologia Accademica – CPA).
8. Within the School of Medicine we invite to raise a discussion on the opportunity to teach principles of evidence-based psychological treatments for Anxiety and Depression in the residency programs of Psychiatry and Developmental Neuropsychiatry.
9. Another important issue to rise regards the problem of clinical psychology

training after the end of the Master. In Italy the possibility to follow a residency program in Psychotherapy within the Universities is available but, at the moment almost unapplied. This peculiar situation has different causes at various levels including legislative, academic and administrative issues. However, residency programs in clinical psychology and psychotherapy within University may represent an important momentum for the developing of future clinicians who should be expert in evidence-based treatment of Anxiety and Depression. Among other pieces of expertise this should be especially trained to be spent within the national health care system facilities.

10. The Minister of University and Education together with the Ad-Hoc Commission for the accreditation of the private psychotherapy schools should also pay particular attention to the fact that one of the requirement for such accreditation is the evidence-based efficacy of the taught psychological treatment. Moreover, the evidence-based psychological treatments should be more considered and detailed within the CME programs for psychologists and physicians.
11. We hope that Government, Parliament and Regional Councils consider the present document as a starting point to start discussions and debates on evidence-based psychological treatments. In particular, we sustain the necessity of specific and tailored founding programs for: a) training and updating Mental Health Care clinicians with programs inspired to the English IAPT; b) sustaining the pilot projects already active in our country; c) sustaining the research on effectiveness and efficacy of psychological treatments; d) disseminating evidence-based treatments in order to make them available to the general population.
Finally, the Ministry of Health and the National Agency for Regional Healthcare (Agenzia Nazionale per i Servizi Sanitari Regionali – AGENAS), should promote a survey on the effectiveness of psychological treatments within the public health care system at least as far Anxiety and Depression are concerned.
12. We hope that the so-called Essential Levels of Care (Livelli Essenziali di Assistenza –LEA) for psychological treatments of Anxiety and Depression will be effectively available for everyone who needs them. In this sense evidence-based treatments should be:
 - a. Available and accessible (even upon direct request of the patient)
 - b. Appropriate and timely (cutting on waiting list even using external private facilities)
 - c. Efficient and effective as proved by a continuous evaluation of outcomes
13. We invite Granting Institutions active in health-care research to promote and invest on studies aimed at understanding therapeutic processes and outcomes in psychotherapy (including the so-called common factors such as therapeutic alliance, doctor-patient relationship, motivation toward treatment). The empirical study and identification of such processes may be fundamental to create and develop effective and efficient treatment protocols and to design coherent training programs.