Transnational Policy for e-Mental Health

A guidance document for European policymakers and stakeholders

Interreg
EUROPEAN UNION
North-West Europe
eMEN
European Regional Development Fund

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Describing the use of terms in the context of mental health

It is well recognised that the use of certain terms related to mental health may medicalise ways of thinking and feeling, which may result in stigma associated with the topic of mental health (1). To our knowledge, there is no universally acceptable terminology. This paragraph reflects the Transnational Policy Working Group's discussion regarding the concerns associated with certain terms in the context of mental health.

Mental health refers to "the state of well-being in which the individual realizes his or her own abilities, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to his or her community" (2).

Whereas mental health is clearly defined, the absence of mental health is more difficult to describe, and several terms are commonly used, some interchangeably. *Mental illness*, for example, describes the absence of mental health due to psychological distress or *mental disorders* that often require treatment (1). Mental disorders describe a state that reaches a clinical threshold of a diagnosis according to a psychiatric classification system such as the International Classification of Diseases (ICD-11) on mental, behavioural and neurodevelopmental disorders (3). *Psychological distress* refers to "symptoms or conditions that do not reach the clinical threshold of a diagnosis within the classification systems, but which can account for significant suffering and hardship, and can be enduring and disabling" (3). Overall, terms such as mental illness, mental ill-health or mental health problems interchangeably describe the absence of mental health (3).

Glossary of terms

AAL	Active Assisted Living Programme
API	application programming interface
BfArM	Federal Institute for Drugs and Medical Devices (Germany)
BIT	behavioural intervention technology
CBT	cognitive behavioural therapy
cCBT	computerised cognitive behavioural therapy
CE	Conformité Européenne (European Conformity)
CIOMS	Council for International Organizations of Medical Sciences
CME	continuing medical education
CPG	clinical practice guidelines
CRPD	Convention on the Rights of Persons with Disabilities
DALY	disability-adjusted life year
DSM	Digital Single Market strategy
DVG	Digitale-Versorgung-Gesetz (Digital Health Care Act)
EAP	Employee Assistance Programme
EC	European Commission
eHealth	electronic health
EMA	Ecological Momentary Assessment
eMH	electronic mental health
EPA	European Psychiatric Association
EU	European Union
f2f-session	Face-to-face session
FDA	US Food and Drug Administration
GDE	Global Digital Exemplar
GDP	Gross Domestic Product
GDPR	General Data Protection Regulation (EU 2016/679)
GP	General Practitioner
HSE	Health and Safety Executive (UK and Ireland)
HTA	Health Technology Assessment
IAPT	Improving Access to Psychological Therapies
iCBT	internet-delivered cognitive behavioural therapy
ICT	information and communication technology
IMI	internet- and mobile-based interventions
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care)
IT	information technology

LHCR	local health and care records
MAST	Model for Assessment of Telemedicine
MHCC	Mental Health Commission of Canada
mHealth	mobile health
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NHS	National Health Service
NWE	North-West Europe
PTSD	post-traumatic stress disorder
RCT	randomised controlled trial
SES	socioeconomic status
SME	small- and medium-sized enterprises
UK	United Kingdom
VCSE	voluntary, community and social enterprise
VR	virtual reality
WHO	World Health Organization
WLAN	wireless local area network
WPA	World Psychiatric Association
XR	extended reality, which encompasses virtual reality, augmented reality and mixed reality

Key messages

Why eMH and what can it contribute?

Although mental health is recognised as the key for a healthy society, more than a third of EU citizens experience some kind of mental disorder every year (4). Together with a scarcity of staff and financial constraints, the increasing demand for mental health care poses a tremendous challenge to European societies and health systems. Digital technologies in mental health promotion, care and prevention efforts (also called e-mental health or eMH), may enlarge the scope of mental health services, provide accessible, affordable, high-quality mental health service delivery and can contribute to improving population-level mental health throughout Europe. eMH may support and improve mental health service delivery (starting from health promotion and prevention, through diagnosis and early intervention, to treatment and relapse prevention) through a wide variety of digital technologies such as internet-based interventions, mobile apps, wearables, virtual reality and social media (5).

Evidence for the efficacy of digital technologies in mental health care and the prevention of mental health problems is emerging and positive, but not yet conclusive (6–12). eMH is expected to promote awareness of mental health, empower users with knowledge and tools, engage patients and improve their self-management abilities, support the continuity of care and personalise mental health treatments to the individual needs. It is, in particular, the variety of application options (e.g. guided or unguided self-management, in combination with face-to-face therapies, telemental health) that make eMH an important contributor to improved and accessible mental health promotion and care throughout Europe.

Despite the promises of eMH, the implementation and adoption of eMH solutions remain challenging in eMEN partner countries and beyond. Although the development, dissemination and implementation of eMH varies widely throughout eMEN partner countries, common challenges could be identified that provide a basis for this Transnational Policy.

Why does eMH implementation remain a challenge?

The disruptive nature of implementing digital solutions (including eMH) into health care comes with reservations and scepticism by some mental health professionals, managers and policymakers in terms of privacy, usability and the feeling of additional workload with only marginal benefits or even risks for the users. A major concern is the risk that core services will be replaced by cheaper digital alternatives with a loss of quality. Thus, legislation as well as quality assurance and financial systems need to be established to allow for the adoption of safe, effective and high-quality eMH solutions in routine mental health prevention and care. Potential users are often not sufficiently aware of available eMH products and services as well as about their quality and the underlying evidence, or just prefer face-to-face rather than digital contact. Inadequate digital health literacy skills and limited training and education further hamper the application of eMH solutions. Furthermore, knowledge is still vague in terms of when and how to include an eMH solution. In particular, the roles of human support and therapeutic alliance in successful treatment need to be investigated in more detail.

Nevertheless, the interest in eMH at research, practice and policy levels increases. At the European level, several initiatives and policy documents refer and contribute to the digitalisation of (mental) health care: the *Joint Action on Mental Health and Wellbeing*, the *eHealth Network* and the *eHealth Action Plan*. At the national level, eMH plays as yet only a minor to moderate role in relevant policies (see Appendix A for more information). eMH implementation protocols, which would facilitate the uptake of eMH, are still rarely available in Europe. A comprehensive and multidisciplinary approach to overcome these barriers and foster facilitators for eMH implementation may be most effective in order to promote eMH in Europe.

To conclude, the momentum for eMH is growing. With this Transnational Policy, the eMEN consortium aims to foster the potential for adoption and implementation of eMH solutions throughout Europe.

What is needed to promote eMH?

Based on literature reviews (conducted between 2017 and 2019), stakeholder interviews and experiences from within the eMEN project, this document provides guidance at policy level in terms of how the implementation and adoption of eMH solutions can be accelerated. It aims at complementing activities targeting eMH at EU level by highlighting specific areas of interest in the field of eMH. Overall, the challenges to accelerating eMH uptake among North-West Europe (NWE) member countries are manifold.

In the broad concept of digital health, eMH in specific is still a rather underrepresented topic at the EU level, and plays a minor to moderate role in (national) mental health policies. It is time to set the vision, mission and objective for future mental health systems (including the use of eMH solutions) and to strengthen the role of eMH in mental health policies, strategies and action plans (at EU and national levels). Strong political commitment and leadership is needed to use the potential eMH offers (see recommendation 1).

Adequate legislation, standards and processes (e.g. health technology assessment (HTA) processes) and a digital infrastructure for eMH implementation need to be developed to initiate substantial change. An appropriate regulatory framework guided by an overall eMH implementation strategy will stimulate innovation. Mental health systems must evolve and become resilient against future challenges in order to improve European citizens' mental health (see recommendation 2).

So far, the financial systems for eMH are in development or remain unclear in most NWE member countries. Effective reimbursement systems, adequate funding models and a rise in financial incentives for eMH are needed to foster the uptake of eMH in the long-term and stimulate innovation (see recommendation 3).

Reliable evidence guides decision-making. Despite promising evidence of the efficacy of eMH solutions, eMH's potential has scarcely been realised, partly due to methodological limitations in available studies such as a lack of representative population samples (e.g. selection bias due to self-referral recruitment procedures), small population sizes or limited research on factors that affect the implementation to the real-world setting. Methodologically rigorous eMH evaluation studies are needed. Furthermore, it appears advisable to support a European joint development of appropriate research methods for the rapidly changing social and technological environment of digital health interventions that enhance evidence generation for digital solutions. Building stronger networks and interdisciplinary collaboration throughout Europe will support these efforts (see recommendation 4).

However, potential users face an ever-increasing flood of eMH solutions available on the market, with only limited options to identify high-quality ones in terms of efficacy, effectiveness and safety. National and transnational organisations, research and expert groups have suggested certain quality criteria for eMH products and services. Aligning these initiatives and developing a catalogue of quality criteria at European level may further facilitate the development of quality assurance mechanisms at national level (see recommendation 5).

In this context, user preferences and usability as well as interoperability are major factors for the adoption of eMH solutions. Promoting co-creation (meaningful input of involved target users,) interoperability and quality standards will increase the quality of available eMH products and services and prevent low user engagement and adherence (see recommendation 6).

Awareness and acceptance of eMH as well as good digital health literacy in general are key contributors to the successful adoption of eMH solutions. Stakeholder-tailored approaches are required in order to raise awareness and acceptance, and to prepare involved actors, including (potential) users, for eMH adoption (see recommendation 7).

Implementing eMH is a disruptive process. However, despite a growing evidence base and increasing interest, the lack of implementation research and overarching implementation strategies challenge the implementation process. Systems require concepts on how to embed eMH into established routine health care workflow processes, integrate eMH in treatment protocols where applicable (e.g. stepped care, blended care), develop organisational readiness (technological infrastructure, workflow, support by the management, etc.) and sustainable financial models. Training the (mental) health workforce, adequately educating them by integrating eMH into curricula and offering supervision and support will all contribute to the adoption of eMH solutions in routine care (see recommendation 8).

Readers' guide

eMH has proven its potential to improve mental health prevention and care. However, the meaningful implementation and adoption of eMH solutions into (mental) health care systems remains challenging. This Transnational Policy provides guidance for decision-makers and other relevant stakeholders at European and national level with regard to addressing and overcoming the identified challenges and facilitating the development, dissemination, implementation and adoption of high-quality eMH products and services. In order to accomplish this endeavour, a multidisciplinary approach that involves all relevant stakeholders will be necessary.

Overall, this Transnational Policy aims at providing guidance for **decision-makers in health care (politicians and policy makers)**, which is why the whole document is of relevance for them. Of particular interest for this stakeholder group may be chapters 1.2 ('eMH: an opportunity to improve mental health'), 2.1 ('The critical role of political commitment and leadership') and 2.4.2 ('Education and training of the health workforce').

Patient associations as well as people with mental health problems may be eager to learn more about eMH solutions (1.2 'eMH: an opportunity to improve mental health') as well as how to improve awareness and acceptance (2.3.1.1 'General public' and 2.3.1.2 'Users'). Additionally, usability, ethical and privacy aspects are addressed in chapters 2.2.2 ('Usability and user preferences'), 2.1.4 ('Ethics') and 2.1.1.1 ('Privacy and data security'), which may also be relevant for them. Furthermore, chapter 2.3.2 ('Digital health literacy') addresses how to improve the public's digital health literacy in order to be able to cope with the digitalisation of health care.

The mental health workforce may be interested to read about the potential eMH can offer to improve mental health (1.2 'eMH: an opportunity to improve mental health'), and how acceptance may contribute to improved mental health prevention and care (2.3.1.3 'Professionals' and 2.3.1.4 'Organisations'). Furthermore, it may be of relevance how the quality (2.2 'Quality of eMH solutions') and usability (2.2.2 'Usability and user preferences') of eMH solutions may be ensured, ethical issues addressed (2.1.4 'Ethics'), and how eMH may affect the clinical workflow (2.4.1 'Challenges in routine care').
Readers who are interested in what **health care payers and insurance companies** can contribute to the uptake of eMH may want to read chapters 2.2.1 ('The role of quality criteria'), 2.1.3 ('Financial aspects'), 2.1.4 ('Ethics'), 2.2 ('Quality of eMH solutions') and 2.3.1 ('Awareness and acceptance').

For **researchers and academics**, this document provides a general overview about the evidence base of eMH (1.2 'eMH: an opportunity to improve mental health') and implementation issues that must be resolved through accelerated research and development (2 'Promoting and implementing ', 2.2.3. 'Evaluation methods for eMH solutions' and 2.4 'Dissemination and implementation of ').

SMEs and developers of eMH solutions may be interested in the development of quality criteria and other regulatory preconditions (2.2.1 'The role of quality criteria') for the implementation of eMH in mental health care systems. Furthermore, the aspects of usability, interoperability and ethical considerations in the context of eMH are discussed in chapters 2.2.2 ('Usability and user preferences') and 2.1.4 ('Ethics'). Licensing and other financial aspects are described in chapter 2.1.3 ('Financial aspects').
Aside from the above mentioned stakeholders, this document provides information for other stakeholders active in the field of improving European citizens' mental health such as **NGOs, professional organisations and alliances** for mental health.

Executive Summary

Mental health in Europe

The burden of mental health problems poses a tremendous challenge to European societies and health care systems. About 17.3 percent of the European adult population (the European Union plus Switzerland, Iceland and Norway), equating to about 84 million people, are affected by mental disorders each year (3). Despite comparatively well-developed mental health care systems, access to treatment is limited (13) and many people who suffer from mental disorders do not receive timely and adequate treatment (14). Long waiting lists, perceived stigma and negative attitudes towards psychotherapy (15) or mental health care services are among the reasons why such a treatment gap in mental health care is still noticeable in European societies. Not only is there an increasing demand for mental health care services, but also a scarcity in terms of health care staff and financial resources. Overall, more than a third of EU citizens experience some kind of mental disorder every year, corresponding to an estimated 164.7 million people (4). Moreover, 4.1 percent of all deaths in the European Union in 2015 were attributed to mental and behavioural disorders (16). Each year, mental disorders contribute to approximately 15 percent of Europe's disease burden (measured as disability-adjusted life years (DALY) (17)), yielding €600 billion of direct and indirect costs (3). By 2030, depressive disorders are expected to become the leading cause of disability in high-income countries (18). In order to deal with these challenges, Europe's mental health systems must evolve by improving the utilisation of and access to available mental health care resources.

eMH: an opportunity to improve mental health

Digital health solutions come with enormous potential to improve *"prevention, diagnosis, treatment, monitoring and management of health and lifestyle"* (19). As part of digital health solutions, eMH presents an opportunity to enlarge the scope of mental health care services and address some of the above-mentioned (future) challenges of mental health systems.

Info box 1: Definition of eMH

"'E-mental health' is a generic term to describe the use of information and communication technology (ICT) when these technologies, particularly those related to the internet, are used to support and improve mental disorders and mental health care, including care for people with substance use. E-mental health encompasses the use of digital technologies and new media for the delivery of **screening, health promotion, prevention, early intervention, treatment and relapse prevention** as well as for **improvement of health care delivery** (e.g. through the use of electronic patient files), **professional education** (e-learning), and **online research in the field of mental health**" (5).

eMH can contribute to accessible, affordable, high-quality and effective care for people with mental health problems (7, 20). Evidence for the efficacy of digital technologies in mental health care is emerging and positive (6–12), but not yet conclusive. eMH can be utilised in all phases of the health care continuum: from promotion of mental health and prevention of mental health problems, through early intervention, screening, diagnostics and treatment to rehabilitation, relapse prevention and follow-up care.

eMH offers potential as an adjunct and complement to traditional mental health care services. It is not only about technology, but also represents a cultural change in the provision of mental health prevention and care: eMH may play an important role in the promotion of mental health awareness and mental health literacy (e.g. educate the public and disseminate information) and may support practitioners in their daily routine (21). Furthermore, eMH may improve the accessibility of appropriate and high-quality mental health prevention and care for individuals in need, reduce waiting times, support the continuity of care (by bridging the gap between in- and out-patient

services), and promote the early identification of people who are at risk of developing mental health problems. eMH can further help to enhance the care of people with mental health problems, empower users with knowledge, tools and self-management abilities (so they can exercise greater choice and control), and support system-level efforts to improve mental health (22).

There is a wide spectrum of application fields for eMH products and services (occasionally also referred to as *eMH solutions* within this document). They can be used as self-directed programmes with or without guidance. Alternatively, eMH products and services may be combined with more traditional treatment methods such as face-to-face meetings with a health professional[1] , utilising the so-called blended care approach. Mobile apps and wearables can contribute to improved monitoring or medication adherence, and serious gaming and virtual reality products offer new ways for mental health prevention and care.

Overall, eMH products and services have the potential to reach more people in need than traditional services (e.g. those who prefer more confidential and flexible ways of mental health care) and may help to overcome the limited availability of face-to-face services. Thus, they may contribute to the enhancement of mental health care delivery, improve population-level health and reduce the burden of mental health problems.

eMH implementation: barriers and facilitators

Despite emerging evidence underlining the beneficial potential of eMH, the implementation and adoption of eMH products and services remains challenging (23–27).

The disruptive nature of implementing digital solutions (including eMH) into health care comes with concerns and scepticism in terms of privacy, usability and the feeling of additional workload with only marginal benefits or even risks for the users. Potential users are often not sufficiently aware of available eMH products and services, or their quality and the underlying evidence. Moreover, a major concern is the risk that core services will be replaced by cheaper digital alternatives with a resultant loss of quality. Inadequate digital health literacy skills and limited training and education further hamper the application of eMH solutions.

At system level, a lack of coordinated and structured actions, clear visions, objectives, policy and legal guidance further contribute to limited or incoherent implementation. At national level, eMH plays as yet only a minor to moderate role in relevant policies and strategies (see Appendix A for more information). The financial system, legislation and quality assurance mechanisms are not yet prepared to foster the adoption of safe, effective and high-quality eMH solutions. Attention to targeted eMH implementation protocols and coordinated efforts at policy levels have so far been limited. Knowledge in terms of when and how to include an eMH solution is still vague. In particular, the value of human support and therapeutic alliance for the treatment's success needs to be investigated in more detail. eMH implementation protocols and standards are warranted to meaningfully integrate eMH solutions into established workflows. Priming organisations for the adoption of eMH in terms of digital infrastructure and preparing the mental health workforce is therefore important. Nevertheless, as discussed earlier, the interest in eMH at research, prac-

[1] *Within this Transnational Policy, professionals are defined as clinical staff (such as medical doctors, psychiatrists, general practitioners), occupational therapists, psychologists, therapists/counsellors and nurses) as well as non-clinical staff (workers in the statutory, voluntary and community sector, and professionals outside the typical mental health care sector but involved in public mental health work, e.g. social workers).*

tice and policy levels increases. At the European level, several initiatives and policy documents refer and contribute to the digitalisation of (mental) health care such as the *Joint Action on Mental Health and Wellbeing*, the *eHealth Network* and the *eHealth Action Plan*. Furthermore, research and expert groups foster the development of high-quality eMH solutions by promoting quality criteria or initiating research on implementation. Thus, the momentum for eMH is growing.

A structured, comprehensive and multidisciplinary approach to address this multitude of challenges would facilitate and enhance the adoption of eMH products and services. An in-depth analysis of the challenges identified, as well as suggestions for how to address them, are presented in chapter 2.

Based on the results of the conducted analyses, the eMEN consortium developed **eight recommendations** that aim
to guide this endeavour. In combination with a **Proposed Action Plan**, which provides concrete actions related to each recommendation, they aim to address and overcome the identified challenges to improve population-level mental health and reduce the burden of mental health problems. The recommendations are as follows:

1. Promote and advocate strong **political commitment**, governance and leadership for the development, dissemination, implementation and adoption of eMH.

2. Ensure legal clarity and ethical correctness, and avoid insecurities in users with regard to the **safeguarding** of human rights, privacy and data security in the digital age.

3. Develop adequate financing strategies and guarantee the **financial viability** of eMH in the long term.

4. Stimulate, promote and fund eMH **research** within existing and future European research programmes (e.g. Horizon Europe).

5. Promote and facilitate eMH development and research processes that are based on the highest standards of **usability and interoperability**.

6. Ensure that only **high-quality** eMH products and services are implemented in the (mental) health care sector.

7. Increase **awareness and acceptance** of eMH products and services, foster **trust** in digital tools in mental health care and prevention efforts, and enhance **digital health literacy and skills** in the public and the (mental) health workforce.

8. **Integrate** eMH into established (mental) health care models and other key areas of interest such as mental health in the workplace or mental health in schools.

Conclusions

It is time to place eMH at the heart of national and European health care strategies and policies in order to facilitate a structured and effective approach for eMH implementation. Mental health systems need a well-balanced combination of guidance, regulation, legislation and training, plus acceptance and awareness campaigns to ensure that the use of safe, effective and high-quality eMH products and services is promoted to benefit the mental health of all European citizens. More attention should be given to campaigning to and sensitising the public, developing needs-tailored approaches for specific target groups, improving training for the mental health workforce, and developing guidelines and transparent information about high-quality eMH products and services. In addition, more research is required to identify how European citizens may effectively benefit from eMH in all its varieties, which may include research on clinical efficacy, (cost-) effectiveness and implementation strategies. In order to achieve these goals, the engagement of all stakeholders (health professionals, developers, patients, users and policy makers) is required.

This Transnational Policy helps to explain the benefits of eMH products and services and their impact on improving population-level mental health throughout Europe. It outlines the challenges that are yet to be overcome in order to facilitate the implementation and adoption of eMH solutions, and provides a practical guide to achieve these goals.

1 Introduction

1.1 Mental health in Europe

Mental disorders present one of the greatest health challenges in Europe and are related to high individual, social and financial burdens (28). The absence of good mental health relates to severe distress, functional impairment, and may even lead to premature mortality. In 2015, over 84,000 people died of mental illness and suicide across EU countries (3). Each year, mental disorders contribute to approximately 15 percent of Europe's disease burden (17) and were the leading global cause of non-fatal burden of disease in 2010 (29). Overall, mental disorders are the third leading cause of disability-adjusted life years (following cardiovascular diseases and malignancies) and the largest contributor of the disease burden of chronic conditions in Europe (and the first cause of years lived with disability (YLD) (30, 31)). Furthermore, in 2016, one in six people in EU countries (approximately 84 million people) were affected by a mental health problem (not necessarily reaching a clinical threshold) (3). On average, nearly 5 percent of the European population suffered from depressive disorders in 2015, and about 4 percent experienced some type of anxiety disorder (32). Depression is now the leading cause of disability worldwide (32). By 2030, depression is expected to become the leading cause of disability in high-income countries (18). Altogether, more than a third of European citizens experience some kind of mental disorder every year (4), of which only about half receive professional treatment (13). The stigmatisation associated with mental disorders and using mental health care services, and the long waiting lists due to limited service accessibility, are among the factors that hinder people from receiving appropriate treatment (15, 33). Unmet needs and treatment gaps (i.e. gaps between a limited capacity to provide treatment and the need for mental health care services) are reported not only throughout Europe, but also globally (14, 15, 34–37).

In the EU, the direct and indirect costs of mental ill-health amount to over €600 billion (4 percent of gross domestic product (GDP)) per year (3), and are expected to double by 2030 (38). Societal challenges such as globalisation, increasing social inequalities, demographic changes (including ageing populations and high rates of immigration) as well as social isolation are among the key factors that can be held accountable for this predicted development (39). Europe's mental health systems must evolve and respond adequately to these challenges by improving the access and utilisation of the available resources. The need for innovation in the field of mental health care seems to be greater than ever.

Accordingly, the Council of the European Union has emphasised the importance of innovative approaches in health care (40)and invited the EU member states and the EU Commission to accelerate the work on digital solutions in the promotion of health care (41). Digitalisation is one major approach to foster innovation in mental health care (and other fields of health care). Technology has become an increasingly important factor in the daily routines of European citizens, affecting communication, finance and health care (33). Using technology for the delivery of mental health services promises several advantages such as improved access, better quality of care, increased availability of treatment options for people in need and empowerment of people in looking after their own mental health. Among others, digital health interventions are the kind of instruments to address future challenges, which health systems will be facing due to the increased prevalence rates of chronic diseases, limited human and financial resources and an ageing population with growing demands (40). Consequently, European policies such as the *eHealth Action Plan 2012–2020* support and advocate the need for greater attention to digital health in Europe (42). With the emergence of innovative digital interventions for mental health care and the prevention of mental health problems (eMH), digital technologies may contribute towards preparing mental health systems for future challenges. The future role of digital technology in mental health and psychiatric care is already widely recognised (22, 43), but must be supported in terms of research methods, care delivery models and transparency and quality standards (43).

1.2 eMH: an opportunity to improve mental health

The scope of eMH

The World Psychiatric Association (WPA) ascribes to eMH the potential to improve access to early diagnosis, intervention and care; improve efficiency; help to ensure the continuity of care and more equitable access to care; help promote mental health and prevent mental illness; and increase outpatient engagement (44).

Digital health interventions in all their varieties are expected to complement established mental health services through providing affordable, high-quality and effective approaches for mental health care and the prevention of mental health problems. Consequently, eMH may increase the reach of mental health services, enhance self-management and improve the empowerment of users throughout the treatment process, while improving overall population-level mental health. Moreover, eMH offers confidentiality and may contribute to providing care to those who otherwise would not seek help due to the stigma associated with mental health services (45), or because they have difficulty physically attending appointments.

The number of e-(mental) health projects and products is rapidly growing across Europe (46), indicating that the mental health care landscape seems to be receptive for innovative solutions.

Due to the evolving nature and rapid developments in the field of digital health interventions for mental health care and prevention efforts, it is challenging to clearly define and describe the term 'eMH'. However, for the purpose of this Policy, the definition by Riper and colleagues provides a good approach:

"A generic term to describe the use of information and communication technology (ICT) – in particular, the many technologies related to the internet – when these technologies are used to support and improve mental health conditions and mental health care, including care for people with substance use. eMH encompasses the use of digital technologies and new media for the delivery of screening, health promotion, prevention, early intervention, treatment, or relapse prevention as well as for improvement of health care delivery (e.g. through the use of electronic patient files), professional education (e-learning), and online research in the field of mental health" (5).

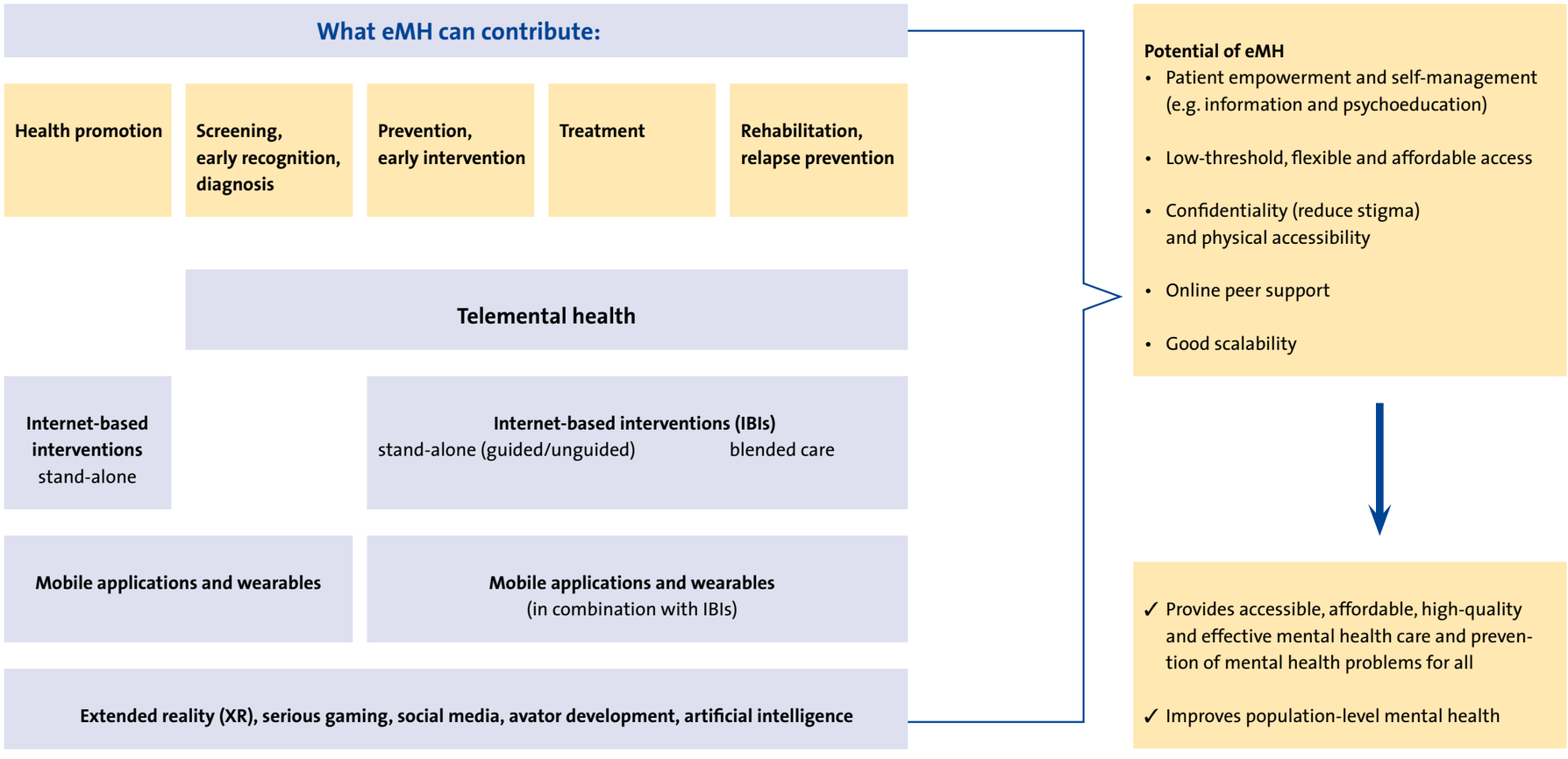
In this Policy, the focus is on the use of digital technologies and new media for both prevention and mental health service delivery within different care settings (primary care, specialist care, etc.). Of special interest are internet- or computer-based interventions, mobile applications (apps) and new media such as wearables, virtual reality (VR) and serious gaming, and their role and integration in future mental health care services. While also being important components for mental health care, telemental health, online support and information-seeking are not the main scope of this Policy. Furthermore, e-learning components or systems to improve the delivery of health care, such as electronic health files, are out of the scope of this Policy.

eMH is a very broad term and many different classifications and categorisations exist in this field, which makes it difficult to describe and categorise eMH solutions in a structured manner. They may be rated according to their role in mental health care/the way they are provided (self-management, blended care, apps, etc.), their purpose (psychoeducation, (suicide) prevention, diagnosis, monitoring, treatment, rehabilitation, etc.), use of data (e.g. local data, consumer-driven data or data sharing with electronic medical records) or their inherent risk and function (comparable to the categories used for medical devices) (47). Therefore, Figure 1 gives an overview of what eMH encompasses and what it can contribute to achieve an improvement in mental health systems. This Transnational Policy refers mainly to eMH as an adjunct for mental health care services, i.e. for the promotion of

mental health and prevention of mental health problems, through early intervention, screening, diagnostics, treatment to rehabilitation, relapse prevention and follow-up care. So-called wellness apps, which focus on meditation, fitness or nutrition for wellbeing, are out of the scope of this Transnational Policy.

eMH can be applied to the whole spectrum of mental health care services by using telemental health, internet-based interventions (guided, unguided, blended care), mental health apps, serious gaming or VR, with most evidence available for disorders such as depression and anxiety. Research and clinical practice often focus solely on treatment (48), but eMH offers a broad spectrum of possibilities, including psychoeducation or prevention tools on smartphones (49), or the collection of data through wearables for diagnostic purposes (50). Aside from being used for treatment purposes, eMH products and services should play a part in the prevention and early detection of mental illnesses. In particular, people who experience mental health problems, but who are not necessarily mentally ill yet, can benefit from using eMH products and services, and in this way prevent the onset of a more serious mental disorder. Screener apps, for example, can help to assess symptoms, obtain an early diagnosis and therefore also increase the likelihood of early intervention if needed (44). However, this also carries the risk of overdiagnosis, which needs to be considered and, most importantly, avoided. Attention concerning eMH use in severe and enduring mental health problems is growing (51). The following review presents an overview of different types of eMH and its evidence. For an overview of European research projects, initiatives and networks related to eMH, please refer to Appendix B.

Figure 1: Potential of eMH within the spectrum of mental health service delivery



Telemental health

Telemental health refers to traditional therapy approaches that are applied using media such as telephone, SMS message contact, video or text/chat groups or email in an asynchronous (e.g. mail) or synchronous manner (e.g. chat). The term *telemental health* encompasses telecounselling/telepsychology and telepsychiatry.

Telemental health may improve the reach of specialists, e.g. for consultations. Patients can be reached irrespective of their mobility, location or the time of day. This is especially convenient for people unable to travel, or for those living in rural or underdeveloped areas. Furthermore, it provides the option for more frequent contact and follow-up and is thus an expansion of inpatient services for those who otherwise would not receive mental health care (52). The described benefits explain why eMH – and especially telemental health – is widely applied in countries with geographically large areas such as Scandinavian countries, Canada, Australia and the United States (53).

In eMEN partner countries, there are currently only a few telemental health activities. Examples are the services within the *IAPT (Improving Access to Psychological Therapies)* programme in England (UK) and some telepsychiatry activities in Scotland (53). Guidance for telemental health is available in English-speaking countries such as the UK, Australia, the US and Canada. For example, the *APA Telepsychiatry Toolkit* encompasses themes such as training, legal and reimbursement issues, technical considerations, and practical and clinical issues (54).

Despite the mentioned benefits, telemental health comes with the risk of violating patient privacy, limited therapeutic alliance and few options to address crises. Nevertheless, developments are positive and telemental health activities may contribute to better follow-up of patients, improved reach and will enable better access to specialist expertise.

Internet-based interventions

Programmes, interventions or services that mainly extend on principles of established evidence-based psychological therapies and that offer therapy or support for people with mental health problems via the internet will herein be summarised under the term *internet-based interventions* (other terms used are *online-based interventions*, *computer-based interventions* or *technology-supported interventions*). Most of the available internet-based interventions are built upon established therapies developed for face-to-face therapy (e.g. cognitive behavioural therapy (CBT), psychodynamic or interpersonal therapies) (55) and follow an evidence-based protocol or treatment pathway that the user follows via different (thematic) modules. These modules contain various sets of tools such as general "information, psychoeducation, formal decision aids, behaviour change support, interactions with health care professionals and other patients, self-assessment or monitoring tools (questionnaires, wearables, monitors)" (56). Some of these interventions are connected to apps that can be installed and used on mobile phones or tablets and that support users in their therapy by sending reminders, monitoring health behaviour, frequent mood assessments or the option of writing a diary.

Internet-based interventions differ with regard to the amount of human support, their role in the treatment process and the field of application. They can be used as stand-alone interventions in the form of *self-management tools* (mostly focusing on psychoeducation and information in order to equip people with skills to manage and monitor their condition) or *self-help interventions (guided or unguided)* that help people in need to improve their health and modify their behaviour (57). Self-help may be applied for prevention, treatment and relapse prevention (57). Furthermore, internet-based interventions may support and complement established treatment pathways in a so-called *blended setting* (blending internet-based interventions with face-to-face therapy in one treatment concept (for more information, see info box 2)).

Evidence

Research on internet-based interventions is still a young field. Nevertheless, in recent years, more than 300 controlled trials on iCBT (internet-delivered cognitive behavioural therapy) have been published (58). Most studies suggest positive outcomes of internet-based interventions for various disorders and conditions (20, 58). However, most research focuses on iCBT for depression (55) or anxiety (6).

Increasingly, meta-analyses and systematic reviews address the efficacy of internet-based interventions. A number of systematic reviews and meta-analyses indicate positive results for guided self-help and self-guided psychological treatment compared to face-to-face-therapy (10, 11). Appendix C lists more systematic reviews and meta-analyses in the field of eMH, most of them focusing on depression or anxiety disorders. A Cochrane Review from 2015 indicates that "therapist-supported iCBT appears to be an efficacious treatment for anxiety in adults", although the low to moderate quality and low quantity of the included studies needs to be considered (59). With regard to the effectiveness of internet-based interventions in the prevention of mental disorders, the body of research is still limited but a recent review revealed promising results for depression and anxiety (60).

Research concerning the role of guidance in internet-based interventions has not come to a final conclusion. Findings suggest that guided treatment for depression delivered via the internet leads to similar outcomes compared to face-to-face treatment (61) and that the guidance of a human therapist benefits patient outcome (7, 62). According to a meta-analysis on computer-based psychological treatments for depression, human support in computer-based psychological treatment may reduce dropout rates by 30–40percent and result in higher effect sizes (7). This may, however, be indication-specific for depression. Nevertheless, research clearly suggests that guided treatments improve the adherence rate and prevent dropouts (55).

Despite those promising outcomes, meta-analyses and systematic reviews also reveal a number of limitations of the present RCTs on internet-based interventions, such as selection bias (often highly educated female groups, with mild to moderate disorders, and computer literate) (7) or other methodological limitations, such as small sample sizes, subjective outcome measures, high dropout rates, non-compliance and uncontrolled follow-up groups (attrition bias), inactive control groups (e.g. waiting lists) and negligence of long-term effects (6, 7). Therefore, more rigorous research on the efficacy, effectiveness and cost-effectiveness of internet-based interventions compared to, e.g. traditional psychotherapy (face-to-face-therapy) may be warranted (6, 26, 60, 63). Research should furthermore focus on practical issues such as when and how to include which eMH solution for whom, and also on the quality and amount of human support, or the role of the therapeutic alliance (64). In particular, the latter needs to be investigated in more detail as well as the long-term and potential negative effects of mediators of change and outcomes (see also info box 3).

Info box 2:
Integration into established mental health services

Stepped care
Stepped care refers to an evidence-based staged system, which matches the treatment – with full respect of the patient's preferences – to the patient's needs by applying the least resource-intensive but clinically proven treatment first (65). The treatment process is monitored carefully, and treatments can be adapted to the patient's needs at all times. The aim of this model is to simplify the treatment pathway, provide access to more people in need and improve treatment outcomes (66). Moreover, with more people using less resource-intensive treatments (if appropriate), the workforce and technol-

ogy can be used most efficiently while ensuring effective, accessible and safe care for people in need.
In Australia, the Mental Health Stepped Care Model has been fully implemented in 2019 with digital mental health playing an important role in the treatment pathway for people at risk (early symptoms, previous illness) and with mild mental illness (65).

Note: A stepped-care model needs to be distinguished from the step up/step down concept which refers to services that are delivered to bridge the time until, e.g. hospitalisation starts or as follow-up treatment after inpatient care (65).

Blended care: Least disruptive or most beneficial?

Blended care or *blended treatment* describes the combination of face-to-face meetings and online sessions within the same treatment protocol (67). It appears to be a less disruptive way of integrating eMH into routine care than other forms of eMH such as standalone approaches (26, 68, 69). Blended care is expected to complement and support traditional therapy by providing an integrated treatment concept that combines the advantages of traditional and online therapy (63). This form of care delivery aims at increasing the intensity of therapy, reducing the number of face-to-face meetings or the extent of therapist guidance (68, 69), improving the ability to apply new skills in everyday life (improving autonomy and empowerment), and moreover optimising the therapeutic process, efficiency and effectiveness (70-73). Blended care is expected to free capacities and may thus reduce the burden on mental health systems (e.g. due to a shortage of staff).

Besides being less disruptive in terms of treatment pathways, blended care combines the human relationship and therapeutic alliance with the advantages of digital services. As the human relationship is seen as indispensable for the therapeutic alliance, health professionals in particular tend to have a rather open attitude towards blended care and expect fewer disadvantages (74, 75). This is also true for other stakeholders, who generally show greater acceptability towards blended treatment compared to stand-alone interventions (67), and patients reporting adequate working alliances with their therapist (76). However, therapists emphasise that blended treatment protocols should ensure a certain level of flexibility concerning the choice of number of f2f-sessions and online sessions (customisability), taking into account the need for a human relationship (69).

However, research in terms of safety, efficacy and efficiency of blended treatment is rather young (68). The eCOMPARED project evaluated the comparative effectiveness of blended care to treatment as usual for adult depression in eight European countries (77). First results indicate that blended care was non-inferior to treatment as usual in terms of effectiveness. However, in terms of cost-effectiveness, blended care was not significantly less costly than treatment as usual. A naturalistic study came to the result that blended care yielded more face-to-face sessions, more therapist time and thus higher costs, indicating the necessity for proper implementation strategies that integrate eMH rather than add it to established services (78).

Positive attitudes towards blended care and promising results in terms of effectiveness underline the necessity to **foster research related to blended care concerning dropout rates, adherence, level of human support and combination of f2f-sessions and online support**. Moreover, benefits for the health system and users need to be clear in order to embed blended care into routine practice.

Cost-effectiveness

In contrast to the high number of systematic reviews and meta-analyses on the efficacy of internet-based interventions for mental disorders and target groups, only a few systematic reviews on cost-effectiveness are available (79–83). The overall evidence base of the cost-effectiveness of internet-based interventions is thus rather tentative.

To provide a short overview, a recent systematic review about the cost-effectiveness of internet- and mobile-based interventions (IMIs) for depression reports good potential of IMIs being cost-effective (83), but concludes that more research is needed. An individual-participant data meta-analysis of guided internet-based interventions for depression with data from 1,426 participants concludes that internet-based interventions are not considered as cost-effective compared to controls (84). These results underline that the informative value of cost-effectiveness evaluations is still limited, as only few RCTs investigated the cost-effectiveness of internet- and mobile-based interventions. It is too early for definite conclusions yet.

Nevertheless, in the context of eMH's promise of accessible and affordable mental health care and prevention efforts, cost-effectiveness may be an important argument for decision-makers for its implementation. In 2018, Paganini and colleagues identified 26 ongoing trials with a focus on economic evaluations of eMH interventions, among others in blended care or stepped care settings (83). Results of these ongoing trials may contribute to an improved level of evidence concerning the cost-effectiveness of eMH.

Besides efficacy, individuals' preferences and needs, and other criteria, cost-effectiveness is only one element for choosing between alternative health services. However, limited resources and an ageing population that uses more resources both need to be considered in research on the cost-effectiveness of eMH interventions, which will further contribute to informed decision-making concerning the implementation of eMH. Therefore, future eMH evaluations should routinely investigate the effectiveness and cost-effectiveness of eMH solutions.

Benefits and risks

Internet-based interventions promise the improvement of population-level mental health and the mental health system through improved access to and availability of evidence-based treatments, flexible and convenient use (low-threshold and anonymous), improved monitor options for therapists to prevent suicide crises, and improved user involvement (active recipients), peer support and self-management skills (patient empowerment).

Stand-alone internet-based interventions (guided or unguided) may help those to manage their mental health issues who may be reluctant to contact a therapist (e.g. due to stigma reasons, social isolation or time and geographical constraints). Therefore, based on a non-systematic narrative review, some experts suggest that self-help interventions may contribute to larger reach, better scalability and affordability of mental health services for mental health prevention, early intervention, treatment and relapse prevention – potentially with a considerable impact on the disease burden of common mental disorders (61). Those people in need who otherwise would not be reached by conventional treatments may benefit especially. For this to become a reality, ways of dissemination and promotion that reach the target population need to be established (see chapter 3.3).

Moreover, using internet-based interventions within established treatment processes (internet-based interventions as add-on or blended care) has the potential to optimise the therapeutic process and increase treatment intensity. For example, internet-based interventions may help patients to do their homework assignment (e.g. cognitive restructuring or psychoeducation), which allows the therapist to use the time more efficiently when the patient is physically attending a session. This will further improve the intensity of

care, treatment efficiency and the self-management skills of patients.

Despite promising evidence and potential benefits, eMH also comes with certain risks, limitations and ethical concerns: the role and quality of human support and the therapeutic alliance in the treatment process is contingent (limited nonverbal communication; limited response options in crisis situations, particularly in the context of self-help interventions; limitation for diagnostic procedures). In addition, inequalities in access to care may prevail or even grow due to limited digital health literacy or digital access, use and handling of privacy data and high investment costs. Moreover, the identification of patients who are likely to benefit from eMH solutions is important to avoid negative responses and attitudes or deterioration in those who have other preferences. Further research needs to identify the risks and negative effects of internet-based interventions in (sub-) groups of users.

Info box 3: What we do not know (yet) about eMH

- High quality effectiveness and implementation research (research-to-practice gap, organisational research); eMH research in the context of severe and enduring mental health difficulties; research of long-term effects of internet-supported psychological treatment (6).
- What side effects or negative outcomes/harms can occur after using internet-based interventions (61, 85)?
- What are the key determinants and characteristics of effective eMH? For whom does which eMH service work, how to identify these people and what are mediators for change (e.g. predictors such as being able to use a computer and read, cognitive function) (48, 86) and moderators of outcomes (6, 20) or contraindications (64)?
- What are the benefits and risks related to user characteristics (e.g. age, digital affinity/literacy) and which inequalities may occur in terms of access, uptake and use of health and care technologies by age, SES or ethnic group (87)?
- What is the appropriate and preferred implementation approach to integrate eMH? What level of usage is most effective, what is the appropriate medium to use and how can users be supported to engage at that level? What is the appropriate frequency of providing support or the type of communication to support user engagement or adherence while using the technology (86, 88)?

- What is the role of the therapeutic alliance and what is the appropriate amount of guidance and adequate frequency and intensity of human support (e.g. number of f2f-sessions and online sessions) (55, 64, 86), and what level of provider qualifications does human support require (88)?
- What are determinants of dropout and non-response? Does support (in any form) predict dropouts (7, 55)?
- What is the appropriate way to recruit patients/conduct more studies in clinical settings (55, 89)?
- What effect does eMH have on the delivery system of mental health care overall (capacity, access to services, availability, waiting times, cost-effectiveness, social and economic impact (e.g. contribution to the reduction of stigma), etc.)? (See also (90))
- What are the benefits and advantages of eMH compared to traditional treatment (68)?
- What is the appropriate and preferred point in the care pathway (prevention, diagnostics, treatment, relapse prevention, rehabilitation, etc.) and how to manage co-morbidity (55)?
- What are the likely preferences of service users? Research concerning tailoring/customising treatment to individual preferences and needs (88).

Mobile apps and wearables

Mobile health (also called mHealth), which encompasses the use of apps on smartphones or tablets, and wearables add new opportunities to mental health care and prevention efforts and may support and improve mental health service delivery. Mobile health apps and wearables are available 24/7 and may:

- improve treatment accessibility, reach of therapeutic help and participant retention,
- deliver personalised information, feedback and motivational support that adds to user empowerment and patient autonomy (helps to make informed and better choices),
- send reminders (improve adherence to treatment, etc.),
- measure real-time data (e.g. biofeedback, psychophysiological data, behavioural) and monitor activity through ecological momentary assessment (EMA) and associate these measurements with other indicators of mental health (61, 91, 92).

Mobile apps offer a very broad range of applications in the field of mental health. With more than 10,000 mental health apps available in app stores, the number of apps related to mental health is still growing (47). Meta-analyses of the efficacy of smartphone-based mental health interventions for depressive symptoms and anxiety disorders indicate that smartphone-based treatments are a promising and efficacious managing method for mental disorders (8, 9). However, these systematic reviews identified only 31 apps for depression and anxiety disorder that were evaluated using an RCT study design. Most of the available apps have not been evaluated in terms of their effectiveness, and the level of quality varies considerably, resulting in limited trust in these services (47). Various initiatives by regulatory bodies such as the FDA, NICE or from Ministries of Health (e.g. in Belgium and Germany) among others, have started to establish a certification and approval system for health apps. These developments are relatively new but very important, as the use of mobile applications in the context of mental health promotion, care and prevention efforts comes with certain risks that need

to be considered. Examples are technical problems, issues of data security, patient privacy and the identification and timely management of crises and risk of harm (49, 93). Transparency in terms of how data is handled, who is the developer and whether mental health apps build upon evidence-based concepts and theories will be important in order to establish trust in these services.

Serious gaming, VR and other digital mental health tools

Serious gaming is described as the use of "games that engage the user, and contribute to the achievement of a defined purpose other than pure entertainment (whether or not the user is consciously aware of it)" (94). Typically, these games entail certain objectives, such as learning, and make it easier to apply certain interventions and ensure patient engagement (61). A systematic review suggests that serious gaming interventions may be effective for reducing symptoms across a range of conditions including depression, post-traumatic stress disorder (PTSD), autism spectrum disorder and alcohol misuse order (95).

Extended reality (ER) combines traditional treatment approaches with digital technologies, for example exposure therapy with virtual reality (VR). While there is strong evidence for the use of VR for exposure therapy in clinical controlled studies (96), its potential for use in routine mental health care and prevention efforts has scarcely been realised. VR proves to be a promising tool for treating common mental disorders (97), but more research and development may be necessary in this field.

Last, but not least, the internet in general and social media in particular offer the chance for crisis lines to improve their accessibility, connect peers and increase their reach. The detection of suicidal thoughts by screening tweets or comments is another option of how to identify people at risk and how to intervene in a timely manner.

More developments in this field will be expected in the near future with regard to avatar developments, artificial intelligence, augmented reality, big data, automated decision-making, developments in VR therapy, and social media, altogether underlining the necessity to find a common way to meaningfully integrate eMH into mental health care and prevention efforts.

1.3 eMH in NWE countries

eMH offers numerous advantages to improve population mental health. In order to do so, however, it needs to be embedded in health systems, disseminated and appropriately implemented. An analysis of the eMH statuses of the six NWE countries (Belgium, France, Germany, Ireland, the Netherlands and the United Kingdom), revealed remarkable differences. While some countries are relatively far ahead with regard to eMH implementation, others are just starting to embed it into their health care systems. The following chapter provides a comprehensive overview of the current eMH status within each of the six eMEN partner countries (a more detailed analysis can be found in Appendix A).

Belgium

Both eHealth in general and eMH specifically are expected to rank highly on Belgian policy agendas in the coming years. So far, however, eMH is underrepresented on policy and practice levels, and lack of awareness and acceptance are among the major barriers for large-scale eMH adoption. Aside from this, limited options for training and education, the lack of a reimbursement system for eMH solutions, as well as the complex state structure, hinder the upscaling of eMH in Belgium.

With support from the federal and regional governments, an increasing number of related initiatives and projects are being carried out, and higher education is starting to embed eMH in research, although slowly. Investments in campaigning and sensitisation, knowledge exchange, training and general education as well as a reimbursement system for eMH would further foster the adoption of eMH. Overall, more support from policy makers, co-creation and collaboration between all relevant stakeholders and transparent information about the quality of eMH solutions are needed in order to facilitate the adoption of eMH.

France

Among the six eMEN partner countries, France appears as the latecomer with regard to eMH development, dissemination, implementation and adoption. While there is great interest on the research level and eMH solutions are used within research projects, eMH products and services are not yet fully embedded in the mainstream public mental health care system. To facilitate this shift, some areas for improvement concern the trust and acceptance by all stakeholders of digital tools. Moreover, users and professionals consider that these tools need to be developed in complement to face-to-face care. A first *National eHealth Strategy 2020* was released in 2016. However, important political steps forward have been made since 2018: eMH has been officially identified as a priority action in the *Mental Health and Psychiatry* political roadmap, issued by the Ministry for Solidarity and Health in June 2018, which has led to the establishment of a multiprofessional ministerial working group. Besides this, the *Ma Santé 2022* plan identified digital health as a major challenge and, as a result, the *Accelerate the Digital Shift* roadmap was issued in 2019, setting out the main goals of a digital health policy.

Overall, an exponential growth in interest and use of eMH in France has taken place during the last four years, showing that there is good potential for upscaling eMH in the future, as interest in eMH solutions is continually on the rise. In order to continue this development and to adopt eMH in mainstream mental health care, political commitment, strong leadership and adequate (legal) frameworks in terms of quality assurance, reimbursement and funding, as well as e-capacity building among service users, are needed.

Germany

Interest in eHealth in general and, more specifically, in eMH is growing in Germany. Increasing activities at the policy level and the self-governance level will further promote the use of eHealth in Germany (modifications of the professional codes in terms of the use of media, the *Digital Health Care Act (Digitale-Versorgung-Gesetz* – DVG), etc.). Currently, private and statutory health insurance companies offer eMH solutions to their clients, but eMH programmes are not yet embedded as a core component of the mainstream public mental health care system. An overall comprehensive strategy to implement and adopt digitalisation in mental health care is missing. However, specific digital health applications and their monitoring by a medical doctor have become reimbursable with the ratification of the DVG at the end of 2019. The interest in research related to eMH is high and will provide knowledge for future directions. Through funding research related to eMH, the *Innovation Fund* (financed by the Ministry of Health and statutory health insurance companies) further promotes research related to eMH implementation. Nevertheless, more legal guidance will be required in terms of quality assurance, liability and reimbursement in terms of eMH. Initiatives such as *AppQ* and quality criteria for internet-based interventions that reduce mental health symptoms will contribute to these developments. Furthermore, at the beginning of 2019, the German Medical Association changed their professional code in order to make remote treatment possible.

Ireland

Interest in eMH is strong in Ireland, on both policy and practice levels. While a number of eMH products and services have been developed organically, and are already publicly available, there is not yet much direct deployment in the mainstream public mental health care system. However, a combination of 'top-down' and 'bottom-up' developments have begun to converge and encourage eMH deployment. From the 'top-down' perspective, initiatives by the Department of Health and the Minister with responsibility for mental health are being implemented through pilots in the HSE mental health services at primary and secondary care levels, as well as initiatives driven by HSE services themselves. A number of these are building on more 'bottom-up' initiatives by third sector mental health organisations that have begun to provide eMH services on their own initiative (including online counselling, online CBT programmes, and other applications). A *Youth Mental Health Task Force report* has also recommended investment in eMH.

Despite the political commitment to eMH and developing interest and activity within the HSE, structural and capacity issues in the public mental health care system and an underdeveloped IT infrastructure, make system-wide innovation difficult. Overall, the goal is to overcome the barriers to upscaling and accelerate development and deployment of eMH across the system. More 'proof of concept' trials and agile evaluation approaches are required to drive implementation at scale for common mental health conditions, as well as targeted smaller-scale projects (e.g. eMH for empowerment of people with enduring and more severe mental health issues) to encourage attention to specific/important topics. Practical guidance on implementation and training on eMH for mental health professionals is also important. The development of standards and quality criteria, and structures to enable collaboration between developers, clinicians and users to foster innovation, will also facilitate the adoption of eMH.

The Netherlands

eMH research and development in the Netherlands started about 10 years ago. Yet the government did not work on this in a coordinated way at first and there was no national strategy for eHealth and eMH, leading to fragmented deployment of eMH. As a result, almost every mental health care service provides some form of eMH product or service, but there is no widespread use of it. In fact, only around 15 percent of mental health providers offer eHealth as part of their treatment. Furthermore, lack of training and education of the mental health workforce, lack of implementation research and continuity in research as well as an inadequate reimbursement structure and limited transparency in terms of quality control and privacy assurance hamper the uptake of eMH.

However, the interest and involvement on the political level is growing. In recent years, Dutch policy-makers became aware of the opportunity offered by eHealth services and started to address this topic in a more coordinated and ambitious way, leading to more investments and coordinated approaches. There is currently a lot of focus and also subsidy schemes for information exchange standards. These standards must make information exchange easier between care institutions so patients can get easier access to health care information. With this, the government hopes to improve the self-management and self-sufficiency of citizens and to promote shared decision-making. It is desirable to organize care around the patient in his own environment as much as possible. Cooperation on local/community level is therefore supported. Implementation research, a change in the reimbursement structure, training and education facilities and a clear benefit may contribute towards enhancing the implementation of eMH on a larger scale. Involvement and support by the government is required to approach this topic in a more structured and aligned way.

Last but not least, in May 2019, two large Dutch insurance companies (CZ and VGZ, with 43% market share) in the Netherlands have pleaded for a reduced role of the DTC (Diagnostic Treatment Combination) reimbursement system in the mental healthcare sector. Instead of DTCs, a transformation of the reimbursement system should be made towards 'blended psychiatry', where the experience of patients, knowledge of healthcare professionals, and knowledge from hard data are combined.

In 2017, a pilot based on the English cluster model started in the mental healthcare sector. In this model the needs of the patient are central, instead of only the clinical diagnosis. The national healthcare authority in the Netherlands (NZa) wants to introduce this model from 2020 onwards. A new reimbursement system for mental health care in the Netherlands is on its way, with a crucial role for e-mental health.

United Kingdom

Developments with regard to eMH differ greatly among the four countries of the United Kingdom. Levels of investment in digital mental health are increasing, though to varying degrees in each of the UK countries. While eMH has a comparatively low profile in Northern Ireland, Wales and Scotland, it has a key strategic position in mental health policy in England. Overall, eMH is accelerating in England. eMH solutions are increasingly being adopted by health care services, with more than 50 percent of GPs using some sort of eMH product or solution, predominantly self-management interventions. Key technologies that are poised to impact mental health care over the next 20 years include: telemedicine (impact timescale: 1–5 years); sensors/wearables (impact timescale: 2–5 years); smartphones (impact timescale: 2–5 years); digital therapies (impact timescale: 1–3 years); social media (impact timescale: 3–7 years); genotyping microarrays (impact timescale: 5–10 years); neuroimaging (impact timescale: 7–10+ years); electronic health records (EHRs) and patient health records (PHRs) (impact timescale: 2–5 years); health care data collections (impact timescale: 1–3 years); natural language processing (NLP) (impact timescale: 2–7 years); artificial intelligence (impact timescale: 3–10+ years); virtual reality (impact timescale: 3–5 years); and augmented reality (impact timescale: 5–10 years) (98).

In Scotland, Wales and Northern Ireland, eMH products and services such as *moodgym* and *Big White Wall* are mostly commissioned by NHS boards and education institutions. Yet, due to different challenges, there is not as much direct deployment in Scotland, Northern Ireland and Wales as there is in England. Although the barriers for the implementation of eMH differ among these four countries, there are a few common issues. Overall, limited knowledge and guidance about how to implement digital approaches as well as little awareness and lack of co-creation between developers, providers, users, researchers and clinicians hamper the uptake of eMH in the UK. Furthermore, one key concern is the translation of policy announcements into action on the local level. Cooperation of industry, clinical and research communities as well as health care providers and users may facilitate eMH by ensuring that it is engaging, acceptable, evidence-based, scalable and sustainable. Aside from this, ensuring that eMH is considered across all government policies not only in mental health, but also in health generally and in wider, cross-government policies (the *Mental Health in All Policies* approach), will foster the upscaling of eMH in the UK.

1.4 The need for a European policy

Some publications, such as the "Situation analysis and recommendations for action" by the EU Joint Action on Mental Health and Well-being have already analysed the field of eMH, highlighted the need for change and proposed recommendations for action. Yet, only little progress has been made within the last couple of years and it seems that a coordinated approach to overcome the barriers to eMH implementation is lacking.

Thus, in order to advocate a structured and harmonised European approach on the policy level, the eMEN consortium developed this Transnational Policy aiming to facilitate the uptake of innovative, evidence-based, effective and safe eMH products and services in North-West Europe.

The purpose is to achieve coordinated action in terms of eMH on the EU level with the aims of fostering the development, dissemination, implementation and adoption of high-quality eMH products and services, improving population-level mental health and reducing the burden of mental health problems. It aims to provide guidance on the European level for all relevant stakeholders towards policy actions to unlock the potential of eMH for European citizens and European mental health care systems. It also intends to stimulate fruitful discussions and promote the uptake of safe and effective eMH products and services. Besides providing guidance on the European level, this Transnational Policy aims to be informative to national policy makers and governments, mental health service providers, the mental health workforce, academics and researchers, people with mental health problems, their relatives, general consumers, eMH developers and SMEs.

Based on the results of comprehensive literature reviews conducted between 2017 and 2019, input obtained during stakeholder interviews and experiences by the project partners of the eMEN project, this Transnational Policy comprises:

- an introduction to the **challenges of the mental health care sector and to eMH** as an element of mental health care
- a depiction **of the different levels of eMH developments** in the NWE partner countries Belgium, France, Germany, Ireland, the Netherlands and the United Kingdom, and on the wider European level (including a detailed analysis in Appendix A)
- a **detailed analysis of the identified challenges (barriers and facilitators)** for the development, dissemination, implementation and adoption of eMH solutions
- **recommendations** targeted towards stakeholders on the European level on how to address the identified challenges and facilitate the dissemination, implementation and adoption of high-quality eMH solutions
- a **Proposed Action Plan** with actions for the European Commission and other relevant stakeholders (such as National Health Ministries) on how to implement the recommendations.

Corresponding with the described aims, the following vision and objectives of this Transnational Policy were defined:

Vision

- Improve European citizens' mental health by fostering safe, integrated, effective, accessible and high-quality eMH products and services
- Increase access to appropriate care at the right time for all EU citizens
- Empower people in managing their mental health and mental disorders
- Improve mental health care service delivery and increase efficacy

Objectives

To cover the full scope, nine objectives were developed to:

- Promote, integrate and establish accessible, affordable, low-threshold and effective eMH products and services as an adjunct to conventional methods in mental health care services
- Ensure that every European citizen is aware of (available) quality-assured and effective eMH products and services, and has sufficient knowledge to make informed choices
- Ensure the continuity of care and embed eMH into routine mental health prevention and care and the education system of (future) professionals
- Improve the quality of eMH solutions and use them in the most effective way
- Ensure that eMH solutions are developed in co-creation with users so that they are user-friendly, accessible and culturally acceptable
- Use health care resources efficiently and offer integrated, safe and better targeted mental health prevention and care that promotes self-management and empowerment
- Increase the use of eMH products and services in order to decrease the burden of mental health problems and enhance population-level mental health
- Create leadership, supervision and coordination within eMH implementation processes
- Increase cooperation and policy impact of regulations and actions, and prepare European mental health systems for future challenges

2 Promoting and implementing eMH

Despite promising evidence, the adoption of eMH solutions is still limited and implementation processes remain slow (24–27). So far, the dissemination of eMH is rather uncoordinated and widely unregulated. As a result, eMH's potential to improve population-level health and reduce the burden of mental problems has scarcely been realised. There is no doubt that translating research knowledge into clinical practice is the most challenging part (39, 99). However, attention to targeted eMH implementation protocols (25, 100) and coordinated efforts on the policy level have so far been limited.

In spite of early movements towards implementing eMH as a complement to traditional mental health service delivery in the UK, the Netherlands and Scandinavian countries (101), the overall structured implementation of eMH solutions (apart from the research context) proceeds slowly in Europe (27). Until now, only a few EU Member States have included eMH in their mental health policies (see Appendix A). eMH implementation action plans rarely exist (57).

Systematic reviews about determinants that influence the implementation of eHealth and eMH identified several key barriers and facilitators for the uptake of digital innovations in health care. Important hindering factors relate to the characteristics of the intervention itself (i.e. costs, complexity and adaptability to the local organisation), financial and legislative support and individual staff characteristics (102). Research suggests that besides quality of health care and costs, workflow plays a considerable role for the successful uptake of digital health interventions (26, 103). For example, if a new intervention comes with additional workload or technical failures or just does not fit within workflows, adoption will be unlikely (26, 103).

"eMental health technology requires extensive change to systems, structures and individual workflow" (26). Streamlining it with and embedding it into established treatment pathways will be highly relevant for its sustainable adoption. Yet, in spite of large differences with regard to the dissemination and implementation of eMH among eMEN partner countries, the analysis of the status of eMH dissemination in NWE countries reveals that there are a number of challenges for eMH implementation and adoption that seem to exist transnationally.

On an individual level, low awareness about available evidence-based eMH products and services (26), scepticism towards digital technology, concerns about privacy and data security, limited digital (health) literacy and preference for face-to-face therapy all result in a reluctance to use eMH solutions and are among the major barriers for eMH implementation. The acceptance of digital interventions by service users and the (mental) health workforce is perceived as an important determinant (27). In particular, the roles of human support and the therapeutic alliance in the treatment process were mentioned as essential and hence, a blended care format was perceived as a less disruptive (but possibly more effective) approach of eMH implementation (26).

On the system level, a lack of coordinated and structured alignment, clear vision, objectives and policy and legal guidance largely contribute to limited or incoherent implementation and adoption of eMH in NWE countries. Lack of quality criteria, adequate funding models and reimbursement schemes, and few quality control mechanisms (HTA processes) that identify evidence-based high-quality eMH products and services in publicly-funded health services were mentioned as impeding factors. Furthermore, research concerning eMH mainly focuses on efficacy and effectiveness, often neglecting research on implementation. Knowledge is still vague in terms of when and how to include what eMH solution for whom. In particular, the role of human support and the therapeutic alliance for treatment success needs to be investigated in more detail. Long-term effects and potential negative effects need to be investigated as well as mediators for change and outcomes. Furthermore, the effects on the processes of mental health care should be evaluated (cost-effectiveness, access to services and availability, etc.).

Other important determinants for successful implementation and adoption of eMH in NWE countries are related to the organisational level, such as sufficient training for health professionals, adequate eMH implementation protocols, and strategies and standards to meaningfully integrate eMH solutions into workflows. The role of eMH in mental health care and prevention efforts and its value for health professionals, people with mental health problems and the mental health care system often remain unclear. Moreover, collaborations between developers, the health care sector, users and clients in creating eMH products and services (co-creation) are rarely seen. The appropriateness of eMH in addressing the individual's needs and usability are perceived as important determinants for successful implementation (27, 99). Outdated or underdeveloped digital infrastructure further hampers the large-scale use of eMH in mental health service delivery.

There are also a number of facilitating factors for eMH implementation such as an increase in the number of research projects and collaborations on eMH, increasing interest in the levels of research, practice and policy, and the promise of eMH for improved accessibility of affordable mental health care and prevention efforts, patient empowerment and improved overall quality of care. Research and expert groups contribute to the improvement of eMH solutions by developing and suggesting quality criteria for internet-based interventions or health apps. Characteristics related to the advantages of eMH such as low-threshold access, good overall accessibility (irrespective of time and place), disinhibition effects regarding use of mental health care services, and anonymity facilitate its adoption (99). Moreover, the adaptability of the intervention to the user's needs and adequate digital skills of the (mental) health workforce and users serve as facilitators (99).

In order to foster a structured, coordinated and harmonised implementation process, a combination of activities at the national and European levels will be warranted:

- strengthening the role of eMH in European and national health strategies and/or action plans for mental health and creating a regulatory (financing, quality control) and legal (liability, privacy) environment that enables the use of eMH in routine care in an ethically appropriate way (44, 45, 57, 104, 105) (see chapter 2.1)
- ensuring that eMH products and services are of high quality by defining common quality criteria and developing eMH products and services according to target group needs and preferences (co-creation/usability), based on robust evidence about effectiveness using established evidence-based research designs (see chapter 2.2)
- improving knowledge about and awareness of eMH among all relevant stakeholders and increasing the acceptance of eMH and digital health literacy skills (see chapter 2.3)
- preparing (mental) health systems, provider organisations and other actors for the adoption of eMH through the development of targeted implementation strategies (including eMH training), which are informed by comprehensive implementation research, and through education and training of the health workforce (see chapter 2.4).

Based on the results of the analysis of the eMH policy context and developments in the eMEN partner countries (Belgium, France, Germany, Ireland, the Netherlands and the United Kingdom) and experiences from the eMEN project, (trans-)national challenges for the implementation of eMH were identified. This chapter focuses on analysing those identified challenges one by one and providing guidance for European stakeholders on how to enable successful implementation and adoption of eMH solutions.

2.1 The critical role of political commitment and leadership

"eMental health care needs the clear endorsement and guidance from the health care system" (26).

The European Commission's *Digital Single Market (DSM) Strategy* acknowledges digital health as a key component for increasing the wellbeing of millions of European citizens (106). Digital solutions can *"radically change the way health and care services are delivered to patients, if designed purposefully and implemented in a cost-effective way"* (106). In order to support this development, the *Joint Action on Mental Health and Wellbeing* has already provided recommendations for action to mainstream eMH and to improve design and dissemination (57). The recommendations encompass including eMH interventions into publicly-funded health services and align them with standards and practices, initiating agreements with developers addressing ethical issues, intellectual property and dissemination practices, raising awareness and capacity of mental health professionals, as well as setting up quality control mechanisms for eMH solutions at EU level, and integrating eMH into overall eHealth policies at EU and national levels (57). Furthermore, for the purpose of improving the design and dissemination of eMH, they recommend to blend models of service delivery (combining eMH with face-to-face services), design products and services for engagement and retention of users, collaborate with technology experts, improve quality and feasibility of evaluation studies, and develope an EU-wide repository of eMH solutions (57). Other initiatives that aim to facilitate the use of digital solutions within the health sector are the *eHealth Network* and the *mHealth Hub*. The eHealth Network focuses its activities on interoperability and standards for eHealth, and fosters cooperation between EU Member States (107) The *mHealth Hub* (funded by the Horizon 2020 programme), assists EU Member States with collecting and sharing national experiences of working with mHealth at scale and to introduce mHealth programmes (107) (see Appendix A for more information about e(mental)health activities at EU level). Together with relevant regulations and directives such as the *GDPR* (108), which provides rules for the protection of privacy and data security, and the *Medical Device Regulation* (109), which aims at improving the quality, safety and reliability of medical devices, these initiatives and documents give directions for the role of digital health in European health systems. Thus, policy actions and networks that advocate digital solutions for health and care (eHealth and eMH) and promote the exchange of good practices and funding of activities are already in place on a European level.

As part of the broader eHealth development, eMH benefits from the above-mentioned developments at EU level. The analysis of eMH developments in Belgium, France, Germany, Ireland, the Netherlands and the United Kingdom (see Appendix A for further information) indicates that eMH has gained importance in recent years, not only in countries such as Australia and Canada, but also throughout more of Europe. However, within the broad concept of digital health, eMH specifically is still a rather underrepresented topic at EU level. It still plays a minor to moderate role in national mental health policies and adoption into practice remains slow and limited (see Appendix A for a list of policies related to eMH for eMEN partner countries).

In eMEN partner countries, there is a pressing **need for a regulatory framework, clear policy guidance and adequate legislation.** The lack of structured alignment, clear vision and objectives largely contribute to the limited or incoherent implementation of eMH in NWE countries. In order to unlock the power of technology, the efficient implementation of eMH solutions in mental health systems requires not only an appropriate technological infrastructure, but also a **political climate that is receptive and enlightened by reliable research, knowledge and information on eMH** (see chapter 3.2). The necessity of substantial political commitment, governance and strong leadership for implementing change in mental health service delivery is obvious (26). By embracing the eMH means of user engagement and improved accessibility, a **paradigm shift in thinking and cultural change in mental health service delivery** and prevention of mental dis-

orders may help to approach current and future challenges of mental health systems in a sustainable and successful manner. It is time to set the vision, mission and objectives for future mental health systems and to develop adequate structures, standards and processes to benefit from eMH. An appropriate regulatory framework guided by an overall eMH implementation strategy will facilitate succeeding in this endeavour and will stimulate innovation.

The examples of Australia, Canada and Denmark (see info box 4) indicate potential key determinants for a successful transformation process: a coherent and transparent long-term strategy, sustainable investment and, above all, the involvement of all stakeholders in an early phase not only to establish trust, but also to tease out interest, commitment and a general openness towards new ways.

National eMH strategies may want to focus on setting-specific characteristics such as raising targeted awareness (see chapter 2.3.), establishing a national infrastructure including training and education of health professionals (see chapter 2.4.2), setting incentives for the use of eMH and establishing adequate legislation and regulation frameworks that surround the delivery of eMH. A multidisciplinary process that involves and engages stakeholders in the implementation process of eMH is essential to ensure a common vision and overall commitment. Moreover, political guidance and regulations will be important to create trust among health professionals, consumers and developers. By actively shaping, framing, prioritising and controlling the use of eMH, health systems have the chance to initiate substantial change, keep mental health systems resilient against future challenges and improve European citizens' mental health. Therefore, **national digital health strategies should outline mandates, legislation and a sustainable investment plan specific to mental health**. Sustainable funding and investment in the digitalisation of health care (including a digital infrastructure) is a prerequisite for the robust uptake of eMH (see also chapter 2.1.3). In September 2018, the agreement between EU Member States to develop a guideline for targeted Europe-wide promotion and investment programmes in the eHealth sector may be seen as a first step towards sustainable eHealth investment across EU Member States (110).

Since some eMH products and services will be accessible transnationally, a comprehensive European action plan that addresses the future role of eMH in mental health systems will be important to ensure the safe and efficient use of eMH. Moreover, an action plan will strengthen the position and attractiveness of the European health care market in the long-term. Although the implementation process itself is strongly dependent on country-specific conditions, stakeholders indicate that guidance and support at EU level may accelerate the implementation process of eMH within EU Member States. European legislation or requirements applicable to eMH products and services, such as the GDPR or the Medical Device Regulation, will advance the development and implementation of eMH at the national level while respecting national competences. **Political commitment and leadership, as well as specific policy development for eMH concerning aspects such as data protection and privacy, awareness, quality criteria and interoperability at EU level will foster developments in the field of eMH throughout Europe**. Sharing experiences in deploying eMH and general knowledge exchange across EU Member States may contribute to an enhanced uptake of eMH. By **incorporating eMH in future Action Plans for mental health and other strategies**, the European Commission may provide a vision for Europe's mental health system in the digital age.

Without timely governance of this development, mental health systems run the risk that people will use eMH products and services that are ineffective, unsafe or even harmful, and with only limited standards in terms of quality and privacy. Therefore, timely governance, endorsement (e.g. in the form of effective incentives) and stewardship at health care system level are strongly advocated to develop coherent and transparent eMH implementation strategies and

digital health policies that encourage, enable and enhance implementation and adoption of eMH (26).

Recommendation 1 addresses the importance of *political commitment and policy development* and suggests how to foster it in order to *facilitate the implementation and adoption of eMH solutions*. The recommendation is supplemented by the *Proposed Action Plan* with concrete suggestions for actions (see p.87 for actions for the EC and p.94 for actions for other stakeholders).

Info box 4: Best practices – political activities

eMH implementation efforts in Australia, Canada, Denmark and England underline the potential of eMH for contributing to improved mental health services. The eMH Strategy for Australia, the guidance documents in Canada, the Action Plan in Denmark and the NHS Long Term Plan in England largely contributed to or will contribute to enhanced developments in eMH. The strategies provide successful examples of how policies, including clear strategical steps in combination with research, may successfully contribute to the implementation of innovation and, hence, sustainable health care provision.

Australia

In the late 1990's, Australia faced a high suicide rate among adolescents that resulted in a strong need for (policy) action. In collaboration with non-governmental organisations such as ReachOut Australia, Australian academics advocated the development of an eMH sector to prevent suicides and forced decision-makers to take action. In 2006, the Australian Government funded several eMH projects and, later on, established an eMH Expert Advisory Committee which provided advice on the eMH strategy in 2012 (111).

According to this strategy, eMH is referred to as *"an alternative, and an adjunct to face-to-face mental health care"*. Combined with high investment in mental health services (AUS$2.2 billion) and an extension of the National Broadband Network, the Australian Government aimed at establishing a mature eMH system. The strategy focused on access, quality and integration of eMH and resulted in 1) an eMH portal (https://headtohealth.gov.au), 2) a virtual clinic (https://mindspot.org.au/) and 3) a productive eMH service environment (marketing strategy) (111).

Today, Australia is recognised as the frontrunner in research, development and delivery of eMH products and services to people in need.

Canada

In Canada, implementation of eMH comprises different activities initiated by both research and governance.

In 2014, the Mental Health Commission of Canada (MHCC) (a national non-profit organisation created by the Canadian government in 2007) published a Briefing Document. Within this document, experts from Canada and around the world provided key considerations concerning the transformational potential of and challenges to the use of eMH. It showcased eMH and provided guidance for future eMH use in Canada (33).

In the following years, the MHCC published more documents describing and evaluating the tremendous potential of eMH for the transformation of the mental health system. *"RE-AIMing e-mental health"*, for example, provides a comprehensive overview about eMH interventions and guidance for decision-makers and service providers to fully realise the potential of eMH in Canada (112). The *"Toolkit for e-mental health implementation"*, published in 2018, goes a step further (113). It aims at informing the workforce about what eMH is, and when and how to use it.

Thus, in Canada, the interplay of non-profit organisations, researchers, experts and the government creates target-oriented guidance that contributes to eMH developments and helps to facilitate eMH implementation throughout Canada.

Denmark

Denmark launched its first eHealth strategy in 1994 and established a health network with national standards for exchanging data that is still widely used by the Danish population today. Compared to other European countries, Denmark is way ahead in terms of using a health network for health care delivery. Besides a coherent strategy, the population's general trust in how data was handled, support among all stakeholders and an investment strategy that created interest in the success of the project were key features of this development. As digital transformation is an ongoing process, Denmark launched a new digital strategy *(A Coherent and Trustworthy Health Network for All)* in 2018 (114).

England

In England, the *NHS Long Term Plan* (published in January 2019) (115) strongly promotes the development of digitalised health care. According to the Plan, progress has been made in achieving the ambitions set out in the *Five Year Forward View for Mental Health* (116) and the Wachter report on *Harnessing the Power of Health Information Technology to Improve Care in England* (117). New enhanced digital and technology systems and services have been delivered since 2016 including access to high-quality NHS information and digital services through the transformed nhs.uk website, plus access to more than 70 apps (including 18 mental health apps) that have been assessed and approved via the NHS Apps Library. WLAN is being installed across the NHS estate. The national roll-out of the NHS App has begun, and will provide citizens with access to NHS 111 online, their general practitioner (GP) record, the ability to book appointments, update data sharing preferences and register for organ donation, all from their computer or smartphone (115).

There are plans to work with the wider NHS, the voluntary sector, developers and individuals in creating a range of apps to support particular conditions. The aim is that by 2020, a number of technologies that deliver digitally-enabled models of therapy for depression and anxiety disorders for use in IAPT services across the NHS will be endorsed. This is expected to expand to include therapies for children and young people through other modes of delivery, such as virtual and augmented reality, which are already demonstrating early success through the mental health Global Digital Exemplar (GDE) programme. An Application Programming Interface (API) and appropriate governance models will be created to underpin this work, so that technical barriers will not stand in the way of innovation (115).

By 2024, secondary care providers in England, including acute, community and mental health care settings, will be fully digitised, including clinical and operational processes across all settings, locations and departments. Data will be captured, stored and transmitted electronically, supported by robust IT infrastructure and cybersecurity, and LHCRs (local health and care records) will cover the whole country (115).

Digitally-enabled primary and outpatient care will go mainstream across the NHS to provide convenient ways for patients to access advice and care. For patients and staff, the starting point is interoperability of data and systems. Then, building on progress already made on digitising appointments and prescriptions, a digital NHS 'front door' through the NHS App will check symptoms, provide advice and connect people with health care professionals – including through telephone and video consultations. Patients will be able to access virtual services alongside face-to-face services via a computer or smartphone. There will be continued investment in the nhs.uk platform so that everyone can find helpful advice and information regarding their conditions. The NHS will continue to support the development of apps and online resources to support good mental health and enable recovery (115).

2.1.1 Regulatory framework

Every new technology brings new risks. Wherever laws are missing or inadequate, an uncertain environment prevails and legal risks increase. The people involved will avoid exposing themselves to situations with unknown consequences. Therefore, unclear legal contexts are further reasons to resist using eMH products and services.

One of these reasons, among others, is the liability concern regarding the use of eMH products and services. It is still unclear who is accountable for therapy failures or clinical complications due to using eMH solutions. What happens in cases of technical failures that may endanger the treatment process or even result in harming the user's health or socioeconomic status? (118) In the context of eMH, there is a need to establish a legal framework that creates trust and certainty in users and health professionals concerning the use of eMH products and services.

Decision-makers in health care should promote and enhance the clarification of mandates and legislation concerning privacy (26), liability and other legal issues surrounding eMH (such as intellectual property rights). **They should verify that legal risks are as low as possible while ensuring that legislation safeguards individuals and society, rather than impedes the use of digital innovations (e.g. in terms of liability or the use of data)**. Clear and adequate legislation will be an important milestone to create trust in using eMH solutions. It will decrease insecurities in terms of legal rights and will have a signalling effect for developers that will, in turn, enhance developments in the field of eMH implementation.

2.1.1.1 Privacy and data security

Now that the internet and technology dominate the everyday lives of most European citizens and make data accessible from nearly everywhere, privacy and data security have become important concepts.

Both privacy and data security share the purpose of protecting users' data, although they differ in their focal points. Privacy is a fundamental human right that is protected under Article 12 of the *United Nations Universal Declaration of Human Rights* (119) and Article 8 of the *European Convention on Human Rights* (120). Yet, it is a concept for which there is no clear definition (121), as privacy is subject to cultural and policy variations (122). When put into the context of eHealth or eMH, the term usually refers to information privacy, which has been described as a concept of controlling how one's personal information is acquired and used (123–125), or a state in which the individual retains control over his or her data, even when that data is maintained or shared by another party (126). Data security refers to the *"physical, technological, or administrative safeguards or tools used to protect identifiable health data from unwarranted access or disclosure"* (127). Thus, information privacy is about controlling how the parties that have access to personal data handle and use it, while data security is about protecting that data from unauthorised access by external parties.

While information privacy and data security are crucial in general, they need to be focused on even more when it comes to eMH. Health data may be the most personal, sensitive and intimate information that one may acquire about an individual (128). Such data being disclosed inappropriately or accessed by unauthorised parties may lead to not only embarrassment, but also major issues for individuals such as with insurability or employment (129). Moreover, mental health data may be valued as even more sensitive than other health data due to the low acceptance of mental disorders and persistent stigmatisation in society. Consequently, evidence suggests that privacy and data security of eMH products and services are a major concern for most (potential) users (130, 131). Thus, in order to enable the successful implementation of eMH solutions, information privacy and data security are among the major challenges that need to be considered in the planning, development and implementation phases.

The core consideration with regard to protecting information privacy and data protection is the EU *GDPR (Regulation (EU) 2016/679)* (108), which is legally binding and has been applied since 25 May 2018. The General Data Protection Regulation modernised and

harmonised privacy laws across Europe, and extended citizens' rights with respect to their privacy and data protection. **Overall, it aims to ensure the provision of unified and high standards for data protection and privacy for everyone in Europe**. Even when a company's place of business is outside Europe, the GDPR applies as soon as the company conducts any kind of business in Europe that involves EU citizens' data. Non-compliance with the GDPR is sanctioned with substantial fines (for more information see Appendix A).

In order to comply with the GDPR and ensure information privacy and data security, there are a few methods and actions that developers and providers may utilise. First and foremost, organisations that develop or implement eMH products and services need comprehensive data governance policies, strategies and concepts on how to protect private data and respond to cyberattacks (132). When developing such policies, strategies and concepts for data security and information privacy, four data related dimensions need to be considered:

- unauthorised access,
- unauthorised secondary use,
- errors (i.e. inadequate protection against intentional and accidental errors), and
- collection of information (i.e. collection and storage of extensive amounts of personally identifiable data) (133).

To go a step further, Bennett and colleagues (134) recommend that data security is ensured by taking action on three different levels: methodological, technical and procedural data security. Firstly, the intervention design, the technology used and the type of data and its management need to be determined (methodological security). Secondly, the technical features and deployment of the intervention need to be designed in a manner to ensure data security (technical security). Thirdly, the storing and handling of data by operators needs to be regulated (procedural security). As well as that, ongoing risk assessments in all of those areas are recommended (134).

Secondly, it is essential to consider the potential threats to data security that stem from interactions between people and information systems (121). Depending on the state that the information is in, several variables need to be considered: storage (who will have what kind of access?); transmission (what level of education do users need to ensure that the secure transmission of information will not be compromised?); and use (is the user trained well enough to ensure that the data is safe while processing it?) (121).

Lastly, aside from the actual data collection and storage on the organisations' side, data transmission needs to be secured on the professionals' and patients' side. Patients' and professionals' digital literacy need to be improved. They need to be educated about how to identify unsafe products and how to avoid risks on their side (e.g. unsafe WLAN connections or computer viruses).

Overall, the GDPR is a major step forward in terms of protecting European citizens' privacy and data security, aiming at giving EU citizens better control over the use of their personal data by others. However, the GDPR is also quite an extensive and complex piece of regulation, making it difficult for laypeople to understand their rights and obligations. (Potential) users of eMH solutions may not be aware of how the GDPR protects their privacy and what choices they have (e.g. the right to be forgotten), so that they may still be worried about how their data is handled. Developers, on the contrary, are challenged with developing GDPR-compliant products, while providers need to safeguard privacy and data security when working with eMH solutions. Researchers might face yet other challenges, such as figuring out how to enable data sharing in research while complying with the GDPR. Hence, in order to avoid insecurities and promote eMH products and services, all relevant stakeholder groups may benefit from some sort of guidance for eMH development, research or use, providing tailored information for the specific stakeholder group. Besides such guidance, researchers may benefit from the initiation of a public dialogue about the use of patient-generated digital data in the research context in order to clarify the possibilities and boundaries.

Hence, with a view to prevent stakeholder insecurity, not only is the safeguarding of privacy and data security crucial for the successful implementation and adoption of eMH, but also the education of relevant stakeholders with regard to the GDPR, privacy and data security.

Recommendation 2 addresses the importance of *legislation, privacy and data security of eMH products and services* and suggests how to foster them in order to *facilitate the implementation and adoption of eMH solutions*. The recommendation is supplemented by the *Proposed Action Plan* with concrete suggestions for actions (see p.87 for actions for the EC and p.94 for actions for other stakeholders).

2.1.2 Quality control mechanisms

It is without question that digital health interventions will play a role in future health care delivery. In publicly-funded health care systems, digital health interventions rely on the same scarce resources as more traditional health care interventions. Therefore, if eMH is to be integrated into publicly-funded health systems as a supplement or an equivalent to established therapies, the standards of evidence-based medicine should apply for their evaluation (135). The requirements for evidence generation of digital health solutions are new, still rather unregulated and create new challenges concerning evaluation methods and quality criteria, and hence, limit the adoption of eMH solutions (26). Existing HTA structures and criteria are still difficult to apply to digital health interventions (136). Therefore, publicly-funded health systems are faced with the challenge of developing a system that ensures that patients only get access to effective and financially profitable eMH solutions, while recognising the specific characteristics of digital health interventions such as rapid development cycles and their tendency to steadily iterate, update and improve (135). However, issues such as information governance, usability, ethics and the option to make use of real-world evidence should be recognised (135). Despite these characteristics, specific standards for eMH may be warranted but still need to ascertain efficacy, effectiveness and both product and patient safety. Only processes and criteria need to be adapted to specific characteristics of digital health solutions, such as how to handle continuous updates of the software, content or functionality, and their respective role and integration in the health care system. For example, what happens if a digital health intervention that has already received approval for its use in publicly-funded health services is updated? Does this mean that the approval also requires reassessment? In the context of mental health apps, Torous and colleagues suggest that this is only necessary if the modification or the update comes with essential changes to the intervention (137). This approach would avoid administrative resources being bound up by continuously reassessing updated versions. Other regulatory bodies offer advice for developers of digital technolo-

gies (e.g. the BfArM (the German Federal Institute for Drugs and Medical Devices)) or started to develop and test frameworks. In 2018, NHS England initiated the development of an *Evidence Standards Framework for Digital Health Technologies* (138). Together with the *Code of Conduct for Data Driven Technologies*, these documents provide guidance for developers, evaluators and regulatory bodies in the field of digital health in England (see info box 5). Initiatives such as Mobile Health Belgium (see info box 5) indicate that there is a need for information and guidance about the quality and evidence base of digital health interventions in general, and eMH products and services in particular. Taken together, these guides and initiatives may foster innovation in health care through developing quality control mechanisms that apply rigorous evaluation methods and transparently inform the public.

Overall, the regulatory framework should provide timely access to high-quality eMH solutions and, furthermore, should provide reasonable assurance of effectiveness and safety to decision-makers, health professionals and users (26). Moreover, appropriate quality criteria and HTA processes will facilitate the reimbursement of costs, which, in turn, will further foster adoption. Nevertheless, it will be a challenge to establish these processes while ensuring that they do not stifle innovation and growth (135, 139). Regulatory processes should not inhibit new initiatives or discourage innovation by applying standards that are too strict, prevent implementation or even lead developers to label their products as 'health and wellness products' in order to avoid undergoing assessment, thus increasing the risk of causing even more harm (47). There is no doubt that only evidence-based and safe eMH products and services should be accessible to the public. Digital exceptionalism is no option and *"failing to robustly evaluate digital health interventions presents the greatest risk for patients and health systems"* (140).

Scrutiny and rigorous evaluation will be the answer to decrease this risk (see also chapter 3.2). Now is the time to shape and harmonise quality control mechanisms for digital health solutions in mental health care and prevention efforts in Europe, which will further boost the innovative potential of digital health throughout the European market. Further multidisciplinary collaboration is needed if eMH is to achieve its full potential.

Recommendation 6 addresses the importance of **quality control mechanisms** and suggests how to foster them in order **to facilitate the implementation and adoption of eMH solutions**. The recommendation is supplemented by the *Proposed Action Plan* with concrete suggestions for actions (see p.87 for actions for the EC and p.94 for actions for other stakeholders).

Info box 5: Best practices – quality control

The Digital Health Innovation Action Plan: the FDA approach

The evaluation of software that aims to diagnose or treat is not comparable to the process of approval for medical devices or pharmaceuticals. In 2017, the FDA outlined a 'de novo' software Precertification Program in its Digital Health Innovation Action Plan in order to facilitate a better approach to review such services and ensure timely access to innovative solutions. This program describes a premarket review pathway for low-to-moderate risk devices, i.e. to certify the software developer or digital health technology developer rather than a specific product. If the developer receives a certificate, the developer is allowed to put products on the market without a prior specific product review (141). However, the FDA stated clearly that they will not assess apps with a low level of risk (142).

Mobile Health Belgium

In 2018, Mobile Health Belgium (https://mhealth-belgium.be) was launched by the Belgian federal government together with technology developers, which provides detailed information on validated health applications for health care professionals and patients. A three-tier validation pyramid distinguishes between different, increasingly more demanding standards that applications can adhere to: 1) having a CE mark (Conformité Européenne / European Conformity) and complying with national quality standards; 2) guaranteeing interoperability; and 3) being able to provide proof of (cost-)effectiveness.

The eMEN product development toolkit

A tool that provides a structured approach and guidance for developers with regard to the development, evaluation and implementation phases of an eMH product or service, with the goal of supporting them in getting a high-quality eMH solution market-ready.

United Kingdom

IAPT (Improving Access to Psychological Therapies) Programme

NHS England is working with NICE (National Institute for Health and Care Excellence) to assess digitally-enabled therapies (the criteria studied include: content, digital standards, effectiveness, cost and resource impact) in order to select high-quality, evidence-based, cost-effective products, which achieve good outcomes (143).

Evidence Standards Framework for Digital Health Technologies

Led by NHS England, a working group developed the *Evidence Standards Framework for Digital Health Technologies*, which sets the effectiveness and economic standards for evidence generation of digital health technologies in order to demonstrate value for the health system. It complements other regulatory and information governance standards, such as the *Code of Conduct for Data Driven Technologies in England*. The evidence standard framework aims at informing evidence development plans and decision-makers and is only suitable for digital health technologies that incorporate artificial intelligence using fixed algorithms (adaptive algorithms are out of scope) (138).

The Framework classifies technologies according to their function. To each function, an evidence tier is assigned (evidence tier 1-3b). "*The evidence standards in tier 3b are intended to be complementary to the requirements for regulatory approval under the Medical Device Regulations*" (138). The evidence for effectiveness standards proves to be relevant to current pathways (proven by published or publicly available evidence) to acceptability with users (tier 1) as well as to high-quality intervention studies (tier 3b). For detailed information, please refer to the Framework (138)

2.1.3 Financial aspects

Financial coverage of eMH

"Funding for e-mental health should be made on the basis of whether a service is effective for people in need, not solely on the basis of whether it is delivered face-to-face by a clinician." (44)

Sufficient and adequate financial coverage of eMH products and services will be a key factor for the sustainable adoption of eMH solutions. Although health insurance models and reimbursement schemes differ throughout NWE partner countries, financial coverage for eMH is either absent or in development; existing ones are *"only spotty and vague"* (26). Health professionals reported *"no concept for reimbursing the use of new technology, no concept for funding additional activities such as writing and sending reminders or motivational mails"* as main barriers for the integration of new technologies (69).

Furthermore, unreliable coverage is considered as a main barrier for physicians to refer patients to eMH solutions, as they would like to avoid out-of-pocket expenses for their patients (26). Besides the financial burden, out-of-pocket expenses entail the risk that patients get the feeling that a service is preying on them (26) while, on the other hand, free services often create the impression of being of minor quality or relying on business models such as selling data. Therefore, it will be important to ensure that out-of-pocket expenses for patients are as low as possible. Furthermore, concepts for coverage and reimbursement to compensate the working hours of health professionals dedicated to getting acquainted and working with eMH are needed. It is strongly recommended to develop business models that enable treatment centres to buy high-quality eMH products or services (e.g. through licenses), which may support the large-scale implementation of such eMH solutions, and may prevent treatment centres from developing their own products, which would lead to even higher fragmentation and lack of market transparency. In addition, available resources need to be efficiently spent, i.e. that the integration of eMH into routine care should not result in reimbursing two care services at the same time (e.g. due to the separate use of eMH and face-to-face therapy, instead of utilising the blended approach, in which the two methods complement each other). Therefore, it has to be ensured that eMH and traditional mental health service delivery complement each other not only in terms of effectiveness of care, but also financially.

Available reimbursement schemes and remuneration models do not represent the time and effort of health professionals working with eMH. Inadequate or lacking reimbursement schemes and remuneration models for the use of eMH strongly impede the diffusion of eMH. Health innovations that do not fit into reimbursement schemes, or for which no reimbursement scheme exists, will not be sustainable or be implemented (118). A financially viable framework needs to define who pays what to whom and under which conditions. What are additional activities in the context of using eMH? Will a health professional be paid for sending a reminder to a patient via email? In addition, what is the reimbursement structure and remuneration model for blended care treatment? Will the health professional be able to bill for prescribing eMH to patients? It will be important and essential to find answers to these questions. A roadmap that describes and assesses available coverage and reimbursement systems throughout European countries may help to establish financially-viable funding systems and reimbursement schemes in the long-term, which in turn may positively contribute to eMH implementation.

Reimbursement schemes that incentivise the use of innovative services by giving professionals more time to get to know a programme, for example, may benefit the uptake of new digital services (26). With its new reimbursement system, the Netherlands suggests a structure that follows exactly this notion (see info box 6: best practices).

Thus, **there is a clear need to update or complement existing reimbursement schemes and remuneration models to enable the adoption and implementation of eMH and to ensure that eMH products and services do not financially overburden patients, health professionals or the health system**. As reimbursement schemes and payment models strongly influence the uptake of innovation, they should therefore also motivate or incentivise providers to engage with eMH.

Info box 6: Best practices – financing

Updated reimbursement schemes in the Netherlands

In 2022, the Netherlands will start a new reimbursement system for mental health care services, not based on the current Diagnostic Treatment Combination. This system will support a new achievement structure in which mental health professionals are paid per activity and not for the complete treatment (at the moment the financial compensation for e-mental health is the same as for face-to-face sessions). Service providers will have to make individual agreements with insurance companies with regard to the maximum compensation for e-mental health treatment, which will be a separate costs category. Furthermore, service providers who contribute most to the reduction of waiting lists will also be covered by the insurance company. The new funding structure will support correct and timely up- or downgrading of care and proper use of care – keeping care accessible for everyone and afordable.

Top of the pyramid in Belgium

The framework set out by Mobile Health Belgium allows for the potential reimbursement of apps that adhere to standards that have been set out (GDPR compliance, interoperability, and proven clinical and cost-effectiveness). Although reimbursement is not implied by default, registered applications that obtain these highest standards can apply for such reimbursement.

Status quo in Germany

In Germany, some eMH products and services may be reimbursed by health insurance based on special payment systems for pilot projects, in the context of prevention (e.g. online resilience training "GET.ON Fit im Stress") or within selective contracting (e.g. online health coaching "TK-GesundheitsCoach"). Some health insurance companies provide their members with free access to selected eMH products and services.

Free health care in England

With the exception of some charges, such as prescriptions, optical services and dental services, the NHS in England remains free at the point of use for all UK residents. This will include any patient referral to an eMH product or intervention.

Reimbursement for teleconsultations in France

Medical teleconsultations for psychiatry (via the Doctopsy platform https://doctopsy.com) benefit from the same reimbursement procedures of social security and insurance companies as in-office consultations.

Funding and investment

"It will be warranted that policy addresses funding and investment issues as early as possible and identifies suitable ways to ensure the investment and funding of infrastructure for new technologies in health care." (26)

Moreover, for sustainable uptake, it will be important to assure the financial viability of eMH in the long-term. Costs for developing eMH products and services, maintaining them, keeping them running and adjusting them are high. Thus, national incentives and/or European grants may focus on promising SMEs in the mental health field that otherwise would not be able to finance the often high development and research costs and hence would not access the market. Unbureaucratic funding options may contribute to enhance the use of eMH. Evidence-based innovations, in turn, will contribute to improved mental health care and prevention efforts and more resilient mental health systems in the long-term.

Tendering and (public) procurement processes influence the availability and proliferation of digital mental health solutions. As an example, as reported in a stakeholder interview, tendering and procurement processes of digital strategy and innovation in Newfoundland led to the implementation of multiple programmes for digital mental health and addiction solutions. Newfoundland now has the highest proliferation of digital solutions in all provinces of Canada. Furthermore, a European digital health care market with well-established and clear processes will attract more SMEs, which will further stimulate development and innovation across EU Member States.

Financial support of promising products and services and effective and easy tendering and procurement processes will help to enhance the uptake of eMH. Such processes may enable health care providers to buy (or license) safe, effective and high-quality eMH solutions from 'certified' developers. The EC will be responsible for developing processes that allow European health care providers to rely on available eMH solutions on the European market.

Recommendation 3 addresses the importance of a **financially viable framework** and suggests how to foster it in order **to facilitate the implementation and adoption of eMH solutions**. The recommendation is supplemented by the *Proposed Action Plan* with concrete suggestions for actions (see p.87 for actions for the EC and p.94 for actions for other stakeholders).

2.1.4 Ethics

Just as in any other sector, ethical issues need to be considered in eMH research and implementation. Ethics is a branch of philosophy which deals with the moral consequences of human actions (144), to distinguish whether a behaviour is acceptable or unacceptable.

When considering ethics in terms of eMH, there are two aspects that need to be considered: 1. is the use of eMH ethically justifiable overall?, and 2. which aspects need to be considered in order to ensure the ethical use of eMH products and services in practice/daily use?

Everyone, including people with disabilities, is entitled to the full and equal enjoyment of all fundamental freedoms and human rights (145) – that is what the *Convention on the Rights of Persons with Disabilities (CRPD)* of the United Nations states. These freedoms and rights include *"the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability"*((145): p.18). When applying this to mental health, it can be said that people with mental health problems have the right to the best possible health outcome achievable, just as people with a somatic issue. If this best possible health outcome can be achieved with the help of eMH solutions, then the existence and use of eMH products and services can be considered as ethically justifiable.

Aside from the question of whether or not the use of eMH solutions is ethically justifiable, ethics play a considerable part in every step – from eMH research into implementation, to evaluation and daily use. Research ethics on the one hand *"govern the standards of conduct for scientific researchers"* and are important *"in order to protect the dignity, rights and welfare of research participants"* (146). Medical ethics, on the other hand, govern the practice of medicine and health care and aim to protect patients. During the past decades, several ethics guidelines have been developed on international and national levels, such as the *Nuremberg Code* and the *UNESCO Universal Declaration on Bioethics and Human Rights*. A pertinent document is the *Declaration of Helsinki* of the World Medical Association, which comprises a set of ethical principles for medical research involving human subjects. It includes general principles, such as respect of the individual and protection of their health, as well as more specific principles on research ethics, such as seeking informed consent of participants, or the use of a research protocol (147). Another important set of moral norms in health care was outlined in *Principles of Biomedical Ethics* by Beauchamp and Childress, which distinguishes four categories of ethics (148): 1. respect for autonomy (to respect people and to respect and support autonomous decisions), 2. nonmaleficence (to do no harm), 3. beneficence (to minimise harms and maximise benefits, and to balance benefits against risks and costs), and 4. justice (to equitably distribute both burdens and benefits). The four principles can be applied to both research and health care, and may be considered when developing and implementing an eMH solution. Compliance with such guidelines ensures the protection of the rights and wellbeing of research participants and patients. The International Ethical Guidelines for Epidemiological Studies by the Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organization (WHO) are based on these four Principles of Biomedical Ethics. Consequently, it is stated that prior to conducting research with human participants, each study needs to be reviewed and approved by a competent ethical committee (149).

When it comes to mental health care practice, the principles are meant to guide professionals as to whether or not a decision or act is ethically justifiable. For example, a professional may only propose to use an eMH product or service for treatment if he/she considers it to be beneficial for the patient's health. If that patient, however, does not want to be treated with the help of an eMH solution, the professional needs to respect the patient's autonomous decision.

The professional does need to make sure, however, that the patient can make an informed decision. For example, providing sufficient information and a rationale as to why online interventions for mental disorders and mental health problems can be useful, has shown to significantly increase the willingness of patients to make use of such interventions (150).

Aside from this, it should be considered that the goal of large-scale digitalisation of public services is not and should not be to collect as much data as possible and to force people to share their data.

Recommendation 2 addresses the importance of an **ethical perspective** in the context of eMH implementation and adoption and suggests how to foster it in order **to facilitate the implementation and adoption of eMH solutions**. The recommendation is supplemented by the *Proposed Action Plan* with concrete suggestions for actions (see p.87 for actions for the EC and p.94 for actions for other stakeholders).

2.2 Quality of eMH solutions

eMH and its integration into routine mental health care and prevention efforts can only have a positive impact on mental health in Europe if the provided eMH solutions are of high quality. Quality, however, is a broad concept and can be interpreted in various ways, such as: Is the eMH product or service effective? Does it do what it is supposed to do? Is it safe to use? Is it easy to use/intuitive? If eMH products and services are not of high quality, they may not be able to effectively help users when and where needed, users may not be able or willing to use them (appropriately), and organisations may not be able to integrate them into their systems and/or work routines.

Thus, when talking about and aiming to increase the quality of eMH solutions, a variety of factors needs to be considered. The following chapters analyse the importance of (developing) harmonised quality criteria, address user preferences and ensure usability as well as considering the importance of the rigorous evaluation of eMH solutions.

"The ongoing building of ethical and evidence based practice is core to health care delivery and to the ongoing development of e-mental health. All new interventions should be considered in terms of potential risks and benefits, treatment effectiveness, equitable utilisation and prioritisation of limited resources." **WPA Position Statement on e-mental health** (44).

2.2.1 The role of quality criteria

To date, health professionals, patients, relatives and providers face an ever-increasing number of eMH products and services. Although numerous eMH products and services provide evidence about their efficacy, effectiveness and safety, **users have only limited options to identify high-quality eMH solutions**. A lack of established quality criteria as well as limited, opaque and unstructured quality and safety information add to the complexity of digital services for mental health. Currently, there is little guidance available to help health professionals, patients, relatives and health care organisations identify relevant eMH solutions.

The field of quality assurance for eMH products and services is still rather unregulated and complex. Various organisations, research and expert groups have suggested quality criteria for internet-based interventions for mental health care (151) and mental health apps (142, 152, 153), or suggested a framework for evaluating (e-mental) health apps (154). One example is the App Evaluation Model developed by the American Psychiatric Association (APA), which provides a structured approach for psychiatrists and patients to evaluate apps in order to determine whether the respective app is appropriate or not (155). Table 1 provides more examples and further initiatives. Furthermore, at EU level, the *Privacy Code of Conduct on mobile health apps*, which is currently being revised to adequately address the requirements of the GDPR, provides guidance for developers of health apps in terms of how to handle data and privacy (156). These initiatives differ in terms of their development process (how), underlying expertise (who), as well as multi-professional and overall scope (what). Due to the complexity of the market and the contingent promise of recognition, developers focus (if at all, and if the functionality of the service applies) on CE marks for marketability purposes (139). One of the few examples for standardisation is Medappcare (Certilife brand), which is the first European company to have developed an independent standard for evaluating mobile health applications in 2012. It is governed by the international standard ISO 17 065 and was accredited by the French Accreditation Committee (Cofrac) in January 2019. Nevertheless, **across the EU, there is a strong need for harmonised standards, quality criteria and control mechanisms for digital health solutions (including eMH)**.

Info box 7:
Development of quality criteria for internet-based interventions that reduce mental health symptoms

The eMH task force of the DGPPN (the German Association for Psychiatry, Psychotherapy and Psychosomatics) and DGPs (German Association for Psychology), which is a collaboration of German experts in eMH, suggests ten quality criteria for internet-based interventions. The aim is to enhance the development of a certification process, which, in turn, may positively contribute to the adoption of internet-based interventions.
Based on the components of MAST (Model for Assessment of Telemedicine Applications), quality criteria for internet-based (and app-based) interventions in the context of prevention and treatment were adapted and established. These criteria were primarily established for self-help programmes but may be extended to other programmes at a later stage.
Quality criteria were agreed on by health professionals, professional bodies, research organisations, patient associations and self-governing bodies. They are distinguished into **deal breakers** such as *indication, description of the intervention, qualification, efficacy (at least one RCT showing non-inferiority compared to standard treatment), patient safety, privacy and data security, integration into health care, and costs, and* **descriptive criteria** (among others, *transparency and usability*). See Klein et al. 2018 (151) for more information.

In the context of developing quality criteria, a prerequisite is the categorisation of eMH products and services. The respective category determines which quality criteria apply and who will be responsible for the assessment. Due to the nature of eMH, it will be challenging to establish such categories. For example, eMH products and services that offer interventions require the same standards as established face-to-face therapies. Digital health interventions for mental health may be rated according to their role in mental health care and prevention efforts (self-management, blended care or others), their purpose (prevention, diagnosis, monitoring, treatment, rehabilitation, etc.), use of data (e.g. local data, consumer-driven data or data sharing with electronic medical records) or their inherent risk and function (comparable to the categories used for medical devices) (142). These are only examples; other categories are possible, which indicates the complexity of such a categorisation process. In Germany, in the course of drafting the Digital Health Care Act (DVG), categories for the directory of reimbursable digital health applications are currently being developed.

The working group of the European Commission (EC) on guidelines for mHealth assessment started to develop *"guidelines for assessing the validity and reliability of the data that health apps collect and process"*, but in the end the group was not able to come to an agreement on a set of guidelines (166), proving the difficulty of such a process.

The above-mentioned initiatives offer points of orientation for further developments and discussions. Following this, the initiation of a working group that helps to align initiatives at the European level and develop a common understanding of standards and quality criteria and mechanisms may promote developments of suitable regulatory structures at the national level (HTA processes). **Quality criteria should be defined that apply to a defined group of products and services and that provide a manual for developers in terms of level of evidence, privacy and data protection, quality and technical aspects, etc.** A common ground of quality criteria, agreed on by a multiprofessional (international) group of experts, that are harmonised at EU level, as suggested in the *Joint Action on Mental Health and Wellbeing* (57), will help to promote the dissemination and implementation of eMH solutions throughout Europe. Such quality criteria will, in turn, help to establish appraisal and approval processes for digital health interventions – the second important step in facilitating the adoption of eMH. At the national level, such quality criteria may serve as reference points and may be supplemented by specific national criteria.

Recommendation 6 addresses the importance of **developing quality criteria** and suggests how to use them in order **to facilitate the implementation and adoption of eMH solutions**. The recommendation is supplemented by the *Proposed Action Plan* with concrete suggestions for actions (see p.87 for actions for the EC and p.94 for actions for other stakeholders).

Table 1: Frameworks and guidelines that aim at enhancing the quality of (mental) health apps

Evaluation Frameworks (Mental Health Apps)	Evaluation Frameworks (Health Apps)
Towards a Framework for Evaluating Mobile Mental Health Apps A research group in the U.S. presents a framework to encourage the development of professionally acceptable guidelines and clinical frameworks for mobile mental health apps (152).	**Mobile App Rating Scale (MARS)** MARS (Mobile App Rating Scale) is a multidimensional measure that has been developed by an expert multidisciplinary panel for trialling, classifying and rating the quality of mobile health apps. Criteria of indicators such as engagement, functionality, aesthetics, information and subjective quality are assessed using a Likert-type scale. The mean score describes the overall quality of the app (excluding the indicator "subjective quality") (154).
Assessment Framework for eMH Apps in Canada A Delphi process identifying principles such as evidence base, gender responsiveness, cultural appropriateness, etc., and criteria for evaluating mental health apps (effectiveness; transparency of information security; information security; functionality; usability; clinical criteria; developer transparency; funding transparency; user inclusion; user desirability; audience; support platforms; app price; meaningful inclusion; interoperability) (153).	**Code of Conduct on Privacy for mHealth Apps (European guidance)** Developed by a team of industry members and supervised by the European Commission, the Privacy Code of Conduct provides practical guidelines for health app developers focusing on handling data and privacy information (156). It is currently being revised in order to adequately address the requirements of the GDPR (159).
ASPECTS Based on clinical experience, a research group developed the evaluation framework ASPECTS, which provides guidance for evaluating apps in the context of clinical care in psychiatry. According to the framework, an app must be actionable, secure, professional, evidence-based, customisable and transparent (157).	**Health apps: Towards a balanced life (A toolkit to help you) (patient perspective)** A toolkit developed by PatientView for patients, carers, the public and health care professionals that informs and guides them with regard to eMH products and how to get started/make an informed choice. It includes a checklist with six steps to determine whether an app is appropriate (160).
App Evaluation Model (American Psychiatric Association) A resource to help psychiatrists and their patients make the best-informed (individual) choice about whether or not to use an eMH product or service. Split into five levels (background information, risk/privacy and security, evidence, ease of use, and interoperability), it provides information and questions to help to make an informed decision (155).	**Good Practice Guidelines on Health Apps and Smart Devices (Mobile Health or mHealth) (Haute Autorité de Santé, France)** A guideline for manufacturers and evaluators providing guidance for, promoting the use of and increasing confidence in mHealth (161).
Information brochure: Mental health in the digital age (Psycom, France) A guide for users, carers, health professionals and the general population, which provides information on eMH and aims at raising awareness concerning the wise use of digital health technologies (158).	**Mobile Health Apps 101: A Primer for Consumers (American Health Information Management Association)** A guide for users that provides information about mHealth (applications), aiming at enabling them to make informed decisions (162).

Evaluation Frameworks (Health Apps)

Digital Assessment Questions (NHS Digital Library)
The NHS Commissioning Board (via NHS Digital) launched an NHS Apps Library in 2015 to help people manage their health. In 2018, the number of apps reached 70. To be NHS-approved, each app must fit the eligibility criteria and address health and mental themes with the most significant need. The Digital Assessment contains approximately 46 questions. The vetting process was developed by subject matter experts from across a number of specialist organisations, who designed a set of Digital Assessment Questions (DAQ). These questions cover a series of clinical and technical standards and best practice, and aim to help developers enhance digital products to the required and recommended standard (163).

AppQ
Supported by the German Federal Ministry of Health, the Bertelsmann Stiftung started to develop a set of quality criteria for health apps in 2019. The objective is to enhance the collection and provision of standardised information about health apps. Relevant criteria are privacy, data security, interoperability, consumer protection, technical quality, usability in the German health system, information and motivation, and clinical relevance and benefit (in development) (164).

Medappcare
This is the first accredited certification society in the area of mobile health care. For its certification activity, Medappcare has developed the "Certilife" brand and relies on a reference system that builds around four themes: content and handling, legal aspects, digital security, and health, disability and loss of autonomy (165).

2.2.2 Usability and user preferences

2.2.2.1 Digital inclusion

Among the many advantages of eMH is the fact that users are not required to be physically present at treatment facilities. This comes in handy especially for people who live far away from treatment facilities or those who have difficulties travelling or leaving their home. However, while the digitalisation of health care promises new chances and opportunities to improve health service delivery, it also bears the risk of introducing a digital divide in society, which should be avoided under all circumstances. After all, **the advantages of eMH only come into play when those in need are able to access and use the appropriate products and services according to their needs, for which digital inclusion is crucial**. *"Digital inclusion, or rather, reducing digital exclusion, is about making sure that people have the capability to use the internet to do things that benefit them day to day – whether they be individuals, SMEs or VCSE [voluntary, community and social enterprise] organisations"*, as stated in the UK's *Digital Inclusion Strategy* (167). Consequently, barriers to digital inclusion need to be anticipated and considered in the development and implementation of eMH products and services in order to realise the full potential of eMH. Barriers to digital inclusion are described as all challenges related to accessibility, connectivity and digital skills (167).

First, eMH products and services and relevant information need to be physically and economically accessible (168).

Second, **eMH products and services need to be interconnected and interoperable**, for which access to (broadband) internet is crucial. The EU's *Digital Agenda for Europe 2020* presents a first step towards equal access to broadband internet for everyone, yet much remains to be done, and a digital strategy beyond 2020 is needed. Other major contributors to achieving connectivity are technical standards. With regard to eHealth and mHealth, technical standards

are necessary to ensure national and international compatibility (118). Especially in the context of proceeding digitalisation and globalisation, including in the mental health sector, compatibility and connectivity are crucial. Furthermore, widely acknowledged international standards would save time and resources in the development process of eMH products and services (118). Following the development of international standards, IT systems and structures need to be adapted and updated accordingly, and fragmentation between and within countries needs to be avoided. Furthermore, considering that the digital world is a rapidly developing field, those standards will need to be re-evaluated on a regular basis. Besides access to the internet and the development of technical standards, connectivity requires interoperability, which has been defined as *"the ability of disparate and diverse organizations to interact towards mutually beneficial and agreed common goals, involving the sharing of information and knowledge between the organizations, through the business processes they support, by means of the exchange of data between their respective ICT systems"* (169). Establishing interoperability is an essential factor for the success of eHealth interventions (170) and has the potential to benefit all involved stakeholders in the delivery and receipt of health care. The advantages of established interoperability for the involved stakeholders are numerous. Consequently, over half of all European countries promote standards and interoperability (171). Yet, achieving interoperability is a complex process that can be very challenging (172). Differences in organisational cultures, behaviours and business processes, legal systems (172) and the heterogeneity of health information systems (173) are only a few examples of hurdles to interoperability. Overall, overcoming this diverse set of barriers and establishing interoperability in (e-)mental health care requires co-creation and collaboration between involved stakeholders. Furthermore, establishing national health data governance frameworks may foster interoperability between eMH stakeholders and should therefore be promoted.

Third, users need to possess the digital skills that are required in order to utilise eMH products and services, and developers should design eMH solutions in a co-creation process so that the eMH products and services do not need much explaining. The term *digital skills* refers to the ability and confidence to use digital devices, applications and channels in a safe way, i.e. digital literacy. A detailed analysis of digital literacy can be found in chapter 2.3.2.

Overall, digital inclusion is a key determinant of successful eMH implementation and should thus be included in policies, strategies and programmes in order to overcome digital exclusion issues.

2.2.2.2 User-friendliness

"Mental health technologies must be designed for the people who will use them" (88).

Info box 8: Framing usability

The term *usability*, which was initially derived from the term *user friendly* (174), refers generally to the context-specific appropriateness for a purpose ('fit for purpose') (175, 176). DIN EN ISO 9241-11, originally describing quality standards for human-machine interactions, defines usability as "*the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use*" (177). Accordingly, effectiveness, efficiency, satisfaction and context of use determine usability as an attribute for the users' satisfaction. Other components such as understandability, operability, learnability, lack of errors and attractiveness are also widely used quality attributes of usability research and complement the definition of the DIN EN ISO 9241-11 (178).

Moreover, the evaluation of usability is a young and expanding field with a broad spectrum of evaluation methods and tools. Common methods are interviews, focus groups, logs (i.e., registering the activity in the programme or on the server) or the Think Aloud Test (in which the participant verbalises his/her thoughts and actions while performing a set of specified tasks) (179). Numerous standardised questionnaires and tools are available to measure usability attributes such as the Standardized User Experience Percentile Rank Questionnaire (SUPR-Q) (180) and the System Usability Scale (SUS) (175).

Usability is a critical element for the uptake of eMH solutions, but no standardised approach in terms of methods or reporting has yet been established. Methods, tools for, and reporting of usability evaluations require a standardised, valid and reliable approach. Lack of usability evaluation standards hampers the comparability of results and reduces their trustworthiness. **Guidance for usability testing of eMH solutions may help to standardise and strengthen this field** and, as a result, boost the importance of the attribute usability, e.g., in the context of quality criteria. A combination of qualitative and quantitative measures (mixed-methods approach) and a mix of stakeholders will be beneficial for the evaluation of users' needs.

In the context of eMH, usability aims to identify the usefulness of an intervention, improving its perceived ease of use (intuitiveness of an interface, technical stability, error rate, etc.) (181) and increasing the capabilities of users. **Shortfalls or failures in meeting user demands may result in low engagement, high dropout rates and low uptake** (26). For example, failure in the log-in procedure may lead to frustration, negative experiences and, hence, negative attitudes that may affect the willingness of future use. By meeting user demands of design and interface of technologies, eMH may enhance the abilities of users, their experience, satisfaction and engagement, and may reduce the likelihood of high dropout rates (182) or diminished task performances (26). Attributes of usability are design and functions, technical stability, customisability, level of support, context of use and required technical components (desktop, laptop or mobile device). The aspect of customisation (also called *adaptive tailoring or automated personalisation*) in terms of personal support required, monitoring/follow-up, or programme content, for example, are critical for task engagement and subsequently efficacy (183), keeping the target group engaged in the intervention over time. These aspects are critical elements for

treatment compliance, user acceptance and, eventually, the successful and sustainable uptake of innovative technology in mental health care (184, 185) and its effective use.

Given that decreased motivation is a core characteristic of mental health problems such as depression, obtaining engagement in eMH solutions is critical and even more challenging (142, 184). A service that is difficult to understand or to use may not be successful. Furthermore, intentions to adhere to a programme may be disrupted by the severity of a mental health problem, lack of follow-up, the patients' feeling of how the illness is reflected back to them or the risk of experiencing additional failures due to the demands of the programme.

Factors which influence user acceptance and, hence, user engagement of eMH products and services may be:

- Lack of identification with the programme/adaptive content/user-centric design (142, 184, 186) – tailoring to the capacity of the individual may improve the outcomes of the intervention (55)
- An absence of support to adhere to the programme/lack of follow-up (a contact person/motivational and emotional support) (184, 186, 187)
- Adequate computer and internet skills (see also chapter 2.3.2) (184, 186, 187)
- Severity of mental disorder (184).

Thus, **preferences, user acceptance and engagement, and digital skills of end users should play a key role during the development process of eMH products and services** (142, 185, 187). In addition, site aesthetics (quality and appropriateness of videos, images, animations, icons and illustrations) have been rated as critical to overall usability and satisfaction (188, 189). **Meaningful input of involved target users (people with mental health problems, health professionals, administrators, providers and investors) (co-creation) should drive the development process** (concept, design, testing and implementation phase) to avoid a lack of user orientation (142, 190). Currently, however, there is little involvement of people with mental health problems in the development process of apps (142). A good example is the approach utilised by mHabitat (UK), which brings patients, citizens and professionals together with academia, healthtech companies and digital innovators in order to design, develop, implement and evaluate eHealth tools. Evaluating usability needs to be placed at the heart of the development, evaluation and implementation processes of eMH. Moreover, patient characteristics need to be considered (e.g. computer literacy, demographics, severity of disease and co-morbidities) (191). Therefore, participants in usability evaluations should be representative of the target group to produce generalisable results. Specific subgroups and preferences may be taken into account. People of higher ages, for example, tend to report more technological challenges in trials investigating the use of internet-based technologies (192). **Meaningful co-creation will enable an understanding of the most effective design features, optimal dosage and guidance that meet the respective target group demands**. Given the heterogeneity of users' preferences and needs, customisability of eMH products and services, and personalisation of treatment pathways will be essential. The pilots that were conducted by the eMEN project are a good example of this approach. In order to further develop and improve eMH solutions, relevant stakeholders, such as users and GPs, were involved in assessing how the products can be improved. Furthermore, it will be important to continuously evaluate (i.e. gain critical iterative user feedback throughout the lifecycle of an eMH solution) and adapt programmes to the needs and requirements of the target groups (e.g. larger text size, intuitive design, more technological support). This will lead to more tailored, appealing and accessible interventions, which will, in turn, enhance the adoption of eMH and reduce dropouts.

The design of eMH products and services should align with users' capacities (skills, knowledge, severity of illness, digital literacy) (181) in order to enhance users' engagement, satisfaction and motivation. Actionable

design features, appropriate support (peer or health professional), level of control or content and language that is adequate to the level of the patient's abilities (tailored content) may refine interventions and eliminate potential barriers for implementation (182, 184).

However, the challenge will be how to involve and engage people with mental health problems and other vulnerable groups in the development process. The involvement of patient organisations therefore will be crucial. In an ideal case, usability will address cultural, disability and sociodemographic accessibility, and should therefore be established as a key element for the quality of eMH products and services. If expectations are not met, it is likely that people will not use online interventions.

2.2.2.3 Group-specific challenges

Just as in physical health, the mental health status of an individual is not only determined by genetics, but also shaped by environmental, economic and social factors (193). Accordingly, individuals may differ significantly in their mental health and there are variations in prevalence rates of mental disorders among countries and within populations.

While mental health problems generally present a burden for those affected, receiving adequate treatment may be especially difficult for certain groups. When it comes to eMH solutions, the following groups and their specific challenges should be considered while developing and implementing eMH products and services: minorities, the elderly, young people, and further groups.

2.2.2.3.1 Minority groups

There is no internationally agreed definition, but the term 'minorities' usually refers to groups of national, ethnic, cultural, religious or linguistic identity as stated by the United Nations General Assembly (194). Research suggests that racial and ethnic minorities are significantly more likely to delay, refrain from or drop out of mental health treatments (195). As stated previously, each individual's mental health status is shaped by a wide variety of factors, and minorities often combine several distinctive factors that need to be considered when aiming for adequate mental health care and prevention efforts.

Communication and language barriers present significant challenges often experienced in the care of, for example, migrants and refugees. Individuals may have limited or even no proficiency in the local or national language, making it very difficult to access and receive care. Besides language barriers, communication may be challenging (196) as there are differences as to which language and expressions are used to describe mental health (197), and individuals may not know how to communicate their needs in the local or national language (198). In some cultures, for instance, the language to describe mental health problems may not even exist (197), leading individuals to express mental distress with physical attributes (198). Hence, it is crucial that good quality interpretation services are available where necessary. Information about (e-)mental health products and services (through different channels, e.g. print, audio-visual) should be easily accessible and communicated/provided in an understandable manner.

The way health is viewed and illnesses are handled is largely determined by culture (198). Culture is a set of beliefs, characteristics and social behaviour of a particular group of people or society. It determines every individual's daily life and the choices he or she may make. Similarly, culture determines the perception of health and illness, and how health problems are handled (198). Cultures differ widely with regard to beliefs and practices used to manage health issues and mental difficulties. Accordingly, the acceptability of mental health problems differs among cultures, leading to different levels of stigma and discrimination. While experiences of discrimination and perceived public stigma are reported to be high across all racial and ethnic groups, self-stigma is found to be higher among ethnic minorities (199). Alternatively, there may be a lack of awareness of mental health

problems so that individuals may not recognise that they are experiencing mental health problems and are in need of help (197, 198). Furthermore, individuals may lack cultural understanding and knowledge about available mental health services and how to access them (196). Alternatively, individuals may have knowledge about such services, but issues of mistrust might prevent them from accessing treatment (197).

Thus, awareness in minority groups with regard to mental health services and how to access them must be increased, and stigma reduced (e.g. by mental health promotion or anti-stigma programmes), just as in the general public. Additionally, culture plays a central role in the treatment of mental disorders, and whether and how eMH solutions can be implemented successfully. Even if a product or intervention has worked successfully elsewhere in the world, it may fail when being implemented without adapting it to the cultural background of the target population. Cultural diversities are large in Europe – even within EU Member States and their regions, cultures may differ significantly. Hence, ignoring cultural aspects may hamper the implementation of eMH solutions (112).
It is of great importance that culture and cultural diversities are considered when developing and implementing eMH products and services. This can be achieved by establishing cultural awareness and sensitivity among developers, providers and professionals so that eMH products and services are developed and implemented in a culturally appropriate way: respecting beliefs (about health and disease), local traditions, health literacy, and expectations towards the health care system (112) through conducting promotional campaigns and training for developers, providers and professionals. Co-creation needs to be established between developers and locals/individuals of the target group to develop products in a culturally appropriate way. Available (local) resources should be evaluated as to whether they fulfil the requirements for successful implementation of eMH solutions, and develop them according to cultural limitations (112).

Professionals need training to develop or improve their cultural awareness and competency to effectively deliver mental health care services that meet the cultural and linguistic needs of patients in a respectful and empathetic way. Overall, mental health services should be reviewed in order to deliver culturally competent services, and to ensure that the (mental) health care needs of minority groups are met.

2.2.2.3.2 The elderly

The world's population is ageing rapidly and the proportion of the elderly will increase further in the future. To be more specific, the proportion is expected to almost double between 2015 and 2050 (from 12 percent to 22 percent) (200). This demographic change brings along some challenges not only for societies and economies, but also for the health care sector. It is estimated that about 15 percent of people aged 60 and over suffer from a mental disorder (200). In addition to stressors that affect people in each age, older people may be faced with stressors that are common in later life. Such stressors, as chronic pain, reduced mobility or a drop in socioeconomic status due to retirement for instance, may result in loneliness, isolation or psychological distress.

Research has shown that internet usage in the homebound elderly leads to positive outcomes such as fewer depressive symptoms and feeling less isolated (201, 202). Furthermore, evidence suggests that digital interventions have the potential to improve the quality of life, psychosocial wellbeing of older people, and therefore reduce the family and care-giver burden (203).

However, older people tend to be resistant to use new technologies – their readiness for technology is rather low (204) and they tend to prefer personal contact with professionals (204). In fact, some elderly people not only show disinterest in using new technologies but are even anxious towards them (205). Besides this, even if older people are encouraged to use such new technologies, they show more difficulties in doing so than younger people (204). This may be because the

elderly have less familiarity and mastery in the handling of such technologies – the older the age group, the lower the levels of internet use (206, 207). Moreover, older people may not be aware that they suffer from a mental health problem and are possibly in need of professional help. Alternatively, they may not be willing to accept that they are experiencing mental health problems due to self- and perceived stigma.

In order to overcome these challenges and successfully implement eMH solutions in the elderly population, age-related issues such as decreased mobility, memory-related issues or impaired vision (208) should be considered in the design and development of eMH products and services. If possible, the elderly should be involved in the development so that the products meet their special needs. Furthermore, promotional campaigns, which consider that reaching the elderly may require using different channels than other parts of the population, should be conducted (i.e. promotion through digital channels may not be as effective). It needs to be ensured that, a) interventions are provided with appropriate training for the elderly if needed so that people of higher ages can acquire the necessary skills to use the technology, and b) that sufficient support (i.e. someone to contact in case an older person struggles with using an eMH product) is offered.

2.2.2.3.3 The young generation

Given the fact that technology and smartphones are almost ubiquitous among the young, younger patients may very likely already have the necessary digital literacy and skills to actively use an eMH solution. Being confronted with technology from an early age onwards is also the reason why this may be the age group that is most open to using eMH products and services. Yet, depending on the target group age, products should be designed so that they are used in a playful way – the younger the target group, the more playful the product should be. Overall, eMH solutions should be developed according to younger people's characteristics and preferences. Furthermore, younger people may not have sufficient knowledge about mental health problems and their symptoms, or even if they do, they may fear being stigmatised. Moreover, just because this specific group has the highest use of technology in their everyday lives, it should not be assumed that younger people automatically also prefer using technology for their mental health or in the context of treatment. Thus, promotional and educational campaigns regarding mental health problems and eMH solutions should be conducted through age-appropriate channels, such as social media or in schools and universities.

2.2.2.3.4 Others

Further groups that require separate considerations are, for example, intellectually disabled people or dyslexic patients. Moreover, individuals who are part of more than one of the named groups with special challenges need to be considered. Therefore, eMH products and services need to be designed and developed according to the target group's specific needs. Intellectually disabled people, for example, need very simple and easily understandable tasks and texts, while dyslexic patients may benefit from products that do not require a lot of reading or involve text-to-speech features. Furthermore, the target groups' special requirements need to be considered when planning and conducting promotional activities as well as during the implementation phase (i.e. some groups may require more assistance or support than others).

Recommendation 5 addresses the importance of **usability under consideration of the target group and suggests how to foster it in order to facilitate eMH implementation and adoption**. The recommendation is supplemented by the *Proposed Action Plan* with concrete suggestions for actions (see p.87 for actions for the EC and p.94 for actions for other stakeholders).

2.2.3 Evaluation methods for eMH solutions

"The rapid pace of technology development relative to the slow pace of research methods often results in mental health technologies that are outdated and obsolete by the time they are validated" (88).

Literature and stakeholder interviews suggest that the perceived lack of a strong evidence and knowledge base about eMH and benefits of using eMH solutions impedes its diffusion (26, 74). The potential of eMH has scarcely been realised, partly due to difficulties in generating an evidence base that clearly guides and informs decision-making concerning the delivery of eMH for improving individual and population health (56). **Methodologically rigorous eMH evaluation studies are needed.** The standards of evidence-based medicine require randomised controlled clinical trials for *"judging whether a treatment does more good than harm"* (209). Along this line, the German Association for Psychiatry, Psychotherapy and Psychosomatics (DGPPN) together with the German Association for Psychology (DGPs), have recently recommended that internet-based psychotherapy should be based on one of the scientific psychotherapeutic methods and should be supported by evidence from at least one non-inferiority randomised clinical trial (151) (see info box 7 for more information).

eMH products and services, especially apps, are easily available to the public and treatment centres and professionals already use them. But only a small number of apps or services have been evaluated to prove clinical efficacy and effectiveness using established evaluation designs. As an example, out of approximately 10,000 mental health apps available in app stores, a recent review found only 22 apps for depression and 9 for anxiety disorders which had been evaluated using a randomised controlled trial (47).

To our knowledge, no standardised way for data collection and analysis for clinical studies evaluating the efficacy and effectiveness of eMH solutions (standardised outcome measures and comparators, study designs, etc.) has been established. Reviews show that research often reports "soft" outcome criteria like patient self-reports about usability or user satisfaction, perform psychotherapy studies with waiting list groups (in which, by experience, effect rates are higher than in clinical studies using active control groups (see (8) as an example) or do not use rigorous clinical diagnostic criteria (51, 210). Clinical trials on eMH solutions are often either underpowered or lack methodological rigour (211). Other methodological limitations are the use of soft in- and exclusion criteria, a lack of representative population samples (selection bias due to self-referral recruitment procedures for example), small population sizes and limited research on factors that affect the implementation in the real-world setting. Furthermore, high dropout rates and a lack of long-term follow-up studies (i.e. these often focus on short-term effects) (210) are reasons for limited trust and confidence in research outcomes.

However, transparent and rigorous scientific evaluation of eMH products and services is critical for several reasons:

1) to protect the public from harmful interventions,
2) to demonstrate efficacy,
3) to ensure trust and confidence in eMH.

Moreover, decision-makers require an adequate knowledge base about efficacy, (cost-)effectiveness, safety and user acceptability of innovative services to decide whether or not to implement an innovative intervention into health care systems (56, 212). Thus, evaluating the efficacy and effectiveness, as well as the safety and user acceptability of eMH products and services, is highly influential on its uptake and implementation. Methods, designs or frameworks used for the evaluation process should be transparent, accurate and valid in order to increase trust and confidence in evidence-based eMH.

There are emerging evaluation methods that aim to enhance the continuous assessment of digital innovations and that may contribute to the adaptation of established evaluation methods to the dynamic environment of digital health. Digital health solutions (encompassing eMH) are related to a rapidly developing technical environment with short development cycles, continuous quality improvements and a complex changing environment that poses new challenges to traditional evaluation designs. In biomedical contexts, RCTs are the gold standard to evaluate the efficacy, effectiveness and safety of interventions in health care (209, 213, 214). RCTs in psychotherapy research are highly relevant to prove that an effect can be attributed to a certain therapy and compare an experimental intervention against a control psychotherapy, an active control group, an irrelevant intervention in psychotherapy studies or treatment as usual (215), with confounding factors isolated as far as possible. In the literature, concerns are expressed that RCT designs are not compatible with the rapidly changing (social and technological) environment of digital health interventions (212, 216-218), although this would mean that the rapidity of development would become more important than a rigorous clinical trial intervention, which is time-consuming and costly.

RCTs are established in order to evaluate the efficacy, effectiveness and safety of a "locked" intervention; for instance, a new medication with a predefined outcome such as a reduction in blood pressure (218). Traditional RCT designs follow strict randomisation protocols, often involving lengthy recruitment, enrolment and study periods (long cycle time) (217). To ensure high internal validity, strict in- and exclusion criteria apply, bearing the risk that the enrolled participants are not representative of the patients who are likely to receive the intervention under study. Simultaneously, criteria for the success of the intervention uptake, such as users' acceptance or integration into workflow processes, are often neglected. Thus, common evaluation methods provide essential evidence for assessing efficacy and safety, but of limited use for the following implementation process.

Moreover, development cycles of digital (health) solutions are rather short and often not complete when a product enters the market. Even when a new eMH product is in use, it needs to evolve and adapt continuously to changes in the environment, i.e. its content and functionality may be updated or modified regularly (139, 190, 218). Current evaluation methods and implementation studies can require years of time and resources to validate an intervention (219, 220) and may be useless if the technology has to be modified or adapted afterwards. It is out of the question that all interventions need to prove their efficacy, effectiveness and safety – there is no room for digital exceptionalism. Nevertheless, inadequate and lengthy evaluation methods should not prevent interventions from being available for people in need. Traditional development-test-implement cycles may be limited in scaling up digital health interventions in a timely and comprehensive manner (26). **To prevent obsolescence, digital health interventions require rapid, timely, responsive and continuous evaluation processes that incorporate continuous quality improvement** (139, 190, 218). In addition, evaluation should determine and optimise the reach and uptake of the eMH solution in its intended population and the context it will be implemented in (56).

Currently, research efforts are underway to supplement the traditional RCT design with innovative evidence-generating adaptive research designs (see info box 9). It remains to be seen if these designs can generate evidence that helps to identify strong candidates for classic RCTs, for example, and whether this approach will be more rapid and less costly. These approaches have not yet been thoroughly tested, but conditional approval in combination with evidence generation is considered as one option to integrate digital health solutions in publicly-financed health care systems (e.g. NICE, FDA, IQWiG). In terms of eMH, it is too early to foster the application of innovative evaluation designs yet, but such designs may contribute to improved evidence generation. **It appears advisable to support the European joint development of such innovative research methods for**

digital health solutions with a view to increasing the adaptability of evidence-based medicine standards to rapid digital product cycles throughout Europe. In addition, European research initiatives and funding authorities would greatly support the implementation of eMH solutions by providing sufficient funding for traditional RCT designs. **Building and establishing stronger networks and (interdisciplinary) collaboration throughout Europe between academics, health professionals, providers and users will support these efforts** (26). Not only product specific research, but more general research on eMH will be required.

The eMEN consortium acknowledges and stresses the importance of RCTs for assessing the effect of an intervention compared to a control group. Reliable, valid and robust research methods are the foundation for trust and confidence in the result of evaluations of interventions and may accelerate the uptake of eMH. Nevertheless, other types of valid evaluation methods may contribute to improved evidence generation for the implementation of eMH. New evaluation designs and methods need to demonstrate that they are more capable of adapting to distinctive features of eMH products and services such as short development cycles, continuous quality improvement processes, a focus on patient preferences and integration in real-life settings. More pragmatic approaches that evaluate clinical measures and implementation models (e.g. factorial research designs, adaptive designs or mixed methods approaches) can contribute to speeding up the development process by providing knowledge about the usefulness, applicability and feasibility of digital interventions for mental health care (58, 88, 101). However, they may not be equally suitable compared to RCTs when questions of efficacy and patient safety are concerned.

Recommendation 4 addresses the importance of **rigorous eMH research** and suggests how to foster it in order **to facilitate the implementation and adoption of eMH solutions**. The recommendation is supplemented by the *Proposed Action Plan* with concrete suggestions for actions (see p.87 for actions for the EC and p.94 for actions for other stakeholders).

Info box 9:
Overview of current developments in research designs

RCTs are the gold standard of demonstrating the efficacy and effectiveness of medical interventions and inferring causality (209). The standard way of treatment allocation to the experimental or control group is on the individual level. However, depending on the intervention to be studied, other allocations are possible: through clusters (cluster RCT) or based on the time the intervention is implemented (stepped-wedge-design; SWD). SWD may be suitable for eMH services that have proven their efficacy and for which the upscaling process should be evaluated while simultaneously generating more efficacy evidence (see best-practice example ImpleMentALL project). The SWD design may be a reasonable, timely option for continuous evidence generation (68). Still, in the context of evaluating eMH products and services, the drawbacks of RCTs including neglecting user engagement, user preferences and experiences, and implementation outcomes resulted in the development of new emerging adaptive designs. Examples are CEEBIT (Continuous evaluation of evolving behavioural intervention technologies) (212), MOST (Multiphase Optimization Strategy Trials; a formal framework for developing and testing complex interventions), SMART (Sequential multiple assignment randomized trial) (221) and TIP (Trials of Intervention Principles) (218). These are supportive designs that have originally been constructed for behavioural intervention technologies (BITs). These adaptive designs may add value to the assessment of digital health interventions and aim to enhance and adapt traditional RCT designs to new characteristics of digital health solutions such as users' preferences, behaviours, knowledge and attitudes. These designs may be used in an early phase of the product development process and may speed up the upscaling and knowledge translation process of innovations in mental health care and prevention efforts.

Other options to improve the output of an RCT may be pragmatic RCTs, factorial research designs or the combination with qualitative designs (mixed methods) (for detailed information about enhancements of RCT designs, please see Appendix D). **The key position of RCTs in the decision-making process of health care will and should not be affected,** but these new methodologies may accelerate processes of evidence generation.

2.3 Awareness, acceptance and digital health literacy

2.3.1 Awareness and acceptance

Evidence suggests that acceptance and awareness are among the key factors for a successful implementation of eHealth (102). In order to use any kind of product or service, it is necessary that potential users, professionals and providers are aware of its availability and benefits, and accept it as an effective treatment source (222). Without awareness and acceptance, a product or service will not be successfully implemented and used – no matter how helpful it may be. A product that is widely known and accepted, on the contrary, is more likely to be used and to fulfil its potential. Accordingly, awareness and acceptance can act as both facilitators and barriers (102) in the upscaling of eMH.

Overall, it has been reported that mental health stakeholders in Europe are aware of the potential benefits of iCBT, but with great variations in terms of knowledge (67). In most eMEN partner countries, however, awareness and especially acceptance with regard to eMH were reported to be rather low. **Lack of awareness was identified as one of the main challenges in the implementation processes of eMH products and services**. It has been pointed out that awareness and acceptance need to be given at all levels (87) in order to enable a successful implementation of a product. Therefore, it is necessary to approach these two determinants in a stakeholder-tailored way in eMH dissemination and implementation processes. Besides raising awareness and acceptance among the general public, it is of great importance to target those who are directly involved or in contact with eMH solutions, such as professionals, health care providers and people with mental health problems. The following subchapters will outline the different challenges of the involved stakeholder groups and offer recommendations for action.

2.3.1.1 General public

So far, public awareness of available eMH products and services is reportedly rather low (26) and there is little evidence regarding the acceptability of online interventions in the treatment of depression (223). High acceptance of blended care approaches has been reported (67), and computerised cognitive behavioural therapy for depression seems to be perceived positively, although there are methodological challenges of how to define user acceptance (26). It seems that lack of awareness is a major issue, while people tend to accept eMH solutions relatively quickly as soon as they become familiar with them (150). Research suggests that interventions should focus on increasing public knowledge with regard to internet-based therapies and their effectiveness, aiming to promote their acceptance and uptake (224). However, acceptance and awareness do not only present a challenge with regard to eMH – the whole mental health sector is still challenged by a lack of awareness and acceptance, as well as stigmatisation. Therefore, **public health approaches aiming to raise awareness and acceptance of eMH should be combined with approaches for mental health**. Thus, awareness and acceptance of eMH and mental disorders will be raised, which will, in turn, have a positive impact on the mental health of European citizens in the long-term, and stigma will be reduced. It is exactly this ability – to raise awareness and acceptance among the general public – that makes public health approaches so valuable and crucial for the uptake of eMH.

In general, **improved public marketing and eMH education are required (26) while considering the heterogeneity of (potential) users. Approaches need to be tailored to the specific target group and its individual determinants such as socioeconomic status, educational level, access to mental health promotion, care and prevention efforts, access to the internet and culture**.

To be more specific, universal interventions (promotion and education campaigns) should be implemented in order to raise awareness and acceptance regarding eMH among the different target groups. This includes interventions for the general public or approaches that are specifically tailored to populations at high risk such as unemployed or financially poor citizens (225), and to those with early signs of mental health problems, as well as tailored approaches for the purpose of relapse prevention. Promotion campaigns should furthermore focus on labelling eMH as a secure and effective product to support traditional mental health care (i.e. face-to-face treatment) and to reduce the treatment gap within the mental health sector. Moreover, eMH should be integrated into existing policies and regulations in order to facilitate overall awareness and acceptance.

2.3.1.2 Users

Before (potential) users integrate a product or service into their daily lives, they first need to be aware of that product and its benefits, and then accept it as a reasonable treatment method for themselves. Consequently, users' lack of awareness of existing evidence-based eMH solutions as effective treatment sources has been identified as an implementation barrier (45). User acceptance, on the other hand, has been identified as a prerequisite for a programme to be effective (222).

So far, eMH products and services are only used by a small number of people – research from Australia suggests that they are predominantly used by women and those who are more educated and socioeconomically advantaged (226). Mental health problems, however, can affect everyone and are not limited to specific groups of people. The fact that eMH products and services are only used by so few people and predominantly by specific groups stresses the need to consider raising awareness and acceptance of all potential users when developing and implementing eMH solutions.

Overall, **transparency and knowledge are the keys to promoting acceptance by potential users**. The more people know about eMH and how it works, the more they will be open to and confident in using it. Educating (potential) users about the way eMH products and services work and being transparent about how their privacy and data are protected will help to foster acceptance of eMH. Additionally, making it visible that a specific product or service is compliant with the GDPR will foster users' acceptance further. Ideally, eMH solutions should also be developed in line with the *Code of Conduct on privacy for mobile health applications* of the European Commission and promoted accordingly. Furthermore, (potential) users also need to be educated about (assumed) benefits and made aware of potential negative aspects of the available eMH solutions (227). So far, the market remains widely unregulated; anyone can develop an eMH product or service and put it onto the market. Therefore, **it is important that (potential) users become aware that not all available eMH solutions are evidence-based and beneficial, and to educate users on how to identify helpful products**. The development and support of a website or portal on which consumers can access information on objectively assessed eMH products and services may be beneficial to foster awareness and acceptance in (potential) users.

2.3.1.3 Professionals

eMH solutions can be used by either the individual alone or in collaboration with a professional – the latter being so-called "guided care" or, if the eMH product or service is combined with face-to-face sessions in one treatment protocol, so-called "blended care" approach. The acceptability of blended care has been reported to be high (67). Within guided and blended treatments, professionals are often the first stakeholder group to actively use an eMH solution throughout the dissemination and implementation process. As they are the main contact persons for people with mental health problems and usually have gained their patients' trust, it is critical that pro-

fessionals are aware and convinced of the benefits of evidence-based eMH products and services. **Lack of awareness by professionals was identified as a key implementation barrier (45) and doubting professionals will most likely transfer their concerns to their patients, ultimately leading to low acceptance and use of eMH solutions**. Raising awareness and acceptance in professionals can therefore be seen as just as important as for people with mental health problems, and just as complex. Lack of acceptance by professionals can result from a variety of factors, such as lack of awareness, concerns about the efficacy, lack of financial incentives, resistance to changes in practice, and viewing eMH as a threat to face-to-face services (45). Furthermore, a lack of acceptance by professionals can result from different types of resistance (228). The resistance may be oriented towards the technology itself (e.g. dependability) or the policy that is reflected in the technology, such as when disease management is shifted from the professional to the patient. Other reasons for resistance may be the (im-)balance between (bureaucratic) means and professional ends, or the effect the technology has on professional relationships and interactions (e.g. the perception that a remote interaction is less professional than a face-to-face interaction).

Overcoming all these barriers may not always be possible, such as when there is resistance towards a change in the patient-professional relationship as a result of integrating an eMH solution into the treatment. Nevertheless, there are a few approaches that can be undertaken to reduce those barriers.

Overall, professionals need to be properly educated about eMH products and services, their use and their benefits (see also chapter 2.3.1.3). Digital literacy of professionals needs to be improved, too, which will increase their confidence in using eMH products and services, and therefore also increase acceptance. Furthermore, the establishment of local champions has been identified as a key instrument for persuading peers that an eMH product is safe, effective and 'normal' (87). Finally, yet importantly, job insecurity needs to be avoided so that professionals do not feel threatened by eMH solutions. Information that a product will not replace a professional, but rather support him/her, is one of the key messages that needs to be communicated.

2.3.1.4 Organisations

Evidence suggests that organisational readiness for implementing an innovation, as well as the characteristics, attitudes and behaviours of an individual that adopts an innovation or persons within the adopting organisation, may determine the uptake and use of an intervention (229). This means that the organisation in which the adopting professional works (with all its individuals) plays a significant role, too. Consequently, it is crucial that awareness and acceptance are given on all levels of the adopting organisation as well. This, however, is determined by a variety of factors, of which the organisational structure, the leadership and a (non-)risk-taking climate are only a few examples (87). Each organisation has its own characteristics and therefore a different level of readiness to change. However, evidence also suggests that an innovation is generally more likely to be implemented if there is widespread support for the innovation, good innovation-system fit and a strong willingness for change (230). **The more people in an organisation accept an eMH solution as an effective treatment method, and the better it fits into the workflow, the more likely it is going to be implemented**. Thus, it is not only important to achieve awareness and acceptance by those professionals who actively work with eMH products and services, but also by all the other individuals of the organisation, even if they are not necessarily involved in the implementation and adoption process. Hence, those that are in charge of an organisation need to be convinced of eMH products and services in order to enable the structural change (e.g. access, digital infrastructure), while those who will directly work with it also need to be willing to adopt the new work routine. Those who have neither direct contact with a product nor decision-making powers are not directly influential in the eMH implementation process. However, they still need to be approached in terms of awareness and acceptance as they have an

impact on the organisation's climate and overall attitude towards eMH.

Achieving awareness and acceptance on an organisational level may require several approaches. **Each individual who is part of an organisation, no matter in which function, affects the awareness and acceptance therein**. Thus, public health approaches as well as approaches targeting professionals are of major importance for awareness and acceptance on organisational level. Furthermore, sustained and effective involvement of staff in the implementation process of eMH solutions is important. This includes the involvement of staff in changes to the organisational structures such as policies, procedures, referral pathways and ICT support (27). Moreover, the management level is key to accepting changes in the workflow, as managers define cultures, strategies and policies and will highly influence the acceptance of new innovations in organisations. Therefore, people at management levels also need to be convinced by eMH approaches and should be supported in change management.

2.3.1.5 Policy makers and politicians

Finally, yet importantly, the awareness and acceptance of policy makers and politicians are crucial for the successful uptake and implementation of eMH, as they are able to influence or even determine the political agenda to a large degree. The political agenda in turn determines whether the uptake of eMH will be facilitated or not. Hence, **it is of great importance that policy makers and politicians are aware of eMH products and services, regard them as useful and efficient treatment methods for mental health problems and are willing to facilitate their uptake with supportive measures**.

Although there are no statistics available about policy makers' awareness and acceptance with regard to eMH, it can be assumed that they may be rather low, as eMH is still relatively low on the political agendas of EU and eMEN partner countries, although attention to its potential has been on the rise for the past few years.

When aiming to conduct measures to increase awareness and acceptance among politicians and policy makers, different approaches can be utilised. Promotion and education campaigns targeting the general public are not only beneficial for increasing awareness and acceptance among potential users and professionals, but also politicians and policy makers, as they will be exposed to interventions in their environment. Besides this, oral and written briefings directed at single politicians and policy makers can be an effective method to gain attention and increase awareness. Personal encounters may take place at public events, social gatherings, within ministries or through the media. It is advisable to accompany any oral briefing with a written note, as it is unclear how much time one may have for the briefing (231). When aiming to gain a policy maker or politician's interest, it may be useful to integrate the topic of eMH into current news, events or trends that are prominent at present. The megatrend of digitalisation, for example, is widely acknowledged and very prominent on political agendas across the world and could be used as a stepping-stone to higher awareness of eMH. The fact that the Digital Agenda is one of the seven pillars of the Europe 2020 Strategy stresses the importance of the topic. Hence, it may be **useful not to present eMH as a separate and new topic, but to link it to issues that are already on politicians' and policy makers' agendas**.

2.3.1.6 How to establish trust?

Another factor which determines the acceptance and consequently the uptake of eMH solutions is trust. Establishing trust is not only critical for the acceptance of eHealth systems, but also determines whether and to what extent people will use an eMH product or service (232). Only if (potential) users have trust in mental health services, and believe that their safety, confidentiality and respect for dignity are guaranteed, will they actually approach and use such products or services (13). Consequently, **trust in mental health services has been identified as an important factor for user satisfaction and service use** (233). Lack of trust, in turn, may negatively affect the user's willingness to

provide personal information, which may be relevant for diagnosis or treatment (232).

Among the determinants of trust are non-modifiable factors (e.g. age or culture) and a variety of modifiable factors, such as knowledge about services, prevention and reduction of stigma and discrimination, and the safety of provided services (233). Interventions to foster awareness and acceptance among the different target groups (as described in chapter 2.3) may therefore also be able to establish or increase trust in (potential) users, as these factors have an impact on knowledge and stigma. With regard to safety, however, additional activities are required in order to enable trust in (potential) users. Please see chapter 2.1.1.1 for more information on how to ensure privacy and data security. Yet, not only providing privacy and data security as such is crucial, but the communication of such measures is just as important. Perceived data security and privacy issues reportedly mediate the acceptance of medical technology (227). Greater concerns related to information privacy lead to lower acceptance of eHealth systems (234) and lower intentions to use online services (235). Research suggests that users' confidence in eHealth interventions requires appropriate security measures not only being in place, but also being easily visible (236), and that building up such trust in (potential) users may be achieved by measures as, for example, clear communication of privacy policies (237). Such **a transparent public communication rationale includes a clear strategy to target users' perception of privacy and data security and the provision of information about both critical aspects and assumed benefits** (227). The provided information about how privacy and data security are ensured (i.e. privacy policy) and how misconduct will be handled furthermore needs to be provided in a user-friendly manner: it should be precise (e.g. one-page), easily accessible and understandable for laymen. Accordingly, it should be made visible that a specific product or service is compliant with the GDPR and that the (potential) user is the sole owner of his or her data and in full control of who may access the data. Aside from this, eMH products and services should ideally be developed in line with the *Code of Conduct on privacy for mobile health applications* of the European Commission (see Appendix A) and are promoted accordingly to foster users' trust and acceptance.

The introduction of a uniform and widely acknowledged privacy seal (visibly marking a website, service or product as GDPR-compliant) may also be beneficial in fostering trust in (potential) users (238). Approaches for the provision of information should be tailored according to the specific target group. In general, the insights, needs and requirements of (potential) users should be considered at an early stage of the implementation process (151). Furthermore, they should be included early in the development of technologies in order to consider their opinions in the development and public communication policy (227).

Overall, **lack of awareness, acceptance and trust with regard to eMH present the greatest challenges for the uptake of eMH. Tackling these should be prioritised and requires multifaceted approaches at different levels, taking into account the diversities of the different stakeholder groups**. Only in doing so can the successful dissemination and implementation of eMH be ensured.

2.3.2 Digital literacy and digital health literacy

"New knowledge and skills are needed in the health care sector to be able to utilise this potential." (40)

After awareness and acceptance (including trust) are given, there is another factor that determines whether eMH solutions are successfully adopted: individuals need sufficient knowledge and skills in order to work with or use an eMH product or service. Poor mental health literacy, defined as a lack of *"knowledge and beliefs about mental disorders, which aid their recognition, management, or prevention"* (28, 239), is identified as a key barrier to the access of mental health care (28). The same is true for poor digital (health) literacy concerning the uptake of eMH. Limited knowledge of and experience with eMH, lack of availability of eMH products and services in routine mental health care and preventative services, as well as a lack of training among the health workforce and supervision are important barriers for the wider use of eMH (25, 69). **Even though eMH is associated with the notion to improve access and availability of mental health services and to empower people to be involved in their own care, this can only become reality if the public and the health workforce are comprehensively prepared to use such digital tools**. Offering appropriate time for education and training, for example, is recognised as a facilitator for implementation of eMH into health care systems (69). Acquiring sufficient digital skills related to the use of eMH may prevent that patients will feel overburdened and the eMH uptake from remaining slow. Moreover, sufficient digital literacy of the public may even avoid increasing inequalities in access to (e-)mental health care and prevention efforts. Therefore, eMH can only contribute to improved mental health throughout eMEN partner countries if the awareness and acceptance of eMH solutions among (potential) users and health professionals is increased, the (future) mental health workforce receives proper eMH education and training, and adequate digital and mental health literacy is provided to the public.

Digital health literacy

With the emergence of digital technologies in health care, digital literacy and digital health literacy (or eHealth literacy) become relevant concepts for mental health services (see info box 10 for definitions of digital literacy and digital health literacy). Understanding and appraising information becomes highly relevant for the success of mental health care. **Besides just being able to navigate and operate technological devices, confidence in using eMH and the associated information requires certain skills and knowledge**. Health professionals who are not confident in using digital technology will likely be reluctant to recommend using digital technologies to their patients. In order to benefit from eMH on system- and population-levels, promoting the digital health literacy capacity of the workforce, the public and providers will be key in future priorities to ensure adaptability to change and continuity of care (26).

Info box 10:
Definition of digital literacy and digital health literacy

Definition: digital literacy
Digital literacy is the awareness, attitude and ability of individuals to appropriately use digital tools and facilities to identify, access, manage, integrate, evaluate, analyse and synthesise digital resources, construct new knowledge, create media expressions, and communicate with others, in the context of specific life situations, in order to enable constructive social action, and to reflect upon this process (240).

Definition: digital health literacy
Digital health literacy (or eHealth literacy) is the ability to seek, find, understand and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem (241).

The public's digital health literacy

"Promoting patients' eHealth literacy skills now becomes a priority to enhance the continuity of mental health care." (26)

Health care is transforming, with patients being increasingly more involved in prevention, treatment, decision-making or self-management (242). For an active involvement in health care processes, patients require appraisal and communication skills that help them to obtain and understand health information. "Health literacy" describes a multidimensional and dynamic concept, mediated by education, language and culture (243), for making decisions concerning health care (244, 245). It is defined as *"the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions"* (246). People with high health literacy are more likely to use different forms of digital health tools (247). Moreover, a recent study found that those with the lowest levels of health literacy were most likely to misinterpret documents like app privacy policies, often believing that they are beneficial to their rights when they are not (247). There is emerging evidence that health information technology adoption is correlated with users' health literacy (247).

eMH solutions will affect *"both the way providers are used to working and the way patients are used to engaging with the health system"* (26). eMH products and services promise to empower people with mental health problems by taking control of their own care and are perceived to be beneficial in educational settings (improving the mental health literacy of individuals). In this regard digital health literacy, confidence in using digital services, coping skills and self-management of treatment and care are highly relevant concepts for the delivery of eMH products and services. eMH may contribute to improved patient-centred care with more people engaged in their own care and improved self-management (e.g. early prevention). However, the availability of eMH solutions and services alone will not automatically contribute to improved mental health care and prevention efforts. The potential of eMH can only be realised if preconditions such as sufficient digital health literacy and confidence in using eMH are set.

Besides concerns in terms of online safety, data protection and clinical effectiveness, the limited digital health literacy of users presents a barrier to the implementation of eMH (67). Moreover, in the context of iCBT, digital health literacy is an important prerequisite to acquire knowledge through iCBT (248). Neglecting proper digital health literacy of the public would not only hamper sustainable implementation of eMH or increase the risk of digital adverse events (249, 250), but may additionally lead to the digital exclusion of certain populations due to a lack of skills and knowledge or financial resources to use digital health tools (251, 252). Equal access to mental health care and prevention efforts for all are very sensitive issues, and eMH is meant to improve access to mental health services and thereby reduce inequalities. **The risk of certain populations being underserved or digitally excluded (digital divide) has to be prevented** (253, 254) through digital health literacy campaigns that reduce the potential for a digital divide (142). Some regions have already established digital skills courses or campaigns (see info box 11 for more information). The following list provides some examples of the skills that are needed to use the broad spectrum of applications and digital devices in health care (251):

- being able to use a computer and internet browser (operational and navigation skills)
- using retrieval skills and the ability to manage incoming information (searching information skills)
- ability to identify reliable information sources (appraisal and evaluation skills)
- critically assess the information ("critical thinking") to make informed judgements
- awareness of "people networks" as a source of advice and help
- adding self-generated content to the internet (being able to express oneself in written language and being comfortable with publishing and communicating information)

- considering one's own and others' privacy (understand how personal data is handled, who can access data and how the user themselves can access the data).

Furthermore, the European Commission's *eHealth Action Plan 2012–2020* indicated that a lack of awareness of eHealth opportunities and challenges hampered the wider uptake of eHealth solutions (255). Therefore, in 2014, the EC *"proposed to support activities aiming at increasing citizen's digital health literacy"* (255) and described in its *Digital Single Market (DSM) Strategy* the objective of improving digital skills to use digital health services adequately (256). Individuals should be able to use computers, understand relevant information (e.g. privacy information) when using an electronic device and be able to assess and judge online information. Research funds, such as Horizon 2020, the European Innovation Partnership on Active and Healthy Ageing and the Assistive Living Programme (AAL) support projects that enable the digital inclusion of the elderly, people with disabilities or the less educated. Such initiatives should be strengthened and eMH-related issues should be integrated.

Taken together, improving the digital competencies of the public will enhance acceptance and readiness to use eMH products and services, and will reduce reluctance to its use due to insecurity. Knowledge and learning are important topics in the eMH context, which need to be explored further (248). It will be essential to promote and increase the digital literacy of the workforce, service users and the public by establishing structures that enable everyone who is willing to become informed and feel confident to access digital services.

Recommendation 7 addresses the importance of **awareness, acceptance and digital health literacy**, and suggests how to foster them in order **to facilitate the implementation and adoption of eMH solutions**. The recommendation is supplemented by the *Proposed Action Plan* with concrete suggestions for actions (see p.87 for actions for the EC and p.94 for actions for other stakeholders).

Info box 11:
Examples of learning digital health skills

- Online Centres (https://www.onlinecentresnetwork.org/), which are a network of grassroots organisations all over the UK, provide places where people can go to get online in supported environments. Most also provide training in digital skills.
- Digital health skills are promoted through UK-wide digital inclusion initiatives, digital champions and awareness campaigns such as the "Get Online Week" (https://uk.getonlineweek.com/) led by the Good Things Foundation (https://www.goodthingsfoundation.org/) and funded by NHS Digital (257). More specifically, the Good Things Foundation is currently running a three-year programme, Widening Digital Participation, which aims to reduce digital exclusion in the UK, and ensure that people have the skills they need to access relevant health information and health services online. Phase 2 of the programme runs from April 2017 to March 2020, following Phase 1, which was delivered between 2013 and 2016 (258).
- In Northern Ireland, the Department of Finance and Personnel (DFP) introduced the Go ON NI programme in 2011, which continues to promote a range of projects to help people get online and improve their web knowledge and skills, and increase the number of citizens in NI accessing the internet. In 2018, this programme was annexed to the Get Online Week in Northern Ireland, also launched by the Department of Finance (259).
- In 2018, the Wales Co-operative Centre and the Carnegie UK Trust published a report about *Digital Inclusion in Health and Care in Wales* addressing the potential for digital inclusion to improve the health and wellbeing of older people and people with a limiting, long-standing illness, disability or infirmity. Digital inclusion is identified as one of the major public policy issues that requires attention. The strategy of both organisations is to maximise the benefits of digital inclusion and to address the digital agenda in relation to its application in health and care. Specific barriers to digital inclusion, including lack of digital skills and lack of access (including affordability and broadband connectivity), are central in this strategy (260).
- The Welsh Government's *Digital Inclusion Strategic Framework* (2016) has an ambitious 15-point delivery plan. A dedicated national digital inclusion programme, Digital Communities Wales, is delivered by the Wales Co-operative Centre. This includes strategies to provide digital training and education for selected target groups including schools, older and disabled people, those in social housing, those on lower incomes, and the unemployed and economically inactive (261).
- The Scottish Government is working to increase the number of people using digital services by helping communities to develop digital skills and confidence. This is being achieved via their digital participation strategy: A National Framework for Local Action (2014), their national digital strategy: Realising Scotland's full potential in a digital world, their Digital Participation Charter Fund (2014, promoting digital participation and basic digital skills) and the successful Let's Get Online project, which supports people in developing basic internet skills and confidence (262-265).
- PIX (https://pix.fr/) is an online public service in France aiming to support the development of digital skills among the general population, offering services including evaluation and certification of digital skills.

2.4 Dissemination and implementation of eMH

"Digital technologies should be seen as an integral part of health and care and geared towards the wider objectives of health systems." (266)

Implementation research

In 2016, the European Commission published the *Joint Action on Mental Health and Wellbeing*, in which mainstreaming of eMH solutions in European Member States was considered a key objective (57): *"Include eMH interventions alongside with face-to-face interventions into publicly funded health services, and align them with national health standards and practices"* (57).

Despite promising evidence for the efficacy and effectiveness of internet-based interventions for mental health problems, and a clear statement by the European Commission to mainstream eMH, **sustainable and effective implementation of eMH is still limited** (88) and the uptake of eMH outside the research context remains challenging (23, 25–27, 267).

Dissemination and implementation into clinical settings is hampered by several issues. Overall, as for every innovation, the willingness of the practitioners is essential. If they do not refer patients or offer them eMH as an adequate and equal treatment option, eMH will not be used in practice. Therefore, besides regulative and legal clarity, proper training, organisational readiness (technical, time and resources) and clinical guidelines/treatment pathways are essential factors that need to be taken into account.

Currently, there are no explicit dissemination models for eMH throughout eMEN partner countries. Some evidence-based eMH products and services that require no clinical guidance are freely offered to the public (partly supported by government grants). Others are offered and advertised through traditional health services (e.g. moodgym in the UK) or through health insurance companies, which offer their clients specific programmes (e.g. Deprexis in Germany). Furthermore, private for-profit organisations offer eMH products and services to users who have to pay for the programmes or apply for financial support from their health insurance companies.

Limited research on factors that affect implementation in the real-world setting hampers the decision-making process, as decision-makers lack adequate information about context, setting and implementation strategy to enable the use of eMH in routine care. Most research mainly focuses on the efficacy and effectiveness of eMH and less attention has been paid to the process of dissemination and implementation (25, 27, 100), hampering the adoption of eMH into publicly-funded health services. Outcomes of an intervention may differ when implemented into real-world settings compared to research settings (268).

There is a research-to-practice gap that needs to be overcome to benefit population-level health (88). Translation of research results into clinical practice is, in general, challenging due to a multitude of factors. End users tend to use interventions differently in real-world settings compared to trial settings (269) and, more importantly, implementation of eMH into existing mental health care processes is disruptive in the sense that it changes traditional ways of supplying mental health care. Hence, implementation research needs to address multiple components at an early stage (270) and will be essential for sustainable adoption of eMH in (mental) health care systems. **It is of utmost importance that the implementation process as such plays a major role in future research designs**. A review of implementation studies on eMH may help to capture the status quo in this field.

In addition, standardising eMH implementation research may further facilitate the adoption of eMH in different settings (e.g. clinics, the workplace or schools). For example, clinical implementation studies may need to routinely publish their study protocols. Using standardised implementation protocols, such as *Standards for Reporting Implementation Studies (StaRI)* – a checklist with 27 items in terms of transparently reporting the accuracy and consistency of implementation studies and implementation outcomes

(271, 272) – may foster implementation research (25). Structured and systematic implementation research may provide useful information about the effects of specific implementation strategies for different contexts (25).

In order to enable between-programme comparisons, implementation studies may consider reporting on a standard set of data on uptake and engagement of users, such as the number of levels/activities completed by users, the amount of time the user logged on, or other clinical change and effectiveness measures (269).

Due to limited implementation research and scarce initiatives that advance the adoption of eMH solutions into routine care, the role and benefits of eMH outside the research context are often not yet clear to decision makers, health professionals and, above all, users and patients – altogether impeding the adoption of eMH. Research will be essential to indicate for whom, when and what kind of eMH may be beneficial. Some European research projects (e.g. E-COMPARED or ImpleMentAll (see info box 12)) provide a good start in demonstrating the benefits of eMH in Europe and developing an implementation toolkit, respectively. They address not only effectiveness research, but also provide information about how to predict for whom eMH may be useful (273) and how to best implement internet interventions for mental health (ImpleMentAll).

Nevertheless, there is a pressing need for more implementation initiatives and related research on eMH. Research on knowledge translation, which may help to guide implementation processes throughout the EU, will help to define the role of eMH in publicly-funded health services and will contribute to improved uptake in routine care. This encompasses answers to questions such as:

1) when to use eMH (prevention, diagnostics, treatment, relapse prevention, etc.)
2) in which context to use eMH
3) for whom to use eMH (target groups) and how to adapt it to individual needs and preferences (88)
4) how to use eMH (intensity and amount of support, methods for engaging, etc.) (45)
5) how to include different service delivery models (48)
6) how to implement eMH successfully (25) (i.e. ensure adequate uptake of services, adherence and completion rate in real-world settings)
7) how to integrate eMH in a way that improves population-level mental health.

Research concerning the effectiveness and implementation of eMH should be conducted in the setting it is intended for in order to demonstrate its benefit and its appropriateness to the context (88). In addition to implementation research on individual level characteristics, such as changing knowledge, behaviour or attitudes of individuals, organisational (system context) implementation research may contribute to improved uptake of eMH. This also encompasses research on leadership and management (25). (Financial) incentives by governments can foster research into key factors for the implementation of eMH. Due to differences in the mental health systems throughout eMEN partner countries, efforts in national eMH (implementation) research also need to be strengthened. However, through cooperation, mutual learning and knowledge exchange in this field, the dissemination and implementation of eMH may be accelerated. Thus, **the combination of strengthening national research initiatives with strong networks between academics, health care providers, SMEs, patients and other users on a European level will foster the adoption of eMH throughout EU Member States**.

Info box 12:
Best practices – implementation research

ImpleMentAll

ImpleMentAll is a EU-funded, multidisciplinary and international collaboration that aims to provide an evidence-based answer to the gap between knowledge generation and practice, and to improve implementation of eHealth interventions. Using internet interventions for mental health as an example, the project investigates implementation processes in eight European countries plus Australia. A theory-based framework for Intervention Tailoring Strategies (the ItFits-toolkit) has recently (2018) been published and its impact on the implementation of eMH application will be tested during the remaining project period. A randomised stepped-wedge design is used to generate information about process-related effects (274).

2.4.1 Challenges in routine care

"An understanding of professional behaviour, local context, personal and organizational development, change management and diffusion of innovation all impact health systems' capacity to implement eMental Health care technologies." (26)

The readiness of organisations, their workflows, coordination of care (processes) and multidisciplinary collaboration are all important aspects for the sustainable adoption of eMH in mental health systems. Because of the disruptive nature of eMH, coordinated action is required to integrate eMH solutions into established treatment processes. The delivery of eMH within present systems is perceived as the major barrier (67).

Overall, an organisational culture is needed that endorses the introduction of new technologies and avoids resistance in the organisational setting. This includes providing time and resources for using eMH solutions (not just on top of existing services), time, resources and space for training and education (testing and learning about eMH), and adequate compensation for time spent using eMH products and services (structural financing). Health professionals need to be convinced of the benefits of the innovation. Furthermore, roles and responsibilities should be clear at all times (74). Therefore, comprehensive organisational support for integrating eMH will be a precondition to prevent frustration or failures in the delivery of mental health care. **Dedicated commitment from the workforce and managers of organisations in combination with adequate capacity building** (see also chapter 3.4.1) **will be required to push the transition from project-level to permanent services**. In order to achieve this dedicated commitment from both the managers and the workforce, a vision should be developed with all individuals of the organisation being involved (i.e. shared decision-making).

A coordinated approach will be important, as eMH also comes with the risk of overburdening health professionals or threatening the continuity of care (28). In stakeholder interviews, health professionals ex-

pressed concerns that the digitalisation of health care somewhat adds to their workload. Health professionals expect that they may have to juggle more tasks and more responsibility in their routine practice. As an example, timely online communication may be a new task, which is considered time-intensive and challenging (74). Moreover, some tasks that come with eMH, such as sending reminders to patients, may not only be time-consuming but also may be perceived as annoying and frustrating (69).

"Ensuring that new technologies are streamlined within existing health system workflows was regarded as essential to increasing uptake." (26)

Psychologists, for example, reported in a study on barriers and drivers for the adoption of eMH that using only eMH products and services (i.e. full time) appears as rather unattractive (275). Apart from the fact that eMH will complement rather than replace established health care services, the workforce will face not only additional and new tasks (e.g. online communication with patients), but also the implementation of eMH into existing health care systems requires a cultural shift and may even change health professionals' roles in mental health service delivery. In the future, patients' preferences and decisions will play an increasing role for patient treatment pathways. In these scenarios, eMH will only be acknowledged if the benefits of eMH are clear to the people in need and to health professionals. Therefore, the prerequisites of successful eMH implementation are:

- well-functioning and mature technology (no usability problems or functionality issues; technical problems are examples of hampering the uptake of technological innovations in health care in practice) (69, 74)
- fit into the workflow processes (flexible and adaptable to the working conditions of health professionals) with meaningful benefits (which may not only mean saving money) (74, 88, 275)
- using eMH solutions should not mean additional work (88)
- an effective and adequate treatment approach for the mental health problem (suitable to patient needs)
- sufficient education and training for health professionals.

Apart from establishing regulatory oversight, quality assurance and good usability, guidance is needed that helps to ensure that eMH is used effectively and efficiently in routine practice. Ross and co-workers describe seven steps for successful eHealth implementation, which may frame future eMH implementation guidance (102):

1) Selection of appropriate eHealth intervention
2) Inclusion of key stakeholders and implementation champions
3) Sufficient financial and legislative support
4) Certain standards for interoperability, security and privacy
5) Planning the implementation and assessing the organisational readiness
6) Training and assessment of staff
7) Continuous evaluation and monitoring

Administrative and technical requirements, compliance with the GDPR, training and education of the workforce – health care providers need support in organising and coordinating all of these processes. eMH implementation protocols or instruments are currently rarely available: however, the Mental Health Commission of Canada developed an implementation toolkit which aims at informing the workforce about what eMH is and when and how to use it (113). Another example is a toolkit for eMH implementation for general practitioners developed by the Trimbos Institute within a research project (276). **Providing guidance as support for health care organisations to structure this process will be essential for successful and sustainable uptake of eMH in routine practice**.

Clinical pathways

"If whatever we do does not fit within the clinical workflow of the practice in the real world [...], they are not going to use it." (26)

Lack of concepts about how to integrate eMH into established workflow processes of routine care is perceived as an important barrier when it comes to the implementation of digital interventions (69, 103). Such concepts may address the workload, role definition, alignment with clinical processes, etc. However, treatment protocols for using eMH are yet largely missing. In this context, clinical practice guidelines (CPGs) are important tools with regard to changing treatment protocols and, hence, to bridge the gap between research and practice. CPGs provide guidance for diagnosis, management and treatment of health care with the aim of improving the quality, effectiveness and appropriateness of health care (277).

So far, eMH plays only a minor role in clinical practice guidelines on mental health. For example, the clinical guideline *"NICE 2009 Depression: the treatment and management of depression in adults"* recommends computerised cognitive behaviour therapy (cCBT) as an alternative treatment option for people with persistent subthreshold depressive symptoms or mild to moderate depression (278). The German S3-guideline for unipolar depression (2015) discusses the evidence for cCBT and refers to the NICE assessment of the available literature without considering cCBT in further recommendations (279). However, cCBT is only one form of eMH; other options are not yet considered. Nevertheless, current developments are promising and may contribute to the uptake of eMH in routine practice. The NICE guideline on "Depression in adults: treatment and management", for instance, is currently being updated and expected to be published in December 2019 (280). Therein, the role of digital and app-based interventions for the treatment of depressive disorders will be considered. People will be able to choose how they prefer the delivery of interventions (face-to-face or digitally) (280).

Both health professionals and patients see the professional-patient relationship as an important contributor to successful treatment (27). Overall, the therapeutic alliance is considered as an essential factor of psychotherapy (75). Therefore, and against the background that the therapeutic alliance in the context of internet-based interventions is perceived as difficult (67), the role of the therapeutic alliance in the context of eMH requires special attention in research and for the inclusion of eMH into care pathways.

For example, in the UK, in recent research and discussions among key stakeholders and conferences focusing on digital mental health, there is a call for co-production between clinicians, developers and users to inform both the design and commissioning of digital tools for their appropriateness for implementation into UK-based services (90, 281). In this context, there is agreement that collaboration between clinicians, researchers and industry must ensure that eMH fits within usual care pathways, enhance care and be of practical benefit to clinicians, service providers and users (281). It is emphasised that online and digital solutions must be fit for purpose. While commercial organisations have knowledge of app-based technology and may produce usable and engaging products, they often lack knowledge on the care pathway or the clinical, patient and health care system benefits that are required to develop cost- and clinically-effective products, and provide solutions to existing problems.

For benefiting people in need and supporting the sustainability of health systems, eMH needs a clear and equal role in the treatment process of mental health. Guidelines and protocols that define when and according to which criteria eMH products and services may be used, for which patient groups and in what form, may help to adopt eMH in publicly-funded health services. Patient- and demand-oriented eMH that is *"designed to meet the needs of people and health systems and thoughtfully implemented to suit the local context"* (106) should be at the centre of further implementation initiatives. Furthermore, concepts such as informed decision-making, self-empowerment and prevention play increasing roles in health care – eMH may largely contribute to improved patient-centred and personalised care.

2.4.2 Education and training of the health workforce

"Professionals resistant to change, uncertain of the value of technology, and stringent on established processes can generate a digital divide between early adopters and laggards." (26)

Health professionals play a central role in health care. Their professional norms, as well as their knowledge and beliefs, highly influence health care practice and the uptake of innovation in health care. Using eMH products and services in mental health service delivery involves more than integrating a new intervention. It affects the way providers work and requires a cultural shift (behaviour change). eMH products and services can only deploy their full potential and improve mental health care and prevention efforts overall if all people involved have sufficient knowledge and skills to use them properly. According to a recent scoping review, knowledge and guided support of health professionals are relevant determinants for successful implementation of internet- and mobile-based interventions (IMIs) in routine care (25). However, care providers from eight European countries reported an overall moderate level of knowledge about IMIs, depending on the geographical area (67). Health professionals who feel insecure or overwhelmed by digital tools, or who are unaware and uninformed about available eMH products and services, are rather unlikely to act as digital champions, nor will they recommend eMH to their patients or help them with these services (282). Capacity building (e.g. training, building internal assets) is thus one core component for successful adoption of services (219). For the effective implementation of eMH solutions, it will be of utmost importance that the workforce is sufficiently skilled to handle changes in mental health service delivery, accept and adapt to it. Furthermore, prejudices and negative attitudes towards eMH may further impede its diffusion (67). Besides increasing awareness and knowledge about available eMH products and services (i.e. reduce myths, scepticism and concerns that online therapy affects professional freedom and autonomy; see chapter 2.3.1.3), health professionals need to "get acquainted with the treatment format" (69).

Info box 13: Status quo: eMH in universities

The Netherlands

Currently, many psychology students in the NL receive introductory courses on eMH. The Open University first started offering eMH courses (with an introduction and advanced course) (for more information, see www.ou.nl). However, these minor courses are not compulsory, and each university is developing its own courses. The quality and content of the courses are not regulated at national level. Furthermore, the courses do not prepare future psychologists to work in a 'blended care' setting. eMEN has started to bring Dutch universities together to discuss and promote this topic.

Germany

Within the grant-aided "Curriculum 4.0" Programme, an interdisciplinary team developed a teaching concept for the general use of digital services in health care. Students at the medical school of the University of Mainz can optionally choose this one-week module that addresses issues such as health professional-patient contact in the digital age, social networks, smart devices and medical apps, telemedicine, virtual and augmented reality, artificial intelligence and big data (283).

Since 2016, the private university of Witten-Herdecke has offered a general course about how to handle digital media (including big data and data safety). All students may attend this course, including students at the medical school (284).

These two examples indicate a starting point for integrating digital technology's future impact on society (and health care) in the training and education of future health professionals. Follow-up initiatives are planned.

Belgium

So far, only little attention has been given to eMH in higher education. Lectures on technological applications in mental health care are mostly on an ad hoc basis, with only one course at a major university focussing on eMH (E-health and health promotion, which started in 2019 at Ghent University at the faculty of psychology and educational scienc-

es). However, two universities of applied sciences, Howest and Thomas More, each offer a course with an explicit focus on eMH (called "'e-mental health and applied psychology & technology") at their departments of applied psychology.

France

Several initiatives for university education in eHealth offer courses for health care professionals, managers and other involved actors. These courses provide training on legal, deontological and technical aspects, as well as on socioeconomic challenges with regard to eHealth. They are, however, not specific to eMH but to the broad field of eHealth, and are not regulated at the national level.

United Kingdom

In the United Kingdom, 'Digital Health' is a recognised area of postgraduate study, typically delivered in Masters or PhD degree (taught/research) courses. Such courses incorporate a wide range of biomedical research areas, in addition to mental health, dementia, addiction, wellbeing and fitness. Researchers and consortia work with clinicians, industry (from SMEs to global corporations), health care providers, patient groups, charities and policy groups. Examples of universities that are well-known internationally for their Digital Health strands include (for England) University College London, University of Nottingham (Institute of Mental Health/NIHR MindTech HTC), Oxford University, University of Warwick, University of Cambridge, Cumbria University; (for Scotland) University of Strathclyde; and (for Northern Ireland) Queen's University Belfast and University of Ulster. A significant number of completed and ongoing research projects focus on digital mental health, specifically in relation to the possible benefit of smartphones, apps and online interventions (see https://www.ucl.ac.uk/digital-health/Research/more-research-projects for more information (285)). It is demonstrated that this research has had a wide-reaching readership and impact. Such institutions work with external stakeholders including the NHS, NHS England and NICE, as well as collaborating with commercial partners to transform fundamental research into usable technologies. Funding opportunities from organisations including the Welcome Trust, National Institute for Health Research (NIHR) Biomedical Research Centres, RCUK Large Centre Grants and Doctoral Training Centres are frequently targeted, giving research output the platform for government influence. In terms of undergraduate study (BSc Psychology), occasionally eHealth is offered as an optional module of study in the fourth year of study (e.g. Northumbria University), although this is not commonplace.

Currently, digital literacy and knowledge about eMH in mental health are barely evident in role requirements of health professionals – neither in training nor in education. In order to facilitate the uptake of eMH, **the professional bodies by which health professionals are registered may refresh their codes of conduct and include explicit statements about key knowledge, skills and attitudes required of each profession in a digital age** of person-centred health care delivery (286).

With the exception of England, where 'Digital Health' is a recognised area of postgraduate study, eMH training and education are scarcely implemented throughout the education landscape of future mental health professionals in eMEN partner countries. In Belgium, one university and two universities of applied sciences offer courses with an explicit focus on eMH. Some Dutch universities offer non-compulsory courses to psychology students and some universities in Germany offer general digital (health) literacy courses (see info box 13 for more information). **eMH training and courses at universities for future mental health professionals should therefore be extended to improve digital skills**.

Besides training and education at university level, other organisations (e.g. health care providers) and professional bodies may need to be put in charge to ensure that health professionals have profound levels of digital competencies, skills and knowledge to adapt to changes related to the digitalisation of health care.

Practitioners in health care organisations need the option of keeping up with recent developments. **Continued training and retraining will be required to take the workforce along in such a process**. Furthermore, such training sessions provide the chance to address fears, concerns or other threats associated with the digitalisation of health care.

Health care providers and professional bodies need to support the workforce by providing time and resources to become acquainted with eMH solutions, have the chance to exchange their experiences and receive supervision. A structured approach may help to foster this development, as this has to be organised without neglecting the day-to-day work. Therefore, health professionals should not feel overwhelmed by additional services (275), feel as if technology would be imposed on them, resulting in additional work, or that they have to give up their free time. **The "added value" and technology benefits must be obvious at any time** (26). Offering Continuing Medical Education credits for digital health literacy courses or special eMH training will enhance the likelihood that health professionals would be willing to invest time and resources in this new field.

Specific training can change knowledge about, attitudes toward and confidence in delivering eMH (27). Therapists who have worked with internet interventions report that these experiences increased their willingness to use it (69).

Getting to know specific eMH products and services requires a lot of time and an additional question is how eMH can be meaningfully integrated into routine care (see also chapter 3.5). This question is associated with high uncertainty of health professionals, e.g. in terms of what is the appropriate amount of time spent getting to know a specific eMH product or service such as iCBT (275). A comparative analysis of implementation challenges of iCBT revealed that supervision sessions (discussing issues related to online therapy) and ongoing coaching proved to be beneficial and supportive for health professionals in using eMH solutions (275). Overarching information platforms, such as eMHPrac in Australia (see info box 14), or government-initiated programmes for improved digital literacy of health professionals, such as the "Building a Digital Ready Workforce Programme" in England, may support and supplement educational efforts on university and organisational levels. Such **platforms may help to improve eMH knowledge and skills on a large scale, to exchange experiences with other peers** and may help to:

1) build awareness of existing eMH products and services
2) build capacities that allow successful and efficient integration of eMH solutions into routine mental health care and prevention efforts
3) build resources on the organisational level that allow such services to be used in an efficient manner in day-to-day practice (with repeated reflection and feedback for continued maintenance), and
4) coordinate with organisations and professionals in community organisations (e.g. school counsellors, establishing a client-referral process to these services).

It will be important to streamline such processes and to establish networks in order not to waste efforts through duplication of work. Using established networks at EU level (such as the Digital Skills and Jobs Coalition) that bring together organisations that are active in improving European citizens' digital skills and that promote successful initiatives (287), may facilitate efforts and may create synergies.

Recommendation 8 addresses the importance of **eMH implementation protocols and education and training of the health workforce**, and suggests how to foster them in order **to facilitate the implementation and adoption of eMH solutions**. The recommendation is supplemented by the *Proposed Action Plan* with concrete suggestions for actions (see p.87 for actions for the EC and p.94 for actions for other stakeholders).

Info box 14: Best practices – education and training of the (mental) health workforce

eMental health in practice initiative (eMHPrac)
In 2013, the Australian Government started eMental health in practice (eMHPrac) as an initiative to engage health professionals in using eMH and to promote the use of eMH resources among primary health care service providers across Australia. The eMHPrac team provides free eMH training and support to GPs, allied health professionals and health professionals providing services to Aboriginal and Torres Strait Islander peoples. The eMH training builds on face-to-face workshops, webinars, and online professional development training courses, and introduces clinicians to eMH programmes, tools and resources. Furthermore, it demonstrates how eMH can be integrated into practice and service delivery. The eMHPrac Community is an online community consisting of a blog and forum. It is open to all GPs and other practitioners with an interest in mental health generally and digital mental health resources particularly, and aims to provide a forum for discussion and exchange of experiences with peers (288).

A Digital Ready Workforce: example from England
By the Building a Digital Ready Workforce programme, Health Education England, commissioned by the National Information Board, is leading work on helping "everyone in the health and care sector in England, become comfortable enough with digital tools that they can contribute to" a sustainable way of providing health and care services in England (289). The programme consists of four work streams: leadership and culture, professionalism, digital academy and digital literacy. The digital literacy workstream is to improve the digital capabilities of those working in health and social care by conducting research into how to upskill workforces. Digital capabilities are associated with "a positive attitude towards technology and innovation and its potential to improve care and outcomes", whereas insufficient digital capabilities were identified as a barrier for the use of digital tools in practice (290).

Info box 15:
Examples of required skills and competences

An extensive, structured, systematic, multidisciplinary and coherent approach for the training and education of health professionals is required in order to reduce the technical burden of eMH products and services. Health professionals not only require access to reliable information about safe, effective and high-quality eMH solutions (see chapter 3.1.1 and 3.2), but they also have to be trained in:

1) handling eMH solutions (addressing how eMH solutions work, their underlying concepts and theories, how they are used, the risks (and how to minimise these), the technical support required, suitable target groups),
2) integrating eMH solutions effectively into care processes, i.e. deciding when such services may be useful (see also chapter 3.5),
3) adequate communication skills and communication styles (e.g. providing concise and clear written feedback) (275),
4) assessing the associated risks for using eMH solutions (the rights and obligations in terms of liability, privacy, cybersecurity, treatment adherence, etc.).

3 Conclusions

eMH offers potential as an adjunct and complement to traditional mental health care services. The digitalisation of mental health care services may play an important role in the promotion of mental health awareness and mental health literacy, and may support practitioners in their daily routine. Furthermore, eMH may improve the accessibility of appropriate and high-quality mental health care and prevention efforts for individuals in need, reduce waiting times, support the continuity of care, and promote the early identification of people who are at risk of developing mental health problems. eMH can further help to enhance the care of people with mental health problems, increase their empowerment and self-management abilities and support system-level efforts to improve mental health.

Yet, hampered by a wide variety of barriers, the uptake of eMH products and services into routine health care is limited. Literature reviews, country status reports and stakeholder interviews show a wide variety of determinants of eMH implementation that can serve as either barriers or facilitators.

In the broad concept of digital health, eMH specifically is still a rather underrepresented topic at EU level, and still plays a minor to moderate role in (national) mental health policies. It is time to set the vision, mission and objective for future mental health systems (including the use of eMH solutions), and to strengthen the role of eMH in mental health strategies and action plans (at EU and national levels). Strong political commitment and leadership is needed to use the potential eMH offers (see recommendation 1).

Adequate legislation, standards and processes (e.g. HTA processes) and a digital infrastructure for eMH implementation need to be developed to initiate substantial change. An appropriate regulatory framework guided by an overall eMH implementation strategy will stimulate innovation. Mental health systems must evolve and become resilient against future challenges in order to improve European citizens' mental health (see recommendation 2).

So far, the financial systems for eMH are in development or remain unclear in most NWE member countries. Effective reimbursement systems, adequate financing strategies and an increase of financial incentives for eMH are needed to foster the uptake of eMH in the long-term and stimulate innovation (see recommendation 3).

Reliable evidence guides decision-making. Despite promising evidence in terms of the efficacy of eMH solutions, the potential of eMH has scarcely been realised, partly due to methodological limitations in available studies, such as a lack of representative population samples (selection bias due to e.g., self-referral recruitment procedures), small population sizes, or limited research on factors that affect the implementation in the real-world setting. Methodologically rigorous eMH evaluation studies are needed. Furthermore, it appears advisable to support a European joint development of appropriate research methods for the rapidly changing (social and technological) environment of digital health interventions with a view to enhancing the evidence generation process of digital solutions. Building stronger networks and interdisciplinary collaboration throughout Europe will support these efforts (see recommendation 4).

In this context, user preferences and usability, as well as interoperability, are major factors for the adoption of eMH solutions. Promoting co-creation (meaningful input by users), interoperability and quality standards will increase the quality of available eMH products and services, and prevent low user engagement and adherence (see recommendation 5).

Potential users face an increasing number of eMH solutions available on the market, with only limited options to identify high-quality eMH solutions in terms of efficacy, effectiveness and safety. National and transnational organisations, research and expert groups have suggested quality criteria for eMH products and services. Aligning these initiatives and developing a catalogue of quality criteria at European

level may further facilitate the development of quality assurance mechanisms at national level (see recommendation 6).

Awareness and acceptance of eMH as well as, in general, good digital health literacy are key contributors to the successful adoption of eMH solutions. Stakeholder-tailored approaches are required in order to raise awareness and acceptance and to prepare the involved actors, including (potential) users, for eMH adoption (see recommendation 7).

Implementing eMH is a disruptive process. However, despite a growing evidence base and increasing interest, the lack of research and overarching strategies challenge the implementation process. Systems require concepts on how to embed eMH into established routine health care workflow processes, integrate eMH into treatment protocols where applicable (e.g. stepped care, blended care), develop organisational readiness (technological infrastructure, workflow, support by the management, etc.) and develop sustainable financial models. Training the (mental) health workforce and adequately educating it by integrating eMH into curricula, and offering supervision and support, will altogether contribute to the adoption of eMH solutions in routine care (see recommendation 8).

Based on these results, the eMEN consortium has developed **eight policy recommendations** (Chapter 4) and a *Proposed Action Plan* (Chapter 5) for the EC (p.87) and other stakeholders (p.94).

4 Recommendations

Based on the results of the analyses performed in the framework of this Transnational Policy, the eMEN consortium has developed **eight recommendations**, which aim to guide the upscaling of eMH throughout the European Union and beyond. For their successful adoption, the EC may endorse these recommendations and reinforce their implementation.

In combination with the **Proposed Action Plan** (Chapter 5), the recommendations aim to address and overcome the identified challenges to improve population-level mental health and reduce the burden of mental health problems.

The recommendations are as follows:

1. **Promote and advocate strong** *political commitment*, **governance and leadership for the development, dissemination, implementation and adoption of eMH solutions through:**
- concentrating efforts on fostering and facilitating cooperation between EU Member States on different governance levels (regional, national, European)
- making commitments to eMH in party manifestos and government programmes and promoting digital mental health in public statements
- developing strong and integrated (e-)mental health policies that provide clear direction regarding the developments in the field of eMH
- enabling funding mechanisms and allocating public funds for digital mental health development
- prioritising eMH in future action plans for mental health and other strategies addressing Europe's future mental health systems
- creating a quality assurance and regulatory framework that stimulates innovation and underpins usability, safety and effectiveness

2. **Ensure legal clarity and ethical correctness, and avoid insecurities in users with regard to the** *safeguarding* **of human rights, privacy and data security in the digital age through:**
- promoting the clarification of mandates and legislation with regard to privacy, liability and other legal issues (e.g. intellectual property rights)
- clarifying the interpretation of the General Data Protection Regulation ((EU) 2016/679) in EU Member States and all organisations that conduct any kind of business in Europe, in the context of eMH innovations, in order to ensure privacy while not hindering implementation
- developing a widely acknowledged privacy seal
- developing tailored and informative guidance in terms of how the GDPR ensures privacy, individual rights and ethical correctness in the field of eMH for:
  - researchers
  - developers
  - providers
  - users
- stimulating public dialogue about the use of patient-generated digital data in the research context (e.g. sharing research data between EU Member States) under consideration of the GDPR and other ethical and legal considerations

3. **Develop adequate financing strategies and guarantee the** *financial viability* **of eMH in the long-term through:**
- developing a roadmap that describes financial aspects and funding models related to eMH in health systems in EU Member States to identify and promote best practices
- promoting the development of financial systems and structures that ensure the sustainable adoption of eMH solutions (e.g. in terms of funding and licensing, grants for research and effective tendering and procurement processes)

4. **Stimulate, promote and fund eMH research within existing and future European *research* programmes (e.g. Horizon Europe). To be specific, research should focus on:**
- large-scale research initiatives that evaluate the efficacy and (cost-)effectiveness of eMH products and services
- EU-wide standards for evaluation methods (including data collection, design and analysis, recruitment processes, etc.)
- eMH implementation, its issues and possible solutions, long-term and negative effects, as well as the required level of human support

5. **Promote and facilitate eMH development and research processes that are based on the highest standards of *usability and interoperability* through:**
- promoting development approaches that put user needs and preferences at the centre of development efforts through co-creation
- promoting and funding research on user needs and preferences as well as on reasons for low user engagement/adherence
- defining overall usability standards and promoting 'usability' as a criterion for overall quality of eMH solutions
- developing EU-wide technical standards and protocols that guide eMH development

6. **Ensure that only *high-quality* eMH products and services are implemented in the (mental) health care sector through:**
- defining common quality criteria for eMH at EU level through consultation with stakeholders (these may serve as reference points for national efforts)
- promoting rigorous and independent evaluation of eMH products and services and encouraging EU Member States to review and update their quality control mechanisms (HTA processes)
- promoting end-user involvement in quality evaluation
- ensuring that relevant EU regulations, directives and decisions are up to date to foster and stimulate innovation in health care
- establishing options (e.g. a European platform) to transparently inform about the quality and evidence base of available eMH solutions

7. **Increase *awareness and acceptance* of eMH products and services, foster *trust* in digital tools in mental health care and prevention efforts, and enhance *digital health literacy and skills* in the public and the (mental) health workforce through:**
- (tailored) educational and promotional activities
- creating opportunities to have easy access to up-to-date information about objectively assessed and effective eMH products and services

8. ***Integrate* eMH into established (mental) health care models and other key areas of interest such as mental health in the workplace or mental health in schools through:**
- providing transparent guidance for mental health professionals in terms of available eMH products and services as well as the possibilities and risks that eMH entails
- promoting the development of eMH implementation protocols
- piloting eMH implementation within health care settings, and sharing the learnings
- stimulating the development of a multidisciplinary strategy to prepare health care provider organisations for eMH implementation in terms of (clinical) workflows, care pathways, responsibilities, professional roles, financing, training, etc.
- integrating eMH and cultural awareness in (future) professional training and education
- setting standards for digital (health) literacy in the (mental) health workforce

5 Proposed Action Plan

Based on the results of the review of eMH policy contexts in eMEN partner countries, the analyses of (trans-)national challenges and the formulated recommendations, a Proposed Action Plan for eMH implementation was developed.

In this chapter, the eMEN consortium proposes specific actions for each of the eight formulated recommendations. In order to initiate a change with regard to eMH dissemination and implementation at the highest political level, proposed actions per recommendation addressed at the European Commission can be found on p.87. However, as successful uptake and implementation requires the involvement of a multitude of parties, this is followed by suggested actions at national level (p.94), pointing out which institution or stakeholder is expected to carry out the respective action. This Proposed Action Plan is to be considered as a collection of "point in time" actions and may be subject to later revision.

Proposed actions for the European Commission

Goals	Actions
Recommendation 1: Promote and advocate strong political commitment, governance and leadership for the development, dissemination, implementation and adoption of eMH solutions.	
Establish political commitment and strong leadership for eMH.	Develop a vision for the role of eMH (at national and European levels) within Europe's mental health systems in the digital age by setting clear objectives. Incorporate eMH into future action plans and strategies for mental health and eHealth. Encourage targeted distribution of scientific evidence that efficiently contributes to decision-making in policy. Promote digital mental health in public statements
Foster national digital health policies/ strategies that support and guide eMH implementation and stimulate innovation.	Invite EU Member States to place eMH at the heart of future policies and strategies, depicting clear visions and objectives (including investment in infrastructure, reimbursement, other regulatory issues, clinical practice guidelines (conversion protocols), quality criteria and licensing, investment in mental health (including procurement) and digital access (see subchapters for detailed descriptions of these aspects)). Stimulate the development of a sustainable implementation model for eMH.
Foster collaboration between EU Member States to stimulate innovation and promote a receptive culture for change in mental health systems.	Establish working groups or platforms (informative or interactive), which help to exchange knowledge and experience, generate cross-border knowledge and contribute to the sustainable uptake of eMH in Europe. Extend the reach/intent of established networks in the field of eHealth (e.g. eHealth network, eHealth hub) to cover eMH.

Goals	Actions
Recommendation 2: Ensure legal clarity and ethical correctness, and avoid insecurities in users with regard to the safeguarding of human rights, privacy, and data security and individual rights in the digital age.	
Safeguard individuals and society concerning the adoption of eMH.	Promote and enhance the clarification of mandates and legislation with regard to privacy, liability and other legal issues (e.g. intellectual property rights).
Facilitate trust by relevant stakeholders.	Initiate the development of a widely-acknowledged privacy seal and its introduction into the market.
Ensure ethical correctness, create trust and avoid insecurities among stakeholders.	Initiate the development of tailored guidance documents for: ▸ researchers (e.g. on how to enable data sharing in research while complying with the GDPR and ensuring consideration for ethical procedures) ▸ developers (on how to develop an eMH health product that complies with the GDPR and follows ethical principles) ▸ providers (on how to safeguard privacy, data security and ethical standards when working with eMH products and services) ▸ users (e.g. on how the GDPR protects their privacy and data security, explaining their rights (e.g. the right to be forgotten)).
Ensure information privacy and data protection in eMH products and services.	Promote and clarify the GDPR and support its appropriate implementation in EU Member States. Promote the Code of Conduct on privacy for mobile health applications (ensure that developers know the Code and develop eMH products and services accordingly).
Clarify the handling of patient-generated digital data in research and avoid insecurities among researchers.	Stimulate a public dialogue about the use of patient-generated digital data in the research context (e.g. sharing of research data between EU Member States) under consideration of the GDPR and other ethical considerations.

Goals	Actions
Recommendation 3: Develop adequate financing strategies and guarantee the financial viability of eMH in the long-term.	
Identify appropriate funding models for effective and high-quality eMH solutions in routine practice.	Develop a roadmap that describes financial flows related to eMH in public and private European health systems.
Assure the financial viability of eMH solutions and enhance the uptake of eMH throughout the EU in the long-term.	Invite EU Member States to review and adapt their existing fiscal systems with regard to eMH products and services. Provide funds and grants to support SMEs with promising high-quality eMH solutions. Promote the development of easy and effective tendering and procurement processes for digital solutions in health care.
Recommendation 4: Stimulate, promote and fund eMH research within existing and future European research programmes (e.g. Horizon Europe).	
Generate knowledge about the generalisability and transferability of eMH products and services.	Promote (large-scale) research initiatives at national and transnational level to evaluate the efficacy and (cost-)effectiveness of eMH solutions and generate more knowledge in terms of, among others, mental health implementation, its issues and possible solutions, long-term and negative effects, and the required level of human support (see also info box 3).
Establish appropriate, rigorous, valid and internationally established evaluation methods for digital health solutions (incl. eMH).	Stimulate, promote and fund (large-scale) research initiatives and collaborations that develop and test reliable evaluation methods for digital health solutions. Encourage joint efforts and strong (interdisciplinary) collaboration between academics, health professionals, providers and end users that set EU-wide standards for evaluation methods (including data collection and analysis, recruitment processes, utilisation patterns, etc.), evaluation criteria and reporting of (patient-reported) outcomes (consensus across a multidisciplinary network of research excellence in Europe).

Goals	Actions
Recommendation 5: Promote and facilitate eMH development and research processes that are based on the highest standards of usability and interoperability.	
Increase the end user satisfaction and experience; create and develop eMH solutions that meet user demands and capacities and match their socioeconomic and cultural backgrounds.	Promote research on end user demands and preferences, as well as on reasons for low user engagement/ adherence. Define overall usability standards and promote 'usability' as a criterion for overall quality of eMH solutions. Call upon developers to actively and routinely involve end-users in the development process in collaboration with patient organisations.
Improve the interoperability of eMH products and services.	Establish international standards and protocols (IT systems and structures) for eMH: • data models • terminologies • formatting of data Invite EU Member States to establish national health data governance frameworks for eMH data.

Goals	Actions
Recommendation 6: Ensure that only high-quality eMH products and services are implemented in the (mental) health care sector.	
Ensure the safety, quality and reliability of digital health innovations.	Invite and engage EU Member States to initiate working groups (including all relevant stakeholders) to extend established approval (HTA) processes or develop new processes in order to rigorously and independently evaluate eMH products and services (pool synergies). Continuously critically assess and/or update relevant regulations (e.g. GDPR) and directives (e.g. the Medical Device Regulation), which are applicable to digital health innovations in terms of their appropriateness, and adapt them to current development or new established standards if necessary.
Create a common understanding of quality criteria for eMH.	Put in place a suitable working group (consisting of a multidisciplinary group of experts) that aligns existing suggestions for eMH quality criteria and that establishes a basic set of quality criteria that is applicable throughout all European countries. These criteria may then be used at the national level as a reference point and may be extended according to national specifications.
Make sophisticated information about effective and safe eMH accessible.	Establish a European platform (maybe in conjunction with the EU database on Medical Devices (EU-DAMED)) that provides reliable, comprehensive and transparent information about available evidence-based eMH solutions, and that is informative for all relevant stakeholders. Such a platform may also serve as a central point for communicating damages and problems.

Goals	Actions
Recommendation 7: Increase awareness and acceptance of eMH products and services, foster trust in digital tools in mental health care and prevention efforts, and enhance digital health literacy and skills in the public and the (mental) health workforce.	
Increase awareness, acceptance and cultural awareness in the general public and relevant stakeholder groups.	Call upon EU Member States to conduct public campaigns and (tailored) educational and promotional activities regarding eMH and cultural awareness.
Improve eMH knowledge, digital health literacy and skills among stakeholders.	Strengthen the role of digital health literacy skills in relevant strategies, e.g. the new Skills Agenda for Europe or the Digital Single Market (DSM) strategy.
Ensure that users are able to understand relevant information concerning eMH solutions.	Enforce developers to provide relevant information (e.g. privacy policies) in an understandable manner (set standards, e.g. 6th grade reading level).
Facilitate trust and acceptance of eMH solutions among stakeholders.	Establish an overarching reliable source for accurate information provision about available safe, effective and high-quality eMH solutions (see also Proposed Actions for Recommendation 4: European platform).

Goals	Actions
Recommendation 8: Integrate eMH into established (mental) health care models and other key areas of interest such as mental health in the workplace, or mental health in schools.	
Integrate eMH as a treatment option alongside face-to-face interventions.	Promote collaboration, exchange of knowledge and experience on a transnational level (e.g. by promoting networks between academics, health care providers, end users, etc.) in terms of the development of eMH implementation protocols that support and guide the implementation and adoption, taking into account the circumstances of the specific setting (e.g. clinics, schools or workplaces).
Provide guidance for the mental health workforce.	Develop and maintain an information system (e.g. a European platform) that transparently informs about available high-quality eMH products and services and the possibilities that eMH entails. Involve and engage all stakeholders in the implementation process by e.g. setting up round table discussions, expert groups and working groups to develop a generic strategy for eMH implementation and/or toolkit that outlines mandates, legislation and a sustainable investment plan. Initiate the development of a multidisciplinary strategy for eMH implementation in health care provider organisations (workflows, responsibilities, roles, financing, training, etc.), which involves all relevant stakeholders. Provide information (concepts, standards, etc.) about eMH training and education through e.g. a European platform (see also Proposed Actions for Recommendation 4: European platform).
Facilitate trust and acceptance of eMH solutions and increase cultural awareness in the health workforce.	Call upon EU Member States to set standards for digital (health) literacy in the health workforce and integrate eMH and cultural awareness in (future) health workforce training and education.

Proposed Actions for Recommendation 1

Promote and advocate strong political commitment, governance and leadership for the development, dissemination, implementation and adoption of eMH.

Goals	**Activity**	**Responsible**/involved parties
Establish a sustainable environment and set a mutual commitment for the uptake of eMH.	Revise existing mental health policies and strategies, and integrate and describe the future role of eMH. Make commitments to eMH in party manifestos and Government programmes. Integrate eMH into the national health sector strategic plan on primary care, community, regional and state levels, and align objectives. Affirm the role of eMH in mental health care in Ministerial statements. Establish and maintain a Ministerial advisory board for the questions related to the adoption and implementation of eMH. The advisory board should consist of interdisciplinary and multiple stakeholders that cover all perspectives (providers and professionals, patients, ethical, juridical, research, developers and other relevant groups).	• **National and regional government (Ministry of Health)** • Health Authorities • NGOs • Expert groups
Ensure sustainable investment.	Prepare costings for eMH implementation and identify multi-annual funding streams for this investment.	• **National and regional government (Ministry of Health)** • Health Authorities

Proposed Actions for Recommendation 2

Ensure legal clarity and ethical correctness, and avoid insecurities in users with regard to the safeguarding of human rights, privacy, data security and individual rights in the digital age.

Goals	Activity	Responsible/involved parties
Create trust and certainty in users concerning the use of eMH solutions.	Verify that legal risks are as low as possible and align, clarify and revise national regulatory and legal frameworks or guidelines concerning the use of eMH products and services. Establish a liability system. Create and establish a legal basis for using eMH products and services using a multidisciplinary process with appropriate stakeholder engagement.	• **National and regional government (Ministry of Health)** • Health Authorities • Regulatory Authorities
Ensure information privacy and data protection in eMH products and services.	Monitor the application of and compliance with the GDPR in stakeholders involved in the development, implementation and maintenance of eMH products and services. Design and implement eMH products and services according to the GDPR and its principles: • Provide transparent information • Right to access and right to data portability • Right to be forgotten • Right to correct • Right to object • Appoint a Data Protection Officer (DPO) • Data protection by design and by default • Provide proper notification in the case of a data breach • Conduct a Data Protection Impact Assessment (DPIA)	• **National Supervisory Authorities** • **Developers** • Providers

Goals	Activity	Responsible/involved parties
Ensure data protection in eMH products and services.	Make provision to ensure data security on methodological, technical and procedural levels. Develop and maintain comprehensive data governance policies, concepts and strategies (i.e. how to protect the users' data and how to respond to cyberattacks). Develop eMH products and services according to the Code of Conduct on Privacy for Mobile Health Applications of the EC, when it has been approved. Establish national health data governance frameworks for eMH data.	• **Developers** • Providers • **National and regional government (Ministry of Health)**
Facilitate trust in relevant stakeholders.	Provide information on how user privacy and data protection is ensured in a user-friendly manner (precise, compact (e.g. one or two pages), easily accessible and understandable for laypeople). Label eMH products and services as GDPR-compliant. Tailor the provided information on how information privacy and data security are assured (i.e. channel, style of providing, complexity) according to the specific target group.	• **Developers** • Providers
Ensure ethical correctness in eMH products and services.	Follow ethical principles when developing eMH products and services: • Respect for autonomy • Nonmaleficence • Beneficence • Justice Follow ethical principles when conducting studies on eMH products and services involving human participants. Examine whether an eMH study/research involving human participants follows ethical principles.	• **Developers** • **Ethics commissions**

Proposed Actions for Recommendation 3

Develop adequate financing strategies and guarantee the financial viability of eMH in the long-term.

Goals	Activity	Responsible/involved parties
Enable the use of eMH in routine practice.	Update, refine or complement existing funding models with regard to which role eMH has in the treatment process (unguided, guided, blended, etc.). Ensure that eMH does not financially overburden patients, health professionals or health systems.	• **National and regional government (Ministry of Health)** • Health Authorities • Regulatory Authorities • Health insurance companies
Ensure that SMEs stay active in the field of eMH.	Support SMEs by establishing flexible and supportive structures to access public mental health systems. Provide funds and grants to support SMEs.	• **National and regional government (Ministry of Health)** • Health Authorities • Regulatory Authorities

Proposed Actions for Recommendation 4

Stimulate, promote and fund eMH research within existing and future European research programmes (e.g. Horizon Europe).

Goals	Activity	Responsible/involved parties
Ensure comparability/ transferability of eMH research.	Establish, agree on and use a common set of standards, methods and outcomes for the evaluation of digital health products and services.	• **National and regional government (Ministry of Health)** • Health insurance companies • Developers • Researchers
Establish trust in the efficacy and effectiveness of eMH products and services.	Provide structured, reliable and understandable information about the evidence of eMH products and services (promote good reporting). Oblige developers to transparently inform users about the evidence base in an understandable manner.	• **Health Authorities** • Developers • Researchers • **National and regional government (Ministry of Health)** • Health Authorities
Strengthen research on eMH effectiveness and safety (build a strong evidence base).	Focus future research on long-term effects, negative effects and level of human support (for more open research questions, see info box 3).	• Researchers

Proposed Actions for Recommendation 5

Promote and facilitate eMH development and research processes that are based on the highest standards of usability and interoperability.

Goals	Activity	Responsible/involved parties
Increase the end user satisfaction and experience; create and develop eMH products and services that meet user demands and capacities.	Involve target users (people with mental health problems, patient organisations, health professionals, health care providers, funding providers, etc.) in the development process (co-creation). Tailor interventions according to user demands and preferences as well as the needs of the care process. Initiate research on the needs of target groups, reason for low user engagement, etc.	• **Developers** • Researchers and academic institutions
Establish technical interoperability (information can be transferred between different organisations).	Integrate eMH products and services into existing health care information systems.	• **National and regional government (Ministry of Health)** • Developers
Support the integration of eMH into strategic plans of other sectors.	Facilitate liaison with other relevant sectors (e.g. education).	• **National and regional government (Ministry of Health)**
Establish interoperability to improve effectiveness and quality of mental health prevention and care.	Establish collaboration and co-creation between stakeholders who are involved in the implementation of eMH products and services.	• **National and regional government (Ministry of Health)** • Health insurance companies • Developers • Providers • Professionals
Increase the quality of eMH products and services.	Establish national and international standards and protocols (IT systems and structures) for eMH: • Data models • Terminologies • Formatting of data	• **National and regional government (Ministry of Health)** • Developers
Establish technical interoperability.	Establish national health data governance frameworks for eMH data.	• **National and regional government (Ministry of Health)** • Developers

Proposed Actions for Recommendation 6

Ensure that only high-quality eMH products and services are implemented in the (mental) health care sector.

Goals	Activity	Responsible/involved parties
Establish quality criteria for eMH products and services.	Initiate working groups (involving all relevant stakeholders) that define a set of quality criteria for eMH products and services.	• **National and regional government (Ministry of Health)** • Health Authorities • Regulatory Authorities • Health professionals/professional bodies • Patient organisations / people with mental health problems
Create trust in the quality, safety and effectiveness of eMH products and services.	Define and agree the level of evidence, quality criteria (including technical and privacy components) and outcomes that are required to prove the efficacy and effectiveness of eMH solutions (e.g. compared to usual care) in routine practice in a multidisciplinary (and transnational) process.	• **National and regional government (Ministry of Health)** • Health insurance companies • Developers • Researchers
	Initiate working groups (involving all relevant stakeholders) that develop adequate structures, supplement existing ones or think of new procedures in order to establish reliable, objective and valid approval processes that: • apply agreed upon quality criteria (that should also address user preferences and usability), • ensure the efficacy, effectiveness and safety of eMH products and services according to standards of evidence-based medicine, • ensure that eMH products and services meet privacy, data protection and technical standards, • eliminate harmful interventions or enforce developers to address harmful elements.	• **National and regional government (Ministry of Health)** • Health Authorities • Regulatory Authorities Health professionals / professional bodies • Patient organisations / people with mental health problems
	Select an independent organisation/institution that will be responsible for undertaking these processes. The responsible institution should provide clear guidance on what information is required for proving the quality, safety and effectiveness of eMH products and services.	• Provider organisations • Health insurance companies • Researchers/experts

Goals	**Activity**	**Responsible**/involved parties
Provide information about effective and safe eMH.	Establish an information website that provides reliable, comprehensive and transparent information (e.g. state-run or regulatory agency website) to identify appropriate eMH products and services. Include the option to communicate with peers. Interlink the platform with the European platform. Information should cover e.g. purpose, clinical effectiveness, safety, adherence to privacy criteria, certificates and descriptions of how to integrate services into routine practice (when to use it, who should use it, and in which part of the treatment process).	• **National and regional government (Ministry of Health)** • Health Authorities • Regulatory Authorities • Health insurance companies • Patient organisations / People with mental health problems • Health professionals
Ensure that developers provide relevant information about the product in a transparent and understandable manner.	Define information that developers need to provide to the end user, such as (139): • Who financed and developed the programme/app? • What are the qualifications of those involved? • What is the function of the programme? • What is the evidence? • When was the information last updated? • What are the risks? • What happens with the data/who has access to data/where is the data stored? Set in place mechanisms that ensure that developers comply with these reporting requirements (on a mandatory or voluntary basis), e.g. providing information as a prerequisite for coverage in publicly-funded health services.	• **National and regional government (Ministry of Health)** • Health Authorities • Regulatory Authorities • Developers

Proposed Actions for Recommendation 7

Increase awareness and acceptance of eMH products and services, foster trust in digital tools in mental health care and prevention efforts, and enhance digital health literacy and skills in the public and health professionals.

Goals	**Activity**	**Responsible**/involved parties
Raise awareness, knowledge and acceptance of eMH solutions in: • The general public • Populations at high risk • Populations with early signs of mental health problems • Treated people with mental health problems (for relapse prevention) • Professionals • Heads/management of mental health institutions • Policy makers Prevention and early detection. Educate (potential) users about how to identify (un)safe eMH products and services and how to avoid risks on their end (e.g. unsafe WLAN connection). Establish cultural awareness and sensitivity among • Developers • Providers • Professionals Ethically appropriate development and implementation of eMH products and services.	Facilitate promotion and education campaigns for eMH products and services. Label eMH solutions as a secure and effective way to: • support traditional mental health prevention and care • reduce the treatment gap.	• **National and regional government (Ministry of Health)** • Centres for health education • Developers • Providers

Goals	**Activity**	**Responsible**/involved parties
Raise awareness and acceptance in relevant stakeholders.	Educate relevant stakeholders about the benefits as well as risks of eMH products and services.	• **National and regional government (Ministry of Health)** • **Providers**
Facilitate trust in (potential) users.	Create opportunities for (potential) users to have easy access to up-to-date information about objectively assessed and effective eMH products and services (e.g. platform/website). Provide information on how the respective eMH product or service works.	• **National and regional government (Ministry of Health)** • **Providers** • **Providers**
Establish an infrastructure for overall good digital (mental) health literacy.	Define required skills (by a multidisciplinary group) and create an infrastructure that receives all target groups (irrespective of age, culture, educational level or language). Initiate national digital health literacy campaigns or programmes, respectively streamline or boost existing initiatives and establish networks. Establish collaborations with other agencies on social aspects of care (e.g., primary care, social services, local authorities) and foster place-based approaches.	• **National and regional government (Ministry of Health)** • Centres for health education • Health Authorities • NGOs
Achieve good digital literacy for those groups that have difficulty in accessing digital services.	Establish special programmes/effective educational strategies for elderly or other groups that need more help and information. Information should be presented by using a tone, language and information level that are suitable for the target population and its condition.	• **National and regional government (Ministry of Health)** • Centres for health education • NGOs
Create trust in digital services for mental health care.	Establish an overarching reliable source for accurate information provision. Present information about data use and privacy in a common and easy-to-understand language.	• **National and regional government (Ministry of Health)** • Centres for health education • NGOs • Professional bodies • Providers

Goals	**Activity**	**Responsible**/involved parties
Improve knowledge and confidence of patients. Individuals should be able to: • use computers • understand relevant information • be capable of assessing and judging information	Offer digital health literacy courses to patients in clinics, which could be extended to the use of eMH products and services. Improve the risk education of using health apps or eMH products and services; the public should be well aware of the benefits as well as the potential risks and how to handle them. For example, patients should be aware that they have to be careful when apps are free, since providers might collect personal data for their own purpose.	• **National and regional government (Ministry of Health)** • **Centres for health education** • NGOs • Providers
Raise cultural awareness in relevant stakeholders.	Facilitate public campaigns targeting cultural awareness. Establish co-creation between developers and locals/individuals of the target group.	• **National and regional government (Ministry of Health)** • **Developers**
Assure that the eMH product or service is a needs-oriented product. Assure the cultural appropriateness of eMH products and services.	Establish co-creation between developers and locals/individuals; evaluate available local resources prior to developing and implementing eMH products and services in a setting, and develop them according to identified cultural limitations.	• Developers • Providers

Proposed Actions for Recommendation 8

Integrate eMH into established (mental) health care models and other key areas of interest such as mental health in the workplace, or mental health in schools.

Goals	**Activity**	**Responsible**/involved parties
Integrate eMH as an equal treatment option alongside face-to-face interventions.	Review implementation studies to identify good implementation strategies. Define the role of eMH in publicly-funded health services. Consider eMH as a treatment option in future revisions of clinical practice guidelines for mental disorders and ensure that they are adaptable to individual needs and preferences.	• **Health care provider organisations** • Researchers and academic institutions • Health Authorities • Professional bodies • Patient organisations/ People with mental health problems • Health insurance companies
Improve eMH implementation research.	Put implementation at the centre of future evaluation designs. Foster implementation research in general, and specifically longitudinal data collection and evaluation in the setting eMH will be implemented (national implementation research). Use standardised implementation protocols for reporting. Strengthen implementation research at organisational level (system context). Provide funding for implementation research.	• **National and regional government (Ministry of Health)** • Researchers and academic institutions • Health Authorities
Prepare organisations for the uptake of eMH and ensure an open organisational culture.	Develop a multidisciplinary strategy that involves all relevant stakeholders and that addresses the main elements for the implementation of eMH in health care provider organisations (workflow, responsibilities, roles, financing, training, etc.). Build organisational capacities (e.g. provide time and resources for the use of eMH and respective training). Integrate digital literacy and eMH approaches into the vision and strategies of health care provider organisations.	• **Managers of health care provider organisations** • Health professionals • Patient organisations/ People with mental health problems • Health insurance companies

Goals	Activity	Responsible/involved parties
Raise awareness and acceptance in professionals.	Integrate digital literacy and eMH approaches into the vision and strategies of health care provider organisations.	• **Providers**
Improve digital literacy in professionals to improve confidence in using eMH products and services. This will raise awareness and improve acceptance.	Ensure appropriate access to digital resources and tools, and reward learning to support the development and improvement of digital capabilities in organisations.	• **Management of Provider Organisations** • **Professional bodies** • **Higher education institutes** • National Supervisory Authorities • Providers
Raise awareness and acceptance in (future) professionals and prevent the perception of job insecurity among professionals.	Include digital competencies in role requirements of health professionals (i.e. determine relevant key knowledge, skills and competencies of the workforce for the digitalisation of health care). Define core competencies of undergraduates and postgraduates and adapt them according to ongoing developments. Incorporate digital literacy and eMH training (as compulsory) in higher education institutes and residency curricula in a structured and coherent manner, as well as into state medical licensing criteria for future (mental) health professionals. Revise existing teaching concepts and curricula in educational settings for future mental health professionals in collaboration with all stakeholders involved. Educate professionals about eMH products and services, their use, and their benefits and risks. Develop training programmes, and define the quality and content of eMH teaching concepts and courses on federal and/or regional level (establish standards) to address the needs of professionals and those entering the mental health workforce.	• **National Supervisory Authorities** • **Higher education institutes** • Professional bodies

Goals	**Activity**	**Responsible**/involved parties
Provide eMH education and training to the health workforce (integrate it into career development) (26).	Establish training and education concepts (including the benefits and risks of eMH) in organisations (based on established standards) for those health professionals that may use digital media and/or eMH products and services. Provide them with sufficient time and resources to acquire competences, skills and knowledge (see info box 15). Establish and create training and education sessions that suit the needs of the workforce (match eMH training to work roles and time requirements in organisations).	• **Management of Provider Organisations** • Health professionals • Professional bodies
Create an open attitude and initial acceptance through knowledge and information.	Provide structures for ongoing supervision, feedback and peer networking while promoting the use/training of eMH solutions (awareness campaigns, education platforms such as eMHPrac, offering CME credits for digital health literacy courses or eMH training, etc.). Involve employers with upcoming changes at an early stage of the change process (establish efficient change management). Establish local digital champions in work environments.	• **Management of Provider Organisations** • Health Authorities • Health professionals • Professional bodies

References

1. HM Government/DH. No Health Without Mental Health: A Cross-Government Mental Health Outcomes Strategy for People of All Ages 2011 [cited 6 May 2019]. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/213761/dh_124058.pdf.
2. World Health Organization. Mental Health: A State of Well-Being 2014 [cited 6 May 2019]. Available from: https://www.who.int/features/factfiles/mental_health/en/.
3. OECD/EU. Health at a Glance: Europe 2018: State of Health in the EU Cycle. Paris; 2018.
4. Wittchen HU, Jacobi F, Rehm J, Gustavsson A, Svensson M, Jonsson B, et al. The Size and Burden of Mental Disorders and Other Disorders of the Brain in Europe 2010. Eur Neuropsychopharmacol. 2011;21(9):655-79.
5. Riper H, Andersson G, Christensen H, Cuijpers P, Lange A, Eysenbach G. Theme Issue on E-Mental Health: A Growing Field in Internet Research. J Med Internet Res. 2010;12(5):e74.
6. Carlbring P, Andersson G, Cuijpers P, Riper H, Hedman-Lagerlof E. Internet-Based vs. Face-to-Face Cognitive Behavior Therapy for Psychiatric and Somatic Disorders: An Updated Systematic Review and Meta-Analysis. Cogn Behav Ther. 2018;47(1):1-18.
7. Richards D, Richardson T. Computer-Based Psychological Treatments for Depression: A Systematic Review and Meta-Analysis. Clin Psychol Rev. 2012;32(4):329-42.
8. Firth J, Torous J, Nicholas J, Carney R, Pratap A, Rosenbaum S, et al. The Efficacy of Smartphone-Based Mental Health Interventions for Depressive Symptoms: A Meta-Analysis of Randomized Controlled Trials. World Psychiatry. 2017;16(3):287-98.
9. Firth J, Torous J, Nicholas J, Carney R, Rosenbaum S, Sarris J. Can Smartphone Mental Health Interventions Reduce Symptoms of Anxiety? A Meta-Analysis of Randomized Controlled Trials. J Affect Disord. 2017;218:15-22.
10. Cuijpers P, Donker T, Johansson R, Mohr DC, van Straten A, Andersson G. Psychological Treatment for Depressive Symptoms: A Meta-Analysis. PloS one. 2011;6(6):e21274.
11. Cuijpers P, Donker T, van Straten A, Li J, Andersson G. Is Guided Self-Help as Effective as Face-to-Face Psychotherapy for Depression and Anxiety Disorders? A Systematic Review and Meta-Analysis of Comparative Outcome Studies. Psychol Med. 2010;40(12):1943-57.
12. Andersson G, Cuijpers P, Carlbring P, Riper H, Hedman E. Guided Internet-Based vs. Face-to-Face Cognitive Behavior Therapy for Psychiatric and Somatic Disorders: A Systematic Review and Meta-Analysis. World Psychiatry. 2014;13(3):288-95.
13. World Health Organization. The European Mental Health Action Plan 2013–2020 Copenhagen 2015 [cited 15 March 2018]. Available from: http://www.euro.who.int/__data/assets/pdf_file/0020/280604/WHO-Europe-Mental-Health-Acion-Plan-2013-2020.pdf.
14. Kohn R, Saxena S, Levav I, Saraceno B. The Treatment Gap in Mental Health Care. Bulletin of the World Health Organisation. 2004.
15. Andrade LH, Alonso J, Mneimneh Z, Wells JE, Al-Hamzawi A, Borges G, et al. Barriers to Mental Health Treatment: Results from the WHO World Mental Health Surveys. Psychol Med. 2014;44(6):1303-17.
16. Eurostat. Mental Health and Related Issues Statistics 2018 [cited 14 December 2018]. Available from: https://ec.europa.eu/eurostat/statistics-explained/index.php/Mental_health_and_related_issues_statistics#Deaths_from_mental_and_behavioural_disorders.2C_Alzheimer.E2.80.99s_disease_and_intentional_self-harm.

17. World Health Organization. Mental Health – Data and Statistics 2017 [cited February 21 2018]. Available from: http://www.euro.who.int/en/health-topics/noncommunicable-diseases/mental-health/data-and-resources.
18. Mathers C, Loncar D. Projections of Global Mortality and Burden of Disease from 2002 to 2030. PLoS Med 2006;3:e442.
19. European Commission. eHealth: Digital Health and Care 2018 [cited 8 November 2018]. Available from: https://ec.europa.eu/health/ehealth/overview_en.
20. Andersson G. Internet-Delivered Psychological Treatments. Annu Rev Clin Psychol. 2016;12:157-79.
21. Mental Health Commission of Canada. Advancing the Evolution: Insights into the State of E-Mental Health Services in Canada Ottawa 2017 [cited 11 February 2018]. Available from: https://www.mentalhealthcommission.ca/sites/default/files/2017-08/eMH%20Environmental%20Scan_FINAL%20EN.pdf.
22. Patel V, Saxena S, Lund C, Thornicroft G, Baingana F, Bolton P, et al. The Lancet Commission on Global Mental Health and Sustainable Development. The Lancet. 2018;392(10157):1553-98.
23. Kazdin AE, Blase SL. Rebooting Psychotherapy Research and Practice to Reduce the Burden of Mental Illness. Perspect Psychol Sci. 2011;6(1):21-37.
24. Waller R, Gilbody S. Barriers to the Uptake of Computerized Cognitive Behavioural Therapy: A Systematic Review of the Quantitative and Qualitative Evidence. Psychol Med. 2009;39(5):705-12.
25. Drozd F, Vaskinn L, Bergsund HB, Haga SM, Slinning K, Bjorkli CA. The Implementation of Internet Interventions for Depression: A Scoping Review. J Med Internet Res. 2016;18(9):e236.
26. Wozney L, Newton AS, Gehring ND, Bennett K, Huguet A, Hartling L, et al. Implementation of eMental Health Care: Viewpoints from Key Informants from Organizations and Agencies with eHealth Mandates. BMC Med Inform Decis Mak. 2017;17(1):78.
27. Vis C, Mol M, Kleiboer A, Buhrmann L, Finch T, Smit J, et al. Improving Implementation of eMental Health for Mood Disorders in Routine Practice: Systematic Review of Barriers and Facilitating Factors. JMIR Ment Health. 2018;5(1):e20.
28. Nicholas J, Huckvale K, Larsen ME, Basu A, Batterham PJ, Shaw F, et al. Issues for eHealth in Psychiatry: Results of an Expert Survey. J Med Internet Res. 2017;19(2):e55.
29. Whiteford HA, Degenhardt L, Rehm J, Baxter AJ, Ferrari AJ, Erskine HE, et al. Global Burden of Disease Attributable to Mental and Substance Use Disorders: Findings from the Global Burden of Disease Study 2010. The Lancet. 2013;382(9904):1575-86.
30. World Health Organization. Global Health Estimates 2016. Summary Tables: DALYs by Cause, Age and Sex, by WHO region, 2000-2015 [cited 5 July 2018]. Available from: http://www.who.int/healthinfo/global_burden_disease/estimates/en/index1.html.
31. World Health Organization. Global Health Estimates 2016 Summary Tables: YLD by Cause, Age and Sex, by WHO Region, 2000-2016 [cited 5 July 2018]. Available from: http://www.who.int/healthinfo/global_burden_disease/estimates/en/index1.html.
32. World Health Organization. Depression and Other Common Mental Disorders: Global Health Estimates Geneva: World Health Organization; 2017 [cited 15 March 2018]. Available from: http://apps.who.int/iris/bitstream/handle/10665/254610/WHO-MSD-MER-2017.2-eng.pdf;jsessionid=8B3551BCBBC97215F4543EB845E855B6?sequence=1.

33. Mental Health Commission of Canada. E-Mental Health in Canada: Transforming the Mental Health System Using Technology Ottawa 2014 [cited 11 February 2018]. Available from: https://www.mentalhealthcommission.ca/sites/default/files/MHCC_E-Mental_Health-Briefing_Document_ENG_0.pdf.
34. Alonso J, Codony M, Kovess V, Angermeyer MC, Katz SJ, Haro JM, et al. Population Level of Unmet Need for Mental Healthcare in Europe. Br J Psychiatry. 2007;190:299-306.
35. Demyttenaere K, Bruffaerts R, Posada-Villa J, Gasquet I, Kovess V, Lepine JP, et al. Prevalence, Severity, and Unmet Need for Treatment of Mental Disorders in the World Health Organization World Mental Health Surveys. J Am Med Assoc. 2004;291(21):2581-90.
36. Alonso J, Liu Z, Evans-Lacko S, Sadikova E, Sampson N, Chatterji S, et al. Treatment Gap for Anxiety Disorders Is Global: Results of the World Mental Health Surveys in 21 Countries. Depress Anxiety. 2018;35(3):195-208.
37. Thornicroft G, Chatterji S, Evans-Lacko S, Gruber M, Sampson N, Aguilar-Gaxiola S, et al. Undertreatment of People with Major Depressive Disorder in 21 Countries. Br J Psychiatry. 2017;210(2):119-24.
38. Trautmann S, Rehm J, Wittchen HU. The Economic Costs of Mental Disorders: Do Our Societies React Appropriately to the Burden of Mental Disorders? EMBO reports. 2016;17(9):1245-9.
39. Giacco D, Amering M, Bird V, Craig T, Ducci G, Gallinat J, et al. Scenarios for the Future of Mental Health Care: A Social Perspective. Lancet Psychiatry. 2017;4(3):257-60.
40. Council of the European Union. Health in the Digital Society – Making Progress in Data-Driven Innovation in the Field of Health. Brussels; 2017.
41. Permanent Representatives Committee (Part 1). The Economy of Wellbeing - Draft Council Conclusions. 2019.
42. European Commission. eHealth Action Plan 2012-2020 – Innovative Healthcare for the 21st Century. Brussels; 2012.
43. Bhugra D, Tasman A, Pathare S, Priebe S, Smith S, Torous J, et al. The WPA-Lancet Psychiatry Commission on the Future of Psychiatry. Lancet Psychiatry. 2017;4(10):775-818.
44. World Psychiatric Association. WPA Position Statement on E-Mental Health 2017 [cited 29 January 2018]. Available from: https://imh.org.rs/wp-content/uploads/2017/07/1FINAL-WPA-Position-statement-on-eMental-Health-10072017.pdf.
45. Batterham PJ, Sunderland M, Calear AL, Davey CG, Christensen H, Teesson M, et al. Developing a Roadmap for the Translation of E-Mental Health Services for Depression. Aust N Z J Psychiatry. 2015;49(9):776-84.
46. EU Joint Action on Mental Health and Well-being. European Framework for Action on Mental Health and Wellbeing. Final Conference; 21 - 22 January 2016; Brussels2016.
47. Torous J, Haim A. Dichotomies in the Development and Implementation of Digital Mental Health Tools. Psychiatr Serv. 2018;69(12):1204-6.
48. Andersson G. Internet Interventions: Past, Present and Future. Internet Interv. 2018;12:181-8.
49. Luxton DD, McCann RA, Bush NE, Mishkind MC, Reger GM. mHealth for Mental Health: Integrating Smartphone Technology in Behavioral Healthcare. Prof Psychol. 2011;42(6):505-12.
50. Van Daele T, Vanhoomissen T. Portable Technology in Mental Health Care. De Psycholoog. 2015;Special edition:34-9.
51. Gaebel W, Grossimlinghaus I, Kerst A, Cohen Y, Hinsche-Bockenholt A, Johnson B, et al. European Psychiatric Association (EPA) Guidance on the Quality of eMental Health Interventions in the Treatment of Psychotic Disorders. Eur Arch Psychiatry Clin Neurosci. 2016;266(2):125-37.

52. Renzulli C. Telemental Health. J Am Psychiatr Nurses Assoc. 2018;25(4):253-4.
53. Cullen K. eMental Health: State-of-the-art & Opportunities for Ireland: Work Research Centre; 2018 [cited 25 May 2018]. Available from: https://www.mentalhealthreform.ie/wp-content/uploads/2018/05/eMental-health-review_report_final_may10_NEWcover.2.pdf.
54. American Psychiatric Association (APA). Telepsychiatry Toolkit 2018 [cited 14 January 2019]. Available from: https://www.psychiatry.org/psychiatrists/practice/telepsychiatry/telepsychiatry-toolkit-home.
55. Andersson G, Titov N. Advantages and Limitations of Internet-Based Interventions for Common Mental Disorders. World Psychiatry. 2014;13(1):4-11.
56. Murray E, Hekler EB, Andersson G, Collins LM, Doherty A, Hollis C, et al. Evaluating Digital Health Interventions: Key Questions and Approaches. Am J Prev Med. 2016;51(5):843-51.
57. Joint Action on Mental Health and Well-being. Depression, Suicide Prevention and E-Health - Situation Analysis and Recommendations for Action: DG SANCO, European Commission; 2016 [cited 18 February 2018]. Available from: https://www.mentalhealthandwellbeing.eu/assets/docs/publications/WP4%20Final.pdf.
58. Andersson G, Titov N, Dear BF, Rozental A, Carlbring P. Internet-Delivered Psychological Treatments: From Innovation to Implementation. World Psychiatry. 2019;18(1):20-8.
59. Olthuis JV, Watt MC, Bailey K, Hayden JA, Stewart SH. Therapist-Supported Internet Cognitive Behavioural Therapy for Anxiety Disorders in Adults. Cochrane Database Syst Rev. 2015(3):CD011565.
60. Sander L, Rausch L, Baumeister H. Effectiveness of Internet-Based Interventions for the Prevention of Mental Disorders: A Systematic Review and Meta-Analysis. JMIR Ment Health. 2016;3(3):e38.
61. Cuijpers P, Kleiboer A, Karyotaki E, Riper H. Internet and Mobile Interventions for Depression: Opportunities and Challenges. Depress Anxiety. 2017;34(7):596-602.
62. Baumeister H, Reichler L, Munzinger M, Lin J. The Impact of Guidance on Internet-Based Mental Health Interventions – a Systematic Review. Internet Interv. 2014;1(4):205-15.
63. Erbe D, Eichert HC, Riper H, Ebert DD. Blending Face-to-Face and Internet-Based Interventions for the Treatment of Mental Disorders in Adults: Systematic Review. J Med Internet Res. 2017;19(9):e306.
64. Ebert DD, Van Daele T, Nordgreen T, Karekla M, Compare A, Zarbo C, et al. Internet- and Mobile-Based Psychological Interventions: Applications, Efficacy, and Potential for Improving Mental Health. Eur Psychol. 2018;23(2):167-87.
65. Australian Government (Department of Health). PHN Primary Mental Health Care Flexible Funding Pool Implementation Guidance. Stepped Care. 2019 [cited 17 January 2019]. Available from: http://www.health.gov.au/internet/main/publishing.nsf/content/2126B045A8DA90FDCA257F650001826O/$File/1PHN%20Guidance%20-%20Stepped%20Care.PDF.
66. Krebber AM, Leemans CR, de Bree R, van Straten A, Smit F, Smit EF, et al. Stepped Care Targeting Psychological Distress in Head and Neck and Lung Cancer Patients: A Randomized Clinical Trial. BMC Cancer. 2012;12:173.
67. Topooco N, Riper H, Araya R, Berking M, Brunn M, Chevreul K, et al. Attitudes Towards Digital Treatment for Depression: A European Stakeholder Survey. Internet Interv. 2017;8:1-9.
68. Ruwaard J, Kok RN. Wild West eHealth: Time to Hold our Horses? The European Health Psychologist. 2015;17(1):45-9.
69. Titzler I, Saruhanjan K, Berking M, Riper H, Ebert DD. Barriers and Facilitators for the Implementation of Blended Psychotherapy for Depression: A Qualitative Pilot Study of Therapists' Perspective. Internet Interv. 2018;12:150-64.

70. Kooistra LC, Ruwaard J, Wiersma JE, van Oppen P, van der Vaart R, van Gemert-Pijnen J, et al. Development and Initial Evaluation of Blended Cognitive Behavioural Treatment for Major Depression in Routine Specialized Mental Health Care. Internet Interv. 2016;4:61-71.
71. Kleiboer A, Smit J, Bosmans J, Ruwaard J, Andersson G, Topooco N, et al. European COMPARative Effectiveness Research on Blended Depression Treatment versus Treatment-as-usual (E-COMPARED): Study Protocol for a Randomized Controlled, Non-inferiority Trial in Eight European Countries. Trials. 2016;17(1):387.
72. Berger T, Krieger T, Sude K, Meyer B, Maercker A. Evaluating an E-Mental Health Program ("Deprexis") as Adjunctive Treatment Tool in Psychotherapy for Depression: Results of a Pragmatic Randomized Controlled Trial. J Affect Disord. 2018;227:455-62.
73. Zwerenz R, Becker J, Knickenberg RJ, Siepmann M, Hagen K, Beutel ME. Online Self-Help as an Add-On to Inpatient Psychotherapy: Efficacy of a New Blended Treatment Approach. Psychother Psychosom. 2017;86(6):341-50.
74. Feijt MA, de Kort YA, Bongers IM, WA IJ. Perceived Drivers and Barriers to the Adoption of eMental Health by Psychologists: The Construction of the Levels of Adoption of eMental Health Model. J Med Internet Res. 2018;20(4):e153.
75. Schuster R, Pokorny R, Berger T, Topooco N, Laireiter A-R. The Advantages and Disadvantages of Online and Blended Therapy: Survey Study Amongst Licensed Psychotherapists in Austria. J Med Internet Res. 2018;20(12):e11007.
76. Etzelmueller A, Radkovsky A, Hannig W, Berking M, Ebert DD. Patient's Experience with Blended Video- and Internet Based Cognitive Behavioural Therapy Service in Routine Care. Internet Interv. 2018;12:165-75.
77. E-COMPARED. European Comparative Effectiveness Research on Internet-based Depression Treatment (E-Compared). Final Report 2017 [cited 22 November 2018]. Available from: https://cordis.europa.eu/docs/results/603/603098/final1-e-compared-final-report-publishable-summary.pdf.
78. Kenter RMF, van de Ven PM, Cuijpers P, Koole G, Niamat S, Gerrits RS, et al. Effects of Internet Cognitive Behavioral Treatment Blended with Face-to-Face Treatment: Results from a Naturalistic Study. Internet Interv. 2015;2(1):77-83.
79. Tate DF, Finkelstein EA, Khavjou O, Gustafson A. Cost Effectiveness of Internet Interventions: Review and Recommendations. Ann Behav Med. 2009;38(1):40-5.
80. Arnberg FK, Linton SJ, Hultcrantz M, Heintz E, Jonsson U. Internet-Delivered Psychological Treatments for Mood and Anxiety Disorders: A Systematic Review of Their Efficacy, Safety, and Cost-Effectiveness. PloS one. 2014;9(5):e98118.
81. Donker T, Blankers M, Hedman E, Ljotsson B, Petrie K, Christensen H. Economic Evaluations of Internet Interventions for Mental Health: A Systematic Review. Psychol Med. 2015;45(16):3357-76.
82. Hedman E, Ljotsson B, Lindefors N. Cognitive Behavior Therapy Via the Internet: A Systematic Review of Applications, Clinical Efficacy and Cost-Effectiveness. Expert Rev Pharmacoecon Outcomes Res. 2012;12(6):745-64.
83. Paganini S, Teigelkotter W, Buntrock C, Baumeister H. Economic Evaluations of Internet- and Mobile-Based Interventions for the Treatment and Prevention of Depression: A Systematic Review. J Affect Disord. 2018;225:733-55.
84. Kolovos S, van Dongen JM, Riper H, Buntrock C, Cuijpers P, Ebert DD, et al. Cost Effectiveness of Guided Internet-Based Interventions for Depression in Comparison with Control Conditions: An Individual-Participant Data Meta-Analysis. Depress Anxiety. 2018;35(3):209-19.

85. Andrews G, Basu A, Cuijpers P, Craske MG, McEvoy P, English CL, et al. Computer Therapy for the Anxiety and Depression Disorders Is Effective, Acceptable and Practical Health Care: An Updated Meta-Analysis. J Anxiety Disord. 2018;55:70-8.
86. Dodd AL, Mallinson S, Griffiths M, Morriss R, Jones SH, Lobban F. Users' Experiences of an Online Intervention for Bipolar Disorder: Important Lessons for Design and Evaluation. Evid Based Ment Health. 2017;20(4):133-9.
87. Greenhalgh T, Wherton J, Papoutsi C, Lynch J, Hughes G, A'Court C, et al. Beyond Adoption: A New Framework for Theorizing and Evaluating Nonadoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies. J Med Internet Res. 2017;19(11):e367.
88. Mohr DC, Weingardt KR, Reddy M, Schueller SM. Three Problems With Current Digital Mental Health Research . . . and Three Things We Can Do About Them. Psychiatr Serv. 2017;68(5):427-9.
89. Romijn G, Batelaan N, Kok R, Koning J, van Balkom A, Titov N, et al. Internet-Delivered Cognitive Behavioral Therapy for Anxiety Disorders in Open Community Versus Clinical Service Recruitment: Meta-Analysis. J Med Internet Res. 2019;21(4):e11706.
90. Hollis C, Sampson S, Simons L, Davies E, Churchill R, Betton V, et al. Identifying Research Priorities for Digital Technology in Mental Healthcare: Results of the James Lind Alliance Priority Setting Partnership. The Lancet Psychiatry. 2018;5(10):845-54.
91. Donker T, Petrie K, Proudfoot J, Clarke J, Birch M-R, Christensen H. Smartphones for Smarter Delivery of Mental Health Programs: A Systematic Review. J Med Internet Res. 2013;15(11):e247.
92. Lipschitz J, Miller CJ, Hogan TP, Burdick KE, Lippin-Foster R, Simon SR, et al. Adoption of Mobile Apps for Depression and Anxiety: Cross-Sectional Survey Study on Patient Interest and Barriers to Engagement. JMIR Ment Health. 2019;6(1):e11334.
93. Burns MN, Begale M, Duffecy J, Gergle D, Karr CJ, Giangrande E, et al. Harnessing Context Sensing to Develop a Mobile Intervention for Depression. J Med Internet Res. 2011;13(3):e55.
94. Susi T, Johannesson M, Backlund P. Serious Games - An Overview. Sweden: School of Humanities and Informatics - University of Skövde; 2007. Contract No.: Technical Report HS-IKI-TR-07-001.
95. Lau HM, Smit JH, Fleming TM, Riper H. Serious Games for Mental Health: Are They Accessible, Feasible, and Effective? A Systematic Review and Meta-analysis. FPSYT. 2017;7:209.
96. Carl E, Stein AT, Levihn-Coon A, Pogue JR, Rothbaum B, Emmelkamp P, et al. Virtual Reality Exposure Therapy for Anxiety and Related Disorders: A Meta-Analysis of Randomized Controlled Trials. J Anxiety Disord. 2019;61:27-36.
97. Lindner P, Miloff A, Hamilton W, Reuterskiold L, Andersson G, Powers MB, et al. Creating State of the Art, Next-Generation Virtual Reality Exposure Therapies for Anxiety Disorders Using Consumer Hardware Platforms: Design Considerations and Future Directions. Cogn Behav Ther. 2017;46(5):404-20.
98. Foley T, Woollard J. The Digital Future of Mental Healthcare and Its Workforce: A Report on a Mental Health Stakeholder Engagement to Inform the Topol Review: Health Education England; 2019 [cited 15 August 2019]. Available from: https://topol.hee.nhs.uk/wp-content/uploads/HEE-Topol-Review-Mental-health-paper.pdf.
99. Aref-Adib G, McCloud T, Ross J, O'Hanlon P, Appleton V, Rowe S, et al. Factors Affecting Implementation of Digital Health Interventions for People with Psychosis or Bipolar Disorder, and Their Family and Friends: A Systematic Review. The Lancet Psychiatry. 2018;6(3):257-66.

100. Vis C, Kleiboer A, Prior R, Bønes E, Cavallo M, Clark SA, et al. Implementing and up-Scaling Evidence-Based eMental Health in Europe: The Study Protocol for the MasterMind Project. Internet Interv. 2015;2(4):399-409.
101. Moock J. Support from the Internet for Individuals with Mental Disorders: Advantages and Disadvantages of e-Mental Health Service Delivery. Frontiers in public health. 2014;2:65.
102. Ross J, Stevenson F, Lau R, Murray E. Factors That Influence the Implementation of E-Health: A Systematic Review of Systematic Reviews (an Update). Implement Sci. 2016;11(1):146.
103. Granja C, Janssen W, Johansen MA. Factors Determining the Success and Failure of eHealth Interventions: Systematic Review of the Literature. J Med Internet Res. 2018;20(5):e10235.
104. Jorm AF, Morgan AJ, Malhi GS. The Future of E-Mental Health. Aust N Z J Psychiatry. 2013;47(2):104-6.
105. MasterMind Consortium. Policy Recommendations Based on MasterMind Results 2017 [cited 22 January 2018]. Available from: http://mastermind-project.eu/wp-content/uploads/2017/08/MMind_Policy-brief.pdf.
106. European Commission. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Enabling the Digital Transformation of Health and Care in the Digital Single Market; Empowering Citizens and Building a Healthier Society. In: CNECT, editor. Brussels: European Commission; 2018.
107. World Health Organization. EU mHealth Hub Project - Horizon 2020. 2017 [cited 21 August 2019]. Available from: http://www.who.int/ncds/prevention/be-healthy-be-mobile/hubs/en/.
108. European Parliament, Union CotE. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data, and Repealing Directive 95/46/EC (General Data Protection Regulation) Brussels: Official Journal of the European Union. 2016 [cited 21 August 2019]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN.
109. European Parliament, Council of the European Union. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, Amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and Repealing Council Directives 90/385/EEC and 93/42/EEC Brussels: Official Journal of the European Union. 2017 [cited 21 August 2019]. Available from: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN.
110. European Commission. Informal Meeting of Health Ministers Puts Investment in Digital Health High on the Agenda 2018 [cited 22 November 2018]. Available from: https://ec.europa.eu/digital-single-market/en/news/informal-meeting-health-ministers-puts-investment-digital-health-high-agenda.
111. Australian Government. E-Mental Health Strategy for Australia: Department of Health and Ageing; 2012 [cited 11 February 2018]. Available from: https://www.health.gov.au/internet/main/publishing.nsf/Content/7C7B0BFEB985D0EBCA257BF0001BB0A6/$File/emstrat.pdf.
112. Wozney L, McGrath P, Newton A, Hartling L, Curran J, Huguet A, et al. RE-AIMing e-Mental Health: A Rapid Review of Current Research: Mental Health Commission of Canada; 2017 [cited 21 August 2019]. Available from: http://www.nweurope.eu/media/3970/emh-literature-review_final-en.pdf.
113. McGrath P, Wozney L, Rathore SS, Notarianni M, Schellenberg M. Toolkit for e-Mental Health Implementation. Ottawa, ON.: Mental Health Commission of Canada.; 2018 [cited 21 August 2019]. Available from: http://www.mentalhealthcommission.ca/.
114. Kostera T, Briseño C. Learning from the Danish Example: Trustworthiness, Standards and a National Health

Portal Strategy 2018 [cited 25 September 2018]. Available from: https://blog.der-digitale-patient.de/en/smarthealthsystems-denmark-national-health-portal/.

115. NHS. The NHS Long Term Plan 2019 [cited 15 May 2019]. Available from: https://www.longtermplan.nhs.uk/wp-content/uploads/2019/01/nhs-long-term-plan.pdf.
116. The Independent Mental Health Task Force. Five Year Forward View on Mental Health: A Report from the Independent Mental Health Task Force to the NHS in England 2016 [cited 4 December 2017]. Available from: https://www.england.nhs.uk/wp-content/uploads/2016/02/Mental-Health-Taskforce-FYFV-final.pdf.
117. Wachter RM. Making IT Work: Harnessing the Power of Health Information Technology to Improve Care in England. Report of the National Advisory Group on Health Information Technology in England 2016 [cited 15 May 2019]. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/550866/Wachter_Review_Accessible.pdf.
118. Albrecht U-V. Chancen und Risiken von Gesundheits-Apps (CHARISMHA). 1st ed: Medizinische Hochschule Hannover; 2016.
119. The Universal Declaration of Human Rights. Sect. 12 (1948).
120. European Convention on Human Rights. Sect. 8 (1950).
121. Sahama T, Simpson L, Lane B, editors. Security and Privacy in eHealth: Is it Possible? 2013 IEEE 15th International Conference on e-Health Networking, Applications and Services (Healthcom 2013); 2013 9-12 Oct. 2013.
122. Bellman S, Johnson EJ, Kobrin SJ, Lohse GL. International Differences in Information Privacy Concerns: A Global Survey of Consumers. Inform Soc. 2004;20(5):313-24.
123. Stone EF, Gueutal HG, Gerdner DG, McClure S. A Field Experiment Comparing Information-Privacy Values, Beliefs, and Attitutes across Several Types of Organizations. J Appl Psychol. 1983;68(3):459-68.
124. Warren SD, Brandeis LD. The Right to Privacy. Harv Law Rev. 1890;4(5):193-220.
125. Westin AF. Privacy and Freedom. Wash & Lee L Rev. 1968;25(1):166-70.
126. Avancha S, Baxi A, Kotz D. Privacy in Mobile Technology for Personal Healthcare. ACM Comput Surv. 2012;45(1):1-54.
127. National Committee on Vital and Health Statistics (NCVHS). Privacy and Confidentiality in the Nationwide Health Information Network 2006 [cited 21 August 2019]. Available from: http://library.ahima.org/doc?oid=75960#.W4Pvx9Izbcs.
128. Gostin LO. Health Information Privacy. Cornell Law Rev. 1995;80(3):451-528.
129. Cannoy SD, Salam AF. A Framework for Health Care Information Assurance Policy and Compliance. Commun ACM. 2010;53(3):126-31.
130. Becker D. Acceptance of Mobile Mental Health Treatment Applications. Procedia Computer Science. 2016;98:220-7.
131. Dockweiler C, Kupitz A, Hornberg C. Acceptance of Online-based Therapy by Patients with Light to Moderate Depressive Disorders. Gesundheitswesen. 2018;80(11):1013-22.
132. Jessop D. Safe and Sound: Why a Robust and Workable Data Security Policy Is Fundamental in Healthcare Programs. mHealth. 2016;2:19.
133. Smith HJ, Milberg JS, Burke JS. Information Privacy: Measuring Individuals' Concerns About Organizational Practices. MIS Quarterly. 1996;20(2):167-96.

134. Bennett K, Bennett AJ, Griffiths KM. Security Considerations for E-Mental Health Interventions. J Med Internet Res. 2010;12(5):e61.
135. Greaves F, Joshi I, Campbell M, Roberts S, Patel N, Powell J. What Is an Appropriate Level of Evidence for a Digital Health Intervention? The Lancet. 2019;392(10165):2665-7.
136. Knöppler K, Koch H, Oschmann L. Transfer von Digital-Health-Anwendungen in den Versorgungsalltag. Teil 2: Bedarfsgerechte Innovations- und Forschungsförderung: Innovationspotenzial, Förderbedarf und Implikationen. Gütersloh: Bertelsmann; 2017 [cited 27 June 2018]. Available from: https://www.bertelsmann-stiftung.de/fileadmin/files/BSt/Publikationen/GrauePublikationen/VV_Studie_Transfer_DHA_Teil_2_final.pdf.
137. Torous J, Andersson G, Bertagnoli A, Christensen H, Cuijpers P, Firth J, et al. Towards a Consensus around Standards for Smartphone Apps and Digital Mental Health. World Psychiatry. 2019;18(1):97-8.
138. National Institute for Health and Care Excellence (NICE). Evidence Standards Framework for Digital Health Technologies (March 2019) 2019 [cited 24 April 2019]. Available from: https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/evidence-standards-framework/digital-evidence-standards-framework.pdf.
139. Albrecht U-V, Kuhn B, Land J, Amelung VE, von Jan U. Nutzenbewertung von digitalen Gesundheitsprodukten (Digital Health) im gesellschaftlichen Erstattungskontext. Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz. 2018;61(3):340-8.
140. The Lancet (editorial). Is Digital Medicine Different? The Lancet. 2018;392(10142):95.
141. FDA (U.S. Food and Drug Administration). Digital Health Innovation Action Plan 2018 [cited 6 February 2019]. Available from: https://www.fda.gov/media/106331/download.
142. Torous J, Nicholas J, Larsen ME, Firth J, Christensen H. Clinical Review of User Engagement with Mental Health Smartphone Apps: Evidence, Theory and Improvements. Evid Based Ment Health. 2018;21(3):116-9.
143. NHS England. Digital Therapy Selection 2017 [cited 4 December 2017]. Available from: https://www.england.nhs.uk/mental-health/adults/iapt/digital-therapy-selection/.
144. Tulchinsky TH, Varavikova EA. The New Public Health, Third Edition. San Diego: Elsevier, Academic Press; 2014.
145. Convention on the Rights of Persons with Disabilities, (2006).
146. World Health Organization. Ethical Standards and Procedures for Research with Human Beings 2018 [cited 5 October 2018]. Available from: http://www.who.int/ethics/research/en/.
147. Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (2013).
148. Beauchamp TL, Childress JF. Principles of Biomedical Ethics. Seventh ed. New York: Oxford University Press; 2012.
149. World Health Organization. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants. Geneva: World Health Organization; 2011.
150. Ebert DD, Berking M, Cuijpers P, Lehr D, Portner M, Baumeister H. Increasing the Acceptance of Internet-Based Mental Health Interventions in Primary Care Patients with Depressive Symptoms. J Affect Disord. 2015;176:9-17.
151. Klein JP, Knaevelsrud C, Bohus M, Ebert DD, Gerlinger G, Günther K, et al. Internetbasierte Selbstmanagementinterventionen: Qualitätskriterien für ihren Einsatz in Prävention und Behandlung psychischer Störungen. Nervenarzt. 2018;89(11):1277-86.

152. Chan S, Torous J, Hinton L, Yellowlees P. Towards a Framework for Evaluating Mobile Mental Health Apps. Telemed J E Health. 2015;21(12):1038-41.
153. Zelmer J, van Hoof K, Notarianni M, van Mierlo T, Schellenberg M, Tannenbaum C. An Assessment Framework for e-Mental Health Apps in Canada: Results of a Modified Delphi Process. JMIR mHealth and uHealth. 2018;6(7):e10016.
154. Stoyanov SR, Hides L, Kavanagh DJ, Zelenko O, Tjondronegoro D, Mani M. Mobile App Rating Scale: A New Tool for Assessing the Quality of Health Mobile Apps. JMIR mHealth and uHealth. 2015;3(1):e27-e.
155. American Psychiatric Association (APA). App Evaluation Model 2018 [cited 28 May 2019]. Available from: https://www.psychiatry.org/psychiatrists/practice/mental-health-apps/app-evaluation-model.
156. European Commission. Code of Conduct on Privacy for mHealth Apps Has Been Finalised 2016 [cited 21 August 2019]. Available from: https://ec.europa.eu/digital-single-market/en/news/code-conduct-privacy-mhealth-apps-has-been-finalised.
157. Torous JB, Chan SR, Yellowlees PM, Boland R. To Use or Not? Evaluating ASPECTS of Smartphone Apps and Mobile Technology for Clinical Care in Psychiatry. J Clin Psychiatry. 2016;77(6):e734-8.
158. Psycom. Santé mentale et numérique 2019 [cited 29 May 2019]. Available from: http://www.psycom.org/file/download/75289/1762160/file/SanteMentaleEt_numerique_Psycom.pdf.
159. European Commission. Privacy Code of Conduct on Mobile Health Apps 2018 [Available from: https://ec.europa.eu/digital-single-market/en/privacy-code-conduct-mobile-health-apps.
160. PatientView. Health Apps: Towards a Balanced Life 2015 [cited 28 March 2019]. Available from: https://app.box.com/s/19funxqefp3uqks50swk5dhhzy6rt121.
161. Haute Autorité de Santé. Good Practice Guidelines on Health Apps and Smart Devices (Mobile Health or mHealth) 2016 [cited 28 May 2019]. Available from: https://www.has-sante.fr/portail/upload/docs/application/pdf/2017-03/dir1/good_practice_guidelines_on_health_apps_and_smart_devices_mobile_health_or_mhealth.pdf.
162. American Health Information Management Association. Mobile Health Apps 101: A Primer for Consumers 2019 [cited 29 May 2019]. Available from: http://bok.ahima.org/PdfView?oid=302677.
163. NHS. NHS Apps Library 2019 [cited 30 April 2019]. Available from: https://www.nhs.uk/apps-library/.
164. Bertelsmann Stiftung. AppQ: Diese Themen umfasst unser Entwurf eines Gütekriterien-Kernsets für Gesundheits-Apps 2019 [cited 30 April 2019]. Available from: https://blog.der-digitale-patient.de/appq-guetekriterien-kernset/.
165. Medappcare. Why Medappcare? 2019 [cited 12 August 2019]. Available from: https://www.medappcare.com/en/.
166. European Commission. Report of the Working Group on mHealth Assessment Guidelines. February 2016 - March 2017. Brussels; 2017.
167. Cabinet Office - Government Digital Service. Government Digital Inclusion Strategy 2014 [cited 12 December 2018]. Available from: https://www.gov.uk/government/publications/government-digital-inclusion-strategy/government-digital-inclusion-strategy.
168. World Health Organization. Gender, Equity and Human Rights 2018 [cited 23 November 2018]. Available from: https://www.who.int/gender-equity-rights/understanding/accessibility-definition/en/.
169. eHealth Network. Refined eHealth European Interoperability Framework Brussels 2015 [cited 15 August 2019]. Available from: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co03_en.pdf.

170. The American Telemedicine Association. Telemedicine, Telehealth, and Health Information Technology – An ATA Issue Paper 2006 [cited 21 August 2019]. Available from: http://www.who.int/goe/policies/countries/usa_support_tele.pdf.
171. OECD Council. Recommendation of the OECD Council on Health Data Governance Paris 2017 [cited 21 August 2019]. Available from: https://www.oecd.org/health/health-systems/Recommendation-of-OECD-Council-on-Health-Data-Governance-Booklet.pdf.
172. Adebesin F, Foster R, P. K, van Greunen D. A Review of Interoperability Standards in E-Health and Imperatives for Their Adoption in Africa. SAC J. 2013;50(1):55-72.
173. Health Information and Quality Authority. Overview of Healthcare Interoperability Standards. Dublin; 2013.
174. Bevan N. Measuring Usability as Quality of Use. Software quality journal. 1995;4:115-50.
175. Brooke J. SUS - a Quick and Dirty Usability Scale. Usability evaluation in industry. 1996;189(194):4-7.
176. Jake-Schoffman DE, Silfee VJ, Waring ME, Boudreaux ED, Sadasivam RS, Mullen SP, et al. Methods for Evaluating the Content, Usability, and Efficacy of Commercial Mobile Health Apps. JMIR mHealth and uHealth. 2017;5(12):e190.
177. International Organization for Standardization. Ergonomic Requirements for Office Work with Visual Display Terminals (Vdts) – Part 11: Guidance on Usability. (ISO 9241-11:1998). Vernier, Geneva, Switzerland: International Organization for Standardization 1998.
178. Nielsen J. Usability 101: Introduction to Usability: Nielsen Norman Group; 2012 [cited 15 August 2018]. Available from: https://www.nngroup.com/articles/usability-101-introduction-to-usability/.
179. Zapata BC, Fernandez-Aleman JL, Idri A, Toval A. Empirical Studies on Usability of mHealth Apps: A Systematic Literature Review. J Med Syst. 2015;39(2):1.
180. Sauro J, Lewis JR. Quantifying the User Experience. Practical Statistics for User Research. Waltham (MA), USA: Elsevier Inc; 2012.
181. Wozney L, Baxter P, Newton AS. Usability Evaluation with Mental Health Professionals and Young People to Develop an Internet-Based Cognitive-Behaviour Therapy Program for Adolescents with Anxiety Disorders. BMC Pediatr. 2015;15:213.
182. Fuller-Tyszkiewicz M, Richardson B, Klein B, Skouteris H, Christensen H, Austin D, et al. A Mobile App-Based Intervention for Depression: End-User and Expert Usability Testing Study. JMIR Ment Health. 2018;5(3):e54.
183. Birk MV, Mandryk RL. Improving the Efficacy of Cognitive Training for Digital Mental Health Interventions Through Avatar Customization: Crowdsourced Quasi-Experimental Study. J Med Internet Res. 2019;21(1):e10133.
184. Knowles SE, Lovell K, Bower P, Gilbody S, Littlewood E, Lester H. Patient Experience of Computerised Therapy for Depression in Primary Care. BMJ open. 2015;5(11):e008581.
185. Wallin E, Norlund F, Olsson EMG, Burell G, Held C, Carlsson T. Treatment Activity, User Satisfaction, and Experienced Usability of Internet-Based Cognitive Behavioral Therapy for Adults With Depression and Anxiety After a Myocardial Infarction: Mixed-Methods Study. J Med Internet Res. 2018;20(3):e87.
186. Gerhards SA, Abma TA, Arntz A, de Graaf LE, Evers SM, Huibers MJ, et al. Improving Adherence and Effectiveness of Computerised Cognitive Behavioural Therapy without Support for Depression: A Qualitative Study on Patient Experiences. J Affect Disord. 2011;129(1-3):117-25.
187. Rost T, Stein J, Lobner M, Kersting A, Luck-Sikorski C, Riedel-Heller SG. User Acceptance of Computerized Cognitive Behavioral Therapy for Depression: Systematic Review. J Med Internet Res. 2017;19(9):e309.

188. Tractinsky N, Katz A, Ikar D. What Is Beautiful Is Usable. Interact Comput. 2000;13(2):127–45.
189. David A, Glore P. The Impact of Design and Aesthetics on Usability, Credibility, and Learning in Online Courses. In: Sanchez J, Zhang K, editors. Proceedings of E-Learn 2010 - World Conference on E-Learning in Corporate, Government, Healthcare, and Higher Education. Orlando, Florida, USA: Association for the Advancement of Computing in Education (AACE); 2010. p. 42.
190. Mohr DC, Riper H, Schueller SM. A Solution-Focused Research Approach to Achieve an Implementable Revolution in Digital Mental Health. JAMA psychiatry. 2017;75(2):113-4.
191. Boudreaux ED, Brown GK, Stanley B, Sadasivam RS, Camargo CA, Jr., Miller IW. Computer Administered Safety Planning for Individuals at Risk for Suicide: Development and Usability Testing. J Med Internet Res. 2017;19(5):e149.
192. Crabb RM, Cavanagh K, Proudfoot J, Learmonth D, Rafie S, Weingardt KR. Is Computerized Cognitive-Behavioural Therapy a Treatment Option for Depression in Late-Life? A Systematic Review. Br J Clin Psychol. 2012;51(4):459-64.
193. World Health Organization, Calouste Gulbenkian Foundation. Social Determinants of Mental Health. Geneva, Switzerland; 2014.
194. Assembly UNG. Declaration on the Rights of Persons Belonging to National, Ethnic, Religious and Linguistic Minorities: UN General Assembly; 1992 [cited 21 August 2019]. Available from: https://www.ohchr.org/en/professionalinterest/pages/minorities.aspx.
195. McGuire TG, Miranda J. Racial and Ethnic Disparities in Mental Health Care: Evidence and Policy Implications. Health Aff (Millwood). 2008;27(2):393-403.
196. Grey T, Sewell H, Shapiro G, Ashraf F. Mental Health Inequalities Facing U.K. Minority Ethnic Populations. Journal of Psychological Issues in Organizational Culture. 2013;3(S1):146-57.
197. Mental Health Reform. Ethnic Minorities and Mental Health: Guidelines for Mental Health Services and Staff on Working with People from Ethnic Minority Communities Dublin 2016 [cited 15 August 2019]. Available from: https://www.mhcirl.ie/File/guidelines_ethnicmhs.pdf.
198. Memon A, Taylor K, Mohebati LM, Sundin J, Cooper M, Scanlon T, et al. Perceived Barriers to Accessing Mental Health Services among Black and Minority Ethnic (BME) Communities: A Qualitative Study in Southeast England. BMJ open. 2016;6(11):e012337.
199. Wong EC, Collins RL, Cerully J, Seelam R, Roth B. Racial and Ethnic Differences in Mental Illness Stigma and Discrimination Among Californians Experiencing Mental Health Challenges. Rand Health Quarterly. 2017;6(2):6.
200. World Health Organization. Mental Health of Older Adults: World Health Organization; 2017 [cited 2 October 2018]. Available from: http://www.who.int/news-room/fact-sheets/detail/mental-health-of-older-adults.
201. White H, McConnell E, Clipp E, Bynum L, Teague C, Navas L, et al. Surfing the Net in Later Life: A Review of the Literature and Pilot Study of Computer Use and Quality of Life. J Appl Gerontol. 1999;18(3):358-78.
202. Carpenter BD, Buday S. Computer Use among Older Adults in a Naturally Occurring Retirement Community. Comput Human Behav. 2007;23(6):3012-24.
203. Blaschke CM, Freddolino PP, Mullen EE. Ageing and Technology: A Review of the Research Literature. Brit J Soc Work. 2009;39(4):641-56.
204. Bujnowska-Fedak MM, Grata-Borkowska U. Use of Telemedicine-Based Care for the Aging and Elderly: Promises and Pitfalls. Smart Homecare Technol Telehealth. 2015;3:91-105.

205. Iancu I, Iancu B. Elderly in the Digital Era. Theoretical Perspectives on Assistive Technologies. Technologies. 2017;5(3):60.
206. Gracia E, Herrero J. Internet Use and Self-Rated Health Among Older People: A National Survey. J Med Internet Res. 2009;11(4):e49.
207. Hill R, Beynon-Davies P, Williams MD. Older People and Internet Engagement: Acknowledging Social Moderators of Internet Adoption, Access and Use. Inform Technol People. 2008;21:244-66.
208. Zarbo C, Brugnera A, Cipresso P, Brignoli O, Cricelli C, Rabboni M, et al. E-mental Health for Elderly: Challenges and Proposals for Sustainable Integrated Psychological Interventions in Primary Care. Front Psychol. 2017;8:118.
209. Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence Based Medicine: What It Is and What It Isn't. BMJ. 1996;312(7023):71-2.
210. Gaebel W, Grossimlinghaus I, Mucic D, Maercker A, Zielasek J, Kerst A. EPA Guidance on eMental Health Interventions in the Treatment of Posttraumatic Stress Disorder (PTSD). Eur Psychiatry. 2017;41:140-52.
211. Olff M. Mobile Mental Health: A Challenging Research Agenda. Eur J Psychotraumatol. 2015;6(1):27882.
212. Mohr DC, Cheung K, Schueller SM, Hendricks Brown C, Duan N. Continuous Evaluation of Evolving Behavioral Intervention Technologies. Am J Prev Med. 2013;45(4):517-23.
213. Phillips B, Ball C, Sackett D, Badenoch D, Straus S, Haynes B, et al. Oxford Centre for Evidence-based Medicine – Levels of Evidence (March 2009) 2009 [cited 25 July 2018]. Available from: https://www.cebm.net/2009/06/oxford-centre-evidence-based-medicine-levels-evidence-march-2009/.
214. Harbour R, Miller J. A New System for Grading Recommendations in Evidence Based Guidelines. BMJ. 2001;323(7308):334-6.
215. Guidi J, Brakemeier EL, Bockting CLH, Cosci F, Cuijpers P, Jarrett RB, et al. Methodological Recommendations for Trials of Psychological Interventions. Psychother Psychosom. 2018;87(5):276-84.
216. Baumel A. Making the Case for a Feasible Evaluation Method of Available E-Mental Health Products. Adm Policy Ment Health. 2018;45(1):1-4.
217. Michie S, Yardley L, West R, Patrick K, Greaves F. Developing and Evaluating Digital Interventions to Promote Behavior Change in Health and Health Care: Recommendations Resulting From an International Workshop. J Med Internet Res. 2017;19(6):e232.
218. Mohr DC, Schueller SM, Riley WT, Brown CH, Cuijpers P, Duan N, et al. Trials of Intervention Principles: Evaluation Methods for Evolving Behavioral Intervention Technologies. J Med Internet Res. 2015;17(7):e166.
219. Brownson R, Colditz G, Proctor E. Dissemination and Implementation Research in Health Translating Science to Practice. Second Edition. New York: Oxford University Press; 2018.
220. Ioannidis JP. Effect of the Statistical Significance of Results on the Time to Completion and Publication of Randomized Efficacy Trials. J Am Med Assoc. 1998;279(4):281-6.
221. Collins LM, Murphy SA, Strecher V. The Multiphase Optimization Strategy (MOST) and the Sequential Multiple Assignment Randomized Trial (SMART): New Methods for More Potent eHealth Interventions. Am J Prev Med. 2007;32(5 Suppl):S112-8.
222. Rost T, Stein J, Löbner M, Kersting A, Luck-Sikorski C, Riedel-Heller SG. User Acceptance of Computerized Cognitive Behavioral Therapy for Depression: Systematic Review. J Med Internet Res. 2017;19(9):e309.
223. Arensman E, Koburger N, Larkin C, Karwig G, Coffey C, Maxwell M, et al. Depression Awareness and Self-Management Through the Internet: Protocol for an Internationally Standardized Approach. JMIR research protocols. 2015;4(3):e99.

224. Apolinário-Hagen J, Harrer M, Kählke F, Fritsche L, Salewski C, Ebert DD. Public Attitudes Toward Guided Internet-Based Therapies: Web-Based Survey Study. JMIR Ment Health. 2018;5(2):e10735.
225. World Health Organization. Risks to Mental Health: An Overview of Vulnerabilities and Risk Factors 2012 [cited 16 August 2019]. Available from: https://www.who.int/mental_health/mhgap/risks_to_mental_health_EN_27_08_12.pdf.
226. Meurk C, Leung J, Hall W, Head BW, Whiteford H. Establishing and Governing e-Mental Health Care in Australia: A Systematic Review of Challenges and A Call For Policy-Focussed Research. J Med Internet Res. 2016;18(1):e10.
227. Wilkowska W, Ziefle M. Privacy and Data Security in E-Health: Requirements from the User's Perspective. Health Informatics J. 2012;18(3):191-201.
228. Greenhalgh T, Swinglehurst D, Stones R. Health Services and Delivery Research. Rethinking Resistance to 'Big IT': A Sociological Study of Why and When Healthcare Staff Do Not Use Nationally Mandated Information and Communication Technologies. Southampton (UK): NIHR Journals Library; 2014.
229. Rabin BA, Brownson RC, Haire-Joshu D, Kreuter MW, Weaver NL. A Glossary for Dissemination and Implementation Research in Health. J Public Health Manag Pract. 2008;14(2):117-23.
230. Greenhalgh T, Stramer K, Bratan T, Byrne E, Mohammad Y, Russell J. Introduction of Shared Electronic Records: Multi-Site Case Study Using Diffusion of Innovation Theory. BMJ. 2008;337:a1786.
231. Jenkins R. How to Convince Politicians That Mental Health Is a Priority. World Psychiatry. 2013;12(3):266-8.
232. Dinev T, Hart P. An Extended Privacy Calculus Model for E-Commerce Transactions. Info Sys Research. 2006;17(1):61-80.
233. Gaebel W, Muijen M, Baumann AE, Bhugra D, Wasserman D, van der Gaag RJ, et al. EPA Guidance on Building Trust in Mental Health Services. Eur Psychiatry. 2014;29(2):83-100.
234. Gajanayake R, Iannella R, Sahama T. Consumer Acceptance of Accountable-eHealth Systems. Stud Health Technol Inform. 2014;205:980-4.
235. Belanger F, Hiller JS, Smith WJ. Trustworthiness in Electronic Commerce: The Role of Privacy, Security, and Site Attributes. J Strategic Inf Sys. 2002;11:245-70.
236. Chhanabhai P, Holt A. Consumers Are Ready to Accept the Transition to Online and Electronic Records If They Can Be Assured of the Security Measures. MedGenMed. 2007;9(1):8.
237. Andrade EB, Kaltcheva V, Weitz B. Self-Disclosure on the Web: The Impact of Privacy Policy, Reward, and Company Reputation. Adv Consum Res. 2002;29:350-3.
238. Wang S, Beatty SE, Foxx W. Signaling the trustworthiness of small online retailers. J Interact Mark. 2004;18(1):53-69.
239. Jorm AF, Korten AE, Jacomb PA, Christensen H, Rodgers B, Pollitt P. "Mental Health Literacy": A Survey of the Public's Ability to Recognise Mental Disorders and Their Beliefs About the Effectiveness of Treatment. Med J Aust. 1997;166(4):182-6.
240. Martin A, Grudziecki J. DigEuLit: Concepts and Tools for Digital Literacy Development. ITALICS. 2006;5(4):249-67.
241. Norman CD, Skinner HA. eHealth Literacy: Essential Skills for Consumer Health in a Networked World. J Med Internet Res. 2006;8(2):e9.
242. van der Vaart R, van Deursen AJAM, Drossaert CHC, Taal E, van Dijk JAMG, van de Laar MAFJ. Does the eHealth Literacy Scale (eHEALS) Measure What it Intends to Measure? Validation of a Dutch Version of the eHEALS in Two Adult Populations. J Med Internet Res. 2011;13(4):e86.

243. Nutbeam D. The Evolving Concept of Health Literacy. Soc Sci Med. 2008;67(12):2072-8.

244. Petric G, Atanasova S, Kamin T. Ill Literates or Illiterates? Investigating the eHealth Literacy of Users of Online Health Communities. J Med Internet Res. 2017;19(10):e331.

245. Institute of Medicine Committee on Health Literacy. Health Literacy: A Prescription to End Confusion. Nielsen-Bohlman L, Panzer AM, Kindig DA, editors. Washington (DC): National Academies Press; 2004.

246. Ratzan S.C., Parker RM. Introduction. In: Selden CR., Zorn M., Ratzan SC., Parker RM., editors. National Library of Medicine Current Bibliographies in Medicine: Health Literacy. Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services; 2000.

247. Mackert M, Mabry-Flynn A, Champlin S, Donovan EE, Pounders K. Health Literacy and Health Information Technology Adoption: The Potential for a New Digital Divide. J Med Internet Res. 2016;18(10):e264.

248. Berg M, Rozental A, Johansson S, Liljethörn L, Radvogin E, Topooco N, et al. The Role of Knowledge in Internet-Based Cognitive Behavioural Therapy for Adolescent Depression: Results from a Randomised Controlled Study. Internet Interv. 2018;15:10-7.

249. Hsu W, Chiang C, Yang S. The Effect of Individual Factors on Health Behaviors among College Students: The Mediating Effects of eHealth Literacy. J Med Internet Res. 2014;16(12):e287.

250. Neter E, Brainin E. eHealth Literacy: Extending the Digital Divide to the Realm of Health Information. J Med Internet Res. 2012;14(1):e19.

251. van der Vaart R, Drossaert C. Development of the Digital Health Literacy Instrument: Measuring a Broad Spectrum of Health 1.0 and Health 2.0 Skills. J Med Internet Res. 2017;19(1):e27.

252. Robotham D, Satkunanathan S, Doughty L, Wykes T. Do We Still Have a Digital Divide in Mental Health? A Five-Year Survey Follow-up. J Med Internet Res. 2016;18(11):e309.

253. Chung SY, Nahm ES. Testing Reliability and Validity of the eHealth Literacy Scale (eHEALS) for Older Adults Recruited Online. Comput Inform Nurs. 2015;33(4):150-6.

254. Chesser A, Burke A, Reyes J, Rohrberg T. Navigating the Digital Divide: A Systematic Review of eHealth Literacy in Underserved Populations in the United States. Inform Health Soc Ca. 2016;41(1):1-19.

255. European Commission. Flash Eurobarometer 404. European Citizens´ Digital Health Literacy. Report 2014 [cited 25 November 2018]. Available from: http://ec.europa.eu/commfrontoffice/publicopinion/flash/fl_404_en.pdf.

256. European Commission. Communication from the Comission to the European Parliament, the Council, the European Economic and Social Committee and Committee of the Regions. A Digital Single Market Strategy for Europe 2015 [cited 24 November 2018]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52015DC0192&from=EN.

257. Good Things Foundation. Get Online Week 2019 [cited 7 August 2019]. Available from: https://uk.getonlineweek.com/.

258. Good Things Foundation. NHS Widening Digital Participation 2019 [cited 8 August 2019]. Available from: https://www.goodthingsfoundation.org/projects/nhs-widening-digital-participation-phase2.

259. Finance Do. Go Digital at Get Online Week 2018 2018 [cited 18 September 2018]. Available from: https://www.finance-ni.gov.uk/news/go-digital-get-online-week-2018.

260. Wales Co-operative Centre with Carnegie UK Trust. Digital Inclusion in Health and Care in Wales 2018 [cited 11 September 2019]. Available from: https://d1ssu070pg2v9i.cloudfront.net/pex/carnegie_uk_trust/2018/11/06155134/Digital-Inclusion-in-Health-and-Care-in-Wales.pdf.

261. Government W. Delivering Digital Inclusion: A Strategic Framework for Wales 2016 [cited 24 September 2019]. Available from: https://gov.wales/sites/default/files/publications/2019-05/digital-inclusion-framework_0.pdf.
262. Government S. Digital Participation - A National Framework for Local Action Edinburgh 2014 [cited 24 September 2019]. Available from: https://www.gov.scot/publications/digital-participation-national-framework-local-action/.
263. The Scottish Government. Realising Scotland's Full Potential in a Digital World: A Digital Strategy for Scotland. Edinburgh 2017.
264. Scottish Council for Voluntary Organisations - The Scottish Government. Digital Participation Charter 2019 [cited 7 August 2019]. Available from: https://digitalparticipation.scot/charter.
265. Digital Scotland TSG. Let's get online 2019 [cited 8 July 2019]. Available from: http://letsgetonline.scot/.
266. European Commission. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: European Interoperability Framework – Implementation Strategy. Brussels; 2017.
267. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations. Milbank Q. 2004;82(4):581-629.
268. Staples LG, Fogliati VJ, Dear BF, Nielssen O, Titov N. Internet-Delivered Treatment for Older Adults with Anxiety and Depression: Implementation of the Wellbeing Plus Course in Routine Clinical Care and Comparison with Research Trial Outcomes. BJPsych open. 2016;2(5):307-13.
269. Fleming T, Bavin L, Lucassen M, Stasiak K, Hopkins S, Merry S. Beyond the Trial: Systematic Review of Real-World Uptake and Engagement With Digital Self-Help Interventions for Depression, Low Mood, or Anxiety. J Med Internet Res. 2018;20(6):e199.
270. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and Evaluating Complex Interventions: The New Medical Research Council Guidance. BMJ. 2008;337: 979-83.
271. Pinnock H, Barwick M, Carpenter CR, Eldridge S, Grandes G, Griffiths CJ, et al. Standards for Reporting Implementation Studies (StaRI) Statement. BMJ. 2017;356:i6795.
272. Pinnock H, Barwick M, Carpenter CR, Eldridge S, Grandes G, Griffiths CJ, et al. Standards for Reporting Implementation Studies (StaRI): Explanation and Elaboration Document. BMJ open. 2017;7(4):e013318.
273. van Breda W, Bremer V, Becker D, Hoogendoorn M, Funk B, Ruwaard J, et al. Predicting Therapy Success for Treatment as Usual and Blended Treatment in the Domain of Depression. Internet Interv. 2018;12:100-4.
274. ImpleMentAll. About the Project 2017 [cited 20 November 2017]. Available from: http://www.implementall.eu/2-about-the-project.html.
275. Folker AP, Mathiasen K, Lauridsen SM, Stenderup E, Dozeman E, Folker MP. Implementing Internet-Delivered Cognitive Behavior Therapy for Common Mental Health Disorders: A Comparative Case Study of Implementation Challenges Perceived by Therapists and Managers in Five European Internet Services. Internet Interv. 2018;11:60-70.
276. Trimbos-instituut. E-Mental Health in De Huisartsenpraktijk [cited 8 May 2019]. Available from: https://www.huisarts-emh.nl/.
277. Field MJ, Lohr KN, Institute of Medicine Committee to Advise the Public Health Service on Clinical Practice Guidelines. Clinical Practice Guidelines: Directions for a New Program. Washington (DC): National Academies Press; 1990.

278. National Collaborating Centre for Mental Health. National Institute for Health and Clinical Excellence: Guidance. Depression: The Treatment and Management of Depression in Adults (Updated Edition). Leicester (UK): British Psychological Society; 2010.

279. DGPPN, BÄK, KBV, AWMF (Hrsg.) für die Leitliniengruppe Unipolare Depression. S3-Leitlinie/Nationale Versorgungs Leitlinie Unipolare Depression – Langfassung, 2. Auflage. Version 5. 2015 [cited 2 November 2018]. Available from: www.depression.versorgungsleitlinien.de.

280. National Institute for Health and Care Excellence (NICE). Depression in Adults: Treatment and Management. Full Guideline. (Consultation Draft) 2018 [cited 2 November 2018]. Available from: https://www.nice.org.uk/guidance/gid-cgwave0725/documents/full-guideline-updated.

281. Hill C, Martin JL, Thomson S, Scott-Ram N, Penfold H, Creswell C. Navigating the Challenges of Digital Health Innovation: Considerations and Solutions in Developing Online and Smartphone-Application-Based Interventions for Mental Health Disorders. Br J Psychiatry. 2017;211(2):65-9.

282. NHS Digital. Digital Inclusion for Health and Social Care. Supporting Digital Inclusion Locally 2019 [cited 6 October 2018]. Available from: https://digital.nhs.uk/about-nhs-digital/our-work/digital-inclusion/supporting-digital-inclusion-locally.

283. Kuhn S. Medizin im digitalen Zeitalter – "Do It by the Book ... but Be the Author!" 2017 [cited 26 September 2018]. Available from: https://hochschulforumdigitalisierung.de/de/blog/medizin-im-digitalen-zeitalter-do-books-be-author.

284. Hillebrand E, Böhme P, Ehlers JP. Quo vadis Medizinstudium? Digitale Versorgung als zentraler Bestandteil der Ausbildung – Das Beispiel Uni Witten/Herdecke 2018 [cited 25 July 2018]. Available from: https://blog.der-digitale-patient.de/quo-vadis-medizinstudium-uni-witten/.

285. Institute of Digital Health. Research Projects 2019 [cited 28 May 2019]. Available from: https://www.ucl.ac.uk/digital-health/Research/more-research-projects.

286. NHS Health Education England. Health Education England 2018 [cited 29 November 2018]. Available from: https://www.hee.nhs.uk/.

287. European Commission. The Digital Skills and Jobs Coalition 2018 [cited 2 May 2019]. Available from: https://ec.europa.eu/digital-single-market/en/digital-skills-jobs-coalition.

288. eMHPrac. eMHPrac Provides Free E-Mental Health Training and Support for Health Practitioners 2019 [cited 12 August 2019]. Available from: http://www.emhprac.org.au/.

289. NHS Health Education England. Building a Digital Ready Workforce 2018 [cited 22 November 2018]. Available from: https://www.hee.nhs.uk/our-work/building-digital-ready-workforce.

290. NHS Health Education England. Digital Literacy 2018 [cited 22 November 2018]. Available from: https://www.hee.nhs.uk/our-work/digital-literacy.

291. Government of the Netherlands. Government Encouraging Use of eHealth 2014 [cited 9 August 2017]. Available from: https://www.government.nl/topics/ehealth/government-encouraging-use-of-ehealth.

292. Steunpunt Welzijn VeG. Bouwstenen voor een Vlaams Actieplan Onlinehulp. 2014 [cited 15 March 2018]. Available from: https://steunpuntwvg.be/images/rapporten-en-werknotas/bouwstenen-voor-een-vlaams-actieplan-online-hulp.

293. Nictiz, NIVEL. Consciously Choose eHealth. Summary eHealth Monitor 2017 [cited 9 May 2018]. Available from: https://www.ehealth-monitor.nl/wp-content/uploads/2017/09/Nictiz_-Samenvatting_Eng.pdf.

294. The Scottish Government. Health and Social Care Delivery Plan 2016 [cited 17 July 2018]. Available from: http://www.gov.scot/Resource/0051/00511950.pdf.

295. National Youth Mental Health Task Force (YMHTF). National Youth Mental Health Task Force Report 2017. 2017 [cited 23 August 2018]. Available from: https://health.gov.ie/wp-content/uploads/2017/12/YMHTF-Final-Report.pdf.
296. The Scottish Government. Mental Health Strategy 2017-2027 2017 [cited 4 December 2017]. Available from: http://www.gov.scot/Resource/0051/00516047.pdf.
297. Stevenson D, Farmer P. Thriving at Work: The Stevenson / Farmer Review of Mental Health and Employers. London, England; 2017.
298. mHealthBELGIUM. Why mHealthBELGIUM? 2018 [cited 22 August 2019]. Available from: https://mhealthbelgium.be/en/about-us/.
299. Ministère des solidarités et de la santé. Feuille de Route: santé mentale et psychiatrie 2018 [cited 8 September 2018]. Available from: https://solidarites-sante.gouv.fr/IMG/pdf/180628_-_dossier_de_presse_-_comite_strategie_sante_mentale.pdf.
300. The Scottish Government. Scotland´s Digital Health & Care Strategy. Enabling, Connecting & Empowering 2018 [cited 17 July 2018]. Available from: http://www.digihealthcare.scot/wp-content/uploads/2018/04/25-April-2018-SCOTLANDS-DIGITAL-HEALTH-AND-CARE-STRATEGY-published.pdf.
301. Department of Health and Children (DOHC). A Vision for Change: Report of the Expert Group on Mental Health Policy. Stationery Office Dublin; 2006 15 May 2018.
302. Department of Health. e-Health Strategy for Ireland 2013 [cited 16 May 2018]. Available from: http://www.ehealthireland.ie/Knowledge-Information-Plan/eHealth-Strategy-for-Ireland.pdf.
303. Ministère des Affairs Sociales et de la Santé. Stratégie nationale e-santé 2020 2016 [cited 15 March 2017]. Available from: http://solidarites-sante.gouv.fr/IMG/pdf/strategie_e-sante_2020.pdf.
304. Bundesministerium für Gesundheit (BMG). Gesetz für sichere digitale Kommunikation und Anwendungen im Gesundheitswesen sowie zur Änderung weiterer Gesetze. Bundesgesetzblatt 2016;Teil I(54).
305. Welsh Government. Together for Mental Health: Delivery Plan 2016-2019 2016 [cited 4 December 2017]. Available from: https://gov.wales/sites/default/files/consultations/2018-01/160118documenten.pdf
306. The Department of Health (Northern Ireland). Health and Wellbeing 2026: Delivering Together 2016 [cited 4 December 2017]. Available from: https://www.health-ni.gov.uk/sites/default/files/publications/health/health-and-wellbeing-2026-delivering-together.pdf
307. Stockman S. Digital Northern Ireland 2020 2017 [cited 11 April 2018]. Available from: https://secure.investni.com/static/library/invest-ni/documents/digital-northern-ireland-2020-report.pdf.
308. Ministère des solidarités et de la santé. Dossier de presse - Ma santé 2022 : un engagement collectif 2018 [cited 3 September 2019]. Available from: https://solidarites-sante.gouv.fr/IMG/pdf/ma_sante_2022_pages_vdef_.pdf.
309. Welsh Government. A Healthier Wales: our Plan for Health and Social Care. 2018.
310. Ministère des solidarités et de la santé. Feuille de Route: Accélérer le virage numérique 2019 [cited 12 December 2019]. Available from: https://solidarites-sante.gouv.fr/IMG/pdf/190425_dossier_presse_masante2022_ok.pdf.
311. NHS Ipswich and East Suffolk and NHS West Suffolk. Live Life to the Full – Launch of Online Mental Wellbeing Resources 2019 [cited 15 August 2019]. Available from: https://www.westsuffolkccg.nhs.uk/live-life-to-the-full-launch-of-online-mental-wellbeing-resources/.
312. Haute Autorité de Santé. Rapport d'analyse prospective 2019 - Numérique: quelle (R)évolution? 2019 [cited 12 December 2019]. Available from: https://www.has-sante.fr/upload/docs/application/pdf/2019-07/rapport_analyse_prospective_20191.pdf.

313. Chevreul K, Berg Brigham K, Durand-Zaleski I, Hernández-Quevedo C. France: Health System Review. Health Syst Transit. 2015;17(3):1–218.

314. Kessler RC, Aguilar-Gaxiola S, Alonso J, Chatterji S, Lee S, Ormel J, et al. The Global Burden of Mental Disorders: An Update from the WHO World Mental Health (WMH) Surveys. Epidemiol Psichiatr Soc. 2009;18(1):23-33.

315. Morgiève M, Sebbane D, De Rosario B, Demassiet V, Kabbaj S, Briffault X, et al. E-Mental Health: "Fashionable Gimmick" or "Serious Stuff You Use"? Analysis of the Re-Composition of Norms and Representations in the Field of Psychiatry/Mental Health. 2019, forthcoming/in press.

316. World Health Organization Collaborating Centre Lille (WHOCC Lille). Etude EQUME - Étude Qualitative des attentes, besoins et Usages des M-Health (technologie de e-santé en santé mentale) par l'Ensemble des parties prenantes, in progress. 2018.

317. Pressemitteilung – Konstituierende Sitzung des neuen Sachverständigenrats [press release]. 27 February 2019.

318. Deutsche Gesellschaft für Psychiatrie und Psychotherapie Psychosomatik und Nervenheilkunde (DGPPN). Neue Lösungen für wachsenden Hilfebedarf 2017 [cited 14.01.2018.
Available from: https://www.dgppn.de/schwerpunkte/versorgung.html.

319. Melchior H, Schulz H, Härter M. Faktencheck Gesundheit: Regionale Unterschiede in der Diagnostik und Behandlung von Depressionen. Gütersloh: Bertelsmann Stiftung; 2014 [cited 15 November 2017]. Available from: https://faktencheck-gesundheit.de/fileadmin/files/BSt/Presse/imported/downloads/xcms_bst_dms_39547_39548_2.pdf.

320. Deutsche Gesellschaft für Psychiatrie und Psychotherapie Psychosomatik und Nervenheilkunde (DGPPN). Zahlen und Fakten der Psychiatrie und Psychotherapie 2017 [cited 30 November 2017]. Available from: https://www.dgppn.de/_Resources/Persistent/9e1cae06b40f7ea98d988c21d5ad17c2f77f5ace/Factsheet_Psychiatrie.pdf.

321. Kowitz S, Zielasek J, Gaebel W. Die Versorgungssituation bei psychischen Störungen in Deutschland: Aktueller Stand und Perspektiven [Mental healthcare in Germany – current situation and perspectives]. Dtsch Med Wochenschr. 2014;139(23):1249-52.

322. Bundespsychotherapeutenkammer (BPtK). Ein Jahr nach der Reform der Psychotherapie-Richtlinie. Wartezeiten 2018. 2018 [cited 16 April 2018]. Available from: http://www.bptk.de/fileadmin/user_upload/Publikationen/BPtK-Studien/Wartezeiten_2018/20180411_bptk_studie_wartezeiten_2018.pdf.

323. CDU, CSU, SPD. Ein neuer Aufbruch für Europa. Eine neue Dynamik für Deutschland. Ein neuer Zusammenhalt für unser Land. Koalitionsvertrag zwischen CDU, CSU und SPD, 19. Legislaturperiode 2018 [cited 24 July 2018]. Available from: https://www.bundesregierung.de/Content/DE/_Anlagen/2018/03/2018-03-14-koalitionsvertrag.pdf;jsessionid=6362AAA25EADD8385EBE02337A7460AB.s2t1?__blob=publicationFile&v=6.

324. Bielefeld PSU. Ökonomische Bestandsaufnahme und Potenzialanalyse der digitalen Gesundheitswirtschaft 2015 [cited 15 December 2017]. Available from: https://www.bmwi.de/Redaktion/DE/Publikationen/Studien/oekonomische-bestandsaufnahme-und-potenzialanalyse-der-digitalen-gesundheitswirtschaft.pdf?__blob=publicationFile&v=4.

325. Bernnat R, Bauer, M., Schmidth, H., Bieber, N., Heusser, N., Schönfeld, R. Effizienzpotentiale durch eHealth. Studie im Auftrag des Bundesverbands Gesundheits-IT – bvitg e.V. und der CompuGroup Medical SE 2017 [cited 27 April 2017].
Available from: https://www.strategyand.pwc.com/media/file/Effizienzpotentiale-durch-eHealth.pdf.

326. Bundesministerium für Wirtschaft und Energie (BMWi). Digitalisierung der Gesundheitswirtschaft. Eckpunktepapier 2017 [cited 20 November 2017]. Available from: https://www.bmwi.de/Redaktion/DE/Publikationen/Wirtschaft/eckpunkte-digitalisierung-gesundheitswirtschaft.pdf?__blob=publicationFile&v=16.

327. Arbeitsgruppe Gesundheit der CDU/CSU-Fraktion im Deutschen Bundestag. Die Digitalisierung des Gesundheitswesens entschlossen vorantreiben 2018 [cited 24 July 2018]. Available from: https://www.cducsu.de/sites/default/files/2018-06/Die%20Digitalisierung%20des%20Gesundheitswesens%20entschlossen%20vorantreiben%20%28003%29.pdf.

328. Bundesministerium für Gesundheit (BMG). E-Health – Digitalisierung im Gesundheitswesen 2018 [cited 25 March 2019]. Available from: https://www.bundesgesundheitsministerium.de/e-health-initiative.html#c11938.

329. (BMG) BfG. Health Innovation Hub startet 2019 [cited 9 August 2019]. Available from: https://www.bundesgesundheitsministerium.de/ministerium/meldungen/2019/health-innovation-hub.html.

330. VdEK. Die Ersatzkassen. Neue Chance für die Versorgung: Onlinebasierte Interventionen bei psychischen Störungen 2018 [cited 28 November 2018]. Available from: https://www.vdek.com/content/dam/vdek-site/vdek/presse/2018/vdek_Eckpunkte_onlinebasierte_Interventionen_Apps_bei%20psychischen%20_Stoerungen.pdf.

331. Kassenärztliche Bundesvereinigung (KBV). KBV-Positionen zur Digitalisierung in der Gesundheitsversorgung 2017 [cited 24 August 2017]. Available from: http://www.kbv.de/media/sp/2017_09_12_Positionspapier_Digitalisierung.pdf.

332. Bundespsychotherapeutenkammer (BPtK). BPtK-Standpunkt. Internet in der Psychotherapie 2017 [cited 23 September 2017]. Available from: http://bptk.de/uploads/media/BPtK-Standpunkt_-_Internet_in_der_Psychotherapie.pdf.

333. GwG – Gesellschaft für Personzentrierte Psychotherapie und Beratung e.V. Stellungnahme der unterzeichnenden Psychotherapieverbände zur Nutzung elektronischer Kommunikationsmedien in der Psychotherapie 2016 [cited 15 December 2017]. Available from: https://www.bvvp.de/files/20160531_pt-verbaende_stellungnahme_internettherapie.pdf.

334. Deutsche Psychotherapeuten Vereinigung (DPtV). Online-Interventionen gehören in die Hand von Psychotherapeuten 2017 [cited 20 September 2017]. Available from: https://www.deutschepsychotherapeuten-vereinigung.de/index.php?eID=dumpFile&t=f&f=6204&token=76c7cfb6dee3e3a316688c617390dbd192ae3a4d.

335. Zwerenz R, Beutel ME. Online-Interventionen zur Behandlung psychischer Erkrankungen und Belastungen. ASU. 2017; 52:452-60.

336. Bundespsychotherapeutenkammer (BPtK). BPtK-Standpunkt. Gesundheits-Apps nutzen, ohne Patienten zu gefährden – Zur Digitalisierung in der Psychotherapie 2019 [cited September 23 2019]. Available from: https://www.bptk.de/wp-content/uploads/2019/09/BPtK-Standpunkt-Gesundheits-Apps-nutzen-ohne-Patienten-zu-gef%C3%A4hrden-Zur-Digitalisierung-in-der-Psychotherapie-1.pdf.

337. Bundespsychotherapeutenkammer (BPtK). Videosprechstunde auch für Psychotherapeuten möglich 2018 [cited 25 March 2019]. Available from: https://www.bptk.de/videosprechstunde-auch-fuer-psychotherapeuten-moeglich/.

338. Bundespsychotherapeutenkammer (BPtK). Muster-Berufsordnung für die Psychologischen Psychotherapeutinnen und Psychotherapeuten und Jugendlichenpsychotherapeutinnen und Kinder- und Jugendlichenpsychotherapeuten 2014 [cited 20 September 2017]. Available from: http://www.bptk.de/fileadmin/user_upload/Recht/Satzungen_und_Ordnungen/musterberufsordnung.PDF.

339. Bundespsychotherapeutenkammer (BPtK). Muster-Berufsordnung für die Psychologischen Psychotherapeutinnen und Psychotherapeuten und Jugendlichenpsychotherapeutinnen und Kinder- und Jugendlichenpsychotherapeuten (geändert mit dem Beschluss des 33. Deutschen Psychotherapeutentages in Berlin am 17. November 2018) 2014 [cited 25 March 2019]. Available from: https://www.bptk.de/fileadmin/user_upload/Recht/Satzungen_und_Ordnungen/Muster-Berufsordnung_der_BPtK.pdf.

340. Landesärztekammer Baden-Württemberg. Berufsordnung der Landesärztekammer Baden-Württemberg vom 10. Dezember 2012 Ärzteblatt Baden-Württemberg 2013, S. 21, Beilage) 2016 [cited 27.03.2018. Available from: http://www.aerztekammer-bw.de/10aerzte/40merkblaetter/20recht/05kammerrecht/bo.pdf.

341. Gemeinsamer Bundesausschuss (G-BA). Der Innovationsfonds und der Innovationsausschuss beim Gemeinsamen Bundesausschuss 2018 [cited 24 July 2018]. Available from: https://innovationsfonds.g-ba.de/.

342. Gieselmann A, Böckermann M, Pietrowsky R. Internetbasierte Gesundheitsinterventionen. Psychotherapeut 2015;60::433–40.

343. Dockweiler C, Kupitz A, Palmdorf S, Hornberg C. Online Therapy for Depressive Disorders : An Acceptance-Based Analysis from the Perspective of Therapists. Nervenarzt. 2019.

344. Tonn P, Reuter SC, Kuchler I, Reinke B, Hinkelmann L, Stockigt S, et al. Development of a Questionnaire to Measure the Attitudes of Laypeople, Physicians, and Psychotherapists Toward Telemedicine in Mental Health. JMIR Ment Health. 2017;4(4):e39.

345. Schulze N, Reuter SC, Kuchler I, Reinke B, Hinkelmann L, Stockigt S, et al. Differences in Attitudes Toward Online Interventions in Psychiatry and Psychotherapy Between Health Care Professionals and Nonprofessionals: A Survey. Telemed J E Health. 2018.

346. Surmann M, Bock EM, Krey E, Burmeister K, Arolt V, Lencer R. Einstellungen gegenüber eHealth-Angeboten in Psychiatrie und Psychotherapie. Der Nervenarzt. 2017;88(9):1036-43.

347. Dorow M, Stein J, Forster F, Lobner M, Franz M, Gunther R, et al. Der komplementäre Einsatz des internetbasierten Selbstmanagementprogramms "moodgym" bei Menschen mit depressiven Erkrankungen in der stationären Versorgung - die Perspektive von Patienten und Behandlern [Implementation of the Internet-Based Self-Management Program "moodgym" in Patients with Depressive Disorders in Inpatient Clinical Settings - Patient and Expert Perspectives]. Psychiatr Prax. 2018;45(5):256-62.

348. Irish Association for Counselling and Psychotherapy (IACP). Recommended Approach for Online Counselling and Psychotherapy 2017 [cited 25 May 2018]. Available from: https://iacp.ie/onlinecounselling.

349. Riper H. 15 jaar onderzoek naar ehealth You Tube 2015 [cited 9 January 2018]. Available from: https://www.youtube.com/watch?v=qNooFKgXQUc.

350. Nederlandse Patiënten Consumenten Federatie (NPCF). Nationale Implementatie agenda (NIA) e-health 2012 [cited 16 August 2018]. Available from: https://www.rijksoverheid.nl/documenten/rapporten/2012/06/07/nationale-implementatieagenda-e-health-nia.

351. Kenter RMF, van Straten A, Hobbel SH, Smit F, Bosmans J, Beekman A, et al. Effectiveness and Cost Effectiveness of Guided Online Treatment for Patients with Major Depressive Disorder on a Waiting List for Psychotherapy: Study Protocol of a Randomized Controlled Trial. Trials. 2013;14(1):412.

352. Lokkerbol J, Adema D, Cuijpers P, Reynolds CF, 3rd, Schulz R, Weehuizen R, et al. Improving the Cost-Effectiveness of a Healthcare System for Depressive Disorders by Implementing Telemedicine: A Health Economic Modeling Study. Am J Geriatr Psychiatry. 2014;22(3):253-62.

353. Smeets O, Martin Abello K, Zijlstra-Vlasveld M, Boon B. E-health in de GGZ: hoe staat het daar nu mee? [E-Health within the Dutch Mental Health Services: What Is the Current Situation?]. Ned Tijdschr Geneeskd. 2014;158:A8589.

354. van 't Land H, Grolleman J, Mutsaers K, Smits C. Trendrapportage 2008 GGZ. Deel 2. Toegang en Zorggebruik. Basisanalyse. 2008 [cited 23 July 2018]. Available from: http://www.nvag.nl/afbeeldingen/Bibliotheek/OGGZAlgemeen/trendrapport%20ggz%20deel%202%20toegang%20en%20zorggebruik.pdf.

355. Krijgsman J, Swinkels I, van Lettow B, de Jong J, Out K, Friele R, et al. Meer dan techniek. eHealth-monitor 2016. 2016 [cited 26 July 2018]. Available from: https://www.nivel.nl/sites/default/files/bestanden/ehealth-monitor_2016_meer_dan_techniek.pdf.

356. Huson A. Technologische ontwikkelingen in de GGZ 2008 [cited 15 July 2018]. Available from: https://www.igj.nl/documenten/rapporten/2008/10/31/technologische-ontwikkelingen-in-de-ggz.

357. Putters K, Janssen M, van der Wel T, Kelder M. E-health: Face-to-Facebook. Over e-health en zelfredzaamheid van patiënten in de GGZ. 2012 [cited 23 July 2018]. Available from: www.ape.nl/include/downloadFile.asp?id=287.

358. Riper H, Smit F, van der Zanden R, Conijn B, Kramer J, Mutsaers K. E-Mental Health. High Tech, High Touch, High Trust. Programmeringsstudie E-Mental Health in opdracht van het ministerie van VWS. 2007 [cited 26 July 2018]. Available from: https://extranet.infopuntveiligheid.nl/Infopuntdocumenten/ICOM%20-%20Programmeringsstudie%20E-mental%20Health.pdf.

359. NatCen and the University of Leicester. Adult Psychiatric Morbidity Survey: Survey of Mental Health and Wellbeing, England, 2014. 2016 [cited 4 December 2017]. Available from: https://digital.nhs.uk/catalogue/PUB21748.

360. Mental Health Foundation. Mental Health in Wales: Fundamental Facts 2016 [cited 4 January 2018]. Available from: https://www.mentalhealth.org.uk/sites/default/files/FF16%20Wales.pdf

361. Mental Health Foundation. Mental Health in Northern Ireland: Fundamental Facts 2016 [cited 4 January 2018]. Available from: https://www.mentalhealth.org.uk/sites/default/files/FF16%20Northern%20ireland.pdf

362. Mental Health Foundation. Mental Health in Scotland: Fundamental Facts 2016 [cited 4 January 2018]. Available from: https://www.mentalhealth.org.uk/publications/mental-health-scotland-fundamental-facts.

363. National Information Board Department of Health. Personalised Health and Care 2020. Using Data and Technology to Transform Outcomes for Patients and Citizens: A Framework for Action 2014 [cited 4 December 2017]. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/384650/NIB_Report.pdf.

364. Department of Health. A Framework for Mental Health Research. 2017 [cited 9 January 2018]. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/665576/A_framework_for_mental_health_research.pdf.

365. Bennion MR, Hardy G, Moore RK, Millings A. E-Therapies in England for Stress, Anxiety or Depression: What Is Being Used in the NHS? A Survey of Mental Health Services. BMJ open. 2017;7(1):e014844.

366. Digital Northern Ireland 2020. Invest Northern Ireland 2017 [cited 4 January 2018]. Available from: https://secure.investni.com/static/library/invest-ni/documents/digital-northern-ireland-2020-report.pdf

367. Expert Panel Report. Systems, Not Structures: Changing Health and Social Care. 2016 [cited 9 January 2018]. Available from: https://www.health-ni.gov.uk/sites/default/files/publications/health/expert-panel-full-report.pdf

368. European Commission. E-Health – Making Healthcare Better for European Citizens: An Action Plan for a European E-Health Area. Brussels; 2004.

369. European Commission. Green Paper. Improving the Mental Health of the Population: Towards a Strategy on Mental Health for the European Union. Brussels: Health & Consumer Protection Directorate-General; 2005.

370. European Commission. European Pact for Mental Health and Well-Being 2008 [cited 19 August 2019]. Available from: http://ec.europa.eu/health/ph_determinants/life_style/mental/docs/pact_en.pdf.

371. European Coordination Committee of the Radiological Electromedical and Healthcare IT Industry. eHealth Governance Brussels 2017 [cited 19 August 2019]. Available from: https://www.cocir.org/regulations/digital-health/ehealth-governance.

372. European Commission. Green Paper on mobile Health ("mHealth") Brussels 2014 [cited 19 August 2019]. Available from: http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=5147.

373. European Commission. New European Interoperability Framework Luxembourg; 2017.

374. European Commission. Topic 3: Connecting Europe Facility (CEF) – for Adoption. 5th eHealth Network 13 May Brussels 2014 [cited 19 August 2019]. Available from: http://www.ehgi.eu/Lists/Posts/Attachments/15/eHealth%20Network%205%20[Athens%202014]%20Topic%203%20-%20CEF%20-%20proposal%20for%202015%20workplan.pdf.

375. European Parliament, Council of the European Union. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). Official Journal of the European Union. 2016;L 119/1.

376. European Parliament, Council of the European Union. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the Application of Patients' Rights in Cross-Border Healthcare. Official Journal of the European Union. 2011.

377. Berrouiguet S, Courtet P, Perez-Rodriguez M, Oquendo M, Baca-Garcia E. The Memind Project: a New Web-based Mental Health Tracker Designed for Clinical Management and Research. Eur Psychiatry. 2015;30(Supplement 1):974.

378. Berrouiguet SB, Alavi AZ, Vaiva GV, Courtet PC, Baca-Garcia EBG, Brandt SB, et al. Siam (Suicide Intervention Assisted by Messages): the Development of a Post-acute Crisis Text Messaging Outreach for Suicide Prevention. Eur Psychiatry. 2015;30(Supplement 1):957.

379. Berrouiguet S, Larsen ME, Mesmeur C, Gravey M, Billot R, Walter M, et al. Toward mHealth Brief Contact Interventions in Suicide Prevention: Case Series From the Suicide Intervention Assisted by Messages (SIAM) Randomized Controlled Trial. JMIR mHealth and uHealth. 2018;6(1):e8.

380. NHS. Local Digital Roadmaps 2017 [cited 4 December 2017]. Available from: https://www.england.nhs.uk/digitaltechnology/info-revolution/digital-roadmaps/.

381. Husain N, Gire N, Kelly J, Duxbury J, McKeown M, Riley M, et al. TechCare: Mobile Assessment and Therapy for Psychosis – an Intervention for Clients in the Early Intervention Service: A Feasibility Study Protocol. SAGE open medicine. 2016;4:1-9.

382. mHabitat. Digital Development Lab 2017 [cited 4 December 2017]. Available from: http://wearemhabitat.com/portfolio/digital-development-lab/.

383. NHS. The Five Year Forward View on Mental Health: One Year On 2017 [cited 23 August 2019]. Available from: https://www.england.nhs.uk/wp-content/uploads/2017/03/fyfv-mh-one-year-on.pdf.

384. E-COMPARED. European Comparative Effectiveness Research on Internet-based Depression Treatment – About Us 2017 [cited 23 August 2019]. Available from: https://www.e-compared.eu/about-us/mission/.

385. ICare. ICare - Integrating Technology into Mental Health Care 2017 [cited 23 August 2019]. Available from: http://www.implementall.eu/2-about-the-project.html.

386. Heber E, Ebert, D. D., Lehr, D., Cuijpers, P., Berking, M., Nobis, S., & Riper, H. The Benefit of Web-and Computer-Based Interventions for Stress: A Systematic Review and Meta-Analysis. J Med Internet Res. 2017;19(2):e32.

387. Karyotaki E, Riper H, Twisk J, Hoogendoorn A, Kleiboer A, Mira A, et al. Efficacy of Self-Guided Internet-Based Cognitive Behavioral Therapy in the Treatment of Depressive Symptoms: A Meta-Analysis of Individual Participant Data. JAMA psychiatry. 2017;74(4):351-9.

388. Königbauer J, Letsch J, Doebler P, Ebert D, Baumeister H. Internet-and Mobile-Based Depression Interventions for People with Diagnosed Depression: A Systematic Review and Meta-Analysis. J Affect Disord. 2017;223:28-40.

389. Păsărelu CR, Andersson G, Bergman Nordgren L, Dobrean A. Internet-Delivered Transdiagnostic and Tailored Cognitive Behavioral Therapy for Anxiety and Depression: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Cogn Behav Ther. 2017;46(1):1-28.

390. Twomey C, O'Reilly, G., & Meyer, B. Effectiveness of an Individually-Tailored Computerised CBT Programme (Deprexis) for Depression: A Meta-Analysis. Psychiatry Res. 2017;256:371-7.

391. Kuester A, Niemeyer H, Knaevelsrud C. Internet-Based Interventions for Posttraumatic Stress: A Meta-Analysis of Randomized Controlled Trials. Clin Psychol Rev. 2016;43:1-16.

392. Seyffert M, Lagisetty, P., Landgraf, J., Chopra, V., Pfeiffer, P. N., Conte, M. L., & Rogers, M. A. Internet-Delivered Cognitive Behavioral Therapy to Treat Insomnia: A Systematic Review and Meta-Analysis. PloS one. 2016;11(2):e0149139.

393. Sijbrandij M, Kunovski, I., & Cuijpers, P. Effectiveness of Internet-Delivered Cognitive Behavioral Therapy for Posttraumatic Stress Disorder: A Systematic Review and Meta-Analysis. Depress Anxiety. 2016;33(9):783-91.

394. Vigerland S, Lenhard F, Bonnert M, Lalouni M, Hedman E, Ahlen J, et al. Internet-Delivered Cognitive Behavior Therapy for Children and Adolescents: A Systematic Review and Meta-Analysis. Clin Psychol Rev. 2016;50:1-10.

395. Zhou T, Li, X., Pei, Y., Gao, J., & Kong, J. Internet-Based Cognitive Behavioural Therapy for Subthreshold Depression: A Systematic Review and Meta-Analysis. BMC Psychiatry. 2016;16(1):356.

396. Ebert DD, Zarski, A. C., Christensen, H., Stikkelbroek, Y., Cuijpers, P., Berking, M., & Riper, H. Internet and Computer-Based Cognitive Behavioral Therapy for Anxiety and Depression in Youth: A Meta-Analysis of Randomized Controlled Outcome Trials. PloS one. 2015;10(3):e0119895.

397. Richards D, Richardson T, Timulak L, McElvaney J. The Efficacy of Internet-Delivered Treatment for Generalized Anxiety Disorder: A Systematic Review and Meta-Analysis. Internet Interv. 2015;2(3):272-82.

398. Riper H, Blankers M, Hadiwijaya H, Cunningham J, Clarke S, Wiers R, et al. Effectiveness of Guided and Unguided Low-Intensity Internet Interventions for Adult Alcohol Misuse: A Meta-Analysis. PloS one. 2014;9(6):e99912.

399. Ye X, Bapuji SB, Winters SE, Struthers A, Raynard M, Metge C, et al. Effectiveness of Internet-Based Interventions for Children, Youth, and Young Adults with Anxiety and/or Depression: A Systematic Review and Meta-Analysis. BMC Health Serv Res. 2014;14(1):313.

400. Johansson R, Andersson G. Internet-Based Psychological Treatments for Depression. Expert Rev Neurother. 2012;12(7):861-9.

401. Lewis C, Pearce J, Bisson JI. Efficacy, Cost-Effectiveness and Acceptability of Self-Help Interventions for Anxiety Disorders: Systematic Review. Br J Psychiatry. 2012;200:15-21.

402. Foroushani PS, Schneider J, Assareh N. Meta-Review of the Effectiveness of Computerised CBT in Treating Depression. BMC Psychiatry. 2011;11(1):131.
403. Newman MG, Szkodny LE, Llera SJ, Przeworski A. A Review of Technology-Assisted Self-Help and Minimal Contact Therapies for Anxiety and Depression: Is Human Contact Necessary for Therapeutic Efficacy? Clin Psychol Rev. 2011;31(1):89-103.
404. Tulbure BT. The Efficacy of Internet-Supported Intervention for Social Anxiety Disorder: A Brief Meta-Analytic Review. Procedia Soc Behav Sci. 2011;30:552-7.
405. Andrews G, Cuijpers P, Craske MG, McEvoy P, Titov N. Computer Therapy for the Anxiety and Depressive Disorders Is Effective, Acceptable and Practical Health Care: A Meta-Analysis. PloS one. 2010;5(10):e13196.
406. Calear AL, Christensen H. Review of Internet-Based Prevention and Treatment Programs for Anxiety and Depression in Children and Adolescents. Med J Aust. 2010;192(11):12-4.
407. Griffiths KM, Farrer L, Christensen H. The Efficacy of Internet Interventions for Depression and Anxiety Disorders: A Review of Randomised Controlled Trials. Med J Aust. 2010;192(11):4-11.
408. Amstadter AB, Broman-Fulks J, Zinzow H, Ruggiero KJ, Cercone J. Internet-Based Interventions for Traumatic Stress-Related Mental Health Problems: A Review and Suggestion for Future Research. Clin Psychol Rev. 2009;29(5):410-20.
409. Andersson G, Cuijpers P. Internet-Based and Other Computerized Psychological Treatments for Adult Depression: A Meta-Analysis. Cogn Behav Ther. 2009;38(4):196-205.
410. Cuijpers P, Marks IM, van Straten A, Cavanagh K, Gega L, Andersson G. Computer-Aided Psychotherapy for Anxiety Disorders: A Meta-Analytic Review. Cogn Behav Ther. 2009;38(2):66-82.
411. Reger MA, & Gahm, G. A. A Meta-Analysis of the Effects of Internet- and Computer-Based Cognitive-Behavioral Treatments for Anxiety. J Clin Psychol. 2009;65(1):53-75.
412. Barak A, Hen, L., Boniel-Nissim, M., Shapira, N. A. A Comprehensive Review and a Meta-Analysis of the Effectiveness of Internet-Based Psychotherapeutic Interventions. J Technol Hum Serv. 2008;26(2/4):109-60.
413. Palmqvist B, Carlbring P, Andersson G. Internet-Delivered Treatments with or without Therapist Input: Does the Therapist Factor Have Implications for Efficacy and Cost? Expert Rev Pharmacoecon Outcomes Res. 2007;7(3):291-7.
414. Brown CA, Lilford RJ. The Stepped Wedge Trial Design: A Systematic Review. BMC Med Res Methodol. 2006;6:54.
415. Beard E, Lewis JJ, Copas A, Davey C, Osrin D, Baio G, et al. Stepped Wedge Randomised Controlled Trials: Systematic Review of Studies Published between 2010 and 2014. Trials. 2015;16:353.
416. Hemming K, Haines TP, Chilton PJ, Girling AJ, Lilford RJ. The Stepped Wedge Cluster Randomised Trial: Rationale, Design, Analysis, and Reporting. BMJ. 2015;350:h391.
417. Lei H, Nahum-Shani I, Lynch K, Oslin D, Murphy SA. A "SMART" Design for Building Individualized Treatment Sequences. Annu Rev Clin Psychol. 2012;8:21-48.
418. Kilbourne AM, Neumann MS, Pincus HA, Bauer MS, Stall R. Implementing Evidence-Based Interventions in Health Care: Application of the Replicating Effective Programs Framework. Implement Sci. 2007;2:42.
419. Lavori PW, Dawson R. Dynamic Treatment Regimes: Practical Design Considerations. Clin Trials. 2004;1(1):9-20.

420. Klasnja P, Hekler EB, Shiffman S, Boruvka A, Almirall D, Tewari A, et al. Microrandomized Trials: An Experimental Design for Developing Just-in-Time Adaptive Interventions. Health Psychol. 2015;34(Supplement):1220-8.

421. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-Implementation Hybrid Designs: Combining Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health Impact. Med Care. 2012;50(3):217-26.

422. Tunis SR, Turkelson C. Using Health Technology Assessment to Identify Gaps in Evidence and Inform Study Design for Comparative Effectiveness Research. J Clin Oncol. 2012;30(34):4256-61.

423. Collins LM, Murphy SA, Nair VN, Strecher VJ. A Strategy for Optimizing and Evaluating Behavioral Interventions. Ann Behav Med. 2005;30(1):65-73.

424. Tunis SR, Stryer DB, Clancy CM. Practical Clinical Trials: Increasing the Value of Clinical Research for Decision Making in Clinical and Health Policy. J Am Med Assoc. 2003;290(12):1624-32.

425. Glasgow RE, Magid DJ, Beck A, Ritzwoller D, Estabrooks PA. Practical Clinical Trials for Translating Research to Practice: Design and Measurement Recommendations. Med Care. 2005;43(6):551-7.

426. Leischow SJ, Best A, Trochim WM, Clark PI, Gallagher RS, Marcus SE, et al. Systems Thinking to Improve the Public's Health. Am J Prev Med. 2008;35(2, Supplement):196-203.

427. Trochim WM, Cabrera DA, Milstein B, Gallagher RS, Leischow SJ. Practical Challenges of Systems Thinking and Modeling in Public Health. Am J Public Health. 2006;96(3):538-46.

428. Institute of Medicine (US) Roundtable on Evidence-Based Medicine. The Learning Healthcare System: Workshop Summary. Washington (DC): National Academies Press 2007.

Appendices

Appendix A

Status quo of eMH – comparison of country specifics in NWE

The potential of digitalisation in health care to improve the equity of access, delivery and quality of care has been widely discussed throughout European countries in the last decade. Several actions at EU level have been initiated to foster cooperation between EU Member States such as the *eHealth Network, the eHealth Action Plan, the Digital Single Market (DSM) Strategy* and the *European Interoperability Framework* (see Chapter 3.1).

Moreover, improving European citizens' mental health is considered key for promoting and strengthening healthy lifestyles and has already resulted in EU programmes such as the *Joint Action on Mental Health and Well-being (2013–2016)*.

The *Joint Action on Mental Health and Well-being* (depression, suicide prevention and eHealth) provides recommendations for mainstreaming eMH in European Member States and underlines its potential to address future challenges of health care systems such as limited human and financial resources, an increasing demand for health services and a dwindling workforce (57). However, despite early movements towards integrating eMH as a complement to traditional mental health care services in the UK, the Netherlands and Scandinavian countries (101), the overall implementation of eMH solutions outside the research context proceeds slowly in Europe (27).

By analysing the policy context and research at national levels concerning the implementation of eMH into national mental health care systems, this chapter aims to identify the national and transnational challenges facing the eMEN partner countries for integrating eMH into mental health systems. Best practices as well as projects and initiatives serve as examples to foster discussion, enhance the use of eMH in the long-term and advocate a structured approach. Therefore, in the context of the eMEN project, eMEN partners performed 1) a review on national policies and agendas in eMEN partner countries related to eMH, 2) a systematic literature review, and 3) conducted *52 interviews between April 2017 and May 2019* with relevant stakeholders in the field of eMH.

Three questions guided the information retrieval:

a. To what extent is eMH included in national and European mental health policies?
b. How is eMH used in eMEN partner countries, and what are relevant projects and initiatives for the implementation of eMH?
c. What are the challenges in eMEN partner countries with regard to the implementation of eMH into routine care?

Using these questions as a framework, the current state of eMH usage in eMEN partner countries will be described with the particular aim being to provide an understanding of any distinctive characteristics in terms of eMH implementation in each eMEN partner country, and identify main areas for policy actions.

Summary

An analysis of the substantial between-country differences, such as policy objectives or eMH policies, may shed light on potential drivers for a wider use of eMH and associated policy implications. In the years 2013 to 2018, policies, action plans and laws relevant to eMH emerged throughout eMEN partner countries. Info box 16 provides an overview about eMH-related policy developments in these countries and in the European Union (EU). Specific eMH policies or eMH implementation action plans are not yet available in most European Member States. eMH is, if at all, mentioned in current mental health strategies or seen as part of a general strategy for digitalisation of health care. In the UK, where health care is a devolved matter, eMH has been strongly foregrounded in a number of high-profile policy documents in England (e.g. the *Mental Health Five Year Forward View*) and has taken a key position in strategic approaches to improve mental health. As a result, eMH products and services are accelerating, with more than 50 percent of GPs using eMH in their daily practice.

In Belgium and the Netherlands, the Flemish government and the Dutch Ministry of Health, Welfare and Sports respectively, set objectives and policy actions to push eHealth developments (291, 292). Still, deployment is rather fragmented, and the structural use of eMH solutions in routine practice in the Netherlands is only +/- 15 percent due to too little effort at policy level to implement eMH products and services (including an adequate reimbursement structure) and a lack of implementation research. In addition, there are only limited training and education possibilities.

In Belgium, France, Germany and Ireland, eMH solutions are not embedded as a core component of the mainstream public mental health care system. However, eMH products and services are available in the context of (research) projects, offered or refunded by some health care insurance companies (Germany and Belgium), offered by public health services or third-sector organisations (Belgium, Ireland, the Netherlands), or offered by private for-profit organisations.

Although there is not yet much direct deployment as part of the mainstream public mental health care systems, there is now quite strong interest in eMH at policy and practice levels. A number of policy initiatives and research projects (see info boxes 16-18) currently address eMH to accelerate developments, among others the *Youth Mental Health Task Force Report* (Ireland), initiatives by the Department of Health (Mental Health Unit) (Ireland), and the creation of a ministerial multiprofessional group, which is specifically dedicated to the development of eMH in France.

Hence, despite different starting points, eMH is gaining momentum throughout all eMEN partner countries. However, a lack of structured alignment, clear vision, objectives and legal guidance largely contribute to limited or incoherent implementation of eMH in NWE countries. Evidence from the literature and from stakeholder interviews reveals that, despite increasing attention paid to the promises of eMH, a number of barriers to its implementation into routine care prevail.

Reluctance to use eMH services among health professionals and clients results from limited awareness about available evidence-based eMH products and services, scepticism towards digital technology, preference of face-to-face therapy and limited digital literacy. eMH training and education is still rare throughout NWE countries. Furthermore, quality criteria, adequate reimbursement schemes and accreditation structures that identify evidence-based high-quality eMH products and services are not yet in place. The role of eMH in mental health care and prevention efforts, and its value for health professionals, users, clients and the mental health care system often remains unclear. Research about eMH is focused on effectiveness, neglecting research on implementation. Moreover, collaborations between developers, the health care sector, users and clients in creating eMH products and services are not often seen yet. Outdated or underdeveloped information technology further hampers the large-scale use of eMH in mental health care and prevention efforts. A recent review of determinants of practices for the implementation of eMH in routine practice supports this conclusion: out of 37 determinants, acceptance of eMH, appropriateness and availability, reliability and interoperability were the most frequently reported ones (27).

There are a number of facilitating factors for eMH implementation, such as increasing research projects and collaborations on eMH, increasing interest at policy and practical levels, and promoting the promise of eMH of greater availability and accessibility of mental health care and prevention efforts, patient empowerment and improved quality of care.

However, in order to foster a structured, coordinated and harmonised implementation process, a combination of activities at national and European levels will be warranted:

- improving knowledge about and awareness of eMH among health professionals, clients and users,
- developing eMH products and services according to patient preferences and needs (co-creation/usability),

- providing robust evidence about effectiveness,
- focusing more on implementation research,
- creating a regulatory (accreditation, reimbursement), legal (liability, privacy) and technical (broadband access, information technology infrastructure) environment that enables the use of eMH in routine care,
- strengthening the role of eMH in European and national health strategies and/or action plans for mental health.

Info box 16:
Policy activities related to eMH in NWE countries

2014 **The Netherlands:** *Three eHealth objectives and actions* set by the Ministry of Health, Welfare and Sport; annual progress report *eHealth monitor* published by NIVEL/NICTIZ (293).

2015 **Belgium:** *Ten online care policy actions* set by the Flanders government to increase the use, development, quality and knowledge of online care.

2016 **England:** The *Mental Health Five Year Forward View* is the cornerstone of the current mental health strategy and made a commitment to expanding access to digital services and ensuring investment in digital infrastructure (116). A new 10-year plan for the National Health Service (NHS) in England is being developed during 2018-19.

Scotland: The *Health and Social Care Delivery Plan* – a plan to improve public health in Scotland – refers to computerised cognitive behavioural therapy services as a way to improve access to mental health support and aims to roll out computerised cognitive behavioural therapy services nationally by 2018 (294).

2017 **Ireland:** The *National Youth Mental Health Task Force Report* includes a recommendation for increased investment in age-appropriate, scalable digital youth mental health support (295).

Scotland: *Mental Health Strategy 2017–2027* includes only cursory references to digital approaches (action to develop a digital tool to support young people with eating disorders) (296).

2017/18 **Northern Ireland:** In order to support the implementation of "mental health core and enhanced standards", the *Thriving at Work: the Stevenson/Farmer Review* recommended that "Individuals get clearer advice on using appropriate digital support, which has the potential to provide low cost, scalable support for employees", that "NHS bodies should provide clear ratings for apps and other digital platforms which provide mental health support", and that "Digital tools and products are an enabler of change and there is a significant opportunity for low cost, scalable interventions in workplaces" (297). The Northern Ireland Executive accepted all of the report's 40 recommendations, including that the HSE (Health Service Executive) revises its stress guidance to address mental health issues caused by issues beyond the workplace.

2018 **Belgium:** Launch of Mobile Health Belgium (https://mhealthbelgium.be/en/home-3/), which provides detailed information on validated health applications. A validation pyramid is used to test whether health applications comply with quality, safety and effectiveness standards (298).

France: The French Ministry for Solidarity and Health launched its new *Feuille de route santé mentale et psychiatrie (Roadmap for Mental Health and Psychiatry)*, which is a political plan indicating the future priorities for the mental health care system. Action No. 7, *Promouvoir la santé mentale 3.0 (Mental Health Promotion 3.0)*, emphasises eMH as an opportunity to improve population mental health, and specifically mentions the eMEN project as a good approach to foster eMH in Europe (299).

Scotland: *Digital Health and Social Care Strategy* sets the strategy for the digitalisation of the Scottish NHS to enable Scotland's people and services to fully maximise the potential of digital health (its framework was set by the Health and Social Care Delivery Plan) (300).

Info box 17: Other policy activities contributing to eMH development

2006 **Ireland:** *A Vision for Change* (currently being updated) provides the existing mental health policy framework. It makes brief mention of the role of videoconferencing and telemedicine in neuropsychiatry services (301).

2013 **Ireland:** The *Irish eHealth Strategy* focuses mostly on health information systems and electronic health records. It also makes some reference to eHealth applications in mental health. Follow-up implementation activities have addressed eMH (302).

2016 **France:** *National eHealth Strategy* focuses on general recommendations in terms of eHealth (303).
Germany: The *eHealth law* focuses on digital infrastructure, the electronic health insurance card and the legal basis for video consultations within the context of public services (304).
Wales: Digital approaches play a low-key role within the Welsh Assembly's *Together for Mental Health: Delivery Plan 2016–2019* for improving mental health in Wales (305).

2017 **Northern Ireland:** Digital work features only minimally in Northern Ireland's strategy for health, *Health and Wellbeing 2026: Delivering Together* (306), and there is no mention of mental health in the overarching digital strategy for Northern Ireland's *Digital Northern Ireland 2020* (307).

2018 **France:** National health strategy: The bill on the organisation and transformation of the health system, *Ma santé 2022*, is based on five priorities, including the digital transformation of the health system (308).
Ireland: A number of policy initiatives are currently addressing eMH. These include initiatives by the *Department of Health (Mental Health Unit) and Government Minister* and the attention to eMH by the *Oversight Group*, supporting an updating of *A Vision for Change*.
Wales: The Welsh Government commissioned a Parliamentary review of the long-term future of health and social care: *A Healthier Wales: our Plan for Health and Social Care* (June 2018) (309).

2019 **France:** Roadmap for the increased use of eHealth, *Accelerer le virage numérique (Accelerating the Digital Shift)* (310).
Germany: Medical health care apps become reimbursable within the *Digital Health Care Act (Digitale-Versorgung-Gesetz)*.
Wales: Steps have been taken to develop evidence standards for digital health care technologies in Wales. On May 29th 2019, a joint workshop took place between Health Technology Wales and Digital Health Ecosystem Wales to explore what needs to be done to adopt a Framework for digital health care in Wales. This will include digital mental health products.

Info box 18: eMH initiatives in eMEN partner countries and the EU

2014

Wales **Book prescription Wales** is a scheme for health professionals to prescribe self-help books and digital mental health products for people experiencing mild and moderate mental ill-health. The scheme helps people access information, and provides guidance and tips on ways to self-manage their conditions. New books available on prescription support people dealing with dementia, eating disorders and post-traumatic stress disorder. The digital component includes e-couch, a self-help interactive programme with modules including depression, anxiety and worry (https://ecouch.anu.edu.au/welcome), and moodgym, an interactive self-help book, which helps people to learn and practice skills that can help to prevent and manage symptoms of depression and anxiety. (https://moodgym.com.au/)

2015

EU **ICare:** The aim of ICare researchers from Germany, Austria, Switzerland, Spain, the UK and the Netherlands is to improve access to appropriate and evidence-based online interventions for the prevention and treatment of mental health conditions by establishing a comprehensive model of promoting mental health in Europe. The ICare online platform encompasses evidence-based risk detection, disease prevention and treatment facilitation for common mental disorders. ICare is designed to improve existing health care models, open new access paths and overcome traditional implementation barriers. (https://www.icare-online.eu/en/)

Ireland **Technology, Mental Health and Suicide Prevention in Ireland – a Good Practice Guide**: This guidance document was commissioned by the Health Service Executive's National Office for Suicide Prevention to develop good practice guidelines for the safe delivery of online mental health information and support. Development of the guidelines was informed by the Technology and Mental Health Network (TMHN), comprising personnel from a number of public agencies and voluntary organisations interested in and/or active in this field. (https://www.hse.ie/eng/services/list/4/mental-health-services/nosp/resources/goodpracticeonline.pdf)

2016

EU **eMEN:** The eMEN project undertakes a unique combination of activities in research, product development, policy and communications, and creates a transnational platform for eMH innovation and implementation in North-West Europe. (http://www.nweurope.eu/emen)

EU **eCOMPARED:** The project aims to provide mental health care stakeholders with evidence-based information and recommendations about the clinical effectiveness and cost-effectiveness of blended depression treatment. Comparative Effectiveness Research is conducted in nine European countries to determine what treatment works best, for whom, and under which circumstances. Current practice of cognitive behavioural therapy (CBT) in routine and specialised mental health care is compared with 'blended' treatment for depression that combines both internet, mobile technologies and face-to-face interventions. (https://www.e-compared.eu/)

2017

England **IAPT project:** The Improving Access to Psychological Therapies (IAPT) programme has ambitious goals for offering services to people with anxiety and depression which can only be met through digital solutions. The English National Health Service set up a new digitally-enabled therapy assessment programme, where up to 14 digital therapy products will be assessed for use in IAPT services by 2020. (https://www.england.nhs.uk/mental-health/adults/iapt/digital-therapy-selection/)

Belgium **Mobile health Belgium:** The Federal Public Health Service started 24 pilot projects in 2017 in which eHealth and eMH projects are being tested. The pilots are part of the action plan *eHealth 2015–2018*. The goal is to develop a validation pyramid for e-(mental) health applications that can be used to evaluate the quality of the applications and to develop a juridical framework and reimbursement model for e-(mental) health. (www.mhealthbelgium.be)

France **StopBlues:** An app that is part of the research programme "Printemps", led by the French National Institute for Medical Research. It is a web-based and mobile primary suicide prevention intervention tested and evaluated in 40 cities for the general population. (https://www.stopblues.fr/)

EU **ImpleMentAll:** A European collaboration (plus Australia) towards faster and more effective implementation of eHealth interventions. The project is founded on the notion that implementation of new services and technologies is time-consuming and costly – and often fails completely – not least in the health care domain. (http://www.implementall.eu/)

2018

Germany

Innovations Fund projects: The innovation fund promotes research projects that improve health care. Some of these projects focus on research on the use of eMH in routine practice in Germany (see Appendix B for an overview of research projects). (https://innovationsfonds.g-ba.de/)

Ireland **eMental Health – State of the art report:** A report on the current status of eMH and opportunities presented for Ireland. Jointly funded by Mental Health Reform and HSE, the report was launched at an eMEN event in Dublin in October 2018. (https://www.mentalhealthreform.ie/projects/emen-project/news-and-events)

Northern Ireland

A digital hub, centred on mental health education, support and information has been developed by the Northern Area Mental Health Initiative ('The Initiative'). This Initiative is led by Cookstown and Western Shores Area Network (CWSAN), in partnership with Action Mental Health and Nexus NI. It offers free mental health awareness and resilience training, internet safety, sexual abuse and exploitation education to children and young people aged from 8 to 25 in schools, youth clubs and through key contacts such as teachers, youth group leaders and parents' groups.

Northern Health and Social Care Trust (NHSCT) developed an app (released August 2018) called CollaBoraTe. The app has been developed by a group of psychotherapists and clinical psychologists at the Northern Trust Psychological Therapies Service and is now freely available. It offers CBT tools that can be used alongside therapy or independently. (https://appadvice.com/app/nhsct-collaborate/1404309384)

2019

England Since 2019, Live Life To The Full, a new online resource of support courses is being funded by NHS Ipswich and East Suffolk and NHS West Suffolk clinical commissioning groups, and is delivered in partnership with the Norfolk and Suffolk NHS Foundation Trust. These free online courses, written by an expert in CBT, are for the treatment of low mood and depression, as well as problematic thinking styles and behaviour patterns (311).

Northern Ireland

In June 2019, Queen's University Belfast launched an Immersive Technologies and Digital Mental Health Network, a trans-disciplinary partnership of academics, practitioners and technology companies, focusing on therapeutic and pedagogical advances in mental health and social care through digital means. The focus is to increase the accessibility and capacity of immersive technologies among social science researchers, educators and practitioners. (https://www.qub.ac.uk/research-centres/cesi/News/LaunchofImmersiveTechnologies-andDigitalMentalHealthNetwork.html)

Country-specific analyses

Belgium

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Info box 19:
Context of eMH implementation in Belgium

Summary: Even though eMH solutions have an important potential to reduce waiting lists and costs for mental health care, Belgium only shows initial levels of awareness of eMH products and services in various stakeholder groups. eMH-related initiatives and projects are evolving with support from federal and regional government, and higher education is starting to embed eMH in research. However, these processes are moving slowly; in part because of the complex Belgian state structure. To improve and facilitate the implementation of eMH products and services, Belgium needs more alignment and support of policy-makers, including investments in sensitisation campaigns, knowledge exchange, a quality system for eMH, a reimbursement system for eMH and education.

Policy developments and relevant policy documents

- Both eHealth in general and eMH specifically are expected to be among the major agenda points in upcoming years.
- Policy actions on a regional level: *Flemish Action Plan Mental Health* (strategic plan 2017–2019); Jo Vandeurzen Policy paper 2014–2019; ten online care policy actions for the coming years launched in 2015; The policy paper 2019–2024 of Flemish minister of Public health Wouter Beke presents innovation and digitalisation of the health services as one of the strategic goals.
- Policy actions on a federal level: General policy paper *mHealth care in 2014; Action Plan eHealth 2015–2018* (point 19 of the Action Plan eHealth is specifically on mobile health)
- Continued policy actions across all levels of government, with the *Action Plan eHealth 2019–2021*, including, amongst other points, a tool that will allow software developers to be guided towards a formal validation, homologation and registration of their mHealth applications.

Main barriers for eMH implementation

- Low awareness of and acceptance by health care professionals and patients (they rather prefer (some level of) face-to-face contact and have privacy concerns)
- Outdated information technology systems
- Limited options for training and education
- Complex state structure (communities and regions with their own juridical responsibilities; three different languages)
- Current lack of reimbursement system for eMH (but possible in the new Mobile Health Belgium system (see info box 6) under specific strict conditions)

Enabling factors

- Campaigning/sensitisation and knowledge exchange
- Support and opportunities to interact with peers (famous endorsers and believers)
- Involvement of policy makers (e.g. formal guidelines and quality labels)
- Support and involvement of higher level management
- General data protection regulation; more clarity about legal situation on data security; and guidelines regarding eMH products and services

Best practices

- **Improve training and education possibilities**: The "best thesis on online care" award fostered eMH research and was organised to award the best student-run research on eMH and adjacent topics (https://www.flanderscare.be/steunmaatregelen/scriptieprijs-onlinehulp-2017-2018).

Policy developments, initiatives and challenges of eMH implementation in Belgium

Mental health care in Belgium

Mental health care in Belgium is a small but diverse sector that is currently reforming to align the care it offers to patients' needs (i.e. patient-centeredness and community-based care). The aim is to help diminish its historically-grown very strong focus on residential mental health care, to increase treatment effectiveness and to reduce related costs. Access to this very broad and diverse wellbeing and health landscape is not highly structured or controlled, as many people initially contact their GP or social service provider when experiencing mental health problems. In the case of more severe mental health issues, patients are referred to psychologists, psychiatrists, outpatient centres for mental care, psychiatric departments of general hospitals or psychiatric hospitals. Hence, a strong cooperation with/collaboration between diverse groups of stakeholders involved in mental health care is required in order to create sufficient support for the opportunities of eMH in Belgium.

eMH-related policy developments, research projects and initiatives

Belgium currently focuses on prevention and early detection of mental health problems to further optimise care. Interest in the potential of digital services in health care to help achieve this goal is currently on the rise. However, eMH is still relatively unknown to many patients and professionals. Stakeholders are not aware of the possibilities offered by eMH solutions. In a general policy paper in 2014, the Federal Government stated that it believes in an exponential increase in eHealth via self-help possibilities, compliance and patient empowerment (292). Additional policy papers on a regional (Flemish) level illustrate how politicians expect eHealth in general and eMH specifically to be among the major agenda points in upcoming years. One of these initiatives is a validation pyramid for mobile applications in the health sector, which can be used to evaluate the quality and scope of each application. Another one is the BelRAI mobile

tool (a Belgian implementation of the internationally-established Resident Assessment Instrument), which is an assessment tool to measure care-dependency of patients in different sectors. Further examples of the growing interest in eMH are the numerous regional initiatives related to eMH such as the Carewear Onlinehulp Vlaanderen projects (see Appendix B for more information), which are supported by the Flemish and federal governments, and the ten concrete online care policy actions. These actions were introduced in 2015 at a congress by the Flemish government of Welfare, Public Health and Family, of which today a number have already been met.

Challenges for the implementation of eMH

Regulations associated with eMH and its implementation are still rather limited in Belgium. A complex state structure (communities and regions with their own juridical responsibilities and three different languages) leads to slow legislation processes, and an overarching eMH strategy does not yet exist. The current reimbursement system is not yet sufficiently up to date to easily incorporate the reimbursement of eMH services. Some health insurance companies refund online consultations and blended care for specific target groups, e.g. children and adolescents, whereas others do not. This might be improved in the future as, in Belgium, clinical psychologists have been a recognised health profession since 2016, with their services being reimbursed from 2019 onwards. What began as a pilot case, will probably become a standard part of Belgian mental health care. Limited options for training and education are furthermore mentioned as barriers to successful large-scale implementation of eMH in Belgium, in addition to structural difficulties, outdated internet technology systems, lack of technical competencies and limited eMH awareness by patients and professionals. Despite increasing interest in eMH in recent years, awareness and acceptance of eMH by health professionals and patients need to evolve in order to overcome the perceived fear of professionals of being replaced by technology, or service users' concerns that eMH may be too impersonal and non-transparent. Aside from these barriers, there are promising developments as far as research is concerned. eMH is a growing field of interest in higher education in Belgium. Nevertheless, more empirical and both qualitative and quantitative research is needed. One way to foster research on eMH and adjacent topics is the *Best Thesis on Online Care* award at a Flemish level, which awarded the best student-run research on eMH-related topics. However, professionals' and organisations' knowledge of eMH is still rather limited and requires more focus and a strategic approach. Furthermore, the EU General Data Protection Regulation is perceived as a factor strengthening data privacy and its compliance in Belgium, which will improve trust and confidence in eHealth tools.

Conclusion

Belgium needs more alignment between eMH developers and the care sector, as well as the support of policy makers in order to benefit from innovations in health care in the long term. In order to achieve a cultural shift away from sticking to face-to-face-therapy only, investment in campaigning and sensitisation, knowledge exchange, training and general education will be necessary. Co-creation with all stakeholders involved (e.g. information technology specialists, caregivers and patients) will be key in creating successful e-tools. Furthermore, formal (quality) guidelines, transparent information about the quality of tools (e.g. a juridical label of recognition), best practices on implementation and room for discussion, combined with support and endorsement by higher level management, may facilitate eMH implementation in mental health care in Belgium.

France

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Info box 20:
Context of eMH implementation in France

Summary: Compared to other North-West European countries, France appears as a latecomer in terms of the development and implementation of eMH. There is high research interest by universities, with many eMH products and services being used within (research) projects. However, eMH services are not embedded as a core component of the mainstream public mental health care system. Policy focuses on eHealth, but the interest in eMH is growing, as can be seen from regional and local eMH initiatives. Overall, France presents good potential for future uptake of eMH, but needs e-capacity building among service-users, strong leadership and an adequate (legal) framework in terms of quality assurance, reimbursement and funding.

Policy developments and relevant policy documents

- Policy focus on eHealth, but increasing interest in eMH
- 2016: National eHealth Strategy (general recommendations in terms of eHealth) (303)
- 2018: *Roadmap for Mental Health and Psychiatry* (including the action "Mental health promotion 3.0") (299)
- 2018: National health strategy: The bill on the organisation and transformation of the health system, *Ma santé 2022*, is based on five priorities, including the digital transformation of the health system (308)
- 2019: Roadmap for the increased use of ehealth, *Accelerer le virage numérique (Accelerating the Digital Shift)*, including the following public actions:
  - "Tour de France for Digital Health" by ministerial delegates visiting 17 regions in France
  - "Citizen eHealth Workshops" (one in mental health is planned) (310)
- 2019: Ministerial working group on eMH
- 2019: Prospective report on eHealth by the National Authority for Health (Haute Autorité de Santé) (312)

Main barriers

- Lack of acceptance by and negative attitude of health care professionals
- Low trust in digital tools (privacy and data security)
- Human relationship as the perceived key in mental health service delivery
- Lack of coordination/strategy

Enabling factors

- Establish legal clarity and quality of eHealth tools and services
- Establish an appropriate value-based reimbursement and funding framework
- Change management and strong leadership
- Ensure democratic and equal access
- Co-creation and established e-capacity (e.g. training programmes)

Best practice example

- **Large scale implementation**: *Printemps* is a research project led by the French National Institute for Medical Research. It is a web-based and mobile primary suicide prevention intervention tested and evaluated in 40 cities for the general population (see https://www.stopblues.fr/ for more information).

Policy developments, initiatives and challenges of eMH implementation in France

Mental health care in France

In France, mental health care is provided by both the health care sector and the social and health care sector for people with disabilities. In general, GPs, medical psychological centres, and private psychiatrists or psychologists deal with the majority of care in the psychiatric sector. 77 percent of patients are treated on an outpatient basis (313). Concerning the national mental health status, France has high rates of anxiety and mood disorders (314). Access to health care facilities differs by geographical area. By improving access to health care, eMH products and services may address these inequalities.

eMH-related policy developments, research projects and initiatives

In France, mental health policy is defined at national level through a national mental health plan, which is implemented locally by the Regional Health Agencies (ARS). In terms of development and implementation of eMH, France appears as a latecomer compared to other North-Western European countries. In 2016, the French government presented its first national eHealth strategy with general recommendations (303). Since then, texts specifically related to the development of eMH (Action No. 7 of the *Roadmap for Mental Health and Psychiatry*) and, more recently, to the *Acceleration of the Digital Shift* in health, have proposed operational frameworks (299, 310). Decision-makers and legislators have therefore begun to address the issue of digital technology in mental health care with a view to continue maintaining actions and strong leadership to enable the deployment, implementation and evaluation of solutions developed in the field of eMH.

Several projects exist at local or regional levels. The app StopBlues was developed as part of the *Printemps* project, which is evaluated by the French National Institute for Medical Research. It is a web-based and mobile primary suicide prevention intervention tested and evaluated in 40 cities in France and addresses the general population. Another interesting projects is the Papageno programme, which is a French national suicide prevention programme, aiming to prevent suicide contagion, and to promote mutual support and care access, through contemporary communication channels. There is also a programme using telemedicine in geriatric psychiatry (see Appendix B for more information on the projects).

In 2018, several announcements with some good perspectives for the future were made. In June 2018, the French Ministry for Solidarity and Health launched its new *Feuille de Route santé mentale et psychiatrie (Roadmap for Mental Health and Psychiatry*), a political plan indicating the future priorities for the mental health care system. Action No.7, "Promouvoir la santé mentale 3.0" (Mental Health Promotion 3.0) mentions eMH as a specific sub-action (299). Furthermore, the 2019 edition of the *French Mental Health Information Weeks* (two weeks of events on mental health dedicated to the general public) focused on the theme "Mental Health in the Digital Age".

Challenges for the implementation of eMH

Many political steps have been taken in France since 2016, including the recent creation of a ministerial delegation for digital health, the reimbursement of telepsychiatry consultations and the writing of a roadmap specifically dedicated to "accelerating the digital shift" in health. Apart from developments at policy level, the results of a recent qualitative study highlight a fragmentation of points of view on eMH, suggesting that representations of these new technological devices are still far from stabilised (315). Private certification labels and public guidelines on quality criteria for the development of eHealth tools, as well as data protection and privacy related to eHealth tools, are subjects of great concern, indicating that trust in digital tools for mental health is still lacking. Legal clarity and a high quality of eHealth tools and services, co-creation with all stakeholders involved, change management, improvement of users' digital skills, better eHealth literacy, and strong leaders who support actors at local levels and implementation research will all be key for a sustainable implementation process of digital solutions in health care. Apart from the described challenges, France presents good potential for the future uptake of eMH. As described above, research projects exist in collaboration with universities and research sites that specialise in eMH. Furthermore, a low rate of smartphone use and poor knowledge of information technologies are not a reality anymore in France (316). Moreover, current research reveals that patients seem to trust physicians in the field of digital health, and that service users, as well as a new generation of health professionals, see the potential of eMH as an important adjunct to empowered and shared decision-making.

Conclusion

In order to ensure equal access for people in need, an e-capacity/digital health competency among service users needs to be established by providing training programmes for health professionals and service users, for example. This may improve the acceptability and the uptake and use of eMH products and services in France. Overall, creating commitment on a high national level will be required to spread and generalise different local experiences.

Germany

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Info box 21:
Context of eMH implementation in Germany

Summary: Interest in eHealth in general and more specifically in eMH is growing in Germany. Numerous position papers by a number of stakeholders (professional bodies, self-governing bodies or parties) have been published addressing the future role of eHealth in Germany. Private and statutory health insurance companies offer eMH solutions to their clients, but eMH programmes are not embedded as a core component of the mainstream public mental health care system yet. The interest in research related to eMH is high and will provide knowledge for future directions. At policy level, the eHealth law of 2016 was a starting point for establishing a legal framework for the use of eHealth in the German health care system, and the Digital Health Care Act (DVG), which takes effect in January 2020, will further promote the use of eHealth. Nevertheless, in terms of eMH, more legal guidance will be required regarding quality assurance, liability and reimbursement.

Policy developments and relevant policy documents

- 2016: eHealth law: focus on the development of a digital infrastructure
- 2018: The Medical Assembly decided to change the *Professional Code for Physicians* to enable physicians to use remote consultation in routine practice
- 2018: The Assembly of the Federal Chamber of Psychotherapists also decided to change point 5 of their *Professional Code of Psychological Psychotherapists and Child and Adolescent Psychotherapists* concerning the use of media
- 2018/2019: *Pflegepersonal-Stärkungsgesetz* will enable reimbursement of video consultations, irrespective of the indication
- 2019: The goal of the New Expert Council *Health* (appointed by the Minister of Health for the period from February 2019 to January 2023) is to identify suitable framework conditions for evidence-based digital health care in Germany (317)
- 2019: Approval of the Digital Health Care Act *(Digitale-Versorgung-Gesetz – DVG)*, which addresses, among others, the use of health apps in routine care and video consultation

Main barriers

- Low awareness and acceptance of eMH by mental health professionals
- Lack of standards (accreditation, privacy, reimbursement)
- Liability issue for health professionals
- Multitude of players and decision makers (complex roll out)
- Limited training and education of health professionals

Enabling factors

- Support and involvement of professional health care bodies
- Development of a digital infrastructure (standards for telematics infrastructure)
- High involvement of universities in eMH research
- Innovation Fund as an option to test and evaluate innovations in eMH care

Best practices

- **Improvement of standards:** The eMH task force, established by the DGPPN* and DGPs**, developed a set of quality criteria (151).
- **Provision of guidance:** The BfArM*** established a so-called "innovation office" on its website that offers initial guidance for SMEs to support them when entering the health care market. (https://www.bfarm.de/DE/Medizinprodukte/Abgrenzung/MedicalApps/_node.html)
- **Evaluate framework conditions:**
  - The CHARISMHA study developed proposals for the adaption of legal frameworks from a multidisciplinary perspective (funded by the Federal Ministry of Health) (118) (https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/A/App-Studie/charismha_abr_v.01.1e-20160606.pdf);
  - The Fraunhofer Institute for Open Communication Systems (FOKUS) has created a catalogue with over 200 meta criteria for the description and evaluation of health apps aimed at professional societies, self-help groups and associations (available since June 2018) (www.appkri.de).
- **AppQ:** The goal of AppQ is to define a core set of quality criteria (based on AppKri) for structured quality reporting by Health Apps Providers. It is endorsed and funded by the Federal Ministry of Health (https://blog.der-digitale-patient.de/appq-guetekriterien-kernset-gesundheits-apps/).

**DGPPN: German Association for Psychiatry, Psychotherapy and Psychosomatics (Deutsche Gesellschaft für Psychiatrie und Psychotherapie, Psychosomatik und Nervenheilkunde)*

***DGP: Deutsche Gesellschaft für Psychologie*

****BfArM: The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte)*

Policy developments, initiatives and challenges of eMH implementation in Germany

Mental health care in Germany

Psychiatrists, specialists in psychosomatic medicine, GPs, psychologists, nurses, social workers and specialist therapists are engaged in mental health care in Germany in outpatient and inpatient settings as well as in additional services such as centres for psychosocial counselling or social support (318). Data of the Bundesgesundheitssurvey reveal that around 50 percent of people with depression do not receive adequate treatment, and only 20 percent of people with a diagnosis of a mental disorder receive professional support (319, 320). The mental health care system in Germany faces an increasing demand for mental health care service delivery (321, 322). To meet future demand and to prevent a lack of specialists, investment in innovative, interdisciplinary and individually tailored mental health care may be warranted (320, 321).

Overall, the German health care system encompasses a multitude of players, responsibilities and regulations on federal and state levels.

eMH related policy developments, research projects and initiatives

At policy level, the eHealth law, which took effect in 2016, focuses on the adoption of the electronic health insurance card and the development of a digital infrastructure. Together with the *Pflegepersonalstärkungsgesetz* (2019) and the *Digitale-Versorgung-Gesetz* (2019), these legislations will facilitate the digitalisation of health care in Germany. However, there is no overarching strategy behind the use of eHealth yet, and eMH is not addressed specifically by legislators. According to governmental parties, the digitalisation of health care is currently one of the biggest challenges for the health care system – accessing digital interventions, interoperability and digital security in health care are mentioned as cornerstones of future work in this field (323). Moreover, analyses reveal that the digitalisation of health care may con-

tribute to economic growth in Germany (324, 325). The Federal Ministry for Economic Affairs and Energy underlines the necessity of adequate structures and an open dialogue to foster this development (326) (327). The Federal Ministry of Health appointed the New Expert Council Health for the period from February 2019 to January 2023. Its goal is to identify suitable framework conditions for evidence-based digital health care in Germany (328). Furthermore, the Federal Ministry of Health has started a 'health innovation hub', which is meant to identify innovative ideas in the field of digital health care (329).

Besides these ongoing initiatives at governmental level, professional bodies and self-governing bodies published opinion papers to guide and foster the future role of eHealth and eMH in Germany (e.g. (330, 331)). The professional bodies involved in mental health care stress, among others, the importance of ensuring access to eMH products and services for all patients, the expertise of educated staff, the important role of face-to-face diagnostics as well as the necessity of rules in cases of emergencies (332-336).

Furthermore, in May 2018, the members of the Assembly of the German Medical Association decided to modify the *Professional Code for Physicians* concerning the use of media (see info box 21 for more information). In November 2018, the Assembly of the Federal Chamber of Psychotherapists also decided to liberalise section 5 of their *Professional Code of Psychological Psychotherapists and Child and Adolescent Psychotherapists* concerning the use of media (337).

Altogether, these recent developments promote and further contribute to the use of digital solutions in health care in Germany.

Info box 22:
Professional codes determine the use of media in health care in Germany

According to the 2014 version of the *Professional Code of Psychological Psychotherapists and Child and Adolescent Psychotherapists*, it was possible to use electronic communications tools for individual clinical management, but only in justified cases and under specific conditions (i.e. diagnosis and patient education need to be ensured in person) (§ 5 (5)) (338). Furthermore, state-level Associations for Psychotherapists were able to approve research projects, which offer psychotherapeutic treatment, exclusively via electronic communications media. In November 2018, the 33rd Assembly of the Federal Chamber of Psychotherapists decided to liberalise section 5 of their Professional Code of Psychological Psychotherapists and Child and Adolescent Psychotherapists in order to enable video consultations under the specified conditions mentioned above (339).
The Professional Code for Physicians was stricter concerning the use of media – even in terms of research. Only in Baden-Württemberg (since 2016) and in Schleswig-Holstein, does the *Professional Codes for Physicians* allow research projects that exclusively use telehealth interventions (with prior approval by the respective Association of Statutory Health Insurance Physicians (§7 (4)) (340). In May 2018, the German Medical Association decided to modify the Professional Code for Physicians in order to enable health professionals to use remote consultation. The decision has been approved by the large majority of the German Medical Association members, may have a signalling effect and can be seen as another step forward in facilitating the use of digital health in German health care.

Challenges for the implementation of eMH

In general, eMH is widely perceived as an important adjunct to conventional treatment rather than as a replacement of traditional therapy (332-336).

Numerous eMH research projects are already in place (see Appendix B for more information), and several private and statutory health insurance funds recommend and offer their members specific eMH solutions. The attitude of health care insurance funds in Germany towards eMH appears to be quite positive.

The German Innovation Fund is a research programme created by the Federal Government that aims at fostering the development and evaluation of innovative care processes, implementing innovations faster into routine care and closing the gap between research and practice (341). Among others, the Innovation Fund also funds several projects related to eMH (e.g. eRECOVER, HELP@APP and PSYCHOnlineTHERAPIE). Currently, eMH is not used as a large-scale option in the German mental health care system, and these projects may generate relevant information for the process of eMH implementation.

In order to avoid a fragmented and limited deployment of eMH, it will be key to establish a legislative framework that encompasses defined quality criteria, liability issues, reimbursement and the digital infrastructure to enhance the use of eMH in Germany. Professional bodies foster discussions concerning an appropriate framework for the large-scale implementation of eMH by suggesting quality criteria for internet-based interventions (DGPPN and DGPs) or by publishing a position and guidance paper (BPtK).

Many German studies concerning eMH awareness and acceptance focus on patient views and indicate that the acceptance of and attitude towards eMH is quite ambivalent. According to a recent survey, advantages of eMH such as flexible, timely and anonymous help are recognised (342, 343). But fear of being left alone in crises, reluctance to use eMH products and services due to data protection issues (131, 342), fear of data leakage and loss of personal data plus transparency issues (131) play an important blocking role for service users with regard to eMH. Recently, an 8-item questionnaire on attitudes towards telemedicine was published, which can be used for laypeople, physicians and psychotherapists (344). This questionnaire was tested on a representative sample of the public in Germany and a small sample on professionals, and indicated that non-professionals seem to be more critical with regard to the use of internet services or telemedicine for mental health care (345). There is less research about the attitudes of mental health professionals in Germany, but the potential of eMH in mental health prevention and care seems to be recognised (346, 347).

Conclusion

With the ratification of the Digital Health Care Act (DVG), insured persons will be entitled to digital health applications. Digital health applications might soon be prescribed by doctors and might gain access to the primary healthcare market. At request of the provider, the application willbe audited by the Federal Institute for Drugs and Medical Devices (BfArM) for compliance with all legal requirements, data protection and data security as well as for positive healthcare effects. If the application complies with all requirements, it will then be included in the directory of reimbursable digital health applications. However, it is criticised that evidence for positive healthcare effects can be sufficiently based on case reports or expert opinions and hence no scientific evidence is needed. The digital health application must be a medical device with a low risk class, i.e. risk class I or IIa (according to the Medical Device Regulation) in order to be listed as reimbursable. Stand-alone software, which prepares and provides information to decide on diagnoses or treatments, would be classified in risk class IIa. Yet, if an eMH product or service may directly or indirectly cause a serious deterioration in health, it will be categorised in a higher risk class. As a result, many health applications might be excluded from the new regulation. However, existing quality criteria (DGPPN and DGPs, BPtK, or Bertelsmann Stiftung (AppQ)) are in place that may promote establishing adequate certification processes. A national eHealth strategy should encompass eMH and consider its specific requirements.

Ireland

McDaid, S., Cullen, K., Topolska, D. (Mental Health Reform)

Info box 23:
Context of eMH implementation in Ireland

Summary: In Ireland, there is now quite strong interest in eMH at policy and practice levels. A variety of eMH products and services are available, but so far there is not much direct deployment as part of the mainstream public mental health care system. However, a number of policy initiatives are currently addressing eMH and are likely to accelerate developments. These include a *Youth Mental Health Task Force* report, initiatives by the Department of Health (Mental Health Unit) and the government Minister responsible, and attention to eMH by the Oversight Group supporting an updating of overall mental health policy. The eMEN project in Ireland is influencing and supporting many of these developments, has triggered a lot of activity and interest, and is recognised as a key contributor to the evolution of the field.

Policy developments and relevant policy documents

- 2006: *A Vision for Change* – overall mental health policy framework *(currently being updated)*
- 2013: Irish eHealth Strategy: some reference to mental health, but limited
- 2017: Evidence review for a refresh of *A Vision for Change* – suggests more attention to eMH
- 2017: *Youth Mental Health Task Force* report recommends investment in eMH
- 2018: Oversight Group for a refresh of *A Vision for Change* – is addressing eMH
- 2018: Department of Health/Minister (mental health) announces some eMH plans

Main barriers

- Structural and capacity issues in the public mental health care system
- Underdeveloped IT infrastructure (including lack of access to equipment at frontline)
- No overall eMH strategy, although coherence in activity is increasing
- Lack of structures for developers, clinicians and users to work together
- Preference for existing approaches and/or resistance to change amongst some professionals

Enabling factors

- Large scale pilots – demonstration, proof of concept, etc. – would help accelerate deployment
- Targeted smaller-scale projects (e.g. eMH for empowerment of people with enduring and more severe mental health issues) would encourage attention to specific/important topics
- Structures to bring together developers, clinicians and users, and thereby foster innovation
- Development of standards and quality criteria, including safety and data protection
- eMH in initial/continuing professional development for mental health professionals

Best practices

Use of eMH on a national level:

- The sector of non-governmental organisations is already quite active in using eMH to enhance services; examples include AWARE (https://www.aware.ie/education/life-skills-online-programme/); Bodywhys (https://www.bodywhys.ie/recovery-support-treatment/other-resources/seemyself-programme/); Turn2Me (https://turn2me.org/).
- HSE Digital mental health projects – telepsychiatry, crisis text, online CBT, etc.
- HSE primary care: eWell online CBT programme for adolescents now under development.

Policy developments, initiatives and challenges of eMH implementation in Ireland

Mental health care in Ireland

Overall mental health policy in Ireland is currently guided by *A Vision for Change* (301). This framework was published in 2006 and is currently being refreshed. There is also an eHealth Strategy (published in 2013) that makes some reference to eMH (302). More recently, a report from the *Youth Mental Health Taskforce* recommended implementation of eMH products and services (295).

The Irish health system (and the mental health system as part of this) is characterised by a unique public-private mix of service funding, provision and user access. In addition to the public-private mix, third sector organisations are also important players in the mental health care and support system. Moreover, third level students can also access primary care type mental health services provided by their colleges, and employees in large organisations may have access to such services through employee assistance programmes (EAP). There are public mental health care programmes operated by the HSE for access to psychological and counselling services at primary care level. This includes in-house psychologists and referral to external counsellors under the *Counselling in Primary Care programme* (CIPC). Both have limited capacity and waiting lists, and consequently there is substantial unmet need for access to psychological support at this level. Public services also have difficulties in recruiting sufficient numbers of professionals. eMH has a role in addressing these challenges, and there are already some initiatives underway. Mental health non-governmental organisations are also active in this field and are increasingly deploying eMH solutions to extend their capacity and reach.

eMH-related policy developments, research projects and initiatives

The HSE (the Irish Health Service) as well as third sector organisations (that receive funding from the public health system to provide complementary or ancillary services) clearly have a positive and receptive orientation to eMH, and are developing strategies in this field. The public mental health care sector has been active in developing eMH products and services for the last few years. A supported online CBT programme for adolescents (eWell) is being developed within the HSE primary care psychology service, with plans for deployment at primary care level across the country with support provided by assistant psychologists. The HSE is also developing a range of digital mental health projects including telepsychiatry, crisis text and online CBT. Furthermore, it is involved in the Bipolar Lighthouse project (under the eHealth Strategy initiative), which will include a portal allowing patients to access their care plan, a mobile app, early warning sign monitoring, a means of contacting service professionals via the portal, and a health care professional portal.

A number of other organisations have also developed eMH solutions. Third sector organisations such as AWARE and Bodywhys have engaged in the development of eMH products and services (e.g. See*my*Self, Life Skills Online, Turn2me: see Table 3, Appendix B); in some cases through collaboration with the main commercial eMH player SilverCloud. The SilverCloud product suite is designed as a supported online CBT delivery platform and is used by mental health service providers, third level institutions and employee assistance schemes, although most deployment is in the UK and US so far.

University-based research and innovation has played an important role in the development of a number of the current Irish eMH offerings (e.g. SilverCloud and PeskygNATs). Some have received funding from public technology innovation sources and, also from private venture capital sources in some cases. There has been a limited amount of research on efficacy and effectiveness of eMH in Ireland, so further research and evaluation in the Irish context is important.

Most professional bodies in the mental health field in Ireland appear not to have specific eMH policies or positions; on the other hand there does not seem to be any provider policy or regulation in Ireland that

restricts remote consultation in this field. The *Irish Association for Counselling and Psychotherapy* has published guidance on online counselling, although the focus is on telemental health rather than eTherapy (348). There is also a guide on *Technology, Mental Health and Suicide Prevention in Ireland – a Good Practice Guide* commissioned by the HSE's National Office for Suicide Prevention. Mental Health Reform and the HSE also funded a report on *eMental Health: State-of-the-art & Opportunities for Ireland* that helps to map out the eMH ecosystem to inform policy and practice in Ireland (53).

Challenges for the implementation of eMH

In stakeholder interviews, issues or concerns raised around eMH included the undesirability of replacing face-to-face services (the therapist-patient relationship is key in the therapeutic setting and irreplaceable), limited digital knowledge amongst health professionals, and concerns around confidentiality, data protection and storage issues. In addition, for eMH progress it is important to put in place suitable certification/standards to ensure apps/programmes adhere to key attributes (e.g. safety, confidentiality, ease of use). A recent review of the field mentions many of these issues (53). It suggests that large-scale pilot projects would be very helpful, enabling demonstration and proof of concept in the real world of public mental health care. The report also recommends the creation of structures to bring together developers, mental health sector providers/professionals and end users, and facilitate their inter-working. This is already happening to some extent in the university-based innovation area, but could be extended to the broader mental health provider/practitioner sector as well.

Conclusion

Overall, interest in eMH is strong in Ireland, on both policy and practice levels. These include a *National Youth Mental Health Task Force Report* recommendation for increased investment in "age-appropriate, scalable digital youth mental health supports", initiatives by the Department of Health (Mental Health Unit) and the government Minister responsible, and attention to eMH by the Oversight Group supporting an updating of overall mental health policy (*A Vision for Change* (301)).

While a number of eMH products and services have been developed organically, and are already publicly available, there is not much direct deployment in the mainstream public mental health care system yet. However, a combination of 'top-down' and 'bottom-up' developments have begun to converge and encourage eMH deployment. eMEN has actively supported developments at both levels through fostering information exchange, awareness-raising, stakeholder consultations and other activities. From the 'top-down' perspective, initiatives by the Department of Health and the Minister with responsibility for mental health are being implemented through pilots in the HSE mental health services at primary and secondary care levels, as well as initiatives driven by HSE services themselves. A number of these are building on more 'bottom-up' initiatives by third sector mental health organisations that have begun to provide eMH services on their own initiative (including online counselling, online CBT programmes and other applications).

Despite the political commitment to eMH and developing interest and activity within the HSE, structural and capacity issues in the public mental health care system, and an under-developed IT infrastructure, make system-wide innovation difficult. Overall, the goal is to overcome the barriers to upscaling and accelerating development and deployment of eMH across the system. More 'proof of concept' trials and agile evaluation approaches are required to drive implementation at scale for common mental health conditions, as well as targeted smaller-scale projects (e.g. eMH for empowerment of people with enduring and more severe mental health issues) to encourage attention towards specific/important topics. Practical guidance on implementation and training on eMH for mental health professionals is also important. The development of standards and quality criteria, and structures to enable collaboration between developers, clinicians and users to foster innovation, will also facilitate the adoption of eMH.

The Netherlands

Vlijter, O., Versluis, C., Hiemstra, H.J. (Stichting Arq)

Info box 24:
Context of eMH implementation in the Netherlands

Summary: eMH development and related research started about ten years ago. Although eMH is available to most mental health providers, the structural use of eMH in routine practice is only +/- 15%. Due to a lack of national strategy in terms of eHealth and eMH, the deployment of eMH developed very fragmentally in the early years. The interest and involvement on the political level is growing and leads to more investment and coordinated approaches. Implementation research, a change in the reimbursement structure and a clear benefit may contribute to enhance the implementation of eMH on a larger scale.

Policy developments and relevant policy documents

- 2014: eHealth objectives set by the Ministry of Health, Welfare and Sports (yearly evaluation and (small) adaptation of objectives based on the monitoring of Nictiz (centre of expertise for eHealth))

Main barriers

- Lack of training and education of (future) mental health care professionals
- Lack of implementation research and continuity in research (research-to-practice gap; unproven effectiveness; limited co-creation)
- Inadequate reimbursement structure and remuneration model
- Privacy issues and non-transparency (e.g. quality control)
- Undefined (evidence-based) benefit of eMH

Enabling factors

- Long-term vision (added value) with standards (e.g. quality label), guidelines, funding and adequate knowledge (training and education of (future) mental health care professionals)
- Dissemination, involvement and support by the government (established in a structured and aligned way)
- Improving the digital knowledge of the general population
- Studies/research initiatives that evaluate effectiveness, including implementation research

Best practice

- Improve training and education possibilities: Many psychology students in the Netherlands receive introductory courses on eMH. However, these minor courses are not obligatory and do not prepare the participants to work in a 'blended care' setting. The quality and content of these courses is not regulated at the national level, and each university is developing its own courses. The Open University first started offering eMH courses (with an introduction and advanced course): see https://www.ou.nl/-/PM1002_E-mental-health-interventies.

Policy developments, initiatives and challenges of eMH implementation in the Netherlands

Mental health care in the Netherlands

Mental health care in the Netherlands focuses on patient-centred care and connecting health care with social support. eHealth is one component to achieve and support this overall aim. eMH development and research started about 10 years ago in the Netherlands, but the market developed in a fragmented way. At present, almost every mental health care institution provides some form of eMH service, but there is no widespread use of it. Only around 15 percent of mental health providers offer eHealth as part of their treatment (349). As a result, there is only limited added value for the people in need. In consequence, there is a need to scale up the use (implementation) of eMH so that it becomes commonplace in mental health care with a clear benefit.

eMH-related policy developments, research projects and initiatives

In the early years of eMH development, the government did not work in a coordinated way. This led to the fragmented deployment of eMH. In 2014, the Ministry of Health, Welfare and Sports set three objectives for the development of eHealth to be realised within five years:

- improved access to medical records ("At least 80% of chronically ill people should have access to their own medical records by 2019, and at least 40% of other members of the population");
- health monitoring ("By 2019 75% of chronically ill people and vulnerable elderly people should be able to monitor certain aspects of their own health and share the data with their health provider");
- online contact with care provider ("People receiving care and support at home should be able to communicate with their care provider 24 hours a day via a screen, if they wish") (291).

Nictiz, the national competence centre for eHealth, publishes an annual progress report, which also refers to eMH in terms of availability, use and practicability. In 2017, Nictiz indicated that there is still a long way to go to meet the goals set for 2019 (293). In recent years, Dutch policy-makers became aware of the opportunity offered by eHealth services and started to address this topic in a more coordinated and ambitious way. Since 2012, for example, there is the National Implementation Agenda eHealth, a collaboration between patient federations, general practitioners and health insurance companies, which aims to develop a coordinated approach of the implementation of eHealth (350). More recently, in 2017, the *Acceleration programme information exchange between patient and professional* (VIPP) started. This government-funded programme firstly aims to implement necessary standards so that information exchange is possible. Organisations that apply for a grant need to make sure that standards, which are set by MedMij and the Information Beraad (Information Board) (see Appendix B), are being met. Secondly, VIPP aims at introducing value-based eHealth and eMH.

In 2017, the Dutch Health Care Authority published a report on the state of mental health care in the country. One of the Authority's conclusions is that a shift has taken place from specialised to basic and (GP level) primary (mental) care, so that now more patients are treated in basic/primary (mental) care rather than in specialised care. Moreover, waiting list times are often long, especially for people with autistic spectrum disorders or personality disorders. To resolve this, a national approach was launched in which the Ministry of Health, health care insurers, caregivers and local authorities developed an action plan. For example, actions to reduce waiting lists are thorough screening and preventing unnecessary treatment. Moreover, care givers and health insurers should make good and specific (multi-year) agreements about the treatment of people with personality disorders and autism. On the GP level, the use of eMH is now very common and structurally integrated in treatment approaches (patients who cannot be treated on the GP level will move to the basic or specialised mental health care level).

On the other hand, the development of eMH products, services and pilots is very promising and manifold in terms of mental disorders to be addressed (depression, anxiety, post-traumatic stress disorder, etc.) and in terms of the format (computer-based online therapy with app support, wearables or platforms).

Challenges for the implementation of eMH

eMH research has mainly focused on effectiveness and cost-effectiveness (351, 352), but the added value is often not clear and efficiency gains are still low. Other barriers for the large-scale implementation of eMH are the research-to-practice gap, inadequate funding (353) and reimbursement structures (354), limited acceptance by stakeholders involved and a lack of blended treatment protocols or guidelines (see Monitoring report 2017) (293, 355). Moreover, eMH is not yet integrated into the curricula of higher education. eMH courses are only offered on a voluntary basis.

A long-term vision with standards (e.g. quality label), guidelines and adequate knowledge dissemination needs to be established (356, 357). Involvement and support by the government are required to approach this topic in a more structured and aligned way (358). This includes funding, training and education of (future) mental health care professionals and improving the digital literacy of the general population.

Conclusion

Overall, implementation needs to be the centre of attention not only on the local level, but also on the research level. A collaboration between IT developers and the care sector may be warranted to avoid technical issues and achieve sustainable results (co-creation).

United Kingdom

Thorpe, L., Murphy, C., Elliott, I., Pollard, A. (Mental Health Foundation)

Info box 25:
Context of eMH implementation in the United Kingdom

Summary: Since devolution, the health systems in the United Kingdom (England, Scotland, Wales and Northern Ireland) have developed different systems of governance and different methods of providing care and pursue differing policies, with different funding and priorities. Developments in the area of eMH, therefore, differ significantly between the four countries. eMH has a key strategic position in mental health policy in England, with comparatively lower profiles in Northern Ireland, Wales and Scotland.
In England, eMH is accelerating (>50% GPs use eMH) with a focus on self-management. Services such as moodgym and Big White Wall are often commissioned by Scottish NHS Boards (and also in other parts of the UK) and education institutions. Commercial organisations have primarily taken the lead on the development of digital mental health innovations in the UK: various industry-produced e-therapies have been commissioned across the UK's NHS, and apps have been listed on the NHS website. However, there is a pressing need for effective joint-working between industry, clinical and research communities, health care providers and end-users to ensure that eMH in all four countries of the UK is engaging, acceptable, evidence-based, scalable and sustainable.

Policy developments and relevant policy documents

- 2016: England: *Mental Health Five Year Forward View*; 2018–2019: new NHS 10-Year Plan (forthcoming)
- 2016: Scotland: *The Health and Social Care Delivery Plan*
- 2017: Scotland: *Mental Health Strategy* 2017–2027
- 2018: Scotland: *Digital Health and Social Care Strategy*
- 2017: Northern Ireland: *Northern Ireland's Strategy*

Main barriers

- Limited knowledge and guidance about how to implement digital approaches
- Limited awareness
- Limited co-creation between developers, providers, end-users, research and clinicians
- Translation of policy announcements into action on the local level

Enabling factors

- Key position in strategic approaches and foregrounded in a number of high-profile policy documents in England – commitments made in the *Mental Health Five Year Forward View*.
- Ensure that mental health is considered across all government policies, not only in health (the Mental Health in All Policies approach).

Best practices

- **Improve standards:** Development of Mental Health Global Digital Exemplars – selected Mental Health Trusts – and their Fast Followers, to embed new technology and test new approaches. Improve research on implementation.
- **IAPT project:** The Improving Access to Psychological Therapies (IAPT) programme has ambitious goals for offering services to people with anxiety and depression, which can only be met through digital solutions. NHS England has set up a new digitally-enabled therapy assessment programme, where up to 14 digital therapy products will be assessed for use in IAPT services by 2020.

Policy developments, initiatives and challenges of eMH implementation in the United Kingdom

Mental health care in the United Kingdom

In the UK, health systems are a 'devolved' matter and eMH policy is developed by the Westminster Parliament (for England), the Scottish Parliament, the Welsh Assembly Government and the Northern Ireland Assembly.

Mental health care in the UK is available under the National Health Service (NHS) (the NHS is a publicly-funded national health care system, which is available universally). There is a mixed economy of provision from the public, voluntary and private sectors, and a private health care system operates alongside the NHS. The levels of mental health problems in the UK are causing significant concern. The most comprehensive recent prevalence study for England, the 2014 *Adult Psychiatric Morbidity Survey* (APMS), found that every week, one in six adults experiences symptoms of a common mental health problem such as anxiety or depression; and one in five adults has considered taking their own life at some point (359). Similar levels of mental ill-health are seen in Scotland, Wales and Northern Ireland, with the highest levels of mental distress occurring in Northern Ireland (360-362).

Historically, mental health provision, research and policy in the UK has been neglected compared to physical health. The 2007 APMS found that 24 percent of people with a mental health problem such as depression or anxiety accessed treatment. While this had risen in 2014, it was only to 37 percent. The current Westminster government and the previous administration (2010–15) have made mental health a priority area and its visibility in the policy arena has been growing. Recent announcements by the government have recommitted to giving mental health 'parity of esteem' with physical health, and investment in mental health services is increasing.

eMH-related policy developments and research projects and initiatives

There has been much greater activity on research, dissemination, implementation and policy of digital mental health in England compared to Wales, Scotland and Northern Ireland. While services such as moodgym and Big White Wall are often commissioned by Scottish NHS Boards and education institutions, and in other parts of the UK, there is a higher level of digital health engagement in England.

England

Digital mental health has been strongly foregrounded in a number of high-profile policy documents in England, and has taken a key position in strategic approaches to mental health. For example, the cornerstone of the current mental health strategy in England, the *Mental Health Five Year Forward View* (MHFYFV), made a commitment to expanding access to digital services and ensuring investment in digital infrastructure (116). Digital approaches have been placed at the heart of health approaches more broadly, and the National Information Board has argued that these have a particular value within mental health (363). The Department of *Health's Framework for Mental Health Research* gave a strong profile to digital approaches and highlighted the opportunities offered by the digital sector (364). With the development of *Mental Health Global Digital Exemplars* to test new approaches, there is a clear intention to place England at the vanguard of digital innovation in mental health.

eMH solutions are increasingly being adopted by services, and this is driving further innovation. The *Improving Access to Psychological Therapies* (IAPT) programme aims at increasing access to mental health services for common conditions, and has ambitious goals for offering services to people with anxiety and depression with the help of digital solutions (telephone, video and instant chat). NHS England have set up a new digitally-enabled therapy assessment programme, where up to 14 digital therapy products will be assessed for use in IAPT services by 2020 (143). A 2015 survey of the e-therapies being used for stress, anxiety and depres-

sion in England found that 13 different web apps and 35 different smartphone apps for depression, anxiety or stress were available either though referral services or the online NHS Apps Library (365).

Scotland

The Scottish government recently released the *Mental Health Strategy 2017–2027* with only cursory references to digital approaches. However, it does contain a specific action to develop a digital tool to support young people with eating disorders (296). Moreover, the *Health and Social Care Delivery Plan* (2016) refers to computerised cognitive behavioural therapy (cCBT) services as a way to improve access to mental health support and aims to roll out cCBT services nationally by 2018. In Scotland, the overall digital strategy is set in the *Digital Health and Social Care Strategy*, published in Spring 2018, in which eMH is not explicitly mentioned but includes the following aspiration for service users: "I have access to the digital information, tools and services to help maintain and improve my health and wellbeing". This has the potential to include activities to connect the needs of mental health services and users with digital infrastructure investments.

Northern Ireland

Digital work is featured only minimally in Northern Ireland's strategy for health (306), and there is no mention of mental health in the overarching digital strategy for Northern Ireland (366). However, the report on the configuration of health and social care services in Northern Ireland, *Systems, Not Structures* (October 2016), recognised the valuable contribution of telecare, telemonitoring and electronic assistive technologies, referring to the eHealth Strategy as the policy driver (367).

In addition, a digital mental health hub has been launched for young people (March 2018) developed by the Northern Area Mental Health Initiative, a project led by Cookstown and Western Shores Area Network, in partnership with Action Mental Health and Nexus NI. The new one-stop mental health and resilience digital hub was created to complement and reinforce the learning provided through the initiative's free awareness-raising workshops.

The hub offers age-appropriate platforms, through a bespoke website, for young people, their families and the professionals who support them. Digital tools are provided on the hub for young people to have their voice heard, take part in surveys, lobby local commissioners and policy makers, create society shifts throughyouth culture ('youth quakes'), build resilience walls and participate in innovative social media platforms to inform service development.

Finally, to support the implementation of "mental health core and enhanced standards", T*hriving at Work: the Stevenson/Farmer review* (October 2017) recommended that individuals get "clearer advice on using appropriate digital support, which has the potential to provide low cost, scalable support for employees"; that "NHS bodies should provide clear ratings for apps and other digital platforms which provide mental health support"; and that "Digital tools and products are an enabler of change and there is a significant opportunity for low cost, scalable interventions in workplaces". The Government accepted all of the report's 40 recommendations when it responded in December – including that the HSE revise its stress guidance to address mental health issues caused by issues beyond the workplace.

Wales

There is only a low-key role for digital approaches within the Welsh Assembly's delivery plan for improving mental health in Wales, with digital rights included as part of an educational plan for children and young people. More recently, steps are being taken to develop evidence standards for digital health care technologies in Wales. On May 29th 2019, a joint workshop took place between Health Technology Wales and Digital Health Ecosystem Wales to explore what needs to be done to adopt a Framework for the Wales context. This will include digital mental health products.

Challenges for the implementation of eMH

Accordingly, the challenges in each jurisdiction differ in terms of eMH implementation. NHS England have been investigating the relatively low take-up of digital tools in IAPT services, and identified a number of barriers for services, managers, commissioners and therapists. These include: lack of knowledge about digital mental health (what is available and what works); lack of knowledge and guidance about how to implement digital approaches; and difficulties around communication between digital mental health developers and those running services (for example in terms of what evidence is required and how this should be presented) *[Personal communications, Mental Health Foundation, January 2018]*. Analysts have suggested that the national guidance body NICE (National Institute for Health and Care Excellence) acts as both a facilitator and a blocker of innovation in digital mental health, because once a programme or app has been endorsed by NICE, this can close the door on competition from others (365). The app that has been endorsed by NICE often does not develop further because doing so risks invalidating the endorsement. Overall, it is unclear whether the change being pushed from the top aligns with the realities and priorities at local level. In contrast, the main issues encountered for the implementation of eMH in Wales are the confidentiality and privacy issues associated with sharing information online, lack of technology infrastructure (e.g. poor WLAN connection), equal access options (such as the availability of budget for the requirement for Welsh-language versions), limited knowledge about how to best use online and eMH solutions, and other considerations (e.g. professional, legal, social or financial).

In Northern Ireland, a lack of leadership and accountability due to the suspension of the Northern Ireland's Assembly hampers any eMH developments.

While there are thus significant challenges in all of the UK countries, over the coming years eMH is likely to be a growth area in the UK.

Conclusion

While there is wide variation in how and to what extent England, Scotland, Wales and Northern Ireland are engaging in eMH, there is an overarching sense of optimism and positivity around the potential of these technologies in the UK. There is also important political energy in this arena and levels of investment in digital mental health are increasing, though to varying degrees in each of the UK countries. The key concern within the sector is ensuring that these policy announcements translate into action on the ground and to ensure that eMH is considered across all government policies not only in mental health, but also in health generally and in wider, cross-government policies (the Mental Health in All Policies approach).

European context

Gaebel, W., Trost, N., Diekmann, S., Lukies, R., Zielasek, J. (LVR-IVF)

The EU is an economic and political union of 28 Member States (as of November 2019) comprising large diversities in terms of culture and health care governance. When aiming for successful implementation and use of eMH in Europe, those diversities and a wide range of further variables need to be considered. As depicted in the country profiles above, Member States of the EU considerably differ in terms of eMH implementation in clinical practice. Yet, despite these differences, all EU Member States have in common that eMH is a relatively new and emerging field. There are several transnational challenges: there is a general lack of regulatory frameworks so that clinicians are uncertain about liability issues and remuneration matters. Joint EU quality standards for eMH products and services would be warranted to ascertain the highest possible standards. Medico-ethical guidelines may need to be amended or tailored to answer questions emerging with eMH. Legal and technological interoperability between eMH solutions and other elements of the health care system may need to be developed. A European approach – such as one initiated with this Transnational Policy – may be an appropriate way to address these challenges and to support the development of eMH in Europe. It will be important to consider and build upon the EU's past actions regarding eMH. Hence, the following chapter will briefly outline relevant European documents, policies and actions. So far, there are no EU policies that specifically address eMH. Table 2 presents a chronology of past developments in mental health and eHealth (Note that not all documents and actions presented in Table 2 may be directly related to eMH. Nevertheless, they were or still are of great significance for the development of mental health or eHealth).

Much progress with regard to mental health and eHealth has been made within the past 15 years. Action plans and policies have been developed and working groups have been formed. While some documents mentioned in Table 2 are primarily listed for the purpose of completeness, others still have a direct or indirect effect on (e-)mental health care.

For instance, CEF Transport, the work of the eHealth Network, the Code of Conduct on privacy for mHealth apps, the European Framework for Action on Mental Health and Well-Being, and the European Interoperability Framework are all relevant EU actions and documents for eMH. CEF Transport is the EU's key funding mechanism for eHealth (374). Overall, it supports digital services infrastructure (DSI) projects (including eHealth) that facilitate the development of a Digital Single Market and promote the interconnection and interoperability of national, regional and local networks. The eHealth Network influences eMH in so far that it works towards a common vision and strategy for eHealth in Europe (371). It aims to foster cooperation between EU Member States, ensure interoperability and develop guidelines, all of which are vital for the development and implementation of eMH. The European Framework for Action on Mental Health and Wellbeing affects eMH on another basis. It helps EU Member States to review their mental health-related policies and share experiences regarding the improvement of policy effectiveness and efficiency (46). The Draft Code of Conduct on privacy for mHealth apps has yet another focus. Its aims are to promote trust among users of mHealth apps and to provide a competitive advantage to complying developers (156). One overarching document of significance for eMH is the New European Interoperability Framework (373). Interoperability is one of the key factors determining the (successful) implementation of eMH and needs to be ensured on several levels. Not only information technology infrastructure, but also legal/regulatory bodies and processes, policies, care processes and information exchange need to be interoperable. Following a first EIF in 2010, a new European Interoperability Framework was adopted in 2017. The new EIF consists of 47 recommendations on how public administrations can improve the setup and governance of interoperable digital public services (373). Applying the framework is voluntary but highly recommended in order to enable a successful implementation of eMH on all levels.

Table 2: Chronology of European documents and actions relevant for eMH (including mental health (yellow) and eHealth (blue))

Year	Document/action	Aims
2004	eHealth Action Plan	Increase the awareness regarding eHealth and the deployment of beneficial eHealth systems and services (368).
2005	Green Paper on mental health	Stimulate a debate on how to improve mental health care (369).
2008	European Pact for Mental Health and Well-Being	Strengthen the cooperation between Member States, relevant stakeholders and EU institutions (370). Five objectives: 1) preventing depression and suicide, 2) mental health in youth and education, 3) mental health in workplace settings, 4) mental health of older people, and 5) combating stigma and social exclusion.
2011	eHealth Network	Define a common vision and strategy for eHealth in Europe; foster cooperation between Member States; ensure interoperability of electronic health systems and eHealth; develop guidelines.
	eHealth Governance Initiative (2011–2014)	Enhance cooperation between Member States and create a mechanism that links the political and operational levels (371). (Preparatory body for eHealth Network decisions.)
2012	eHealth Action Plan (2012–2020)	Propose a set of 16 actions in four areas (42): 1) achieving wider interoperability in eHealth services, 2) supporting research, innovation and competitiveness in eHealth, 3) facilitating deployment and adoption of eHealth, and 4) promoting international cooperation on eHealth at a global level.
	eHealth Stakeholder Group	Assist the European Commission in preparing legislative proposals and policy initiatives; support the eHealth Network; give input on the design, implementation and evaluation of eHealth policy activities.
2013	Joint Action on Mental Health and Wellbeing (2013–2016)	Development of a framework for action on mental health policy matters; contribution to the promotion of mental health, the prevention of mental illness, improvement of care, and social inclusion of people suffering from mental disorders.
2014	Green paper on mobile health (mHealth)	Identify the best way to unlock the potential of mHealth (372).
	Connecting Europe Facility (CEF) Transport	Support digital services infrastructure (DSI) projects, which facilitate the development of a Digital Single Market and promote the interconnection and interoperability of national, regional and local networks. (Replaces eHealth Governance Initiative.)

Year	Document/action	Aims
2015	European Mental Health Action Plan 2013–2020 (WHO)	Propose action to strengthen mental health while focusing on seven interlinked objectives (13). Four core objectives: 1) equal opportunity to realise mental wellbeing throughout a person's lifespan, 2) full value, protection and promotion of human rights in people with mental health problems, 3) accessibility and availability of mental health services according to need, and 4) entitlement to respectful, safe and effective treatment. Three cross-cutting objectives: 5) health systems provide good physical and mental health care for all, 6) mental health systems work in well-coordinated partnerships with other sectors, and 7) mental health governance and delivery are driven by good information and knowledge.
	EU-Compass for Action on Mental Health and Well-Being (2015–2018)	Identify and disseminate good practices; organise annual reports and forum events; hold mental health workshops; collect information on stakeholders' and national activities.
2016	European Framework for Action on Mental Health and Wellbeing	Support EU Member States with reviewing their mental health-related policies; share experiences regarding the improvement of policy effectiveness and efficiency; support countries with the implementation of the commitments that they agreed on by signing the WHO's Global and European Mental Health Action Plans (46). (Outcome of the Joint Action on Mental Health and Well-being.)
	Stakeholders' working group on mHealth assessment guidelines	(Was not able to find consensus on a guideline (166).)
	Draft Code of Conduct on privacy for mHealth apps	Promote trust among users of mHealth apps and provide a competitive advantage to complying developers (156).
2017	New European Interoperability Framework	47 recommendations on how public administrations can improve the setup and governance of interoperable digital public services (373). (Replacing the previous EIF (2010).)

As depicted in this chapter, there are a number of documents and actions that affect eMH development and implementation. What is striking, however, is that all of these documents were developed for either mental health or eHealth, and even though they affect eMH to some extent, they do not specifically address eMH itself. There is a clear lack of EU documents and actions that specifically deal with eMH. Thus, it appears that eMH still seems to be a rather underrepresented area within EU policies.

EU legislation affecting eMH

While there are no EU policies that explicitly deal with eMH yet, there are a few relevant legislative acts that have a direct impact on eMH development and implementation. Legislation and its relevance for eMH will be addressed in the following sections.

General Data Protection Regulation (Regulation (EU) 2016/679)

eMH products and services deal with sensitive data, which is why privacy and data security are two major topics of discussion. One significant legislative act of the EU affecting eMH is the General Data Protection Regulation (Regulation (EU) 2016/679; hereinafter GDPR), which provides rules for the protection of privacy and data security. It came into force on 24th May 2016 and has been applied since 25th May 2018 in all EU Member States, repealing the previous Data Protection Directive (375). Overall, the GDPR was developed to modernise and harmonise data privacy laws across Europe. This includes an extended territorial scope, increased penalties and strengthened conditions for consent compared to the previous Data Protection Directive. Furthermore, citizens' rights have been extended by introducing the concepts of breach notification, right to access, right to be forgotten, data portability, privacy by design and data protection officers. As the GDPR applies to all eMH solutions that deal with any kind of sensitive data, developers and suppliers are required to comply with the rules and requirements of the GDPR.

Medical Device Regulation (Regulation (EU) 2017/745)

Depending on the purpose of an eMH product or service, it can be classified as a medical device, meaning that it will fall under Regulation (EU) 2017/745 (109). The so-called Medical Device Regulation entered into force on 25th May 2017 and will apply from Spring 2020, replacing the existing Directive. Aside from harmonising the medical device laws across Europe, the purpose of the Medical Device Regulation is to improve the quality, safety and reliability of medical devices (through stricter controls for high-risk medical devices). Furthermore, it is intended to strengthen transparency of information for consumers, and enhance vigilance and market surveillance.

Cross-Border Directive (Directive 2011/24/EU)

eMH care can be carried out and used almost everywhere; it is not bound to a specific location. Users may travel across Europe but still make use of their eMH app, and servers that manage the respective data may be located in another country than the user. This is why the so-called Cross-Border Directive is of great significance for eMH (376). Not only does it provide rules for facilitating the access to high-quality and safe cross-border health care, but it also promotes cooperation between EU Member States. Aside from that, the Directive recognises the importance of (interoperability of) information communication technologies in health care, patient access to eHealth applications, and calls for strengthened international cooperation in the evaluation of new health technologies.

Overall, eMH seems to be a field that is still rather underrepresented within EU policies and legislation, but is gaining more and more attention in the EU. First steps towards greater diffusion and propagation of eMH have been made by the initiation of innovative projects, which will foster research in the field of eMH. Yet, it is undeniable that much remains to be done in order to disseminate and implement eMH on a large scale within the EU and its Member States. Joint European regulatory frameworks may support the development of future national regulations by providing an essential backbone.

Appendix B

eMH research projects, initiatives and networks in Europe

Due to the rapidly evolving eMH field, more and more interventions, applications and services are emerging. It is therefore difficult to provide an up-to-date overview about eMH projects and initiatives in eMEN partner countries. Table 3 provides insights into the field of eMH projects at national and European levels without being comprehensive.

Table 3: eMH projects at national and European levels (content not warranted for completeness)

Name (and organisation)	Type	Description
Belgium		
BelRAI (Resident Assessment Instrument) Pilot project in Flanders in collaboration with the federal government (in the context of the eHealth plan)	Assessment tool	Standardised and structured assessment tool to measure care-dependency in different sectors at once. Responses need to be registered online; different organisations can retrieve and exchange information. Underlying intelligent algorithms can provide guidelines and possible interventions. BelRAI focuses on acute care, home care, long-term care facility and palliative care, but could be extended, according to the interRAI assessment tool, to dietary data, mental health and so forth. Results are included in the Electronic Patient File, improving transparency, efficiency and coordination. In 2019, it was decided to opt for a wider implementation of BelRAI as a structural part of Belgian health care. *Website: https://belrai.org/en*
BLENDED	Research project (blended therapy)	Research project of Depressiehulp which investigates whether blended therapies are (cost-)effective as treatment for depression, and whether they are as (cost-)effective as traditional treatments that consist of face-to-face sessions alone. *Website: https://depressiehulp.be*

Name (and organisation)	Type	Description
Carewear project Financed by the Flemish government and local organisations	Wearable technology (burn-out and depression)	The Carewear project explores the implementation of wearable technology, combined with an online platform for use in mental health care. Two intervention programmes are being developed using wearables measuring (amongst others) skin conductance and heart-rate variability. The focus is on burn-out prevention and treatment of depression. *Website: http://carewear.be/en/*
HappyCare Increase your own mental resilience	Online self-help (employee assistance programme)	HappyCare is an online self-help tool that helps to increase mental resilience by means of exercise, testimonials, advice and information. The strategies used within HappyCare are based on scientific research: positive psychology, cognitive behavioural therapy, mindfulness and health psychology. *Website: https://www.happycare.be/*
Mijn Gezondheid/Ma Santé	Information sharing	An online health portal, also called 'Personal Health Viewer'. Through this central gateway, users gain insight into various personal details about their health and about health in general. *Website: https://www.mijngezondheid.belgie.be/*
Onlinehulp Vlaanderen	Information sharing	Central bundling of online care expertise; central contact for online care by the Network Onlinehulp Vlaanderen, Steunpunt Mens en Samenleving & Steunpunt Geestelijke Gezondheid. *Website: http://www.onlinehulp-vlaanderen.be*
RADAR-CNS International research project on the remote assessment of disease and relapse in central nervous system disorders	Research project	RADAR-CNS aims to improve people's quality of life and change how depression, epilepsy and multiple sclerosis are managed and treated. Data from mobile devices can give a full picture of a person's condition at a level of detail that was previously impossible. This offers the potential to detect changes in behaviour, sleep or mood before the individuals themselves are aware of it. This could help to predict – or even avoid – a relapse. *Website: https://www.radar-cns.org/*

Name (and organisation)	Type	Description
SIMBA	Research project	This project implements the use of ICT applications in which professionals and patients can see and hear each other in real-time (e.g. Skype) in mental health care. It investigates the possibilities and the difficulties in implementing this technology. *Website: https://www.onlinehulp-arteveldehogeschool.be/onlinehulpmethodiek/simba-beeldbellen/*
France		
AGETELEPSY project Project of the Guillaume Régnier Hospital, Rennes	Telemedicine	Use of telemedicine in geriatric psychiatry. *Website: http://www.ch-guillaumeregnier.fr/*
ASC – Agenda de Sommeil et de Comportements	Smartphone application for the management of sleep disorders and addictions	Not-for-profit application developed collaboratively (under the direction of Assistance Publique Hôpitaux de Paris) proposing a sleep and consumption agenda and, in the long term, a data export function for research. To be used by the patient alone or as part of a follow-up with a health care professional. *Website: https://play.google.com/store/apps/details?id=com.ionicframework.rydan803090&hl=it*
Bloom-up app Developed by Sainte-Anne Hospital	eMobile app for depression	In the context of decreasing medical demographics and limited access to validated psychotherapies, a mobile application in French called Bloom-up attempts to provide outpatients with information, auto-evaluation, cognitive behaviour tools and cognitive remediation. *Website: http://bloom-up-app.fr/*

Name (and organisation)	Type	Description
Blue Buddy	Mobile app for anorexia and bulimia	The app aims to help people with anorexia and bulimia problems and has been co-designed by patients, psychiatrists and psychologists of Sainte-Anne Hospital. Blue Buddy received the Education Thérapeutique Prize (Challenge de l'Innovation en Santé New Health 2016). *App store: https://itunes.apple.com/fr/app/blue-buddy/id1221007158*
C3R-P centre (at Sainte-Anne Hospital in Paris)	ICT for cognitive remediation	Care centre using new technologies for cognitive remediation. *Website: https://c3rp.fr/*
CESM project	Online centre for users' empowerment	Maison Blanche Hospital, in collaboration with housing and social support services and public health information centres, is creating a Centre for Empowerment in Mental Health using both face-to-face training and virtual tools to give all citizens access to knowledge and skills related to mental health. *Website: n/a*
Doctopsy platform	Online consultation and therapy	Web platform aimed at delivering online psychotherapies. Developed by a team of mental health practitioners. *Website: https://doctopsy.com*
EMMA	Mobile app for assessment, prediction and intervention in suicide risk management	A programme that aims to detect the risk of suicidal relapse at an early stage and to propose interventions in real time and real situations. Emma was developed by the research grant Chair of Excellence in Suicidal Behaviour, supported by the scientific cooperation foundation Fondation FondaMental and the SNCF (the French National Railway Company). *Website: n/a*

Name (and organisation)	Type	Description
Memind project Developed by Brest University Hospital and University of Montpellier.	Web-based mental health tracker designed for clinical management and research	Longitudinal observational study for patients suffering from mental disorders. This mental health tracker encompasses electronic health records (EHR) and personal health records (PHR), monitoring and interventional systems. Since July 2014, 6,000 patients have participated in the study. Publications: Berrouiguet et al. 2015 (377)
MHASC app Developed by the University Hospital of Lille	Free blended app to assess early-onset hallucinations	Application to help children with hallucinations. *Website: http://mhasc.fr/*
MyReVe Project of La Pitié-Salpêtrière Hospital and CNRS	Virtual reality therapy in the care management of anxiety disorders	Development and evaluation of a platform for the delivery of automated virtual reality therapeutic programs directly to people with phobias without consulting a health professional. *Website: https://www.myreve.fr/*
ORIAS	Online intervention	The PHRC (Hospital Clinical Research Program) aims to evaluate the effectiveness of an online intervention via social media to prevent suicide among adolescents and young adults. *Website: n/a*
Owlie	Conversational Chatbot	Owlie is a conversational chatbot for psychological support via Facebook Messenger. It was developed by a psychiatrist, a psychologist and a mental health service user on voluntary basis. *Website: m.me/owliechatbot*
Papageno programme	Suicide prevention intervention through social media	A French national suicide prevention programme aiming to prevent suicide contagion, and to promote mutual support and care access, through contemporary communication channels. *Website: https://papageno-suicide.com/*

Name (and organisation)	Type	Description
Petit Bambou	Meditation app	Free application for mindfulness meditation on mobile phones (available in French, Spanish and German). Used by more than 3,000,000 people to meditate. *Website: https://www.petitbambou.com/*
PHOENIX Developed by Sainte-Anne Hospital.	Smartphone application to help managing craving in addictions	Real-time support for patients wishing to reduce or stop their consumption. Used between two consultations, its main target is the management of cravings, without being specific to a product or addictive behaviour. Strategies are personalised and cross-referenced to the craving context and patient profile using machine learning algorithms. *Website: https://get-phoenix.com/*
PsyLab YouTube channel Conceived by mental health practitioners of the University Hospital of Lille.	Education and destigmatisation through ICT tools	Use of web tools (YouTube videos) for mental health education and destigmatisation. *Website: https://www.youtube.com/LePsyLab*
SIAM project Developed by Brest University Hospital	Suicide prevention intervention through mobile phone	Mobile phone text messaging intervention in mental health care. **Publications:** Berrouiguet et al. 2015 (378) Berrouiguet et al. 2018 (379)
Stopblues (Printemps project) Project conceived by the French National Institute for Medical Research (INSERM)	Web-based and mobile suicide prevention intervention	A web-based and mobile primary suicide prevention intervention tested and evaluated in 40 cities for the general population. *Website: https://www.stopblues.fr/*

Name (and organisation)	Type	Description
Germany		
Funded by the Federal Ministry of Education and Research		
PROVIDE	Video consultation (depression and anxiety)	ImPROving cross-sectoral collaboration between primary and psychosocial care: An implementation study on VIDEo consultations (PROVIDE). *Website: https://www.provide-project.de/ziel-konzept/?lang=en*
Funded by the Innovation Fund of the Ministry of Health		
DemTab		Outpatient care for people with dementia using a tablet as support system. Includes guideline-based treatment plans, individual case management and network. *Website: https://medizinsoziologie-reha-wissenschaft.charite.de/forschung/alternsforschung/demtab/*
Embloom (former Telepsy)	Platform	Embloom is a 12-month case management programme using an eMH platform for patients with depression and anxiety involving GPs, medical assistants and patients. *Website: https://www.embloom.de/ueber-uns/*
HELP@APP	eMH tool (app) for traumatised refugees	Development and evaluation of a self-help app for traumatised Syrian refugees in Germany. Project start: 2017. *Website: https://innovationsfonds.g-ba.de/projekte/versorgungsforschung/helpatapp-entwicklung-und-evaluation-einer-selbsthilfe-app-fuer-traumatisierte-syrische-fluechtlinge-in-deutschland.32*

Name (and organisation)	Type	Description
MEHIRA – Mental Health in Refugees and Asylum Seekers	Innovative stepped care model with an app	For refugees with depression; group therapy and an app will be developed and compared to routine care. *Website: https://www.charite.de/forschung/forschung an_der_charite/forschungsprojekte/innovationsfonds/mehira/*
Mind:Pregnancy	Online-based mindfulness intervention	Online-based mindfulness intervention to strengthen the mental health status of pregnant women and to promote a physiological birth. *Website: https://www.mindpregnancy.de/*
NPPV	Online therapy	Improving health care for mental and neurological disorders including development of IT structure (IVPnet) and online therapy (novego). *Website: https://nppv-nordrhein.de/*
POSOP	Online self-help	Psychosocial Online Self-help for Oncologic Patients (POSOP). *Website: https://www.unimedizin-mainz.de/uct/aktuell/newsletter/2018-q1/projekt-posop.html*
RECOVER	Platform	Community care based approach to improve the quality of treatment in relation to the level of severity of the mental health issue. It is an intersectoral collaboration between GPs, hospitals, employers and relative associations, using innovative therapies (e.g. eMH platform). *Website: https://www.recover-hamburg.de/*
WASH		Evaluation of web-assisted self-help training (WASH) for parents of children with attention deficit hyperactivity disorder. *Website: https://innovationsfonds.g-ba.de/projekte/versorgungsforschung/wash-evaluation-eines-web-assistierten-selbsthilfe-trainings-fuer-eltern-von-kindern-mit-aufmerksamkeits-defizit-hyperaktivitaetsstoerung.30*

Name (and organisation)	Type	Description
Examples of eMH programmes offered by German private clinics and health insurance funds*		
AOK (Allgemeine Ortskrankenkasse)	**moodgym** (reduction of depressive symptoms and prevention of depression)	Translating moodgym to German has been funded by the AOK. The AOK recommends moodgym to their members. However, moodgym is free for everyone. *Website: https://rh.aok.de/inhalt/selbsthilfe-bei-depression-moodgym-10/* *Website: https://moodgym.de/*
Barmer Ersatzkasse	**Pro Mind** (stress management and prevention of depression)	Free access for people insured with the Barmer Ersatzkasse. *Website: https://www.barmer.de/gesundheitscampus/kurse/online-kurse/psychische-gesundheit-pro-mind*
DAK (Deutsche Angestellten-Krankenkasse)	**Deprexis** (minor to moderate depression)	Offered to people insured with the DAK. Access via general practitioner or Veovita, a company that offers innovative psychosocial care with behavioural therapy, video chats and online programs. *Website: https://www.dak.de/dak/leistungen/online-therapie-deprexis24-1791504.html*

* Health insurance that fund novego programmes: AXA Krankenversicherung AG, Gothaer Krankenversicherung AG, Debeka Krankenversicherungsverein a.G., Barmenia Krankenversicherung a.G., HALLESCHE Krankenversicherung a.G., Signal Iduna Krankenversicherung a.G., BKK Pfalz, novitas BKK, Siemens BKK (SBK), BKK VBU, Pronova BKK, Postbeamtenkrankenkasse (PBeaKK), Versicherungskammer Bayern, Union Krankenversicherung AG.

Name (and organisation)	Type	Description
Schön Online clinics (private clinic)	Online video therapy and online follow-up care (for depression, burnout, eating disorders) with an online-therapy platform (MindDoc)	A face-to-face consultation for diagnosis and information about the programme follows an online survey before video psychotherapy starts. This is also offered to inpatient care for relapse prevention if they were not able to find an outpatient therapist in time. Reimbursement by health insurance funds only applies for specific health insurances, for those insured with another health insurance, additional procedures apply. The Ludwigs-Maximilian-University of Munich and the Friedrich-Alexander University in Erlangen-Nürnberg are involved and responsible for the evaluation. *Website: https://www.minddoc.de/*
Techniker Krankenkasse (TK)	**Depressionscoach** (minor to moderate depression)	In collaboration with C. Knaevelsrud (Free University Berlin), the TK developed and evaluated the programme Depressionscoach. The TK only offers the programme to its members. *Website: https://www.tk.de/techniker/service/gesundheit-und-medizin/behandlungen-und-medizin/psychische-erkrankungen/tk-depressions-coach-2016410*

Name (and organisation)	Type	Description
Ireland		
AWARE Life Skills Online / Beat the Blues	Online supported CBT-based psychoeducation product	AWARE is a national organisation providing support, information and education regarding depression, anxiety and related conditions – including an email support service and Life Skills Online (an online supported CBT-based psychoeducation product). AWARE offers Beat the Blues (a mental health education programme for young people) to schools. *Website: https://www.aware.ie/*
Bodywhys **SeemySelf / Bodywhys Connect / Youth connect**	Online support services (psychoeducation/ e-therapy for eating disorders)	Bodywhys is the Eating Disorders Association of Ireland and offers Bodywhys Connect and YouthConnect as online support services and SeemySelf for free (online supported psychoeducation and e-therapy product for eating disorders). *Website: https://www.bodywhys.ie/*
Drugs.ie	Online interactive information and support service	Independent website which provides an interactive online information and support service. *Website: http://drugs.ie/*
MindWise	Supported online CBT for treatment of anxiety and depression	MindWise was developed within the public system (HSE) but is not technically supported at the moment (not available for use). Linked to the eMEN project, the HSE is currently developing and implementing a version of MindWise for adolescents. There are plans to deploy this at primary care level across the country, to provide a service supported by assistant psychologists. *Website: http://www.mindwisenv.org/*
Pesky gNATS	Serious gaming (CBT for young people with anxiety or low mood)	Offered to professionals for £150 by non-profit company (Handaxe CIC) founded by the developers. Online training available free of charge. *Website: https://www.peskygnats.com/*

Name (and organisation)	Type	Description
SilverCloud	Online CBT (supported)	Commercial offering – subscription platform for mental health services (mainstream, colleges, EAPs, etc.) *Website: https://www.silvercloudhealth.com/*
Technology and Mental Health Network (TMHN)	Network	Supports development in the mental health field (comprising the third sector, HSE and others, e.g. ReachOut.com (online youth mental health service)). *Website: n/a*
Turn2me	Structured online support groups	A not-for-profit organisation that provides online mental health support. Funded by sponsors and donations (public and private sector). Fee of €30 per session for people living outside of Ireland. *Website: https://turn2me.org/*
YourMentalHealth	Suicide Prevention	YourMentalHealth.ie,operated by the HSE National Office for Suicide Prevention, addresses the general population and provides information about mental health. *Website: http://www.yourmentalhealth.ie/*

Name (and organisation)	Type	Description
The Netherlands		
eGGZ Centrum	Virtual reality Platform	A project to create innovative virtual reality applications in co-creation and set up a platform for knowledge sharing. *Website: https://www.e-mence.org/nl/projecten/eggz-centrum*
eHealth monitor from Nictiz (the national competence centre for eHealth)	Annual monitoring report	Annual monitoring report about the status of e-(mental) health use in the Netherlands. *Website: https://www.nictiz.nl/ehealth/ehealth-monitor*
Informatieberaad Zorg (Information Board)	Agreements, standards and provisions for health data	Thanks to eHealth applications, people get more control over their own health, and health care professionals can respond faster with better information. The Informatieberaad has been set up to make agreements, standards and provisions for this so that health care data can be shared safely and reliably. *Website: https://www.informatieberaadzorg.nl/*
MedMij programme	Health data storage and information sharing	MedMij enables safe storing and sharing of health data by setting procedures and agreements. Patients can access their health data in a safe way and exchange health information with health professionals. *Website: https://www.medmij.nl/zorggebruikers/*
Modular Motion-assisted Memory Desensitisation and Reconsolidation (3MDR)	PTSD	3MDR is a new treatment that aims to reduce cognitive avoidance and augment engagement with therapy. The research purpose is to determine if 3MDR therapy is able to reduce symptoms of PTSD. The focus of the research is on people who have not responded to, or are unable to engage with, treatments that are currently available. *Website: https://www.centrum45.nl/nl/nieuws/3mdr-innovatie-traumabehandeling*

Name (and organisation)	Type	Description
Online Help Hallmark	Platform	Insights about the quality of eMH (fee applies). *Website: www.onlinehulpstempel.nl*
Triple-E-health	Promotion	Triple-E focuses on promoting eMH: digital technologies and new media in mental health care. *Website: https://www.triple-ehealth.nl/en/*
Versnellingsprogramma Informatieuitwisseling Patient en Professional (VIPP)	Standards for information exchange	Ensures that the necessary standards are implemented so that information exchange is possible. *Website: https://www.vipp-programma.nl/*
Virtual Reality Exposure Therapy (VRET)	Virtual reality	VRET has been scientifically proven to be effective by the University of Amsterdam (UvA), the Delft University of Technology (TU Delft) and many other international research groups. After a decade of research, CleVR combines the effectiveness of exposure therapy with the accessibility of a virtual environment. *Website: http://clevr.net/*

Name (and organisation)	Type	Description
England		
Global Digital Exemplars	Implementation of digital approaches	Investment in NHS Mental Health Trusts which will use world-class digital approaches to improve services. *Website: https://www.england.nhs.uk/digital-technology/connecteddigitalsystems/exemplars/*
Good Thinking	Digital wellbeing service	Online service for Londoners, giving people 24-hour access to digital tools and resources to improve sleep, anxiety, depression and stress. *Website: https://www.good-thinking.uk/*
Local Digital Roadmaps (several example projects) (380)	Information Portal	Led by local and sub-regional NHS trusts, digital health programmes that are being delivered on the ground in the UK are described (for both mental and physical health). *Website: https://www.england.nhs.uk/digitaltechnology/connecteddigitalsystems/digital-roadmaps/*
MindTech	Centre of Innovation	Partnership between the University of Nottingham and Nottinghamshire Health Care NHS Trust (funded by the National Institute for Health Research). *Website: https://www.mindtech.org.uk/*
TechCare mobile app (psychosis) (381), followed by mHabitat Digital Development Lab (382)	Digital Development Lab	To help develop the evidence base for digital therapies and support emerging tools; it will be the principle focal point for taking forward innovation in eMH in the UK (in partnership with MindTech and Social Spider) (382, 383) Publications: https://wearemhabitat.com/open-library *Website: https://wearemhabitat.com/*

Name (and organisation)	Type	Description
Scotland		
Aye Mind project	Promotion	Example in co-production to ensure that young people's voices are heard in digital policy-making. *Website: http://ayemind.com/*
Digital Health and Care Institute	Centre of Innovation	Partnership between the University of Strathclyde, Glasgow School of Art, National Health and Care Services Scotland. *Website: http://dhi-scotland.com/*
NHS 24	Health care information and self-care service	NHS 24 brings guided cognitive behavioural therapies such as "Living Life to the Full" at scale. *Website: https://www.nhs24.scot/*

Name (and organisation)	Type	Description
European projects		
eMEN	Platform	EU-wide platform for eMH innovation and implementation that will be formed by private and public partners in North-West Europe. *Website: http://www.nweurope.eu/emen*
E-COMPARED (2014–2017)	Comparative Effectiveness Research	Aimed to provide mental health care stakeholders with evidence-based information and recommendations about the clinical and cost-effectiveness of blended depression treatment (384). Comparative Effectiveness Research was conducted in nine European countries to determine which treatment works best, for whom, and under what circumstances. Current practice of CBT in routine and specialised mental health care was compared with blended treatment for depression that combines internet, mobile technologies and face-to-face interventions. *Website: https://www.e-compared.eu/*
ImpleMentAll (2017–2021)	Implementation	A European collaboration towards faster and more effective implementation of eHealth interventions through the development, application and evaluation of tailored implementation strategies of current eHealth implementation initiatives (274). The project's raison d'être is founded on the notion that implementation of new services and technologies is time-consuming and costly – and often fails completely – not least in the health care domain. Solidly based in research, and in a collaboration spanning from all corners of Europe to Australia, the project will construct its answer to this widespread problem. *Website: http://www.implementall.eu/*
ICare (2015–2019)	Promotion	Aimed to establish a comprehensive mental health promotion model integrating information communication technologies (385). *Website: https://www.icare-online.eu/*

Name (and organisation)	Type	Description
MasterMind (2014–2017)	Implementation research	The project examined barriers and success factors of implementing internet treatments at large scale in different settings (105). Its activities included assessing the impact of computerised cognitive behavioural therapy (cCBT) and video conference on the care and treatment of depression. One of the main project outcomes was the publication of the document 'Policy recommendations based on MasterMind results'. It entailed six policy recommendations for the successful upscaling of eMH: (1) development of a clear implementation strategy and plan, (2) congruent financial metrics, (3) community strategy, (4) change management, (5) technical solutions and support, (6) organisational structure and stepped processes. *Website: https://mastermind-project.eu/*
mHealth Hub (2017–2021) Collaboration of the World Health Organization and the International Telecommunication Union (ITU).		Aims to collect best practices on the use of mobile health (mHealth) in Europe. The objective of the project is to help EU member states with the introduction of mHealth programmes and the establishment of regional and global relationships within this field. *Website: http://mhealth-hub.org/*
Therapy 2.0 (2016–2018)		Therapy 2.0 was a project that aimed to raise awareness of the potentials of eMH solutions. Furthermore, it developed a practical guide to the different ways of how technology can be used in therapeutic and counselling processes, best practice examples and a mobile application. *Website: https://www.ecounselling4youth.eu/*

Appendix C

Meta-analyses and systematic reviews in the context of eMH

Table 4: Overview of meta-analyses and systematic reviews in the context of eMH (content not warranted for completeness)

Author	Title	Method	Objective	Disorder	Incl. studies
1. Andrews et al. 2018 (update Andrews et al. 2010)	Computer therapy for anxiety and depressive disorders is effective, acceptable and practical health care: An updated meta-analysis (85).	Updated meta-analysis	Internet-delivered CBT (iCBT)	Anxiety and depressive disorders	64 RCTs (31 additional studies) (before 09/2016)
2. Carlbring et al. 2018 (update Andersson et al. 2014)	Internet-based vs. face-to-face cognitive behaviour therapy for psychiatric and somatic disorders: an updated systematic review and meta-analysis (6).	Meta-analysis + systematic review	Internet-based vs. face-to-face cognitive behaviour therapy	Psychiatric and somatic disorders	20 RCTs (7 new studies) (2005 to 2016)
3. Erbe et al. 2017	Blending face-to-face and internet-based interventions for the treatment of mental disorders in adults: Systematic review (63).	Systematic review	Blending face-to-face and internet-based interventions	Mental disorders in adults	44 studies, including 27 RCTs
4. Firth et al. 2017	Can smartphone mental health interventions reduce symptoms of anxiety? A meta-analysis of randomised controlled trials (9).	Meta-analysis	Smartphone mental health interventions	Anxiety	9 RCTs
5. Firth et al. 2017	The efficacy of smartphone-based mental health interventions for depressive symptoms: a meta-analysis of randomised controlled trials (8).	Meta-analysis	Smartphone-based mental health interventions	Depressive symptoms	18 RCTs
6. Gaebel et al. 2017	EPA guidance on eMental health interventions in the treatment of posttraumatic stress disorder (PTSD) (210).	Systematic review	eMental health interventions	Posttraumatic stress disorder (PTSD)	40 studies

Table 4: Overview of meta-analyses and systematic reviews in the context of eMH (content not warranted for completeness)

Author	Title	Method	Objective	Disorder	Incl. studies
7. Heber et al. 2017	The benefit of web- and computer-based interventions for stress: a systematic review and meta-analysis (386).	Meta-analysis + systematic review	Web- and computer-based interventions	Stress	26 RCTs
8. Karyotaki et al. 2017	Efficacy of self-guided internet-based cognitive behavioural therapy in the treatment of depressive symptoms. A meta-analysis of individual participant data (387).	Meta-analysis	Self-guided internet-based cognitive behavioural therapy (iCBT)	Depressive disorders	13 RCTs
9. Königbauer et al. 2017	Internet- and mobile-based depression interventions for people with diagnosed depression: a systematic review and meta-analysis (388).	Meta-analysis + systematic review	Internet- and mobile-based depression interventions	Diagnosed depression	29 RCTs
10. Lau et al. 2017	Serious games for mental health: are they accessible, feasible, and effective? A systematic review and meta-analysis (95).	Meta-analysis + systematic review	Serious gaming	Mental disorders	10 RCTs in the review and 9 in the meta-analysis
11. Păsărelu et al. 2017	Internet-delivered transdiagnostic and tailored cognitive behavioural therapy for anxiety and depression: a systematic review and meta-analysis of randomised controlled trials (389).	Meta-analysis + systematic review	Internet-delivered transdiagnostic and tailored cognitive behavioural therapy	Anxiety and depression	19 RCTs
12. Twomey et al. 2017	Effectiveness of an individually tailored computerised CBT programme (Deprexis) for depression: a meta-analysis (390).	Meta-analysis	An individually-tailored computerised CBT programme (Deprexis)	Depression	8 RCTs
13. Gaebel et al. 2016	European Psychiatric Association (EPA) guidance on the quality of eMental health interventions in the treatment of psychotic disorders (51).	Systematic review	eMental health interventions	Psychotic disorders	24 studies

Table 4: Overview of meta-analyses and systematic reviews in the context of eMH (content not warranted for completeness)

Author	Title	Method	Objective	Disorder	Incl. studies
14. Kuester et al. 2016	Internet-based interventions for post-traumatic stress: a meta-analysis of randomised controlled trials (391).	Meta-analysis	Internet-based interventions	Posttraumatic stress disorder (PTSD)	20 RCTs
15. Sander et al. 2016	Effectiveness of internet-based interventions for the prevention of mental disorders: a systematic review and meta-analysis (60).	Meta-analysis + systematic review	Internet-based interventions	Prevention of mental disorders	17 RCTs (moderate quality)
16. Seyffert et al. 2016	Internet-delivered cognitive behavioural therapy to treat insomnia: a systematic review and meta-analysis (392).	Meta-analysis + systematic review	Internet-delivered cognitive behavioural therapy	Insomnia	15 RCTs
17. Sijbrandij et al. 2016	Effectiveness of internet-delivered cognitive behavioural therapy for post-traumatic stress disorder: a systematic review and meta-analysis (393).	Meta-analysis + systematic review	iCBT	Post-traumatic stress disorder	12 RCTs
18. Vigerland et al. 2016	Internet-delivered cognitive behaviour therapy for children and adolescents: A systematic review and meta-analysis (394).	Meta-anaylsis + systematic review	Internet-delivered cognitive behaviour (children and adolescents)	Psychiatric condition	25 studies (RCTs, quasi-RCTs, open trials) in systematic review, 24 of them in meta-analysis
19. Zhou et al. 2016	Internet-based cognitive behavioural therapy for subthreshold depression: a systematic review and meta-analysis (395).	Meta-analysis + systematic review	Internet-based cognitive behavioural therapy	Subthreshold depression	8 RCTs
20. Ebert et al. 2015	Internet and computer-based cognitive behavioural therapy for anxiety and depression in youth: a meta-analysis of randomised controlled outcome trials (396).	Meta-analysis	Computer- and internet-based cognitive behavioural treatments (cCBT)	Anxiety and/or depression	13 RCTs

Table 4: Overview of meta-analyses and systematic reviews in the context of eMH (content not warranted for completeness)

Author	Title	Method	Objective	Disorder	Incl. studies
21. Olthuis et al. 2015	Therapist-supported internet cognitive behavioural therapy for anxiety disorders in adults (59).	Systematic review Cochrane Collaboration	Therapist-supported iCBT	Anxiety disorder	38 studies (RCTs, cross-over, cluster)
22. Richards et al. 2015	The efficacy of internet-delivered treatment for generalised anxiety disorder: a systematic review and meta-analysis (397).	Meta-analysis + systematic review	Internet-delivered psychological interventions	Generalised anxiety disorder	20 studies including 11 RCTs, which were used for meta-analysis
23. Andersson et al. 2014	Guided internet-based vs. face-to-face cognitive behaviour therapy for psychiatric and somatic disorders: a systematic review and meta-analysis (12).	Meta-analysis + systematic review	Guided internet-based vs. face-to-face cognitive behaviour therapy	Psychiatric and somatic disorders	13 RCTs (until June 2013)
24. Arnberg et al. 2014	Internet-delivered psychological treatments for mood and anxiety disorders: a systematic review of their efficacy, safety, and cost-effectiveness (80).	Meta-analysis	iCBT versus waiting list	Mood and anxiety disorders	39 reports (with 40 RCTs and 2 long-term follow-ups)
25. Baumeister et al. 2014	The impact of guidance on internet-based mental health interventions – a systematic review (62).	Systematic review	(1) guided vs. unguided interventions, (2) different doses of guidance, (3) different qualification levels of e-coaches, (4) synchronous vs. asynchronous	Mental health problems	14 RCTs
26. Riper et al. 2014	Effectiveness of guided and unguided low-intensity internet interventions for adult alcohol misuse: a meta-analysis (398).	Meta-analysis	Guided and unguided low-intensity internet interventions	Adult alcohol misuse	16 RCTs
27. Ye et al. 2014	Effectiveness of internet-based interventions for children, youth, and young adults with anxiety and/or depression: a systematic review and meta-analysis (399).	Meta-analysis + systematic review	Internet-based interventions	Anxiety and depression	7 RCTs

Table 4: Overview of meta-analyses and systematic reviews in the context of eMH (content not warranted for completeness)

Author	Title	Method	Objective	Disorder	Incl. studies
28. Hedman et al. 2012	Cognitive behaviour therapy via the internet: a systematic review of applications, clinical efficacy and cost-effectiveness (82) (not open access).	Systematic review	Cognitive behaviour therapy via the internet	Psychiatric disorders and other clinical problems	108 RCTs
29. Johansson & Andersson 2012	Internet-based psychological treatments for depression (400).	Systematic review	Guided self-help vs. face-to-face treatment	Depression	21 RCTs
30. Lewis et al. 2012	Efficacy, cost-effectiveness and acceptability of self-help interventions for anxiety disorders: systematic review (401).	Meta-analysis + systematic review	Self-help intervention vs. waiting list and therapist-administered treatment	Anxiety disorders	31 RCTs
31. Richards & Richardson 2012	Computer-based psychological treatments for depression: a systematic review and meta-analysis (7).	Meta-analysis + systematic review	Computer-based psychological treatments	Depression	19 RCTs
32. Cuijpers et al. 2011	Self-guided psychological treatment for depressive symptoms: a meta-analysis (10).	Meta-analysis	Self-guided psychological treatment	Depressive symptoms	7 RCTs
33. Foroushani et al. 2011	Meta-review of the effectiveness of computerised CBT in treating depression (402).	Meta-analysis + systematic review	Computerised cognitive behaviour therapy (cCBT)	Moderate depression	12 reviews
34. Newman et al. 2011	A review of technology-assisted self-help and minimal contact therapies for anxiety and depression: is human contact necessary for therapeutic efficacy? (403)	Systematic review	Technology-assisted self-help and minimal contact therapies	Anxiety and depression	Not specified
35. Tulbure 2011	The efficacy of internet-supported intervention for social anxiety disorder: a brief meta-analytic review (404).	Meta-analysis	Internet-supported interventions	Social anxiety disorders	8 RCTs

Table 4: Overview of meta-analyses and systematic reviews in the context of eMH (content not warranted for completeness)

Author	Title	Method	Objective	Disorder	Incl. studies
36. Andrews et al. 2010	Computer therapy for anxiety and depressive disorders is effective, acceptable and practical health care: a meta-analysis (405).	Meta-analysis	Computer therapy	Anxiety and depressive disorders	22 RCTs
37. Calear et al. 2010	Review of internet-based prevention and treatment programmes for anxiety and depression in children and adolescents (406).	Systematic review	Internet-based prevention and treatment programmes	Anxiety and depressive disorders	8 studies (RCTs, RUTs, CTs, uncontrolled pre-post evaluations)
38. Cuijpers et al. 2010	Is guided self-help as effective as face-to-face psychotherapy for depression and anxiety disorders? A systematic review and meta-analysis of comparative outcome studies (11).	Meta-analysis + systematic review	Guided self-help compared to face-to-face psychotherapy	Depression and anxiety disorders	21 RCTs
39. Griffiths et al. 2010	The efficacy of internet interventions for depression and anxiety disorders: a review of randomised controlled trials (407).	Systematic review	Internet interventions	Anxiety and depressive disorders	29 reports describing 26 RCTs
40. Amstadter et al. 2009	Internet-based interventions for traumatic stress-related mental health problems: a review and suggestion for future research (408).	Systematic review	Computerised and internet-based interventions	Traumatic stress related conditions	36 RCTs
41. Andersson & Cuijpers 2009	Internet-based and other computerised psychological treatments for adult depression: a meta-analysis (409).	Meta-analysis	Internet-based or computerised psychological treatment	Depression	12 RCTs
42. Cuijpers et al. 2009	Computer-aided psychotherapy for anxiety disorders: a meta-analytic review (410).	Meta-analytic review	Computer-aided psychotherapy	Anxiety disorders	23 RCTs

Table 4: Overview of meta-analyses and systematic reviews in the context of eMH (content not warranted for completeness)

Author	Title	Method	Objective	Disorder	Incl. studies
43. Reger & Gahm 2009	A meta-analysis of the effects of internet- and computer-based cognitive behavioural treatments for anxiety (411).	Meta-analysis	Internet- and computer-based cognitive behavioural treatments	Anxiety	19 RCTs
44. Barak et al. 2008	A comprehensive review and a meta-analysis of the effectiveness of internet-based psychotherapeutic interventions (412).	Meta-analysis	Internet-based psychological interventions	Variety of problems	92 studies
45. Palmqvist et al. 2007	Internet-delivered treatments with or without therapist input: does the therapist factor have implications for efficacy and cost? (413).	Systematic review	Internet-delivered computerised CBT	Psychiatric problems	15 RCTs

Appendix D

Overview of evaluation methods

(270, 414-416)

Classic RCT

RCTs are the gold standard to demonstrate efficacy and effectiveness of traditional medical interventions and infer causality. In RCTs, study participants on an individual level are allocated randomly on an individual basis either to the new intervention or to a control group (standard treatment, placebo, or remaining on the waiting list). In case the allocation would lead to a contamination between individuals of the treatment group and of the control group, cluster randomised controlled trials (cRCTs) provide an alternative to prevent biases in the estimation of effects. Cluster randomisation means that the allocation is based on an organisational or group level.

Strengths: Controlled setting; high internal validity; comparable to other trials; clear, transparent and internationally well-established methodology.

Limitations: Strict; non-adaptive protocols; time-consuming and costly.

Stepped-wedge design (SWD)

The SWD design is another form of a cluster RCT, which randomises based on the time the intervention is implemented, i.e. SWD designs use a sequential roll-out of the intervention at the target sites (randomly selected). Every cluster starts in the control phase. The SWD design is structured into a pre-study phase, a time for rollout phase and a follow-up phase. Data collection happens at the end of each time segment or wedge – in this way process evaluation is possible. Example: ImpleMentAll, see Appendix B for more information.

Strengths: Overcomes practical or ethical objections to experimentally evaluating an intervention for which there is some evidence of effectiveness, or which cannot be made available to the whole population at once; workable (the intervention does not start in several settings at the same time); every cluster implements the intervention; a stepwise approach allows for process evaluations over time (measures time effects); good for interventions with short time effects; suitable for multisite scale-up studies; aligns with the realities of real-world settings.

Limitations: Not suitable for interventions which need time to develop their effects; difficult to calculate sample sizes, since time needs to be acknowledged as possible confounder; increased sample size needed to achieve adequate statistical power; requires complex evaluation methods.

Enhancements to traditional approaches

In general, the above-mentioned designs rely on the core principle of RCT designs, i.e. comparing an intervention and a control group. However, compared to traditional RCT approaches, the designs take into account that behavioural information technologies (BITs) consist of several components. A component may be the content of the programme itself, the way that it is delivered or the intended effect of the intervention (221). With innovative, agile design elements such as iterative design, preference-based randomisation or sequential randomisation, these designs suggest focusing on several (continuously evolving) components of a technology rather than focusing on the intervention as a whole while simultaneously reducing the observation period.

Trials of Intervention Principles method (TIP) – an extension of RCT processes (218)

The suggested framework for "trials of intervention principles" (TIP) offers the option of continuously improving the quality of the interventions during the evaluation phase, e.g. due to user feedback or other intervention outcomes. However, the principles and concepts of a BIT, which will be evaluated in the RCT, must be defined a priori. Therefore, adequate laboratory and field-testing is crucial in the development phase. Examples for the principles and concepts of a BIT may be underlying behavioural strategies, what is delivered, how it is delivered (characteristics), when it is delivered (workflow) or, above all, clinical outcomes. TIP is based on the principles of RCTs, i.e. each patient may be randomised and assigned to treatments multiple times based on intermediate outcomes or usage data (see also SMART).

Strengths: Flexible and adaptable; supplement to traditional RCT approach.

Limitations: Complex and new framework (not yet established, may require further enhancements).

Multiphase Optimisation Strategy (MOST) – building an efficient intervention (221)

MOST is a method for behavioural interventions to identify the main components of the intervention and their optimal combination (e.g. dosages) before a traditional RCT is undertaken. It uses a fractional factorial design structured in three phases: 1. Preparation/screening (identify optimal intervention components). 2. Optimisation/refining (develop components and define, e.g. optimal dosage). 3. Assessment/confirmation (evaluate the optimal combination of components in a traditional RCT). MOST provides the option to evaluate and measure every single component of the intervention as well as their interactions, and tests the relative effects of components within an intervention.

Strengths: Real-life setting; evaluates indirect outcomes (effectiveness of single components of the intervention); preparation for traditional RCT of optimised intervention (more efficient use of time and resources); uses randomisation.

Limitations: Not suitable for highly integrated programmes (identification of single influential components is difficult).

Sequential Multiple Assignment Randomised Trial (SMART) – building time-varying adaptive intervention (221, 417-419)

SMART is a rather holistic yet rigorous iterative research design that provides a framework best suited to building time-varying adaptive interventions and their implementation strategy. Its aim is to identify the best tailoring sequence of intervention components and decision rules for an intervention, especially using individual (e.g. preference, severity of condition) or setting level (e.g. local processes and resources) variables. SMART provides the option to prospectively decide about the type and intensity of an intervention (e.g. optimal length or level of support) and is seen as useful, e.g. in the refining phase of MOST. Each patient may be assigned randomly to conditions more than once; the reassignment is based on intermediate out-

comes or usage data. This way, decision rules for adaptive interventions may be operationalised. Moreover, it is possible to readapt or refine the intervention or implementation strategy during the implementation. Overall, SMART offers the chance to evaluate systems that provide different components at various times with the goal being to identify a sequence of intervention components depending on specified criteria that maximise a health outcome (218). SMART may have a considerable value, e.g. in investigating questions such as workflow (218) ,and ensures that the intervention will be tested in its most powerful version in a subsequent RCT.

Strengths: Flexible and adaptive; re-adaption or refining possible during implementation (e.g. when circumstances change, or burden and cost have to be reduced); considers usability (co-production with users); prospective data collection of influencing factors; reduces effects of cohorts; based on randomised experimentation.

Limitations: The intervention is not compared to a control or comparative treatment condition.

Micro-Randomised Trial (420)

Just-in-time adaptive interventions, such as mHealth technologies, require iterative (i.e. within the cycles for development) data collection within "real-life-settings". In Micro-Randomised Trials, participants are allocated to an intervention and control group and outcomes are continuously measured. Compared to classic experimental designs, it incorporates behavioural therapy approaches and evaluates specific components of the intervention and its effects over time to understand when and in what contexts an intervention should be delivered. In the early stages of the development phase, it may be incorporated into the MOST design as an alternative experimental design.

Strengths: Continuous data collection; evaluates causal effects.

Limitations: Developed for mHealth interventions.

Continuous Evaluation of Evolving Behavioural Intervention Technologies (CEEBIT) – a methodological framework (212, 218)

Mohr and colleagues propose a methodology for evaluating Behavioural Intervention Technologies (BIT) as an alternative to traditional RCTs, including randomised and non-randomised methods (e.g. need-based assignment) and statistical methods (e.g. propensity score matching) to improve non-randomised selections, standards for in- and exclusion criteria and evaluation outcomes. In order to enhance the evaluation of multiple behavioural intervention technologies (BITs) or evolving versions, CEEBIT provides a methodological framework that offers the option to create prospective, continuous and systematic evidence (in terms of safety and efficacy) of multiple interventions simultaneously. It is a "learning system" , i.e. it uses dynamic alterations, dismisses failure (inferior) versions (with bad outcomes), and includes new and promising versions. CEEBIT proposes to collect data in real-time and comparatively evaluate BITs in local settings (e.g. clinical care organisations). It aims to combine initial evaluation and post-marketing surveillance by allowing organisations to provide BITs to their consumers and continuously evaluate their usefulness.

Strengths: Data collection in real-time; flexible (adaptable to new environments, population changes, technology updates); learning system (eliminates the necessity for several RCTs); includes user preferences as outcome.

Limitations: No control group (no comparison to treatment as usual, evaluates only efficacy and efficiency); risk of exposing the public to inefficient and potentially harmful technologies.

Hybrid study designs/effectiveness-implementation hybrid designs (421)

Hybrid designs aim to blend the characteristics of effectiveness and implementation studies in order to generate a more timely uptake of desirable interventions, more effective implementation strategies and more relevant information for future scale-up activities. Curran and colleagues suggest three hybrid designs: 1. Primary focus on testing the effectiveness of an intervention while implementation-relevant data is also collected as a secondary outcome. 2. Parallel testing of intervention and implementation strategy effectiveness. 3. Focusing on testing of the effectiveness of an implementation strategy while also gathering information on the intervention impact on relevant outcomes are secondary outcomes.

Strengths: Potential for rapid translational gains; better implementation strategies; improving the usefulness and relevance of clinical research for policy.

Limitations: Construct still in evolution (feasible and affordable within the limits of health care budgets); complex to execute.

Other acknowledged study designs and approaches in the context of the evaluation of digital mental health solutions/mHealth solutions are:

- Comparative Effectiveness Research (CER) (422)
- No-of-1 trials that aim to identify an intervention component that is effective in a particular patient (218)
- "Cumulative trials" (a sequence of smaller trials that test single or multiple adaptations in the technology and are evaluated in a combined fashion) (218)
- Mixed methods approach for complex research questions, which involves the collection and analysis of multiple, both qualitative (e.g. identifying aspects of delivery and context) (217) and quantitative data in a single study
- Multiphase optimisation strategies (MOST) and factorial designs are alternatives to test multiple principles in one trial (strategy for optimising and evaluating behavioural interventions) (423)
- Pragmatic (or practical) clinical trials aim to enhance external validity to answer praxis-relevant questions faced by decision makers (424, 425)

Other relevant theories, which prospectively will gain importance in evaluative methods, are system thinking (426, 427) and learning health care systems (428).