

D-1.2 REPORT ON THE REVIEW OF TREATMENT OPTIONS

MESAFE – MEntal health for aviation SAFETy

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SUMMARY

Problem area

Mental disorders can influence pilot and air traffic controllers' performance in many detrimental ways. Their effects can bring about incapacitation, which erodes safety margins and might disrupt normal operations. On a more critical level, they can lead to errors, violations, inappropriate automatic hurried actions or biased decision making.

Currently, there are no specific, standard, validated mental health assessment methods for aeromedical use, incorporating the specific operational needs, to address the incapacitation risk due to mental disorders in the framework of the fitness for duty certification process.

MESAFE stands for "MEntal health for aviation SAFETy". It is a research project, funded by EASA under the framework of the European Union's Horizon Europe research and innovation programme. Started in May 2022 and lasting 2 years, the project aims at overcoming challenges preventing the effective implementation of the Aeromedical certification process for pilots and air traffic controllers (ATCOs) with regards to the incapacitation risk associated with mental health conditions. The project will provide evidence-based recommendations for new medical developments for the early diagnosis as well as treatment of mental health conditions which could pose a safety risk for aviation and would consequently lead to pilot and ATCO unfitness or the limitation of their licence privileges for safety purposes.

Two questions are prominent in this light. The first question is: "Can the safety impact of mental disorders be assessed, both in qualitative as well as quantitative terms, and given the proposed solutions and mitigations?". It is important to be aware that the total impact may be relatively small, but even then, it may be so that some aspects of the certification process will become less efficient, whereas others will become more efficient. A second question is "what will the impact on regulations be?". To answer this question, it is important to understand, given the proposed changes to aeromedical certification operations, what part of the regulation will be influenced by these changes, so as to be aware of the amount and type of adjustments to regulations that might be expected.

Description of work

The present document is the D-1.2 REPORT ON THE REVIEW OF TREATMENT OPTIONS of the MESAFE project and provides an overview of existing evidence and procedures in treating mental disorders.

In line with the EASA technical requirements, this document provides the following information:

- Review of the state-of-the-art treatment options for the most frequent mental disorders;
- Review of the state-of-the-art treatment options' potential incompatibility with the different classes of aeromedical certification;
- Overview of mental health care methods and options currently used in aviation;
- Main findings.

Results and Application

There are several evidence-based biological treatments for mental disorders. Although most biological treatment options cause side-effects, these are usually less severe compared to the disorder the treatment is prescribed for.

There is evidence that psychotherapy is effective for the treatment of mental disorders. Medications have proven to be most effective for more severe symptoms.

There is evidence that psychotherapy is effective for the removal of the psychopathological symptoms and/or the maintenance of effectiveness over time (decrease in relapses). In line with this, the presence of psychotherapeutic treatment in between two aeromedical examinations and/or in a given current timeframe should be evaluated carefully before being considered as disqualifying.

There is no evidence that online therapy less effective than face to face therapy, although the acceptance level might depend on age, culture and IT literacy. This kind of intervention can prove to be suitable with job challenges of aeronautical personnel, as it is compatible with shifts and distance from home. In general, all the psychosocial interventions are compatible with pilots', ATCOs and UAS pilots' duties and responsibilities.

When several conditions are met, some biological treatments for mental disorders are compatible with certification. When determining the compatibility of a certain treatment with certification, it is important to make a combined assessment of the risks related to the underlying disorder and the effects and side-effects of the treatment.

The self-declaration principle is weakened when it applies to people consuming psychoactive substances or suffering from mental disorders. Strengthening the link between peer support groups and the AMEs, the medical assessors and the mental health specialists, might work as a mitigation to manage the safety hazards related to the weakened self-declaration principle when it applies to mental disorders.

A critical approach towards CISM is useful, as literature is inconclusive and for some interventions, a harmful effect cannot be ruled-out.

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ABBREVIATIONS

ACRONYM	DESCRIPTION
ACT	Assertive community treatment
ADD	Attention deficit disorder
ADHD	Attention deficit hyperactivity disorder
AME	Aviation Medical Examiner
ANSP	Air Navigation Service Providers
AOC	Air Operator's Certificate
APA	American Psychological Association
APA	American Psychiatric Association
ATC	Air Traffic Control
ATCO	Air Traffic Controller Operator
CBT	Cognitive behavioural therapy
CIRP	Critical Incident Response Programmes
CISM	Critical incident stress management
COVID	Coronavirus disease
CYP1A2	Cytochrome P450 family 1, subfamily A member 2
CYP2C9	Cytochrome P450 family 2 subfamily C member 9
CYP2C19	Cytochrome P450 family 2 subfamily C member 19
CYP2D6	Cytochrome P450 family 2 subfamily D member 6
CYP3A	Cytochrome P450, family 3, subfamily A
CYP3A4	Cytochrome P450 family 3 subfamily A member 4
EASA	European Union Aviation Safety Agency
ECG	Electrocardiography
ECGT	Electrochemogene Therapy
ECT	Electro-convulsive treatment
EMDR	Eye Movement Desensitization and Reprocessing
EPPSI	European pilot peer support initiative
EU	European Union
FAA	Federal Aviation Administration
HIMS	Human Intervention Monitoring System
MAO-inhibitors	Monoamine oxidase inhibitor

MDMA	3,4-Methylenedioxymethamphetamine
MESAFE	Mental health for aviation safety
MHP	Mental health professional
NAA	National aviation authority
NSAIDS	Nonsteroidal anti-inflammatory drug
PET	Positron emission tomography
PSP	Peer support group
PTSD	Posttraumatic stress disorder
Q&A	Question & Answer
rTMS	Repetitive transcranial magnetic stimulation
SNRI	Serotonin–norepinephrine reuptake inhibitor
SSRI	Selective serotonin-reuptake inhibitors
TCA	Tri-cyclic antidepressants
UAS	Unmanned Aircraft Systems
US	United States
WHO	World Health Organization

1. Introduction

The present document is the D-1.2 REPORT ON THE REVIEW OF TREATMENT OPTIONS of the MESAFE project and provides an overview of existing evidence and procedures in treating mental disorders.

MESAFE stands for “MEntal health for aviation SAFETy”. It is a research project, funded by EASA under the framework of the European Union's Horizon Europe research and innovation programme. Started in May 2022 and lasting 2 years, the project aims at overcoming challenges preventing the effective implementation of the Aeromedical certification process for pilots and air traffic controllers (ATCOs) with regards to the incapacitation risk associated with mental health conditions.

To achieve this, MESAFE will assess new medical developments for the early diagnosis as well as treatment of mental health conditions which could pose a safety risk for aviation and would consequently lead to pilot and air traffic controller (ATCO) unfitness or the limitation of their medical certificate for safety purposes.

The MESAFE expected outcome will be as follows:

- evidence-based recommendations for updating the mental health requirements in Part-MED and Part-ATCO.MED in line with the medical developments;
- evidence-based recommendations for mental health assessment methods suitable for aeromedical fitness assessments;
- an impact assessment of the recommended regulatory changes;
- guidance material on the updates to the fitness assessment of applicants for aeromedical examiners and medical assessors;
- guidance material on mental health assessment and the updates to the fitness assessment of applicants for peer support groups and the trained peers involved in the peer support programs; and
- material to support the management of the proposed changes, e.g., presentations of the results obtained under this contract and training material suitable for professional audiences.

MESAFE will be a safety practitioner driven project, fostering the communication and cooperation among Aeromedical examiners, Mental Health Specialists, Aviation Psychologists and peer support groups, for the sake of civil protection of citizens in the fight against safety hazards related to mental disorders during flight and air traffic control operations by a set of cooperation actions. In line with this, the project will put at the centre of the research not only aeromedical examiners and medical assessors but also the applicants (pilots and ATCOs), and will assess and evaluate how the mental fitness certification process affects them, and how they perceive it, while respecting EU fundamental rights.

This deliverable includes a state-of-the-art synopsis of the recent scientific literature about methods and procedures to treat mental disorders. This study will feed the next steps of the project, aimed at developing and validating treatment options or assessing the applicability of existing procedures for use in the aviation environment.

1.1 Background

This project was launched by EASA as an initiative to include the study of mental health of pilots and ATCOs as well as its screening and monitoring as one of the prioritised topics in the area of health to be updated in Aviation Medicine.

The Mental Health topic has been the subject of great attention after the Germanwings accident of 2015 and has led to important regulatory integrations for the mitigation of the related incapacitation risk. The Commission

Regulation 2018/1042 was a first attempt for building proper barriers against the incapacitation risk due to mental disorders of safety-critical operators (EU Commission Regulation 2018/1042).

The Regulation introduced new technical requirements and administrative procedures related to implementing support programmes, psychological assessment of flight crew, as well as systematic and random testing of psychoactive substances to ensure medical fitness of flight and cabin crew members.

Mental Health has therefore been clearly identified as an element of risk and consequently the state of Well-being as an enabling factor. A different attention and treatment have been reserved to the pre-clinical states of the operational front-line staff to whom companies must offer a support service in a confidential and friendly atmosphere with peers or through suitable professionalism; this must be done promptly and long before crisis situations, which may arise as a result of life and work events, are structured in pathological disorders according to a line of progression (EASA, Easy access rules for the EU Regulation 2018/1042).

This project works as follow-up of these activities, extending the commitment to address the psychological aspects in aviation as well as the management of the mental health elements of personnel seeking a certification of aeromedical fitness, including not only pilots and aircrew, but also air traffic controllers.

1.2 Scope of the document

The present document is the second deliverable of the Task 1 of the project and includes the output of subtask 1.3.

Task 1 *“Review and critique of the state-of-the-art in the diagnosis and care of mental health conditions”* lasts 6 months and runs in parallel to Task 3 *“Identify screening and confirmation tests for psychoactive substances suitable for use in aeromedical fitness assessment”*. The objective of this Task is to produce a gap analysis of currently available diagnostic methods and treatment options for mental health conditions in aviation aeromedical examinations for mental fitness, based on a review of currently existing diagnostic and treatment procedures.

Subtask 1.3, *“Review existing evidence and guidelines regarding the treatment of mental health conditions and assess their compatibility with the duties for each class of aeromedical certification”* has carried out a review of the state-of-the-art treatment options for the most frequent mental disorders and their potential incompatibility with the different classes of aeromedical certification.

In line with this and following the EASA technical requirements, this document provides the following information:

- Review of the state-of-the-art treatment options for the most frequent mental disorders
- Review of the state-of-the-art treatment options’ potential incompatibility with the different classes of aeromedical certification
- Overview of mental health care methods and options currently used in aviation
- Main findings

1.3 Structure of the document

This deliverable is structured as follows:

- Section 1 is this one, introducing the document in the framework of the project and its research ambition and scope;
- Section 2 provides information about the state-of-the art treatment options for mental disorders, including biological treatments and psychosocial interventions;

- Section 3 reviews the aforementioned options in line with their compatibility with pilots', Air Traffic controllers' and UAS pilots' duties;
- Section 4 presents the mental health care methods and options currently used in aviation
- Section 5 collects main findings
- Section 6 is the bibliography

2. Overview of the state-of-the-art treatment options for the most frequent mental disorders

2.1 Biological treatments

2.1.1 Antidepressants

2.1.1.1 SSRI's

SSRI's (selective serotonin-reuptake inhibitors) are considered the first-line biological treatment of depressive and anxiety disorders, as they are generally well-tolerated and have a good clinical effect (Zorgstandaard Depressieve stoornissen 2018, Spijker et al 2013). The best known and studied SSRI's are fluoxetine, sertraline, paroxetine, citalopram and escitalopram. They inhibit the reuptake of serotonin in the presynaptic neuron, thereby increasing the availability of serotonin in the synaptic gap. The exact mechanism of action is unknown, but in the longer term SSRI's cause a post-synaptic modification of the serotonin-receptor, and a decrease of 5HT₂-receptors. It usually takes several weeks for depressive disorders, and up to two to three months for obsessive-compulsive disorders, before patients notice an effect. Then, patients may experience a less depressed mood, feeling less anxious, have less panic and less obsessive-compulsive symptoms. (Farmacotherapeutisch Kompas). Also, after recovery, SSRI's may be helpful in preventing a relapse. Unfortunately, the clinical response varies significantly between patients. A substantial number of patients who do not respond to a first SSRI, will have a response on a second one (Spijker et al 2013).

Common side-effects of SSRI's are gastro-intestinal (nausea, vomiting, diarrhea, constipation), sleep problems (either increased sleepiness or insomnia), headaches, dizziness, a dry mouth, hyperhidrosis, and sexual dysfunction (decreased libido, erection problems, difficulties in getting an orgasm). Especially during the starting phase, some patients may experience an increased feeling of anxiety or increased depressed feelings. Rarely, patients develop (increased) suicidal thoughts during the starting phase. Also, rarely starting an SSRI can cause a manic episode, because of a hidden bipolar disorder (Farmacotherapeutisch Kompas). For these reasons, during the starting phase and after increasing the dosages, patients should be monitored closely, and be well instructed what to do and who to contact in case of an emergency. However, many of the side-effects diminish or disappear after a few weeks, and most patients tolerate SSRI's well.

SSRI's have relatively little interactions with other drugs. Still, caution is necessary with other serotonergic agents because of the increased risk of a serotonin-syndrome (over-stimulation of serotonin receptors which may cause severe sickness, neurological symptoms and in severe cases, death) (Sadock et al 2018). Also, a combination of SSRI's and NSAIDs or anticoagulants may cause an increased risk of (gastro-intestinal) bleeding (Farmacotherapeutisch Kompas). As almost all other psychotropic drugs, SSRI influence the QTc-time. This is hardly ever significant (except in case of comorbid cardiac disease), however caution must be taken with other drugs that influence QTc-times as well.

When making a choice between the various SSRI's, it is important to keep in mind that paroxetine has a very short half-life (one day), making that patients who forget to take their medication for one day may already get withdrawal symptoms, and that tapering and stopping paroxetine may in some cases be quite difficult. On the other hand, fluoxetine has a half-life of 4-6 days, making that forgetting one dosage generally causes no symptoms and that tapering is easy, but on the other hand that switching to a different antidepressant may take more time. The half-life of sertraline, escitalopram and citalopram is a bit more than one day. Generally, these SSRI's are not difficult to taper.

When patients experience severe side-effects at the lowest dosages, or no effect at the highest dosages, cytochrome testing may be considered (Van Westrhenen & Mulder, 2020).

It is generally recommended to continue SSRI-treatment for at least a half year after the symptoms have been stable, and after this, to taper it very slowly to diminish the chances of a relapse. Unfortunately, a substantial portion of patients will suffer from a relapse after stopping their antidepressant, and in these patients, long-term or in some cases life-long treatment is advised (Zorgstandaard Depressie 2013).

2.1.1.2 SNRI's

The best known SNRI's are venlafaxine and duloxetine. As well as inhibiting the serotonin re-uptake, these agents also inhibit the re-uptake of norepinephrine. They are generally considered the second treatment step, if an SSRI is not effective (although many clinicians will choose to try a different SSRI first). Side-effects are largely similar to those of SSRI's, but especially venlafaxine is well-known to cause extremely vivid dreams. In the long term, it may lead to increased cholesterol-levels. (Farmacotherapeutisch Kompas). Whereas venlafaxine more frequently causes a weight-gain, duloxetine often causes weight loss and dizziness (Farmacotherapeutisch Kompas).

2.1.1.3 Tri-cyclic antidepressants

Compared to SSRI's and SNRI's, tri-cyclic antidepressants generally cause more side-effects. These agents also inhibit the synaptic re-uptake of norepinephrine and/or serotonin, but they also have anticholinergic and/or antihistaminergic properties. Due to their side-effects, TCA's are generally considered the second or third line of treatment, after a SSRI or SNRI, although some clinicians may prefer to start with a TCA, and it is often prescribed as the first drug in severely depressed patients that have been admitted to a clinic (Zorgstandaard Depressieve stoornissen 2018). Best known are nortriptyline, amitriptyline and clomipramine. Most side-effects are due to the anticholinergic properties. Often, a dry mouth, gastrointestinal side-effects, urine-retention, problems with accommodating, sedation, orthostatic hypotension, weight gain and sexual problems are reported (Farmacotherapeutisch Kompas). TCA's have the advantage that they can be dosed and monitored by blood-levels. The TCA amitriptyline is also known for its effect on neuropathic pain, migraine and headache, although for these indications it is mostly prescribed in lower dosages than for depressive disorders. The TCA clomipramine is especially known for its effect in severe anxiety disorders, most notably severe obsessive-compulsive disorders (Zorgstandaard angstklachten en angststoornissen 2017).

2.1.1.4 Mirtazapine and bupropion

Mirtazapine and bupropion are antidepressants that do not fit into one of the above-mentioned categories, but that are often prescribed and therefore worth mentioning. Mirtazapine (and mianserine) stimulate the release of norepinephrine. This increases the release of serotonin. It also has strong antihistaminergic properties (Farmacotherapeutisch Kompas). Although it can be an effective antidepressant, it also has some important side-effects. Many patients experience a weight-gain. Also, due to its antihistaminergic properties, it may cause sedations and sleepiness. Due to this side-effect, mirtazapine is often prescribed in a low dosage as a sleep-agent.

Bupropion is an antidepressant that can be used for treating depressive disorders, but also for ADHD and to support smoking cessation. It inhibits the reuptake of norepinephrine and dopamine. Its exact working mechanism in depressive disorders is unknown. It is generally well tolerated and can be prescribed as an alternative to a SSRI (Sadock et al 2018). Common side-effects include sleeping problems, headache and dizziness. In high dosages, there is an increased chance of developing epileptic seizures (Farmacotherapeutisch Kompas).

2.1.1.5 MAO-inhibitors

These drugs inhibit the enzyme monoamine-oxidase. This inhibits the degradation of neurotransmitters such as serotonin, norepinephrine and dopamine, making them more available in the central nervous system. Although effective antidepressant drugs, they have important side-effects, such as orthostatic hypotension, dizziness, sleepiness, dry mouth and constipation. An important risk is that in combination with tyramine containing foods, (potentially lethal) hypertensive crisis may occur. Therefore, a strict diet with no tyramine-containing foods (such as several cheeses and prepared foods) has to be followed. Also, there are several and potentially harmful interactions with other drugs (Farmacotherapeutisch Kompas). Therefore, MAO-inhibitors are usually reserved for those patients in which other treatments fail (Spijker et al 2013, Zorgstandaard Depressieve stoornissen 2018).

2.1.1.6 Electro-convulsive treatment

Usually, electro-convulsive treatment is reserved as a last-resort treatment for severe depressive disorders, or in severe cases where catatonic features occur, or patients cannot eat and drink anymore. It requires general anaesthesia before the shocks are applied. An important side-effect is memory loss, especially for things happening during the treatment period. Also, patients often encounter cognitive problems, although these may also result from the underlying depressive disorder. An ECT -treatment usually takes several weeks to months, with two to three treatment sessions per week. In some patients, long term maintenance treatment to prevent relapses, is necessary (Van den Broek et al 2010).

2.1.1.7 rTMS

A relatively new development is rTMS (repetitive transcranial magnetic stimulation). It gives short electromagnetic pulses to induce electrical currents in cortical neurons. There is increasing evidence that rTMS may have an antidepressant effect in patients who cannot tolerate a pharmacological treatment or who have received at least one pharmacological and psychotherapeutic treatment without sufficient effect. An important side-effect is that it may cause an epileptic insult, although the chances of this appear to be very small. In about 60% of the patients, the response lasts for 6-12 months. In some patients, maintenance-treatment may be necessary. As it seems to yield a good clinical response and side-effects are generally mild, there is a good chance that in the next few years, rTMS will gradually become more accepted as one of the preferred treatments for depressive disorders. A challenge is that in many countries, the availability of this treatment-option is still limited (Arns et al 2019).

2.1.1.8 Light-therapy

For patients with a seasonal affective disorder, light-therapy is likely a useful treatment option (Spijker et al., 2013; Zorgstandaard Depressieve stoornissen, 2018).

2.1.1.9 New developments

Several research groups study the antidepressant properties of psychedelic drugs. The most promising developments are MDMA, ketamine and psilocybin.

MDMA is getting increased attention as a potential option for treatment-resistant PTSD. Mostly, it is used to support a psychotherapeutic process (Breeksema et al., 2020; De Gregorio et al., 2021).

Ketamine has for long been used as an anaesthetic drug, but it is increasingly being recognized for its antidepressant properties. In some countries it has now been registered for the treatment of treatment-resistant depressive disorders. Important side-effects are nausea, dissociation, dizziness, headache and hypertension (De Gregorio et al., 2021; Sadock et al., 2018).

Psilocybin is the active ingredient in psychedelic mushrooms, and is studied for the treatment of depressive and anxiety disorders in several countries. Results are promising, but it is not yet accepted as a regular treatment option (Carhart-Harris et al., 2021).

The last year, increasing research is being done on the beneficial effects of a healthy diet. Although the scientific evidence for most interventions is scarce, omega-3 fatty seems promising (Thesing, 2020).

2.1.2 Anti-anxiety

2.1.2.1 Anxiolytics

The cornerstone of the biological treatment of anxiety disorders is with antidepressants. However, severe anxiety or panic attacks, as well as severe sleep problems or severe agitation may be treated by benzodiazepine-agonists. Although there are several different benzodiazepines, their mode of action is similar, and the main differences are in how fast they act and how long. Besides anxiolytic and sleep-inducing, all benzodiazepines may cause sedation, decreased alertness and muscle relaxation. In most countries, driving or operating heavy machines is not allowed when under the influence of a benzodiazepine. Also, benzodiazepines are prone to cause dependency and addiction, and -except for those patients with severe and debilitating mental disorders- are recommended to be prescribed only for a limited period of time.

2.1.2.2 Brain surgery

In severe, treatment-resistant obsessive-compulsive disorders, deep-brain stimulation can be considered, as well as a cingulotomy (Sadock et al., 2018).

2.1.3 Stimulants

In the treatment of Attention Deficit Hyperactivity Disorder and in Attention Deficit Disorder, most often methylphenidate and amphetamines (dexamphetamine or lisdexamfetamine) are prescribed. In some patients with an autism spectrum disorder, they are also prescribed off-label. Patients often experience better concentration and less hyperactivity. Common side-effects include a loss of appetite, weight-loss, sleeping disorders, headaches, and an increase in heart rate and blood pressure (Farmacotherapeutisch Kompas, Cortese et al., 2018). A rare, but potentially dangerous side effect in the starting phase is the development of a psychosis or a mania as a result of a hidden bipolar disorder. In rare cases, there can be misuse and addiction. However, compared to other psychotropic drugs, treatment for ADHD is generally well tolerated by patients. In many countries these drugs are listed as forbidden substances and travelling inside but especially outside the EU with these medicines may cause difficulties.

If methylphenidate or (lis)dexamphetamine is not effective, treatment with the stimulant modafinil (which is also being prescribed for narcolepsy) or with the non-stimulants atomoxetine and bupropion may be considered. Modafinil often causes headaches and is less well studied compared to the other treatment options. The advantage of atomoxetine is that it works relatively long and that there is no risk of addiction. Side-effects include dizziness, a dry mouth, less appetite, nausea and feeling tired. As said, also the anti-depressive agent bupropion may be considered in the treatment of ADHD.

2.1.4 Antipsychotics

Antipsychotics can be broadly divided into two subgroups, the classical and the atypical antipsychotics. Whereas the classical antipsychotics primarily act by blocking the dopamine D2-receptor, the atypical antipsychotics block several more receptors. Antipsychotics are prescribed in the treatment of schizophrenia and other psychotic disorders, but also during manic episodes, and in severe obsessive-compulsive disorders. They can

also be used to support patients with severe personality disorders, severe autism spectrum disorders or in severe PTSD. Furthermore, they may be prescribed in tic disorders and in rare cases of severe nausea or itching.

Increasingly, due to their antihistaminergic properties, low dosed atypical antipsychotics (mainly quetiapine) are prescribed to aid sleep in a broad range of mental disorders, such as depressive and anxiety disorders. However, prescribing antipsychotics for this purpose, which is mostly off-label, is subject to discussion (Boldingh Debernard, 2019).

As most psychotropic drugs, antipsychotics influence QTc-time. Classical antipsychotics, due to their blocking of the D2-receptor, often cause so-called extrapyramidal side-effects, particularly in high dosages. Features may be parkinsonism, akathisia and dystonias. Also, they may have a sedative effect, may cause orthostatic hypotension and may lead to hyperprolactinemia (Farmacotherapeutisch Kompas). The best-known classical antipsychotic is haloperidol.

Atypical antipsychotics block more receptors of more neurotransmitters. Compared to classical antipsychotics, these cause more sedation and, in many cases, induce weight gain. There can be changes in lipid and glucose metabolism, and in the long-term patients are at an increased risk for developing cardiovascular disorders (although this risk may be further influenced by an unhealthy lifestyle). Also, anticholinergic side-effects are often seen (such as a dry mouth, constipation, problems with accommodating and urinary retention) (Farmacotherapeutisch Kompas). Commonly prescribed atypical antipsychotics are olanzapine, quetiapine, risperidone and aripiprazole. The atypical antipsychotic clozapine deserves special mention. It is one of the oldest, and, due to its broad receptor affinity, most effective antipsychotics. However, in rare cases it can cause agranulocytosis, which may lead to severe and possibly lethal infections. Therefore, during treatment, white blood cell count should be monitored, and in most guidelines, clozapine is reserved for treatment-resistant schizofrenia or the treatment of delirium in patients with Parkinson's disease (due to its low risk of parkinsonism).

2.1.5 Mood stabilizers

Mood stabilizers are typically used in the treatment of bipolar disorders, especially in type I bipolar disorder (in which both manic and depressive episodes occur). The best known is lithium. It can both be used for the treatment of acute manic episodes (although acute manic episodes are also often treated with an antipsychotic), and as a maintenance treatment. It is sometimes also prescribed for cluster headache. Lithium is reported to have an anti-suicidal effect (Del Matto et al., 2020). The exact working mechanism of lithium is unknown. Although an effective drug, lithium has a narrow therapeutic range and some important side-effects. Lithium is dosed by blood levels and can easily become toxic when the dosage is too high, in case of dehydration, or when a deliberate overdose is taken. Especially when starting, but also later during treatment, blood levels should be monitored frequently. As it is a salt, dehydration for example due to fever or diarrhoea may cause toxic lithium levels. Furthermore, lithium may damage the kidneys, even in therapeutic dosages, so the kidney function must be checked regularly. Also, thyroid function and parathyroid function have to be monitored, as these may be influenced by lithium (Kupka et al., 2015). Other common side-effects of lithium include polydipsia, polyuria, tremors and nausea.

As an alternative to lithium, the anti-epileptic drugs valproic acid, lamotrigine and carbamazepine may be used. Valproic acid is teratogenic and should if possible, not be prescribed to women that can or want to become pregnant. Other common side-effects are tremors and nausea. Lamotrigine prevents depressive episodes in patients suffering from a bipolar type I disorder. Most important side-effects are a skin-rash and headaches. Carbamazepine often causes leukopenia, dizziness, ataxia, sleepiness, nausea, urticaria and an elevated gamma-GT. Also, it induces CYP2C9, CYP3A and CYP1A2 causing interactions with several other drugs (Farmacotherapeutisch Kompas). Therefore, most clinicians prescribe carbamazepine only when other mood-stabilizers fail.

Several atypical antipsychotics also can be used in the treatment of acute manic episodes and for preventing new manic and/or depressive episodes, namely aripiprazole, olanzapine, quetiapine and risperidone.

2.2 Psychosocial interventions

The National Academy of Medicine defines psychosocial interventions as “interpersonal or informational activities, techniques, or strategies that target biological, behavioural, cognitive, emotional, interpersonal, social, or environmental factors with the aim of improving health functioning and well-being” (England et al., 2015). Interventions are intended by APA as “any action intended to interfere with and stop or modify a process, as in treatment undertaken to halt, manage, or alter the course of the pathological process of a disease or disorder” (American Psychological Association, 2015)

To date no widely accepted categorization of psychosocial interventions exists. The term covers a wide range of intervention types, including psychotherapy (e.g., cognitive therapy, behaviour therapy, humanistic therapy, integrative therapy, psychoanalysis, and psychodynamic therapies); community-based treatment (e.g., Assertive community treatment (ACT)); peer support services; contingency management; etc. Any theoretical perspective comprises a variety of different interventions that can target different and specific topics (e.g., specific mental issue, substance abuse).

There are some key characteristics shared by the psychosocial interventions (England et al., 2015):

1. Each intervention activities, techniques, or strategies can have nonspecific (e.g., the therapeutic alliance) and specific (unique theoretical orientation or approach e.g., cognitive restructuring) elements belonging to the intervention.
2. Then, each intervention influences the outcomes through changes across bio-psychosocial factors (e.g., perceptions and beliefs). Changes that can be observed in biological, behavioural, cognitive, emotion, interpersonal, social and environmental characteristics.
3. Lastly, the outcomes of such interventions cover one or more of these three aspects:
 - a. Health (e.g., reduction of physical and mental health symptoms)
 - b. Functioning (e.g., performance of tasks)
 - c. Well-being (e.g., life satisfaction, quality of life)

Below a comprehensive but not complete list of psychosocial interventions is presented. The rationale behind their presentation is based on the typology of delivery: individual, group, mixed.

Psychotherapy will be addressed in section 2.3.

2.2.1 Individual counselling

2.2.1.1 Motivational interviewing

Motivational interviewing is intended to support people to have difficulties in committing to change, enhancing their intrinsic motivation for change (Tsuang, 2006), where specific strategies and goals are set. Four key principles drive this approach: 1) expressing empathy, 2) developing discrepancy, 3) supporting self-efficacy, and 4) rolling with resistance (Chanut, 2005); and five are the stages of the process: 1) pre-contemplation, 2) contemplation, 3) preparation, 4) action, and 5) maintenance (Tsuang, 2006). One of the pillars of this approach to achieve change regards the confidence in the ability to be developed by participants. This treatment is often used for substance misuse and can be delivered either individually or in small groups.

2.2.1.2 Cognitive - behavioural counselling

A variety of interventions are included in the cognitive behavioural approach (Rector, 2012), ranging from counselling to psychotherapy and having in common some defining features:

- emphasis is put on a functional analysis of the behaviour, in order to understand the underlying reasons;
- importance is given to the skill training of understanding and acknowledging the reasons for the behaviour and the consequences.

For example, in case of substance misuse, a cognitive behavioural intervention aims at establishing a link between the drug use, the irrational beliefs, and misperceptions, to appropriately thoughts, feelings and actions, promoting suitable and effective ways of coping with stress (Jones, 2004 ; Jones, 2012 ; Thoma, 2015).

The cognitive – behavioural psychotherapy (CBT) will be addressed in section 2.3.1.1.

2.2.2 Group counselling

2.2.2.1 Social skill training

These trainings aim at supporting people in developing interpersonal skills in order to establish and maintain relationship with others. This approach helps dealing with conflicts, handling with social situations, etc. (Mueser, 2004; Mueser, 2013). These interventions are mainly highly structured using correcting feedbacks, roleplay and homework. They are usually held in groups but can also be used in individual treatments as a CBT counselling type.

2.2.2.2 Assertive community treatment (ACT)

These psychosocial interventions, provided by a community-based and interdisciplinary team, have a vast range of services and interventions (Stein and Test, 1980). Teams are formed by psychologists, psychiatrists, case managers, peer support workers, nurses and vocational specialists. The approach provides support to people with mental health and substance abuse through psychiatric treatment and rehabilitation. A central goal is to provide support helping skills development, maintaining community leaving, improving quality of life and avoiding as much as possible hospitalization. This approach is based on recovery goals, assertive outreach, treatment and support, crisis readiness and an array of psychosocial interventions such as family psychoeducation and motivational interviewing.

2.2.2.3 Psychoeducation

As a psychosocial intervention, psychoeducation teaches people to acknowledge their condition then presenting viable treatment options. This approach is intended for families, friends, but also individuals, on topics like coping strategies, problem-solving skills, recognition of signs of relapse and health protective behaviours. Psychoeducation can often help ease tensions, recovering partially from mental illness experiences. Examples of psychoeducation programs are peer-to-peer groups. Peer support will be presented more extensively and comprehensively in section 4.1.

2.2.3 Contingency management

Contingency management is a psychosocial intervention specifically designed for substance use disorders. This behavioural approach has an evidence-based practice established on operant conditioning principles, incentives to reward a person upon achieving and meeting the desired outcomes. In literature, incentives found to be effective include both voucher/cash equivalents and prize-based approaches (Silverman et al., 2008; Stitzer and Petry, 2006).

2.2.4 Standard Care

2.2.4.1 Case management

Case managers professionals are workers with a certification in case management and/or degrees in social work. A case manager has knowledge of local medical facilities, housing opportunities, employment programs and social support networks. They are aware of local, state and federal assistance programs. This person can serve an important role in helping people to get the best treatment possible. With the case management approach needs are assessed and resource availability are explained. A case manager will then keep in touch with the person to ensure a continuous treatment based on the person needs.

2.2.4.2 Residential treatment

Residential care is generally offered to individuals who are in need of a high level of treatment intensity (Twohig et al., 2015). A distinction exists between residential and inpatient treatment, where inpatient services offering medical refeeding and monitoring which is not commonly offered at residential care centres (Twohig et al., 2015). Residential treatment centres provide full-time housing and multi-disciplinary treatment in a non-hospital-based treatment setting. Treatment normally includes individual and group therapy components, meal support and various forms of recreational activities (Friedman et al., 2016). For individuals who are medically stable but require more intensive care than is offered by out-patient services, residential care may provide a valuable bridge between hospital-based inpatient treatment and traditional outpatient services (Thompson-Brenner et al., 2018).

2.3 Psychotherapy

Psychotherapy is a practice to treat mental disorders emerging from clinical psychology and psychiatry, and is provided by a psychotherapist (psychologist or doctor, adequately specialized), who deals with the treatment of psychopathological disorders of different nature and entity, ranging from personal discomfort to severe symptoms, and which can manifest themselves in symptoms that harm the well-being of a person to the point of hindering its development, often causing maladaptiveness in the life of the individual.

Etymologically the word psychotherapy leads back to the therapies of the psyche carried out with psychological tools such as interview, inner analysis, comparison, relationship, etc., in the purpose of changing the psychological processes which the discomfort or inadequate lifestyle depends on, and often featured by symptoms such as anxiety, depression, phobias, etc. To this end, psychotherapy makes use of application techniques of psychology, dividing itself into its various theoretical approaches: psychodynamic psychotherapy, cognitive-behavioural psychotherapy, systemic psychotherapy, humanistic psychotherapy, EMDR.

What follows provides brief explanation of such approaches.

2.3.1 Psychotherapeutic approaches

2.3.1.1 Cognitive-behaviour therapy

Cognitive-Behaviour Therapy (CBT) is currently considered internationally one of the most reliable and effective models for the understanding and treatment of mental disorders (Stewart R.E., Chambless D.L., 2009). It has assumed the role of treatment of choice for anxiety disorders, as attested by recent documents released by the World Health Organization (WHO, 2012).

This approach postulates a complex relationship between emotions, thoughts and behaviours highlighting how emotional problems are largely the product of dysfunctional beliefs that are maintained over time, in spite of

the suffering that the patient experiences and the possibilities and opportunities to change them, due to the maintenance mechanisms.

The underlying theory emphasizes the importance of cognitive distortions and subjective representation of reality in the origin and maintenance of emotional and behavioural disorders. This implies that it would not be events that would create and maintain psychological, emotional, and behavioural problems, but these would be rather largely influenced by the cognitive structures and constructions of the individual.

What characterizes and distinguishes cognitive psychotherapy, in fact, is the explanation of emotional disorders through the analysis of the relationship between thoughts, emotions and behaviours.

Cognitive-behavioural therapy (CBT) aims, therefore, to help patients identify recurrent thoughts and dysfunctional patterns of reasoning and interpretation of reality, in order to replace them and / or integrate them with more functional beliefs.

2.3.1.2 Psychoanalysis and psychodynamic therapies

The term psychoanalysis is the translation from German of the neologism used by Freud indicating a procedure of investigation of mental processes otherwise inaccessible to consciousness and represents, also, a therapeutic method having as its purpose the treatment of neuroses, based on a series of assumptions about the functioning of the psyche.

The goal of psychoanalysis is, therefore, to induce repressed/removed thoughts into the conscious state, thus strengthening one's ego. To bring unconscious thoughts to the level of consciousness, the classic method involves sessions in which the patient is invited to make free associations starting from their dreams.

Psychoanalysis is not an introspective method, since it does not presuppose an active role of the observer, but, on the contrary, the subject is required to let himself go to the flow of ideas that come to mind, free associations, a technique for which thought is allowed to run in order to let unconscious images emerge. So, the patient is required to tell everything that comes to mind, including things that he considers of little importance, unpleasant or embarrassing images. The exhibition can consist of a free narration, or it can start from images of a dream, from a lapsus, from a neurotic symptom. The task of the analyst consists in the interpretation of the experiences narrated by the subject, widening the understanding and highlighting those meanings that reveal unconscious desires and representations. Therapy aims to make the subject aware of his unconscious processes, and awareness should lead to the dissolution of the unconscious conflict and the neurotic symptom that emerges from it.

Another important element of psychoanalysis is the assumption, by the analyst, of a detached attitude that allows the patient to project during the analysis the thoughts and sensations on the analyst. Through this process, called transference, the patient can exhumate and resolve the removed conflicts, especially the childhood ones, related to the formation and family of origin.

2.3.1.3 Humanistic therapy

Humanistic psychotherapy represents a set of approaches and currents developed around the 60s in the United States as a reaction and alternative to the psychological orientations prevailing at that time: psychodynamic and behavioural orientation.

The need was to find a model that went beyond the dominant schemes, linked to deterministic conceptions that focused on a single aspect of the human being.

For this reason, humanistic psychology is also called the "third force", distinguishing itself precisely as a third element that went to undermine the now classical academic conceptions.

In particular, humanistic psychology focuses on the individual in his entirety and complexity, arguing that only a reading on several levels and from multiple points of view (emotional, neurological, behavioural, cognitive ...) can describe the human being.

Another fundamental point is the idea of the importance of subjective experience understood as the perception of the individual with respect to emotions, beliefs and needs, beyond logical interpretations.

But the central aspect of the humanistic approach is the belief that each individual possesses potential, often unexpressed, that must be discovered and developed in order to really talk about the well-being of the person.

Humanistic psychotherapy, in fact, promotes the authentic and creative expression of the personality that must not be "normalized", but valued in its uniqueness and diversity.

The humanistic approach in psychology is also called humanistic-existential because it refers to two strands of thought: humanism understood as a current that puts the human being at the centre, revaluing it with respect to pre-existing static and dogmatic conceptions, and existentialism, the philosophical current born in the '900 that reflects on the drama of the human condition, on the sense of loneliness and on the anguish that derive from it, but without falling into resignation and passivity.

One of the most important contributions is that of Carl Rogers who strongly supports the possibility of self-realization of the person, responsible for his own change.

2.3.1.4 EMDR therapy

Eye movement desensitization and reprocessing (EMDR) is a structured psychotherapeutic method that facilitates the treatment of different psychopathologies and problems related to both traumatic events and more common but emotionally stressful experiences.

It is an interactive and standardized psychotherapeutic approach, scientifically proven by more than 44 randomized controlled trials conducted on traumatized patients and documented in hundreds of publications that report its effectiveness in the treatment of numerous psychopathologies including depression, anxiety, phobias, acute bereavement, somatic symptoms and addictions.

EMDR therapy has as its theoretical basis the AIP (Adaptive Information Processing) model that addresses the unprocessed memories that can give rise to many dysfunctions. Numerous neurophysiological studies have documented the rapid EMDR post-treatment effects.

2.3.1.5 Systemic therapy

Systemic psychotherapy originates from the more generic theory of systems, deriving from the thought of mathematicians, physicists and engineers and was born in the late 40s.

This theory was reworked and expanded by Ludwig von Bertalanffy and was considered common to all scientific disciplines, since it explicitly defined the concepts of openness and closure of living systems, homeostasis, self-regulation and equifinality, that is, a series of concepts that are the basis of the regulation of each system.

The systemic-relational approach can be useful for people who believe they have difficulties in specific relationships (couple, parenting, work, etc.).

In particular, it can be useful for the occurrence of developmental problems by children, adolescents and young adults. Psychotherapeutic work is therefore not purely aimed at the treatment of the symptom presented but at the relational situations that generated it.

2.3.2 Psychotherapy effectiveness

Research on the effectiveness of psychotherapy has had a great development in the last 60 years, through some standardized methods such as meta-analysis, surveys, neuroimaging studies.

Meta-analysis consists in listening, viewing and statistical re-elaboration of the recorded sessions. Meta-analyses are not, of course, able to give totally generalizable results, given the specificity of each individual patient and each individual therapist; however, it is possible to take the comparative meta-analyses between the various psychotherapeutic approaches as guidelines for a generic evaluation of statistical efficacy. Numerous meta-analyses have reported that psychotherapy helps reduce medical expenses and hospitalization times, as well as reduce disability, morbidity, mortality and hospitalizations in psychiatric wards (Linehan et al., 2006; Pallak et al., 1995). When integrated into primary care, psychotherapy appears to reduce the cost of medical expenses by about 20-30% (Cummings et al., 2003). In addition, it is interesting to note that about 50% of patients prefer psychotherapy to drug treatments, due to the possible negative side effects of the latter. It would be reasonable to think that, if psychotherapy were proposed to patients who prefer it, there would be greater adherence to treatment (Deacon & Abramowitz, 2005; Paris, 2008; Patterson, 2008; Solomon et al., 2008; Vocks et al., 2010). The results over the past forty years reveal a significantly higher average efficacy rate for cognitive-behaviourally oriented treatments than others.

Other results of interest are for example those of the Depression Collaborative Research Program (Elkin et al., 1989), which have shown that, in the treatment of depression, cognitive-behavioural psychotherapy with or without Mindfulness protocol is at least as effective as psychotropic drugs. The result takes into account the rapidity of the removal of the symptom and the maintenance of effectiveness over time (decrease in relapses). Medications are most effective for more severe depressions. Other more recent studies have extended these findings to other types of disorders as well.

A series of recent studies have shown the effectiveness of psychotherapy, in particular cognitive-behavioural psychotherapy, also through Neuroimaging methods (examinations that visually record the functionality of neurons in the brain). The experimental studies made use of the current methods of in vivo visualization of the brain, which are positron emission tomography (PET) and functional magnetic resonance imaging (fMRI). Different groups of patients with obsessive-compulsive disorder, specific or social phobia, and others with major depressive or schizophrenic disorders were examined. Among these studies, Schwartz et al. tried to compare the effectiveness of the psychiatric approach through psychotropic drugs and cognitive-behavioural psychotherapy, both on the biological and behavioural levels.

The researchers found that psychotherapy brings significant changes in patients' functional brain activity, and such changes are closely related to clinical improvement. These changes also affect the functional activity of the areas, both cortical and subcortical, involved in the specific pathology, and not other areas. But what is interesting is that research has shown that both psychotherapy and medication are effective in the treatment of different psychiatric pathologies, both generating effective clinical improvement: both treatment options modify neuronal activity, often of the same areas of the brain, also inducing changes in the same direction of some biological parameters. In all psychotherapies, the better results are obtained, the greater the therapeutic alliance or trust between patient and therapist.

2.3.3 Online psychotherapy

Looking at different research and reviews, if it cannot be said with certainty that online therapy has the same value as traditional therapy (there does not seem to be enough data), it can certainly be said that: there is no evidence that online therapy is less effective than face to face therapy.

For example, Barak, Hen, Boniel-Nisseim et al (2008), did a meta-analysis on 64 studies (with a total sample of 9764 participants), which concerned different psychotherapeutic orientations and different types of disorders, and found that the overall effectiveness is comparable to face-to-face psychotherapy (Mean effect size: 0.53,

medium effect). Even a study on online CBT directed at patients with major depression or anxiety disorders, concludes that online CBT is a good alternative to the traditional one comparing costs and benefits (Heath Quality Ontario, 2019). Still, a review by Lewis, Roberts, Benthell et al (2018) that examines studies comparing traditional and online CBT for PTSD, highlights some benefits of online therapy, although the quality of the studies does not allow definitive conclusions on the comparability of treatments.

There is no evidence that online therapy is not effective even in critical or crisis situations, such as disasters, traumas, suicidal behaviors. On the contrary, online CBT interventions in crisis situations reveal good effectiveness (Silva, Siegmund, Bredemeier, 2015). There is no evidence that experiential procedures are not applicable and equally effective in online therapy. In contrast, interventions based on online mindfulness show efficacy ranging from medium to large effect size (Ma, She, Zeng et al., 2018).

Adherence is perhaps one of the critical aspects of online therapy: according to a review by Beatty and Binnion (2016) there are no definitive data on the lower or equal adherence in the two settings, but only that predictors of a higher adherence to the telematic setting are: female sex, high expectations on therapy, availability of time and personalization of treatment.

The reported data seem consistent with what is reported by therapists who implemented online therapy (Femia G. et al, 2020) during the COVID pandemic: once patients adhere to online treatment, they seem not to show particular difficulties and not report relational problems; in addition, there are no limits in the application of the CBT procedures normally used. The real problem concerns the adherence to treatment by patients who may not adhere both for purely psychological reasons, and above all for reasons related to the difficulty of organizing themselves with an online setting for lack of familiarity, space, privacy at home and so on. In part, probably, the lower adherence concerns an idea of less effectiveness and the presence of a prejudice about this method.

Culture, IT literacy and maybe age of the patients might also play a role. The ability to connect to the internet and go online is the result of specific digital skills, which relate to being able to access the equipment, software, data or internet needed to effectively participate in digital mental health services. A review of the combined effects of age and digital competence on the use of online health and social care services demonstrated that higher age, starting from around the age of 60, was associated with a lower likelihood of using online services for receiving test results, renewing prescriptions and scheduling appointments. Good digital competence was able to hinder the age-related decline in online services use, but only up to around the age of 80 (Heponiemi T., Kaihlanen A.M., Kouvonen A., Leemann L., Taipale S., Gluschkoff K., 2022). Another review, conducted in Italy in 2021, showed that the people interested in online psychotherapy are mainly people between 18 and 44 years old (Agostini M, 2021). Among these users, the 68% are even under 35 years old. Besides, the 71.8% are women and 28.2% are men.

In the recent IPPAC Conference taking place in London in the period 7-9 November 2022, representatives of pilot support programs from around the world shared their experience and it was revealed that depending on the cultural background, the age, and the support culture various options are used by the pilots asking for support. For example, while in Japan the pilots rather use mobile apps to ask and receive support, in the US and Australia they prefer to use face to face counselling, phone or even video counselling (IPPAC, 2022). Adherence could therefore also concern therapists. In fact, from the data on the difference between those who had previous experience and those who did not, it is clear that perhaps those who already had some experience of online therapy had greater ease in adhering to and favouring the compliance of patients to the online mode. Expertise does not concern either specific training on this modality or a preference for this mode or a large number of patients followed, but only the fact of having already had the opportunity (even just one) to deliver online therapies.

That said, the certain limits of online therapy perhaps concern on the one hand the greater fatigue for the therapist and on the other some specific psychosocial characteristics of the patient, as for example age, IT literacy and sense of intimacy.

Knowing the type of access an individual needs to use mental health digital services, such as a stable internet connection or access to a device that can be used for video conferencing, should help guide conversations with people who use these services to understand the barriers they might face. Key areas to take into account are:

- digital skills - being able to use digital devices such as computers or smart phones and the internet
- connectivity - access to the internet through broadband, wi-fi and mobile
- accessibility - services need to be designed to meet all users' needs, including those dependent on assistive technology to access digital services.

With this information, mental health practitioners can be more targeted in the design of their service and in the support, they can offer to an individual. Mental health practitioners should consider the minimum requirements needed to effectively engage in digital mental health services in terms of environment, hardware, software and assistive technology, and ensure any equipment they provide has the necessary requirements installed. For example: private space stable internet connection video conferencing or word processing software hardware such as laptops, tablets, phones, webcams, headsets assistive technology such as closed captions, translation services, screen readers (NHS Confederation, 2020).

A patient with greater difficulties with intimacy, on one hand is very favoured by online therapy (and this also emerges in a second work in progress (Femia G. et al., 2020): there are patients who feel more reassured and manage with this mode more easily to make the therapist access to highly emotional content); on the other, and perhaps for the same reason, online therapy becomes less of an experience of greater acceptance and familiarization with greater degrees of intimacy. Or, following this line of analysis, cultural distrust and personological suspiciousness are certainly characteristics that inhibit and make complex this type of intervention.

Some possible reflections, to be explored further, but on which there are no certain data, concern the non-verbal context, understood as the dynamic interaction of many elements, codes, messages, which influence and stimulate the global perceptual system, with which we enter into relationship with the environment and in communication with the other. Among these elements we can identify the gestural, the bodily, the movement, the proximal, (think of all the studies of proxemics, from Stern onwards), mimicry, smell, temperature, etc., in addition to the verbal one.

Perhaps, a drastic reduction of these elements in the interaction, or the transition from a proximal presence (although with limitations given by the blocked position and sitting and the setting that are used, except when body-oriented psychotherapies are concerned) could determine an influence on communication in therapy, but in reality, we do not know how much this phenomenon can be a limit, or simply a transformation. In fact, although it seems possible to expect that the telematic channel, involving a focus of interaction through the visual channel and the framing field of the camera (or even only of the audio channel, in phone calls, or only of the written verbal channel, in the case of chats) implies differences in approach and interaction, to date, we cannot define to what extent these changes involve real contraindications in terms of effectiveness.

On the other hand, it seems realistic to think that these variations play a role with respect:

- to the greater fatigue witnessed by all therapists;
- the difficulty of using some techniques;
- to the "psychological" resistance of a part of the patients, who in fact choose to suspend and not adhere to online therapy;
- to the "prejudices" of many therapists, who consider online therapy more complicated or perhaps less effective.

The interesting point is that it is not at all said that this important difference in setting leads to a general reduction in the effectiveness of the intervention. Therefore, in the light of the various observations offered,

we can conclude by stating that this modality (albeit as an integration and extension of the classical setting) seems to preserve the function of care, support and intervention also in terms of relationship, security and empathy, as well as offering itself as an element of transformation, evolution and enhancement of the standard mode of psychotherapeutic intervention.

Online psychotherapy is not the only digital service for mental health care. There are currently various self-help applications to monitor stress levels and provide mental health support (Tomasello P., Drogoul F., 2020). These range from heart rate measurement applications, to applications which, by means of a subjective stress assessment, offer a range of methods at various levels (e.g., meditation exercises, link to peer support groups and mental health specialists, etc.) to reduce stress levels. These applications allow users to keep track of mood swings and emotions experienced throughout the day and check, in the long run, which activities cause the most stress, so helping users make contingency plans to cope with subsequent stressful events. Links to mental health practitioners and support groups are also provided. Some examples are:

- Pacifica: <https://www.thinkpacific.com/>
- What's Up: <https://play.google.com/store/apps/details?id=com.jacksontempra.apps.whatsup>

2.4 Take-away messages

There are several evidence-based biological treatments for mental disorders. Although most biological treatment options cause side-effects, these are usually less severe compared to the disorder the treatment is prescribed for. Good care means that the side-effects of the treatment are less than the beneficial effects on the symptoms, meaning that there will be a net improvement. This is what all psychiatrists will aim for.

There is evidence that psychotherapy is effective for the treatment of mental disorders. Medications have proven to be most effective for more severe symptoms.

There is evidence that psychotherapy is effective for the removal of the psychopathological symptoms and/or the maintenance of effectiveness over time (decrease in relapses). In line with this, the presence of psychotherapeutic treatment in between two aeromedical examinations and/or in a given current timeframe should be evaluated carefully before being considered as disqualifying.

There is no evidence that online therapy less effective than face to face therapy, even if the level of acceptance may differ with age, cultural differences and IT literacy. This kind of intervention can prove to be suitable with job challenges of aeronautical personnel, as it is compatible with shifts and distance from home.

For the scope of MESAFE, the following take-aways can be taken into consideration:

Take away ID	Take away message
2.1	There are several effective biological and psychotherapeutic treatment options for mental disorders.
2.2	Online psychotherapy might be a suitable approach for aeronautical personnel, even if the level of acceptance may differ with age, cultural differences and IT literacy.
2.3	The presence of psychotherapeutic treatment in between two aeromedical examinations and/or in a given current timeframe should be evaluated carefully before being considered as disqualifying, as it works as a safety net to prevent relapses. It would be beneficial if the AME could consult the psychotherapist and obtain information regarding the evolution of the applicant

Table 1 - Take-away messages on state-of-the-art treatment options for mental disorders

3. Review of the state-of-the-art treatment options' potential incompatibility with the different classes of aeromedical certification

3.1 Pilots (Class 1)

3.1.1 Biological treatments

The compatibility of psychotropic drugs with the ability to perform flying or ATC duties cannot be determined without knowing the underlying disorder the psychotropic drugs are prescribed for, and the compatibility with flying or ATC-duties of the underlying disorder itself. In most cases, the risk in an individual pilot will be mostly determined by the underlying disorder, and only partly by the specific drug treatment that is applied. Nevertheless, as all psychotropic drugs have side-effects, which are in most cases most prominent during the starting phase, and less when a stable dosage is being used for a longer time, it is useful to discuss some psychotropic medications and other biological treatments that may influence the ability to fly or to perform ATC duties, while at the same time the underlying disorder is compatible with certification. Logically, the risks caused by, and the severity of the underlying disorder generally outweigh the side-effects of the medication prescribed for it. Therefore, biological treatments in most cases will have a beneficial effect on flying duties, for example if the concentration is enhanced or feelings of anxiety disappear. In many cases, the total risk resulting from both the underlying disorder and the treatment that is applied, is smaller than the risk of the underlying disorder itself, especially if the treatment is in a stable phase.

Mathematically, it can be depicted as follows:

Total compatibility with flight duties = compatibility of the underlying disorder x compatibility of the biological treatment (risks and side-effects) x benefits of the biological treatment.

When the total compatibility is larger than the compatibility of the underlying disorder, biological treatment may be considered, but only if the underlying disorder by itself is compatible with flying duties. For example, a psychotic episode is incompatible with flying duties, even if the patient is taking antipsychotic treatment.

From a conceptual point of view, it would be better not to consider established biological treatments whose effect and side-effects are known, incompatible based on their side-effects only, except for those treatments that have clear cognitive effects or act as a sedative agent. It would be better to include the biological treatment in a total estimation of risk factors (risks due to the underlying disorder, but also due to personal factors, comorbidities, and treatments) and protective factors (both from treatment, but also personal factors and psychosocial factors). This would lead to a more nuanced view of the pilot-patient as a whole. More important, stringent acceptability of certain treatments, with the exclusion of others, could lead to undertreatment. Both pilots and physicians may consider not to apply an optimal treatment if this could endanger the medical certification of a pilot. This would lead to undertreatment, increasing the risks associated with the disorder and prolonging sickness. Even worse, some pilots may not declare their treatment. It would be far better if the healthcare provider and the pilot-patient feel free to consider the treatment they consider optimal to enhance recovery (and therefore, safe flying), and that an assessment of its acceptability for flying duties is made afterwards.

As there is no convincing evidence in civil aviation and it is highly questionable from an ethical point of view, the use of psychotropic drugs to enhance performance in otherwise healthy individuals is not discussed here any further. Except for the rare event of specific research settings, aerospace medicine professionals and psychiatrists should refrain from supporting these practices. However, they should be aware that some pilots,

with and without mental disorders, may use psychotropic drugs from the black market with the sole purpose of enhancing their performance. This can be the use of benzodiazepines to sleep better in order to be more fit during the day, but also the use of methylphenidate to improve concentration or, even worse, lose weight or fight sleepiness.

The following points may be taken into account when determining the compatibility of psychotropic drugs with flying and/ or ATC duties:

- the underlying disorder, its risks and especially the risk of (unexpected) relapses
- side effects
- long term risks and side effects
- benefits of the medication (risks that are diminished)
- is the medication part of a larger treatment plan?

Given the fact that most side-effects, especially those that can imminently threaten safety, occur in the early treatment phases, it is recommended that during the initiation phase of a treatment, a pilot or ATC does not perform his duties. As for most drugs and disorders that are compatible with flying duties, the major side effects will present during the first four weeks of treatment, it is recommended that at least during the first four weeks of treatment the pilot does not fly. After four weeks, an evaluation can be performed, whereby possible side-effects should be monitored. However, besides the presence of side effects, it is even more important that the underlying disorder is in remission when a pilot starts flying again. In most cases, it takes about one to two months in an effective dosage for a drug to have an optimal effect. Consequently, when the symptoms are in remission, usually side-effects will also be stable for some time. In practice, the following guidelines may be useful:

- Flying may be considered when the symptoms of the underlying disorder are (to a large extent) in remission.
- Side effects must be stable and have no influence on the ability to perform flying duties.
- At least during the first four weeks after initiation of treatment, or after a dosage increase, a pilot should not fly.
- After four weeks AND when symptoms are in remission, an evaluation to resume flying duties can take place.

For example, in case of a pilot presenting with a depressive disorder who is being treated with an SSRI, this would mean that, if treatment is successful, he or she will be grounded for about at least three months after the initial presentation with a mental healthcare professional (as it takes some time to complete the diagnostic process, make a treatment plan and initiate SSRI treatment, and take some time for the treatment to be effective and to perform an evaluation. Especially during the initiation phase good collaboration between AME, occupational physicians and the treating psychiatrist is important. More detailed recommendations for this cooperation will be provided in later deliverables.

With the exception of some SSRI's, the experience with biological treatments in class I pilots, ATCO's and UAS operators is limited. Therefore, it may be considered to, if all other conditions are met, only to provide a waiver when the pilot is participating in a study protocol, such as mentioned under rule ARA.MED.330 Special Medical Circumstances (EASA, <https://www.easa.europa.eu/downloads/115485/en>) in which is mentioned that "When new medical technology, medication or procedures are identified that may justify a fit assessment of applicants otherwise not in compliance with the requirements, research may be carried out to gather evidence on the safe exercise of the privileges of the licence". This could be applied for a selected group of pilots or ATCOs and will,

besides good monitoring, also be useful to gather data for future use. Australian data suggest that such a protocol could be safe (Ross et al 2007).

3.2.1.1 Antidepressants

SSRI's

There is worldwide experience with the use of SSRI's in aviation (Ross et al 2007, Vuorio et al 2012). The extensive experience with these drugs in the general population and the fact that so many patients tolerate them well and experience tolerable side-effects, also supports this practice. It is further supported by the experience in aviation. There are no large commercial aviation accidents or incidents that were caused by pilot SSRI use, if the SSRI was on a stable dosage as a part of treatment supervised by a psychiatrist in close combination with the AME and/ or the airline's occupational physician. SSRI's are most commonly prescribed for depressive and anxiety disorders and, when these are in a stable remission, there is no sound argument not to qualify pilots. SSRI treatment can help to improve symptoms and also to prevent a relapse. If a patient develops severe side-effects during the early stages, cytochrome testing may be considered. Although it is not yet generally recommended in daily practice, in order to minimise the risk of severe side-effects and to keep the time a pilot cannot fly as short as possible, it can be considered to perform cytochrome testing in more cases before initiating treatment, depending on the availability of testing in the specific setting. This would require an impact assessment evaluating costs and benefits. When choosing the most preferable SSRI, it is important to realise that the differences in tolerability and efficacy of SSRI are not that large. A relative disadvantage of paroxetine is that tapering may be difficult due to its short half-life. A relative disadvantage of fluvoxamine is that it strongly inhibits cytochrome CYP1A2 and CYP2C19, and moderately CYP2C9, CYP2D6 and CYP3A4, leading to increased plasma concentrations of several other drugs. Generally, sertraline, citalopram, escitalopram and fluoxetine are the most prescribed and best tolerated SSRI's. It is good practice to prescribe an SSRI the physician is familiar with, and that is commonly used in the country the patient is living in.

With regards to prescribing SSRI's in airline pilots, there are some general guidelines advisable (that are also applicable to most other psychotropic drugs):

- The treatment should be indicated, initiated and preferably monitored by or under supervision of a psychiatrist.
- During the starting phase, there have been no signs of bipolarity or increased aggression or suicidality.
- The treatment is jointly supported by the mental healthcare provider, AME and occupational physician.
- The patient allows the free sharing of information between mental healthcare providers, AME and the occupational physician.
- At least one family member, friend or relative of the patient is aware of the treatment and is allowed to contact the mental healthcare provider when having worries about the patient. Preferably, this person supports the treatment and joins the patient at clinical follow-up visits from time to time.
- The patient uses a stable dosage for a reasonable amount of time.
- The disorder is in remission for a reasonable period of time.
- Side-effects are stable and tolerable.
- There are no sleep complaints.
- An ECG has been made with no significant increase in QTC time (as most psychotropic drugs tend to increase QTC-time, but generally with no clinical significance).
- If applicable, along with the pharmacological treatment, psychotherapy is offered, as a combination of these two tends to give better results.

- The patient is not using any drugs that give interactions with SSRI's, especially not if they can cause a serotonergic syndrome.
- During changes of the dosage or when stopping, the patient should not fly or perform ATC duties.
- Dose changes, stopping and tapering of the medication need to be supervised by a psychiatrist. Except in case of a somatic indication or severe side-effects, the medication should be tapered gradually. Sufficient attention should be paid to relapse prevention.
- It can be considered not to qualify pilots who have stopped their medication if no sufficient plan to prevent a relapse and to find care in case of a relapse, has been made.

Once again, this list only applies to risks in conjunction with medication use. In practice, the risk of the underlying disorder is almost always more important. For example, a pilot has been stable with SSRI treatment for the last six months. However, in the two years before commencing treatment he made five serious suicide attempts requiring a hospital admission and is being prosecuted for domestic violence during an aggressive outburst during that period. In this case, the underlying vulnerability is such that this cannot be compensated by a stable six-month biological treatment. Certification is not advisable in this situation. On the contrary, if a pilot suffers a first depressive episode, or a long-standing social anxiety, with no history of self-harm or aggression, and the complaints are in full remission after six months of treatment, this is entirely different. Now the risk of the underlying disorder is considerably smaller, and certification will likely be possible.

In pilots, the decision to stop antidepressant treatment is best made by the pilot and the treating psychiatrist together. Although in many countries it is common practice for general practitioners to monitor the tapering of antidepressants, given their safety critical work it is recommended that in class I pilots and ATCO's, this process is being monitored by a psychiatrist. Ideally, antidepressants (as well as other psychotropic drugs) are tapered slowly over several months, in order to prevent a relapse. Relapse-prevention can be considered essential during the tapering phase. Also, during tapering, side-effects may occur. The shorter the half-life of the drug, the larger the chance of side-effects will be. Common side-effects are a feeling of general malaise, headache, irritability and sleep problems. Generally, these last a few days up to a maximum of four weeks. It is recommended that for the first two weeks after lowering a dosage, a pilot does not fly, and then an evaluation takes place. In pilots who encounter severe side-effects during the first tapering steps, this period may need to be longer. After discontinuation of treatment, it is recommended that the pilot is being monitored for at least a year, in in case of doubt longer by a mental health professional to minimize the chances of relapse.

SNRI's

Although SNRI's generally cause more side-effects, they are tolerated well in the majority of patients, and there is no sound argument for excluding patients from flying duties using these drugs when the same prerequisites as in case of SSRI's are met, especially for the widely used venlafaxine and duloxetine.

With regards to venlafaxine, it is important to monitor the cholesterol levels, as these can be increased in long-term use.

Tricyclic antidepressants

As compared to SSRI's and SNRI's, tricyclic antidepressants tend to cause more side-effects, and their use in aviation professionals is more difficult. As in most countries, their use is not allowed in class one pilots, the experience with these drugs in commercial aviation is considerably smaller. The sedative effect may be troublesome. Nevertheless, many patients tolerate TCA's well without experiencing distressing side-effects. In that respect, there is no reason for disallowing them categorically, if there is a stable and well-monitored clinical

situation. It should be ensured that also with different rosters and working schedules, the sedative effect is not interfering with duties. Treatment should also be monitored by blood levels.

Bupropion

If a treatment with bupropion is well tolerated, although there is less experience with this drug in aviation, there are no sound arguments against its use in class I pilots, as long as the same criteria as for SSRI use are met.

Mirtazapine

With regards to mirtazapine, the sedative effect may also be troublesome, and in many cases lead to disqualification regardless of the severity of the underlying disorder. This is especially the case since most pilots have differing rosters and cannot go to bed and wake up at regular times. Only in rare cases, pilots will be able to use mirtazapine without a risk of sedation during their duties. Nevertheless, if there is sufficient proof that this is the case, there is no good reason to disallow mirtazapine categorically.

MAO-inhibitors

As MAO-inhibitors are generally reserved for depressive disorders that do not respond well to SSRI's, SNRI's and TCA's, in most cases the severity of the underlying depressive disorder will hinder certification. Nevertheless, if the disorder would be in a complete remission, their use in combination with flying duties is still troublesome, as the side-effects are considerable, and the dietary measures to comply with can be difficult when working as a commercial pilot. Only in rare cases, their use can be compatible with class 1 certification.

Electro-convulsive treatment

In the far majority of cases, the severity of the underlying disorder and the considerable relapse risk will exclude patients from obtaining a class I medical. The cognitive side-effects (memory loss) will be disqualifying in almost all cases.

Light therapy

As the risks resulting from light therapy in patients suffering from a seasonal depressive disorder are small, this treatment can be considered acceptable for classification. It is important though that the same conditions as with SSRI treatment are met, especially that the treatment is being supervised by a well-trained professional. Incorrect use of light therapy may cause sleeping problems. It is not advisable that pilots buy their own lights and use these without clinical supervision. Theoretically, it can be wondered if pilots would need light therapy when being exposed to the brightness of the sky when flying.

rTMS

This treatment is still too new and less established to be compatible with a class I certification. Nevertheless, as side-effects seem to be limited, it is important to follow the developments with this treatment option actively.

Ketamine, psilocybin and MDMA are still too new and too less studied to be considered acceptable for class one certification. However, it is interesting to follow the developments with these drugs.

3.2.1.2 Antipsychotics

In almost all cases, the risk from the psychotic disorder, including the risk of relapse when antipsychotic treatment is ceased, is such that class I certification is not possible. But besides the underlying risk of psychotic disorders, the sedative effect (especially of the atypical antipsychotics) is troublesome. In the classical antipsychotics, extrapyramidal side-effects may hinder psychomotor abilities. When patients stop their

antipsychotic, psychotic symptoms can appear within days. For these reasons, patients using antipsychotic drugs can only in exceptional cases be considered to qualify for class 1 certification.

3.2.1.3 Stimulants

The biological treatment of ADHD and ADD in itself is often well tolerated, and from that point of view, their use of stimulants in class 1 pilots would not be too problematic if the same conditions as in SSRI treatment would be met. However, the main feature of ADHD and ADD is difficulty with attention and concentration. Given the fact that ADHD and ADD tend to be present from the early ages, it would not be advisable that patients start a flying career, especially not if the disorder is so debilitating that drug treatment is necessary (Front and George miller 2022). Another problem with this medication is that most drugs only work for a limited period of time, and the need to take drugs several times a day (up to seven times per day for some patients using methylphenidate) may be difficult to combine with flying duties. Also, the longer acting stimulants do not work the entire day. This is difficult for pilots with constantly changing schedules. The risk of abuse, for example to fight sleepiness, is worrying. Also, travelling with these drugs internationally can be difficult. So, although the side effects of stimulants in themselves are not per definition problematic, their short acting times, the nature of the disorder they are being prescribed for and the risk of abuse make the compatibility of stimulants with class 1 certification troublesome.

3.2.1.4 Anti-anxiety

Anxiolytics

By their very nature, anxiolytics have a sedative effect, and their use is incompatible with flying duties. Only in rare cases, the use of a short acting benzodiazepine, such as oxazepam, temazepam, zolpidem or zopiclone e.g. to aid sleeping when off-duty, may be considered acceptable (provided that the mental condition is not disqualifying itself), if enough time is available for the effects of the medication to disappear before commencing flight duties. There is always a risk of misuse or dependency that should be kept in mind.

3.1.1.5 Brain surgery

Given the severity of the underlying disorders, brain-surgery will almost always be incompatible with commercial flying.

3.1.1.6 Mood-stabilisers

Given the risk of relapse and its potential hazards to flight safety, most patients taking mood-stabilisers will be disqualified because of their underlying condition and the risks associated with it. When a stable long-term situation is present, the use of mood-stabilisers can still be problematic. First of all, when a mood-stabiliser is stopped, in some patients' manic symptoms may occur within days. So, when a pilot would forget a mood stabiliser during a three-day trip, this could cause a manic episode. But also, the physical effects are concerning. Patients on lithium are susceptible to intoxication when they become dehydrated. This can be dangerous when staying in places with no or limited healthcare facilities. The specific environment of a commercial aircraft can further increase the risk of dehydration. The potential tremors are another potentially dangerous side-effect. Most patients taking valproic acid, lamotrigine and carbamazepine will be disqualified based on their underlying disorder, but otherwise it is important to consider any side-effects, and the risk of a relapse when the treatment is terminated. In conclusion, the use of mood-stabilisers can only be compatible in extremely rare cases.

3.1.2 Psychosocial interventions and Psychotherapy

Among psychosocial interventions and psychotherapies none of them is contraindicated. The most relevant challenges concern the compatibility with pilots' schedules and shifts.

The more the psychosocial intervention and psychotherapy approaches are integrated with pilots' job tasks and activities, the better it is to mitigate emerging mental health symptoms and stress. For that reason, online or combined face-to-face and online interventions might prove to be suitable in overcoming challenges related to spatial distance and shifts.

3.2 ATCOs (Class 3)

3.2.1 Biological treatments

The major impediment of biological treatments for mental disorders with regards to aviation is, besides the risk of the underlying disorder, the risk of sedation and a diminished cognitive and psychomotor performance. Therefore, the remarks made to class 1 certification are to a large extent also applicable to class 3 certification.

Also, for class 3, it is advisable that a total estimation of the risks is made, combining risks due to the underlying disorder, but also due to personal factors, possible comorbidities, and treatments and protective factors (both from treatment, but also personal factors and psychosocial factors).

The risk of mood disturbances during the early treatment phase may be slightly less when working as an ATCO compared to when actually flying but given the impact this may have on the ability to concentrate, it can still be considered better not to perform duties during the initiation phase of treatment, or when changing dosages. Perhaps the time off-work can be slightly shorter than in class 1.

Given the very small risk of QTC prolongation, a standard ECG test may not be necessary when commencing treatment in air traffic controllers.

Some of the physical risks of certain biological treatments are less important in class 3, as the nature of work is on the ground. For example, the dietary restrictions of MAO-inhibitors and the risk of lithium intoxication are less of a problem, but nevertheless the underlying disorder will in many cases be incompatible with ATC work.

In the event an ATCO can work only during regular work hours, the use of medication with sedative properties would be less problematic. For example, if an ATCO would only work during office hours, the use of mirtazapine in the evening will not be problematic. Even the use of benzodiazepines to aid sleeping can under circumstances be considered acceptable then.

3.2.2 Psychosocial interventions and Psychotherapy

Among psychosocial interventions and psychotherapies none of them is contraindicated. The most relevant challenges concern the compatibility with controllers' schedules and shifts.

The more the psychosocial intervention and psychotherapy approaches are integrated with controllers' job tasks and activities, the better it is to mitigate emerging distress. For that reason, online or combined face-to-face and online interventions might prove to be suitable in overcoming challenges related to work-life balance and shifts.

3.3 UAS pilots

3.3.1 Biological treatments

For pilots of remotely controlled aircraft, the nature of the operations they perform is essential to determine the compatibility of biological treatments with certification. Besides the specific properties of the aircraft (its weight and airspaces it is flying in), it is important whether the pilot works during regular hours or during

constantly changing shifts. It seems reasonable to apply the considerations made for Class 3 certification also to UAS-pilots. When working during regular hours, treatments which have sedative side effects are less problematic. For an UAS-pilot who only works during daylight period, taking mirtazapine in the evening in case of a stable depressive disorder may not be problematic. For some operations (for example only light aircraft in sparsely populated areas) less stringent requirements can be made compared to operating heavy unmanned aircraft in densely populated areas.

In line with Class 1 and 3 pilots, also in UAS-pilots, instead of categorically prohibiting certain treatments, it is advisable to perform a total estimation of risk factors (risks due to the underlying disorder, but also due to personal factors, possible comorbidities, and treatments) and protective factors (both from treatment, but also personal factors and psychosocial factors), before considering a treatment acceptable. In some UAS-operations, the risks caused by the operation will be smaller than commercial aircraft or air traffic controller operations, and therefore a larger risk from the underlying disorder, treatment and protective may be acceptable.

3.3.2 Psychosocial interventions and Psychotherapy

Among psychosocial interventions and psychotherapies none of them is contraindicated. The most relevant challenges concern the compatibility with UAS pilots' schedules and shifts.

3.4 Take-away messages

In general, all the psychosocial interventions are compatible with pilots', ATCOs and UAS pilots' duties and responsibilities.

When several conditions are met, some biological treatments for mental disorders are compatible with certification. When determining the compatibility of a certain treatment with certification, it is important to make a combined assessment of the risks related to the underlying disorder and the effects and side-effects of the treatment. In fact, the compatibility of a certain treatment with the ability to perform pilot or ATCO duties cannot be determined without knowing the underlying disorder and the risks related to it, as well as patient-specific protective and risk factors. For most biological treatments, except for those with severe sedating side-effects, it is recommended not to base the eligibility for certification only on the treatment that is applied, as this might lead to undertreatment. Instead, a total estimation of risk factors (risks due to the underlying disorder, but also due to personal factors, comorbidities, and treatments) and protective factors (both from treatment, but also personal factors and psychosocial factors) may be better.

For the scope of MESAFE, the following take-aways can be taken into consideration:

Take away ID	Take away message
3.1	In general, all the psychosocial interventions are compatible with pilots', ATCOs and UAS pilots' duties and responsibilities.
3.2	The compatibility of biological treatment options for mental Health with aviation duties depends on the duties, the disorder, the effects of the treatment, and the side-effects of the treatment. As a general rule, such evaluation must be made on an individual basis by a psychiatrist.
3.3	The following equation can be used as a basis for evaluation of compatibility with aviation duties: <i>Total compatibility with flight duties = compatibility of the underlying disorder x compatibility of the biological treatment (risks and side-effects) x benefits of the biological treatment.</i>

Table 2 - Take-away messages on the compatibility of mental health treatment options for each class of aeromedical certification

4. Overview of mental health care methods and options currently implemented in aviation

4.1 Peer support program

4.1.1 Overview of peer support programmes (PSPs)

The EASA Taskforce Report on Measures Following the Accident of Germanwings Flight 9525 (2015) details the philosophy of pilot peer support:

“Peer support structures provide individuals a place to turn to in order to share their issues with trusted peers in as close to a non-threatening environment as possible, with the knowledge that fellow pilots are likely to help rather than immediately seek to penalise a colleague. The structures also enable organisations to more easily approach individuals that display behavioural or other issues via their peers. As a last resort, reporting systems may be used in case of identified unresolved perceived safety issues. A well organised support system may prevent mental or personal issues from becoming a greater liability to both the individual’s career and the organisation’s safety performance” (source: EPPSI, 2020)

Following the above recommendation of the EASA Taskforce, the Commission Regulation 2018/2014 was made which mandates the design, implementation and conduct of Peer Support Programmes within all EASA AOCs since February 2021 (EASA, 2018; EU, 2020). In AMC1 CAT.GEN.MPA.215 Support programme, EASA has defined principles governing a support programme. It states that access to a support programme should:

- enable self-declaration or referral in case of a decrease in a flight crew member’s medical fitness with an emphasis on prevention and early support;
- if appropriate, allow the flight crew member to receive temporary relief from flight duties and be referred to professional advice.

At present, the regulation is only mandatory for Air Operator's Certificate holders (AOCs). It is, however, recommendable to apply the regulation also to other safety-sensitive professional groups in the aviation industry, such as ATC personnel, cabin crew, maintenance and platform personnel. Implementation of Support Programmes for these professional groups is possible according to GM7 CAT.GEN.MPA.215, which mentions “Nothing should prevent an operator from extending the scope of the support programme to include [...] other safety-sensitive categories personnel”. However, as the scope of the present project is limited to pilots and ATCOs, the considerations in the present report will be limited to these both groups. In that context, it would certainly be recommendable to apply the regulation also to Air Navigation Service Providers (ANSP) in order to prevent significant mental health problems of ATCOs. Although several ANSPs might have various assistance programmes in place, an overview of these programmes and their methods is lacking. Therefore, and because Pilot Peer Support is recently implemented in Europe, most discussions in the present report cover Pilot Peer Support programmes.

4.1.1.1 Rationale

Studies on the prevalence of mental health disorders in Europe showed that 27% of the adult European population (aged 18–65) had at least one mental disorder, such as substance use, psychoses, depression, anxiety in the year prior to the study (Wittchen et al., 2011). Although the prevalence among pilots and ATCOs

may possibly differ from the general EU population, is assumed that aircrew members and air traffic control officers (ATCO's) – being adult human beings - suffer from similar mental health conditions as the general public. A study by Wu et al. (2016) among US pilots showed a 12% incidence of depression and 4% suicidal thoughts (4%). Safety-sensitive responsibilities require pilots and ATCOs to perform at high levels of cognitive and mental function. Because of their personality types and perceived threats to their careers by medical licensing requirements, most of them are reluctant to disclose mental health problems to AMEs or seek assistance with common mental health conditions. The reason for this is stigma: the common belief and fear amongst pilots (and likely also among ATCOs) that any mental health or psychological issues, if known to the outside world, will have the immediate consequence of removal of their medical certificate, with the consequent possible loss of livelihood. This is illustrated by the results of a survey of Hoffman et al. (2022) among 3765 US pilots in which it was shown that 56.1% of the pilots reported a history of healthcare avoidance behaviour due fear for losing their aeromedical certificate. Although response bias and recall bias may have been limitations of the study, the results indicate that many potentially preventable or treatable mental health problems go unnoticed by AMEs and National Authorities. If such mental and psychosocial problems stay hidden for the aeromedical authorities, they might exacerbate into mental health disorders that could threaten flight safety.

Doctors (AMEs) cannot force pilots or ATCOs to talk about their mental health problems or disclose their problem by ticking YES in boxes 118 (Psychological/psychiatric trouble?), 119 (alcohol/drug/substance abuse?), or 120 (Attempted suicide?) of the EASA application form for an Aviation Medical Certificate. The decision to take the first step in opening up about mental health issues will always be a voluntary choice by the pilot, and the most important point of PSPs is making that step as easy and safe as possible. PSPs offer an effective opportunity for pilots to overcome barriers to seeking help and addressing their problems in an effective manner by guaranteeing a “safe harbour zone” where they can be open without fear of retribution or endangering their career and livelihood. In such setting pilots can be directed to appropriate treatment or help and can learn to cope with their life stressors. This may prevent more severe problems and improve wellbeing and job satisfaction

PSPs are to prevent that pilots or ATCOs with mental health issues are driven ‘underground’, but instead come forward to seek help. A successful PSP will help destigmatizing mental health issues and enhance flight safety, while at the same time allowing the airline to retain crews if and after they successfully went through treatment, rather than losing staff.

The importance of pilot support programmes became even more apparent throughout the COVID-19 pandemic. The pandemic, with all its associated consequences, has had a significant impact on overall mental health, including emotional, psychological, and social well-being of aviation personnel (EPPSI, 2020a). In the general population, the most common psychological disorders emerging were anxiety and panic, obsessive-compulsive symptoms, insomnia, digestive problems, as well as depressive symptoms and post-traumatic stress (Rogers et al., 2020). In future pandemics and their possible lockdowns, PSPs will have an important role as a low threshold and safe-haven to support aviation personnel with emotional, psychological, and social problems.

Globally there is a wealth of experience with PSPs, with programmes such as the Qantas / AIPA PAN having been in existence for nearly 30 years and Stiftung Mayday (Europe) for 25 years. The US based Human Factor Intervention and Motivation programme (HIMS, also called also called ‘Human Intervention Monitoring System’) has treated around 5000 pilots and returned them to flying under close supervision. Their success rate is 88-90%. Most, but not all, HIMS cases involve alcohol.

4.1.1.2 Types of PSPs

It is emphasized that a PSP is not an emergency service. In cases of medical or psychiatric emergencies, the first point of contact should always be an appropriate medical emergency service.

There are three basically different Peer Support programmes which can be run separately or can all be included in one larger Peer Support Programme.

- Substance abuse programmes (called “anti-skid” programmes in some countries/airlines);
- Critical incident response programmes;
- Programmes focusing on pilot’s problems.

Substance abuse programmes made to support pilots or ATCOs who have a drug or alcohol problem, whether it is identified by a positive test, via self-report, or peer report. These programmes include assessment, treatment, education, counselling, consultation with health care professionals, residential or non-residential treatment programs, monitoring and follow up action. Such programmes can best be run and coordinated by a Peer Support Programme (or ‘Peer Intervention Programme’) which is an independent body/foundation – in practice usually the professional pilot community led by a Mental Health expert that runs a programme into which pilots can self-report or report concerns about their colleagues in strict confidentiality and/or where pilots can turn to for advice and help with a specific problem, such as problematic substance use.

Critical Incident Response Programmes (CIRP) are a specialised form of peer support, as the stresses and reactions that are generated tend to come from a single traumatic incident. Being involved in a flying incident or accident can have significant traumatic effects on high-achieving professionals, such as pilots and ATCOs for whom any perceived failure to cope can have dramatic effects on their mental wellbeing and can negatively impair their professional performance. These effects can be very different reactions from those generated by ‘life stressors’. The Critical Incident Stress Management (CISM)-protocol used in CIRP needs specific training. Depending on the size of the PPSP and organisation, CISM can be offered by the same PPSP or can be a separate programme. More details on CISM will be presented in section 4.2.

Programmes focusing on pilot’s problems include mental health, psychosocial problems, work related problems, financial worries, health concerns, bereavement issues, relationship / family difficulties, social demands, and burn-out. Because such problems may lead to significant mental health problems in some cases (e.g. Hammen, 2005; Young, 2008), these programmes are aimed at prevention of severe mental health problems and/or safety risks and support pilots and ATCOs to successfully cope with above-mentioned life stressors. The emphasis is on early prevention and support.

Key objectives for a PSP are (EPPSI, 2020):

- To make it as easy as possible for a pilot or ATCO to have a conversation about issues which could potentially affect their safe professional performance.
- To direct the pilot effectively towards appropriate help.
- To provide a mechanism whereby a colleague pilot, or family or friend, can raise a concern about a pilot in a safe and non-jeopardy environment, and it will be acted upon if appropriate.
- To enhance the safety culture within the airline.

Key elements of an appropriate PSP are (EPPSI, 2020):

- A PSP should offer a Confidential Safe Zone to pilots, ATCOs, colleagues, and relatives
- Peers should be appropriately selected and trained

- The team should have a suitably qualified Mental Health Professional supporting peers
- There should be a Programme Lead, or coordinator
- Easy accessibility to the programme
- Clearly defined pathways to help
- The programme should have an Oversight Committee to fulfil the requirement of EASA AMC3(b) CAT.GEN.MPA.215: A support programme should be linked to the management system of the operator, provided that data is used for purposes of safety management and is anonymised and aggregated to ensure confidentiality and AMC3(a) CAT.GEN.MPA.215: procedures including education of flight crew regarding self-awareness and facilitation of self-referral.
- Peer intervention mechanism
- Education of flight crew and ATCOs regarding awareness of mental health issues and facilitation of self-referral.
- Data responsibilities. According to EASA: Disclosure of data to the operator may only be granted in an anonymised manner such as in the form of aggregated statistical data and only for purposes of safety management so as not to compromise the voluntary participation in a support programme, thereby compromising flight safety.

4.1.1.3 Confidentiality

Strict confidentiality is the cornerstone of any PSP. The EASA ED Decision supports confidentiality and protection of data in a dedicated AMC2 CAT.GEN.MPA.215: (a) The personal data of flight crew who are enrolled in a support programme should be handled in a confidential, non-stigmatizing, and safe environment.

The confidentiality of the support process is absolute for everyone involved, except for certain clearly defined circumstances where regulation and standard medical practice require disclosure of information with view to the safety of the person or the public, i.e. flight safety. In case of a serious safety concern confidentiality can be disclosed to the medical assessor of the Competent Authority of the pilot in case of:

- Imminent and high risk of harm to others
- Risk of bodily harm
- Failure to disclose would cause harm

Breaching of confidentiality is possible if the Mental Health Professional determines that there is a serious threat to flight safety, and the pilot refuses to self-report to the operational and medical authority. However, the threshold for breaching confidentiality is high and consent to disclosure is the preferred option.

Access of pilots or ATCOs to a peer support programme is possible via:

- Self-referral: a pilot or ATCO can self-refer by calling the contact Peer of the PSP who is on-call. The peer will take the client in and will discuss further steps with the client after consultation with the supervising Mental Health Professional (MHP = Clinical Aviation Psychologist, or Psychiatrist). If appropriate, the programme will allow the flight crew member or ATCO to receive temporary relief from flight duties and be referred to professional advice.
- A process whereby an individual (colleague, family, or friend) can raise a concern about a pilot or ATCO and that concern is then evaluated by the MHP. If the concern is considered sufficiently serious, the pilot or ATCO is then contacted and persuaded to self-refer for help. If the pilot or ATCO refuses to do

so, then the programme has the ability to remove that pilot or ATCO from the roster for further investigation.

4.1.1.4 Core Support Process (EPPSI, 2020)

To provide an insight of how the PSP process works and what can be expected, the core support process of a PSP will be briefly described below according to the guidance material published by EPPSI (EPPSI, 2020).

Programmes in the US, Australia, New Zealand and Europe indicate that between 70% to 80% of cases are classified as not needing further assistance beyond the Peer and are dealt with at the first basic stage which foresees the following process: within a confidential Safe Zone clients make contact with the programme. A Peer is then allocated to the case either manually by the Programme Lead / Coordinator or automatically by the website or app, depending on which method of contact is used. The Peer then texts the client to arrange a mutually convenient time to talk, and the first of possibly a series of conversations is held. The purpose of these conversations is to gather the relevant information from the client and work with her/him to get her/him to define and then quantify the nature and extent of their situation and problems. Then the Peer continues to work with the pilot (or ATCO) to help them come up with potential solutions to their own issues. Throughout the whole process, the Peer is mentored and supported by the Mental Health Professional (MHP), who is always available to guide the Peer as required through the case. This support will be a combination of advice on individual cases and also overall wellbeing of the Peer. Once the Peer has assisted the pilot in arriving at possible solutions, this may be sufficient for the pilot who can then go away and do what needs to be done by themselves. However, a minority of cases will require further support than the Peer/MHP combination can offer and will need to be directed towards external pathways to help.

This help will be along one of three pathways:

- **Medical / Psychological.** Around 20% of crew members with mental/psychological problems need to be referred to professional support (Stiftung Mayday, personal communication G. Fahnenbruck). In the Medical/Psychological route the MHP keeps an oversight of the initial referral via the Peer. The pilot self-refers to the relevant medical/ psychological care, while the MHP will guide this process in the right direction. It is likely that a pilot who requires specialist treatment will need an assessment as well as a referral. The various agencies which can do this include the pilot's AME, family doctor, the company aeromedical person, or the NAA.
- **Time off work to deal with immediate problems.** The MHP makes the judgement about a pilot's fitness to fly or what constitutes a threat to flight safety in conjunction with the consulting AME or company medical person. This will only be done with the pilot's consent. Pilot's name and case are protected by medical confidentiality. When a pilot needs to be taken off the roster, the Fleet office will be informed that the pilot is 'sick': No details.
- **Other.** The third pathway to help is also with the guidance and support of the Peer/MHP, who retains overview of the case and records basic notes in the programme system for statistical purposes. These cases may concern for example financial and employment issues.

4.1.1.5 The AME and PSPs

Currently, many AMEs are not (yet) familiar with the aims, methods, and procedures of PSPs. Therefore, information should be provided about the aims and procedures of PSPs during the AME training. AMEs should learn that PSPs are to prevent that pilots with mental health issues are driven 'underground', but instead come forward to seek help. They should further know that a successful PSP will help destigmatizing mental health issues and enhance flight safety.

AMEs should provide information for pilots about how the PSP system works and how to access the system in case of problematic drugs and alcohol use or mental health problems of the applicant or of a colleague. The AME should teach pilots or ATCOs about life stresses which can emerge during the professional career and how these can become mental health problems affecting performance, flight safety, and personal well-being. AMEs should also teach pilots that self-reporting of addiction or mental health problems will improve flight safety; that one can recover from addiction and/or mental health problems; and that self-reporting can be the start of regaining a healthy and safe pilot career. Evidence from the FAA (US) shows that in 2017 denial of medical certificates for mental health issues occurred in only 0.08% of cases reported and in the vast majority of cases pilots retained their medical certificate after declaring a mental health issue (Berry, 2018).

Although a pilot or ATCO may meet the fit requirements at the time of the examination, AMEs should consider recommending applicants to self-refer to a PSP in case of suspicion that the applicant's circumstances and/or life-stresses might -on longer term- lead to unfavourable developments in the applicant's mental health status or professional career.

In all cases, the AME or treating physician should clearly explain to the pilot which considerations the reason were to recommend referral to a PSP.

4.1.1.6 Conclusion

Peer Support Programmes, as recommended by the EASA Taskforce Report on Measures Following the Accident of Germanwings Flight 9525, are mandated by EASA within all EASA AOCs since February 2021. It would be recommendable to apply the mandatory regulation also to Air Navigation Service Providers (ANSP) in order to prevent significant mental health problems of ATCOs.

In AMC1 CAT.GEN.MPA.215 Support programme, EASA has defined the following principles governing a support programme:

- enable self-declaration or referral in case of a decrease in a flight crew member's medical fitness with an emphasis on prevention and early support;
- if appropriate, allow the flight crew member to receive temporary relief from flight duties and be referred to professional advice.

Pilots are reluctant to disclose their mental health issues to AMEs due to fear that mentioning mental health or psychological issues will have the immediate consequence of removal of their flying status. The decision to take a first step in opening up about mental health issues will always be a voluntary choice by the pilot, and the most important point of PSPs is making that step as easy and safe as possible. PSPs offer an effective opportunity for pilots to overcome barriers to seeking help and addressing their problems in an effective manner by guaranteeing confidentiality in a "safe harbour zone" where they can be open without fear of being punished or endangering their career. In such setting appropriate support and treatment options can be utilised in order to prevent problems that might threaten flight safety and pilot's career and wellbeing.

In many cases mental health is not a binary sick/not sick status but rather is it a continuum of well - to less well - to illness. In this continuum there are pilots and ATCOs feeling less well for whom deterioration to illness might be prevented by suitable support and/or treatment, while keeping them on an active job status or taking them temporary off the roster during treatment while keeping his/her licence. This group of pilots and ATCOs is currently less likely to disclose their problems to AMEs or seek help due to fear of losing their license. They keep working while their mental problems might endanger flight safety. It would, therefore, be safer to treat or support someone while s/he can continue working under controlled circumstances or take someone temporary off the roster during treatment while keeping his/her licence. Such approaches would favour safety and can be realised by a Peer Support Programme in good collaboration with national authorities. The success

of such approaches is shown by existing Peer Support programmes, such as Stiftung Mayday (Europe) and the US based Human Factor Intervention and Motivation programme (HIMS).

AMEs and aeromedical authorities should be aware that PSPs are an important tool to prevent mental health issues and disorders, that are often undetectable for AMEs (Bor R., Eriksen C., Oakes M., Scragg P., 2017), are becoming a threat to flight safety.

Pilot Peer Support Groups are the ideal available solution to provide a safety mitigation strategy to mental illness.

4.2 CISM: critical incident stress management

The intervention protocol known as Critical Incident Stress Management, or CISM, was created especially for coping with traumatic events (CISM International, 2021). It is a systematic, planned, and professionally acknowledged procedure for assisting persons involved in a critical occurrence in order to share experiences, feelings, learn about stress reactions and symptoms, and get referred for additional support if necessary. However, it is not psychotherapy. It is a confidential, voluntary, and educational practice that is occasionally referred to as "psychological first aid".

Depending on the circumstance, several CISM interventions may be employed. Groups, individuals, families, and workplaces can all benefit from variations of these treatments.

- Debriefing is a proactive intervention that entails a group discussion or discussion regarding a significantly troubling critical incident. Debriefing after a critical incident is also known as CISD. The CISD, which is based on fundamental concepts of crisis intervention, is intended to lessen the effects of a catastrophic incident and help those affected recover from the stress caused by it. A professionally trained team that combines professional and peer support staff facilitates the CISD. It is ideally conducted within 24 to 72 hours of the incident, but in rare cases it could take place later. It should be noted that the scientific evidence for many debriefing interventions is limited, and furthermore, a good body of evidence shows that it may actually be harmful by increasing the risk of developing PTSS. This is especially the case for interventions supervised by a mental healthcare professional (van Emmerik, A.A.P., Kamphuis, J.H., e.a. 2002; Roberts et al, 2019).
- Defusing is an intervention that is a shorter, less formal version of a debriefing. It is best carried out one to four hours after a catastrophic incident and typically lasts between 30 and 60 minutes, though it may last longer. Normally, it is not carried out for longer than 12 hours after the event. It is a discreet and voluntary opportunity to learn about stress, discuss responses to an occurrence, and express feelings, similar to a debriefing. The major goal is to stabilize those who were affected by the occurrence so they can resume their regular lives without undue stress. A formal debriefing should be required when necessary.
- Loss and Grief Sessions help participants understand their own grieving emotions and foster an environment that is open and favourable to discussion about the circumstances of the death. Sessions can be held in groups or individually.
- Crisis Management Briefing is a large, homogeneous group intervention used before, during, and after a crisis to communicate facts, facilitate a brief, controlled discussion, Q&A, and provide information on stress-resilience skills and/or other available support services. It can be repeated as situations change.
- Critical Incident Adjustment Support offers individuals, families, or communities multifaceted humanitarian aid to help them deal with the fallout after an incident and overcome the effects of a fatality or injury.

- Pre-crisis Education provides a foundation for CISM services. It combines incident awareness, crisis response techniques, and the development of coping skills for stress that can mitigate serious issues that could occur. It comes in the form of a handbook for employees, an electronic book, workshops, and/or training sessions.

4.2.1 CISM in aviation

According to the EU Regulation No 2017/373 each ANSP in Europe should have established a CISM programme starting from January 2020.

CISM, in aviation, is a comprehensive and interconnected peer-based program designed to support colleagues after a significant incident. The goal is to control the stress reactions produced on by the critical event (not defined by the severity of the event, but always referred to the individual reactions of the person affected) and regain the person's capacity to work.

EUROCONTROL supports the implementation of a CISM programme with the following material:

- [CISM Implementation Guidelines – a comprehensive compendium](#)
- [CISM Quick Reference Guide - an abridged version of the comprehensive one](#)

The "CISM Implementation Guidelines" is an extensive compendium that includes background information on CISM, definitions, CISM intervention tools, fundamental organizational structures, and an implementation plan that addresses peer selection, program promotion, CISM trainings, program maintenance, as well as practical checklists and samples. The most crucial procedures are summarised in the CISM Quick Reference Guide, which offers a concise summary.

4.3 Take-away messages

The EU Part-MED regulation states that if, in-between two medical examinations, a pilot suffers from a decrease in medical fitness or takes any prescribed or non-prescribed medication which might interfere with flight safety, he/she shall seek the advice of an AME, who will decide whether he/she is fit to resume flying. So, managing the risk of having an unfit pilot on board / ATCO is partially based on the safety assumption that the applicant will self-declare her/his decrease in medical fitness. There is evidence that this principle might fail in some cases (BEA, 2015).

Three main factors might contribute to this failure. First, while suffering from a disease with symptoms of psychiatric disorder, a person may have mental abilities altered, with a probable loss of connectedness with reality and therefore a lack of discernment. Secondly, the financial consequences of losing license would reach considerable financial loss, which might not be covered by loss-of-license insurance. Thirdly, the consequence of losing license might compromise professional ambitions, self-esteem, social recognition and job motivation. Last but not least, the potential impact in terms of safety may be underestimated by applicants, who may overestimate their ability to compensate their decrease in fitness.

The self-declaration principle is therefore weakened when it applies to people consuming psychoactive substances or suffering from mental disorders.

So, mental health problems may be undetectable to AMEs because applicants are sometimes reluctant to disclose them (Bor R., Eriksen C., Oakes M., Scragg P., 2017). This reluctance is independent of the AME's ability to:

- treat information confidentially
- keep the applicant fly/control air traffic as long as possible

It is just a natural self-protective behaviour among applicants and a system with inherent structural weaknesses, leaving uncovered holes in the transport organizations’ barriers against the incapacitation risks related to acute or chronic mental disorders.

PSP can help overcome these challenges:

- By helping to prevent escalation of mental health problems
- By easing self-disclosure
- By providing access to accurate medical information so as to support applicants with medical licensing issues or concerns
- By detecting signs and symptoms of decreased fitness in between two medical examinations
- By promoting a mental well-being culture in a just-culture oriented work environment
- By reporting, discussing and mitigating the impact of organizational stressors on mental health of safety critical personnel

On the other side, The AME can recommend various ways to address mental issues outside of the medical, in order to prevent them becoming an issue that could impact the applicant’s fitness to fly / control air traffic in the future. This might include Peer Support Programmes AMEs should be trained to know the key–principles and the aims of the local PSP(s) and fully utilize its opportunities.

In line with this, the majority of the respondents (72,6%) of the MESAFE online survey targeted to AMEs agree that Peer Support Groups should work closely together with AMEs (for a detailed data analysis of the survey please refer to the MESAFE deliverable D1.1 Report on the review of diagnostic measures). However:

- a considerable percentage of respondents (36%) have never consulted peer support groups
- half of the respondents consult Peer Support Groups only when a particular need arises

Two questions are prominent in this light: what criteria to use to call for peers? What are the challenges preventing the cooperation with peer support groups? This will be discussed in the next deliverables of the project.

In the framework of the MESAFE project, it is proposed to strengthen the link between peer support groups and the AMEs, the medical assessors and the mental health specialists, thus promoting an integrated approach for mental health assessment, monitoring and care. This will work as a mitigation to manage the safety hazards related to the weakened self-declaration principle when it applies to mental disorders.

Such approach delivers a message in which the safety of aviation operations corresponds to the mental health of professionals in charge of generating it.

A critical approach towards CISM is useful, as literature is inconclusive and for some interventions, a harmful effect cannot be ruled-out.

For the scope of MESAFE, the following take-aways can be taken into consideration:

Take away ID	Take away message
4.1	Peer support programmes are an important supplement to professional care as they may provide a low threshold possibility for applicants who otherwise might hold off or avoid making contact for fear of losing their licence or bring subject to stigmatisation. The role of the AME is different from the

different roles within the Peer-support system. It is important that confidentiality, roles and working relationships are carefully considered and discussed, in order to build Trust and confidence on the part of the applicants.

- | | |
|-----|--|
| 4.2 | Peer support programmes implementation should be extended to ANSPs. |
| 4.3 | AMEs should work closely with mental health specialists and peer support groups. |

Table 2 - Take away messages on mental health care methods and options currently implemented in aviation

5. Main findings

This section wrap-ups the take-away messages included in this report.

There are several evidence-based biological treatments for mental disorders. Although most biological treatment options cause side-effects, these are usually less severe compared to the disorder the treatment is prescribed for. Good care means that the side-effects of the treatment are less than the beneficial effects on the symptoms, meaning that there will be a net improvement. This is what all psychiatrists will aim for.

There is evidence that psychotherapy is effective for the treatment of mental disorders. Medications have proven to be most effective for more severe symptoms.

There is evidence that psychotherapy is effective for the removal of the psychopathological symptoms and/or the maintenance of effectiveness over time (decrease in relapses). In line with this, the presence of psychotherapeutic treatment in between two aeromedical examinations and/or in a given current timeframe should be evaluated carefully before being considered as disqualifying.

There is no evidence that online therapy is less effective than face to face therapy, even if the acceptability may be different based on age, cultural differences and IT literacy. This kind of intervention can prove to be suitable with job challenges of aeronautical personnel, as it is compatible with shifts and distance from home.

The compatibility of a certain treatment with the ability to perform pilot or ATCO duties cannot be determined without knowing the underlying disorder and the risks related to it, as well as patient-specific protective and risk factors. For most biological treatments, except for those with severe sedating side-effects, it is recommended not to base the eligibility for certification only on the treatment that is applied, as this might lead to undertreatment. Instead a total estimation of risk factors (risks due to the underlying disorder, but also due to personal factors, comorbidities, and treatments) and protective factors (both from treatment, but also personal factors and psychosocial factors) may be better.

The self-declaration principle is therefore weakened when it applies to people consuming psychoactive substances or suffering from mental disorders.

So, mental health problems may be undetectable to AMEs because applicants are sometimes reluctant to disclose them. This reluctance is independent of the AME's ability to:

- treat information confidentially
- keep the applicant fly/control air traffic as long as possible

It is just a natural self-protective behaviour among applicants and a system with inherent structural weaknesses, leaving uncovered holes in the transport organizations' barriers against the incapacitation risks related to acute or chronic mental disorders.

PSP can help overcome these challenges:

- By helping to prevent escalation of mental health problems
- By easing self-disclosure
- By providing access to accurate medical information so as to support applicants with medical licensing issues or concerns
- By detecting signs and symptoms of decreased fitness in between two medical examinations
- By promoting a mental well-being culture in a just-culture oriented work environment

- By reporting, discussing and mitigating the impact of organizational stressors on mental health of safety critical personnel

The AME can recommend various ways to address mental issues outside of the medical, in order to prevent them becoming an issue that could impact the applicant’s fitness to fly /control air traffic in the future. This might include Peer Support Programmes! AMEs should be trained to know the key–principles and the aims of the local PSP(s) and fully utilize its opportunities.

In the framework of the MESAFE project, it is proposed to strengthen the link between peer support groups and the AMEs, the medical assessors and the mental health specialists, thus promoting an integrated approach for mental health assessment, monitoring and care. This will work as a mitigation to manage the safety hazards related to the weakened self-declaration principle when it applies to mental disorders.

A critical approach towards CISM is useful, as literature is inconclusive and for some interventions, a harmful effect cannot be ruled-out.

For the scope of MESAFE, the following take-aways can be taken into consideration:

Take away ID	Take away message
2.1	There are several effective biological and psychotherapeutic treatment options for mental disorders.
2.2	Online psychotherapy might be a suitable approach for aeronautical personnel, even if the level of acceptance may differ with age, cultural differences and IT literacy.
2.3	The presence of psychotherapeutic treatment in between two aeromedical examinations and/or in a given current timeframe should be evaluated carefully before being considered as disqualifying, as it works as a safety net to prevent relapses. It would be beneficial if the AME could consult the psychotherapist and obtain information regarding the evolution of the applicant
3.1	In general, all the psychosocial interventions are compatible with pilots’, ATCOs and UAS pilots’ duties and responsibilities.
3.2	The compatibility of biological treatment options for mental Health with aviation duties depends on the duties, the disorder, the effects of the treatment, and the side-effects of the treatment. As a general rule, such evaluation must be made on an individual basis by a psychiatrist.
3.3	The following equation can be used as a basis for evaluation of compatibility with aviation duties: <i>Total compatibility with flight duties = compatibility of the underlying disorder x compatibility of the biological treatment (risks and side-effects) x benefits of the biological treatment.</i>
4.1	Peer support Programmes are an important supplement to professional care as they may provide a low threshold possibility for applicants who otherwise might hold off or avoid making contact for fear of losing their licence or bring subject to stigmatisation. The role of the AME is different from the different roles within the Peer-support system. It is important that confidentiality, roles and working relationships are carefully considered and discussed, in order to build Trust and confidence on the part of the applicants.
4.2	Peer support programmes implementation should be extended to ANSPs.
4.3	AMEs should work closely with mental health specialists and peer support groups.

Table 3 - Take-away messages on the review of mental health treatment options

Take-aways will be followed up in the next tasks of MESAFE, where they will be translated into recommendations. A list of key issues that MESAFE will follow-up and translate into guidelines in the next phases of the project include, but is not limited to, the following:

Take away ID	Take away message	Key issues to follow up in the next tasks of the MESAFE project
2.1	There are several effective biological and psychotherapeutic treatment options for mental disorders.	Training for AMEs and applicants about biological and psychosocial treatment for mental disorders, including data about effectiveness and information about side-effects
2.2	Online psychotherapy might be a suitable approach for aeronautical personnel, even if the level of acceptance may differ with age, cultural differences and IT literacy.	Guidelines about how to design online psychotherapy services for aviation professionals
2.3	The presence of psychotherapeutic treatment in between two aeromedical examinations and/or in a given current timeframe should be evaluated carefully before being considered as disqualifying, as it works as a safety net to prevent relapses. It would be beneficial if the AME could consult the psychotherapist and obtain information regarding the evolution of the applicant	Recommendation to involve psychotherapists and cooperation Psychotherapists/AMEs guidelines
3.1	In general, all the psychosocial interventions are compatible with pilots', ATCOs and UAS pilots' duties and responsibilities.	Awareness campaigns about the benefits of digital mental health care services and upskilling of digital skills
3.2	The compatibility of biological treatment options for mental Health with aviation duties depends on the duties, the disorder, the effects of the treatment, and the side-effects of the treatment. As a general rule, such evaluation must be made on an individual basis by a psychiatrist.	Risk assessment Cooperation with psychiatrists Guidelines for AMEs about: <ul style="list-style-type: none"> • review of biological treatment according to the class of medication • definition of safety periods respectively after initiation of the treatment, after changing doses and after the end of the treatment in which most of the side effects should be gone, to take those applicants off duty and monitor any adverse reactions.
3.3	The following equation can be used as a basis for evaluation of compatibility with aviation duties: <i>Total compatibility with flight duties = compatibility of the underlying disorder x compatibility of the biological treatment (risks and side-effects) x benefits of the biological treatment.</i>	Recommendation to involve psychiatrists and cooperation psychiatrists /AMEs guidelines
4.1	Peer support Programmes are an important supplement to professional care as they may provide a low threshold possibility for applicants who otherwise might hold off or avoid making contact for fear of losing their licence or bring subject to stigmatisation. The role of the AME is different from the different roles within the Peer-support system. It is important that confidentiality, roles and working relationships are carefully considered and discussed, in order to build Trust and confidence on the part of the applicants.	Awareness campaign about PSP, including data about effectiveness

4.2	Peer support programmes implementation should be extended to ANSPs.	Recommendation to extend PSP to ANSPs
4.3	AMEs should work closely with mental health specialists and peer support groups.	Definition of cooperation processes among AMEs, PSP, Aviation psychologists and psychotherapists, psychiatrists

Table 4 - List of key issues that MESAFE will follow-up in the next phases of the project

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