Consensus Conference on psychological therapies for anxiety and depression.

FINAL DOCUMENT

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English version

Consensus Conference
promoted by the Department of General Psychology
of the University of Padua

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Istituto Superiore di Sanità
Consensus Conference on psychological therapies for anxiety and depression. Final document. English version.
Working Group "Consensus on Psychological Therapies for Anxiety and Depression"
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The result of the work of the Consensus Group is presented. The Group operated according to the consolidated Consensus Conference model that provides for the formulation of questions, the drafting of a document drawn up by experts in the area and subsequently the evaluation of the work of the experts by a Jury composed of representatives of civil society. The document is organized into two parts. The first part contains in full the report prepared by the Promoting Committee and the Scientific Committee of the Consensus for the members of the Jury with the objectives of the Consensus, the method to be followed and the questions to be answered in the form of Recommendations. The second part contains the Recommendations expressed by the Jury for each question that can also be used independently.

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The composition and articulation of the Working Group "Consensus Conference on Psychological Therapies for Anxiety and Depression" are described in Annex 2 to Part 1 of the document.

Promoter of the Consensus Conference:
Department of General Psychology of the University of Padua

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In brief

Consensus Conference on Psychological Therapies for Anxiety and Depression
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The usual procedure for carrying out a Consensus Conference involves the formulation of questions, the drafting of a document by experts in the area – in this case experts in psychological therapies for anxiety and depression – and subsequently the evaluation of the experts' work by of a Jury composed of representatives of the civil society.

This document reflects the activities of the Consensus as a whole and is organized in two parts. The first part contains the report prepared by the Organizing Committee and the Scientific Committee of the Consensus for the members of the Jury to present them the objectives of the Consensus, the method to be followed and the questions to be answered in the form of recommendations, sub-divided into 6 thematic areas. The first part also includes a series of annexes to offer important information to support the Jury's work. The second part of the document contains the recommendations expressed by the Jury for each question. These recommendations can also be used separately, to favour their dissemination and use in different contexts.

The Jury panel started their work at the beginning of 2021. The Jury was sub-divided into working groups, held five joint meetings, and concluded its work on 15 October 2021. The Jury recognized the extensive and demanding work carried out in over two years by the experts and provided definitive approval of the document they elaborated. Such approval was supported by an extensive report where they reiterated that (1) not all psychological therapies should be recommended, but some of them are supported by scientific literature which certifies that their efficacy is not inferior to commonly used alternative drugs, and that they are recommended by the most authoritative Guidelines; (2) these therapies are under-represented in the Italian health system and patients are induced to resort to the private market with intolerable discrimination in terms of health.

Among its recommendations, the Jury indicates: (1) the development of similar initiatives with specific attention to childhood and adolescence; (2) the dissemination of more correct information among the population, the media and health professionals; (3) the need for stricter criteria for professional training schools qualified for psychotherapy; (4) the opportunity for adequate funding for medium-long term trials in different contexts and locations throughout the country.

Finally, the Jury believes that the problems of anxiety and depression go beyond the competences and possibilities of health ministries and institutions, and that it is appropriate to present the results of this Consensus Conference to highest representatives in the Senate, Parliament and Government.

Preface

It is with great pleasure that I take the opportunity to contribute to the presentation of the results of the Consensus Conference on psychological therapies for anxiety and depressive disorders. I am deeply convinced that this publication is a useful tool for raising awareness and guiding choices and strategies aimed at improving the quality of care for these common mental disorders.

The Consensus and all the documents here presented arise from a fruitful collaboration and intense exchange of experiences between many different actors involved in the topic, such as institutional bodies, including universities and research institutes, health services, regions, professional associations, associations of operators and patients, exponents of the legal system, editorial committees of scientific journals. This collaboration also benefitted from the contribution of researchers from the Istituto Superiore di Sanità, as members of the promoting committee and the jury.

The Istituto Superiore di Sanità has always played a significant role on the topic of common mental disorders (anxiety disorders and unipolar major depression) within the activities of the Reference Centre for Behavioural Sciences and Mental Health. It has recently finalized the analysis of the data collected with the population surveillance system of national relevance PASSI, derived from over 55,000 interviews carried out from 2018 to 2020 to assess the impact of the pandemic on depressive symptoms in adults 18-64 years old resident in Italy. The results will contribute, as is in the spirit of the institution of this surveillance, to the evaluation of the National Prevention Plan and to corporate and regional planning, to allow for a possible reorientation of public health policies at local level in the field of mental health.

Taken as a whole, mental disorders represent the second cause of the burden of suffering and disability linked to all diseases and they account for 14% of all years lived with disability (Years Lived with Disability, YLD), with a prevalence of over 10% in the world. Common mental disorders, together with substance and alcohol abuse disorders, are the ones that contribute most to this burden.

According to the World Health Organization, major depressive disorder alone affects approximately 350 million people worldwide each year and depression is the fourth-largest cause of all disease burden. This burden increased by 37% from 1990 to 2010 and, according to recent projections, major depressive disorder could become the leading cause of disability and suffering from all diseases by 2030. In Italy, people with common mental disorders rarely use health services, even less than in other European countries. Furthermore, the least access to health services is found in the 18-24 age group. This is despite it is being estimated that over 7% of the general population between 18 and 64 years of age has suffered from at least one common mental disorder in the last year and nearly 19% of at least one in life. Considering the numerous and robust evidence on the efficacy of psychotherapeutic interventions, alone or in association with pharmacological treatment, these data

indicate an important health demand that is partly not adequately expressed and channelled. This evidence leads us to reflect on the possible factors contributing to the lack of appropriate assistance and treatment. Among others, one of the obstacles may be identified in the scarcity of services and personnel, in particular of psychiatrists and clinical psychologists.

The results of a recent analysis conducted by the Italian Society of Psychiatric Epidemiology on the relationship between the care needs expressed by users in charge of the Mental Health Departments and the care capacity necessary for carry out all the actions envisaged by recommendations, guidelines, pathways and care protocols, showed that the Departments of Mental Health, in 2019, before the pandemic, were able to respond correctly to just over 55% of the estimated healthcare needs. In these challenging conditions, adult mental health services necessarily prioritize more severe mental disorders, such as schizophrenia and mood disorders with particular severity characteristics. However, the burden of suffering and disability of common mental disorders may be even greater than that of serious disorders, both because even among the former there are extremely disabling forms and because they are significantly more widespread. More specifically, depressive disorders are frequent and characterized by impaired quality of life and higher mortality from suicide and associated to less healthy lifestyles, more risky behaviours and less self-care.

The works of the Consensus to which this volume refers have covered many aspects of assistance aimed at common mental disorders. Without claiming to be exhaustive, it seems to me that they can be framed them within three fundamental areas.

The first area concerns the *recognition of disorders and treatment plans*. Numerous studies, as mentioned, show that a high proportion of patients with these disorders are not treated or in any case do not receive adequate treatment. Among the factors underlying the lack or inadequate treatment, there is the failure to recognize the presence of disorders due to the difficulty of intercepting them at the onset or in any case at an early stage. In this perspective, ensuring their early identification is an important first step. To this aim, the Consensus suggests that all local health services (including primary care services, family clinics, disability services, general practitioners and family paediatricians) and penitential medicine services should be able to identifying patients with common mental disorders or at risk of developing them. All these health services should be nodes networking with the specialized mental health services: they will be responsible for treatment programs structured by levels of severity, according to a stepped care approach. Within such approach, low intensity could include psychoeducational interventions or self-help groups (which avoid the risk of an excess of medicalization), at a higher intensity psychotherapy (whose indication is also supported by its greater acceptability) and finally the psychological treatment integrated with drug therapy.

The second area concerns *access to services* and more generally to treatment. The failure to treat people with common mental disorders, not only in Italy, is due also to the low demand related to stigma. Investing in promoting greater knowledge and awareness of these disorders and in reducing the stigma associated with them could

be a first answer on the demand side. The recommendations of the Consensus propose to invest in communication aimed at and adapted to the different target groups (health workers, the general population, young people), exploiting the potential of mass media and social networks in strict compliance with scientific assumptions. To facilitate access to care, the use of innovative and more sustainable methods integrated into care pathways, such as tele-psychology, also deserves attention and further research.

The third area of interest concerns *academic training and specialization schools*. The Consensus underlines the need for literacy courses on common mental disorders in the course of studies of the three-year degree in Psychology and the degree in Medicine as well as in post-graduate courses envisaged for General Practitioners. As regards the degree in Psychology with a clinical orientation, the recommendations pointed to the need of increasing knowledge on symptomatology, levels of severity of these disorders, as well as on evidence-based treatments and the principles and methods of clinical epidemiology in mental health. Finally, the Jury In its concluding remarks underlined the importance and urgency of supporting research in mental health, including that on psychological interventions involving adults, children, adolescents and third and fourth age.

The recommendations of this Consensus come at a time when our lives have changed due to the SARS-CoV-2 pandemic, which will have, among other impacts, possible repercussions on psychological wellbeing. An example of this are health professionals, most at risk of psychological distress, women, young people worried about their future, family members of COVID-19 patients experienced the threat of losing a loved one, and workers whose livelihoods were threatened with consequent critical issues on the economic as well on social inclusion and mental health. It should not be forgotten that several studies show that the loss of work productivity is among the main determinants of poor mental health and there is strong evidence that, in general, the prevalence of mental disorders is higher in those living in socially disadvantaged conditions (unemployment, lack of education, poverty, marginalization). In our country, depression is twice as frequent in the unemployed.

It is conceivable that due to the pandemic, the demand for psychological and psychosocial interventions and treatments will increase in the coming months and years, especially in the most fragile people. The hope is that this Consensus will promote and encourage special attention in developing a response based on co-planning, involving institutions and actors from the health, education, research, work, and welfare sectors. The person with mental disorders and conditions of social fragility must be at the centre of this effort, to define integrated paths to promote the best possible quality of life.

Prof. Silvio Brusaferro

President of the Istituto Superiore di Sanità

Presentation

The *Consensus Conference* on psychological therapies for anxiety and depression represented a great and unusual cultural effort to re-propose the validity of the various forms of psychotherapy in the field of mental pathologies. The jury with remarkable analytical work responded with a series of recommendations to pre-formulated questions. Adequate scientific research, unfortunately carried out in countries that do not include Italy, has established that some forms of psychotherapy are comparable to the effectiveness of drugs in the treatment of people with anxiety and depressive disorders. The available evidence has been mainly obtained in adult subjects, while it is very important that additional research refers to the pediatric and adolescent area. It is also important to consider the peculiarities of the third and fourth ages. In particular, the possibility of integrating pharmacological treatments with psychotherapeutic interventions by carrying out controlled clinical studies should be emphasized. In this sense, adequate public economic resources are needed so that research can be carried out with the utmost independence.

It is necessary that the models of psychotherapeutic intervention are carried out by level of intensity of treatment avoiding in the lightest forms an excess of medicalization.

Particular consideration should be given to the training of psychotherapeutic staff to be placed in the structures of the Italian National Health Service. The jury recommended in this sense that public graduate schools be increased while the excessive number of private graduate schools be monitored.

The variety of forms of psychotherapeutic intervention must be evaluated in relation to the effectiveness of cognitive psychotherapy, the most studied from a scientific point of view. It is also important that training is complemented by clinical knowledge and is as homogeneous as possible in all regions of the country.

Similarly, psychological knowledge must be integrated into medical schools in order to facilitate the necessary relationships between doctors and psychotherapists. In this sense, the degree in clinical psychology could represent an ideal form of integration. Training must be "continuous" through courses and masters of higher education.

The presence of psychotherapists must be envisaged not only in hospitals, but above all at the level of the territory through their presence in "community homes" with an employment relationship and a propensity to carry out interventions at a direct home level or through forms of telepsychology.

Studies must also be carried out that establish the cost and benefit ratio, essential for the sustainability of the National Health Service, a good that cannot be renounced.

It is necessary to raise public awareness of psychotherapeutic interventions for the form of anxiety and depression involving institutions and especially the mass media and *social networks*.

It is hoped that this document will be disseminated as much as possible at the level of public institutions with particular reference to the Ministries of Education, University and Research, and Health, so that these services can be accessible to all free of charge.

Prof. Silvio Garattini

Chairman of the Jury
and President of the Istituto Mario Negri

Part 1 • FINAL REPORT FOR THE JURY

drawn up by the Promoter Committee, by the Technical Scientific Committee,
and by the Groups of Experts

1. PRESENTATION OF THE CONSENSUS CONFERENCE

1.1 Objectives

The general objectives of the Consensus Conference are to promote the knowledge and use of evidence-based psychological therapies for anxiety and depression and to promote access by the population to appropriate treatment, especially psychotherapy, in order to reduce the current treatment gap.

The objectives are presented exhaustively, argued and explored in Annex 1, which also illustrates the origins and the development process of the Consensus Conference.

The objectives fall into four subject areas:

1. training in the university courses of Medicine and Psychology and in the specialization schools;
2. professional updating, continuous training and scientific publications;
3. professional practice, socio-health services, organizational and economic aspects;
4. raising the awareness of public opinion and the institutions, collaboration with stakeholders and decision makers.

The main issues to be addressed are:

a) efficacy and applicability to the Italian context of the guidelines, therapies and organizational models currently available as reference materials;

b) modalities, tools and procedures for identifying people with anxiety and depressive disorders who may need psychotherapy;

c) training and updating the professionals who work with people affected by anxiety and depressive disorders on effective psychological therapies;

d) resources needed, organizational models and diagnostic-therapeutic plans to facilitate people's access to psychological treatment.

1.2 Method

The recommendations issued by a Consensus Conference are formulated on the basis of the answers provided by a Jury to a series of predefined questions. The questions are formulated by the Promotion Committee in agreement with the Scientific Committee and are then forwarded to the Groups of Experts. Annex 2 shows the various actors of the Consensus Conference and the members of each Group.

With regard to the questions assigned to them, the Groups of Experts have the tasks of:

- preparing a summary of the scientific evidence available on the topic;
- preparing a summary of the information available to the public from different sources on the topics covered by the conference;
- providing the Jury with the reports produced within an established time frame;
- present the data collected during the conference and participate in the discussion.

1.3 Questions put to the Experts

Theme A: Efficacy and applicability to the Italian context of the guidelines, therapies and organizational models currently available as reference;

1. What is the current state of knowledge on the access of people with anxiety and depressive disorders to treatment, to the scientific evidence of the theoretical and practical efficacy, and appropriateness of both psychological and non-psychological treatment for anxiety and depressive disorders?
2. Considering the guidelines available at the international level, specifically on anxiety and depressive disorders, which ones should be taken as reference, especially in relation to their being applicable to the Italian context?
3. Should the guidelines taken as reference or parts of them, be translated into Italian to ensure thorough understanding and wide dissemination? Are additions or comments desirable?

Theme B: Modalities, tools and procedures for identifying people with anxiety and depressive disorders who may need psychotherapy.

1. Is it possible and useful to introduce a model for identifying people with anxiety and/or depression issues, requiring psychological therapies, that is structured according to multiple levels of severity which are matched with corresponding levels of treatment intensity?
2. Are psychological therapies indicated also in the presence of subclinical problems of anxiety and/or depression and, if so, under what conditions?

Theme C: Training and updating of professionals working with people with anxiety and depression issues on effective psychological therapies.

1. What initiatives can be indicated and feasibly applied to the Specialization Schools on Child Neuropsychiatry, Psychiatry, Clinical Psychology and other university and private schools enabling the practice of psychotherapy to make sure that they provide their students with operational skills and with in-depth knowledge about evidence-based psychological therapies for the treatment of anxiety and depression?

2. What should be considered the minimum level of information and training to be provided by medical degree courses and clinically oriented specialist degree courses in Psychology with regard to evidence-based psychotherapy for anxiety and depression?
3. What initiatives can be indicated and implemented in the areas of continuing education and/or other professional development initiatives for Child Neuropsychiatrists, Psychiatrists, Clinical Psychologists and Psychotherapists?

Theme D: Resources required, organizational models and diagnostic-therapeutic plans to facilitate people's access to psychological therapies.

1. Is there evidence in the international literature showing that psychological therapies have a favourable cost-benefit ratio of also in strictly economic terms (absence from work, higher health and social costs, work-related stress, etc.)? What realistic estimates could be made for the Italian context?
2. What strategy appears to be most effective and operationally manageable to facilitate access to psychological therapies by people with anxiety and depressive disorders and reduce the large number of untreated people?
3. What role can the new technologies and online psychology play in improving access and delivery of appropriate treatment for anxiety and depression?
4. What initiatives can be taken to raise awareness, in particular of potential users, about the effectiveness and availability of psychological therapies and to enable patients to actually choose psychological therapies if they prefer them over pharmacological treatment?
5. What initiatives can be taken to raise the awareness of decision makers and socio-health institutions to make psychological therapies for anxiety and depressive disorders effectively available and usable?

1.4 Expert Groups

In order to analyse and summarize the available information and scientific evidence, answer the questions, and submit the reports to the Jury, four groups of experts were set up assigned to the following subject areas:

1. Efficacy, cost-effectiveness and appropriateness of psychotherapeutic treatments for anxiety and depression, applicability of available guidelines to the Italian context: Themes A1, A2, A3, D1.
2. Professional skills required to provide psychotherapy for the treatment of anxiety and depression, training to be provided by university and specialization courses, continuing education and scientific publications: Themes A1, C1, C2, C3.

3. Organizational and management models for the delivery of psychotherapeutic interventions for anxiety and depression: Topics B1, B2 E D1, D2, D3.
4. Mass media, communities and institutions: Themes D4, D5.

2. GLOSSARY OF REFERENCE

Anxiety and depression

In the Final Report for the Jury, the anxiety and depression issues and disorders which are the subject of this Consensus Conference, are referred to by using the more technical expressions of "Common Mental Disorders" (CMDs). These two expressions, which have been coined given the high prevalence of these disorders in the population, basically have the same meaning and the same frequency of use. The former is probably used more by professionals, while the latter is less stigmatizing and used more in social communication.

IAPT Model (Improving Access to Psychological Therapies)

The IAPT model (see Clark, 2017) was summarized by Layard & Clark (2014) in six points:

1. Provide only psychological therapies based on the highest levels of evidence of efficacy. The main reference for knowing what are the psychological therapies with well-established effectiveness is represented by the Guidelines of the National Institute for Health and Care Excellence (NICE). In the case of anxiety and depression the evidence-based psychological therapies are the treatment protocols inspired by: Cognitive and Behavioural Therapy (CBT), Interpersonal Therapy (IPT), Brief Psychodynamic Therapy.
2. Use only psychotherapists with thorough training in specific protocols. This involved and entails a tremendous training effort: tremendous for the number of professionals to be trained, tremendous for the hours of commitment, and tremendous for the territorial differences that need to be bridged. It was estimated that 800-1,000 professionals had to be trained per year. For psychotherapists with previous experience in clinical work, a training year was structured, where two days are dedicated to theoretical training in university structures and three days are dedicated to supervised practice.
3. Collect outcome variables session by session. It may seem excessively meticulousness, but there does not appear to be any other method to analyse the practical effectiveness of the program, compare it with routine practices and traditional interventions, and monitor the growth and development of the IAPT program throughout the country.
4. Adopt the stepped care model according to which the initial assessment ends with the assignment of the patients to be treated to one of the two treatment conditions provided, low intensity or high intensity, different both in terms of time commitment and type of interventions. Once early diagnosis becomes prevalent there will be a smaller number of patients in need of high-intensity treatment.
5. Provide expert supervision on a weekly basis for every psychotherapist.

6. Patients have direct access to the service without necessarily having to go through the General Practitioner or any other specialist.

An essential precondition for this endeavour is economic and organizational autonomy which is crucially important according to our experts: "There are no doubts, the IAPT would never have been so successful had it not been an autonomous service, capable of developing its own ethos and its own standards" (Layard & Clark, 2014, p. 204).
The IAPT project was born in 2006 in the United Kingdom as part of the various responses to the economic crisis of the period, aimed at recovering the competitiveness of the production system and increasing the Gross Domestic Product (GDP). The economic advisors to the Blair cabinet and in particular a paper signed by Lord Richard Layard and published by the London School of Economics and Political Science (LSE), known as *The Depression Report* (LSE, 2006), pointed to the cost of the most common psychopathological disorders: anxiety and depression. These disorders were associated with particularly high social costs with a global economic loss amounting to 21 billion. Among the working-age population, anxiety and depression accounted for 40-50% of days of absence from work. Launched on an experimental basis in two locations, the IAPT project provided evidence of being feasible and effective and today there are more than 200 services throughout the Country, services that currently receive about 1,250,000 requests a year. On the basis of the stepped care process, patients are provided with "low intensity" (less than eight sessions) or "high intensity" (16-20 sessions) psychological treatment, namely real formal psychotherapy treatment, based on the indications of the NICE guidelines.
A recent meta-analysis conducted on the practical efficacy studies (N = 47 for approximately 500,000 patients) of the IAPT services calculates a large effect size for both the treatment of depression (d = 0.87, 95% CI 0.78–0.96, p <.0001) and for the treatment of anxiety (d = 0.88, 95% CI 0.79-0.97, p <.0001) (Wakefield *et al.*, 2020). Furthermore, the IAPT model has been a reference for similar experiences in countries such as Australia, Canada, Japan, Norway.

Psychological therapies

This name refers to all therapies that use psychic means to resolve or reduce the symptoms and discomfort associated with anxiety and depressive disorders; the use of psychic treatment involves knowing and modifying processes and variables of a cognitive, emotional and relational nature.
Psychological therapies include psychotherapy, which is the best known and most studied intervention, counselling and psychological support. In the Italian legal system, psychotherapy is an activity that can be practised by licensed doctors and psychologists.
For sake of completeness and in accordance with the stepped care model (increasing intensity of care), in the Report for the Jury, other non-psychological interventions which have proven to be effective for people suffering from anxiety and depression are mentioned but not discussed. First of all, pharmacological treatment but also, in the more serious cases carrying a high risk of psychopathology, an integrated set of

treatments and necessarily multi-professional management. On the other hand, for low-intensity interventions, mention is made also of interventions that do not qualify as psychological therapies, for example the unguided use of self-help manuals or the promotion of physical activity.
In any case, the Consensus Conference does not enter into the merits of the specificities of individual treatments or the definition of the typical and reserved practice of the professions, referring the reader for any further information to the laws of the State (in particular the Laws 56/1989 and 170/2003, the Presidential Decree 328/1001, and the Ministerial Decree 4/10/2000), to the regulations and indications of the professional associations and to the case law on the matter.

Stepped care model

The Stepped care model provides for increasing levels of intervention depending on the level of patient distress or need. It is based on a hierarchical principle in the delivery of care so that the most effective yet least resource intensive treatment is delivered first and then stepping up to more intensive treatment where required (maximizing results while minimizing costs). Each step represents an intervention, from the least invasive ("low intensity") to the more organized and containing intervention ("high intensity"), depending on the severity of the symptoms and based on empirical evidence. Failure to respond to an intervention entails transition to the next level of treatment (for more details, see Annex 4).

3. QUESTIONS ON ACCESS, EFFECTIVENESS AND APPLICABILITY OF THE GUIDELINES AND PSYCHOLOGICAL THERAPIES TO THE ITALIAN CONTEXT

3.1 Theme A1

What is the current state of knowledge on the access of people with anxiety and depressive disorders to treatment, to the scientific evidence of the theoretical and practical efficacy and appropriateness of both psychological and non-psychological treatment for anxiety and depressive disorders?

Although the health policy of Italy and of most industrialized countries tends to guarantee access to adequate treatment for all people suffering from mental disorders, the picture that emerges from the European and US population studies is not encouraging, since most people with psychological problems do not receive treatment by professionals of the sector nor by the healthcare services in general (Bebbington *et al.*, 2000; Kessler *et al.* 1997; Wang *et al.*, 2005). Furthermore, among the people who do have access to health and specialist services, only a small percentage receive effective treatment in light of available knowledge (Bebbington *et al.*, 2000; Kessler *et al.* 1997; Lepine *et al.*, 1997; Young *et al.*, 2001).

The best source of information on the Italian situation is constituted by the European study ESEMeD (European Study of the Epidemiology of Mental Disorders) (de Girolamo *et al.*, 2005; see www.epicentro.iss.it) whose value has remained unparalleled even if it dates back to the previous decade. Indeed, it is the only prevalence study on Common Mental Disorders (CMDs) and their correlates carried out in Italy on a representative sample of the general population. The study confirmed the widespread diffusion of these disorders, estimating that no less than two and a half million Italians suffer from an anxiety disorder every year and over a million people suffer from major depression, and the milder forms are even more common. The percentage of people with an anxiety or depressive disorder who, during the previous 12 months, had sought help from adequately qualified public or private healthcare professionals was very low, namely 20.7% and 17.4% respectively. Furthermore, the study showed that the pharmacological treatment delivered was often inappropriate, a result also found in other subsequent studies conducted in local Italian contexts (Balestrieri *et al.*, 2004). The data show that relatively few patients are given psychotherapy treatment.

Although the data collected by the ESEMeD study go back several years, there are no reasons to believe that things may have changed significantly since then. **Access to health services by people with these disorders is truly negligible and disappointing**, and the treatment offered by the health facilities is little, disconnected from epidemiological data and unable to reach potential recipients.

The picture that emerges from the literature since 2004 (Balestrieri *et al.*, 2004) up to the present day (Di Cesare *et al.*, 2019) is that most of these people with CMDs do not seek help from health professionals. For example, the prevalence data processed by the Public Services for the various disorders, reported in the Report of the Ministry of Health based on data from the Mental Health Information System (SISM), show that the number of patients with depression or anxiety treated by the Services is much lower than the presumable number of such patients estimated on the basis of the prevalence of these disorders. **The treated prevalence of depression is in fact equal to 0.39%, while the treated prevalence of neurotic and somatoform syndromes is 0.23%** (Di Cesare *et al.*, 2019). In the absence of valid surveys, the experts believe that a comparable percentage is treated at other local health services, such as Family planning centres, Addiction Services and Services for Children or Child Neuro-Psychiatric services, and that a larger number of cases is treated by freelance psychologists, in particular anxiety disorders.

The most recent epidemiological system PASSI *(Progressi delle Aziende Sanitarie per la Salute in Italia* – progress by local health units towards a healthier Italy), activated by the Istituto Superiore di Sanità (ISS) to monitor psychological disorders, confirms that in the 2016-19 three-year period the estimate of symptoms of depression in adults is 6% in the general population, 61.4% of which seek help. It has also been estimated that among these people the average number of days in poor health conditions is 9.7%, and the average number of days of psychological distress is 15.7%. The PASSI data, which are based on a small group of questions and not on structured diagnostic interviews, which however do detect the presence of symptoms, must be read "conservatively" since in our opinion they may very well be distorted by the lack of perception of psychological distress.

The picture that emerges from the literature is therefore that many patients with CMDs do not seek help, and even those who do address the services do not always receive appropriate pharmacological treatment. There is a lack of studies that can be generalized to the national level on the appropriateness of the psychotherapeutic treatments implemented, which in any case are generally relatively few. Instead, it would be necessary to know what psychological therapies are actually used in our Country, since a vast amount of research demonstrates that specific therapies are effective both in the short-term and in the long-term in the treatment of anxiety and depressive disorders. These studies are the basis of the guidelines developed by the health authorities and scientific associations of various countries. They unanimously report that some protocols (which are well specified and some of which have also drawn up manuals) of psychological intervention should be considered as first-line interventions and have evidence of efficacy that is greater or equal to the most appropriate pharmacological therapies, albeit with precise and limited exceptions for some subgroups of patients.

Shortcomings in the availability and access to psychological therapies are further aggravated, at the present time, by the psychological consequences of the COVID-19 pandemic associated with the confinement measures. For example, in the survey conducted by Conti *et al.* (2020), 71% of health workers reported somatization and

55% distress. Obviously, the effects of the pandemic on the psychological sphere will be assessed with greater precision in the months to come, and they will certainly reveal an increase in psychological and psychiatric problems, in particular stress-related issues.

In terms of economic and social costs, today, depression ranks second after cardiovascular disorders, and by 2030 it is estimated to be at the top of the list in terms of lost years of life in good health. Therefore, the national system needs to adopt a real "Pandemic Plan" that envisages increasing access to treatment by people affected by these disorders and above all providing appropriate prescriptions for interventions of proven effectiveness.

What is available at the present time? In our opinion, the structural and organizational resources can be improved. The National Action Plan for Mental Health (*Piano di Azioni Nazionale per la Salute Mentale*, PANSM) approved at the State-Regions Conference is a good starting point because it includes Major Depression in its severe, moderate or medium and mild forms among the four Profiles of Care. Furthermore, it provides a clear definition of which disorders are to be treated (among these is Major Depression) and which are to be taken on for treatment or counselling jointly with other Services; the former includes all CMDs, while the latter includes disorders in adolescents in collaboration with Child Neuropsychiatry. In addition to this, mention can be made of the Essential Levels of Care (*Livelli Essenziali di Assistenza,* LEA) (Ministero della Salute, 2017) and the National Plan for Chronic Disorders (*Piano Nazionale Cronicità,* PNC) (Ministero della Salute, 2016) where psychological care is envisaged for a wide range of conditions with access to various health and socio-healthcare facilities, not only Mental Health establishments, but also Primary Care units and Hospitals. At the present time this reality is extremely diversified across the national territory with different organizational structures and above all at regional and national levels there is a lack of homogeneous data both on the access of people with psychic disorders and on the types of psychological treatment offered.

The intervention models are indicated in the Italian legislation, in the scientific literature and in the international guidelines; many of these treatments are psychological, psychosocial and non-pharmacological.

Given the complexity of the issue, Italian health policies are opting for a strong network of basic services (community homes, community hospitals, counselling centres, mental health centres, proximity centres, integrated group medicines) with psychological therapies cutting across the different levels and contexts of the Italian National Health Service (NHS). In consideration of the psychosocial crisis caused by the exceptional conditions brought about by the SARS-CoV-2 epidemic, the legal provisions require intervention in two areas, namely "making mental health services more efficient and (...) guaranteeing individual and collective psychological well-being "(Law 126/2020); in practice this requires coordinating the activities of psychological competence across the various medical specialties (Law 176/2020).

At the same time a systemic action is required with strategies aimed at promotion and protection, creation of an inter-institutional network (school, socio-health areas, profit and non-profit organizations, etc.), and at training healthcare professionals with various qualifications so that they can deliver treatments that have been proven to be effective and efficient.

This can be achieved if all the protagonists of society collaborate in the drafting of a three-year Plan, previously defined as an actual Pandemic Plan, to further prevent the spread of these disorders and be able to treat them efficiently and effectively.

According to the plan **a first eight-hour working day** could be organized and addressed to the representatives of institutional organizations, the representatives of professional orders and associations and other stakeholders with the aim of **drafting a Memorandum** to be transformed into ad hoc ministerial Recommendations (**Annex 3**).

3.2 Theme A2

Considering the guidelines available at the international level, specifically on anxiety and depressive disorders, which ones should be taken as reference, especially in relation to their being applicable to the Italian context?

The Group of Experts examined the main international guidelines on anxiety and depressive disorders with the aim of **selecting those that comply with the following parameters**:

A. International coverage, number of studies included in support of the guidelines, and authority of the bibliographic databases searched (e.g., Cochrane Library, Embase, MEDLINE, PsycINFO/Psychology and Psychiatry).

B. Updated guidelines, i.e. the more recent ones, considering that according to the Istituto Superiore di Sanità (2019) a Guideline is valid for 3 years from the date of publication, at the end of which the group that produced them should carry out a systematic review of the literature to verify the availability of new evidence that may affect the strength and direction of the recommendations.

C. Number of citations, dissemination and reputation of the guidelines ascertained through the Scopus abstract and citations database.

D. Independence and absence of conflicts of interest, in the sense that, in the opinion of the Experts, the guidelines promoted by governmental bodies are to be preferred over those produced by scientific and professional societies.

Considering that the most important guidelines have been drawn up in Anglo-Saxon countries, it may prove useful to explain the basic concepts on which they are based:

1. Relationship with their national health systems. In the British system, which is public, the General Practitioner (GP) has a filtering, screening, monitoring and decision-making role, also for the psychopathology sector (for example, consider the structure of the British referral system Improving Access to Psychological Therapies (IAPT) (see Clark, 2017). The GP therefore takes on the managerial and economic responsibility of deciding on the referral of a patient based on his own diagnostic and therapeutic considerations and on the local availability of second and third level clinical facilities. The American health system, on the other hand, is private and fundamentally based on the diagnostic and therapeutic plans of Health Maintenance Organizations (HMO). Being private, the backbone of the system is based on the economic principle of profit making to which the principle of universality of care is subordinated.
2. Adoption of the stepped care model. The British National Health Service has adopted the stepped care model which is different from the binary treatment/non-treatment model based on the thresholds of the diagnostic criteria of the North American health system. The difference in the two care models is due to the relationship with their respective health systems, as mentioned earlier, and is therefore related to their respective stakeholders.
3. Criteria adopted for indicating first- and second-line psychotherapies in evidence-based treatments. The criteria are different and not always consistent. For example, the guidelines of the American Psychological Association are based on the concept of Empirically-Supported Treatments (EST) (see Chambless & Ollendick, 2001), adopted from 1998 onwards, where efficacy is indicated on the basis of an established number of Randomized Controlled Trials (RCTs), where comparisons are made also with inert (waiting lists) or inactive controls (i.e. not with another psychotherapy), essentially borrowing the RCT model of drug treatment used by the American Psychiatric Association and more in general of medical treatment.

Based on the evaluation of the aforementioned criteria A, B, C and D, regarding the **guidelines for anxiety disorders** the Experts have discarded several of them, and considered that only the following three guidelines should be taken as reference points, of which the first is British and the other two American:

1. National Institute for Health and Care Excellence (NICE) (UK), 2017-2020;
2. American Psychiatric Association, 2009-2013;
3. American Psychological Association, 2017.

With regard to their **applicability** to the Italian context, it is believed that these guidelines can apply to the Italian context. It is also believed that in order to make the best use of them **it is necessary that the mental health professionals and the health professionals of the local services be given adequate training** on some of the specific psychotherapeutic techniques recommended by these guidelines.

Regarding the **guidelines for depressive disorders**, here as well the experts have discarded several guidelines (for example, the Guidelines of the American Psychiatric Association, because, although being authoritative, they have not been

updated since 2010). The Experts deem that the following five guidelines should be taken as reference points:

1. National Institute for Health and Care Excellence (NICE) (UK), 2018 and 2019;
2. American Psychological Association, 2017;
3. American Academy of Paediatrics (AAP), 2018;
4. American College of Physicians (ACP), 2016;
5. Orygen Youth Health Clinical Program (Australia), 2017

With regard to their **applicability** to the Italian context, it is believed that also these guidelines can apply to the Italian context. And also, in this case the health workers need to receive adequate training on the specific psychotherapeutic techniques recommended by these guidelines.

From what has been said so far, it is clear that the theoretical framework of the selected guidelines must be considered within the context of the respective national health services and that it cannot be borrowed *sic et simpliciter* and applied to other health services, such as the Italian one. Consider, for example, the function of the territorial mental health services that provide care and the widespread practice of private psychotherapy that makes the automatic adoption of any of the 3 guidelines in Italy almost impossible.

For the sake of completeness, it is necessary to mention the fact that during the last ten years studies, editorials and meta-analyses have been published that question the principle of efficacy of a psychotherapy based on traditional RCTs and on the resulting effect sizes (see Westen *et al.*, 2004; Wachtel, 2010; Shedler, 2018).[1]

3.3. Theme A3

Should the guidelines taken as reference or parts of them, be translated into Italian to ensure thorough understanding and wide dissemination? Are additions or comments desirable?

We believe that these guidelines need not be translated – also because the cost of translation rights for some guidelines, for example those of the National Institute for Health and Care Excellence (NICE), is prohibitive. It is sufficient to summarize parts of them integrating them with the data emerging from meta-analyses and controlled studies published after the release of these guidelines. For this purpose, the Experts of the Consensus Conference have drawn up an integrated summary of the guidelines of the NICE, the *American Psychological Association* and the *American Psychiatric Association* referring to the main anxiety and depressive disorders, which can be a useful reference for professionals. This integrated summary constitutes **Annex 4** of this Report.

[1] After examining the guidelines, the Experts decided not to forward this Question to the Jury.

Since the translation of the NICE guidelines referring to the topic of this Consensus Conference, is extremely expensive, not indispensable but certainly desirable, the Experts have nevertheless made a selection, listed in **Annex 5**.[2]

[2] After examining the guidelines, the Experts decided not to forward this Question to the Jury.

4. QUESTIONS ON PROCEDURES AND INSTRUMENTS TO IDENTIFY PEOPLE WITH ANXIETY AND DEPRESSIVE DISORDERS

4.1 Theme B1

Is it possible and useful to introduce a model for identifying people with anxiety and/or depression issues, requiring psychological therapies, that is structured according to multiple levels of severity which are matched with corresponding levels of treatment intensity?

In Italy, the annual prevalence of depressive disorders is estimated at around 6% while anxiety disorders are about 5% (Gigantesco *et al.*, 2013; WHO, 2017). Today it is believed that the conditions identified by these diagnoses (Common Mental Disorders, CMDs) contain a great heterogeneity for a series of variables among which severity plays an important role. It is therefore useful to consider anxiety and depression as dimensional variables with respect to which individual cases are positioned along a continuum of severity.

The importance of making assessments of severity with a view to improving treatment was highlighted by the finding of a discrepancy between the heterogeneity and complexity of the characteristics of people requesting help for CMDs and the uniformity of the responses by the health services. As regards depression in particular, an examination of the international and Italian literature shows that of the people who address primary care with a request for treatment, 80% or more of cases are given a prescription for antidepressant drugs (Mazzoleni *et al.*, 2011; Waitzfelder *et al.*, 2018). Comparing this reality with what emerges from the research on the efficacy and safety of treatments, the differences are evident. In the short term, comparisons between drug treatments and psychological therapies show no differences in efficacy in reducing depressive symptoms, with a small preference for combination therapies (Cuijpers *et al.*, 2020). For anxiety disorders there is an equivalence between pharmacological treatments and individual and group psychotherapies, especially of the cognitive-behavioural type (Bandelow *et al.*, 2017; Barkowski *et al.*, 2020). Regarding severity, taking into account that most of the clinical studies have been conducted on cases of moderate depression, it should be noted that, despite a widespread prejudice, even in the most severe cases of depression the equal efficacy between drugs and psychotherapies and the small advantage for combination therapies is confirmed (Cuijpers *et al.*, 2020; Furukawa *et al.*, 2017, 2021). In contrast, in cases of mild severity, which have not been studied extensively, the evidence is limited for both treatments. In these cases, it should also be considered that there is some evidence of efficacy for alternative therapies such as exercise and herbal therapy (Gartlehner *et al.*, 2016). Moving from short-term to long-term efficacy and the relevant safety assessments, the limitations of

antidepressant drugs are more evident. Regarding duration, there are data from studies with a follow-up of over one year indicating that psychotherapy has greater efficacy in the prevention of depressive relapses (Fava, 2002). In recent years, there has been an increase in the request for caution in the use of antidepressants given the severity of their adverse effects (Carvalho *et al.*, 2016). It is therefore understandable that the steady increase in the consumption of antidepressants, which has doubled in Italy during the last fifteen years reaching an average daily dose (Defined Daily Dose, DDD) of 42.5 per 1000 inhabitants in 2019 (Osservatorio Nazionale sull'impiego dei medicinali, 2019), is such as to make these disorders a serious public health issue. Expanding the forms of treatment for CMDs is therefore a priority, given that in our Country, even in the specialized mental health services, access to psychotherapies for patients with depressive disorders is available in just over 8% of cases (Barbato *et al.*, 2016).

The adoption of an approach based on levels of treatment intensity (stepped care) has two main objectives: to treat the largest possible number of people and achieve the highest possible degree of remission (NCCMH, 2021). A special effort is required to train the personnel of all the local social and health services so that they are able to identify anxiety and depression issues. In this way the request for help can be recognized and managed, whether it is expressed to the General Practitioner (GP), the Primary Care Paediatrician, the District Primary Care Services, the Family planning centres or the Disability Services. The assessment can be made upon the specific request of the patient or proposed by the healthcare professionals when they detect depressive and/or anxiety symptoms and manifestations in the problems presented by the patient. If the presence of a CMD is recognized, the General Practitioner or the Primary Care Paediatrician can: a) intervene directly by recommending self-help manuals or by proposing simple lifestyle changes; b) address the staff of the specialized services either immediately or when the interventions indicated in point a) have not obtained the desired result.

Indeed, it is useful to formalize the treatment of CMDs in a Diagnostic and Therapeutic Care Plan (*Percorso Diagnostico Terapeutico Assistenziale*, PDTA) drawn up with the widest possible participation of stakeholders right from the earliest planning stage which includes, at least, primary care professionals and the specialists directly involved in the project (bottom-up mode) as was done in Great Britain with the *Improving Access to Psychological Therapies* (IAPT) program (see Clark, 2017) (see *The Improving Access to Psychological Therapies Manual*) (NCCMH, 2021). It is important that patients are evaluated at each level of treatment and at each session using the same basic scales. The IAPT proposes the Patient Health Questionnaire-9 (PHQ-9) for depression, the Generalized Anxiety Disorder Scale-7 (GAD-7) for anxiety, and the Work and Social Adjustment Scale (WSAS) for disability associated with the disorder (NCCMH, 2021). Timely assessment facilitates communication between the different levels of treatment and guides the professionals in making the important clinical decisions, such as stepping-up the treatment or stepping it down or ending the treatment. An evaluation drawn up in annual reports is also essential to evaluate the entire process with a view to improving it continuously (Clark *et al.*, 2018).

Level 1. The first level intervention consists in guiding self-help which takes place in a maximum of 6-8 meetings in person or by telephone, during which the healthcare professional introduces the self-help material and evaluates progress with the patient and the outcome of the treatment (NICE, 2011). It can now also be conducted through therapist-led Internet interventions (Thew, 2020). It is an approach characterized by a low number of contacts and a high volume of people treated (low contact-high volume) and is indicated for sub-threshold or medium-low severity disorders, and may also be effective in some cases of more severe disorders (Green *et al.*, 2014). Its efficacy on symptoms is comparable to traditional cognitive-behavioural treatment (Salomonsson *et al.*, 2020). The healthcare professional can meet the patient in the primary care setting, thus facilitating the delivery of care when the disorder is experienced as a source of stigma. Working closely with primary care professionals can foster greater knowledge and collaboration between specialists and primary care services (collaborative care).

Level 2. When the level 1 intervention does not achieve remission of the disorder, the professional and/or the GP or the Primary Care Paediatrician move the patient to the next level of treatment (step-up), starting a psychotherapeutic treatment that is effective and appropriate to the disorder to be treated. The subsequent levels involve the delivery of specialized treatments (psychotherapies) that are best provided by multi-professional teams where psychotherapy can be integrated with other psychosocial interventions and with drug prescription where necessary (Lussetti *et al.*, 2012). At level 2, a more in-depth assessment of the clinical problem is required in order to identify possible comorbidities and decide with the patient what is the key problem to be addressed first and choose the appropriate psychotherapeutic intervention (for example, individual or group therapy).

Level 3. In cases of greater complexity (due to the high intensity of the psychopathological symptoms or advanced disability) or in high-risk situations, it is advisable for the patient to be given treatment in a specialist service (level 3 intervention), considering whether possibly residential or semi-residential treatment may also be necessary. It should be noted that in Italy while the mental health services for adults may be sufficiently organized and have resources to ensure an adequate response, there are serious shortcomings with regard to the facilities for children and adolescents. However, it is advisable that the team treating the CMDs accompany the patient to Level 3 treatment and collaborate with their colleagues in order to quickly return the patient to the less invasive levels of treatment.

In conclusion, the identification of people with CMD structured according to levels of severity is therefore useful if it contributes to diversifying treatment, recognizing that formal psychotherapies, sometimes combined with drug therapies, are the intervention of first choice in cases of moderate or major severity, also taking into account that patient preference goes in this direction and must hence be the discriminating factor of choice when choosing among equivalent solutions (Cuijpers *et al.*, 2020). Various types of interventions of lesser intensity should be reserved for less problematic cases. Assessment based on levels of severity is useful when

made in a context where resources are to be allocated to psychological therapies, preferably in the context of primary care, as happened in Great Britain with the IAPT program where integrated care models such as collaborative care and stepped care have been adopted (Muntingh *et al.*, 2016; Kampman *et al.*, 2020).

4.2 Theme B2

Can access to psychological therapies also be indicated in the presence of subclinical problems of anxiety and/or depression and, if so, under what conditions?

In recent years, there has been growing interest in subclinical anxiety and depressive disorders, given the low performance of the classification systems in use. Subclinical problems are defined in the literature in various ways, and mainly: "sub-threshold (anxiety or depressive) disorder" or "clinically significant (anxiety or depressive) symptoms". In many research and application protocols there is no clear distinction between sub-threshold symptoms and mild severity disorder, even with regard to the cut-off values for the tools used for screening and for patient inclusion.

The most important practical issue is represented by the (numerous) cases in which symptoms of different disorders are present together, and in particular symptoms of anxiety and depression; symptoms that are clinically significant, a source of distress and/or impaired functioning, but do not meet the criteria for any specific diagnosis. Many clinicians also believe that most of the symptoms can be better interpreted using a dimensional approach and not using a presence/absence approach. Furthermore, some studies show that even in the most severe patients, the symptoms do not always express themselves in the same way week after week and that for most of the time the diagnosed disorder may manifest itself below the threshold (Lewinshon *et al.*, 2000).

Many researchers consider sub-threshold symptoms as part of the evolution of the diagnosable disorder over time, for example as a transient phase of major depression in which symptoms are less numerous and less severe (Juruena, 2002); others conceptualize them as residual symptoms of a disorder that is not in complete remission or as prodromal symptoms, in both cases being predictors of a greater risk of relapse (Fava *et al.*, 2002); the two approaches suggest the desirability of treating the sub-threshold symptoms to favourably modify the evolution of the disorder. On the other hand, spontaneous remission in the absence of any treatment is well documented in a considerable percentage of cases: 23% after three months, 32% after six months, 52% after one year (Whiteford *et al.*, 2013). This suggests that in many cases the strategy of waiting before intervening can be adopted, while monitoring the evolution of symptoms over time.

The appearance of an anxiety disorder may emerge independently of a positive history of anxiety disorders and irrespective of the presence of below-threshold anxiety symptoms; but it will emerge more strongly from the joint presence of the

two conditions; similarly, the development of a depressive disorder is predicted by a history of depression, sub-threshold symptoms, and from a combination of these two conditions (Karsten *et al.*, 2011).

Some studies have found that the incidence of major depression is higher in individuals with sub-threshold depression, with a relative risk index that varies according to the study criteria, depending in particular on the definition adopted of sub-threshold depression (Cuijpers & Smit, 2004). A seven-year follow-up study of 17- and 18-year-old adolescents showed that subjects with sub-threshold depressive symptoms had a much higher risk of developing major depression, ideation, and suicide attempts over time (Fergusson *et al.*, 2005). Access to psychological therapies for people with sub-threshold symptoms may be indicated not only for preventive purposes but also to reduce the discomfort, dysfunction and health and social costs that the symptoms still entail. Bosman *et al.* (2019) studied the 3-year prevalence and course of sub-threshold anxiety disorders in the general population: the prevalence during the three years was 11.4%; in 57.3% of cases the disorder caused important limitations in functioning, in 29% it persisted over time, and in 13.8% it progressed into a diagnosable anxiety disorder. With particular reference to the elderly, epidemiological surveys show that sub-threshold anxiety and depressive symptoms are quite important, with estimated prevalence values of 24-43% (anxiety) and 15-25% (depression) (Braam *et al.*, 2013; Heun *et al.*, 2000). A systematic review found that the prevalence of sub-threshold generalized anxiety disorder was double that of the full-blown syndrome, and that personal distress, reduced functioning, economic and social cost, recourse to health care and the risk of developing a diagnosable mental disorder were significantly higher than in the general population (Haller *et al.*, 2014). A prospective cohort study, which lasted 6 years, highlighted two distinct trends in the evolution of anxiety and depressive symptoms in the elderly, both characterized by stability and chronicity, but with different levels of severity and dysfunction; the more severe trend was shown by one in five participants (Holmes *et al.*, 2018).

The guidelines suggest access to psychological therapies in the presence of sub-threshold depression. In particular, the guidelines of the National Institute for Health and Care Excellence (NICE, 2011) on "Common mental health problems" indicate that *Level 2* (low intensity) interventions should be used in people with persistent sub-threshold depressive symptoms, moving on to *Level 3* interventions (intensive interventions) when the response to low intensity treatment is not satisfactory; in the Improving Access to Psychological Therapies (IAPT) program (Clark, 2017) these recommendations are reinforced in cases where there is also a high or medium risk of psychopathology or a significant loss of social and occupational functioning.

With reference to the Italian context, it should be noted that the assessment procedures contained in recent reports edited by the Istituto Superiore di Sanità "Rapporti ISS COVID-19" no. 23/2020 (Gruppo di lavoro ISS Salute mentale ed emergenza COVID-19, 2020a), no. 44/2020 (Gruppo di lavoro ISS Salute mentale ed emergenza COVID-19, 2020b), and the decision-making criteria for access to low

and medium intensity psychological and psycho-social interventions do not provide for a formal diagnosis and equally do not discriminate between mild disorders and sub-threshold symptoms.

In conclusion, it can be stated that psychological therapies are advisable also in the presence of subclinical anxiety and/or depression problems in the following conditions:

- for people who have already suffered from anxiety or depressive disorders in the past, also in order to prevent relapse;
- for adolescents, in order to reduce the risk of developing both the disorder and substance abuse over time and, finally, to reduce the risk of committing suicide;
- for the elderly, in particular for those with significant physical or mental comorbidities and with a decline in personal and social functioning;
- in all conditions in which the sub-threshold symptoms are associated with a medium-high risk of psychopathology (risk of self-harm and suicide, violence towards others, neglect or violence towards their children, loss of functioning that affects basic autonomy) or with a serious worsening in social and occupational functioning;
- for parents with depression problems in the perinatal period, considering the negative consequences that the symptoms, even below-threshold, can have on the couple's relationship and on the affective and cognitive development of the infant.

It is worth recalling that, even more so in subclinical conditions, low intensity interventions and psychological therapies are the first choice, without prejudice to the patient's preference.

5. QUESTIONS RELATING TO THE PROFESSIONAL SKILLS REQUIRED FOR THE DELIVERY OF PSYCHOLOGICAL THERAPIES AND THE RELEVANT TRAINING NEEDS

Working Group 1 preliminarily observed limitations and incorrect definitions in the formulation of the questions which have therefore been modified, as follows.

5.1 Theme C1

What actions can be indicated and made feasible in university schools providing specialization in Psychology, Child Neuropsychiatry and Psychiatry, as well as in other schools that issue licenses enabling the practice of psychotherapy in order to provide thorough knowledge of evidence-based psychological therapies and practical skills for the treatment of anxiety and depression?

The Working Group does not intend to interfere with the competences of the coordination bodies of university specialization schools, it only wishes to point out the presence of useful indications in the guidelines which have been considered. With reference to private psychotherapy schools enabling the practice of psychotherapy, the Working Group acknowledges that "there are still no precise criteria for defining the scientific value of these schools. However, the Technical-Advisory Committee (*Commissione Tecnico-Consultiva*, CTC) of the Ministry of University and Research (*Ministero dell'Università e della Ricerca,* MUR) of Italy is based on two criteria: the extent to which the scientific and methodological proposal of a School is widely adopted at national and international level, and the relevant scientific publications reported in the databases (starting from SCOPUS)" as communicated by prof. Cesare Maffei, the current Chairman of the CTC of the MUR.

This Consensus Conference expresses its satisfaction with the gradual increase in attention paid to the issues of scientifically confirmed efficacy of the accreditation of new psychotherapy schools. It also urges that the documented efficacy criteria be more precisely specified while inviting the schools to review the authorizations issued in the past so as to take into account both recent developments and the current internationally shared criteria.

5.2 Theme C2

What should be considered the minimum level of learning and training to be provided by university courses in Psychology, Medicine, Pharmacy and the Health Professions regarding evidence-based psychological therapies for anxiety and depression?

The Experts believe that in all university degree courses on psychology and health-related subjects there must be a certain number of hours (obviously differentiated for the different courses) dedicated to literacy about the measures of effectiveness of treatments, meta-analytical reviews and consultation of international guidelines. It should also be noted that the current manuals used by students of university degree courses all too often reserve little space to aspects related to the effectiveness of psychotherapies and in some cases the information provided is even outdated.

In the specific case of the training provided by the Master's courses of Dynamic and Clinical Psychology, the Working Group fully endorses the recommendations expressed by the College of University Professors "07-Dynamic Psychology" and "08-Clinical Psychology" (see **Annex 6**), while suggesting the specific additions indicated above.

5.3 Theme C3

What actions can be indicated and made feasible for continuing education and/or other professional updating initiatives for General Practitioners, Child Neuropsychiatrists, Psychiatrists, Clinical Psychologists and Psychotherapists?

A non-exhaustive survey of the current offer of continuing education for Child Neuropsychiatrists, Psychiatrists and Clinical Psychologists provided by the Istituto Superiore di Sanità (ISS, the National Institute of Health in Italy), by the Regions, by Local Health Units, by Universities and by private bodies, suggests that:

- common mental disorders (CMDs) are given very limited space, especially anxiety, in favour of other disorders characterized by lower prevalence, less severity and that are less disabling; in particular, the training opportunities on common mental disorders in children are less than those offered for generalized developmental disorders or for specific learning disorders;
- the training offer within public health is often linked, and functional, to specific intervention projects or to the implementation of Diagnostic Therapeutic Care Plans (DTCP); in this sense, the drawing up of DTCPs by many Regions for depression and for screening and treatment projects for perinatal depression has, in recent years, positively influenced the offer;
- the training proposals on diagnostic procedures and treatment methods or techniques rarely select and privilege the more valid ones, those with evidence of efficacy; while it may be useful to propose new procedures and techniques backed by little evidence to advance research and clinical application, this must not be done at the expense of training in consolidated procedures and techniques backed by sound evidence of efficacy;

- similarly, few initiatives teach how to critically access and use the scientific literature;
- training on the more general topics which constitute the basis for the treatment of CMDs is still rather scarce, i.e., training on diagnosis articulated on increasing levels of severity, treatment structured on several levels of intensity, usefulness of low intensity interventions and systematic evaluation of results;
- the initiatives taken in the past by the Italian National Institute of Health for the dissemination of effective interventions, which have included intensive training, have been extremely useful as regards the treatment and rehabilitation of psychoses and, more recently, the screening and interventions for perinatal depression; a similar commitment for the various CMDs would be desirable in the future.

The experts also believe that the promotion of popular ways of disseminating correct knowledge is useful both for the general population and for professionals, for instance, the creation of a 'portal' (see **Annex 7**) that complements and enriches what is already available on the ISS portal, and that may be easier to access and easier to use. This portal could provide not only informative material, but also self-help materials following the example of the health systems of other countries that have already successfully tested these modalities.

6. QUESTIONS ON THE COST-EFFECTIVENESS, RESOURCES AND ORGANIZATION REQUIRED TO FACILITATE ACCESS TO PSYCHOLOGICAL THERAPIES

6.1 Theme D1

In the specialized international literature, there is evidence of a favourable cost/benefit ratio of psychological therapies, even in strictly economic terms (absence from work, higher health and social costs, work-related stress, etc.). What are the realistic estimates for the Italian context?

As regards the calculation of the overall costs, i.e. direct and indirect costs, Olesen *et al.* (2012) calculated a total cost in Europe in 2010 of 74.4 billion euros for anxiety disorders and 113.4 billion euros for mood disorders. See also Clark (2017) and Wakefield *et al.* (2020) for an assessment of the first 10 years of the British Improving Access to Psychological Therapies (IAPT) program.

We would like to point out, first of all, that Major Depression alone has a significant impact on the social security system. At the national level, a recent study by one of the Experts (Prof. Francesco Saverio Mennini, see **Annex 8**) has estimated the social and welfare costs of major depression on the basis of the latest data available (2009-2015). The beneficiaries of social security benefits were 10,500, most of whom (90%) benefit from an Ordinary Disability Allowance (*Assegno Ordinario di Invalidità,* AOI), and the remainder benefit from a Disability Pension (10%). A total of € 550 million was spent for the Ordinary Disability Allowances during the period of observation, and a total of € 93 million for Disability Pensions. Mennini points out that the trend of applications for disability pensions that were accepted grew by + 70% between 2006 and 2015 and he offers various other more up-to-date data that confirm the growing trend in costs borne by the social security system.

Anxiety and depression are also the cause of absence from work and of the costs linked to the loss of productivity for the Country as a whole: in terms of lost working hours, our Expert has calculated a loss of approximately 4 billion euros per year.

In other Countries there are numerous studies that show the positive effects of psychotherapy on employment rates; Fournier *et al.* (2015), for example, showed in a randomized trial that a follow-up at 28 months of individuals with major depression who were treated with psychotherapy had a significantly higher (18% higher) full-time employment rate than the patients treated with antidepressants (see also Wells *et al.*, 2000; Rollman *et al.*, 2005).

On the international scene, an official document of the American Psychological Association (2012) – to which reference should be made for a thorough bibliography – has taken on historical significance. It recognizes that **psychotherapies have a**

decisive impact on direct non-health costs borne by the patients as well as on indirect costs due, in large part, to the decline in productivity.

Speaking of direct costs, it has been repeatedly pointed out that, for anxiety and depression, common biological treatments are relatively expensive when compared to the cost of psychotherapy, without taking into account their negative side effects. It is also possible and probable that psychotherapy has a lower cost even when it is a long-term intervention (Robinson *et al.*, 1990; Rosenthal, 1990; Lazar & Gabbard, 1997; Barlow *et al.*, 2000; Barlow, 2004; Pyne *et al.*, 2005; Mitte, 2005; Mitte *et al.*, 2005; Hollon *et al*, 2006; Wampold, 2007, 2010; Imel *et al.*, 2008; Walkup *et al.*, 2008; Cuijpers *et al.*, 2010; Lazar, 2010, 2018).

Coming to the costs for the health system, various meta-analyses show that psychotherapy reduces **admissions to hospital, the length of stay and medical expenses** (Chile *et al.*, 2002; Linehan *et al*., 2006; Pallak *et al.*, 1995). There is also a growing body of scientific evidence showing that **psychotherapy reduces disability, morbidity, mortality and psychiatric hospitalization. Models where behavioural health is integrated into primary care have demonstrated a 20-30% reduction in medical expenses above the cost of psychological care** (Cummings *et al.*, 2003). The health costs include in particular, the inappropriate use of other health services (from the general practitioner, to the various specialists and diagnostic investigations). **It is reasonable to state that psychotherapy can also lead to a reduction in the use of medical and surgical services (for instance, the reduction in traumatology resulting from accidents at work or traffic accidents caused by the alcohol ingested to cope with anxiety and depression)**.

Furthermore, many people (about half) prefer psychotherapy to pharmacological treatment: if this preference is met, there will be greater acceptance and compliance (Deacon & Abramowitz, 2005; Paris, 2008; Patterson, 2008; Solomon *et al.*, 2008; Vocks *et al.*, 2010). In some specific circumstances the cost/benefit ratio is even more favourable if we take, for instance, peri-natal depression that will affect the child's affective and cognitive development.

Among the indirect costs, the largest and more easily detectable costs refer to the loss of productivity at work, absenteeism and related social security benefits (for major depression, for example, the estimated cost has been calculated to be € 7,140 per person).

In conclusion, the direct and indirect costs of anxiety and depression are high both for the individuals who suffers from these disorders and, given the high prevalence, for the community. Even a modest increase (10%) in cure rates would likely cover the high costs of a vast campaign, as has occurred in the repeatedly cited case of the British IAPT experience (Clark, 2017).

These costs have risen sharply in the last decade and it is likely that the psychological effects of the pandemic will lead to further increases. These costs must make decision makers think, at central, regional and local levels. In our humble opinion, the objective of prudent health policies should be to reduce the progression

of the disease and the ensuing incremental expenditure generated by the higher levels of disability, through simple models of early diagnosis and possibly early care (including psychotherapy) of the patients and/or individuals at risk (who are mainly adolescents and children).

6.2 Theme D2

What strategy appears to be most effective and operationally manageable to facilitate access to psychological therapies for people with anxiety and depressive disorders and hence reduce the large number of untreated people?

Worldwide, most people with Common Mental Disorders (CMDs) do not receive any treatment (Thornicroft *et al.*, 2017). In high-income countries, for example, only one in six people with major depression receive treatment. Failure to treat is not only determined by the scarce availability of services but also by the low request for help from those suffering from anxiety and depressive disorders. Findings of the *World Mental Health (WMH) Survey* of the World Health Organization (WHO) (Wang *et al.*, 2007) showed that 41% of people with an anxiety disorder and 57% of people with a depressive disorder felt they did not need any treatment. Failure to resort to treatment is therefore also determined by the lack of awareness of having a mental disorder, by misinformation and fear of stigma (Lega & Gigantesco, 2008).

The European Study of the Epidemiology of Mental Disorders (ESEMeD) (Alonso *et al.*, 2004; De Girolamo *et al.*, 2005) showed that in Italy, among people with CMDs, only 17% had addressed the National Health Service in the previous year; of these, 21% had a depressive disorder and 17% an anxiety disorder. Among the people with any disorder in the previous year who had resorted to the health services, a high percentage, 38%, had consulted only the General Practitioner (GP); 21% had consulted only a psychiatrist, 6% only a psychologist and 28% had consulted both a General Practitioner and a mental health professional. This phenomenon highlights how the GP is a central figure in the management of CMDs, and this is probably partly linked to the fact that many of the people with anxiety disorders and depression also have physical health problems. From this point of view, the GP's surgery is a privileged place for early diagnosis and secondary prevention.

The WHO suggests that primary care services are the place of choice to start training programs for health workers aimed at identifying patients at risk of CMDs and for rolling out psycho-educational and care orientation programs (WHO, 2016). In general, these programs require the involvement of mental health professionals and the integration and connection between primary care services and specialist mental health services for the implementation, sustainability and assessment of procedures (Richards, 2012). Several systematic reviews show that this multilevel integration between Services is effective (Bower *et al.*, 2006; Gilbody *et al.*, 2006). Guidelines from the National Institute for Health and Care Excellence (NICE) recommend this type of integrated work especially for the treatment of individuals with depression

and chronic health problems (NICE, 2009). Such integration should include a structured patient management and monitoring plan over time that is managed by a case manager working in primary care services under the supervision of mental health specialists (Bower *et al.*, 2006; Katon *et al.*, 2010; Richards *et al.*, 2008).

The Screening and Enhanced Treatment of Depression in Primary Care (SET-DEP) study (Picardi *et al.*, 2016), involving 15 general practice clinics belonging to the same Local Health Unit located in a central area of Rome, was aimed at examining the efficacy and cost-benefit ratio of an integrated clinical depression screening and management program. The integrated management program included active and substantial specialist support for the diagnostic evaluation and treatment of cases of suspected depression that were identified through screening. Integration was facilitated by the adoption of procedures aimed at promoting mutual communication between GPs and mental health workers and at ensuring the flow of clinical-care communications regarding patients seen at the specialist outpatient clinic that was part of the project. Screening was also well accepted by the patients, who in general saw it as a way of being taken care of by healthcare personnel. Although there is still partial uncertainty as to whether screening in primary care services will ultimately improve mental health outcomes, the preliminary results seem to suggest that programs for identifying and treating depression in these services may be effective if they include the support of the professionals of specialized services (Picardi *et al.*, 2016).

The representatives of the territorial mental health services and the GPs who participated in the EPREMeD (European Policy Information Research for Mental Disorders) project (Lega & Gigantesco, 2008) had already pointed out that the mental health services in Italy are essentially focused on providing care for patients with severe mental disorders which means therefore that insufficient access is provided for patients with CMDs. Failure to seek specialist services by patients affected by CMDs could therefore be motivated by an objective difficulty in finding a response to their need for treatment. A study has analysed the mismatch between the potential demand for psychological treatment for anxiety and depressive disorders in the population and the current offer of professional resources by the Italian National Health Service (NHS) (CREA, 2019). The analysis reveals a substantial gap between the estimate of potential demand and the resources that are actually available. The current offer, in terms of the total number of psychologists operating within the NHS, is sufficient to provide psychotherapy treatment for anxiety and depression for only 20% of the estimated needs; any initiative to reduce the gap should therefore increase the number of psychotherapists. For mild to moderate depression and anxiety disorders, as mentioned, the treatment of choice indicated is represented by psychological therapies of proven efficacy (NICE 2009, 2011; Thornicroft, 2018) which could be provided with different levels of intensity as part of a stepped care approach (Richards *et al.*, 2012).

In Italy, as early as 2008, the representatives of General Practitioners pointed out the lack of alternatives to drug treatment for mild and moderate mental disorders

within the NHS. The ESEMeD study showed that 41% of people with CMDs who contacted a health service received only drug treatment in single or combination therapy, 15% received only psychotherapy treatment, 29% received a combination of psychotherapy and drug treatment and 14% received no treatment at all. Pharmacological treatment therefore represented the main therapeutic option while psychotherapy was found to be a scarcely used form of treatment, and this data is particularly striking if we consider that psychotherapy is considered the treatment of first choice, either alone or in association with pharmacological treatment, for CMDs (NICE, 2004a, 2004b). The total lack or scarce availability of psychosocial interventions in Italy for the treatment of mental disorders is widely reported in the literature (Barbato *et al.*, 2016; Gigantesco *et al.*, 2007, 2009). In Italy, therefore, the psychosocial interventions of proven efficacy are not very common, and along the same lines there are no studies on the efficacy in practice of these interventions to assess whether the experimental evidence is confirmed also in the experience of the NHS.

It should be emphasized that the availability of effective psychological therapies does not in itself guarantee that they are implemented effectively and efficiently. For example, in the UK, the Improving Access to Psychological Therapies (IAPT) program (Clark, 2017) was less effective in providing care to people from minority groups and to older people who for socio-economic reasons could not have access to private sector care. Research is currently focusing on developing integrated treatment protocols that combine in-person therapy with online treatment modules (Kooistra *et al.*, 2019). A recent Consensus Conference suggested that technical assistance centres be set up consisting mostly of experienced academics to provide supervision and to control the quality of the psychosocial and psychotherapeutic interventions in the treatment of mental disorders (Institute of Health Economics, 2014). It would also be important for the NHS to provide psychotherapeutic services for the treatment of CMDs, also through agreements and accreditation where necessary; even in the absence of reliable data, experts believe that at least two thirds of the demand for psychotherapeutic treatments is met in private professional practices, and therefore with costs borne by the patient.

Prior to the development of an effective model for identifying and treating CMDs and for organizing delivery, with an emphasis on the efficient use of resources, a key role is played by the promotion and dissemination of the culture and practice of professional quality. In practice this means attaching special importance to results, and this is all the more important in mental health and social services where the results are still only partially subject to systematic assessment. As regards professional quality, one of the most effective tools is represented by care or diagnostic-therapeutic plans aimed at changing the behaviour of professionals and at ensuring that the recommendations set out in the guidelines that consider scientific evidence, are applied taking into account the local circumstances and involving all the professionals who are affected by the changes or who can influence them. Reviews of studies on the passive dissemination of recommendations have concluded that the impact on practice is low. On the other hand, reminders for healthcare professionals, especially electronic reminders, are generally effective.

Another fundamental step is training and professional updating with active teaching, the usefulness of which has been documented by a series of intensive courses in clinical epidemiology, Evidence-Based Mental Health (EBMH) and Continuous Quality Improvement held at the Istituto Superiore di Sanità (ISS, the National Institute of Health in Italy) (Palumbo *et al.*, 2004). Among the other measures to accelerate the diffusion of more effective interventions, eliminate out-dated interventions and reduce patient consumerism, there is also the training of users or rather of the members of the associations that represent the users (Domenighetti *et al.*, 1998).

Care plans are also a good opportunity for promoting the systematic assessment of outcomes in the NHS, namely the assessment of the effectiveness of therapy. Another fundamental step is the definition of good quality criteria with which psychological therapies must comply, but so far the definition and sharing of quality criteria is only possible for organizational interventions. In particular, in the field of psychotherapy and rehabilitation interventions it is very difficult to achieve consensus on process criteria.

There are still considerable shortcomings in the knowledge on how to change current practice to achieve better mental health outcomes. Further qualitative and epidemiological research is necessary to evaluate the cost-effectiveness of the interventions. The design of most of the studies on the assessment of psychosocial interventions has so far been of the pre-post type, with only internal controls. Furthermore, follow-up to assess the outcomes of treatment in the medium to long term is rarely carried out. A systematic review conducted over 10 years ago in Italy showed that from 2004 to 2006 only 2 multicentre randomized controlled trials had been published in our Country. The review concluded that the lack of these studies in Italy could be due to the absence of specific national funding programs (Galeazzi *et al.*, 2007). Indeed, it is worth recalling that the innovative national research funding experience in the context of the 1997-2001 National Mental Health Project (Morosini *et al.*, 2000) was not followed by subsequent editions. However, some experiences show that by adopting an approach where outcomes are systematically assessed, it is also possible to carry out follow-up studies in common clinical practice (Biondi & Picardi, 2003, 2005; Gigantesco *et al.*, 2006, 2018; Mastrocinque *et al.*, 2013; Mirabella *et al.*, 2016; Picardi *et al.*, 2002; Ruggeri *et al.*, 2001; Veltro *et al.*, 2006b).

In conclusion, it can be stated that different strategies can be implemented with the aim of facilitating access to psychological therapies thus reducing the treatment gap. The main Recommendations can be summarized as follows:

- undertake institutional initiatives to promote literacy in the general population on CMDs. Raise the awareness of the professionals working in the Italian NHS by providing them with all the necessary data, and, in particular, inform primary care personnel about the prevalence of common mental disorders and about the effective treatments that are available;

- undertake institutional initiatives dedicated to informing journalists and media operators on the theme of common mental disorders and effective treatments;
- involve community medicine in offering care services that are integrated and coordinated with second-level mental health services to respond to the physical and mental health demands of patients;
- foster collaboration between GPs, primary care paediatricians and mental health operators in the context of programs aimed at the early diagnosis and treatment of common mental disorders; these programs must take into account patient expectations and preferences so as to improve compliance;
- implement *dedicated* services providing effective and high-quality psychological therapies that can be easily accessed by people with anxiety and depression problems;
- offer psychological therapies with different levels of intensity according to a stepped care approach. Likewise, for supervision and quality control, technical bodies of experts are to be set up to assist the professionals who provide psychological therapy for the treatment of common mental disorders;
- enhance the offer of psychological therapies in public services and possibly introduce forms of agreement and accreditation of private professionals;
- implement initiatives and programs in mental health services to improve professional quality through tools such as diagnostic-therapeutic plans and active training in the principles and methods of evidence-based psychological therapy;
- initiate EBMH training programs for the members of patient and family associations;
- carry out appropriate studies in Italy on effectiveness and on the cost/benefit ratio of integrated interventions that combine therapy in person with online therapy modules;
- introduce the systematic assessment of treatment outcomes in all health facilities; promote uniform and thorough surveys of the psychological therapies for CMDs delivered in all the facilities of the NHS;
- define good quality criteria for assessing psychological performance (which include standards and expected threshold levels of appropriateness) with the emphasis on health outcomes (improvements in or worsening of physical and mental health conditions, including physical and moral suffering and social functioning) rather than on the number of therapies delivered and on cost-to-revenue ratios;
- urge, as part of the ministerial and regional finalized research calls, that every year at least one controlled multicentre project is implemented with the aim of evaluating the effectiveness of the local implementation of care pathways

through process and outcome indicators agreed by a committee of experts and representatives of the various professions;

- annually fund awards for young researchers active in the field of mental health.

6.3 Theme D3

What role can the new technologies and online psychology play in improving access to appropriate treatment for anxiety and depression?

The term *e-mental health* is used to refer to the impact and possibilities of using the new technologies for delivering treatment to patients with mental disorders. This term is more appropriate than "telepsychology" or "telepsychiatry", which limit the scope of the interventions to specific points of view. The term is preferred by the World Psychiatric Association (2017), which defines it as an "umbrella" that includes multiple activities.

The use of e-mental health can be usefully promoted (Myers & Turvey, 2013): 1) where there is a lack of specialists; the availability of human resources can be maximised by rationalizing interventions, abolishing transfers and improving access; 2) where adequate remote services are available, made possible by improvements in videoconferencing technologies; 3) where research grants or funding are available that guarantee the sustainability of the implementation process; 4) where the effectiveness of the interventions to be provided is fully acquired.

The number of experiences and research protocols based on *e-mental health* have increased exponentially, particularly in recent years. This is attributable to the growth and influence that long-distance relationships and communications, in general, have assumed in the globalization process following the introduction of the Internet. To this must be added, as regards 2020, the effect of the health crisis and reduced physical access to services which boosted the use of the Internet and related technologies (American Psychiatric Association, 2020a). With reference to common mental disorders, a variety of activities are carried out online as part of *e-mental health* which can be classified according to different levels of "intensity":

- communications by telephone, text messaging or individual or group messaging systems;
- applications (Apps) for smartphones and online questionnaires for self-diagnosis and for the monitoring of one's clinical parameters. An analysis carried out on 14 published studies has shown that there are no significant differences in the average scores obtained through the App compared with the scores obtained through other methods. However, although the Apps can guarantee greater completeness of the data collected, there is currently insufficient evidence to assess the impact on compliance with the sampling

protocols. In this regard, the use of Apps is not recommended for research and survey purposes, even though the issue deserves further investigation (Belisario *et al.*, 2015);

- information and psycho-educational activities;
- videoconferences among healthcare professionals or between professional and patient for consultation or monitoring;
- structured interventions, such as computerized Psychotherapy (c-psychotherapy), in particular Computerized Cognitive-Behaviour Therapy (c-CBT). This issue has been extensively investigated over the past two decades, and as early as 2006 the National Institute for Health and Care Excellence (NICE) produced guidelines on c-CBT for depression and anxiety.

Most of the efficacy studies conducted to date have used flexible screening and monitoring tools that are adaptable to the online environment (for example, the Patient Health Questionnaire-9, PHQ-9). While requiring further evidence, various authors believe the efficacy and sustainability (in terms of resources/efficacy) of online therapies have been demonstrated (Lokkerbol *et al.*, 2014; Sztein *et al.*, 2013). For example, c-CBT was found to be more effective than the "waiting list" condition in reducing the symptoms of depression.

Other authors have shown that with online psychological therapy, clinical outcomes are obtained that are comparable to those observed following psychological therapy delivered in person (Vis *et al.*, 2015). The cost-benefit ratio and the possible presence of negative effects are also positive (Rozental *et al.*, 2014). Compliance with these therapies appears to be good, especially in individuals with the more severe symptoms of depression; Fuhr *et al.* (2018) observed that compliance was positively associated with the outcome of the treatment after 12 weeks. However, other researchers report that with reference to c-CBT, beneficial effects are observed only in the short term and the risk of treatment drop-out is high (So *et al.*, 2013); these results have also been confirmed by studies that compared the efficacy of c-CBT against the typical services provided by family doctors (Gilbody *et al.*, 2015; Littlewood *et al.*, 2015).

Furthermore, some research has documented the effectiveness of interventions provided via the Internet or mobile phone when the treatment is delivered to patients with sub-threshold depression (Ebert *et al.*, 2018). Recent meta-analyses have shown that online guided self-help (Karyotaki *et al.*, 2017, 2018) has benefits for people with depression symptoms, while documenting the presence of a variety of obstacles that hinder its implementation in clinical practice (Vis *et al.*, 2018). Research is currently focusing on the development of integrated treatment protocols that combine in-person therapy with online treatment modules (Kooistra *et al.*, 2019). As regards Italy, only recently (Favaretto & Zanalda, 2018) has the literature shown keener interest and has reported experiences that have increased also as a consequence of the health emergency caused by the pandemic which seems to have favoured the use of remote devices (Barlati *et al.*, 2020; Gruppo di lavoro ISS Salute mentale ed emergenza COVID-19, 2020c).

In conclusion, it can be stated that:

- it is necessary to offer clear and transparent rules for professionals and Services on working via the telephone and text messaging;
- professionals need ad hoc training and new skills in e-mental health to provide online therapy;
- psycho-educational support/self-help services can be offered online;
- videoconferences can be used by professionals of the NHS to share information and for consulting purposes (General Practitioners [GP], Psychologists, Psychiatrists, Psychosocial workers);
- access to psychological support, in particular c-CBT, needs to be improved; in particular improvements are needed in providing support and in monitoring patients' treatment plans.

Last but not least, the development of web-based therapies needs to be accompanied by an ethical reflection that takes into consideration problems such as fairness, access, privacy and informed consent, as specified by the *National Board of Psychologists* and the *National Board of Physicians*.

6.4 Theme D4

What initiatives can be taken to raise awareness, in particular of potential users, about the effectiveness and availability of psychological therapies and enable them to actually choose psychological therapies if they prefer them over pharmacological treatment?

Even in the absence of appropriate statistical documentation, in the opinion of the Experts, there are four sources (in descending order in terms of outreach) that can be used to inform people and give them guidance: 1) the Internet, 2) General Practitioners (GPs) and primary care paediatricians, 3) pharmacies and herbalists, 4) mental health specialists (Neuropsychiatrists, Psychologists and Psychiatrists).

Today the Internet has become one of the most important sources for gaining knowledge and for gathering the opinions of potential users, but unfortunately it is crowded with advertising materials. A first proposal is to create an authoritative and easily accessible portal; we therefore uphold the proposal to set up a portal made by Working Group 1 which constitutes **Annex 7** of this document. The websites that will host the documents of this Consensus Conference are scientific and healthcare sites and the majority of the population will not refer to them. It will be necessary to prepare abridged and simplified versions of the final document and look for other ways to disseminate them at community level. It is reiterated that the choice of psychological therapies must not be a choice of last resort when all other forms (pharmacological) have proven to be insufficient. When the first symptoms of discomfort appear – without waiting for them to evolve into serious anxiety or

depression pathologies – a psychological diagnosis can evaluate the impact that the symptoms have on the general balance of the person, the functional type and the remote and recent causes; therapeutic treatment is decided on the basis of these elements and after due consideration.

The press, radio and television have always devoted a certain amount of space to the issues of anxiety and depression; it is advisable to prepare press releases and convene one or more press conferences. The communication instruments to be used to reach out to different groups of people, especially the less cultured groups, could include, besides the Internet and the press, also famous testimonials, cartoons, advertising on TV channels, as well as involving the universe of volunteers for establishing direct contact with citizens.

Further, the professional associations that bring together GPs and primary care paediatricians could organize joint initiatives to raise awareness, disseminate information, and organize webinars, seminars, etc.

6.5 Theme D5

What initiatives can be taken to raise the awareness of decision-makers and socio-health institutions to make psychological therapies for anxiety and depressive disorders effectively available and usable?

Awareness raising actions addressed to decision-makers should also include businesses and the labour world in general, since investing economically in psychological therapies means reducing substantially the secondary expenses linked to anxiety and depression. Policy-makers and health institutions need to be made aware of the fact that it costs less to prevent than to cure. They too (as well as the public at large) should be informed of the efficacy data on psychological interventions also in pre-clinical conditions which, if treated in time, can prevent the more serious forms of anxiety and depression that weigh heavily in terms of cost on the health system and on the entire economic system.

Among the bodies and institutions directly or indirectly interested in reducing these costs are the INPS (Istituto Nazionale della Previdenza Sociale: social security agency), the INAIL (Istituto Nazionale per l'Assicurazione contro gli Infortuni sul Lavoro: national institute for insurance against accidents at work), the Health Committees of Parliament and the Regions, the research offices of the Bank of Italy, economic bodies, insurance companies, trade unions, and Confindustria (Federation of Italian Employers). These bodies and institutions as well as many others could be reached through press conferences and conventions, hearings, direct meetings, and initiatives possibly supported by the National Institute of Health with the participation of the scientific associations of psychology.

In addition, the Working Group dealt with three issues.

1. The Working Group unanimously considers it advisable to address the broader issue of the so-called “common mental disorders” without being restricted to the traditional diagnoses of anxiety and depressive disorders, because the pre-pathological conditions deserve attention and interventions, and because of the faint line that separates these common mental disorders from the pathology diagnosed in childhood and adolescence.
2. The Working Group reiterates the importance of all psychological reactions that may occur temporarily following a crisis and emergency situations (such as earthquakes or pandemics) and that do not necessarily constitute diagnosable mental disorders. Therefore, it is useful to organize joint initiatives with associations and organizations operating in mental health in emergency contexts. In this regard, these bodies need to be informed about:
    - the psychological difficulties people need to cope with after experiencing adverse events and emergencies, making it clear that the effects on mental health are bound to last over time;
    - the complexity of the consequences, which requires the intervention of an emergency psychologist, a professional figure that needs to be specifically trained with a job profile to be developed by the health institution;
    - the best practices in the management of psychological emergencies, which highlight the need for the National Health Service to provide a psychosocial response as required by law (DPCM 13/06/2006: www.psy.it/allegati/dpcm_2006_06_13.pdf).
3. In a stepped care perspective, such as that adopted in the United Kingdom with the Improving Access to Psychological Therapies (IAPT) program (Clark, 2017), the first level of intervention has successfully proven to be the self-help actions. In our case and in our Country, the role of patient and family associations is minimal. For depression there do not seem to be any patient associations at all, while for anxiety there are a few (for example, the LIDAP, Lega Italiana contro i Disturbi d’ansia, Agorafobia e attacchi di Panico: Italian league against anxiety disorders, agoraphobia and panic attacks), but their coverage is insignificant. Therefore, albeit with some appreciable exceptions, associations are not expected to play a significant role given the sheer size of the problem.

ANNEXES

Annex 1.
Goals, target, and history of the Consensus Conference

Goals

The primary goal of this Consensus Conference is not to promote psychological treatment *tout court,* but to promote an *effective* treatment of anxiety and depression.

As is known, in order to assess the efficacy of medical care, at present there are methods, procedures and organizations that can assure an acceptable level of reliability. In the case of common disorders such as anxiety and depression, research studies and healthcare organizations agree that psychological therapies should not be considered as a second option but as the treatment of choice in the light of their efficacy and stability in the majority of cases. Moreover, they are the treatments best accepted by patients. In our Country, they are scarcely resorted to both in the case of patients with confirmed disorders and of persons liable to develop full-fledged disorders. They are little used by the National Health Service as it (understandably) concentrates its resources on schizophrenia and other psychoses.

Patients are thus obliged to resort to the private market which produces an intolerable health-related **wealth discrimination** that does not comply with the dictates of the Constitution.

We would like to focus our attention on the British experience known as *Improving Access to Psychological Therapies* (IAPT) (see Clark, 2017), which currently delivers qualified and gratuitous psychological care with no need for GP referral and only on the basis of self-referral, with no stigmas, in ad hoc facilities that are not those of the Mental Health Services. Economists have released evidence-based data showing that the costs, albeit considerable, are abundantly recovered in terms of the savings in the direct and (above all) indirect costs of these disorders.

Moreover, in our Country, psychological therapies are often **misused** by those who can afford them. Just like a drug that is useful for a specific disease is rarely useful for another disease, a psychotherapeutic protocol that is useful for a given problem or disorder is not necessarily useful (or more useful) for another disorder. Admittedly therefore, the most widespread forms of psychotherapy are not necessarily the most efficacious. This often leads people to waste time and money on low-efficacy or ineffective psychological treatments of anxiety and depression. The best psychotherapeutic treatments confirmed to be efficacious are far from being as effective as desired, nor are they the solution to the problem; they document efficacy levels in the same range or in a higher range than that of commonly used psychotropic drugs and they should be equally accessible to the population. The aim is not to combat psychotropic drugs but to promote the best therapies for each specific case and for every disorder without creating the discriminations in terms of information and wealth that we are witnessing today.

Another aim is to disseminate, outside the restricted circle of experts, a bulk of information and indications coming from scientific agencies and guidelines (if released) such as those of the American Psychiatric Association, the American Psychological Association, the Istituto Superiore di Sanità (the National Institute of Health in Italy), the National Institute for Health and Care Excellence (NICE) (an agency of the British National Health Service). They consist of easy-to-use guidelines that guide possible users through the complex world of psychotherapy and enable them to take informed decisions.

The aim of this Consensus Conference *is* **not** to single out the best therapies for anxiety and depression: in this respect there is a massive amount of research and scientific literature, documents issued by prestigious scientific societies, and statements by the health authorities of several nations. Nor is its aim to draft guidelines and provide instructions for professionals as there are other bodies institutionally established to do this.

Whom is the Consensus Conference addressed to?

First and foremost, it is addressed to those millions of citizens who know nothing about psychotherapy, healthcare, or mental disorders but who nonetheless have experienced anxiety and depression problems and/or disorders personally or in their families. We consider it our duty to provide them with correct information.

Secondly, it is addressed to the world of education, both in university and in professional refresher courses. In our opinion, especially in the treatment of anxiety and depression, the teaching is not as up-to-date and incisive as it could be.

Thirdly, it is addressed to the Italian National Health Service. It is a reason of pride for our Country, but the dimension of the aforesaid problems overreaches the resources, the competences, the legislative framework and, in any case, the possibilities of the healthcare system. Patients are obliged to resort to the private market which produces an intolerable wealth discrimination.

Last but not least, it is addressed to the world of scientific research, which is expected to increasingly implement practical research studies (*effectiveness*) and efficiency tests (*efficiency*), capable of indicating paths not yet undertaken or not entirely accomplished.

History of the Consensus Conference

The idea of this Consensus Conference arose at the end of a conference held in Padua on 18-19 November 2016 entitled: "Psychological therapies for anxiety and depression: costs and benefits". The conference's guest of honour was Professor David Clark (*Oxford University*), who delivered a keynote lecture titled "The British experience with Improving Access to Psychological Therapies: evaluation of results" (Clark, 2017). The British experience had already produced results of utmost interest and raised the attention of several nations intending to launch similar programmes (Australia, Canada, Japan, Norway, the Netherlands, Sweden). The Conference closed with 13 recommendations and a 6-page document that has been cited in several websites and reviews and translated into English and that is discussed on pp. 131-135 of issue no. 2/2017 of *Research in Psychotherapy: Psychopathology, Process and Outcome* (RIPPPO), of the Italian Section of the *Society for Psychotherapy Research* (SPR) (the full-text document is available at the Internet site: www.researchinpsychotherapy.org/index.php/rpsy/article/view/284/219).

The promotor of the Consensus Conference is the University of Padua, Department of General Psychology. The initiative is completely **independent**, has no sponsors or financing.

The Promoter Committee was set up in April 2018 and proceeded to designate the Technical-Scientific Committee, which started off by exploring the possibility of translating into Italian the portion of the NICE guidelines that addressed anxiety and depression. It identified the pertinent material (**Annex 3**) and applied for authorization. The project was

abandoned on seeing the large sum requested by the British authorities, taking the opportunity to once again reaffirm that the primary aim was to disseminate efficacious psychological therapies, making them widely accessible with no wealth discrimination, and not to regulate the matter or set forth guidelines.

In Parallel, the Technical-Scientific Committee singled out the Experts, selecting them among academicians, professionals, scientists, and associations of users on the basis of their individual qualifications and not their organization of belonging.

The Committee discussed the questions to ask the experts and came up with twelve questions that could be organized into four themes. The Experts were divided into four Working Groups:

Group 1: "The professional competences required for the delivery of psychotherapeutic interventions for the treatment of anxiety and depression, training in university undergraduate and postgraduate courses, lifelong education and scientific publishing"

Group 2: "Efficacy, cost/effectiveness and the appropriateness of the psychotherapeutic treatments of anxiety and depression, applicability of available guidelines to the Italian context"

Group 3: "Organizational and management models for the delivery of psychotherapeutic interventions for the treatment of anxiety and depression"

Group 4: "Raising the awareness of institutions and communities and the media".

The Working Groups functioned in more than 20 meetings in videoconferencing, producing, discussing, and revising a number of documents. Some of the Experts designated resigned, while others did not actually participate in the work and shall not be mentioned.

In January 2021, the four Working Groups concluded their work and delivered a relevant number of annexed documents in addition to answering the questions posed. Again in January 2021, the Technical-Scientific Committee received the material and proceeded to summarize and standardize it to compile this document.

In December 2020, the Promoter Committee proceeded to empanel the Jury.

About effectiveness

This Consensus Conference deals with psychotherapies that are **effective** in the treatment of anxiety and depression. The term "efficacy" will often turn up, making it useful to specify the definition of the term. The "effective/ineffective" antinomy has long been replaced by dimensional concepts. In the field of psychotherapy, the highest level is represented by treatments that produce a greater increase in wellbeing and health (or, in unfortunate cases, that only reduce suffering and slow down the worsening of the condition and deterioration) than that expected from homeostatic factors linked to the passing of time, the spontaneous actions of families and communities, the relationship with the doctor, a credible context of care, expectations for improvement of patients, doctors, and of the cultural and social community.

In this document, when mention is made of "efficacious" psychotherapeutic treatments, this will imply their efficacy in the broadest sense and fullest meaning. No discredit is meant for

less efficacious interventions which are nonetheless praiseworthy and commendable at human and social level.

In dealing with anxiety and depression, the terms of comparison are represented by the efficacy levels of treatments based on anxiolytic or antidepressant drugs (in experimental designs, it is thus possible to reduce reliance on ethically arguable placebo conditions). Excluding all contention in the references made thereto, the obvious terms of comparison are the therapeutic strategies that are most widespread among the population.

The *gold standard* for research on the efficacy of psychotherapy are the so-called Randomized Controlled Trials (RCT), which are actually not limited to randomly assigning patients to the various groups but present a varyingly sophisticated methodology. To date, in Italy, randomized controlled trials on psychotherapies have not been conducted and repeated by independent research teams, nor are they expected to be run in the near future as the dimensions, complexity, and costs thereof overreach our country's scientific resources.

Depending on the quality and extent of research studies, a ranking is made of the "effectiveness test" of a specific psychotherapeutic treatment or a specific class of disorders, which is what scientific societies and reviews do periodically. The highest level includes "well-consolidated treatments" (which require at least two RCTs conducted by two distinct research groups attesting a higher efficacy compared to the placebo-controlled group or better-than-placebo alternative treatment).

This level includes a number of psychotherapeutic treatments. Let us start off by saying that they are very widespread in our country even if they do not represent the psychotherapies prevalently practised in the private or public healthcare service sector. It would be interesting to know how many university credits, teaching hours, and handbook pages are dedicated to this matter. It would be equally interesting to know the time that professional refresher and lifelong education courses allocate to the psychotherapies that proved to score the highest efficacy levels.

In the evaluation of the efficacy of psychotherapies there is also a lower level of treatments defined as "probably effective": they are based on lower-level evidence and they are not so much defined in terms of clinical efficacy but of an attested higher efficacy than the wait list control groups and the results of the range of credible placebo-controlled trials.

Lastly, we have a group of "experimental/promising treatments" for which, for the time being, only low-level evidence has been produced (for example, a number of controlled clinical cases). They consist of innovative treatments in an "experimental" phase: they are not defined in terms of efficacy although they are worthy of attention, experimenting, financing and research (for an in-depth analysis of Empirically Supported Treatments [EST], *see* Chambless & Ollendick, 2001).

So, nothing special happens in the field of psychotherapy, or anything different from what goes on in other applied sciences and medicine. In a similar way, meta-analytical surveys calculate the *effect size* also in psychotherapies. However, our Country admittedly reveals a peculiarity: overall, many of the widespread and legally practiced psychotherapeutic treatments cannot vaunt even this minimum level of evidence. Although lacking appropriate studies, it is the opinion of this Committee that most of the population and the same health professionals rely on methods that are not proven to be efficacious, in addition to being insufficiently informed of the progress made and the latest developments. This raises the

need for a strong information effort and gives rise to a duty of transparency with consequent implications on professional codes of ethics.

What we have described up to here only constitutes half of the picture. In fact, one half concerns the rather abstract meaning of the term "efficacy" that can only be found in optimal conditions of advanced research: this type of *efficacy* is customarily defined as "theoretical effectiveness" while the other half of the picture is taken up by issues of practical *effectiveness* and *efficiency.*

The first limit of the studies on the theoretical effectiveness lies in how patients are selected through the stringent taxonomy requirements of diagnostic systems, which tend to comprise "pure" cases while the clinical reality of anxiety and depression is crowded with important and broadly documented comorbidities. It is not the task of this Consensus Conference to join the chorus of complaints about the abstractness and artificiality of the diagnostic systems of mental disorders. We limit ourselves to observing that "anxious-depressive syndromes" and "anxiety-depressive neuroses" were the minor psychopathologies most frequently diagnosed through most of the last century.

The second limit of research studies on effectiveness lies in the optimal conditions in which diagnoses and psychotherapeutic treatments take place, with a select group of excellently trained therapists.

Attempts have been made to overcome these limitations with a subsequent research phase defined *effectiveness studies* which takes place with the patients attending Public Health Services and with the customary resource shortage of these services. There is no shortage of effectiveness studies in our country which involve quite a number of our experts.

The evaluation of effectiveness takes place in two steps or phases. A common metaphor used to define these studies is the finetuning of the latest automobile model. The engine is first bench-tested and the body is run through a wind tunnel, the prototypes are then tested on track by expert test drivers. Subsequently, the car is road tested on the ordinary road network and in city traffic, in extreme weather conditions and on the roughest roads. This automobile metaphor takes it for granted that the final user (the car purchaser) only requires a briefing or practice-run of only a few minutes to be able to use the new car.

In the case of psychotherapy, the key resource is the qualification of the psychotherapists and the toughest problem that of *efficiency*. As stated earlier, only a minority of them habitually practice – because they were trained to – treatments based on evidence, albeit little, of their effectiveness. In the medical practice, a medicinal product can quite easily be set aside for a new and better one. In psychotherapy, this comparison might not apply as the differences are too obvious to deserve an illustration. It therefore follows that the natural professional updating process will be slow and will need to overcome very strong resistance to change, which raises doubts on if it is realistic to consider relying on traditional professional updating and lifelong education strategies.

Annex 2.
Committees, Expert Groups and Jury

PROMOTER COMMITTEE

Prof. Massimo Biondi	*Sapienza University of Rome*
Prof. Santo Di Nuovo	*University of Catania – Italian Association of Psychology*
Prof. Mario Fulcheri	*University of Chieti – Italian Association of Psychology*
Prof. Claudio Gentili	*University of Padua*
Dr. Antonella Gigantesco	*Istituto Superiore di Sanità, Rome*
Dr. David Lazzari	*Consiglio Nazionale dell'Ordine degli Psicologi*
Prof. Ezio Sanavio	*University of Padua*

TECHNICAL-SCIENTIFIC COMMITTEE

Dr. Angelo Barbato	*Istituto Mario Negri, Milan*
Dr. Gioia Bottesi	*University of Padua*
Prof. Nino Dazzi	*Sapienza University of Rome*
Dr. Gerardo Favaretto	*Azienda ULSS no. 2, Treviso*
Prof. Paolo Michielin	*University of Padua*
Dr. Paolo Migone	*Journal Psicoterapia e Scienze Umane*
Prof. Piero Porcelli	*University of Chieti*

EXPERT GROUPS

1. Professional competences and training

Prof. Francesco Gazzillo	*Sapienza University of Rome*
Dr. Daniela Leveni	*Azienda Socio Sanitaria Territoriale, Papa Giovanni XXIII*
Prof. Fabio Madeddu	*Bicocca University of Milan*
Prof. Cesare Maffei	*Vita-Salute San Raffaele University, Milan, CTC at MUR*
Prof. Daniele Malaguti	*University of Trento, Edizioni Il Mulino*
Prof. Claudia Mazzeschi	*University of Perugia, Consulta della Psicologia Accademica*
Dr. Gabriele Melli	*IPSICO of Florence, Edizioni Erickson*
Prof. Daniela Palomba	*University of Padua*
Prof. Sergio Salvatore	*University of Salento, Lecce*
Prof. Cristiano Violani	*Sapienza University of Rome*

2. Efficacy and cost-effectiveness

Dr. Ornella Bettinardi	*AUSL, Piacenza*
Dr. Mariangela Corbo	*ASREM, Campobasso*
Prof. Francesco Saverio Mennini	*Tor Vergata University, Rome*
Prof. Paolo Moderato	*IULM University, Milan*
Dr. Angelo Picardi	*Istituto Superiore di Sanità, Rome*
Dr. Franco Veltro	*ASREM, Campobasso*

3. Organizational Models

Dr. Gina Barbano	*Azienda ULSS no. 2, Treviso*
Dr. Tali Mattioli Corona	*Associazione Italia Tutela Salute Mentale*
Prof. Enrico Di Giorgi	*Azienda ULSS no. 2, Treviso*
Dr. Marco Lussetti	*AUSL Toscana Nord ovest*
Prof. Emiliano Monzani	*ASST di Bergamo Ovest – Associazione "Cambiare la Rotta"*
Dr. Giovanni Pisani	*General Practioner, Fontanelle (Treviso)*
Dr. Lorenzo Rampazzo	*Expert in programming health services, Veneto Region*
Dr. Daniela Rebecchi	*Consiglio Nazionale dell'Ordine degli Psicologi*

4. Information and awareness raising

Alma Chiavarini	*Lega Italiana contro i Disturbi d'ansia, d'Agorafobia e da attacchi di Panico (LIDAP)*
Giuseppe Costa	*Lega Italiana contro i Disturbi d'ansia, Agorafobia e attacchi di Panico (LIDAP)*
Dr. Donatella Galliano	*ASL Cuneo 1, Associazione Psicologi per i Popoli*
Dr. Mirella Taranto	*Istituto Superiore di Sanità, Rome*

JURY

Dr. Nicola Artico	*Director, UOC Psicologia Salute Mentale and Serd USL Toscana NordOvest*
Prof. Corrado Barbui	*Professor of Psychiatry, University of Verona*
Dr. Ilaria Bartolucci	*Attorney, President of the Juvenile Court of Padua*
Dr. Elena Bravi	*Società Italiana dei Servizi di Psicologia Ospedaliera e Territoriale (SIPSOT)*
Dr. Gemma Calamandrei	*Istituto Superiore di Sanità, Head of the Reference Centre Behavioural Sciences and Mental Health*
Prof. Anna Costantini	*Clinical Psychologist expert in psycho-oncology, Director of UOD Psiconcologia AOU Sant'Andrea*
Dr. Antonella Costantino	*Società Italiana di Neuropsichiatria dell'Infanzia e dell'Adolescenza (SINPIA)*
Dr. Paola De Castro	*Istituto Superiore di Sanità, Director of the Scientific Communication Unit*
Prof. Tullio Giraldi	*Professor of Psychopharmacology, University of Trieste*
Prof. Giovanni de Girolamo	*Director of the Epidemiological and Evaluative Psychiatry Unit, IRCSS Fatebenefratelli of Brescia*
Prof. Pierpaolo Limone	*Professor of Educational and Developmental Psychology and Dean of the University of Foggia*
Prof. Maria Grazia Monaci	*Professor of Social Psychology and Dean of the University of Valle d'Aosta*
Dr. Alida Montaldi	*former President of the Juvenile Court of Rome*
Dr. Luca Muglia	*Head of UNCMLab@Science and Child Law Research, Honorary Judge of the Juvenile Court of Catanzaro*
Dr. Valerio Sciannamea	*Senior Officer at INPS (Italian Social Security Agency)*
Dr. Giuseppe Spadaro	*President of the Juvenile Court of Trento*

Prof. Renata Tambelli	*Professor of Psychopathology of Childhood, Coordinator of the Clinical and Dynamic Section of the Associazione Italiana di Psicologia (AIP)*
Prof. Giuseppe Vecchio	*Professor of Public Law at the University of Catania, Child and Adolescents Guarantor, Region of Sicily*

President of the Jury	Prof. Silvio Garattini *(President of the Istituto Mario Negri)*
Vice President of the Jury	Dr. Paola De Castro (*Istituto Superiore di Sanità, Director of the Scientific Communication Unit)*

Annex 3.
Proposal to organize a 1-day meeting

Notwithstanding the high prevalence and incidence of Common Mental Disorders, they do not receive the necessary attention from the National Health Service. The one and only epidemiological study carried out in Italy, the ESEMeD-WMH (de Girolamo *et al.,* 2005; *see* www.epicentro.iss.it), confirmed the high incidence of these disorders, especially those in the anxiety and depression range, estimating that no less than 2.5 million Italians are affected by an anxiety disorder a year and over 1 million people suffer a major depressive disorder, albeit the medium-to-mild forms are the most widespread. The latest *Progressi delle Aziende Sanitarie per la Salute in Italia* (PASSI, progress by local health units towards a healthier Italy), the epidemiological system put in place by the Istituto Superiore di Sanità (the National Health Institute in Italy) to monitor psychological disorders, confirms the estimate that 6% of the general adult population reported symptoms of depression in the 2016-2019 three-year period, with 61.4% of them seeking help.

It also estimated that the average number of days in bad physical health of these people amounts to 9.7% and the average number of days in bad mental health is 15.7%. Over this period, it is possible to draw an indirect confirmation of what has been said from the psychological consequences of the pandemic and the relative lockdown mandate. More specifically, the survey conducted by Conti *et al.* (2020) among healthcare workers found that 71% reported somatizations and 55% distress.

These workers' accessibility to healthcare services is really negligible and disappointing.

The picture portrayed in literature from 2004 (Balestrieri *et al.*, 2004) to date (Di Cesare *et al.*, 2019) reveals that most of the people suffering from Common Mental Disorders do not resort to healthcare professionals. The annual incidence of people treated for depression is of 0.39% while the incidence of people treated for "neurotic" or somatoform syndromes amount to 0.23%.

If depression is currently the second pathology after cardiovascular diseases in terms of economic and social costs, by 2030 it is forecast to become the first-ranking disorder in terms of the loss of years in good health. This makes it necessary to upgrade the response of the National Health Service with a full-fledged "Pandemic Plan" that might envisage increasing the accessibility thereto for these disorders and, above all, delivering treatments proven to be efficacious combined with the appropriate prescription drugs.

What is the current state of affairs? In our opinion, there are facilities and organizational resources that show a margin of improvement.

The National Mental Health Action Plan (*Piano di Azioni Nazionale per la Salute Mentale,* PANSM) that was approved by the State-Region Conference is a good place to start from because its 4 Profiles of Care include that of Major Depressive Disorders, broken down into their Severe, Moderate or Medium and Mild forms. Moreover, it clearly sets out what disorders qualify for social Care (including Major Depressive Disorders) and what disorders are eligible for treatment or Counselling Services; Common Mental Disorders can be included in the first group and disorders of adolescents allocated in the second group, in collaboration with Children's Neuropsychiatric services. In addition to these services, we would like to recall the essential levels of care (*Livelli Essenziali di Assistenza,* LEA) (Ministero della Salute, 2017) and the National Plan for Chronicity (*Piano Nazionale Cronicità,* PNC) (Ministero della Salute, 2016), providing psychological support services for a vast range of situations, giving

access not only to several Mental Health and social care facilities, but also to Primary Care facilities and Hospitals.

At present, the situation is extremely diversified across the national territory, with different organizational structures, and above all with a shortage of homogeneous data both on the number of accesses by people with mental disorders and on the type of psychological services offered at regional and national level.

Italian legislature, scientific literature and international guidelines set out the intervention models; many of the treatments are psychological, psychosocial, and non-pharmacological.

In consideration of the complexity of the problem, Italy's healthcare policies are focusing on a strong Basic Services network (community houses, community hospitals, clinics, Mental Health Centres, discount stores, integrated medical groups) offering transversal psychological assistance at different levels and in different contexts of the Italian National Health Service. In consideration of the psychosocial crisis produced by the exceptionality of the SARS-CoV-2 pandemic, legal regulations set out the need for action in two areas: "optimizing the efficiency of mental health services and (…) assuring individual and collective wellbeing» (Law 126/2020); it is concomitantly necessary to put in place the transversal coordination of all the psychological activities (Law 176/2020).

At the same time, it is deemed necessary to design a systemic action through promotional and protection strategies, create inter-institutional networks (schools, social care services, profit and non-profit organizations etc.), and train personnel in several disciplines to deliver services of proven efficacy and efficiency.

This can be achieved if all the key social players collaborate in drafting a three-year Programmatic Strategy, previously defined as a full-fledged Pandemic Plan, to prevent the further spread of these disorders and be able to treat them efficiently and effectively.

We are considering organizing an 8-hour meeting with the representatives of institutional organizations, the representatives of professional associations, and stakeholders for the purpose of drafting a Document of Intent to then be converted into ad hoc Ministerial Recommendations.

The 1-day meeting organized by the Consensus Conference should be attended by:

1) A representative of the Planning Department and a representative from the Prevention Department of the Ministry of Health;
2) A representative of the Ministry of Economy;
3) A representative of the Ministry of Labour;
4) A representative of the INAIL (Istituto Nazionale per l'Assicurazione contro gli Infortuni sul Lavoro: national institute for insurance against accidents at work);
5) A representative of the Istituto Superiore di Sanità;
6) A representative of the AGENAS (Agenzia nazionale per i servizi sanitari regionali: National agency for the regional health services);
7) A representative of the Società Italiana di Psichiatria (SIP);
8) A representative of the Società Italiana Medicina Generale (SIMG);
9) A representative of the Consulta delle Società Scientifiche della Psicologia;
10) A representative of the *Consulta dei Direttori e Responsabili delle Unità di Psicologia* of the National Health Service;
11) A representative of the Collegio dei Dipartimenti di Salute Mentale;
12) A representative of the Itaca Volunteer Association;

13) A representative of the Board of Italian Journalists.

The topics to be addressed are the following:

a) Increasing the accessibility to healthcare services for anxiety and depression through educational campaigns
b) Promoting mental health and psychological wellbeing in schools and in the community
c) Improving the specific training of healthcare workers
d) Adopting evidence-based psychosocial, psychological, and psychotherapeutic interventions to be delivered alongside pharmacological treatments
e) Organizing transversal psychological and psychotherapeutic interventions to be included in the comprehensive network of domiciliary, regional and hospital services.

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Annex 4.
Report on the guidelines for the treatment of disorders of the anxiety-depression spectrum

National Institute for Health and Care Excellence (NICE), *American Psychological Association*, *American Psychiatric Association*

Below is the illustration of the key points of the English (NICE) and American (*American Psychiatric Association* and *American Psychological Association*) guidelines on anxiety and depressive disorders in adults. However, it is fitting to made a premise to explain the founding principles of the guidelines.

The guidelines are grounded on 3 key concepts:

1) The relationship with their respective national health systems. The English system is public and is based on the filtering, screening, monitoring and decision-making role of the *general practitioner* (GP), including in the psychopathology sector (e.g., a comparison should be made with the English *Improving Access to Psychological Therapies* [IAPT] referral system) (Clark, 2017). Therefore, the GP shoulders the management and economic responsibility of the patient's referral on the basis of his/her own diagnostic and therapeutic considerations and the local availability of second- and third-level hospitals. Instead, the American healthcare system is private and is essentially based on the diagnostic and therapeutic policies of the *Health Maintenance Organizations* (HMO): insofar as this healthcare system is private, its core activity is based on the economic principle of marginal profit, which prevails over the principle of universal healthcare.
2) The adoption of the *stepped care model* by the English National Health Service (NHS), which is different from the threshold-based treatment/non-treatment dual system used in the North American healthcare system's diagnostic criteria. As already stated, the difference in healthcare models arises from the relationship with their respective health systems and consequently with their respective stakeholders.
3) The criteria adopted to prescribe first- and second-line psychotherapies in evidence-based treatments. The criteria are different and not always connected. For example, the guidelines of the American Psychological Association are based on the concept of Empirically-Supported Treatments (EST) (*see* Chambless & Ollendick, 2001), adopted from 1998 on, whereby the efficacy may be indicated on the basis of a given number of Randomized Controlled Trials (RCT), checked against inert (waiting lists) or inactive (i.e., another psychotherapy) controls, essentially adopting the RCT-model pharmacological treatments of the American Psychiatric Association.

The foregoing clearly shows that the theoretical framework of the 3 guidelines must be considered within the context of their respective national healthcare systems and cannot simply be borrowed as such from other healthcare systems such as the Italian one. It should be noted that the caregiving function of regional Mental Health Services as well as the widespread private psychotherapeutic practice makes it automatically impossible to adopt any one of the three guidelines in Italy.

A further word of caution derives from studies, editorials and meta-analytic reviews published over the last decade, which shed doubt on the principle of efficacy of traditional RCT-based psychotherapies and on the *effect sizes* derived therefrom. Despite the different

methods used, these studies have revealed some methodological limits of RCT-based psychotherapies on which the guidelines are based and the essential failure of some psychotherapies to outperform others in treating the disorders under study, the follow-up methods, and the desired outcomes.

In relation thereto, consult the following references: Chambless & Ollendick, 2001; Westen *et al*., 2004; Wachtel, 2010; American Psychological Association, 2012; Flückiger *et al*., 2014; Keefe *et al*., 2014; Tolin *et al*., 2015; Cuijpers *et al*., 2016; Clark, 2017; Shedler, 2018; Guidi *et al*., 2018; Thornton, 2018; Cuijpers; 2019.

Below is a list of a few disorders with their relative definitions and characteristics alongside the psychological therapies and treatments suggested by the guidelines.

GENERALIZED ANXIETY DISORDER (GAD)

1. Definition and characteristics

Anxiety disorders are the most common among mental disorders (they affect approximately 30% of the adult population during their lifetime) and, according to the American Psychiatric Association (2021), are characterized by excessive fear and anxiety, compounded with tense muscles, avoidance behaviour and "Fight-or-Flight" responses.

These disorders can push people into attempting to avoid situations capable of triggering or worsening their symptoms, thus impacting and impairing important areas of their social and professional functions. Moreover, they imply low mood, a loss of interest in and the enjoyment of ordinary things, in addition to a range of emotional, physical, and behavioural symptoms.

More specifically, the Generalized Anxiety Disorder (GAD) is characterized by excessive concern for various events and activities, associated with strong tension and the difficulty in controlling this concern. The DSM-IV's formal diagnosis requires the presence of two principal symptoms (excess of anxiety and concern for a set of events and the difficulty in controlling this concern) in addition to three or more symptoms from a list of six.

The symptoms should persist for at least 6 months and should cause a clinically significant malaise or impair the patients' functioning in their social or professional spheres or in other important areas of their functioning. It can be diagnosed also without a condition of comorbidity although it more often represents the primary diagnosis in a clinical picture characterized by other anxiety and depressive disorders.

The GAD can vary in terms of severity and complexity, and this affects the patients' response to treatment, which makes it important to consider the severity and duration of symptoms, the level of anxiety, functional impairment, the personal medical history and comorbidity during the assessment phase.

The course of the disorder can be both chronic and remittent. Where possible, the intervention should aim for complete remission, which is associated with the patient's improved functioning and a lower probability of relapsing.

The impact on families and caregivers. Before involving families and caregivers in the treatment of people with GAD, it is important to provide information on family support groups and volunteer organizations and facilitate access thereto, negotiate the information

to be shared between families and patients, provide written information and memos on GAD and its management – including the way in which families can support the patient – provide contact numbers and information on what to do in case of a crisis.

2. Psychological therapies recommended in the guidelines

The psychological therapies recommended in the guidelines should make up the basis for the proposed interventions insofar as compliance with evidence-based treatments optimizes the results thereof.

With a view to optimizing cost-benefit ratios, the guidelines suggest that the interventions follow a stepped care approach wherever duly indicated.

2.1 The NICE guidelines for the treatment of GAD

Phase 1 – Identification and assessment: organizing educational interventions after notifying the diagnosis and submitting the treatment options, alongside the performance of active monitoring. Attention should be paid to those patients who often present somatic problems for which they access primary care, as well as to those who often show concern for various events and issues. Carefully investigate the existence of a picture of comorbidity with other anxiety or depressive disorders or with other medical conditions, as well as the patients' response to previous treatments. Always give priority to the treatment of the primary disorder.

Phase 2 – Low-intensity psychological interventions: when symptoms have not improved following the Phase 1 intervention, suggest one of the following according to the patient's preference:

(a) an intervention of unfacilitated self-help based on the principles of Cognitive-Behavioural Therapy (CBT)[3] providing for the use of self-help material in paper or digital format, such as books or workbooks, on which patients should work for a minimum of 6 weeks, minimizing contact with the therapist and, for example, keeping telephone conversations to under 5 minutes;

(b) an intervention of guided self-help based on the principles of CBT providing for the use of self-help material in paper or digital format, with the support of a professional to facilitate the performance of the programme and monitor the progress made. The intervention generally provides for 5-7 sessions, in person or in 20-30-minute telephone conversations, scheduled once a week or bimonthly;

(c) psychoeducational groups based on the principles of cognitive-behavioural therapy aimed at encouraging observational learning. This intervention generally provides for six 2-hour weekly sessions.

Phase 3 – In case of interventions for GAD with a serious functional impairment or that do not improve following the Phase 2 intervention, propose a high-intensity psychological intervention, such as a CBT or a relaxation intervention. Both interventions provide for

[3] It should be noted that many of the guidelines privilege the Cognitive-Behavioural Therapy (CBT) over the PsychoDynamic Therapy (PDT) in the light of the higher number of studies historically conducted on the CBT, although recent meta-analytic surveys have shown that the PDT often does not underperform the CBT (*see,* among others, Shedler, 2010; Gerber *et al.*, 2011; Thoma *et al.*, 2012; Cuijpers *et al.*, 2014; Keefe *et al.*, 2014; Tolin, 2015; Steinert *et al.*, 2017; Steinert & Leichsenring, 2017; Leichsenring & Steinert, 2017; Furukawa *et al*., 2021).

a total of 12-15 one-hour weekly sessions. If the patient does not adequately respond to the intervention, propose a pharmacological treatment or a combination of the two, providing detailed information thereon.

Phase 4 – For complex GADs or those refractory to treatment, with a very serious functional impairment, for example marked personal neglect, with a high risk of self-mutilation or committing suicide; a significant comorbidity, for example with substance abuse, a personality disorder, complex problems of health; or in case of an inadequate response to Phase 3 interventions. Treatments must be highly specialized, for example, the combination of pharmacological and psychological treatments in communities or in specialist services. These treatments should only be performed by professionals with specific experience in treating GAD cases of this type.

Pharmacological treatment: SSRI, primarily sertraline in terms of its cost-benefit ratio. It is suggested not to use benzodiazepines, except in the case of a crisis or only in the short term. Do not use anti-psychotic drugs in primary care.

3. Assure the efficacy of interventions

The CBT must exclusively be delivered by adequately trained and supervised professionals who can prove their strict compliance with evidence-based treatment protocols. It is important for professionals to be regularly supervised in order to monitor their compliance with the treatment, possibly through audio and video recordings of the therapeutic sessions if the patient consents to it. Use outcome-measuring systems and make sure to involve the GAD patient in reviewing the treatment's efficacy.

PANIC DISORDER

1. Definition and characteristics

According to the DSM-IV-TR, the key characteristic of the panic disorder is sudden recurring panic attacks followed by at least one month of persisting worrying for a subsequent attack and concern for its consequences, or a significant change in the behaviour with respect to the attacks. A minimum of two sudden panic attacks are necessary to diagnose the disorder and the attacks must not be justified by the use of a substances, a general medical condition, or another psychological problem. The panic disorder can be diagnosed with or without the presence of agoraphobia, and it should be noted that a panic attack does not necessarily imply a diagnosis of panic disorder.

According to the guidelines of the American Psychiatric Association, the panic disorder is very widespread and debilitating and it requires treatment the moment the symptoms or the disorder impairs the patient's functioning or give rise to a significant amount of anxiety. The treatment should not only aim to decrease the frequency and intensity of the panic attacks, but also to reduce the anticipatory anxiety and agoraphobic avoidance, optimally aiming for the full remission of the symptoms and the return to pre-morbid functioning. The panic disorder can vary in terms of severity and complexity, and this affects the response to treatment, which means that in the assessment phase it is important to take into consideration: the severity of symptoms, their duration, the level of anxiety, the patients' functional impairment, personal medical history, and comorbidity.

The course of the disorder can be both chronic and remittent. Where possible, the intervention should aim for complete remission, which is associated with the patient's improved functioning and a lower probability of relapsing.

The impact on families and caregivers. Persons suffering from panic disorder and their families need complete information, delivered in a clear and comprehensible language, on the nature of their condition and on the available treatment options. This information is essential for the joint decision-making process between people suffering from panic disorder and caregivers, especially when having to choose between essentially equivalent treatments. Moreover, in the light of the emotional, social, and economic costs normally produced by the panic disorder, patients and their families can need help in contacting support and self-help groups. Support groups can promote understanding and collaboration between people suffering from panic attacks, their families, and caregivers at all levels of primary and secondary care.

2. Psychological therapies recommended in the guidelines

The psychological therapies recommended in the guidelines (NICE and American Psychiatric Association) should make up the basis for the proposed interventions insofar as compliance with evidence-based treatments optimizes the results thereof.

With a view to optimizing cost-benefit ratios, the guidelines suggest that the interventions follow a stepped care approach wherever duly indicated.

2.1 The NICE (2019) guidelines for the panic disorder

***Phase 1*:** recognizing and diagnosing the disorder. The assessment must be performed by professionals with high-quality training capable of structuring an approach liable to be conducive to a diagnosis, and a disorder management plan. Special attention should be focused on comorbidity with depression or substance abuse.

***Phase 2*:** offer patients evidence-based primary care: psychological and pharmacological therapies and self-help on the basis of the assessment process.

People with a mild to moderate disorder should be recommended the following interventions: unfacilitated self-help, facilitated self-help, information on support groups (CBT-based, with face-to-face and telephone meetings).

***Phase 3*:** for moderate to severe panic disorders, (with or without agoraphobia), reference should be made to a CBT therapy, with an optimal range of 7-14 sessions overall, divided in weekly 1-2-hour sessions, completed in a maximum of 4 months. Briefer CBT therapies should be of approximately 7 sessions and provide targeted information and tasks, supplemented with self-help material. Some people could benefit from a more intensive CBT therapy over a very brief period of time. Alternatively, it is possibly to propose and antidepressant in case of a long-term disorder or if the patient has not benefited from, or has refused, a psychological intervention.

Pharmacological treatment: antidepressants are the only long-term intervention for the panic disorder. The following are the classes of antidepressants that are confirmed to be efficacious: selective serotonin reuptake inhibitors (SSRI), serotonin-norepinephrine reuptake Inhibitors (SNRI), and tricyclic antidepressants (TCA). Benzodiazepines should not be prescribed as they are associated with a less positive long-term outcome, just as sedatives and antipsychotics.

***Phase 4*:** In most of the cases in which two interventions are delivered (any combination of psychological and pharmacological interventions) and the patient still shows significant symptoms, it is necessary to resort to specialist mental health services.

***Phase 5*:** Specialist mental health services should be conducive to a new complete assessment of the patient, also reassessing his/her environment and social context. The treatment options must include: a comorbidity study; a CBT with an expert therapist, unless already provided for, including home-delivered CBT if it cannot be delivered at a care centre; exploring a pharmacotherapy; providing daily support to the patient to lighten the family's workload and referring the patient to a tertiary care centre for counselling, assessment, or case management.

2.2 The guidelines of the American Psychiatric Association for the panic disorder

According to the guidelines of the American Psychiatric Association (2009) for panic disorder, the therapy of choice is individual or group CBT (with a total of 10-15 sessions) and, on its own, an exposure therapy, which envisages the systematic exposure to fear-related signals. Most panic-focused forms of CBT rely on the following treatment systems: (a) psychoeducation; (b) self-monitoring; (c) cognitive restructuring; (d) exposure to fear-related signals; (e) changing anxiety-maintaining behaviours; (f) preventing relapses.

The efficacy of group CBT is confirmed and therefore recommendable, insofar as it facilitates the reduction of the feeling of shame and the stigma and offers a learning and social reinforcement opportunity. No other form of group therapy is recommended for the panic disorder, including patient support groups and monotherapies, although they can prove to be useful in combination with other treatments that are efficacious on some patients.

Another therapy that has proven to be effective in the treatment of panic disorders is the individual Panic-Focused Psychodynamic Psychotherapy (PFPP) (Milrod *et al*., 2007; Busch *et al*., 2012) in twice-weekly sessions for 12 weeks, even if validation data are still limited. It could be recommended in an early phase, as a psychosocial therapy for those patients who feel motivated and engaged with this type of approach.

According to available research, supportive psychotherapy is less effective than standard treatments of the panic disorder, and reliance on therapies such as EMDR, couples or family therapies is discouraged.

When pursuing other forms of treating the panic disorder (e.g., pharmacotherapy), it could also prove useful to educate caregivers on the nature of the disorder to improve compliance with treatment protocols. Combining psychosocial treatment with pharmacotherapy, at the beginning or at a later point in time in the treatment, can improve long-term results and reduce the probability of relapsing once the pharmacological treatment is suspended.

3. Assure the efficacy of interventions

The suggested treatments must exclusively be delivered by adequately trained and supervised professionals who can prove their strict compliance with evidence-based treatment protocols. The intervention should also include a process to assess the beneficial effects on the patient on a case-by-case basis. All the physicians and psychotherapists involved should have completed an accredited training programme.

SOCIAL ANXIETY DISORDER

The American Psychological Association and the American Psychiatric Association have not drafted guidelines specifically for the recognition, assessment, and treatment of the social anxiety disorder. Therefore, below are only the guidelines of the National Institute for Health and Clinical Excellence (NICE) published on 22 May 2013.

NICE guidelines for the recognition, assessment, and treatment of the social anxiety disorder [CG159]

1. Definition and characteristics

The National Institute for Health and Clinical Excellence (NICE, 2013, 2020) defines the social anxiety disorder as persisting fear or performance anxiety for one or more social circumstances and a disproportionate fear compared to the threat posed by the situation. The types of situations that can be a source of anxiety include meeting people, speaking in meetings or before a group of people, starting a conversation, talking to eminent personalities, working, eating, or drinking while being observed, going to school or shopping, performing in public. People suffering from a social anxiety disorder show excessive worry both prior to the event as well as during and after the event. They fear doing or saying something that they deem to be humiliating or embarrassing (e.g., blushing, sweating, appearing boring or stupid, shaking, appearing incompetent or nervous). In children, anxiety can manifest itself differently than in in adults: indeed, in order to avoid interaction, children can cry, freeze, or throw a tantrum. The social anxiety disorder impairs social functioning at work or school and can manifest itself in comorbidity with other mental health problems and especially depression (19%), substance use disorder (17%), GAD (5%), panic disorder (6%) and PTSD (3%). The social anxiety disorder has an average age of early onset (13 years of age) and, if the disorder persists up to adulthood, the possibility of symptoms remitting without treatment is poor if compared to many other mental health problems.

2. Recognition, assessment, and treatment of adults (> 18 years of age) suffering from the social anxiety disorder

2.1 Recognizing a possible social anxiety disorder in adults

The guidelines suggest asking questions that make it possible to recognize the presence of anxiety disorders (in line with recommendation 1.3.1.2. in the *Common Mental Health Disorders, NICE clinical guideline* 123) and, in case of suspecting a case of social anxiety disorder: (a) administer the Mini-Social Phobia Inventory (Mini-SPIN) or (b) address direct questions to the person on his/her tendency to avoid social situations or activities and to feel fear or embarrassment in these situations. If the person scores six or higher in the Mini-SPIN or answers affirmatively to the questions, the caregiver proceeds to make a systematic assessment of the person.

2.2 Assessing adults with a possible social anxiety disorder

The guidelines suggest following the indications contained in the *Common Mental Health Disorders (NICE clinical guideline 123)* in order to outline the structure and content of the assessment. The assessment should make it possible to obtain a detailed description of the person's social anxiety (fearing and avoiding social situations, symptoms of anxiety, safety behaviours, anticipatory and post-event processing), the content of his/her self-image, social functioning at work or at school, and the presence of comorbidity symptoms. Moreover, the guidelines recommend the use of a social anxiety assessment tool such as the Social Phobia Inventory (SPIN) or the Liebowitz Social Anxiety Scale (LSAS).

2.3 Interventions for adults with a social anxiety disorder

- Propose an individual cognitive-behavioural therapy (CBT) based on the Clark & Wells or Heimberg models, specifically developed for the treatment of the social anxiety disorder. Do not suggest a group CBT over an individual CBT;
- To adults taking into consideration another type of psychological intervention, suggest a CBT-based facilitated self-help intervention;
- With adults expressing a preference for pharmacological treatment, discuss the reasons for their unwillingness to start a cognitive-behavioural therapy. If the person wishes to proceed with a pharmacological treatment, offer him/her a selective serotonin reuptake inhibitor (SSRI) (escitalopram or sertraline);
- In case the individual refuses both cognitive-behavioural and pharmacological therapies, suggest a short-term psychodynamic psychotherapy specifically developed to treat the social anxiety disorder.

2.3.1 Psychological interventions for adults with a social anxiety disorder

The psychological therapy must exclusively be delivered by adequately trained and supervised professionals who can prove their strict compliance with evidence-based treatment protocols. It is important for professionals to be regularly supervised in order to monitor their compliance with the treatment, possibly through audio and video recordings of the therapeutic sessions if the patient consents to it. Moreover, the intervention outcome should be regularly monitored through the use of assessment tools such as the Social Phobia Inventory or the Liebowitz Social Anxiety Scale.

- The individual cognitive-behavioural therapy (CBT) based on the Clark & Wells model provides for a maximum of fourteen 90-minute sessions (over approximately 4 months) and includes: (a) social anxiety training; (b) experiential exercises; (c) video-feedback; (d) systematic training on concentrating on an external focus of attention; (e) behavioural experiments; (f) imagery rescripting; (g) cognitive restructuring; (h) preventing relapses.
- The individual CBT based on the Heimberg model provides for fifteen 60-minute sessions and one 90-minute session dedicated to exposure (over approximately 4 months) and includes: (a) social anxiety training; (b) cognitive restructuring; (c) exposure; (d) preventing relapses.
- The CBT-based facilitated self-help intervention provides for up to 9 support sessions in the use of a CBT-based self-help book and 3 hours of support on the use of materials, both face-to-face and over the phone, in the course of the treatment (of approximately 3-4 months).

- The short-term psychodynamic psychotherapy provides or a maximum of 25-30 sessions of 50 minutes (over 6-8 months) and includes: (a) social anxiety training; (b) establishing a positive therapeutic alliance; (c) focus on the key relational conflict; (d) focus on the feeling of shame; (e) encouraging exposure; (f) supporting the improvement of social skills.

2.4 Treatment options for adults not or partially responding to the initial treatment

- Adults whose anxiety symptoms only partially responded to an individual cognitive-behavioural therapy (CBT), after an adequate period of treatment, should be recommended to combine it with a psychological therapy;
- Adults who have only obtained a partial benefit from a 10-12-week pharmacological treatment (SSRI), should be recommended an individual CBT in combination with a pharmacological treatment;
- Adults who have only obtained a partial benefit from a pharmacological treatment (SSRI) or who are intolerant to the side-effects of the drug, should be recommended an alternative SSRI therapy (with fluvoxamine or paroxetine) or with Serotonin–norepinephrine reuptake inhibitors (SNRI) (venlafaxine);
- Adults who have not obtained a benefit from an alternative SSRI or SNRI therapy, should be recommended the use of a monoamine oxidase inhibitor (phenelzine or moclobemide);
- With adults who are unresponsive to treatment, discuss the possibility of an individual cognitive-behavioural therapy.

3. Recognition, assessment, and treatment of children and adolescents (school children up to 17 years of age) suffering from the social anxiety disorder

3.1 Recognizing a possible social anxiety disorder in children and adolescents

In case of a suspected case of social anxiety, the guidelines recommend posing direct questions to the child/adolescent or to their caregivers on his/her tendency to avoid social situations or activities and to experience fear in these situations. If the person answers the questions affirmatively, caregivers should proceed to perform a systematic assessment.

3.2 Assessing children and adolescents with a possible social anxiety disorder

The assessment, performed on the basis of the information provided by the child/adolescent and their caregivers, should be able to obtain a detailed description of the persons' social anxiety (feared and avoided social situations, safety behaviours, anticipatory and post-event processing), the content of their self-image, their social functioning and their functioning at school, their family situation and their broader social context, the disorder-maintaining factors and the presence of comorbidity disorders. Moreover, the guidelines suggest using social anxiety assessment tools such as the Social Phobia and Anxiety Inventory for Children (SPAI-C), the Liebowitz Social Anxiety Scale-child version (LSAS-child version) for children, the Social Phobia Inventory (SPIN), or the Liebowitz Social Anxiety Scale (LSAS) for adolescents; the Multidimensional Anxiety Scale for Children (MASC), and the Revised Child Anxiety and Depression Scale (RCADS) for children and

adolescents suspected of having a depressive disorder or a comorbidity with other anxiety disorders; the Spence Children's Anxiety Scale (SCAS) or the Screen for Child Anxiety-Related Emotional Disorders (SCARED) for children. The guidelines recommend drafting a profile of the child or adolescent to identify their needs and the need for further assessments.

3.3 Interventions for children and adolescents with a social anxiety disorder

Recommend an individual or group cognitive-behavioural therapy (CBT) focused on social anxiety. It is highly recommended to not offer children and adolescents a pharmacological therapy over a psychological therapy. It is possible to take into consideration psychological treatments developed or adults in the case of adolescents of 15 years of age or over who have reached a good level of cognitive and emotional development.

3.3.1 Psychological interventions for children and adolescents with a social anxiety disorder

The psychological therapy must exclusively be delivered by adequately trained and supervised professionals who can prove their strict compliance with evidence-based treatment protocols. It is important for professionals to be regularly supervised in order to monitor their compliance with the treatment, possibly through audio and video recordings of the therapeutic sessions if the patient consents to it. Moreover, the intervention outcome should be regularly monitored through the use of assessment tools such as LSAS-*child version*, SPAI-C, SPIN, LSAS, MASC, RCADS, SCAS or the SCARED. In the light of the impact that the family, school, and broader social environment have on maintaining the social anxiety disorder of the child/adolescent, it is necessary to consider the possibility of engaging parents and teachers with a view to creating a supportive environment for the concerted treatment objectives.

- The individual cognitive-behavioural therapy (CBT) provides for 8-12 sessions of 45 minutes and includes: (a) psychoeducation; (b) exposure; (c) social skills training; psychoeducation and skills training for parents.
- The group cognitive-behavioural therapy (CBT) provides for 8-12 sessions of 90 minutes with children and adolescents in the same age group and includes: (a) psychoeducation; (b) exposure; (c) social skills training; psychoeducation and skills training for parents.

SPECIFIC PHOBIAS

The American Psychological Association, the American Psychiatric Association and the National Institute for Health and Clinical Excellence (NICE) have not developed specific guidelines for the recognition, assessment, and treatment of specific phobias.

In partial contradiction to some of the guidelines reviewed above, especially those by NICE, a recent meta-analysis showed a basic equivalence in the efficacy of CBT and psychodynamic therapies in the treatment of the anxiety disorders taken into consideration up to now (Keefe *et al.*, 2014).

DEPRESSIVE DISORDERS (ADULTS)

1. Definition and characteristics

A depressed mood and/or the loss of pleasure in doing any activity are considered to be the cardinal symptoms of depression. Its level of complexity mainly depends on the number of symptoms and the severity thereof and also on the level of functional impairment (NICE, 2009). It is possible to speak of a depressive disorder characterized by distinct episodes when the symptomatology is manifested for at least two weeks, with correlated affective, cognitive and neurovegetative changes and with the likely engagement of multiple biological systems (e.g., the endocrine and immune systems).

In major depressive disorders, the cardinal symptoms mostly become manifest during the day, almost every day, and are accompanied by other symptoms (significant weight loss or gain, sleeping disorders, suicidal ideation) (DSM-5, 2013).

2. NICE guidelines

Outlining the treatment guidelines requires the prior classification of the severity of the symptomatologic picture. According to the NICE guidelines (2009), it is possible to recognize:

- subthreshold symptomatology (less than 5 symptoms of depression);
- mild depression (the diagnosis requires a minimum of 5 symptoms resulting in a very mild functional impairment);
- moderate depression (moderate number and severity of symptoms);
- severe depression (most of the symptoms cause significant functional impairment and it can occur concomitantly with psychotic symptoms).

Pursuant to an appropriate diagnostic evaluation of the disorder through a biopsychosocial assessment, the NICE guidelines are based on the conceptual structure of stepped care. Stepped care is empirically supported and is grounded on a hierarchical principle based on the maximization of results and the minimization of costs, in which each *step* represents an intervention ranging from the least invasive to the most organized and restrictive, depending on the severity of the symptomatology.

- The first *step* consists of *assessing* the symptomatology and the risk and monitoring it. At an early phase of the symptomatology, this initial supportive and psychoeducational intervention represents a first therapeutic action on the person and can be sufficient to stop the progression of the symptoms.

- The second *step* addresses the symptomatic picture with anxiety episodes and mild-to-moderate symptoms of depression. This subsequent step is characterized by the active monitoring of the sleep-wake rhythm, and low-intensity psychosocial interventions such as individual or group cognitive-behavioural therapy (CBT), computerized CBT and structured group physical activities.

- The third *step* concerns patients that are unresponsive to the treatments delivered and/or who present a moderate-to-severe symptomatology. The guidelines suggest delivering an antidepressant pharmacological therapy customised to the characteristics and needs of the patient, combined with high-intensity psychotherapy. The psychotherapies that are recognised to be the most efficacious are the CBT, the interpersonal therapy (IPT) and the

couples therapy if the patient's relationship with his/her partner contributes to maintain or worsen the depressive symptoms or if the partner is considered to be a potentially positive therapeutic factor.

- The fourth and last *step* concerns cases of severe depression, showing risks of self-mutilation or a high probability of relapsing. It is recommended to deliver a CBT at least twice a week and a mindfulness-based therapy (MBSR), in association with an antidepressant pharmacological therapy. However, a recent systematic review and meta-analysis have shown that the MBRS does not outperform other depression-specific treatments (McCartheny *et al.*, 2020).

The NICE guidelines provide that these interventions be promoted in a biopsychosocial perspective, whereby every action performed on the patient is customised to his/her personal history and the evolution and course of the symptomatology, in collaboration with a multidisciplinary network of experts (psychotherapists, psychiatrists, and general practitioners) and family members. In this respect, best practices lay down that the professional be constantly updated on the techniques and empirical evidence published in the latest literature of reference, in addition to submitting to supervision processes in order to offer efficacious interventions targeted on the needs of the patient.

3. Comparison between the guidelines of the *American Psychological Association* and of the *American Psychiatric Association*

The differences between the guidelines set forth by the two American associations and those by NICE principally concern the methodological and theoretical approach to the disorder. While the NICE guidelines refer to a model based on the severity and persistence of the symptoms, the guidelines by the American Psychiatric Association and the American Psychological Association make therapeutic suggestions on the initial treatment, on the worsening or persistence of the symptoms that do not benefit from the initial treatment, and on preventing relapses. Moreover, it is worthwhile noting that the diagnostic model of reference of the NICE and the American Psychiatric Association guidelines is the DSM-IV-TR (2000) while the guidelines released by the American Psychological Association refer to the DSM-5 (2013).

3.1 *American Psychological Association*

According to the American Psychological Association (2021), it is possible to intervene both with a pharmacological therapy (second-generation antidepressants are recommended) and with psychotherapy, considering the following approaches equally efficacious: behavioural psychotherapy, CBT (including the one based on mindfulness, MBSR), the interpersonal therapy (IPT), psychodynamic psychotherapy and supportive psychotherapy. Moreover, they recommend a couples psychotherapy applying the same criteria indicated in the NICE guidelines. In case the professional opts for a combined pharmacological-psychiatric therapy, the evidence found by the American Psychological Association suggests opting for the CBT or the IPT combined with last-generation antidepressants. Although the criteria for choosing the treatment are not strictly based on the severity of symptoms, for adult patients with a subclinical (subthreshold) depression, the guidelines suggest opting for a frontline psychotherapy – including non-cognitive-behavioural psychotherapies – counselling and problem-solving-oriented therapies. In contrast with the NICE guidelines, the guidelines of

the *American Psychological Association* also list non-evidence-based interventions such as acupuncture, the treatment with Omega-3 fatty acids and physical exercise.

3.2 *American Psychiatric Association*

Also the *American Psychiatric Association (2020b)* sets forth guidelines principally based on the clinical assessment of the major depressive disorder, focusing special attention on diagnosis, which must be performed with the support of tests and questionnaires. In promoting a therapeutic alliance as the principal support of the pharmacological therapy, the guidelines of the American Psychiatric Association give an in-depth description of the different types of antidepressant drugs to be administered, with special attention on the needs and symptoms of the single patient, who is to be constantly monitored throughout the therapeutic process. Together with the pharmacological therapy, the American Psychiatric Association recommends a psychotherapeutic treatment based on the same approaches previously indicated by the American Psychological Association (CBT, IPT, psychodynamic psychotherapy, couples and family psychotherapy). The problem-solving-oriented psychotherapy and group psychotherapy are recommended along the same lines of reasoning laid down above, i.e. in the presence of a subthreshold symptomatology. In contrast with the NICE and American Psychological Association guidelines, the guidelines of the American Psychiatric Association suggest the possible use of somatic therapies such as ECT (electroconvulsive therapy), TMS (transcranial magnetic stimulation) and VNS (Vagus Nerve Stimulation), to be implemented with caution in the cases in which the above-described therapies did not achieve the desired effects.

Annex 5
List of the relevant documents drafted by the National Institute for Health and Care Excellence (NICE) identified as reference material to be made public in view of translating them

Common mental health problems: identification and pathways to care
(Clinical guideline [CG123]; Published date: 25 May 2011)

Depression in children and young people: identification and management
(NICE guideline [NG134]; Published date: 25 June 2019)

Depression in adults: recognition and management
(Clinical guideline [CG90]; Published date: 28 October 2009)

Depression in adults with a chronic physical health problem: recognition and management
(Clinical guideline [CG91]; Published date: 28 October 2009)

Generalised anxiety disorder and panic disorder in adults: management
(Clinical guideline [CG113]; Published date: 26 January 2011; Last updated: 26 July 2019)

Obsessive-compulsive disorder and body dysmorphic disorder: treatment
(Clinical guideline [CG31]; Published date: 29 November 2005)

Post-traumatic stress disorder
(NICE guideline [NG116]; Published date: 5 December 2018)

Social anxiety disorder: recognition, assessment and treatment
(Clinical guideline [CG159]; Published date: 22 May 2013)

Annex 6.
Proposal of integration of the Consensus Conference – Training needs (Core Curriculum/Consensus)

Premise

Reference is herein essentially made to the essential references made in the draft guidelines as rewritten in the document by Gazzillo, Leveni, and Porcelli. In this perspective, the basis for diagnosis and definitions are those laid down therein, including those referring to the severity of the medical picture of depression (NICE, 2009; DSM-5, 2013).

Depression is a broad and heterogeneous diagnosis. Central to it is depressed mood and/or loss of pleasure in most activities. Severity of the disorder is determined by both the number and severity of symptoms, as well as the degree of functional impairment (NICE, 2009). It is possible to speak of a depressive disorder characterized by separate episodes if symptoms are present for at least 2 weeks and are correlated with affective, cognitive, and neurovegetative changes likely to involve multiple biological systems (e.g., the endocrine and immune systems).

In the major depressive disorder, the cardinal symptoms manifest themselves throughout most of the day, almost every day, and they are accompanied by other symptoms (significant weight loss or gain, sleeping disorders, suicidal ideation) (DSM-5, 2013).

Outlining the guidelines for treatment requires a previous classification of the severity of the symptomatologic picture. According to the NICE (2009) guidelines, it is possible to recognize:

- *subthreshold symptoms (at least 5 symptoms of depression);*
- *mild depression (with a minimum of 5 symptoms necessary to make the diagnosis and resulting in a very mild functional impairment);*
- *moderate depression (with a moderate severity and number of symptoms);*
- *severe depression (most of the symptoms significantly interfere with the functioning of the patient. It can occur concomitantly with psychotic symptoms).*

Core Curriculum and depressive pathology

On the basis of the above premise, it follows that it requires several core competences that can be distributed and organized within the areas singled out by the Core Curriculum in Clinical Psychology. This proposal sets out two training levels which can coherently incorporate the topics relative to a biopsychosocial assessment and stepped care, which appear to be the fulcrum of the considerations on the treatment of depressive pathologies (NICE, 2009). More specifically, each step represents an evidence-based intervention that is less invasive and more organized and restrictive according to the severity of the symptoms. This indicates a preliminary knowledge of the main types of clinical psychology interventions.

In the light of the above, the training should be delivered at the two institutionally established levels, in the thematic areas singled out in the document of the Board which make it possible to conclude the training course with competences in the field of:

- Diagnostic assessment with the principal recognized systems.
- Understanding the level of severity.
- Knowledge of the bases of the principal interventions recognized to be efficacious.
- Capacity to make constant reference to empirical and in-depth literature.

In particular, basic knowledge of the depressive disorder should be delivered at Level 1 and an in-depth knowledge of the clinical presentation of the same pathology (and its interrelated relational effects) and the basis of the principal interventions at Level 2.

Level 1

- Knowledge of the principal psychological theoretical models and correlated models (reference to psychosocial and biological models referred to depressive pathologies)
- Knowledge of the principal diagnostic classification systems and of the principal psychopathological diagnostic approaches (DSM, ICD, RDoC and depressive pathologies)
- Knowledge of the principal assessment tools and their theoretical/empirical background (specific tools for depressive pathologies)
- Capacity to understand the methods to read the results of empirical research studies
- Capacity to identify the principal indicators to verify the efficacy of clinical psychology interventions
- Capacity to identify interactive models between individual distress and the psychosocial context
- Adjustment/maladjustment (relational and social processes)
- Basic concepts relative to the span of life

Level 2

- In-depth knowledge of the principal clinical pictures among those most closely correlated with depressive pathologies and risk indexes, also referred to the life span
- Knowledge of the principal aspects of comorbidity in terms of the diagnosis and clinical presentation; in the case of depressive pathologies, anxiety and personality disorders, and addictions
- Knowledge of the principal severity and risk indicators in the different steps relative to depressive pathologies (NICE, 2009) and capacity to recognize subthreshold presentations of the disorders (NICE, 2009; American Psychiatric Association, 2010)
- Basic and updated knowledge of pharmacology and neuropsychopharmacology (including second-generation antidepressants and stabilizers)
- Knowledge of the core issues and differences relative to clinical interventions and, in particular: (a) clinical interventions, with a special focus on supportive and psychoeducational interventions, (b) low-intensity psychosocial interventions, such as individual or group cognitive-behavioural therapies (CBT) and structure group physical activities, (c) high-intensity psychotherapies (CBT, IPT). Preliminary and exemplary references to how to use these clinical interventions in depressive pathologies
- Knowledge of the principal issues relative to the couples therapy (the relationship with the partner contributes to maintaining or worsening the depressive symptoms and the partner is considered to be a potentially positive therapeutic factor). Basic knowledge of the issues relative to caregivers and family members.
- Hints of the mindfulness-based therapy (MBSR) and problem solving
- Basic elements of psychodynamic psychotherapies
- Competence in the concept of Therapeutic Alliance
- Basic knowledge of health psychology, with a special focus on depressive pathologies (medical pathologies and depression)
- Competence in the field of teamwork with different professional profiles (e.g., integrating social, pharmacological, and psychological interventions in cases of depression)
- Competences in the realm of deontology and ethics, with a special focus on depressive pathologies.

Annex 7.
Preliminary project of a Portal for anxiety and mood disorders

A large input of information, on its own and for the purpose of collecting health-related indications, flows daily through Internet search engines. The data released by Istituto Nazionale di Statistica (ISTAT, the Italian Statistics Agency) on the access and use of the Internet report that in 2019, 48% of the users in the 25-34 age group, and an equal percentage in the 55-59 age group, goes online to find healthcare information, peaking at 49% in the same period in the 35-44 age group and never dropping under 40% in the 20-75 age group (ISTAT, 2019). In this context, a possible option of intercepting users and concomitantly providing a service not only based on providing information but also a first consultation and an evidence-based self-help solution for anxiety and mood disorders, could be to develop a web portal (or two separate portals for anxiety disorders and mood disorders respectively) targeted on two different group of users: the first, a general public of users and the second mental health professionals, a category that meets the different objectives of providing information, training and interventions.

In relation to the general public of users, the portal's principal objectives could be the following:

1. provide information on anxiety and mood disorders and their relative treatment guidelines, as well as self-help publications available on the market. It could also be possible to offer, free of charge, one or more e-books on evidence-based treatments, specifically developed for this market segment;
2. publish open-access self-assessment tools and digital and interactive treatment software through which users can learn about their problems, assess their severity, and plan a guided self-treatment strategy;
3. offer the possibility of requesting online or in-person consultations by providing access to a network of professionals and of contacting the contact persons at local level with a view to accessing self-help and mutual aid groups.

With regards to mental health professionals, the portal can offer similar services to the above, providing dedicated access to the three areas outlined above:

1. information: editorial content, downloadable free of charge or purchasable from the relative publishers, including encrypted treatment guidelines;
2. training: multimedia courses, especially through distance learning and *webinars* on the principal evidence-based intervention models, with the ECM (lifelong learning) certification option;
3. intervention: developing channels through which to put in contact, both online and offline, professionals and facilities using encrypted protocols with users.

The portal should be consultable and accessible to principal search engines and to the widest used social networks and apps through different devices (especially smartphones, tablets, and laptops).

As for similar experiences abroad, we can mention New York State's portal of the National Healthcare Service (www1.nyc.gov/site/doh/health/health-topics/depression.page), which is principally targeted on the population, and the portal of the UK National Health Service (www.england.nhs.uk/mental-health/adults), which targets both the general population and mental health professionals, proposing computer-based self-help therapies, the procedures and efficacy of which are widely covered in literature. In this respect, in

relation to their efficacy, we can cite: Webb *et al*., 2017; Cuijpers *et al*., 2017; Health Quality Ontario, 2019; Richards *et al*., 2018 e Karyotaki *et al*., 2017.

Annex 8.
Direct and indirect costs of anxiety disorders and depression

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In the last few years, in Italy as in other Countries, we have witnessed a constant increase in the number of people suffering from Mental Disorders. In the last decade, psychiatric disorders have been on a continuous epidemiological uptrend, with a consequent rise in their "global weight" and impact on public health and on essential social, human, and economic aspects.

In terms of welfare and social security, the social benefits paid out by the Istituto Nazionale della Previdenza Sociale (INPS, the social security agency), for mental disorders are on a continuous uptrend, comparable to those for cancer. Among these, the major depressive disorder (MDD), also known as major depression, is an invalidating disease that impairs both the affective and cognitive spheres of a person, negatively affecting the person's family and working life, as well as his/her physical health, and strongly impacts the person's lifestyle and quality of life in general, but also entails health and social costs. By 2020, it is estimated to be the second-ranking pathology in terms of overall economic costs.

In Italy, direct healthcare costs, which represent only a part of the problem, amount to 5,000 Euros a year per patient. It is an impressive figure although it is in line with other pathologies.

To fully understand the impact of MDD both from a social and economic perspective, it is necessary to look into the impact that this pathology has on indirect social costs **(70% of total costs)**. A recent study (Nardone *et al.*, 2021, being published; also see, Nardone *et al.*, 2018) estimated the social and social security costs of MDD. The period of observation spans from **2009 to 2015** (the latest data available although they are to be updated to 2019). Considering the total number of workers for whom MDDs represent the primary or secondary diagnosis, the number of workers receiving welfare benefits amounts to **10,500**, most of whom (90%) receive ordinary incapacity benefits and the rest (10%) a disability pension. Unfortunately, it must be stressed that the **trend is on the rise (+70% from 2009 to 2015)**. The costs too are relevant and are on an uptrend: in the period under observation, a **total of € 550 million** were spent on ordinary incapacity benefits and a **total of €93 million** for disability pensions. The study shows that, over time, both the number of beneficiaries and costs of MDD as a primary or secondary pathology have grown significantly: **in 2015 the beneficiaries were 20% more than in 2009, and the costs were up 40%.**

Another interesting albeit worrying datum refers to the age groups of the people most affected by this disorder. **The analysis shows that the most represented age group goes from 51 to 60 years of age, which has a considerable impact on the costs arising from the loss of productivity.** With respect to this cost item, the study estimates an expense of approximately **4 billion euros a year in terms of lost working hours**. If we then add to these costs the direct healthcare costs borne by the NHS, we realize the overwhelming economic and social impact that this disorder has in Italy. And this is without overlooking

the weight that the social stigma has on determining strong prejudices against these patients.

These data are food for thought for decision-makers, both at central, regional, and local level, relatively to the importance and need to promote effective actions targeted on prevention, as well as timely and easy access to diagnosis and care in order to improve the patients' health and also have a positive fallout on diminishing both direct and indirect and social costs.

The aim of prudent health policies should be to **slow down the progression** of the disorder and the consequent uptrend in spending arising from greater disability levels, through early diagnosis compounded with the early treatment of patients (without forgetting prevention). We should remember that an increase in the number of patients diagnosed and adequately treated does not always mean an increase in the cost of the disease; quite the opposite: in the medium-term, in addition to improving the level of health, there is a concomitant reduction in direct, indirect, and social costs.

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Part 2 • RECOMMEDATIONS OF THE JURY

Foreword

As described in Part 1 of this document (Report for the Jury), the method of the Consensus Conference provides for the issue of recommendations on the basis of pre-defined questions to which the Jury members mush answer. The questions drafted by the Promoter Committee and the Scientific Committee along with the team of experts have been subdivided into four groups:

- ***Group A*** • *The current state of knowledge on the access to care of people with anxiety and depressive disorders to treatment, the scientific evidence and appropriateness of treatments*
- ***Group B*** • *Procedures and instruments to identify people with anxiety or depressive disorders*
- ***Group C*** • *Train caregivers to provide in-depth knowledge and operational competences in the psychological treatment of anxiety and depressive disorders*
- ***Group D*** • *The resources, organizational models, and the diagnostic and therapeutic training necessary to facilitate people's access to psychological therapies.*

This second part of the document contains the recommendations set forth by the Jury in response to the questions posed for each group.

Group A

Current state of knowledge on the access to care of people with anxiety and depressive disorders, scientific evidence, and the appropriateness of treatments[4]

• Question A1

What is the current state of knowledge on the access of people with anxiety and depressive disorders to treatment, to the scientific evidence of the theoretical and practical efficacy, and appropriateness of both psychological and non-psychological treatment for anxiety and depressive disorders?

The extensive and laboursome efforts made in drafting the Consensus Conference on the Psychological Treatment of anxiety and depression highlight the following:

- a high incidence of anxiety and depressive disorders in the population, with a difficulty in recognizing them and in accessing care;
- difficulty of access to psychological treatment with the consequent use of pharmacological therapies also in cases in which they are not indicated;
- the absence, in daily clinical practice, of a system to monitor the outcome and the performance of the treatments delivered.

Moreover, the experience acquired in the United Kingdom through the Improving Access to Psychological Therapies (IAPT) programme suggests that, in daily clinical practice, it is possible to use evidence-based psychotherapeutic interventions and a culture of assessment to monitor the outcome indicators of said interventions.

The extensive and laboursome analysis of the evidence contained in literature performed by the Consensus Conference Group of Experts however only partially covered the age of development. Although part of the evidence relative to adulthood can be at least partially extrapolated to childhood and adolescence, this age group presents age-specific features, developmental phases, the role played in their lives by their environment, the level of engagement of their families and living environments, comorbidity, types of interventions, and services of reference. This context is particularly neglected both in research studies and in the delivery of adequate services at both national and international level.

[4] Contribution written by: Nicola Artico, Corrado Barbui, Tullio Giraldi (contact person)

Recommendations A1

A1.1 It is hereby recommended to promote a better and more timely **recognition** of anxiety and depressive disorders and their **classification** in terms of the intensity of symptoms (mild, moderate, severe), and of the individual and social functional impairment, differentiating subthreshold mood swings from confirmed clinical forms, for the purpose of limiting the tendency to medicalize common emotional conditions. Special attention must be placed on the diagnostic criteria which must be used homogeneously in order to **align** the work of the different caregivers and institutions involved. In addition to using widespread psychometric symptom scales, use could also be made of tools to measure the functional sphere and the aspects not adequately covered by general yardsticks such as the younger or older age of the patient, the gender and the mood disorders that may accompany childbirth and the perinatal period.

A1.2 In relation to anxiety and depressive disorders, it is hereby recommended to promote reliance on caregiving, supportive, psychoeducational, and **evidence-based** psychotherapies as frontline interventions in mild forms and evaluate the option of combining psychological treatment with an evidence-based pharmacological therapy in moderate and severe cases, as recommended by the NICE guidelines.

A1.3 It is recommended to develop a **communication** system between primary care and local and hospital specialist care with the aim of outlining a service network capable of delivering flexible care according to individual needs.

A1.4 It is recommended to develop a **monitoring** system of the outcome of interventions delivered in public and private facilities, including unmanaged care services. This recommendation aims to improve the **accountability** and certification of treatment-delivering facilities and produce data useful to generate new rigorous and independent research projects on the most sensitive critical issues in the psychotherapeutic and pharmacotherapeutic practice; the results can define, with growing accuracy, the appropriateness of interventions, and lay the grounds for the promotion of up-to-date and incisive training activities. The monitoring system would further make it possible to **assess** the subjective acceptance, the therapeutic alliance, and the level of satisfaction with the psychological treatment that is so closely correlated with the consent and responsiveness of the patient, with a view to observing and managing the differences that, in this field too, exist between the theoretical efficacy and the practical effectiveness of the psychological therapies offered.

A1.5 It is recommended to **further investigate the specific aspects related to childhood and adolescence** and to implement the research dedicated thereto and make an in-depth analysis of the differences and similarities with other interventions on adults (indispensable to plan a possible

transferability of results), and develop new analytic models for research outcomes in clinical practice that can factor in the different levels of complexity, integration, and interconnection between neurobiology and the environment, which is typical of the age of development.

A1.6 It is recommended to promote initiatives aimed at implementing the above-listed actions **homogeneously** throughout the national territory, avoiding the creation of unbalances between contexts assuring and monitoring access to evidence-based treatments and contexts in which access to care remains fragmented and difficult.

A1.7 In the context of evidence-based psychotherapies, as no clinically relevant difference can be detected between the effectiveness of single interventions, it is hereby recommended to give careful consideration to offering a **variety of structured psychotherapies** while at the same time systematically assessing and **monitoring** their outcome.

Group B

Procedures and instruments to identify people with anxiety or depressive disorders[5]

- **Question B1**

Is it possible and useful to introduce a model for identifying people with anxiety and/or depression issues, requiring psychological therapies, that is structured according to multiple levels of severity which are matched with corresponding levels of treatment intensity?

Recommendations B1

B1.1 It is recommended to introduce an **intervention model** for anxiety and depressive disorders **structured according to the level of intensity of the treatment** (stepped care, Level 1: psychoeducational interventions or self-help and mutual aid groups; Level 2: psychotherapy; Level 3: psychotherapy combined with pharmacotherapy), engaging all the Healthcare Services and local socio-medical services (General Practitioners, GPs; primary care paediatricians; Primary Care District Services; Family counselling facilities; Services for Disabilities) and penitentiary medical services, in close coordination with specialist services, and delivered according to specific local organizational models.

B1.2 It is recommended to perform a **multidimensional assessment** also based on validated and shared psychometric instruments capable of facilitating the communication between different treatment levels and of guiding caregivers in taking the most important clinical decisions, such as stepping up or down, or closing the intervention. Special attention should be focused on possible comorbidities, the patient's overall functioning, age, particular phase of life, or relevant gender-or environment-related aspects that often determine the need to reconfigure the interventions and the intensity level of treatments.

- **Question B2**

Can access to psychological therapies also be indicated in the presence of subclinical problems of anxiety and/or depression and, if so, under what conditions?

[5] Contribution written by Elena Bravi, Gemma Calamandrei, Antonella Costantino (contact person), Luca Muglia

Recommendations B2

B2.1 Access to the first level of stepped care interventions in the presence of subclinical problems of anxiety and/or depression is solely recommended **for people with a relevant physical or mental comorbidity or who have already suffered from anxiety and depressive disorders in the past**, especially if they are experiencing a specific phase of life such as adolescence, old and very old age, parents in the perinatal period and any other condition in which subthreshold symptoms are associated with a high risk of psychopathology or a serious drop in school, social and professional performance.

B2.2 For the remaining subthreshold situations, also with a view to avoiding excessive medicalization, it instead appears to be more advisable to promote the activation of **mental health and wellbeing support strategies in non-medical contexts** and monitor their outcome over time.

Group C

Train caregivers to provide in-depth knowledge and operational competences in the psychological treatment of anxiety and depressive disorders[6]

- **Question C1**

What actions can be indicated and made feasible in university schools providing specialization in Psychology, Child Neuropsychiatry and Psychiatry, as well as in other schools that issue licenses enabling the practice of psychotherapy in order to provide in-depth knowledge and practical skills in evidence-based psychological therapies for anxiety and depression?

First of all, it should be noted that the current regulatory framework establishes that the specialization schools qualifying people for the exercise of psychotherapy can be either public or private and that, at present, private schools greatly outnumber public schools and envisage fewer internship hours.

Recommendations C1

C1.1 It is recommended to **increase the number of public specialization schools**, which should possibly be present in all Universities.

C1.2 It is hereby recommended to increase the internship hours in private specialization schools with a view to equating them with public schools.

C1.3 It is recommended to increase the **availability of public managed-care facilities** in the field of psychiatry, paediatric neuropsychiatry and clinical psychology, and **hold internships** for undergraduate students, through an ad hoc planning effort.

C1.4 It is recommended for schools to implement a **careful and targeted monitoring system** of the qualified training delivered to undergraduate students on the high incidence of anxiety and depressive disorders among the population and their invalidating effects, insofar as this is now broadly confirmed by the data in scientific literature.

C1.5 It is recommended to deliver a **clinical training** providing the bases for treating patients with anxiety and depressive disorders in terms of:

[6] Contribution written by: Anna Costantini, Giovanni de Girolamo, Valerio Sciannamea, Renata Tambelli (contact person)

- A diagnosis based on a scale of growing severity
- A treatment structured according to several levels of intensity (the usefulness of low-intensity interventions)
- A systematic assessment of outcomes.

In particular, for private specialization schools, reference is made to the role of the Technical Advisory Committee (*Commissione Tecnico-Consultiva*-CTC of the Italian Ministry of University and Research, MUR), which is responsible for the certification and assessment of the schools, calling on it to set out targeted objectives with respect to the professionalizing function of internships, making sure that they are consistent with the role of Psychotherapy at Basic Care Levels and shoulder the care of the citizens' mental health. It is necessary to develop orientation policies on psychological care that take into consideration the issue of enforcing evidence-based efficacy criteria nationwide. This appears to be evident and necessary pursuant to Law No. 3/2018, which defined the profession of psychologist as a healthcare profession, and to Law No. 176/2020 which transposed the Basic Psychological Care Levels in the "National Recovery and Resilience Plan" (PNRR) (Art. 20-bis), thus highlighting the need to tackle the serious consequences of the Covid-19 pandemic on mental health and psychological wellbeing.

• Question C2

What should be considered the minimum level of learning and training provided by university courses in Psychology, Medicine, Pharmacy and the Health Professions regarding evidence-based psychological therapies for anxiety and depression?

To begin with, it should be pointed out that the question exclusively refers to Master's Degrees. In relation to anxiety and depressive disorders, it seems advisable to differentiate the University Degree in Medicine from the Degree in Psychology with a major in clinical psychology, with a view to integrating their respective specialist knowledge.

Recommendations C2

C2.1 It is recommended to provide an **introductory course on anxiety and depressive disorders in the three-year Psychology degree** (with notions of the theoretical models of clinical psychology and of the principal diagnostic classification systems) and subsequently introduce more advanced knowledge of clinical interventions and measures on the efficacy of treatments in the Master's Degree course in Psychology.

C2.2 With respect to the **degree in Medicine**, it is recommended to introduce in the curriculum specific elements of clinical psychology, and in particular:

- Know of and how to apply **empathy as a relational construct,** which is key to complying with the treatment, communicating the outcome of the treatment, also by designing training programmes that sensitize students to recognize and monitor the way in which the clinician's emotions and behaviour co-build the behaviours and emotions of the patient;
- Know how to intercept and **respond empathically to a request for help**, also in terms of prevention;
- Know the **psychological principles underlying the doctor-patient relationship**, the basic elements of communication and the scientific evidence on the efficacy of psychotherapeutic interventions on anxiety and depressive disorders, also in comparison with pharmacological therapies;
- Know how to screen patients, with a view to **recognizing psychological distress** in its various forms, in particular in cases of anxiety and depressive disorders, also with subthreshold symptoms.
- Know how to guide the patient towards the most appropriate specialist service from the perspective of a therapeutic network.

C2.3 With respect to the **degree in Psychology with a major in clinical psychology**, it is recommended to include in the curriculum an in-depth knowledge of the manifestations of anxiety and depressive disorders along with the severity and risk indicators (together with their relational correlates), as well as the bases and differences of the principal therapeutic interventions, including the measurement of the efficacy of psychotherapies, the meta-analytical reviews and the consultation of international guidelines for these disorders.

The following recommendations on training, although they are specifically developed for the Master's course in clinical psychology, can nonetheless be usefully adopted **in other Master's courses**, such as the one in Labour or on the age of development:

- Know of and how to intervene at different levels of **preventing** psychopathologies;
- Acquire in-depth knowledge of the **principal clinical pictures** of anxiety and depressive disorders (also in their subthreshold presentations), comorbidity aspects (including personality disorders and substance abuse) and the severity and risk indicators (also over the whole span of life);
- Know the principal standardized **assessment** tools and the theoretical/empirical background of anxiety and depressive disorders;

- Know the principles of **pharmacotherapy** of anxiolytics and antidepressants;
- Know the different types of **clinical interventions**: supportive and psychoeducational; group activities; low-intensity psychosocial interventions; high-intensity individual and group psychotherapy;
- Know how to recognize the principal **efficacy indicators** of psychotherapeutic interventions;
- Acquire competences relative to the **therapeutic alliance**, teamwork, and professional deontological ethics.

• Question C3

What actions can be indicated and made feasible for continuing education and/or other professional updating initiatives for General Practitioners, Child Neuropsychiatrists, Psychiatrists, Clinical Psychologists and Psychotherapists?

With reference to the bill of 27 October 2020on qualifying university degrees, the Master's Degree in Psychology (course LM-51) qualifies to practice the profession of Psychologist, similarly to the qualifying Degree in Medicine and Surgery (Law No.27 of 24 April 2020). The training options specifically dedicated to screening, diagnostic procedures and methods, and treatment techniques of anxiety and depressive disorders are very scarce.

Recommendations C3

C3.1 To achieve adequate training, it is hoped that Universities deliver **Advanced Vocational Training and 2nd Level Master's Degrees** in collaboration with specific professional associations, providing young graduate students more updated and qualified training on anxiety and depressive disorders from a technical and practical point of view, also to meet the immediate need to tackle the growing incidence of these critical conditions among the general population that have appeared consequently to the Covid-19 emergency.

C3.2 It is recommended to offer the **refresher courses and lifelong education** necessary for health professionals working in Public Health facilities to obtain the required ECM (lifelong learning) credits, as they are under the deontological obligation of putting into practice the new knowledge and competences with a view to offering a qualitatively useful and updated assistance to their patients.

In particular, it is recommended to expedite qualified **specific initiatives** to deliver adequate scientific knowledge on anxiety and depressive disorders. One such initiative is the partnership between the Italian Istituto Superiore

di Sanità (ISS), the Agenzia nazionale per i servizi sanitari regionali (AGENAS) and the Universities design updated training courses specifically targeted on various health professionals, to then disseminate to Local Health Centres through the Regional Health Service. To this end, it is hoped that adequate budgetary targets are set to favour the participation thereto by health professionals.

Group D

Resources, organizational models, and diagnostic and therapeutic training necessary to facilitate people's access to psychological therapies[7]

- **Question D1**

In the specialized international literature, there is evidence of a favourable cost/benefit ratio of psychological therapies, even in strictly economic terms (absence from work, higher health and social costs, work-related stress, etc.). What are the realistic estimates for the Italian context?

Recommendation D1

D1.1 It is recommended to promote the **use of evidence-based psychological therapies** as frontline interventions for patients suffering from anxiety and/or mild to moderate depression, also in the light of a positive cost-benefit ratio in relation to direct and indirect costs.

- **Question D2**

What strategy appears to be most effective and operationally manageable to facilitate access to psychological therapies for people with anxiety and depressive disorders and hence reduce the large number of untreated people?

Recommendations D2

D2.1 Introduce **strategies that act at all levels of the problem** and that take into consideration the specific structure of the Italian national health system and its interregional variations.

In particular, it is recommended to:

a) activate **awareness-raising initiatives** on anxiety and depressive disorders for the general population, targeted on the different age groups and

[7] Contribution written by: Elena Bravi, Gemma Calamandrei, Antonella Costantino (contact person), Paola De Castro, Luca Muglia

subpopulations most at risk, to combat stigma and expand awareness on the existence of efficacious treatments;

b) develop diagnostic and therapeutic **procedures** for anxiety and depressive disorders to be **shared among professionals and services,** so as to assure the delivery of the three levels of stepped care within the specific local/regional organizations and facilitate transitions and connections between services in the perspective of assuring continuity at local level. In particular, it is advisable that first-level interventions be delivered as part of primary care, networked into an integrated and coordinated system of treatment services linking local facilities and hospitals. It also appears to be essential that the options for children and adolescents be targeted and different from those for adults in the light of specific age-correlated characteristics, development phases, the role of the environment, the relevance of comorbidity, the different types of interventions and services of reference, and that they always provide to engage the families and living contexts.

c) Implement the competences of health professionals and services at primary care (community medicine, district primary care services, family counselling, services for disabled people) and penitentiary medicine level, to enable an **early interception** of anxiety and depressive disorders in said contexts and assure the possibility of the concomitant delivery of first-level interventions.

d) Implement the competences of health professionals and of the psychology, psychiatry, pathological dependencies, and child and adolescent neuropsychiatry services to allow for **appropriate** second- and third-level **treatments** in situations of greater complexity/comorbidity.

e) Provide for an **adequate number of healthcare workers** in primary and specialist care services, with special attention for those dedicated to children and adolescents, to manage the different levels and types of interventions required.

- **Question D3**

What role can the new technologies and online psychology play in improving access to appropriate treatment for anxiety and depression?

Recommendations D3

The spread of online therapies presents an unarguable possibility of providing support from remote, especially in the cases of mild or moderate disorders, and can contribute to reducing the stigma. However, it should be kept in mind that relying

on inadequately supervised online therapies can entail risks both for the user, for the outcome of the treatment and for the possible illicit use of sensitive data.

D3.1 It is recommended to promote the transversal implementation of new technologies and of telepsychology as an **integrating part of treatment procedures** for anxiety and depressive disorders in all services, and especially in mild cases and in the first- and second-level of stepped care, with a view to improving the accessibility and appropriateness of the treatments of these disorders. It is recommended that online psychological support services be supervised by expert professionals on the basis of the best practices and the best and most updated evidence available and pertinent to the therapeutic objectives.

D3.2 It is recommended to always assess, focusing special **attention on the obstacles** that can interfere with the effective implementation of interventions and their efficacy (digital divide, the preferences of the patient, the appropriate sharing of objectives, etc.) and act assertively to implement more research into clinical practice.

- **Question D4**

What initiatives can be taken to raise awareness, in particular of potential users, about the effectiveness and availability of psychological therapies and enable them to actually choose psychological therapies if they prefer them over pharmacological treatment?

Recommendations D4

D4.1 With regards to communicating to different targets, it is recommended to produce scientifically **rigorous contents** that are at the same time **drafted in languages** (textual and multimedia) **accessible and appealing for the specific targets** of reference (e.g., healthcare workers and different average age groups of citizens). Communication on anxiety and depressive disorders should contribute to overcome the stigma and to shape the awareness that there are validated and efficacious interventions and that "do it yourself" treatments are never recommendable (the type of therapy should not be chosen on one's own and it is necessary to discuss the choice of treatment among all the possible options with trained professionals).

D4.2 A clear, targeted, and unambiguous communication is recommended. It will be necessary to draft **brief and simplified summaries of complex documents** and seek different ways of favouring their dissemination within the community. The Institutions' official websites (Ministry of Health, the ISS, Scientific Associations, etc.) represent the preferred place for this communication. Webinars can be organized with experts, enabling citizens

to put questions and obtain answers from acknowledged experts, also in chats.

D4.3 It is recommended to evaluate the possibility of expanding the **communication networks to social media** and to concomitantly promote user loyalty for institutional messages. **Communication tools targeted** on different population segments, especially on the least acculturated, could also include, in addition to web and printed messages, testimonials by celebrities, cartoons, TV advertisement, actions among volunteer organizations for more capillary projects and contacts with the citizens. Additional fundamental initiatives shall have to address associations of GPs and primary care paediatricians, concerting with them awareness raising, and information campaigns, webinars, workshops, etc.

D4.4 It is recommended to activate a *communication strategy* that is:

- **consistent and harmonized** with all the institutions involved in the management of mental health, at various levels, to raise trust in the message disseminated and to favour the most adequate choices, also the elimination of stigma;
- **continued and constant,** in order to gradually raise the people's awareness on the existence and efficacy of the available services and thus combat fake news*;*
- **monitored** (according to the people's expectations) through research, surveys, and focus groups;
- **adapted to different contexts**, also pursuant to the results of monitoring activities, as well as to social and working contexts by using the legislative instruments available (e.g., Law no. 81/2008).

Examples of communication tools relative to specific targets are the following:

- **for health professionals**, an institutional space in which to share a mental health information and communication toolbox for stress management.
- **for the general public,** the dissemination of videos, podcasts, news, virtual communications, in-person and virtual events, passing the word among groups, and engaging schools through social media.
- **for schools**, emotion knowledge and management programmes targeted on the 12-18 age group, to be implemented through specific projects.

- **Question D5**

What initiatives can be taken to raise the awareness of decision-makers and socio-health institutions to make psychological therapies for anxiety and depressive disorders effectively available and usable?

Recommendations D5

D5.1 In communicating to policymakers and health institutions, the **emphasis** should be placed **on** the direct and indirect **costs** of mental health in Italy (Global Burden of Disease approach) and of anxiety and depressive disorders in particular, explaining that it costs less to prevent than to cure. It is important to emphasize the efficacy data of psychological interventions also for sub-threshold conditions which, if treated in time, can prevent the onset of more serious and ultimately chronic disorders, which are burdensome for their social costs, for the health system and for the economy at large. Cards (info-graphic) could be used containing data illustrating the savings associated with prevention and describing the correct management of anxiety and depressive disorders through the stepped care approach.

D5.2 Very clear indications should be provided on the **criticalities** related to the prevention, promotion, and management (care) of mental health in Italy, but also on the potential and resources that exist in the social and health network present in many territories. Particular emphasis should be placed on the **efficacy** of first- and second-line treatments, and on the need for **structural investments** both for hiring new professional figures in the services and for the training of existing staff.

D5.3 The possible **involvement** of entities and institutions directly or indirectly interested in reducing these costs should be considered. It could be possible and useful to raise the awareness of these entities and institutions and other possible bodies by promoting press conferences and conventions, soliciting hearings, direct meetings, and initiatives possibly supported by the Istituto Superiore di Sanità and connected with the scientific psychology associations and societies.

Final remarks

Promote scientific research to promote mental health

In concluding this document, the members of the Jury wish to emphasize the importance of scientific research in the field of anxiety and depression disorders, mental health, and psychological well-being. More specifically, it is recommended that We recommend enhancing both basic and clinical-epidemiological research in mental health and psychological well-being be enhanced and aimed primarily at identifying risk factors and specific vulnerabilities (age-related, biological, socio-demographic, and environmental); this is important both for implementing targeted primary prevention strategies and for developing highly effective therapeutic approaches.

In this context, it would be desirable to implement studies on the effectiveness of the combination of innovative pharmacological and psychotherapeutic treatments and interventions, as well as psychosocial support. It is equally important to promote the development of a system for monitoring the outcomes of the therapeutic tools used in daily clinical practice, through innovative methodologies, such as artificial intelligence, aimed at producing shared data useful for generating new research hypotheses.

Finally, three further aspects are particularly important in the field of mental health research: (i) a multidisciplinary approach, i.e. the promotion of collaborative projects that include various experimental approaches, from genetic and epigenetic to the analysis of behaviour and quality of the living environment and lifestyles, in the light of the complexity of the aetiology of anxiety and depressive disorders; (ii) a translational perspective aimed at preclinical and clinical research that applies innovative methodologies developed in the field of Neuroscience and Psychobiology with potential repercussions on clinical practice; (iii) the perspective of personalized or precision medicine, that is necessary to improve the effectiveness of preventive (consideration of diversified risk factors) and therapeutic strategies (treatments tailored to the individual patient based on the specificity of his/her condition, constellation of symptoms and clinical history).

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