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IMPLEMENTING eMENTAL HEALTH SERVICES IN ROUTINE MENTAL HEALTH CARE

from barriers to strategies

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VRIJE UNIVERSITEIT

Implementing eMental health services in routine mental health care
from barriers to strategies

ACADEMISCH PROEFSCHRIFT

ter verkrijging van de graad Doctor of Philosophy aan
de Vrije Universiteit Amsterdam,
op gezag van de rector magnificus
prof.dr. J.J.G. Geurts,
in het openbaar te verdedigen
ten overstaan van de promotiecommissie
van de Faculteit der Gedrags- en Bewegingswetenschappen
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De Boelelaan 1105

door

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Chapter 1

General Introduction

Background

Medical and health related research output is estimated to double every eight years [1]. Approximately 14% of new evidence-based services successfully enter routine practice [2]. Those who make it, do so 17 years after establishing their clinical efficacy on average [3-5]. Uptake of research by routine practice is low, slow and costly [3, 6, 7]. The gap between what is known about the (in)effectiveness of treatments and what is actually delivered in routine care, is one of the most critical issues in achieving effective, sustainable and equitable mental health care [8]. Building on approaches in implementation science, this dissertation aimed to contribute to understanding, and ultimately reducing, the research-to-practice gap in clinical mental health care.

Depressive and anxiety disorders are common throughout the world. Since 1990, mental disorders rank among the top ten leading causes of burden of diseases world-wide. In 2019, it was estimated that 970.1 million individuals globally suffered from a mental disorder of which 60% are attributed to depression and anxiety [9, 10]. Depression and anxiety are mental conditions that are associated with functional limitations, low quality of life, and considerable economic costs [11-17]. Without proper treatment, a chronic course with intermittent periods of increasing and decreasing symptomatology running over several decades, is not uncommon. Even when treated, persistence rates after several years following treatment can be as high as 50% [18].

A variety of effective treatments are available, including drug-based pharmacotherapy and behaviour-based psychotherapy [19-21]. Whereas less severe symptomatology is mostly treated with psychotherapy, patients experiencing major depressive disorder (MDD) are often treated with antidepressants or a combination of pharmacotherapy and psychotherapy. In brief, current pharmacotherapy enact on inhibiting reuptake of neurotransmitters such as serotonin (SSRI) and noradrenaline (SNRI) in the presynaptic cell in the brain. These neurotransmitters are thought to play an important role in mood regulation [22] and antidepressant pharmacotherapy is associated with restoration of structural, functional and molecular alterations in the brain physiology caused by a mental health condition [23]. Similar to pharmacotherapy, psychotherapy focusses on altering brain activity and structures [24]. However, psychotherapy generally focusses on evaluating and modifying cognition and behaviour and makes use of scientifically validated procedures to help patients develop healthier, more effective thoughts and habits. Psychotherapy often utilizes a collaborative approach that is grounded in dialogue

between a therapist or coach, and the patient. Although differences in efficacy exist between specific patient groups, there are various types of psychotherapy that are equally efficacious in treating mild to moderate depression in adults and have comparable effects as can be achieved with pharmacotherapy [25, 26]. A common type of psychotherapy is Cognitive Behavioural Therapy (CBT), which focusses on identifying and changing harmful or ineffective thinking and behaviour patterns. CBT can be considered as a group of related therapies incorporating a range of therapeutic techniques such as psycho-education, techniques invoking behavioural activation and change, cognitive restructuring, and relapse prevention [27, 28]. Compared to treatment-as-usual or no treatment (incl. waiting), CBT is found effective in treating depressive disorder [29] and in anxiety [30, 31]. CBT often consists of varying combinations of therapeutic techniques utilising different delivery methods, including in individual and group face-to-face settings, using written materials, or Internet-based technologies.

Despite the availability of effective treatments, only a limited number of patients suffering from anxiety or depressive disorder are treated. Noting the differences between national mental health care systems, one in fourteen (6.4%) adults with a mental health disorder use formal health services for improving their mental health in Europe. Irrespective of evidence-base, a little over a third (38.9%) of those who seek help, do not receive treatment from a licensed mental health professional and one in five (21.2%) do not receive a prescription for a specific treatment for their mental health disorder [32-34]. Research showed that low service utilisation is associated with demographic factors such as gender, ethnicity, education levels, marital status, and other factors, such as self-evaluated health status, mental health literacy, chronicity, symptom severity, levels of disability, and comorbidity [35, 36].

Internet-based mental health services, also referred to as electronic Mental Health or eMH, have been developed and studied extensively the last two decades [37]. E-mental health services include a broad spectrum of digital technologies that purport to assess, improve, maintain, promote or modify mental health through diagnostic and therapeutic treatment interventions [37]. Various randomised controlled trials and meta-analyses have demonstrated the effectiveness of eMH services such as Internet-based CBT (iCBT) in treating depression and anxiety [38, 39]. Although clinical effects are small, self-guided services have been found to be effective in reducing symptoms of depression and anxiety [40] and require minimal resourcing [39]. Those services with integrated therapeutic guidance from a coach or therapist, result on average in better clinical outcomes in treating depression

and anxiety [41]. When applied in routine care settings, iCBT services are also found to be effective, notably when employing a model with therapist guidance [42-45]. From an economic perspective, eMH services such as iCBT carry the promise to be a cost-effective alternative to face-to-face psychotherapies which is especially relevant when considering the increasing demand of delivery resources resulting in shortages of mental health providers [46]. However, and although research is maturing, current evidence suggests that guided and blended iCBT compared to CBT that is delivered fully in a face-to-face format, possibly has a limited cost-effectiveness from a societal perspective [45, 47-49]. One possible explanation might be that eMH services are clinically effective, have comparable delivery costs to face-to-face psychotherapy, but have less impact on the time patients return to work, which is the largest cost-driver from a societal perspective. From the perspective of mental health service organisations, eMH services do seem to be a cost-effective alternative to face-to-face psychotherapy, especially when considering that costs of delivery are likely to be optimized when organisations and mental health providers gain experience with delivering eMH services [39, 48].

E-mental health services can be regarded as *complex interventions* consisting of multiple therapeutic, technological, and organisational components [50]. For example, iCBT utilises various digital technologies ranging from user-centric interactive multi-media and multiplatform designs, nudging, serious gaming, ecological momentary measurements, virtual reality, embodied conversational agents, and various communication methods with mental health providers. In addition, various guidance modalities can be embedded in iCBT to foster adherence and therapeutic effectiveness, including self-help with minimal technical and administrative support, online guidance from a mental health provider, and blended approaches where online treatment elements and face-to-face sessions with a mental health provider are integrated into one treatment protocol. In addition to the therapeutic techniques and technological elements, eMH services generally include procedures for patient enrolment and follow-up, a training programme, and patient safety and data security protocols, which combined can be considered as the organisational delivery model. In general, there are two models possible: 1) delivery through a centralised organisation with the sole purpose to deliver eMH services and 2), a dispersed model in which mental health providers in various *existing* mental health care clinics have access to the eMH service and are offered the possibility to deliver eMH to their patients. Notably the implementation of a centralised organisational model has proven to be a viable approach in Australia [51], Canada [52], Denmark [53, 54], Germany [55], the Netherlands [43], Norway [56], Spain [45], and Sweden [57, 58]. Often, these services emerged

from a series of research projects followed by a purposive valorisation program resulting in dedicated organisations established with the main purpose to deliver these eMH services to a region or even nation-wide. Documented examples of decentralised or hybrid organisational delivery models are sparse, but do exist, such as iFightDepression offered by psychiatric services of Azienda Sanitaria Locale Torino 3 (ASLTO3, Piemonte area, Italy), Super@ tu Depresión offered by Badalona Serveis Assistencials (BSA, Badalona area, Spain), and hybrid formats such as Mindway by GGZ inGeest (GiG, Amsterdam area, the Netherlands) [59, 60]. However, only few of these initiatives studied the implementation processes by which they were integrated in existing models of mental health care, and none did so formatively with the aim to improve our understanding of the implementation processes and resulting outcomes.

Moreover, eMH services do not seem to enter routine mental healthcare care at scale [61-64] as they seem to be less well integrated in existing mental health service organisations in primary care [65-67] or existing specialised care settings [68]. Considering that these services (still) do not enter routine mental healthcare care to realise their full potential, this can be considered an implementation problem.

Implementation science is concerned with the scientific study of methods that promote the systematic uptake of research findings and other evidence-based practices with the aim to improve the quality of health care [69]. Implementation is commonly understood as a deliberate and planned process of integrating and embedding whereby an innovation becomes a normal part of daily routine [8, 70, 71]. The last decade, the field of implementation science has grown rapidly resulting in a plethora of taxonomies, frameworks, models and theories aimed at describing, explaining and guiding implementation of complex medical interventions [72]. Implementation is driven by complex multi-level interactions of people involved and affected by the implementation and takes place in a dynamic context or setting [71, 73-77] and many of these frameworks and theories are intervention or context specific. Context can be seen as a set of active and unique factors that influence and modify the eMH service that is to be implemented, the context itself, and the implementation process by which the service is integrated. Contextual factors change over time and manifest at different levels, including at the organisational level and the health care system. Examples of factors in the organisational context are working procedures and guidelines, social norms, technical infrastructure, financial resources, skills, etc. Examples of system level factors include reimbursement policies, requirements for technological certification and staff accreditation, and public opinion [74, 77, 78]. Whereas

system level barriers are often external and outside the sphere of influence of implementers within organisations, organisational contextual factors might be more sensitive to change and hence, can be altered with the aim to improve the implementation of eMH services in routine care. Contextual factors pose an intriguing problem to implementing evidence-based eMH services successfully. Each factor has their own causal mechanism or set of mechanisms, imposing challenges to reliable measurement and to developing effective strategies to ultimately, improve implementation outcomes.

Overall aim and research objectives

The overall aim that guided the research in this dissertation was to advance the understanding of real-world implementation of eMH services for depressive disorder and anxiety in routine care from an organisational perspective. The research included in this dissertation addressed five sub-questions:

1. How are eMH services assessed in informing decision-making in health care organisations regarding the implementation of such services?

2. What factors are known to promote or inhibit successful implementation of eMH in routine care?

3. How can the nature and value of organisational implementation climate in implementing eMH services in routine mental health care be understood?

4. How can processes and outcomes of implementing eMH services in mental health service providers and organisations be measured reliably?

5. Can tailored implementation strategies be effective in implementing eMH services?

In realising evidence-based medicine, systematic and transparent assessment of the clinical, organisational, and societal impact of novel eMH services is warranted to support decision making in what intervention to implement. Health Technology Assessment (HTA) is an established approach to support evidence-informed decision-making by service delivery organisations, regulators, funders, and other actors in the health care system [79, 80]. In Chapter 2, a summary of the state-of-the-art in Health Technology Assessment for digital health including eMH is

provided. A qualitative systematic review of scientific literature was conducted to synthesise the HTA frameworks and methods that are used to assess the impact of eMH services on health and care provision.

In Chapter 3, a taxonomy of barriers to successful implementation of eMH services in practice is provided. Like in clinical practice, a detailed diagnosis is required prior to selecting and applying a targeted implementation strategy. In improving implementation outcomes, the first step is to identify the factors that might promote or inhibit implementation of health care services in routine practice [81]. These factors, also referred to as determinants of implementation practice, can inform the development of specific implementation strategies. A large body of research reports on numerous determinants in implementing evidence-based practices [72, 82-86]. A systematic review of the literature was conducted to provide a broad overview of determinants of implementing eMH services in routine care settings.

Underlined by the systematic review, barriers on organisational and health system level are particularly underrepresented in scientific literature. Therefore, the nature and value of organisational implementation climate in mental health service organisations was explored in Chapter 4. Conceptually, organisational implementation climate can be defined as the shared meaning that staff members attach to organisational events, practices, and procedures they experience and the behaviours they see being rewarded, supported, and expected in implementing evidence-based practices [87-90]. Organisational implementation climate is thought to influence service providers' (e.g. psychologists, psychiatrists) acceptance of and attitude towards implementing new services such as eMH services in practice [68, 88, 89, 91, 92]. This explorative study was conducted in 14 mental health organisations across Europe in the context of the MasterMind Project [59]. A combination of a qualitative concept mapping approach with implementers and a cross-sectional survey amongst service providers was applied.

In improving implementation practices, hindering factors need to be addressed with effective implementation strategies [93, 94]. Measures of the progress and outcome of implementation processes is essential in verifying whether an implementation strategy is effective. However, validated instruments to objectively and reliably monitor implementation processes and assess outcomes are generally lacking [95, 96]. The Normalisation Assessment Development project (NoMAD) aims to address this issue. NoMAD is a brief 23-item self-report questionnaire [97]. It is based on the Normalisation Process Theory which theorises four generative

mechanisms (Coherence, Cognitive Participation, Collective Action, and Reflexive Monitoring), that shape implementation outcomes in health care settings [98]. Initial psychometric evaluations of the NoMAD questionnaire in UK/Australian samples were promising [99, 100]. In chapter 5, a Confirmatory Factor Analysis is reported which aimed to replicate these findings in samples of Dutch mental health service providers.

Considering the relevance of the organisational context in implementing evidence-based practices, the culmination of this dissertation focussed on tailored implementation strategies that mental health organisations can develop and apply to improve the implementation of eMH services. One-size-fits-all solutions do most likely not exist. Implementation takes place in a complex and dynamic context and faces barriers that vary considerably from setting to setting and over time. Tailored implementation is regarded as a viable approach to effectively and efficiently change practices [101]. Tailoring entails a systematic process of identifying the potential factors hindering the implementation, match those to implementation strategies that might be effective and adapt these into detailed work plans, and apply and monitor progress and outcomes of those tailored implementation strategies [102-104]. By purposively addressing the factors that impede integration of eMH services in the context of a local setting, it is expected that these services can be implemented more quickly and more efficiently. Building on the determinants identified in Chapter 3, and the validated outcome measurement instrument reported in Chapter 5, the effectiveness of a self-guided implementation toolkit for tailored implementation is reported in Chapter 6. This was the result of the ImpleMentAll project.

The work concludes in Chapter 7 with a reflection on the findings reported in this dissertation and possible ways forward to further improve implementation of eMH services for depressive disorders and anxiety in practice.

2

Chapter 2

Health technology assessment frameworks for eHealth: A systematic review

Abstract

Objectives. Traditionally, health technology assessment (HTA) focuses on assessing the impact of pharmaceutical technologies on health and care. Resources are scarce and policy makers aim to achieve effective, accessible health care. eHealth innovations are increasingly more integrated in all healthcare domains. However, how eHealth is assessed prior to its implementation in care practices is unclear. To support evidence-informed policy making, this study aimed to identify frameworks and methods for assessing eHealth's impact on health care.

Methods. The scientific literature in five bibliographical databases was systematically reviewed. Articles were included if the study was conducted in a clinical setting, used an HTA framework and assessed an eHealth service. A systematic qualitative narrative approach was applied for analysis and reporting.

Results. Twenty-one HTA frameworks were identified in twenty-three articles. All frameworks addressed outcomes related to the technical performance and functionalities of eHealth service under assessment. The majority also addressed costs (n = 19), clinical outcomes (n = 14), organizational (n = 15) and system level aspects (n = 13). Most frameworks can be classified as dimensional (n = 13), followed by staged (n = 3), hybrid (n = 3), and business modelling frameworks (n=2). Six frameworks specified assessment outcomes and methods.

Conclusions. HTA frameworks are available for a-priori impact assessment of eHealth services. The frameworks vary in assessment outcomes, methods, and specificity. Demonstrated applicability in practice is limited. Recommendations include standardization of: (i) reporting characteristics of eHealth services, and (ii) specifying assessment outcomes and methods following a stepped-approach tailored to the functional characteristics of eHealth services. Standardization might improve the quality and comparability of eHTA assessments.

Background

Health care faces serious challenges when it comes to the economic sustainability of the system. Decisions are made on how to achieve and maintain effective and accessible health care. Thorough impact assessment of existing and new healthcare practices on relevant outcomes is warranted to ensure delivery of the right care at the right time, to the right person. Impact can be understood as the (un)intended consequences that healthcare practices have in different health and care outcomes, including efficacy, safety, effectiveness, costs, and other care provision-related aspects. During the 1980s, health technology assessment (HTA) grew into a discipline, producing and summarizing evidence about efficacy and efficiency of predominantly pharmaceutical innovations [1-4]. Over the years, HTA extended the conceptual and methodological assessment of clinical outcomes and cost-effectiveness of pharmaceuticals to include patient perspectives, organizational dimensions, and other societal aspects [5, 6]. In parallel, the role of technology in health care gradually expanded from a biomedical orientation toward a more holistic approach that includes medical devices such as imaging tools, robotics, and digital healthcare solutions.

Currently, novel interventions are commonly assessed through formal HTA, evaluating mostly clinical outcomes in order to realize evidence-informed decision and policy making. In general, HTA apply frameworks that involves mostly quantitative intervention properties [7]. Such frameworks specify methods for assessing the qualities of the intervention under study, including comparative effectiveness research (CER), systematic, and meta-analytic reviews on the clinical effectiveness of an intervention expressed in numbers-needed-to-treat or cost-effectiveness estimates such as incremental cost-effectiveness ratios [7, 8].

Various national and international organizations are engaged in HTA and involved in creating or guiding the development of standards for the evidence required including for digital technologies. For example, National Institute for Health and Care Excellence in England (NICE) recently developed an Evidence Standards Framework for Digital Health Technologies [9]. This framework provides technology developers with standards of the evidence demonstrating health technologies' (cost)-effectiveness in the UK health and care system. Zorginstituut Nederland (ZIN, the Dutch National Health Care Institute) has statutory assignments to the systematic assessment if healthcare interventions are being deployed in a patent-oriented, clinically effective and cost-effective manner. Such analyses are part of its flagship program "Zinnige Zorg" (appropriate care), specifically designed to

identify ineffective and unnecessary care across a number of themes, including patient-centeredness, shared decision making, and approaches to stepped care [10, 11]. ZIN currently hosts the secretariat of EUnetHTA, a collaborative network aimed to produce and contribute to HTA in Europe. Following the trends of professionalization and widening the focus, HTA practice evolved to structural assessments of the impact of a variety of health innovations across a multitude of health and care organization-related outcomes.

eHealth refers to the organization, delivery, and innovation of health services and information using the Internet and related digital technologies [12, 13]. Being a container concept, it includes a broad spectrum of digital technologies that purport to assess, improve, maintain, promote or modify health, functioning, or health conditions through diagnostic, preventive, and treatment interventions in somatic and mental health care. eHealth is expected to improve accessibility, affordability and quality of health care [14]. eHealth is debated to diverge from traditional health care due to its technological properties, speed of development, and complexity of implementation in existing routine care, as eHealth often impacts interlocking levels of organizational, staff, and client behaviours, beliefs, and norms [15, 16]. Meanwhile investments in eHealth are rising, the urgency of healthcare transformations is pressing and the use of a wide array of both proven and unproven eHealth applications is growing.

Discussions on the necessity of eHealth specific HTA frameworks are ongoing. In general, technology evolves quickly and impact assessment has often been perceived as a hindering factor. A certain level of maturity of the technology is required for which evidence has been provided to inform decision making. Studies have investigated the use of Rapid Relative Effectiveness Assessments (REAs) to address these concerns and reduce the required time for obtaining evidence and conducting the assessments[17]. However, these approaches primarily focus on effectiveness (under routine care conditions) and safety and leave out topics deemed more context dependent such as costs and organizational aspects to improve comparability across healthcare settings.

Nevertheless, the necessity of incorporating eHealth in traditional care practices, and the inherent complexity of achieving sustainable change, requires a multi-perspective and multimethod approach for assessing their impact on relevant outcomes. Ultimately, eHealth is about health and care of and for real people. There should be no exceptions in conducting rigorous assessment of the impact of eHealth services on health and

care. It is unclear how eHealth services can be assessed systematically, to inform and support decision making in policy and practice prior to their implementation [16]. Contrary to traditional HTA, assessments of eHealth services (eHTA) are less forged in structured approaches. Reasons may include the diverse and rapidly evolving nature of the technological properties and the amalgamative nature of eHealth, referring to the interconnectedness of such services with behavioural, cultural, and organizational aspects of healthcare delivery [11, 15, 18, 19].

We conducted a systematic review of the scientific literature to answer the following question: which frameworks are available to assess the impact of eHealth services on health and care provisions? We regard assessment frameworks as providing a conceptual structure to the assessment but not necessarily specifications of the methods and evaluation instruments that should be used to conduct the actual assessments. A conceptual structure includes for example assessing the effectiveness, safety, and the required technical infrastructure of an eHealth service. An example of the methods and instruments used such concepts include conducting randomized-controlled trials to measure change in blood levels as an indication of symptom reduction, or perform data transfer speed tests to establish the required band-width. Because of this nuance, we also identified the specific assessment methods and instruments proposed by the frameworks.

Methods

A broad search strategy was applied with high sensitivity to two key terms: "eHealth" and "health technology assessment." A total of 155 synonyms were formulated, resulting in a fine-grained search string for use in five online bibliographical databases: PubMed (Medline), Cochrane (Wiley), PsychINFO (EBSCO), Embase, and Web of Science (Thomson Reuters/Clarivate Analytics). A trained librarian guided the development of the search strings (see Supplementary file 1).

All identified papers were examined for eligibility by two researchers (CV and LB) independently. Disagreements were solved by discussion. The following inclusion criteria were applied: (a) the assessment was conducted in a clinical setting, (b) used an explicit HTA framework, and (c) the clinical intervention included a digital technological component. Articles were excluded if:

- The primary aim was to establish clinical efficacy, effectiveness, cost-effectiveness, feasibility, piloting, usability testing, or design of eHealth services.

- Services included in the assessment can be categorized as medical devices (assistive technology, imaging, and surgical devices), information systems (electronic health records, decision making tools, scheduling systems, information resources, training, and education), or pharmacological interventions.
- They contain implied viewpoints, commentaries, editorials, study protocols, proposals, presentations, posters, HTA-use reviews, and/or development proposals.
- The full text article was not available or not in English.

A standardized data extraction form was developed to extract relevant data from the remaining articles, including:

- General study characteristics.
- eHealth service assessed (participants, inclusion criteria, intervention aim and working principles, target disorder, technological principles, outcomes, and setting).
- HTA framework used (purpose, structure, advantages, methods, evaluation dimensions and criteria, working principles, and intended users).
- Methods and instruments applied (type, aims, purpose, instruments, data collection methods, and link to framework).

A systematic qualitative narrative approach was applied for analysis [20-22]. Commonalities across the frameworks were examined to structure the analysis in terms of what, when, and how specific properties of eHealth services can be assessed.

Results

The searches, which were performed in March 2018, resulted in 3,915 articles. After removing duplicates, 2,068 titles and abstracts were screened for eligibility. Figure 1 provides an overview of the identification and selection of studies in different phases of the screening.
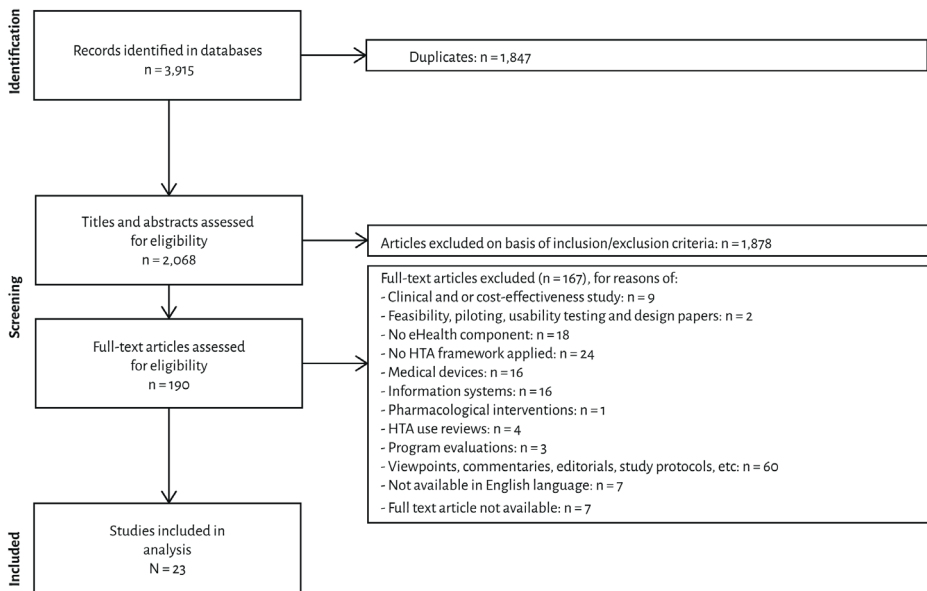
Figure 1: PRISMA flowchart illustrating study identification and selection process.

eHTA Frameworks

The twenty-three articles included in this review report in total twenty-one distinctive eHTA frameworks. Four themes classifying the frameworks emerged from the analysis of the included literature: (i) staged (n = 3, references: [8, 23, 24]), (ii) dimensional (n = 13, references: [6, 25-38]), (iii) hybrid (n = 3, described in references: [39-41]), and (iv) business modelling (n = 2, references [42, 43]). Table 1 provides an overview of the frameworks identified according to their classification. All frameworks included in this review are summarized in Table 2.

Table 1: Classification of the frameworks identified in the review

Framework classification	Technical	Clinical	Economic	Organizational	Ethical and legal	Care system	Information quality	Needs
Staged frameworks (n=3)	3	1	3	3	-	1	-	1
Dimensional frameworks (n=13)	13	9	11	9	3	8	1	-
Hybrid frameworks (n=3)	3	3	3	2	3	2	-	1
Business modelling frameworks (n=2)	2	1	2	1	-	2	-	-
Total (N=21)	21	14	19	15	6	13	1	2

n and N refer to the number of unique frameworks found in this review.
Columns 2–10 indicate the assessment dimensions:
Technical: aspects related to the technical characteristics of the service.
Clinical: aspects of clinical outcomes including effectiveness, well-being, and safety.
Economic: aspects of cost and cost-effectiveness.
Organizational: aspects of an organizational nature such as training, resources, procedures, etc.
Ethical and legal: ethical and legal aspects such as data protection.
Information quality: the quality of the information included in the assessment.
Needs: aspects defining the needs of stakeholders regarding the service under assessment.

Staged Frameworks

Staged frameworks apply a sequential phased approach for assessing outcomes relevant to the developmental phase of the eHealth service. Three frameworks advocate a staged approach, two of which focus on providing guidance on comparing and selecting eHealth devices, and one on informing (further) development of eHealth services. To highlight these different approaches, two frameworks are explained in more depth. For example, Casper and Kenron [23] take a socio-technical systems approach, aligning users' values with functional elements of the eHealth service. The framework has four phases: (i) development of project needs, (ii) survey of potential eHealth services, (iii) evaluation of candidate services, and (iv) selection of the service. Important considerations in the selection process include technological aspects, user-, and environmental factors. For phase three, an unweighted decision list is based on the needs identified in phase one addressing usability, robustness, size and weight, ease of setup, costs, and availability of the eHealth solution.

DeChant et al. [8] argue that besides the clinical and technological performance of eHealth services, the overall impact on health care should also be assessed. This

is because eHealth services, when introduced in routine care, potentially affect a range of aspects of care delivery including care pathways and access to care [8]. Consequently, their framework consists of four successive stages addressing (i) technical efficacy, (ii) healthcare system objectives, (iii) analysis, and (iv) external validity. Each stage focuses on the impact of eHealth services on the quality, accessibility, or costs of care. For each stage, the assessment is tailored to the maturity of the eHealth service.

Dimensional Frameworks

Dimensional frameworks prescribe sets of assessment outcomes grouped in dimensions. The dimensions are categorized in accordance with expected impacts of eHealth services, irrespective of their developmental stage. All thirteen identified frameworks focus on assessment of technical features, clinical, and economic outcomes, with few also addressing organizational, ethical, and system level outcomes. Full details are provided in Table 2. Two frameworks are detailed below due to their distinctive features: the Technology, Economic, Market, Political, Evaluation, Social and Transformation framework (TEMPEST) [26] because of its comprehensiveness, and the Telehealth Evaluation Framework [29] which explicates the importance of different perspectives in assessing eHealth services.

The TEMPEST framework specifies seven domains for comparing benefits of and barriers to eHealth service adoption [26]. The domains concern outcomes of (i) access, usage, emerging technologies, interoperability, and the delivery model, (ii) economy, including funding, performance, and human resources, (iii) engagement and use in terms of the healthcare market, (iv) policy-related matters, (v) governance, regulation, and compliance, (vi) sociological aspects such as care access, and (vii) care reformation, strategies, and implementation. These seven domains are divided into twenty-one sub-themes with eighty-four quantitative outcomes covering different perspectives, including a market, political, commercial, stakeholders, and individuals.

Hebert [29] places the perspective from which an assessment is conducted central in defining the dimensions for evaluation. Building on Donabedian's work [44], the outcomes relate to individual and organizational assessment perspectives. The underlying premise is a relationship between structure–process– outcome. The framework identifies five domains: (i) individual structure including patients' access and acceptability, and providers' training, and changes in practice, (ii) organizational structure related to scheduling, infrastructure, culture, costs, and equipment effectiveness, (iii) care process concerning satisfaction, effectiveness,

and care management, (iv) individual level outcomes such as patient satisfaction, quality of life, functional status, and adverse effects, and (v) organizational level outcomes including resource use, costs, and service utilization.

Hybrid Frameworks

Hybrid frameworks combine a phased perspective on service development with an assessment of the current impact of an innovation using varying sets of criteria to be assessed in a particular order. Three frameworks can be classified as hybrid.

The TM-QC framework [37, 38] brings a technological and quality assurance perspective to eHealth assessments and applies two phases. The first phase comprises seven dimensions for classifying the service. For the second phase, a technical dossier is compiled detailing system design, requirements, security standards, risk analysis, clinical evaluation, and maintenance aspects. In addition, a quality assessment is performed on three dimensions: (i) product requirements regarding patient safety and privacy, (ii) product design, manufacturing, and testing, and (iii) economic evaluation and social aspects. Following the quality assessment, a score is calculated and compared to a predefined threshold.

The Khoja–Durrani–Scott Evaluation Framework (KDS) [40] aligns its evaluation themes to the eHealth services' life-cycle phases comprising: (i) development, (ii) implementation, (iii) integration, and (iv) sustained operation. Across these phases, seven groups of outcomes are assessed: (i) health outcomes, (ii) technology including appropriateness, relevance, use, safety, and effectiveness of the service, (iii) economy related to affordability and willingness-to-pay, (iv) behavioural and sociotechnical outcomes covering (un)intended social consequences and social change processes, (v) ethical aspects, (vi) readiness and change outcomes, and (vii) policy outcomes concerning the facilitation of consistent eHealth service delivery. For each of the assessment outcomes specific evaluation methods are included (KDS tools) [45].

The Model for Assessment of Telemedicine applications (MAST) [39, 41] defines a three-phased assessment of: (i) preceding considerations to determine the relevance of an assessment, (ii) a broad range of outcomes structured in seven domains, and (iii) transferability to understand the potential for scaling-up or -out. For phase one, issues regarding relevant regulatory aspects (financial, maturity, and potential use) are assessed, addressing questions about the purpose, alternatives, required level of assessment (international, national, regional, and local), and the maturity of the eHealth service. Phase two is based on the EUnetHTA Core Model [46, 47] covering

seven domains: (i) the health problem targeted, (ii) clinical and technical safety, (iii) clinical effectiveness, (iv) patient perspectives, including satisfaction, acceptance, usability, literacy, access, empowerment, and self-efficacy, (v) economic evaluation addressing costs, related changes in use of health care, and a business case, (vi) organizational aspects including procedures structure, culture, and management aspects, and (vii) further socio-cultural, ethical, and legal issues. The third phase focuses on assessing the potential to effectively transfer the eHealth service to other healthcare systems and its scalability in terms of throughput and costs.

Business Modelling Frameworks

Where the previous frameworks provide a list of outcomes to consider in assessing eHealth services, business modelling frameworks in this context focus on the economic viability and business models for eHealth services.

Alfonzo et al. [42] places transactional distances in providing and receiving care central in their framework. Transactional distance refers to any factor having an impact on an interaction that creates distance between the parties, such as education, culture, ethnicity, gender, health status, geography, etc. [42]. The purpose of the assessment is to examine the extent to which changes in the transactions result in an improvement or deterioration in health, the associated costs, and access to care.

The Innovating in Healthcare Framework proposed by Grustam et al. [43] takes a business modelling approach to the assessment of eHealth services. The framework consists of three parts: (i) types of healthcare innovation, (ii) a six-dimension assessment, and (iii) business model elements [43]. The assessment includes evaluation of the (i) structure of the system, (ii) financing mechanisms, (iii) regulatory public policies, (iv) technological, developmental, and competitive aspects, (v) consumer empowerment, and (vi) accountability. Business modelling includes assessing the (i) market, (ii) financial viability, (iii) valuations regarding cash flows and rates of return, (iv) financial sustainability, (v) managerial skills and requirements, (vi) societal impact, and (vii) technological risks.

Table 2: Main characteristics of the eHTA frameworks identified in the systematic review

Name	Type and assessment dimensions	Purpose and general approach to the assessment
[Device Selection Matrix] [23]	Type: staged Assessment: Technical, Economic, Organisational	Purpose: to evaluate and compare candidate ICT devices on the basis of established criteria. Provides an unweighted decision list of parameters including and aligned with needs identified in the first phase. Parameters include usability, robustness, size of the unit, ease of setup, cost, weight and availability
[Staged approach to evaluation of telemedicine] [8]	Type: staged Assessment: Technology, Clinical, Economic, Care system	Purpose: to systematically evaluate telemedicine to inform and foster the (further) development of telemedicine technologies. The framework discerns four stages: (1) technical efficacy (accuracy and reliability in ability to transmit accurate information), (2) specific system objectives (to determine feasibility; single endpoints in domains of access, quality or cost), (3) system analysis related to the global impact on access, quality and costs for system, (4) external validity concerning the impact on access, quality and costs in a different system.
[Stepped evaluation of eHealth services] [24]	Type: staged Assessment: Technical, Economic, Organisational	Purpose: to identify specific properties in similar eHealth services and compare them with one another to help decision-makers to select and prioritise eHealth services prior to purchase, development, or implementation in today's health and social care organisations. The framework distinguishes 6 steps: (1) identify and sort goals and effects, (2) determine requirements, needs and preconditions (technical, operational and financial), (3) economic impact (i.e. cost estimation in direct, adjustable, and introduction costs), (4) implementation strategies, (5) rewards and incentives, (6) get a comprehensive picture of the service, i.e. summary of steps 1-5 in terms of objectives, effects, technical, operational, financial requirements, costs, dissemination and reward model.
[Three-dimensional model for telemedicine evaluation] [6]	Type: dimensional Assessment: Technical, Care system	Purpose: to produce objective and credible evidence regarding the merits and problems of telemedicine. Assessment of the application (public health, education, clinical), perspectives (client, provider, society), technological characteristics (synchronous online systems, asynchronous store-and-forward systems, modalities of transmission, bandwidth, peripheral devices for diagnosis and treatment)
[Multi-method telemedicine application evaluation] [25]	Type: dimensional Assessment: Technical, Clinical, Economic, Organisational	Purpose: to assess a telemedicine application's utilisation, clinical and organisational impact, technical functioning and cost-effectiveness. Assessment of utilisation (nature and frequency), clinical impact on clinical decision-making and clinical care, organisational context, technical performance, costs and cost-effectiveness, triangulation (i.e. the ways in which dimensions 1-5 may have influenced and been influenced by the others)

Name	Type and assessment dimensions	Purpose and general approach to the assessment
Technology, Economic, Market, Political, Evaluation, Social and Transformation (TEMPEST) [26]	Type: dimensional Assessment: Technical, Economic, Care system	Purpose: to compare and contrast benefits and barriers in health technology adoption and diffusion. Assessment of access and usage (enabling/emerging technologies, interoperability of eHealth, eHealth service delivery model), economic factors (health care funding, performance and population, labour market segmentation), market (market-driven health care, consumer-driven health care, IT market capabilities and skills), political priorities and barriers (eHealth policy, education and training, institutional structure), health technology evaluation (i.e. eHealth policy governance, regulation and compliance, eHealth adoption/user engagement, performance measurement and benefits realisation), social (social inclusion/access, patient-centred health care, demographics and transformational aspects (i.e. education, training, reform agenda, strategy and implementation).
Unified eValuation using Ontology (UVON) [27]	Type: dimensional Assessment: Technical, Clinical, Economic, Organisational, Ethical & Legal, Care system	Purpose: to evaluate one or more health information systems by organising, unifying and aggregating the quality attributes extracted from those systems. Assessment of accessibility, adherence, affordability, authenticity, availability, efficiency, effectiveness, empowerment, safety, ability to trust.
Health Services Research framework (HSR) [28]	Type: dimensional Assessment: Technical, Clinical, Economic, Organisational	Purpose: to assess the impact of telemedicine on access, quality and costs of care. Assessment of accessibility and timeliness of care, costs of care, quality of care in terms of a) structure (speed and technical quality of transmission, adequacy of equipment, skills, costs, accessibility), b) process (sensitivity and specificity of diagnosis, evidence-base of treatment plan), c) outcome (short-term: clinical outcomes; intermediate: adherence, acceptability, satisfaction; long-term: quality of life, health or functional status).
[Telehealth Evaluation Framework] [29]	Type: dimensional Assessment: Technical, Clinical, Economic, Organisational, Care system	Purpose: to develop a body of knowledge around telehealth evaluation. Assessment of individual structure (i.e. patient access to services, patient acceptability, provider training, provider change in practice), organisational structure (scheduling, equipment location suitability, culture, costs, equipment effectiveness), care process (satisfaction, effectiveness of interaction, management of care process), individual outcomes (satisfaction, quality of life, functional status, number of re-admissions and adverse effects), organisational outcomes (use of resources, cost effectiveness, utilisation).

2

Table 2: Continued

Name	Type and assessment dimensions	Purpose and general approach to the assessment
Commonwealth Scientific and Industrial Research Organisation framework (CSIRO) [30]	Type: dimensional Assessment: Technical, Economic, Organisational, Care system	Purpose: to design delivery, implementation and evaluation of telehealth services. Assessment and classification of health domain (i.e. application area), health services (consultation, diagnosis, monitoring, triage, mentoring, training/education, treatment), technology (postal mail, telephone; email, fax; store and forward, real-time, hybrid; integrated video and data; assistive and censoring; interactive telepresence), communication technology (telephone lines, television lines, fibre optics, wireless, satellite dish), environmental settings (people involved, locations, communication modes, devices used), socioeconomics (costs, benefits, barriers to uptake, outcomes such as early diagnosis, information flow, reduced delays, safety feasibility and improved patient care).
[Assessment of telemedicine applications] [31]	Type: dimensional Assessment: Technical, Clinical, Economic, Information quality	Purpose: to provide a broad description of telemedicine for decision-makers, covering technical, clinical, economic, ethical, legal and organisational issues. Assessment of technical aspects (technical quality of image/voice, reliability, validity and other characteristics), effectiveness (diagnostic quality, quality of life, clinical, management process, know-how, non-health patient outcomes), user assessment (quality, usability and satisfaction with the technology), costs (investment, user charge for equipment, communication lines, staff wages, education costs, other relevant costs (housing, administration, etc.), patient costs, patient lost working hours/leisure time, health-related intangible costs), study design (randomisation, before/after comparison, control groups), economic evaluation methods (costs, cost-effectiveness, cost-benefit ratio, cost-utility analysis), sensitivity analysis.
CHEATS [32, 33]	Type: dimensional Assessment: Technical, Clinical, Economic, Organisational	Purpose: to provide a comprehensive framework from which aspects can be drawn and parts utilised to evaluate any kind of ICT system. Assessment of clinical aspects (quality of care, diagnostic reliability, impact and continuity of care, acceptance, changes in work practices and resources, acceptance and efficacy, cultural differences, interviewing techniques, effectiveness of referral), human and organisational aspects (interfaces between care providers), educational (recruitment and retention of staff, training provisions, acceptability and continuity), administrative (access to care, change in interaction styles, cost-effectiveness), technical (appropriateness, video/sound quality, differences in techniques, ease of use, technology-specific training, reliability) and social interactions.
[8-dimension sociotechnical model of safe and effective IT use] [34]	Type: dimensional Assessment: Technical, Organisational, Ethical & legal, Care system	Purpose: to evaluate the design, development, implementation, use and monitoring of health IT within complex health care systems. Assessment of hardware and software in relation to safe and effective use of ICT, clinical content (data, information, knowledge), human–computer user interface, personnel involved in design, development, implementation, use and management of IT-enabled health care, workflow and communication, organisational policy, procedure, culture, environment, external rules and regulations, and measurement and monitoring.

Name	Type and assessment dimensions	Purpose and general approach to the assessment
[Telemedicine evaluation plan] [35]	Type: dimensional Assessment: Technical, Clinical, Economic, Organisational	Purpose: to assess and continue to develop and assess telemedicine applications in the context of Greenland. Assessment of expectations and reactions of professional users, reactions of clients, logistics, organisation and technology, medical gain, waiting time for patients, patient travel, economy (in addition, also of staff as well as direct costs and admission costs), transferring competence and recruiting/retaining staff.
Clinical Value Compass [36]	Type: dimensional Assessment: Technical, Clinical, Economic	Purpose: to evaluate changes in clinical processes. Assessment of health-related quality of life (physical and emotional aspects), patients' satisfaction (about modality and technological aspects, costs (i.e. ER admissions, hospitalisations) and clinical status (disability, relapse, severity of symptoms).
Telemedicine Quality Control system (TM-QC) [37, 38]	Type: dimensional Assessment: Technical, Clinical, Economic, Ethical & legal	Purpose: to monitor and measure the characteristics of telemedicine products and services. The framework describes two assessment phases, each addressing different outcomes. Phase I concerns a preliminary evaluation of features, classification (area of application, users), preliminary evaluation and areas for improvement. Phase II includes a technical file (TF) detailing (1) performance and functionalities (general description of the product/system, system design, requirements, security standards, product building methods,) correspondence between requirements and documents in the TF, risk analysis, clinical evaluation, documentation, maintenance), and (2) a quality assessment checklist (product requirements related to (a) patient safety, data privacy and integrity, transmission security, system requirements, technical service of the product, software certification, standards used, documentation, medico-legal implications and legal validity, efficacy of the telemedical health service, communication with users, (b) product design, manufacturing and testing, and (c) evaluation of economic and social aspects.
Khoja–Durrani–Scott Evaluation Framework (KDS) [40]	Type: hybrid Assessment: Technical, Clinical, Economic, Organisational, Ethical & legal, Care system	Purpose: to provide a comprehensive platform for developing an evaluation tool for eHealth programs. The framework describes seven themes assessed in four stages of the eHealth life cycle: development, implementation, integration and sustained operation. The seven themes include: health services outcomes (health status, quality of life), technology outcomes (appropriateness, relevance, use, safety, effectiveness), economic outcomes (affordability relative to willingness-to-pay), behavioural and sociotechnical outcomes (intended/unintended social consequences, planned interventions, social change processes), ethical outcomes (arising from clinical practice, research, resource allocation, use, access to technology), readiness and change outcomes, policy outcomes (set of statements, directives, regulations, laws and judicial interpretations required to facilitate structured and consistent eHealth practice).

2

Table 2: Continued

Name	Type and assessment dimensions	Purpose and general approach to the assessment
Model for Assessment of Telemedicine applications (MAST) [39, 41]	Type: hybrid Assessment: Technical, Clinical, Economic, Organisational, Ethical & legal, Care system, Needs	Purpose: to describe effectiveness and contribution of telemedicine applications to quality of care and to produce a basis for decision-making by using a multidisciplinary process which summarises and evaluates information about medical, social, economic and ethical issues related to the use of telemedicine in a systematic, unbiased, robust manner. The framework distinguishes between three phases, each addressing different outcomes. The first phase concerns preceding considerations including legislation, reimbursement, maturity of technology and number of patients. The second phase concerns a multidisciplinary assessment addressing health problem and characteristics of the application, safety, clinical effectiveness (mortality, morbidity, quality of life, behavioural outcomes, usage of health services), patient perspectives (satisfaction and acceptance, understanding of information, confidence in the treatment, ability to use the application, access and accessibility, empowerment, self-efficacy), economic aspects (resources and costs, related changes in use of health care, clinical effectiveness, business case), organisational aspects (process, structure, culture, management), and socio-cultural, ethical and legal aspects. The third phase concerns transferability issues, i.e. potential for expansion to other disorders and/or systems.
[Comprehensive telemedicine evaluation model] [42]	Type: business modelling Assessment: Technical, Clinical, Economic, Care system	Purpose: to examine the extent to which changes in transactions result in an improvement or deterioration in the health of the population, associated costs, and access to that system. The framework discerns three different areas of attention: (1) analysis level (individual, community, or society), (2) focus of analysis (i.e. driving forces of health care related to quality, accessibility, cost, and acceptability), (3) different uses (administrative, educational, intensive care, midlevel care and home care).
Innovating in Health care Framework [43]	Type: business modelling Assessment: Technical, Economic, Organisational, Care system	Purpose: to assess business models to innovate health care. The assessment framework has three parts: (1) the three distinctly different types of health care innovation (i.e. consumer, technology and integrator-based ventures), (2) six-factor alignment, i.e. is the idea viable (in terms of structure, financing, public policy, technology, consumers, accountability), (3) business model elements, i.e. how to make it happen (in terms of strategic market assessment, financial viability, valuation analysis, sustainability, managerial assessment, societal impact and risk assessment).

[]: brackets indicate that the name of the framework is not explicitly mentioned by the authors but is derived from analysing the manuscript.

Staged: means that the framework concerned predominantly applies a staged approach to eHealth Technology Assessment.

Dimensional: indicates that the framework concerned predominantly applies a dimensional approach to eHealth Technology Assessment.

Hybrid: indicates that the framework concerned can be categorised as combining a staged with a dimensional approach to eHealth Technology Assessment.

Business modelling: indicates that the framework concerned focusses solely on business modelling and economic aspects of eHealth Technology Assessment.

Assessment Methods and Instruments

Specific instruments for outcome assessment and data collection methods were reported for six frameworks. Four frameworks specified only the methods for data collection and performing the assessments. Another four frameworks include a list of specific instruments that can be used to assess the outcomes, but not the methods for collecting and evaluating the data. The frameworks, their methods, and instruments are listed in Table 3.

Frameworks that specify a set of methods for data collection and evaluation do so in a broad way. For example, the HSR framework suggests a number of possible broadly defined methodological strategies for assessing outcomes ranging from randomized-controlled trials to quasi-experiments using case-control studies and non-experimental designs such as case studies and correlational research [28].

Four frameworks include operationalized sets of outcomes (i.e., instruments) related to the assessment domains. The most comprehensive set of instruments is provided by the TEMPEST framework [26]. In total, eighty-four specific outcomes are defined, including technology penetration and use to assess emerging technological trends, health expenditures to inform economic assessment, and population level epidemiological outcomes for assessing health policies.

Six frameworks specify concrete instruments and methods for collecting data and evaluating outcomes. For example, KDS includes four separate evaluation tools in accordance with the four eHealth life-cycle phases specified by the framework [40]. Each of these tools include a set of questions for three types of users (managers, providers, and clients), covering seven outcome themes included in the framework.

For seven of the twenty-one frameworks, no specific assessment instruments or methods were reported. The main reason for not specifying methods or instruments for collecting data is that the operationalization of outcomes depends on the purpose, the technology, the patient group, and the context in which the eHealth service is to be implemented. In addition, the choice of outcomes and methods for data collection within each assessment domain must follow current state-of-the-art research methods within the domains to produce valid and reliable assessments [39].

Table 3: Instruments, measurements, and outcomes defined by each framework

Name	Purpose and specification	Outcomes only	Methods only	Methods + outcomes
[Three-dimensional model for telemedicine evaluation] [6]	The purpose of the suggested methods is to assess quality dimensions under a controlled environment. Methods include controlled studies, e.g. RCT, addressing two types of research questions that are appropriate for telemedicine evaluation: safety, effectiveness, access, quality and costs. The framework does not define concrete instruments to be used.		X	
[Multi-method telemedicine application evaluation] [25]	The framework suggests using a multi-method technique to evaluate various aspects of the telemedicine application. Methods are of a descriptive nature; qualitative and quantitative data and analysed using various techniques; each component employed different methods of evaluation (while the clinical and organisational components employed multiple methods of enquiry, the results from which were analysed in relation to one another)		X	
[Device Selection Matrix] [23]	To assess the usability of a device in a specific setting using the decision matrix. Methods applied include Likert scale ratings and sum scores.			X
Technology, Economic, Market, Political, Evaluation, Social and Transformation (TEMPEST) [26]	The TEMPEST framework provides 84 outcomes to assess the evaluation criteria. The outcomes cover the whole range of evaluation criteria.	X		
[Staged approach to evaluation of telemedicine] [8]	The framework proposes assessing quality, costs and accessibility of telemedicine applications at different levels of development. Various methods are suggested ranging from experimental to observational methods depending on stage of assessment.		X	
Unified eValuation using Ontology (UVON) [27]	Unified eValuation using Ontology for assessing the quality criteria of a specific system for different stakeholders. The assessment instruments involve a questionnaire based on the 10 quality criteria formulated by the framework. Two versions of the questionnaire are included: one for the patients and one for the health professionals, each expressing the same concept using a different vocabulary.			X
Telemedicine Quality Control system (TM-QC) [37, 38]	Informative Questionnaire (InQu): preliminary analysis; to collect from the suppliers structured information on their telemedicine applications with emphasis on the architecture; Classification Form (CF): to delimit application areas of product; Technical File (TF): technical dossier of the product, a document that describes all phases of product manufacturing, from design to post-release assistance; Quality Assessment Check List (QACL): assessing the telemedicine product or service quality. The instruments include a questionnaire and check lists.			X

Framework	Description		
Health Services Research framework (HSR) [28]	This framework suggests three different methods or designs for assessment: (1) true experiments: before-and-after measurements provide a valid basis for causal inference, namely that observed differences in access, costs, or quality of care between the two groups can be appropriately attributed to the experimental manipulation, rather than pre-existing differences between the groups; (2) quasi-experimental design: provides estimates of the probability of a given outcome given exposure or non-exposure to the intended intervention; and (3) non-experimental methods: the potential for yielding useful insights into the subject matter. True experiments might follow a randomised controlled trial design. Quasi-experiments could follow case-control study designs, and non-experimental designs could include case studies, case series and correlational designs.		X
Khoja–Durrani–Scott Evaluation Framework (KDS) [40, 45]	KDS Evaluation tool to evaluate e-health programs according to pre-specified themes. Surveys, coding and scoring schemes are available.		X
[Assessment of telemedicine applications] [31]	Assessment of evaluation criteria, no specific instruments are proposed by the framework; i.e. they vary across evaluation criteria, but are not further specified.	X	
CHEATS [32, 33]	Outcomes are designed for assessing the evaluation criteria of CHEATS for evaluating a specific ICT system. The outcomes suggested relate to qualitative and quantitative instruments: semi-structured interviews with key participants, and questionnaire and existing data about service use and clinical effectiveness	X	
[8-dimension sociotechnical model of safe and effective IT use] [34]	Specific instruments to assess the predefined evaluation criteria. The framework includes a set of evaluation items determined to be most relevant to the safety and effectiveness of the device.	X	
[Telemedicine evaluation plan] [35]	Eight different logs and six questionnaires were developed with common types of questions, one of which was copied/based on an existing questionnaire. The framework suggests logging each telemedicine consultation. Questionnaires were designed to be used during structured interviews (repeated) with staff involved.		X
Clinical Value Compass [36]	Health-related quality of life to measure patients' subjective health assessments; patients' satisfaction to measure satisfaction with treatment modality; costs to assess medical costs associated with emergency room admissions, hospitalisations and visits to outpatient clinics; and clinical status to assess clinical outcomes of treatment. A questionnaire is used and phone interviews after 6 months of telecare implementation; cost-data analysis; telephone interview using a structured questionnaire (pre/post) and medical patient file analysis.		X

eHealth Services Assessed

The eHealth services reported in the articles were described broadly, serving mainly illustrative purposes. The clinical purposes that were reported varied between diagnostic (n = 1), monitoring (n=5), and treatment (n=2), and areas of application such as chronic diseases such as multiple sclerosis, chronic heart failure, AIDS, chronic obstructive pulmonary disease (COPD), diabetes, or diabetic foot ulcers. However, patient profiles were not specified. Examples of settings in which an eHealth service was to be implemented included clinical and nonclinical settings or a combination of both. Clinical settings and disciplines were, for example, emergency rooms, tele-diagnosis and telemonitoring in pathology, psychiatry, ophthalmology, wound care, obstetrics, paediatrics, dermatology, and cardiology. Non-clinical settings and disciplines related to, for example, patients' homes, including tele-management systems, tele-rehabilitation, home-based self-monitoring, tele-education, and tele-consultation. The third category of eHealth services aimed to enable collaborative and integrated care between care providers in order to, for example, facilitate knowledge transfer for diagnostic and monitoring purposes.

A limited number of the included studies reported on actual application of the proposed framework. For instance, one study assessed the benefits of short-term implementation of a physical tele-rehabilitation system compared to usual care for Hebrew-speaking patients aged over 18 years old with a relapsing-remitting type of multiple sclerosis [36]. The assessment used the Clinical Value Compass framework, defining the outcomes in four domains, including clinical symptom severity, health related quality of life, patient satisfaction, and medical costs [36]. Another example of a study using an experimental approach to verify the utility of a specific eHealth service assessment framework is a study reported by Ekeland et al. [41]. This study aims to examine the utility of the MAST framework in the context of twenty-one implementation pilots of telemedicine services for diabetes, COPD, and cardiovascular disease.

Discussion

Main Findings

This study revealed twenty-one frameworks for eHTA that can be classified into four categories: staged, dimensional, hybrid, and business modelling focused. Two frameworks were reported in multiple articles: MAST [39, 41] and CHEATS [32, 33]. The majority of the frameworks constitutes a set of assessment domains related

to technical requirements and functionalities, clinical, economic, organizational, ethical, and legal characteristics, as well as characteristics of the healthcare system and stakeholders' needs. There is considerable variation in the guidelines provided by these frameworks regarding the operationalization of outcomes, instruments, and concrete methods for assessing the impact of eHealth services. The eHealth services presented in the articles served mostly illustrative purposes, rendering the proven applicability and real-world usefulness of the frameworks unclear.

The MAST framework provides the most comprehensive approach by including all domains identified in this review. The importance of such comprehensiveness is also found in a review of evaluation criteria for non-invasive telemonitoring for patients with heart failure [48]. However, it could be that not all domains are relevant to a particular eHealth service. Not only because of the development phase, but also because of specific aims and properties of the eHealth service and the context in which it is to be implemented.

The challenge in providing comprehensive standards for assessing all eHealth services versus the relevance of assessment outcomes for a specific eHealth service is underlined by the fact that most authors of the included frameworks have a shared view on the importance of a generic assessment framework for eHealth services and do not include concrete assessment methods. However, specificity is sacrificed and applicability of the frameworks for assessing certain eHealth services is reduced. With the evidence standards framework for digital health technologies, NICE introduces a way to stratify eHealth services into evidence standards in proportion to the potential risk to end-users [9]. A pragmatic functional classification scheme is proposed differentiating the main functions of the eHealth service. For each of these functions, varying levels and types of assessment data are required. Nevertheless, this approach (still) focuses solely on clinical effectiveness of the eHealth service and its economic impact. It does not provide standards for assessing technical requirements and functionalities, organizational, ethical, and legal aspects, nor does it address impacts on the healthcare system as a whole. Although eHealth services deserve no exception in assessing their impact on health and care, an extended NICE Framework might offer practical guidance that steers toward the assessment of impacts beyond clinical effectiveness and cost-effectiveness, as well as harmonization and reduced proliferation of loaded frameworks.

Limitations

This study is limited due to its focus on the scientific literature. As HTA often has an applied emphasis in informing policy, assessment methods and outcomes do not necessarily need to be disseminated through scientific literature. For this study, grey literature was left out due to issues with accessibility, selecting relevant sources, and its heterogeneous, unstructured, and often incomplete nature [49]. However, methods and guidelines in using these resources in systematic reviews are maturing [50]. In addition, practice-oriented expert feedback using qualitative and quantitative methods such as Delphi or Concept Mapping techniques [51] might enrich the results of this study and could prove useful in harmonizing and standardizing frameworks for eHTA.

Recommendations

Considering the variation in domains assessed, and level of detail concerning outcome definitions and instruments in the eHTA frameworks found, assessment frameworks would gain considerably in transparency, comparability, and applicability if: (i) the eHealth service being assessed is defined in a structured manner in terms of the clinical aim, target group, and working mechanism, and what, who and how the service is to be provided, and (ii) the assessment methods are standardized in terms of measurable outcomes and instruments. Moreover, the applicability and usefulness of eHTA frameworks should be reflected upon systematically to validate their utility and applicability in real world assessment practices.

The Template for Intervention Description and Replication (TIDieR) checklist could be a useful resource for reporting eHealth services for eHTA purposes [52]. This checklist is designed to be generically applicable for reporting complex interventions and includes thirteen topics describing the rationale for the eHealth service, materials, and procedures, and provision details, as well as measures for ensuring adherence and fidelity.

In improving the standardization of eHTA, a systematic whole systems dialog with decision makers, policy makers, and HTA experts using a Delphi or Concept Mapping approach, might facilitate consensus-based prioritization and selection of assessment methods and instruments. The outcomes defined by the TEMPEST or CHEATS frameworks, the ontological methods proposed by UVON, and the comprehensive structure of the MAST framework can serve as a starting point. The work laid down by EUnetHTA (JA3/WP6), NICE, and the opinion report on assessing the impact of digital transformation of health services by the European Expert Panel on effective ways of investing in Health (EXPH)[53] should be considered.

A stepped-approach to what and how eHTA should be applied, tailored to the functional characteristics of the eHealth service, can be fruitful in balancing completeness and relevance of assessment outcomes and methods. For example, a first phase could entail the assessment of safety and (negative) effects on clinical outcomes in combination with an economic assessment of costs-effectiveness. In a second phase, the impact on organizational aspects such as required skills, changes in tasks and roles, and required interoperability with relevant eHealth systems could be assessed. Such a stepped-approach should improve adequacy and efficiency of assessments matching the Appropriate Care program of the National Health Care Institute [10] motto of "no more than needed and no less than necessary."

Conclusions

HTA frameworks specifically designed for eHealth services are available. Besides technical performance and functionalities, costs and clinical aspects are described most frequently. Standardized sets of concrete evaluation methods and instruments are mostly lacking and evidence demonstrating the applicability of eHTA frameworks is limited.

Considering the purpose of eHTA to inform healthcare policy making and achieve evidence-based health care, the field would benefit from (i) standardizing the way in which eHealth services are reported and (ii) developing a standardized set of assessment tools by incorporating a stepped-approach tailored to the functional characteristics of the eHealth service. Standardized sets of evaluation methods for each of the domains as well as guidelines scoping the eHealth services might improve transparency, comparability, and efficiency of assessments, as well as facilitating collaboration of eHTA practices across healthcare systems in decision and policy making in digital health care.

3

Chapter 3

Improving Implementation of eMental Health for Mood Disorders in Routine Practice: Systematic Review of Barriers and Facilitating Factors

Abstract

Background: Electronic mental health interventions (eMental health or eMH) can be used to increase accessibility of mental health services for mood disorders, with indications of comparable clinical outcomes as face-to-face psychotherapy. However, the actual use of eMH in routine mental health care lags behind expectations. Identifying the factors that might promote or inhibit implementation of eMH in routine care may help to overcome this gap between effectiveness studies and routine care.

Objective: This paper reports the results of a systematic review of the scientific literature identifying those determinants of practices relevant to implementing eMH for mood disorders in routine practice.

Methods: A broad search strategy was developed with high sensitivity to four key terms: implementation, mental health care practice, mood disorder, and eMH. The reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) framework was applied to guide the review and structure the results. Thematic analysis was applied to identify the most important determinants that facilitate or hinder implementation of eMH in routine practice.

Results: A total of 13,147 articles were screened, of which 48 studies were included in the review. Most studies addressed aspects of the reach (n=33) of eMH, followed by intervention adoption (n=19), implementation of eMH (n=6), and maintenance (n=4) of eMH in routine care. More than half of the studies investigated the provision of mental health services through videoconferencing technologies (n=26), followed by Internet-based interventions (n=20). The majority (n=44) of the studies were of a descriptive nature. Across all RE-AIM domains, we identified 37 determinants clustered in six main themes: acceptance, appropriateness, engagement, resources, work processes, and leadership. The determinants of practices are expressed at different levels, including patients, mental health staff, organizations, and health care system level. Depending on the context, these determinants hinder or facilitate successful implementation of eMH.

Conclusions: Of the 37 determinants, three were reported most frequently: (1) the acceptance of eMH concerning expectations and preferences of patients and professionals about receiving and providing eMH in routine care, (2) the appropriateness of eMH in addressing patients' mental health disorders, and (3) the availability, reliability, and interoperability with other existing technologies

such as the electronic health records are important factors for mental health care professionals to remain engaged in providing eMH to their patients in routine care. On the basis of the taxonomy of determinants of practices developed in this review, implementation-enhancing interventions can be designed and applied to achieve better implementation outcomes. Suggestions for future research and implementation practice are provided.

Introduction

Background

Electronic mental health interventions (eMental health or eMH) for mood disorders such as depression can increase reach and accessibility of mental health services while maintaining comparable clinical outcomes as face-to-face interventions and superior outcomes compared with waiting lists [1-3]. 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., electronic patient files), professional education (e-learning), and Web-based research in the field of mental health [4]. Research on the translation of the results of these studies into routine care is scarce. Translational research can have two dimensions: dissemination and implementation of an innovation in clinical practice. Dissemination concerns the passive and active spread of information about eMH to relevant stakeholders, including consumers, clinical care providers, and decision- and policy makers. Implementation refers to the process of embedding and integrating new practices into actual care settings [5, 6]. It seems that eMH interventions are reasonably well disseminated to clinical practice given that a number of preconditions are fulfilled, such as the availability of technical infrastructures and proper reimbursement of these services [7]. Nevertheless, the actual use of eMH in routine mental health care lags behind expectations. It is unclear why implementation of eMH remains difficult.

A logical approach in addressing this implementation challenge is to identify the factors that might promote or inhibit implementation of eMH in routine practice [8]. On the basis of these determinants, implementation-enhancing interventions might be designed and applied with the aim to improve implementation processes and upscaling of eMH care. Many determinants of different care practices have been identified for a variety of clinical interventions. For example, Krause and colleagues [9] identified over 600 context-specific determinants thought to be

relevant in implementing evidence-based interventions for patients with chronic health conditions, including depression in the elderly, chronic obstructive pulmonary disease, and obesity. Examples of these determinants are status and quality of evidence and clinical recommendations, characteristics of the innovation, delivery modalities, reimbursement modalities, implementation leadership, and organizational readiness [10-12]. Similarly, examples of implementation barriers for eMH include the perceived importance of computer literacy skills, knowledge and awareness of existing eMH services, as well as credibility of these services [13]. In turn, many of these determinants have been clustered and framed, currently resulting in more than 60 frameworks used to study and understand implementation processes [14, 15]. Although such determinants and frameworks are valuable and comprehensive, they lack specificity to any category of intervention and therefore, provide little practical detail to prioritize determinants and guidance for action to improve the implementation of eMH interventions.

The reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) framework provides a heuristic tool for bridging interventions' internal validity established in well-controlled conditions and their external validity in real-world conditions [16, 17]. It is designed to evaluate the public health impact of health promoting interventions, and it is widely used in implementation research [18]. The framework covers five intervention-related areas of impact: (1) reach as the ability to address those in need of an intervention, (2) effectiveness in terms of the impact of interventions on health outcomes, (3) adoption as a decision to proceed with implementing the clinical intervention, (4) implementation as the process of embedding and integration of the intervention in routine practice and its consistency of delivery and costs, and (5) maintenance as the institutionalization of the intervention in routine care [17-20]. Considering the current evidence-base for eMH and the increasing emphasis on comparative effectiveness research in testing clinical and cost-effectiveness of eMH [21], the RE-AIM framework might be a valuable tool to structure determinants of practices that are specific to eMH.

Research Question

Given the absence of a comprehensive overview of determinants of practices, we systematically reviewed the literature to develop a taxonomy relevant to the implementation of eMH. Knowledge on these determinants can inform the study of interventions that aim to improve the implementation of eMH in routine practice. The following research question guided the research: "What determinants of practice are identified as relevant to implementing eMH interventions for mood disorders in routine practice?" A broad view on eMH and care practice

settings, including clinical and community practices, was adopted to provide a comprehensive taxonomy of determinants of mental health practice relevant to implementing eMH.

Methods

Study design
A systematic review of scientific literature was conducted. RE-AIM was used to structure the review. Various implementation studies in the area of mental health care using RE-AIM substantiate the utility of this framework, including evaluations of the implementation of behavioural mental health assessment tools [22]; smoking cessation interventions in people with mental illnesses [23]; mental health, substance abuse, and health behaviour interventions into specific primary care behaviour health programs [24]; tele-mental health consultation program in paediatric primary care in rural settings [25]; and assessing a therapist's role in eMH for patients with depressive disorders [26].

Search Strategy
Due to the novelty of the topics concerned (i.e., eMH and implementation), a broad search strategy was developed with high sensitivity to four key terms (as opposed to a focused strategy with higher specificity [27]): "implementation," "mental health care practice," "mood disorder," and "eMental-health." No time frame was applied. On the basis of literature, benchmark definitions for these concepts were developed, and a total of 408 synonyms were formulated for the search strings. A trained librarian guided the formulation of the search strings. The benchmark definitions and search strings are included in Multimedia Appendix 1. The search was conducted in July 2015 in the three main bibliographical databases (PubMed, PsycINFO, and EMBASE). All identified papers were examined for eligibility by two researchers (CV and MM) independently. Disagreements were solved by discussion and, where necessary, moderated by a third researcher (AK) to reach consensus.

Inclusion and Exclusion Criteria
The inclusion and exclusion criteria are shown in Textboxes 1 and 2.

Text box 1: Inclusion criteria

1. Reporting of empirical research such as observational studies using ethnographic methods or experimental studies following a pre-post or randomized controlled trial design
2. The psychotherapeutic intervention under study had an information and communication technology (ICT) component (eg, using videoconferencing, Web, or mobile technologies to deliver mental health care)
3. The psychotherapeutic intervention targeted a mood disorder.
4. The study targeted (1) an adult population, (2) mental health care professionals (HCPs) or, (3) other persons or organizations involved in implementation of eMH.
5. The study took place in routine mental health care settings.

Text box 2: Exclusion criteria

1. Studies were reporting clinical effectiveness data only.
2. The full-text article was not available through Open Access or library loaning services.
3. The full-text article was not available in the English language.

Data Extraction

A systematic qualitative narrative approach was applied for the data extraction, analyses, and synthesis of the results [28-30]. A field guide was developed to extract relevant data from the retained articles. Items included the study aim, methods, the psychotherapeutic intervention, eMH technology applied, type of mood disorder, implementation intervention (e.g., training of professionals, or a focused marketing campaign to raise awareness of eMH among patients), settings, sample(s), recruitment procedures, results, and findings in terms of determinants of practice. The data were tabulated and categorized in accordance with four of the five RE-AIM dimensions: reach, adoption, implementation, and maintenance. Table 1 presents definitions and adaptations to the RE-AIM dimensions that we applied for the purpose of this study. Effectiveness was not addressed in this review as ample reviews on the clinical effectiveness of eMH for mood disorders are available [1-3]. The implementation dimension was broadened to also include the purposive implementation interventions that might have been employed to achieve better implementation outcomes.

Table 1: Dimensions of reach, effectiveness, adoption, implementation, and maintenance (RE-AIM); their definitions; and its focus.

Dimension	Definitions [17]	Comment
Reach (R)	Participation ratio of patients and their characteristics	-
Effectiveness (E)	Impact of the (clinical) intervention on patients' health, quality of life, and economic outcomes	Not addressed in this study
Adoption (A)	Proportion and representativeness of staff and organizations delivering the services	-
Implementation (I)	(Clinical) interventions' fidelity and (implementation) costs	Added: "deliberate and purposive actions to implement eMH[a] [31]
Maintenance (M)	Extent to which the intervention is and remains to be part of routine care practice	-

[a]eMH: electronic mental health interventions, or eMental health.

Analyses and Synthesis

Thematic analysis was applied to identify the recurrent and most important determinants to implementing eMH in routine practice (i.e. themes) arising in the included literature. Thematic analysis is a common method for identifying, grouping, and summarizing findings from included studies in narrative review [29]. The (groups of) determinants were developed inductively (i.e. without a priori defined topics guiding the analysis). We did not apply a threshold for recurrence of certain themes in the data. Data were extracted by three researchers (CV, MM, and LB) independently. Data files were merged and discrepancies solved by discussion to reach consensus. Freely available reference management software (Mendeley, Elsevier), a spreadsheet (Microsoft Excel, Microsoft Corporation), and qualitative analysis software (ATLAS.ti, Scientific Software Development GmbH) were used to organize and conduct the selection, data extraction, and data analysis.

Results

Study Selection

The searches resulted in 16,718 records. After removing the duplicates, 13,417 unique titles remained and were screened for eligibility against the inclusion and exclusion criteria. In total, 13,159 articles were excluded on the basis of the information in titles and abstracts. A total of 258 articles were retained, and after examining the full-text articles, a total of 48 studies were included in the analysis. Figure 1 provides an overview of the inclusion and exclusion of studies in the different phases of the systematic review.
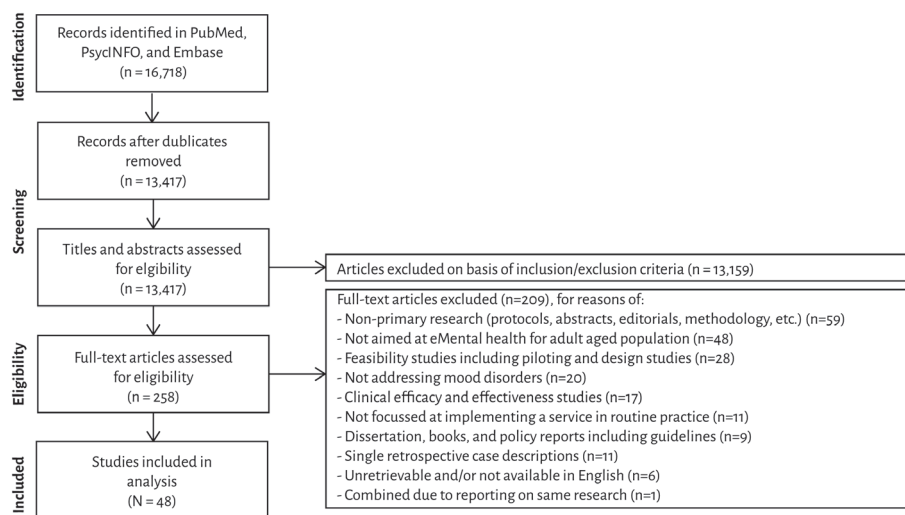
Figure 1: Information flow through the different phases of the systematic review.

General Study Characteristics

Table 2 provides an overview of the main characteristics of the studies, including the RE-AIM dimension(s) addressed, target disorder, therapeutic principles, technology applied, guidance modalities, and study design.

Most studies investigated reach (n=33), followed by adoption (n=19), implementation (n=6), and maintenance (n=4). The specific type of the target disorder was often described in broad terms such as common mental disorders or mood disorders (n=20), or in exemplary disorders such as depression or anxiety (n=17). Most studies (n=39) did not explicitly report the therapeutic principles of the clinical intervention that was implemented. More than half of the studies investigated the provision of mental health services for mood disorders through videoconferencing technologies (n=26), most often by using videoconferencing for support and consultations. The remainder of the studies focused on Internet-based interventions (n=20). Three studies looked at purely self-help interventions (through Web and mobile technologies), and 10 studies did report on a specific eMH intervention but did not report the guidance modality. Eighteen studies specified the eMH intervention and described the guidance modality. The majority (n=44) of the studies were of an observational, that is, descriptive nature. Most of these (n=20) applied mixed-methods (e.g., a survey and semi-structured interviews), followed by a large proportion (n=16) of studies that applied qualitative methods such as ethnography

or consensus-seeking methods using focus-group discussions. Five studies were of an experimental design, applying either quantitative or mixed-methods. More information about the specific studies' aims, designs, settings, participants, and clinical and implementation-related interventions are reported in Multimedia Appendix 2.

Table 2: Overview of studies categorized per reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) domain; technology applied; target disorder; therapeutic principles; and study design.

Characteristic	Reach n=33	Adoption n=19	Implementation n=6	Maintenance n=4	n[a]
Target disorder					
Depressive disorder	8	3	2	-	10
Mood disorders[b]	16	9	-	2	20
Not specified[c]	8	7	4	2	17
Therapeutic principles[d]					
Cognitive behavior therapy	5	3	2	-	8
Other (eg, mindfulness)	1	-	-	-	1
General psychotherapy	27	16	4	4	39
Technology applied					
Internet-based (unguided)	2	-	-	-	2
Internet-based (guided[e])	3	3	1	-	5
Internet-based (minimal guidance)	1	-	-	-	1
Internet-based (therapist guided)	1	-	-	-	1
Internet-based (blended)	1	1	-	-	1
Internet-based (not specified[f])	8	2	1	-	10
Computer-based	1	1	-	-	1
mobile health (unguided)	1	-	-	-	1
Videoconferencing	15	12	4	4	26

Study design					
Experimental—quantitative methods	2	-	-	-	2
Experimental—mixed-methods	-	2	1	-	3
Observational—qualitative methods	10	9	2	1	15
Observational—quantitative methods	6	1	-	1	8
Observational—mixed-methods	15	7	2	2	20

[a]The n in this column are unique references. Some studies were categorized under more than one RE-AIM dimension.
[b]Mood disorders including depressive disorder and/or in combination with other mental health disorders.
[c]Refers to the studies that described the target disorder in exemplary wordings without becoming specific. The generic wordings related to mood disorders.
[d]Not all studies specifically discussed the target disorder or psychotherapeutic principles of the service as studies focused, for example, on perceptions of the delivery method relevant to implementation and not on the specific treatment itself.
[e]Some form of guidance; guidance modality and intensity were not specified.
[f]Not specified if it was a guided intervention or self-help.

Determinants of Practice

In total, 37 specific determinants of practices relevant to implementing eMH in routine care were identified. The 37 determinants were clustered resulting in a taxonomy of six groups: (1) acceptance of eMH by patients and service delivery staff, (2) appropriateness or clinical relevance of eMH, (3) engagement of participants in implementing and delivering eMH, (4) resources for implementing and delivering eMH, (5) work processes in delivering eMH, and (6) leadership in implementing and delivering eMH. Group definitions are provided in Table 3. The spider diagram in Figure 2 shows that the majority of studies reported determinants in the domain reach that were related to acceptance (n=34) and appropriateness (n=23). When categorized under RE-AIM, reach and the domain adoption were studied most often, addressing determinants related to acceptance (n=17), appropriateness (n=11), and engagement (n=10). Least investigated were the domains of implementation and maintenance.

A detailed list of the determinants is included in Table 4, including their definitions, main perspective, RE-AIM dimensions, and references to the source articles. The following subsections detail the determinants for each of the four RE-AIM domains. The perspective from which become apparent are included, differentiating between (1) patients, (2) staff (individuals and groups) involved in delivering mental health services, (3) organizations as the functional and administrative structures aimed to deliver mental health care, and (4) the system perspective as the human and

material resources and organizational arrangements on a community level aimed at to preserve, protect, and restore peoples' health [32]. More detailed information, including the related excerpts of texts retrieved from the articles, are in Multimedia Appendix 2.

Table 3: Identified groups of determinants of practice and their definitions.

Group	Definition	Determinants
Acceptance	The perception among patients, providers, organizations, and systems that eMH[a] is agreeable, congenial, or satisfactory.	Access to treatment; expectations and preferences; observability and experience; evidence base; convenience; technology; awareness; skills and competences; privacy; clinical cultures; education; costs; policy; health care system structures
Appropriateness	The perceived fit, relevance, or compatibility of eMH for the patient in addressing his or her mental disorder.	Professional-patient interaction; effectiveness; personal need; flexibility; negative effects; safety; patient characteristics
Engagement	Continuing implementing, delivering, and receiving eMH and remain doing so in the context of concrete treatment plans.	Organizational structures and procedures; leadership; staffing and roles; access and reliability of ICT[b]; time; collaboration
Resources	The availability and appropriateness of resources required in implementing and delivering eMH, including human resources, equipment, funding, and other infrastructural aspects.	Personnel; funds; infrastructure
Work processes	The course of action (modus of operandi) in service delivery and all other tasks and responsibilities mental health care service organizations have.	Primary process; facilitating processes
Leadership	Directing and controlling the working processes and organizing activities that enable implementation and delivery of eMH.	Culture; communication; management; strategies and priorities; external relations
Health care system	The organization of people, institutions, and resources that deliver mental health care services to meet the health needs of target populations	Policy; resources; community acceptance; collaboration; structure

aeMH: electronic mental health interventions, or eMental health.
bICT: information and communication technology.

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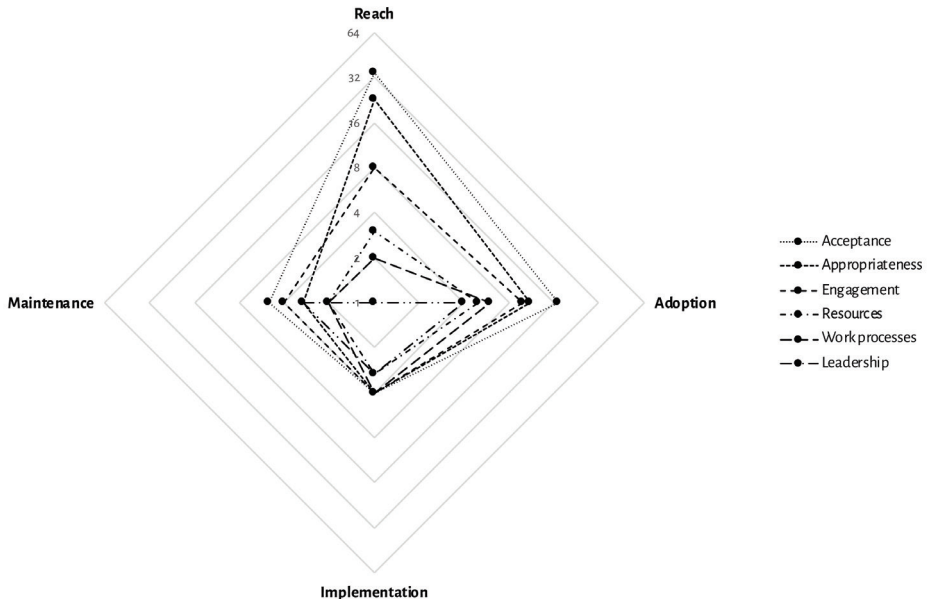
Figure 2: Spider diagram of the spread of the number of studies (n=48) categorized under the RE-AIM dimensions and the six main groups of determinants we identified in literature: acceptance, appropriateness, engagement, resources, work processes, and leadership. RE-AIM: reach, effectiveness, adoption, implementation, and maintenance.

Table 4: Determinants of practice identified in the literature mapped on each reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) dimension, including their proposed definitions, main perspective, and references. Indented are determinants grouped within a group of determinants.

Cluster	Determinant	Perspective	RE-AIM[a]	n	References
Acceptance: the perception among patients and providers that using eMH[b] is agreeable, congenial, or satisfactory					
	Access to treatment: the state of accessibility and the act of accessing mental health services.	Patient	R, A	9	[33-41]
	Expectations and preferences: individual and collective attitudes, expectations, and preexisting preferences about receiving and providing mental health care in general and eMH specifically.	Patient	R, A, I	12	[34, 37, 41-50]
		Staff	R, A, I, M	13	[35, 43, 48, 51-59]
	Observability and experience: the possibility and actual of observations in use (seeing or hearing about the treatment) and experiences of staff in the process of accepting eMH as a valid treatment option.	Staff	R, A, I	7	[35, 43, 51, 52, 58, 60, 61]
	Evidence-base: the scientific evidence of the feasibility and effectiveness of eMH.	Staff	R, A, I	3	[46, 59, 62]
	Convenience: the comfort experienced by patients in accessing and receiving mental health care, including overcoming geographical distances, time constraints, and availability of treatment materials.	Patient	R, A, I, M	14	[33, 34, 39-42, 47, 55, 58, 60, 63-66]
	Technology: the technical aspects of eMH, including availability of and familiarity with ICT, complexity, usability, and working procedures.	Patient	R, A, M	11	[34, 35, 37, 42, 48, 49, 51, 53, 65, 67, 68]
		Staff	R, A, I, M	8	[35, 43, 51-54, 56, 68]
	Awareness: having or showing realization, perception, or knowledge of eMH.	Patient	R, A, M	14	[34, 37, 44-46, 48-51, 55, 58, 69, 70]
		Staff	R, A, I, M	8	[43, 46, 51, 52, 60, 61, 71, 72]
	Skills and competences: specific personal capacities and means required for receiving (patients) or providing (staff) eMH.	Patient	R, A	7	[33, 39, 48, 51, 53, 58, 73]
		Staff	R, A, I, M	5	[48, 53, 59, 65, 68]
	Privacy: respecting patients' and providers' freedom from unauthorized intrusion, including discretion and confidentiality.	Patient	R, A	4	[35, 48, 49, 73]
		Staff	R, A	1	[48]
	Clinical culture: socially defined and agreed "ways of doing," including norms, habits, and roles.	Staff	R, A, I, M	6	[43, 52, 55, 59, 64, 66]
	Education: training of staff in providing eMH in routine care, including technical and therapeutic training, formal education, credentialing, peer-group learning, and supervision.	Staff	R, A, I	13	[43, 46, 51, 52, 57, 59-62, 66, 71, 72, 74]
	Costs: the expenditures made to receive or provide eMH.	Patient	R, A, M	3	[40, 65, 66]

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Appropriateness: the perceived fit, relevance, or compatibility of eMH for the patient in addressing his or her mental disorder

Concept	Perspective		Count	References
Professional-patient relationship: the professional interaction between (mental) health care provider and patient, including the aspects such as trust, comfort, and therapeutic interaction.	Patient	R, A, I	18	[33, 35, 39, 40, 42, 46, 48, 50, 53, 58, 67-70, 73, 75-77]
	Staff	R, A, I	10	[35, 46, 53, 56-59, 68, 72, 77]
Effectiveness: patients' mental health care needs, including information needs and specific (mental) health conditions.	Patient	R	3	[33, 35, 40]
Personal need: individual mental health care needs, including information needs and specific (mental) health conditions.	Patients	R, A, M	8	[33, 35, 42, 57, 58, 64, 69, 75]
Flexibility: the extent to which care providers can alter or adapt the eMH to the (perceived) needs of the patient or care provider.	Staff	R, A, I, M	6	[46, 57, 59, 66, 69, 71]
Negative effects: the perceived and actual negative (clinical) outcomes of receiving eMH.	Patient	R, A	3	[33, 46, 78]
Safety: the physical and mental safety of patients receiving eMH.	Patient	R	3	[35, 68, 78]
	Staff	R, A	3	[58, 62, 68, 69]
Patient characteristics: individual patient characteristics, including age, gender, clinical history, social economic status, and clinical symptoms relevant to eMH.	Patient	R, A	7	[37, 48, 69, 70, 73, 78, 79]
	Staff	R, A, I	4	[43, 58, 59, 62]

Engagement: continuing implementing, delivering, and receiving eMH and remain doing so in the context of concrete treatment plans

Concept	Perspective		Count	References
Organizational structures and procedures: the organizing structures, policies, and procedures for delivery of eMH, including standards and clinical guidelines, administrative support, technical support, and other facilitating services.	Staff	R, A, I	8	[43, 48, 58-60, 62, 68, 71]
Leadership: the managerial capacity and operationalization of an organization, including leadership, goal setting, strategies, and supportive measures	Staff	R, A, I	4	[57, 60, 68, 71]
Staffing and roles: the availability of staff necessary in delivering eMH, including qualifications, roles, and responsibilities.	Staff	R, A, I, M	7	[35, 48, 52, 55, 58, 60, 71]
Access and reliability of ICT: the availability, stability, and reliability of required technology, including interoperability with other existing technology (e.g. electronic patient record).	Staff	R, A, I	10	[43, 48, 52, 54, 58, 60-62, 71, 72]
Time: the time constraints in providing mental health care in general and eMH specifically.	Staff	I	1	[59]
Collaboration: the possibility and actual act of parties involved in delivery of eMH willingly work together, including sharing of information and expertise.	Staff	R, A, I	3	[59, 71, 77]

Resources: the availability and appropriateness of resources required in implementing and delivering eMH, including human resources, equipment, funding, and other infrastructural aspects.

	Level			References
Personnel: the availability, capacity, and capabilities of persons necessary in the delivering eMH.	Organization	A, I	2	[60, 80]
Funds: the availability and sources of pecuniary resources necessary for delivering eMH and its impact on existing (care) budgets	Organization	A, I, M	3	[65, 66, 71, 80]
Infrastructure: availability, quality, and stability of facilitating structures required for delivering eMH, including offices and equipment.	Organization	R, A, I, M	7	[43, 52, 55, 60, 62, 66, 80]
Processes: the course of action (modus of operandi) in service delivery and all other tasks and responsibilities mental health care service organizations have				
Primary process: a series of actions conducing to the primary objectives of a mental health care organization such as referral processes, establishing diagnosis, and providing treatment.	Organization	R, A, I, M	7	[43, 48, 52, 55, 60, 66, 80]
Facilitating processes: the facilitating activities required for primary processes to deliver mental health care services. Facilitating processes do not directly add value to service delivery but are necessary to provide the services.	Organization	R, A, I, M	7	[43, 55, 60, 62, 66, 71, 80]
Leadership: directing and controlling the working processes and organizing activities that enable implementation and delivery of eMH				
Culture: socially defined and agreed "ways of doing," including norms, habits, and roles relevant to delivering eMH.	Organization	R, A, I, M	2	[43, 66]
Communication: The mechanisms, means, and contents of disseminating information across the mental health care organization.	Organization	A, I	1	[60]
Management: the managerial capacity and operationalization of an organization delivering eMH, including leadership, goal setting, strategies, and supportive measures.	Organization	A, I, M	3	[55, 60, 80]
Strategies and priorities: the operationalization of and operationalized objectives into feasible working plans, including vision, mission, priorities, and work plans.	Organization	R, A, I, M	2	[43, 66]
External relations: cooperation and collaboration of various external parties involved and/or affected by delivery of eMH, including sharing knowledge.	Organization	A, I, M	3	[64, 66, 70]
Health care system: the organization of people, institutions, and resources that deliver mental health care services to meet the health needs of target populations				

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	Setting			
Policy: the plans or courses of actions intended to influence and determine decisions and actions relevant to delivery of eMH.	Setting	R, A, I, M	2	[43, 55]
Resources: the availability and appropriateness of resources required in delivering eMH, including HCPs, ICT and standardization, funding, and other infrastructural aspects.	Setting	R, M	4	[55, 64, 70, 72]
Community acceptance: the shared perception among the community that eMH is agreeable, palatable, or satisfactory.	Setting	M	2	[64, 65]
Collaboration: cooperation and collaboration of various parties involved in delivery of eMH, including knowledge sharing.	Setting	R, A, I	1	[43]
Structure: the organizing and organized plan of health services in a given (geographical) context and relevant to the implementation and delivery of eMH.	Setting	M	1	[55]

[a]RE-AIM: reach, effectiveness, adoption, implementation, and maintenance. Please refer to Table 1 for the specific definitions of the RE-AIM framework. The following abbreviations are used in this column: R: reach, A: adoption, I: implementation, and M: maintenance.

[b]eMH: electronic mental health interventions, or eMental health

[c]ICT: information and communication technology.

[d]HCPs: health care professionals.

Reach

The domain reach includes determinants of practices that are related to patients' participation in eMH and their characteristics. Of the 33 studies that were categorized under reach, most investigated patients' and mental HCPs perceptions and attitudes of patients and professionals (n=20), or the actual use (n=9) of eMH in a routine care setting. Most studies were of an observational nature (n=31). Two studies used an experimental design for testing interventions aimed at increasing access and use of eMH.

From the perspective of patients, two main groups of factors appeared to be relevant in implementing eMH in routine care: acceptance and appropriateness. Determinants grouped under acceptance concern the perceived and actual feasibility of interacting with eMH. For example, knowledge about the existence of eMH (awareness, n=13) and technological aspects of the treatment (e.g., usability and stability, n=10) were most often reported in the included literature.

Determinants categorized under appropriateness refers to the patients' perceived fit, relevance, or compatibility of eMH in addressing his or her mental disorder. Within this group, the professional-patient relationship was reported most often by both care providers and patients to be an important aspect that requires consideration when implementing eMH. For example, the perceived importance of interaction and verbal communication was highlighted by van der Vaart, et al [57], showing that the lack in nonverbal communication in Web-based treatments can pose limits to discussing more difficult issues with patients.

From the perspective of staff, engagement emerged as a group of factors next to the determinants grouped under acceptance and appropriateness. Engagement relates to the sustained and effective involvement of staff in implementing and delivering eMH for mood disorders in routine care. Most notably, engagement seem to be related to the organizing structures, policies, and procedures within an organization (n=4), as well as the availability and stability of the required information and communication technology (ICT; n=4). For example, in a qualitative study on expectations of both patients and health professionals in commencing in Internet-based psychotherapy, Montero-Marin et al [48] noted the importance of standardizing Web-based interventions in an integrated service delivery model.

From the perspective of mental health service providing organizations, resources in terms of available and stability of facilitating infrastructure was mentioned

(n=2) as an important determinant. In addition, the modus operandi in service delivery both in terms of primary care processes (e.g., referral pathways, n=2) as well as facilitating processes (eg.., administrative and ICT support and billing processes, n=1) require consideration when implementing eMH in routine practice. Additionally, leadership in terms of existing cultures, strategies, and priorities emerged from the included articles as a determinant of practice (n=1). Regarding the primary care processes, Buist et al [43] showed that considering eMH as a valid service option can influence actual application. Differences in actual use might be caused by differing levels of interest and experience in the eMH service of the service managers.

At health care system level, there were three aspects reported to be of importance, namely policy-making processes (n=2), the availability of appropriate resources including qualified staff (n=2), and collaboration and cooperation within the system and across disciplines (n=1).

Adoption

Adoption mirrors the decision of staff and organizations involved in delivering the eMH services and the extent to which they actually use and deploy the services to their patients. Of the 19 studies that were characterized under adoption, 16 studies investigated adoption-related perceptions and attitudes toward eMH (n=9), or actual use (n=7) of eMH in routine care settings showing adoption. Three studies investigated and tested an adoption-enhancing intervention aimed at increasing the number of staff involved in the delivery of eMH.

Seen from the perspective of staff delivering the services, a frequently mentioned determinant grouped under acceptance was patients' awareness and knowledge of the existence of eMH (n=5). Similarly, the awareness of eMH as a viable treatment option among staff was also identified as a relevant determinant in staff adopting eMH (n=6). Adoption can be facilitated by allowing clinicians to gain experience with eMH and the observability of eMH (n=7). In terms of appropriateness of eMH, the studies indicated that patient-professional relationship is an important determinant to consider when designing interventions aimed at improving adoption rates (n=7). To illustrate, May et al. [53] reported on the use of videoconferencing technology in delivering psychotherapy, indicating that the therapist-patient relation should include strategies that appropriately addresses the disorder for which verbal interaction might be essential. Furthermore, the availability and stability of the technical aspects, including infrastructure and interoperability of related ICT (n=8), can be an influential factor in facilitating

the engagement of professionals in continuing to offer and apply eMH to their patients.

From the organizations' perspective, the determinants addressing adoption related mostly to the availability of infrastructural resources (n=5) and the primary care process (n=5). Infrastructural resources included the availability, quality, and stability of facilitating structures such as office rooms and ICT equipment. Determinants related to the primary care processes included issues with referral procedures, diagnostic procedures, and therapy guidelines and manuals. For instance, Jameson et al [52] highlighted that clinical policies and procedures for initiating a referral and coordinating between the various partners involved in service delivery are necessary for successful and sustainable use of eMH.

One article reported determinants from a health care system perspective. Buist et al. [43] reported on the importance of mechanisms that enable collaboration, sharing of information, and policies supporting better use of these mechanisms.

Implementation

Determinants categorized under implementation relate to the extent to which eMH is used in real-world settings as intended (i.e., fidelity of use), implementation costs, or deliberate and purposive actions to implement eMH. Of the 6 studies identified under implementation, 2 investigated an implementation-related intervention focusing on training mental health providers to use eMH in daily practice. The other 4 studies performed a process evaluation (n=1) and investigated use and utilization of eMH (n=3).

The most frequently reported determinants from the perspective of staff were related to acceptance. These concerned raising staffs' awareness about the existence of eMH (n=3) and providing education to staff (n-4) in applying eMH in routine care. Specific determinants included references to technical and therapeutic training, formal education and credentialing, and peer-group learning and supervision. For example, Willhelmsen et al. [59] showed the importance of training of general practitioners (GPs) in increasing patients' acceptance of eMH, which might strengthen the perceived credibility of eMH.

Furthermore, from the perspective of staff, engagement was found to be influenced by the availability of support and facilitating services (n=4). For example, Avey et al. [71] reported in a qualitative study on implementation processes that coordination and collaboration between the various persons involved in the service delivery

should be facilitated effectively and that a dedicated program coordinator was valued highly among the participating hospitals.

From the viewpoint of an organization, the availability of resources such as staffing (n=2), funding (n=2), and infrastructural facilities (n=2) were reported as relevant determinants. In addition, various factors emerged from the literature related to the primary mode operandi (n=3). For example, Reifels et al. [80] discussed that successful implementation might depend on the existence or establishment of effective primary processes in the service delivery structures. Similarly, implementation outcomes can be determined by factors facilitating and supporting the primary processes in delivering mental health care services (n=4). Examples include issues with office space, availability of equipment, and administrative support as Adler et al. [60] highlighted. Besides the organizational structures and processes, leadership and management (n=3) need to be considered when implementing eMH. This includes scheduling problems, lack of a clear goals, and managerial support to address issues with existing clinical demands.

From the perspective of health care systems, less rich information was found in the included studies. However, Buist et al. [43] did report on determinants of practices relating to the availability of policy measures (n=1) and possibilities to collaborate and share knowledge within and across disciplines and settings (n=1).

Maintenance
Under maintenance, determinants were categorized that relate to keeping the eMH as a normal part of routine care practices. All four maintenance studies were of a descriptive nature aiming to establish usage and utility figures of videoconferencing-delivered mental health services (n=2), capture end-user perceptions (n=1), or describe potential success factors (n=1) of programs that remained in practice after their implementation phase.

From the patients' viewpoint, the convenience of eMH was seen as an important determinant in maintaining the service in practice (n=4). In an evaluation of patients' perceptions of a routine tele-psychiatry service in central Alberta, Simpson et al. [65] highlighted the importance of reducing waiting times and travel time and that this in the long term might outweigh preferences for face-to-face consultations.

From the perspective of mental health staff, the clinical culture in terms of socially defined and agreed ways of doing (n=2), including norms, habits, and roles, are considered to be important in maintaining the services in routine practice. Hailey

et al.[64] showed that traditional patterns might keep staff from changing their practice, even if the service is in operation for a considerable time.

At the organizational level, various determinants were reported, including availability of funds (n=2) and infrastructure (n=2), the primary modes of operation (n=2), supporting structures and activities (n=2), and leadership and management (n=3). Regarding the latter, Whitten et al. [66] showed in a study comparing tele-psychiatry programs that are in routine care for some time that the different business approaches these programs took might have contributed to their success.

From the perspective of the health care system, besides the importance of policy (n=1), community acceptance (n=2), and organizing and organized plans of health services (i.e., structure; n=1), the availability and appropriateness of resources required in maintaining eMH in practice were mentioned (n=2).

3

Discussion

Principal Findings

We developed a taxonomy of 37 determinants of mental health care practices known in the literature as relevant to successfully implement eMH for mood disorders. The determinants of practices clustered in six groups are expressed at (a combination of) patient, staff, organization, and setting levels and address one or more RE-AIM dimensions (see Table 3). Three determinants were reported most frequently: (1) acceptance of eMH in terms of the expectations and preferences of patients and professionals; (2) appropriateness of eMH in addressing the mental health disorder, and specifically, the therapeutic interactions mediated by eMH; and (3) the availability, stability, and reliability of required technologies, including successful interoperability with other existing technologies.

Strengths and Limitations

The search strategy in this review aimed to capture as much relevant scientific literature as possible. For this reason, broadly defined search terms were used. By applying a standardized integrative approach (RE-AIM in combination with qualitative thematic analysis), we were able to search for commonalities in the concepts and underlying study characteristics while preserving the heterogeneous nature of the data retrieved from the studies. However, and although we searched three important bibliographic databases, it is likely that important work from social scientist generalist databases was excluded.

The evidence supporting the determinants identified in this study is mostly of a descriptive nature obtained from observational studies. Due to the limited empirical evidence verifying causality of specific determinants of practices and implementation successes, the findings of this work should be interpreted with care. In an attempt to substantiate this, we conducted a quality appraisal analysis. We included a wide variety of studies ranging from observational case studies using qualitative ethnographic methods to randomized controlled trials quantitatively testing specific implementation interventions. However, because of the heterogeneity of these studies and the absence of validated instruments to assess quality, it proved impossible to come to sensible conclusions about the quality of the evidence. An elaborate approach as done by Greenhalgh et al. [81, 82], meta-narrative approach in developing a model of diffusion of innovations by including the research traditions from which the included studies emerged might be a fruitful approach but was beyond the scope of this review.

Comparison With Other Work

Drozd et al. [83] conducted a scoping review of 164 publications (including grey literature). The investigators applied the Active Implementation Framework (AIF) to identify implementation-related factors [84]. The AIF describes the components of an implementation practice, including aspects of staff and patient selection, training, supervision, performance assessment, decision support, administrative support, system intervention, and leadership. Drozd and colleagues found in their review factors similar to those that emerged from our analysis of the literature, including certain competences of patients and professionals and organizational drivers. Regarding the latter, the authors did not find empirical support for determinants such as leadership. The authors conclude that not finding empirical evidence for organizational drivers merely indicates a gap in the implementation-related research. Despite the low numbers (n=4), our study shows that leadership indeed is found in empirical research to be a relevant determinant in implementing eMH. This difference can perhaps be explained by the methodological choices that were made for reviewing the literature. Where Drozd and colleagues choose to follow a top-down approach (the AIF), our review followed a quantitative inductive process in identifying the topics related to implementing eMH that emerged from the included articles. Furthermore, the search strategy and data sources in light of their quality and comparability most likely influenced the results.

Similarly, Ross et al. [85] updated a systematic review (of reviews, n=44) and looked at qualitative accounts of factors that influence implementation of eHealth interventions in a broader context, including somatic care. Factors identified

by these researchers are comparable with the ones presented here, including complexity factors and adaptability, adding to the users' perception of the acceptability of eHealth interventions. However, it should be noted that the concept of eHealth used by the authors included a variety of ICT-mediated health care services in four main categories: management systems, communication systems, clinical decision support systems, and information systems. In this respect, the authors did not address eHealth to contain purposed intrinsic therapeutic content aimed at improving health conditions as we did. This raises the question of whether generic eHealth both in terms of care setting (health care in general vs mental health care for mood disorders) and purpose (information sharing, support systems vs therapeutic interventions focusing on care and cure) give rise to (partial) different taxonomies of determinants of practice.

Recommendations for Implementation Practice

Implementation practitioners might benefit in implementing eMH in routine care practices by taking into account the barriers and facilitators that are identified in this systematic review. Specific implementation activities can be designed and applied on the basis of these factors to achieve better implementation outcomes.

One of the most frequently mentioned barriers emerging from the literature concerns the expectations and preferences of patients and professionals about eMH services. Negative individual and collective attitudes, expectations, and existing preferences can prohibit successful implementation of eMH. Ebert et al. [45] showed that providing information to patients can enhance their acceptance of eMH. In addressing expectations and preferences of mental health care staff, it is advisable to include service delivery staff in the early stages of decision making and strategy development to increase acceptance and inform concrete implementation activities aimed at the concerns of the end users.

A second important determinant of practice is related to the appropriateness of the eMH intervention in addressing the mental disorder. Within this cluster, the nature and quality of the interactions between the professional and the patient is thought to be highly influential in obtaining favourable clinical outcomes. This includes aspects such as building trust, comfort, and the quality of the therapeutic interactions. eMH interventions delivered through ICT are thought to influence these interactions negatively. Hadjistavropoulos et al.[74, 86] showed that specific training can change knowledge about, attitudes toward and confidence in delivering eMH. Careful development of training programs and (continuous) guidance of HCPs in applying the eMH intervention might lower barriers with

perceived patient-professional interaction through eMH. In addition, innovative models of for integrating therapist support in eMH services might address issues with engagement and the patient-professional relationship [87].

Third, the availability and reliability of required technologies is considered an important determinant for mental HCPs to remain engaged in providing eMH to their patients in routine care. This includes the interoperability with other existing technologies such as electronic health records. It seems important to ensure that the user perspective, including that of the service delivery staff, is taken into account and that the eMH service seamlessly fits within existing technologies and work processes. Here, single-sign on technology and intelligent portal designs might be fruitful avenues to explore.

Future Research
To increase impact and added value of future research on implementation of eMH for mood disorders in routine practice, the following two topics should be taken into account: (1) identifying organization and system-level determinants and (2) empirical evidence on the effects of implementation strategies in addressing specific barriers and exploiting facilitating factors.

Until now, most implementation research was focused on practitioner and patient-level determinants. Service delivery takes place in a social context at micro (individuals, teams), mesa (organizations), and macro (systems) level. Knowledge about how these different contexts influence implementation efforts can facilitate further scaling up of eMH. Research on systems level might focus on the possible policy measures that enhance implementation of eMH at service deliverer level. For example, what resources at organization or health care system-level are required to deliver eMH? This can include processes of task shifting, curricula and certification of mental health staff, ICT and standardization, funding, and other infrastructural aspects. Or, what role does community acceptance have in implementing eMH in routine practice, and how can the shared perception of community as a whole be changed? Detailed knowledge of organization and setting level factors might be more likely to come from a combination of clinical psychology, social sciences, organizational psychology, and policy research. Here, the MasterMind project [88] might provide inspiration for further research on determinants of practices of eMH.

Furthermore, the field would benefit from well-performed experiments designed to test implementation interventions addressing specific determinants of practices. As shown in this review, there is limited evidence on the causal relationship between

determinants and implementation outcomes. Well-designed experiments studying the effects of to the local context–tailored implementation strategies might contribute to the understanding of mechanisms of implementation processes. Do, for example, educational meetings (and in what formats) contribute in raising awareness among GPs about which patient might benefit most from which eMH intervention? Or can championing an Internet-based cognitive behavioral therapy service increase the adoption of other therapists in mental health care team while maintaining the flexibility therapists need to adapt parts of the treatments to the patients' needs? Fusing implementation practices and research into natural implementation laboratories might be a valuable approach to engage in comparative effectiveness studies of implementation interventions. In these types of studies, experimental implementation interventions can be compared with usual implementation activities for their effects on the degree of normalization of a clinical intervention in real-world service delivery settings. The ImpleMentAll project (project position paper and study protocol forthcoming) might be a good example of this approach. This type of future research might lead to a shift from practice-based and evidence-informed to evidence-based implementation of clinically effective and relevant eMH interventions.

Conclusions

This study systematically reviewed scientific literature and developed an evidence-informed taxonomy of six clusters of 37 determinants of practices we found in literature: (1) acceptance of eMH interventions among patients, providers, organizations, and health care settings; (2) appropriateness of eMH interventions in addressing the disorder; (3) engagement in implementing, delivering, and receiving eMH interventions and remain doing so; (4) the availability and appropriateness of resources for implementing and delivering eMH interventions; (5) processes relating to the modus of operandi in delivering eMH interventions; and (6) leadership directing and controlling processes and organizing activities enabling implementation and delivery of eMH interventions. On the basis of these determinants of practices, implementation-enhancing interventions can be designed, tested, and applied to achieve better implementation outcomes. Suggestions for implementation practice are discussed, such as in-depth training of professionals, careful selection, and continuous development of the eMH technology used. In addition, focal points for future research are provided, including implementation-related factors on organization and system level, as well as (quasi) experimental research to test the effectiveness of specific implementation interventions in attaining better implementation outcomes for eMH service provision.

4

Chapter 4

Organisational Implementation Climate in implementing internet-based Cognitive Behaviour Therapy for depression

4

Abstract

Background: Internet-based Cognitive Behaviour Therapy (iCBT) for depression have been implemented in routine care across Europe in varying ways, at various scales and with varying success. This study aimed to advance our understanding of organisational implementation climate from the perspectives of implementers and mental health service deliverers.

Methods: Qualitative and quantitative methods were combined to study the concept of organisational implementation climate in mental health care settings. Based on concept mapping, a qualitative workshop with implementers was used to conceptualise organisational implementation climate for optimizing iCBT use in routine practice. Service deliverers involved in the provision of iCBT were invited to participate in an explorative cross-sectional survey assessing levels of satisfaction and usability of iCBT, and organisational implementation climate in implementing iCBT. The two methods were applied independently to study viewpoints of implementers as well as service deliverers. Corresponding to the explorative nature of the study, inductive reasoning was applied to identify patterns and develop a reasonable explanation of the observations made. Correlative associations between satisfaction, usability and implementation climate were explored.

Results: Sixteen implementers representing fourteen service delivery organisations across Europe participated in the workshop. The top-three characteristics of a supportive organisational implementation climate included: (1) clear roles and skills of implementers, (2) feasible implementation targets, and (3) a dedicated implementation team. The top-three tools for creating a supportive implementation climate included: (1) feedback on job performance, (2) progress monitoring in achieving implementation targets, and (3) guidelines for assessing the impact of iCBT. The survey (n=111) indicated that service providers generally regarded their organisational implementation climate as supportive in implementing iCBT services. Organisational implementation climate was weakly associated with perceived usability and moderately with satisfaction with iCBT services.

Conclusions: Organisational implementation climate is a relevant factor to implementers and service deliverers in implementing iCBT in routine care. It is not only an inherent characteristic of the context in which implementation takes place, it can also be shaped to improve implementation of iCBT services. Future research should further theorise organisational implementation climate and empirically validate the measurement instruments such as used in this study.

Introduction

Depressive disorders are amongst the most prevalent mental health conditions around the world [1]. Internet-based Cognitive Behavioral Therapy (iCBT) can increase reach and accessibility of mental health services [2] with comparable efficacy to face-to-face CBT [3-5]. Moreover, iCBT services in general are found to be appropriate and acceptable strategies in treating depression [6-8]. Consequently, various initiatives emerged across the globe to implement iCBT services in routine care [9, 10]. Implementation here, is to be understood as a deliberate and planned process of integrating and embedding whereby an innovation becomes a normal part of daily routine [11-13].

Clinical effectiveness, perceived appropriateness and acceptability by mental health service deliverers are known to be important determinants of successful implementation of iCBT services in routine care [14-17]. Appropriateness refers to the suitability of iCBT in treating depressive disorders and acceptability concerns the perception of users including patients and service deliverers that the iCBT service is palatable or satisfactory in its use [18]. Besides individual level factors related to iCBT, also the context in which it is implemented on group level can hamper or facilitate implementation efforts [19]. These contextual factors can operate on the level of the health care system, (e.g. rules for reimbursement, certification, and staff accreditation), as well as on organisational level (e.g. procedures, structures, social characteristics, human and financial resources) [16]. One could argue that barriers on the level of organisational context might be more sensitive to change whereas system level barriers are often outside the influence of implementers. Furthermore, the organisational context in which the service delivery and implementation takes place, is of particular relevance as it forms the 'ecosystem' in which patients and service deliverers act and interact to create health and healthcare [20, 21]. Figure 1 provides a schematic simplification of a possible model of implementation success indicating potential relations between appropriateness and acceptability of the intervention, the wider organisational context, and main actors involved in delivery and uptake of iCBT services (i.e. patients and service deliverers).

Organisational context as defined in the Consolidated Framework for Implementation Research (CFIR), includes structural characteristics such as age, size, and governance structure of the organisation, networking qualities which refer to formal and informal communications within and beyond the organisation, and aspects of the organisational implementation climate by which implementation

processes are facilitated or inhibited [19]. Of particular interest is the concept of organisational implementation climate which can be defined as the shared meaning staff members attach to organisational events, practices and procedures they experience and the behaviours they see being rewarded, supported, and expected in implementing new practices [22-25]. Organisational implementation climates are possibly relevant to investigate as they are known to shape staff members' attitudes towards adopting and implementing new interventions into daily practice [22, 25, 26] and professionals' perceptions and attitudes are of particular interest in successfully implementing new interventions [27, 28]. Organisational implementation climate is a conglomerate concept that includes staff members' shared understanding of and experiences with organisations' formal and informal policies and practices (e.g. training) related to implementing new interventions [29]. Through discussion and collaboration, and in the context of these organisational policies and practices, staff members develop a collective sense of what is expected from them, how this can be achieved, and what possible consequences it might cause for them.

Applied to the context of adult mental health care, organisational implementation climate can be characterised in various ways. For example, one characteristic concerns service deliverers' commitment and loyalty to the organisation and its' goals. Commitment and loyalty to the organisation can be considered to be part of a broader concept about individuals' identification and relationship with that organisation and may affect the willingness to implement and use novel interventions such as iCBT services [19, 30]. Another defining characteristic is employees' perceptions of the levels of support, recognition and appreciation by their organisations for implementing new interventions as it can incentivise individuals to adapt or apply a certain behaviour facilitating implementation practices [19, 25, 31]. For mental health service deliverers, examples of such incentives can include salary raises, a promotion to a supervisory role, gratifications, conference visits, and increased stature, respect and trust by granting more autonomy in treating their patients. Another characteristic of organisational implementation climate includes staff members' confidence in their own ability to change their practice and use new interventions such as iCBT in treating their patients. This notion of self-efficacy is a significant component in most individual behavior change theories [32, 33]. Furthermore, professionals' shared perception of the importance of implementing new interventions could be a relevant aspect shaping organisational implementation climates [19, 25, 31]. Similarly, the availability of qualified staff, number and adequacy of resources such as funds, training, and time available to implement and use the new services might

be relevant factors characterising organisational implementation climates as they can enable or hinder actual enactment of implementation efforts [12, 19].
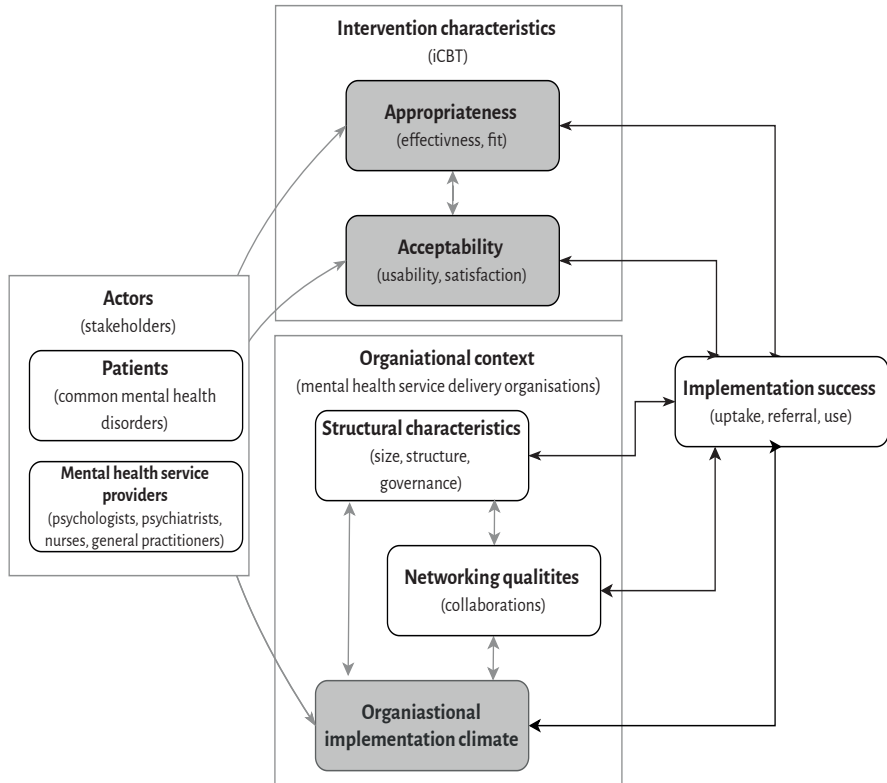
Figure 1: Conceptual model of implementation success, intervention characteristics and wider organisational context. The relation between organisational implementation climate and acceptability of iCBT services that were implemented, was the subject of this explorative study

In the European MasterMind project, unguided, guided and blended iCBT interventions for adults suffering from mild, moderate or severe depressive disorder were implemented in fourteen European regions [34]. The aim of this project was to scale up the use of iCBT services across Europe and by doing so, conduct a summative evaluation of barriers and facilitators in implementing these services in a variety of mental health settings [34]. It also provided the possibility to advance our understanding of the nature and value of organisational implementation climate in implementing such services in routine mental health care from two perspectives. From the perspective of implementers, i.e. staff members tasked with implementing the iCBT services, we sought to qualitatively

identify (a) the characteristics of and (b) practical tools for creating an organisational implementation climate conducive to improving implementation success. In addition, we quantitatively explored and described mental health service deliverers' perspective to gain an initial understanding of the relevance of the concept of organisational implementation climate and whether measures of satisfaction, usability are empirically associated with organisational implementation climate in samples of mental health service deliverers.

Methods

Study setting

The study ran from September 2015 until January 2017 [34]. Table 1 provides an overview of the iCBT services and the organisations involved in the Mastermind project. All implemented iCBT services were based on the main therapeutic principles of Cognitive Behaviour Therapy (CBT), covering sessions of psychoeducation, behavioural activation, and cognitive restructuring. Two regions implemented services that were designed as standalone self-help interventions by which only technical assistance was available to patients. Four regions implemented iCBT services that included a secure asynchronous messaging system by which therapists could offer coaching to the patients using the iCBT service. Two regions implemented iCBT services with a blended treatment protocol by which therapeutic sessions delivered face-to-face or by videoconferencing are combined with online sessions and asynchronous therapeutic guidance. The participating organisations were divided into two implementation waves. Wave-1 organisations were more experienced in providing iCBT services and at the time, could be considered as early adopters due to their involvement in previous research and implementation projects of iCBT services. Wave-2 organisations had limited experience with iCBT services for depressive disorders in routine care and benefitted from sharing knowledge, (parts of) interventions, and lessons learned with wave-1 organisations in developing and implementing iCBT services.

Table 1: Demographic characteristics of the organisations and iCBT services implemented in the MasterMind project.

Wave	Org. ID.	Region, country	iCBT service	Guidance modality[1]	Referral pathways[2]	Referrals[3] n	Reach[4] %	Org. size[5]	Funding[6]
1	1	Scotland, UK	Beating the Blues	Self-help	GP, SP	5,724	5.30	M	Public
1	2	Southern Denmark, DK	NoDep	Guided	S	259	0.72	S	Public
1	3	Amsterdam area, NL	MindDistrict, MoodBuster	Blended	GP, SP	355	3.31	L	Insured
1	4	Hospital group and online provider, DE	Depression Online, Relapse prevention, GET.ON Mood enhancer, Get.On Sleep	Blended	S, O	1,405	0.26	L	Insured
1	5	Tromsø area, NO	MoodGym	Self-help	GP	191	5.46	M	Public
2	6	Basque Country, SP	Super@tuDepression	Guided	GP, SP	216	0.55	L	Public
2	7	Wales, UK	Beating the Blues	Self-help	GP	355	3.34	L	Public
2	8	Aragon, SP	Super@tuDepression	Guided	SP	129	3.00	M	Other
2	9	Badalona, SP	Super@tuDepression	Guided	GP	253	1.01	L	Other
2	10	Galicia, SP	Super@tuDepression	Guided	GP	110	0.11	L	Public
2	11	Piemonte, IT	iFightDepression	Guided	S, GP, SP	161	0.75	L	Other
2	12	Veneto, IT	iFightDepression	Guided	SP	150	0.17	S	Other
2	13	Anatolia, TR	Top Sende	Guided	S	120	1.42	S	Other
2	14	Harju, EE	iFightDepression	Guided	S	56	1.60	S	Insured

1) Guidance modality refers to a categorisation of the online and face-to-face human interaction in the iCBT service. S: self-help by which none or only technical and administrative support is provided. G: therapeutic guidance provided by a therapist online through asynchronous messaging. B: blended in which sessions in face-to-face or videoconferencing format are integrated with online sessions in one treatment protocol.

2) Main patient referral pathway to the iCBT service. GP: via General Practitioner offices; SP: via mental health specialist referral; S: self-referral; O: other, e.g.. via health insurers.

3) Referrals concerns the total number of patients deemed eligible for the iCBT service and received an account to access the treatment. Eligibility was determined following local clinical guidelines and was based on clinical judgement and/or using a structured validated clinical questionnaire (e.g. PHQ-9).

4) Reach is the proportion of eligible individuals in a given (estimated) catchment area and those actually involved in the service.

5) Indicator of the size of the mental healthcare organisation involved in the implementation based on an estimate of the annual revenues and number of employees. L: large organization (revenues > 50 mln. Eur, full time equivalent (FTE) staff positions > 500). M: medium-large organisation (revenues 10-50 mln. Eur., FTE < 500). S: small organisation (revenues < 2 mln. Eur., FTE < 200).

6) Indicator of the source of funding source of the iCBT service. Insured: service use is reimbursed by private health insurances. Public: service is reimbursed by the public health care system. Other: project-based, out of pocket expenses, other sources or a combination of these.

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Table 2: Demographics of the conceptualisation workshop participants

Variable	Pooled	Wave 1	Wave 2
Sample, *n*	16	8	8
Age in years, *M* (SD)	39.3 (10.9)	41.5 (12)	37 (10.1)
Min. – max.	26-61	29-61	26-59
Gender, *n*			
Female	8	5	3
Profession, *n*			
MH professional[1]	7	4	3
Service dev., proj. mgr.[2]	4	1	3
Director, leadership	3	1	2
Consultant, advisor	2	2	0
Managing role, *n*			
Yes	6	3	3
Field experience, *n*			
< 3 years	3	0	3
3 – 5 years	4	3	1
6 – 10 years	5	3	2
> 10 years	4	2	2
Experience with iCBT, *n*			
Yes	7	6	1

1) MH professional means mental health professionals such as psychiatrist, psychologist, mental health nurse, etc.
2) Service dev., proj. mgr. means roles of service developer or project manager.

Methods

Two methods were combined to study the concept of organisational implementation climate in mental health care settings. A qualitative conceptualisation workshop was used to gather data from implementers about (1) characteristics of and (2) practical tools for shaping a supportive organisational implementation climate. Cross sectional survey data was collected to quantitatively describe organisational implementation climate and explore correlations with scores of perceived iCBT service satisfaction and usability amongst mental health service deliverers. The two methods were applied independently of each other to elucidate viewpoints from the two different target groups (implementers and service deliverers). Corresponding to the explorative nature of the study, inductive reasoning was applied to identify patterns in the data and develop a logical explanation of the observations made.

Conceptualisation workshop

A concept mapping approach [35] was used to identify, cluster and rank ideas for two separate themes: 1) characteristics of an organisational implementation

climate specifically focused at fostering successful implementation of iCBT in routine practice, and 2) practical tools implementers use to create and facilitate such supportive organisational implementation climates. Implementers involved in coordinating or executing the implementation of the iCBT services were eligible to participate in the workshop. Two implementers of each region participating in the MasterMind study were invited to participate in the workshop (see Table 2). Following the concept mapping approach, the workshop was structured into four separate steps for both themes to ensure a participatory conceptualisation process [35]:

1) Generate ideas: all participants individually wrote down as much as possible initial ideas concerning the afore mentioned two themes in fifteen minutes. This 'silent groups' format preserves individuality but introduces a possible social facilitation effect from the presence of others.

2) Merge ideas: in group setting, the ideas generated were recorded in rotation, one idea per person on an electronic screen. The rotation procedure removes some of the anonymity of a 'talk in any order' group while at the same time producing a list of ideas that are recorded without authorship.

3) Refine ideas: continuing in the group setting, the ideas from steps one and two were clarified, discussed, combined, or refined as the group saw fit. One idea was discussed at a time and individuals were asked for reasons of agreement or disagreement and constructive suggestions for improvement. Combining and refining was done based on their perceived similarity and the revised ideas were recorded in a new list visible for the whole group.

4) Ranking: as a final step, each participant independently and silently rated the revised ideas in terms of its importance or usefulness to the theme. Ranking was achieved by averaging the individual votes for each theme.

The concept mapping workshop was facilitated by members of the central MasterMind project evaluation team (CV, MM and AK) and designed to last maximal four hours divided into two main parts. The workshop was conducted face-to-face during a MasterMind consortium meeting in Turin, Italy on 13 October 2016.

Cross-sectional survey
The survey focussed on service deliverers' perception of the organisational implementation climate they experienced in the organisation they worked for

and their satisfaction with and usability of iCBT services. These were applied descriptively.

An explorative questionnaire was developed to obtain a preliminary quantitative assessment organisational implementation culture. We defined organisational implementation climate as the shared meaning service deliverers attach to organizational events, practices and procedures they experience and the behaviours they see being rewarded, supported, and expected in implementing new interventions. Starting from this definition and existing literature, the central research team (CV, AK, MM, HR) deductively developed an initial pool of questions. This initial list was improved and corroborated in two review rounds by members of the MasterMind consortium during the start-up phase of the MasterMind project, i.e., prior to the qualitative workshop. The resulting 12 questions related to commitment, loyalty, support, recognition, appreciation, self-efficacy, relative priority, resources, and implementation strategies. Commitment was measured with two questions assessing individual participants perception of their own and of their supervisors' commitment to the organisations' goals. Loyalty to the organisation was measured by one question addressing respondents' own allegiance to the organisation they work for. The extent to which respondents perceive to be incentivised by their organisation was assessed with three questions asking the extent to which respondents felt being supported, recognised, and appreciated when implementing and using iCBT in daily service provision work. Aligned with Bandura's work [36], self-efficacy was measured with two questions addressing respondents' confidence in their own abilities and enthusiasm in implementing and using iCBT service in practice. The perceived availability of resources for implementing iCBT in practice was measured by two questions concerning the availability of qualified staff to provide the iCBT services, and the availability of other resources such as time, training, computers, etc. The extent to which respondents regarded the implementation as deliberate and planned was measured by one question asking about the existence of an implementation strategy for implementing the iCBT service. All questions were rated using a 5-point Likert answering scale ranging from '1. strongly disagree' to '5. strongly agree'. Service deliverers could rate a question as 'not applicable' when the question was perceived to be irrelevant to their situation or organisation.

Satisfaction with the iCBT services was measured with the short version of the Client Satisfaction Questionnaire (CSQ-3) using a 4-point scale with three items [37]. It has good psychometric properties, and it has been tested in numerous studies on diverse samples of patients and professionals [38, 39]. Following the

questionnaire instructions, scale scores were calculated by summing item ratings. Higher ratings indicate higher levels of satisfaction.

Usability was measured with the System Usability Scale (SUS) using a 5-point Likert scale to rate ten items [40, 41]. It has good psychometric properties and is tested in numerous studies including samples of mental health professionals [41-43]. For calculating the SUS scale item's score contribution ranged from 0 to 4. Negative worded items were converted to adhere to the same range order. Score contributions of each item was summed and multiplied with 2.5 resulting in a scale of 0 100 [40]. Higher scale scores are indicative of higher levels of usability.

Mental health service deliverers involved in the provision or referral of patients to the iCBT services, such as licenced psychotherapists, psychiatrists, mental health nurses, and general practitioners, were eligible to be included in the cross-sectional survey. Depending on local circumstances in the participating MasterMind regions, various recruitment strategies were applied, including open, electronic mass mailings, and targeted individual mailings. Starting from January 2015 for wave-1 and October 2015 for wave-2 sites, service deliverers' demographics were collected the moment they enrolled into the MasterMind project. Organisational implementation climate (OIC), satisfaction (CSQ), and usability (SUS) were surveyed in both wave 1 and wave 2 sites at the end of the study in December 2016. The survey was administered online and in local language (Danish, Dutch, English, Estonian, German, Italian, Norwegian, and Spanish) using existing translations. The survey was translated by external translators and checked by the local investigators when no translations were available. Data was uploaded to the central MasterMind database using a standardised codebook. The survey is included in Additional file 2.

Statistical analyses

Survey data was cleaned using descriptive statistics assessing distributions, centrality, outliers and missing values. We did not impute data. Three of the fourteen organisations were exposed to considerable participant drop-out due to staff turnover during the data collection period leading to severe case nonresponse and therefore excluded from the analysis. Overall there were 120 cases in the data set of which nine were removed due to severe item nonresponse. That is, 111 cases responded to at least one item on satisfaction, usability and organisational implementation climate questionnaires (44:57 wave 1 to wave 2 ratio). In total, 80 cases completed all questions of all questionnaires. 103 completed all SUS items, 108 all CSQ items, and 89 responded to all OIC questions. Total OIC scores were

calculated by taking the sum of scores for each question. We assumed that higher scores are indicative of a stronger organisational implementation climate. Scale scores for SUS and CSQ were calculated following the respective prescribed scoring systems. That is, for CSQ we used summed item rating scores. For SUS the summed item ratings were converted to a 0-100 scale using the curved grading scale by Sauro et al. [44], i.e. a score of 68 was considered as the centre of the scale and thus as 'average' in comparison to norm data. Cronbach's alpha (α) was calculated as a measure for internal consistency of SUS, CSQ and OIC in this particular sample. We considered $0.70 < \alpha < 0.90$ as indicative of a good internal consistency [45]. 95% Confidence intervals (95%-CI) around are α were reported to prevent over interpretation. We expected considerable heterogeneity amongst the participating implementers and service deliverers within implementation regions due to the design of the MasterMind project (e.g. wave-1, wave-2 representing experience in delivering iCBT) and geographic diversity and subsequent health systems the service delivery organisations operated in. To gain a descriptive understanding of this variety, differences in demographics and scores due to experiences with implementing and delivering iCBT services between Wave-1 and 2 implementers and service deliverers were analysed using the Wilcoxon rank sum test with continuity correction. The non-parametric Wilcoxon rank sum test was used because of the 4 and 5-point scales used for which the data cannot be assumed to follow a normal distribution. A 95% confidence interval was used. We calculated Spearman's rank-order correlation coefficient (rs) to explore the strength and direction of correlation between OIC questions and SUS, and between OIC and CSQ respectively. We applied the following strength indicators for the correlations: $0 \leq rs < 0.3$ is weak, $0.3 \leq rs < 0.5$ is moderate, and $rs \geq 0.5$ is strong [46]. Data cleaning and statistical analysis was carried out in R [47] using RStudio [48] using packages psych [49], ggplot2 [50] and sjPlot [51].

Results

Conceptualisation workshop

Table 3 provides an overview of the demographic characteristics of the participants of the conceptualisation workshop. Implementers were on average of middle age (M = 39.3 years, SD = 10.9) and had a clinical mental health background ($n = 7$ with 5-10 years of experience in the field of mental health ($n = 5$). Seven out of sixteen implementers had previous experience with iCBT services and six had a management role in the organisation.

Table 3: Extended demographics of delivery staff, pooled and per implementation wave.

Variable	Pooled	Wave 1	Wave 2
Sample, *n* (%)	111 (100)	48 (43)	63 (57)
Gender, *n* (%)			
Female	80 (73)	36 (77)	44 (70)
Profession, *n* (%)			
GP	31 (28)	0 (0)	31 (49)
Licenced psychologist	20 (18)	10 (21)	10 (16)
Psychologist in training	30 (27)	29 (62)	1 (2)
Psychiatrist	6 (5)	1 (2)	5 (8)
General mental health worker	6 (5)	1 (2)	5 (8)
Other	17 (15)	6 (13)	11 (17)
Experience in mental health care, *n* (%)			
< 3 years	18 (17)	7 (15)	11 (18)
3 – 5 years	18 (17)	12 (26)	6 (10)
6 – 10 years	23 (21)	15 (32)	8 (13)
> 10 years	49 (45)	13 (28)	36 (59)
Experience with iCBT, *n* (%)			
Provided a patient < 4 times iCBT	62 (58)	19 (42)	43 (69)
Provided a patient 5 – 10 times iCBT	11 (10)	8 (18)	3 (5)
Provided a patient 11 – 15 times iCBT	8 (8)	6 (13)	3 (5)
Provided a patient 16 – 20 times iCBT	4 (4)	0 (0)	4 (6)
Provided a patient > 20 times iCBT	21 (20)	12 (27)	9 (15)
Received iCBT training, *n* (%)			
Yes	82 (75)	38 (81)	44 (71)
If yes: type of iCBT training received, *n* (%)[1]			
Technical	34 (39)	6 (20)	28 (49)
Therapeutic	4 (5)	1 (3)	3 (5)
Both	47 (54)	23 (77)	24 (42)
Other	2 (2)	0 (0)	2 (4)
State of change in delivering iCBT, *n* (%)[2]			
Orienting	8 (8)	4 (8)	4 (8)
Gained some insight	22 (22)	8 (17)	14 (26)
Decided to change	4 (4)	2 (4)	2 (4)
Trialling usage	34 (34)	10 (21)	24 (45)
It is normal	33 (33)	24 (50)	9 (17)
Perceive an efficiency gain through delivering iCBT, *n* (%)[3]			
Strongly disagree	3 (3)	1 (2)	2 (4)
Disagree	13 (13)	8 (19)	5 (9)
Disagree nor agree	29 (29)	15 (35)	14 (25)
Agree	41 (41)	10 (23)	31 (54)
Strongly agree	14 (14)	9 (21)	5 (9)

1) item-nonresponse: 21.6 % due to not all service deliverers received a training prior to filling out the demographics survey.

2) item-nonresponse: 9%.

3) item-nonresponse: 10%.

4

Theme 1: characteristics of an organisational implementation climate fostering successful implementation of iCBT in routine practice.

A total of 55 items were generated for theme one identifying characteristics of a positive organisational implementation climate in the first individual silent brainstorming round. The items were merged, refined and conceptualised in 9 clusters in group discussions. The clusters were ranked by each participant individually. The results of the workshop including generated ideas, clusters and ranking outcomes are included in Additional file 1. The top-3 ranked clusters of characteristics of a supportive organisational implementation climate included: (1) clarity on role and skills of implementers, (2) feasibility of implementation targets, and (3) instigating a dedicated implementation team.

Theme 2: practical tools to create and facilitate a positive organisational implementation climate.

The second theme addressed practical tools implementers can use to create and facilitate an organisational implementation climate that improves implementation outcomes. For this theme 29 items were generated by the workshop participants individually and in silence. In a structured group discussion (second and third step of the conceptualisation workshop), the items were refined and merged in 10 clusters. In the last step, participants ranked the clusters individually. The ideas, clusters and ranking outcomes are included in Additional file 1. The top-3 ranked clusters of characteristics of practical tools can be used to build a supportive organisational implementation climate included 1) providing regular and structured job performance feedback in delivering iCBT, (2) structurally monitor use of iCBT and implementation progress, and (3) practical guidelines and methods for impact assessment of new interventions such as iCBT in this case.

Cross-sectional survey: demographics, satisfaction, usability and organisational implementation climate

Table 3 presents the demographic data and two items regarding the perceived state of change and efficiency gains in delivering iCBT services. Most service deliverers were female (n = 80, 73%), psychologists (in training or licensed, n = 50, 45%) or general practitioners (GP, n = 31, 28%) with more than 10 years of experience in the field of mental health care. Most service deliverers across both waves had limited experience with delivering iCBT (n = 62, 58% used iCBT with patients less than 4 times). However, service deliverers in wave-1 had significantly more experienced in providing iCBT than wave-2 participants (W = 1739.5; 95%-CI = 0.00, 1.00; p = .01). Most service deliverers received iCBT specific training and the two groups did not differ in their response (W = 1601; 95%-CI = 0.00, 1.00; p = .24). When asked

about their perceived state of change in using iCBT, a third (n = 33, 33%) indicated to perceive delivering iCBT services as a normal practice, and one third (n = 34, 34%) was trialling delivering the service. Significantly more wave-2 service deliverers were in the phase of gaining insight and trialling its use than wave-1 participants (W = 1618; 95%-CI = 0.00, 1.00; p = .01). The fact that wave-2 differed significantly from wave-1 service deliverers in their experience in iCBT delivery and their state of change aligns with what expected differences between organisations with more experience in implementing iCBT services (wave-1) and those with less experience (wave-2).
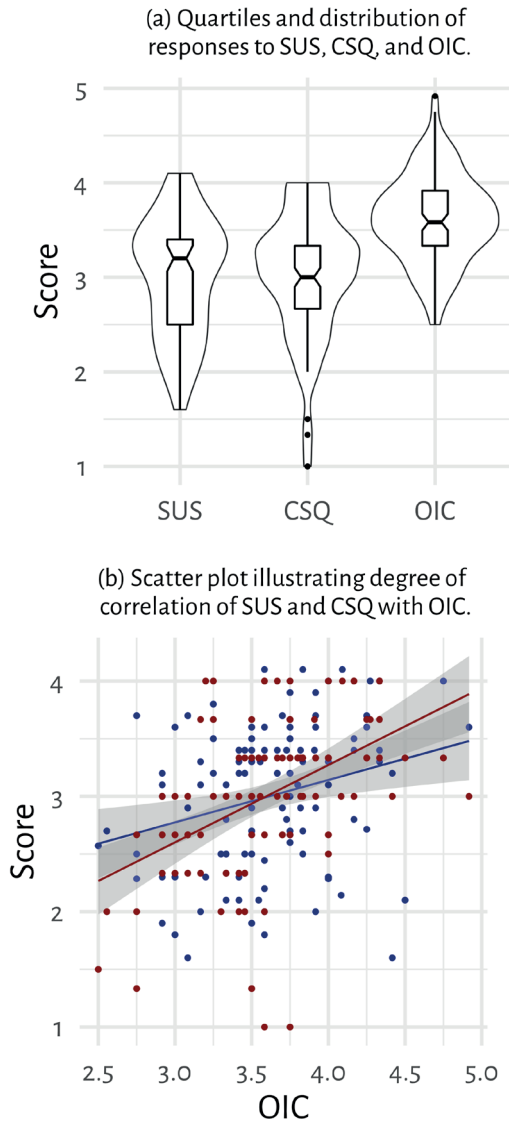
Scores and item ratings
Service deliverers regarded the usability of iCBT services as slightly below average (M_{SUS} = 63.76; SD = 15.53) and satisfactory (M_{CSQ} = 9.11; SD = 1.96). Similarly, organisational implementation climate was also rated slightly above neutral with a total mean score of 43.21 (SD = 5.62). Table 4 provides the statistics for each questionnaire. Detailed item scores are included in Additional file 2. All questionnaires had good internal consistency (α_{SUS} = 0.83, 95%-CI = 0.75, 0.9; α_{CSQ} = 0.82, 95%-CI = 0.73, 0.89; α_{OIC} = 0.76, 95%-CI = 0.64, 0.85). Wave-2 service deliverers scored significantly different on the SUS scale (W = 1919.5; 95%-CI = 7.50, 17.50; p < .05), but not on the CSQ (W = 1569.5; 95%-CI = 0.00, 1.00; p = .42) and the IOC questionnaire (W = 907.5; 95%-CI = -3.00, 2.00; p = .52). The Boxplot in Fig. 2a also indicates that service deliverers agree in their perceived usability (SUS) of iCBT services, and the organisational implementation climate (OIC) they operate in. As indicated in Fig. 2b, organisational implementation climate was weakly associated with variation in the system usability scale (rs = 0.25; p = .03), and moderately correlated with the client satisfaction scale (rs = .51; p ≤ .00).

Table 4: Item and questionnaire scores of perceived usability (SUS-10) and satisfaction (CSQ-3) with iCBT services and organisational implementation climate (OIC) by professionals at post study.

Measure[1] Wave	Item[2]					Scale[3]					
	n	Mean (SD)	Median	Min	Max	n	Mean (SD)	Median	Min	Max	Alpha[4] (95%CI)
SUS-10	111	3.04 (0.29)	3.00	2.14	3.80	103	63.76 (15.53)	67.50	27.50	90.00	0.83 (0.75-0.90)
Wave 1	48	2.99 (0.20)	3.00	2.70	3.60	48	70.26 (10.82)	72.50	42.50	90.00	0.76 (0.65-0.85)
Wave 2	63	3.08 (0.34)	3.10	2.14	3.80	55	58.09 (16.84)	57.50	27.50	90.00	0.84 (0.77-0.90)
CSQ-3	111	3.02 (0.66)	3.00	1.00	4.00	108	9.11 (1.96)	9.00	3.00	12.00	0.82 (0.73-0.89)
Wave 1	48	3.13 (0.51)	3.00	2.00	4.00	48	9.40 (1.54)	9.00	6.00	12.00	0.65 (0.49-0.78)
Wave 2	63	2.93 (0.75)	3.00	1.00	4.00	60	8.88 (2.23)	9.00	3.00	12.00	0.89 (0.83-0.93)
OIC	111	3.62 (0.46)	3.58	2.50	4.92	89	43.21 (5.62)	43.00	30.00	59.00	0.76 (0.64-0.85)
Wave 1	48	3.57 (0.46)	3.54	2.75	4.92	47	42.96 (5.50)	43.00	33.00	59.00	0.76 (0.64-0.85)
Wave 2	63	3.66 (0.47)	3.70	2.50	4.75	42	43.50 (5.81)	43.00	30.00	54.00	0.77 (0.67-0.86)

1) SUS (10 items) applied a 5-point Likert scale with 1 = strongly disagree to 5 = strongly agree. Negative SUS items were rescored to align with positive worded items. CSQ (3 items) applied a 4-point scale with differing response options indicating agreement with statements. OIC (12 questions) applied a 5-point Likert scale with 1= strongly disagree to 5 = strongly agree.

2) Item statistics using raw item ratings. All cases with more than one item rated were included.

3) Scale statistics using summed item rating scores. For SUS-10, the summed item ratings were converted to a 0-100 scale following Brook (1996). Only complete cases were included.

4) Standardised Cronbach's alpha using a correlation matrix.

(a) Quartiles and distribution of responses to SUS, CSQ, and OIC.

(b) Scatter plot illustrating degree of correlation of SUS and CSQ with OIC.

Figure 2: *a* Boxplot indicating the quartiles and response distribution of the SUS, CSQ and OIC questions. *b* Scatter plot indicating the distribution of item responses and illustrating degree of correlation of responses for SUS and CSQ items with OIC questions. Blue and red dots represent SUS and CSQ data points respectively. The blue and red lines represent the linear regression models between respectively SUS and OIC, and CSQ and OIC. The shaded area indicates the 95% confidence interval around the regression lines.

Discussion

In this study, a qualitative concept mapping workshop was combined with an exploratory cross-sectional survey to advance the understanding of organisational implementation climate in implementing iCBT services in mental health care settings. The aim was to obtain a qualitative understanding of how implementers characterise organisational implementation climate and substantiate this with a preliminary quantitative exploration amongst mental health service deliverers in an organisational context.

The main findings from the concept mapping workshop are aligned with Klein and Sorra's integrative model of determinants of the effectiveness of organisational implementation [25]. In their model, implementation effectiveness is in part a function of the strength of an organisation's climate for implementation which comprises a set of organisational policies and practices. According to this theory, different organisational policies and practices may be equifinal in their outcome, skills and motivation play an important role in achieving sustained use of the innovation as unskilled, unmotivated are unlikely to use the innovation at all [25]. This confirms what implementers ranked high in the workshop regarding roles, capabilities and skills of implementers, implementation targets, and the competences of the implementation team as a whole. Similarly, these findings are aligned with the Normalisation Process Theory (NPT) which takes a sociological perspective in theorizing the way people act and interact in integrating and embedding new ways of working in existing practices [52]. For example, the importance of skill sets in organising collective action, corresponds with the finding that for implementers to be effective, they need to have the position and role in the implementation work and team that fits their capabilities and skills. In addition, having realistic implementation time frames, and practical and feasible targets can influence how the new intervention is used in practice. This corresponds to NPT's notion of interactional workability as a factor shaping collective action through operationalization of the innovation into practical ways of working that fit the local context. Furthermore, the finding that members of an implementation team should have a shared interest and beliefs in the implementation goals, corresponds to the theory's notion of coherence referring to processes of individually and collectively determining the innovation's practical meaning and utility.

Turning to the cross-sectional survey, mental health service deliverers were generally satisfied with iCBT (M_{CSQ} = 9.11, SD = 1.96) and regarded usability of the iCBT services as slightly below average (M_{SUS} = 63.76, SD = 15.53). These acceptability

scores are slightly more positive than existing literature on clinicians' perspectives toward delivering Internet-based psychotherapies. In a German survey comparing acceptance of web-based psychotherapy, it was found that clinicians scored around the summed midpoint of the scale (total score = 45.18, scale range = 16-80, n = 428) indicating a more neutral stance [53]. Another study found an overall a neutral stand point (M = 3.45, SD 0.72, 5-point Likert scale with 3 as neutral score, n = 95) on a survey designed to contrast perceived advantages and disadvantages of Internet-based therapies among Austrian psychotherapists [54]. A third study reported similar score patterns of perceptions of computer-based psychological treatments (M = -0.05, SD = 0.79, 5-point Likert scale with 0 as neutral score, n = 26) [55]. This difference in perceived acceptance of Internet-based psychotherapies might be explained by that the majority of the service deliverers (82%) involved in the MasterMind project received iCBT training prior to filling out the survey whereas 80% of the participants in the Schröder study indicated to have no or limited prior knowledge of Internet-based interventions. This might indicative of that the samples were drawn from different groups of mental health service deliverers and the possible difference between intended use by non-experienced professionals and actual use by trained professionals. In addition, the difference in findings might be due varying study designs applied. In our study we choose to use more generic instruments (SUS and CSQ) whereas in the other studies applied questionnaires that were specifically developed for the studies' purposes.

Pending examination of the validity of the OIC questions, a third finding in this explorative study is that a stronger organisational implementation climate is (weak to moderate) associated with higher levels of satisfaction and usability of iCBT. Although causality is not proven by this study, this finding could lead to proposing that acceptability of iCBT services in terms of usability and satisfaction, might vary as a function of organisational implementation climate. That is, more supportive organisational implementation climates might enhance service deliverers' acceptance of iCBT services. Although in this study the measures of usability and satisfaction are iCBT specific, this is aligned with an earlier finding concluding that organisational climate is associated with mental health service deliverers' attitudes towards deciding to adopt evidence-based practices in general [22]. This American study amongst public sector professionals providing youth and family mental health services, showed that supportive organisational cultures for implementing evidence-based practices were associated with positive attitudes of participants towards those practices. Similarly, a weak organisational implementation climate was associated with higher levels of perceived discrepancies between current and new ways of working, most notably when there are unclarities and conflicts about

roles and responsibilities. Authors concluded that clear specification of deliverers' roles and actions can enhance implementation climates and subsequent contribute to implementation success. This aligns with findings from our conceptualisation workshop, where it was ranked as first characteristic of a strong organisational implementation climate conducive of improving implementation outcomes. This reasoning needs to be considered with care as the OIC has been developed pragmatically and requires further investigation of the validity, accuracy and reliability in assessing organisational implementation climates.

When viewed in combination, the qualitative findings from the workshop on the characteristics of a supportive organisational implementation climate conceptually align with the explorative survey used in this study. Despite the pragmatic approach, the questions related to commitment, attitudes, and resources conceptually seem to align to implementers' notions of people and skills, the implementation team, availability of resources and attitudes. This makes sense because, for example, attitudes as referring to the perceived self-esteem in using a new intervention found in the workshop, directly corresponds to a survey item about confidence in ones' own ability to implement. Similarly, the importance of resources supportive to the implementation work such as incentives, skilled people and champions, time, technology, technological support, and policies, qualitatively aligns to survey questions addressing availability of qualified staff, adequate resources, and implementation strategies. In that respect, the findings of the workshop combined with the survey suggests that organisational implementation climate is not only an inherent property of the context in which implementation activities take place, it can also be intentionally shaped to enhance impact of those activities.

Strengths and limitations

This study contributed to an initial understanding of organisational implementation climate in mental health care settings from the viewpoint of implementers, and service deliverers who are required to deliver innovative iCBT services. By combing different viewpoints and methods in one study, a more comprehensive understanding of organisational implementation climate in relation to implementing iCBT services in mental health settings is provided.

However, the findings of this study should be interpreted with care for several reasons, including the inevitable heterogeneity in the settings in which the organisations implemented these iCBT services, and the representativeness of implementers and service deliverers in implementing and delivering the services. Service organisations not only varied in their position in the regional health care

system (primary, secondary care), they also varied in their sources of funding for delivering mental health services (Table 1) driven by underlying regional and national policy contexts. Although in general, most mental health service organisations in Europe are transitioning towards deinstitutionalised care [56], the organizations participated in the MasterMind project likely had differing objectives in implementing the (self-selected) iCBT service. In relation to that, it must be noted that partaking in the MasterMind project and receive (complementary) European funding for implementing and evaluating iCBT services, might have impacted decision-making and enactment of implementation activities. Furthermore, the implementers at the organisations recruited the service deliverers for the survey which might have led to a biased sample of service deliverers who had an interest in innovation and international collaborations in the field of mental health.

Besides the heterogenetic settings, several methodological limitations need to be considered. The workshop was highly structured. Participants received instructions in advance of the meeting, a combination of pen-and-paper and digital recording methods were used, as well as individual silent idea generation and rankings and structured one-by-one group clarification discussions were used to prevent production blocking [57]. The workshop was held in English. Because only two participants were native English speakers, cognitive inertia might have been induced pursuing participants to the same line of thinking and potentially leading to fear of being judged and pressured to remain within the scope of existing options. Although the workshop was designed to include silent individual and group work, this pressure might have influenced the performance of the group in generating a rich variety of ideas during the first two steps and ranking of ideas later on. For the quantitative survey it must be noted that although the questions are aligned with the explorative and pragmatic nature of the study, the empirical validity of the findings represented by the OIC questions is unclear. Question generation and selection were based on a literature review and expert assessment of whether the questions made sense and were meaningful in a mental health setting. We have not performed an empirical psychometric assessment to validate the conceptual and psychometric properties of the questions and the latent constructs they might or might not represent.

Future research
A notion of organisational implementation climate in implementing iCBT services in routine mental health care has been explored in this study. Open phenomenological research is required to further theorise the concept and mechanisms by which organisational implementation climates exerts change in implementing iCBT in

mental health settings. In coherence with this theoretical work, research should focus on developing a reliable, valid, and practical questionnaire to quantify organisational implementation climates. Such questionnaire along with other data sources could then be used to empirically confirm the theoretical assumptions and improve our understanding of the complex interactions between the iCBT, implementers, service deliverers and the organisational context they operate in. In this respect, one important research question could be concerned with how and to what extent organisational implementation climates can be used as an active implementation strategy to effectively improve implementation outcomes.

Conclusion

This study aimed to advance the understanding of the nature and value organisational implementation climate in implementing iCBT services in routine mental health care settings. The qualitative findings from the concept mapping workshop conceptually align with the quantitative approach applied in this study for measuring organisational implementation climate. This suggests that organisational implementation climate is not only an inherent characteristic of the context in which implementation takes place, it might also be shaped to improve the impact of those activities in implementing iCBT services in routine care settings. From the perspective of implementers, a supportive organisational implementation climate includes (1) clarity on skills and roles of implementers, (2) feasibility of implementation targets, and (3) instigating a dedicated implementation team. The top-three tools that can be used to create a supportive implementation climate include: (1) job performance feedback, (2) monitoring in progress in achieving implementation targets, and (3) providing guidelines and protocols for structured impact assessment. From the perspective of mental health service deliverers, the organisational implementation climates they operated in was perceived as supportive to implementing the iCBT services. Explorative analysis revealed that organisational implementation climate was weakly associated with usability and moderately with satisfaction scores. Considering the explorative nature of the current study, future research should theorise and improve the OIC into a valid and accurate instrument for assessing organisational implementation climate. Such empirically validated instrument can be used to design and test implementation interventions that are designed to enhance and use implementation climates for improving implementation outcomes.

4

5

Chapter 5

Toward an Objective Assessment of Implementation Processes for Innovations in Health Care: Psychometric Evaluation of the Normalization Measure Development (NoMAD) Questionnaire Among Mental Health Care Professionals

5

Abstract

Background: Successfully implementing eMental health (eMH) interventions in routine mental health care constitutes a major challenge. Reliable instruments to assess implementation progress are essential. The Normalization MeAsure Development (NoMAD) study developed a brief self-report questionnaire that could be helpful in measuring implementation progress. Based on the Normalization Process Theory, this instrument focuses on 4 generative mechanisms involved in implementation processes: coherence, cognitive participation, collective action, and reflexive monitoring.

Objective: The aim of this study was to translate the NoMAD questionnaire to Dutch and to confirm the factor structure in Dutch mental health care settings.

Methods: Dutch mental health care professionals involved in eMH implementation were invited to complete the translated NoMAD questionnaire. Confirmatory factor analysis (CFA) was conducted to verify interpretability of scale scores for 3 models: (1) the theoretical 4-factor structure, (2) a unidimensional model, and (3) a hierarchical model. Potential improvements were explored, and correlated scale scores with 3 control questions were used to assess convergent validity.

Results: A total of 262 professionals from mental health care settings in the Netherlands completed the questionnaire (female: 81.7%; mean age: 45 [SD=11]). The internal consistency of the 20-item questionnaire was acceptable (.62≤alpha≤.85). The theorized 4-factor model fitted the data slightly better in the CFA than the hierarchical model (Comparative Fit Index=0.90, Tucker Lewis Index=0.88, Root Mean Square Error of Approximation=0.10, Standardized Root Mean Square Residual=0.12, $\chi 2$ =22.5, p≤.05). However, the difference is small and possibly not outweighing the practical relevance of a total score and subscale scores combined in one hierarchical model. One item was identified as weak (λCA.2=0.10). A moderate-to-strong convergent validity with 3 control questions was found for the Collective Participation scale (.47≤r≤.54, p≤.05).

Conclusions: NoMAD's theoretical factor structure was confirmed in Dutch mental health settings to acceptable standards but with room for improvement. The hierarchical model might prove useful in increasing the practical utility of the NoMAD questionnaire by combining a total score with information on the 4 generative mechanisms. Future research should assess the predictive value and responsiveness over time and elucidate the conceptual interpretability of NoMAD in eMH implementation practices.

Introduction

Background

More than 2 decades of research has shown that psychotherapy delivered through the internet, also referred to as eMental Health (eMH) interventions, can be an effective way to treat patients with common mental disorders such as depression and anxiety disorder [1]. Several examples of clinics routinely offering innovative and new eMH services exist, such as the Australian MindSpot clinic [2], GGZ InGeest Mindway [3] and Interapy in the Netherlands [4], Internetpsykiatr in Sweden [5], and Internetpsykatrien in Denmark [6, 7]. Despite these examples, and although the technical infrastructure seems to be in place, large-scale use of eMH interventions in routine care is still lower than expected [8]. Knowledge on factors hindering or facilitating implementation is maturing [9, 10]. However, measuring implementation outcomes reliably remains a challenge [11, 12]. We conducted a psychometric validation study of a recently developed theory-informed implementation measurement instrument: the Normalization MeAsure Development (NoMAD) questionnaire.

Theoretical Underpinning

Various frameworks and theories for understanding implementation processes and evaluating outcomes exist [13, 14]. For example, models such as the Knowledge-to-Action model [15] have been specifically designed to describe and guide implementation processes. Determinant frameworks such as the Consolidated Framework for Implementation Research (CFIR) [16] provide taxonomies of barriers and hindering factors to aid the evaluation of implementation outcomes. Similarly, the Reach Effectiveness-Adoption Implementation Maintenance framework [17] summarizes key indicators for implementation success to inform policy and decision making. Classic psychological behaviour change theories such as the Theory of Planned Behaviour [18] have been used to study the role of attitudes and intentions in the behaviour of individuals involved in and affected by implementation processes. Although such theories can be useful in describing behaviour change mechanisms and explaining how change in individuals involved in implementation processes occurs, they do not necessarily consider what people actually do when implementing innovations in health care practice but rather focus on beliefs and attitudes. The Normalization Process Theory (NPT) [19, 20] aims to fill this void by specifically looking at the process of implementation.

NPT (Figure 1 [19]) states that a normalization process is a process of embedding and integrating health care innovations in routine care as a product of action

of individuals and groups. It focuses on the things that people individually and collectively do to normalize an innovation, that is, for it to become part of routine health care practice. NPT is a heuristic tool to understand the work of implementation, embedding, and integration of new practice and the contribution and roles of individuals and groups to this work. According to the theory, 4 mechanistic constructs play a central role in generating the work of implementation:

- Coherence (CO) of the innovation with the goals of daily routine. Individuals and groups go through a process of sense-making to establish the meaningfulness of the innovation for normal service delivery goals and practices.

- Cognitive participation (CP) as a process of enrolment and engagement of individual participants and groups involved in the implementation processes, through which they become committed to the normalization of the innovation.

- Collective action (CA) by individuals and groups to apply the innovation in daily routine. Here, applying an innovation has certain implications as to what and how normalization should be achieved, which requires investments of effort by the participants.

- Reflexive monitoring (RM) through which participants in the implementation process evaluate and appraise the use of the innovation in practice.

These four constructs are influenced by group processes and social conventions as well as the organizational factors and social structures people operate in. In turn, this social and organizational context defines factors that promote or inhibit the work of individuals and collectives in implementing innovations in daily routines.

Earlier work showed that NPT has good face validity in designing and evaluating implementation processes of innovations [21]. A recent literature review of 108 studies indicated that NPT successfully aids in the conceptual understanding of implementation processes and outcomes across a wide variety of health care settings [22].
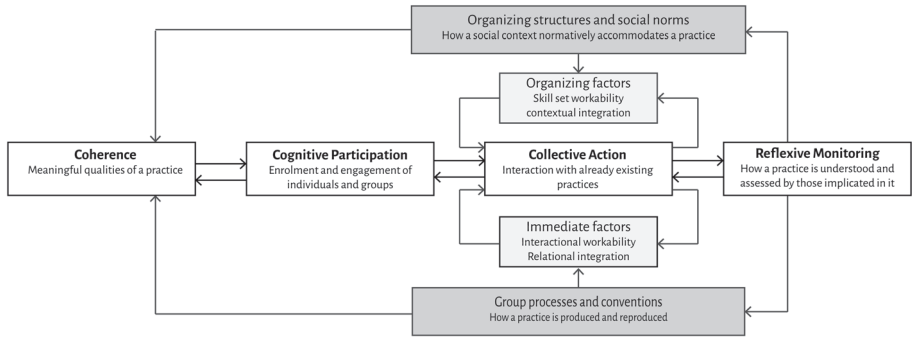
Figure 1: Conceptual model of Normalization Process Theory (NPT): 4 constructs situated in a social and organizational context.

In alignment with the general approach of NPT, the NoMAD study developed a brief self-report questionnaire for the purpose of determining factors likely to affect normalization processes [23-25]. Ultimately, the questionnaire aims to enable (1) assessment of progress toward normalization over time in an implementation project and (2) comparison of normalization (progress or outcomes) between sites in multicentre studies. The NoMAD is intended to be used by people involved in the implementation of innovations in a health care setting and aims to be neutral to the implementation object. The target populations of the instrument are the deliverers and facilitators of the innovation being implemented, such as medical specialists, general practitioners, therapists, nurses, administrators, and managers.

A pool of 46 construct items was generated, appraised, and validated in 5 UK and 1 Australian samples of health care staff (n_{pooled}=413) involved in 6 different implementation projects [23-25]. A psychometric evaluation of the initial item pool resulted in a 20-item questionnaire of which the theoretical model approximated the data acceptably and appeared to have good internal consistency (total Normalization Process Scale (NPS): alpha=.89, CO: alpha=.71, CA: alpha=.78, CP: alpha=.81, RM: alpha=.65) [23].

Objective
We translated the questionnaire into Dutch and aimed to confirm the theoretical factor structure in mental health professionals working to implement eMH in Dutch mental health care settings. We tested 3 factor structures: (1) A 4-factor model to confirm the theorized model, summarizing item scores per construct; (2) A unidimensional model to test whether the items in the questionnaire can be summarized by 1 single factor score; and (3) A hierarchical model to test

whether the 4 first-order factors can be expressed in 1 second-order factor. Where the first model aims to capture a more detailed view on implementation processes, the second model might lend support for practical comparison of those processes. The third model might provide a more detailed understanding of normalization processes on the construct level combined with the practical value of the overall total normalization score in 1 measurement model. Conforming to the English validation study [23-25], we explored potential improvements and the questionnaire's convergent validity with 3 control questions.

Methods

Sample and Recruitment

Using a cross-sectional design, mental health professionals with various occupational backgrounds involved in implementing eMH in Dutch routine mental health care practices were invited to complete the NoMAD questionnaire. We defined involvement in implementation as the situation in which respondents were in the early stages of using eMH in their occupational tasks. By this, novelty to the respondent in applying such interventions in routine care was assumed. Following the English NoMAD study, an open sampling strategy was applied to obtain a sample of 300 respondents. Considering the commonly applied rule of thumb of 7 to 10 complete cases per item with a minimum of 100 complete cases, we expected this target sample size to provide satisfactory statistical power and precision for estimating the model's parameters [26, 27]. Recruitment targeted mental health professionals involved in using novel eMH interventions in (1) primary care for patients with mild symptomatology (general practitioners or general practice–based mental health nurse specialists), (2) basic care for patients with moderate symptomatology, and (3) specialized care provided by specialists to patients with severe mental health complaints. A total of 3 groups of Dutch mental health professionals were identified as suitable for recruitment:

- Group 1: mental health care professionals in 4 large regional mental health organizations for common mental disorders and post-traumatic stress disorders.

- Group 2: general practice–based mental health nurse specialists, in the context of the national electronic health (eHealth) Monitor survey conducted in 2016 for which panels and profession associations were sampled [28].

- Group 3: attendees at the annual Cognitive Behaviour Therapy (CBT) congress held in the Netherlands in 2016, which attracted a nationwide audience of mental health professionals.

A total of 3 different recruitment strategies were applied. Sample 1 was obtained through convenience sampling by which participants were recruited through key contact persons in various mental health organizations. Sample 2 was obtained through existing respondent panels and professional associations in the context of the national eHealth survey. Participants for samples 1 and 2 were invited by email providing general information about the study, a link to more in-depth information, and an anonymous link to the Web-based survey. Sample 3 was recruited through an information kiosk and leaflets at the annual CBT conference.

Translation
The classical Brislin approach to questionnaire translation [29] was used to translate the English NoMAD questionnaire into Dutch. A small (N=3) sample of experts in implementing and using eMH interventions were asked to verbalize their thoughts while interpreting the translated items in a cognitive group interview [30]. The interview focused on the interpretation of the questions, the response scales, and the identification of terms that needed to be adjusted and/or rephrased. Problematic items were rephrased to form the final version of the Dutch NoMAD instrument. Back translation by a blinded professional translator confirmed equivalence of semantic meaning of the corresponding individual items by the principal investigator (TF) of the English NoMAD. The final Dutch translation of the questionnaire is included in Multimedia Appendix 1.

Data Collection
The questionnaire was administered via a commercial Web-based survey system (NETQ Internet Surveys 6.5 [31]). The research team tested the survey for sequencing of the items, technical reliability, and data export procedures. Participants were asked to provide consent for using their (anonymized) data in this study. They provided this digitally through the survey platform before they were allowed access to the survey.

Normalization MeAsure Development Questionnaire
The NoMAD questionnaire in this study consisted of 3 parts: Part A tapping basic demographic information, Part B collecting general normalization ratings about the current use and likelihood of using the intervention in the future, and Part C comprising 20 items measuring the four NPT constructs. Users of the questionnaire

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are required to tailor the implementation object (i.e., intervention) to the context of its application. In this study, the terms (the intervention) were replaced with "eMental health".

Part A: Demographic variables. In line with the English NoMAD, basic demographic variables were included in the first part of the questionnaire, including gender, age, years of working experience, professional job category, and relevant care sector.

Part B: General normalization items. Part B contained 3 questions addressing perceptions of respondents regarding past, current, and future normality of the intervention. The 3 questions were scored on a 1 to 10 Visual Analogue Scale [32]. To increase comparability to the UK study, these 3 items were added to the questionnaire as control questions to assess its convergent validity, that is, the 3 questions are not to be regarded as an integral part of the core of the NoMAD questionnaire [23-25].

Part C: NPT constructs. Part C consisted of the 20 items representing the NPT constructs in four subscales with the following allocation: CO: 4 items; CP: 4 items; CA: 7 items; and RM: 5 items. The 20 original items are listed in Textbox 1.

Scoring

Scale scores were calculated by taking the mean of answered items of a scale. A minimum of 2 items within a scale had to be rated to calculate a scale score. Items rated as "not applicable" were excluded from the calculation. The total NPS score was calculated by taking the mean of all answered items for which complete cases were considered to have less than 15% missing data.

Data Analyses

Descriptive statistics were calculated to summarize the item and scale scores. Internal consistency of the total score and the four theoretical constructs were analysed by calculating the Cronbach alpha [27] for the pooled dataset. The quality of the construct structure was further assessed by applying a confirmatory factor analysis (CFA) using Structural Equation Modelling (SEM). A total of three models were evaluated: (1) the theorized 4-factor model, (2) a unidimensional model, and (3) a hierarchical model. All three models included the 20 items from Part C of the questionnaire. The items were scored on a 5-point Likert scale resulting in an ordinal ordering of the data. The sum scale score of the items approximates a continuous scale by which we expected the latent constructs to be normally distributed. The CFA was run with the robust Weighted Least Square Means and

Variances (WLSMV) estimator using polychoric correlation matrices [26]. Model fit was assessed by estimating the misfit between the observed and implied covariance matrices using the chi-squared test ($\chi^2 \leq 3df$). This was supplemented with four other fit estimators to strengthen the basis for our conclusions: the Standardized Root Mean Square Residual (SRMR≤0.08) as an absolute index of the average discrepancy between the correlations in the implied model and the observed data; the Root Mean Square Error of Approximation (RMSEA≥0.95) providing a population-based goodness-of-fit indication corrected for model complexity; the Comparative Fit Index (CFI≥0.95) providing an index of goodness-of-fit relative to a null model (i.e., no covariances between items); and the Tucker Lewis Index (TLI≥0.95) as an index of goodness-of-fit relative to a null model corrected for model complexity [26, 33, 34]. The three models under evaluation are expected to be nested. We applied the scaled chi-square difference test (χ^2_{diff} test, analysis of variance) to compare the fit of the three models [26].

Text box 1: Normalization MeAsure Development (NoMAD) questionnaire part C items.

Coherence (CO):
CO.1. I can distinguish [the intervention] from usual ways of working.
CO.2. Staff in this organization have a shared understanding of the purpose of [the intervention].
CO.3. I understand how [the intervention] affects the nature of my own work.
CO.4. I can see the potential value of [the intervention] for my work.

Cognitive participation (CP):
CP.1. There are key people who drive [the intervention] forward and get others involved.
CP.2. I believe that participating in [the intervention] is a legitimate part of my role.
CP.3. I'm open to working with colleagues in new ways to use [the intervention].
CP.4. I will continue to support [the intervention].

Collective action (CA):
CA.1. I can easily integrate [the intervention] into my existing work.
CA.2. [the intervention] disrupts working relationships.
CA.3. I have confidence in other people's ability to use [the intervention].
CA.4. Work is assigned to those with skills appropriate to [the intervention].
CA.5. Sufficient training is provided to enable staff to implement [the intervention].
CA.6. Sufficient resources are available to support [the intervention].
CA.7. Management adequately support [the intervention].

Reflexive monitoring (RM):
RM.1. I am aware of reports about the effects of [the intervention].
RM.2. The staff agree that [the intervention] is worthwhile.
RM.3. I value the effects [the intervention] has had on my work.
RM.4. Feedback about [the intervention] can be used to improve it in the future.
RM.5. I can modify how I work with [the intervention].

The items were rated on a 5-point Likert scale (1=completely agree to 5=completely disagree), with an additional response option to indicate if a statement was applicable (0=not applicable). Item 2 (CA.2) in the CA scale is negatively formulated; all other items were formulated in a positive sense. Respondents were required to rate all statements. The Dutch translations are in Multimedia Appendix 1.

Potential improvements to the factor structure were explored by identifying low item-factor loadings (λ<0.3) to ensure that items are meaningfully related to the respective factors [26]. Modification indices (modification index [MI], $\chi^2_{diff} \geq 3.84$) were assessed to identify item-item error covariances that might improve the model fit. In the absence of a gold standard for the assessment of normalization, we exploratively used the 3 general normalization items (part B) to assess the convergent validity of the theorized model. We assessed the Pearson correlation coefficients for all four constructs and general normalization items and applied the following strength indicators for the correlations: $0 \leq r < .3$ is weak, $.3 \leq r < .5$ is moderate, and $r \geq .5$ is strong [35]. These quality indicators were applied in all correlation assessments.

Data cleaning and analyses were performed in RStudio [35, 36] using the following packages: psych [37], ggplot2 [38], sjPlot [39], lavaan [40], semPlot [41], and semTools [42].

Ethical Approval and Consent to Participate

Ethical and scientific approval was granted by the Scientific and Ethical Review Board of the Faculty of Behavioural and Movement Sciences at the VU Amsterdam (file number: VCWE-2016-006).

Results

Sample

Over a period of 10 months (May 2016 to February 2017), 262 respondents completed the questionnaire. Table 1 provides an overview of the samples and participant characteristics. On a pooled level, participants were middle-aged (M= 45, SD=11), female (81.7%), and had over 11 years working experience in their respective fields (52.9%). The response rate for group two was 22.8% (125 out of 547) [28]. For sample groups two and three, response rates are not available because of the convenience and open sampling approach. The time required to complete the questionnaire was 7.56 min on average (SD=6.48, n=134, based on questionnaire log files).

Table 1: Sample composition and demographics of respondents of the Dutch Normalization MeAsure Development questionnaire.

| Variable	Pooled	Group 1[a]	Group 2[b]	Group 3[c]
Cases, n (%)	262 (100.0)	115 (43.9)	125 (47.7)	22 (8.4)
Age (years), mean (*SD*)	46.4 (11)	41.5 (10.7)	48.6 (10.1)	43.1 (11)
Gender, n (%)				
Female	214 (81.7)	91 (79.1)	108 (86.4)	15 (68.2)
Work experience (years), n (%)				
<1	4 (1.7)	3 (1.2)	1 (0.4)	0 (0)
1-2	16 (6.6)	3 (1.2)	13 (5.4)	0 (0)
3-5	46 (19.0)	19 (7.9)	27 (11.2)	0 (0)
6-10	48 (19.8)	21 (8.7)	19 (7.9)	8 (3.3)
11-15	32 (13.2)	17 (7.0)	13 (5.4)	2 (0.8)
>15	96 (39.7)	36 (14.9)	52 (21.5)	8 (3.3)
Sector[d], n (%)				
PC-MH[e]	135 (51.5)	12 (4.6)	122 (46.6)	2 (0.4)
BC-MH[f]	35 (13.4)	20 (7.6)	8 (3.1)	7 (2.7)
SC-MH[g]	114 (43.5)	97 (37.0)	0 (0.0)	17 (6.5)

[a]Group 1: mental health care professionals in large regional mental health organizations. [b]Group 2: general practice–based mental health nurse specialists. [c]Group 3: mental health professionals attending the annual national cognitive behavioral therapy (CBT) congress. [d]Sector: respondents could choose multiple answers: primary care-mental health services, basic care-mental health, and specialist care-mental health. [e]PC-MH: primary care-mental health services. [f]BC-MH: basic care-mental health. [g]SC-MH: specialist care-mental health.

Scale scores

Figure 2 shows the distributional characteristics of the scale scores for the combined samples. The four4 subconstructs (CO, CP, CA, and RM) and the NPS follow similar response patterns.

Considering the length of the boxplot for the scales, respondents vary less in responses to items for the CO construct and more for CP and CA. The distributions of 3 subscales appear to have a slight tendency toward agreement with item statements where CA received mostly neutral responses. Most outliers are in the disagreement end of the scales.

Table 2 shows the mean scale scores, indicating that respondents on average agreed with the item statements. Respondents disagreed considerably with item CA.2, indicating that they did not find the intervention disruptive to working relations (Figure 3).
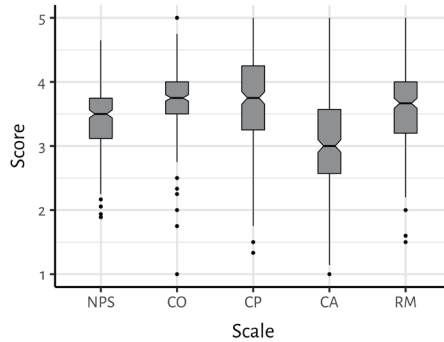
Figure 2: Boxplot of the scale scores for the combined mental health samples. CA: collective action; CO: coherence; CP: cognitive participation; NPS: normalization process scale; RM: reflexive monitoring.

Table 2: Mean scale scores.

Scale[a]	n[b]	Mean (*SD*)	Low[c]	High[c]
Normalization process scale (NPS)[c]	221	3.54 (0.51)	2.11	4.85
Coherence (CO)	259	3.70 (0.67)	1.00	5.00
Cognitive participation (CP)	256	3.69 (0.73)	1.33	5.00
Collective action (CA)	227	3.30 (0.69)	1.29	5.00
Reflexive monitoring (RM)	181	3.55 (0.62)	1.50	5.00

[a]For the total NPS scale, a maximum of 15% missingness was allowed. For the sub-scales, a minimum of 2 rated items were needed to calculate a mean. [b]n varies because of item nonresponse. [c]Low and High represent the lowest (1) and highest (5) score, respectively, rated by the respondents.
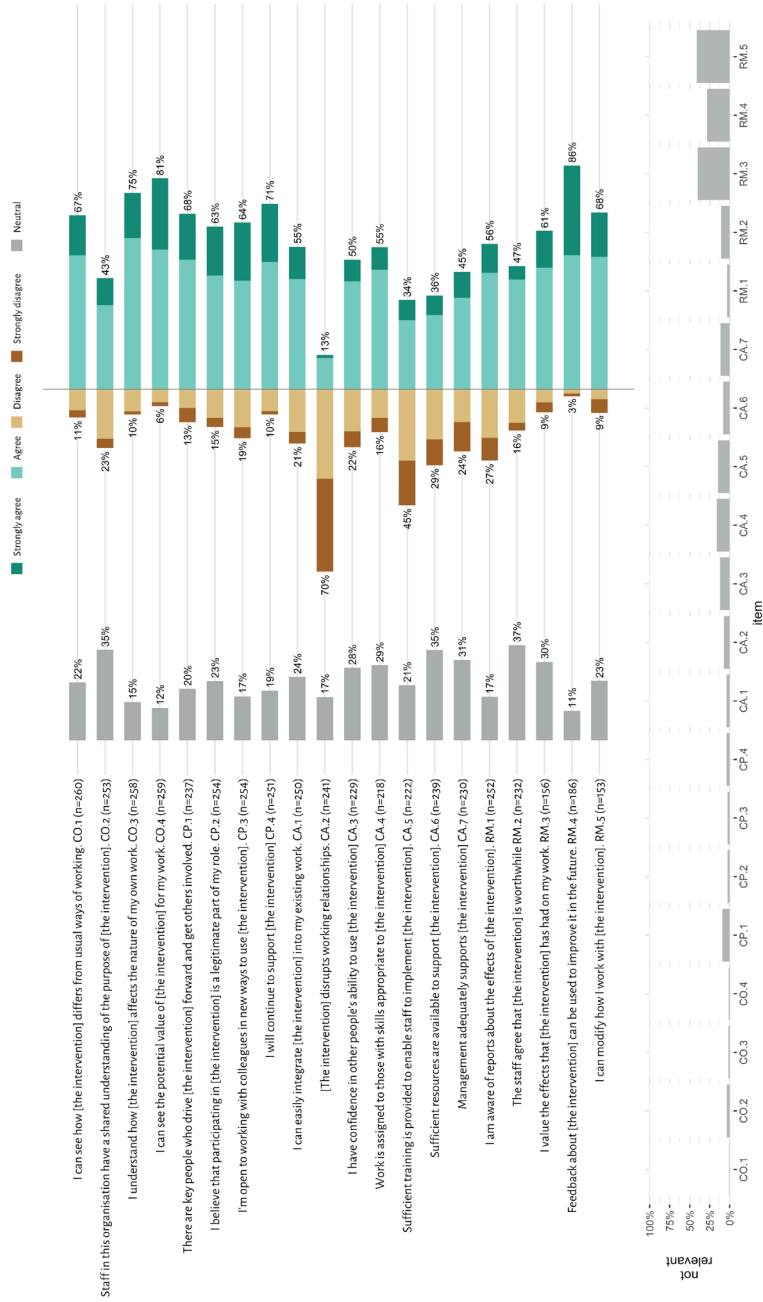
Figure 3: Frequency distribution of item responses. The upper part of the figure shows the percentage of respondents reporting strongly disagree, disagree, agree, or strongly agree. The grey bar coupled to the y-axis indicates the percentage of participants rating an item as "neutral". The lower part of the figure shows the percentage of respondents who chose to not to rate a specific item (i.e., not relevant). CO: coherence, CP: cognitive participation. CA: collective action. RM: reflexive monitoring.

Internal Consistency

Considering the number of items, the internal consistency of the translated NoMAD questionnaire is good for the total score (alpha$_{NPS}$=.85) and ranges from questionable to acceptable for the subscales (.62≤alpha≤.75; Table 3). Internal consistency improved to good when items were dropped.

Table 3: Internal consistency calculated by using Cronbach alpha.

Scale	Cronbach alpha UK[a]	Cronbach alpha NL[b] (95% CI)	Cronbach alpha, if item dropped	Item-rest correlation
Normalization process scale	0.89	0.85 (0.82-0.89)	0.86 (CA.2[c])	.03 (CA.2)
Coherence	0.71	0.71 (0.61-0.81)	0.80 (CO.2[d])	.25 (CO.2)
Cognitive participation	0.81	0.62 (0.51-0.73)	0.75 (CP.1[e])	.10 (CP.1)
Collective action	0.78	0.75 (0.69-0.82)	0.81 (CA.2)	.00 (CA.2)
Reflexive monitoring	0.65	0.64 (0.54-0.74)	—[f]	.36 (RM.1[g])

[a]UK: English validation study results [25]. [b]NL: current Dutch study sample. [c]CA.2: collective action item 2. [d]CO.2: coherence item 2. [e]CP.1: cognitive participation item 1. [f]—: no improvement of alpha found. [g]RM.1: reflexive monitoring item 1.
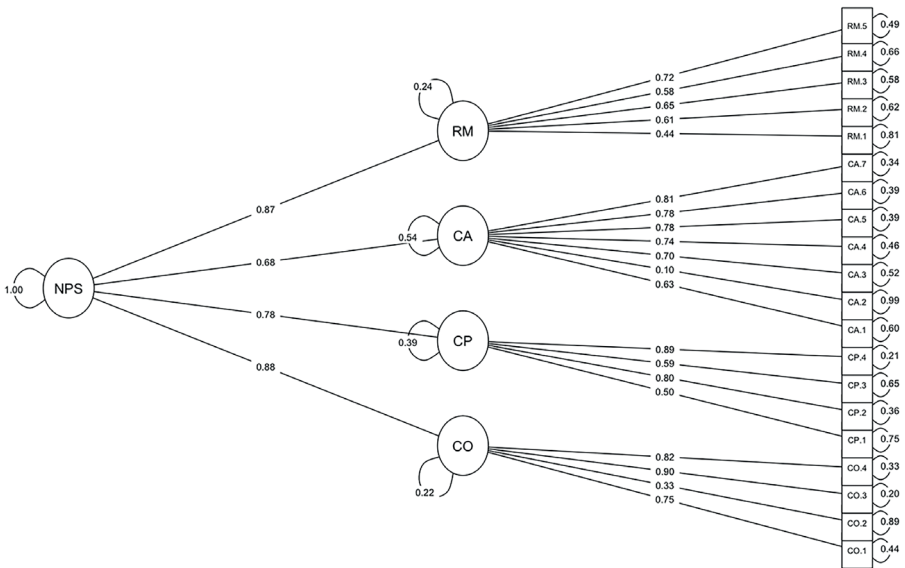
Factor Structure

Table 4 summarizes the CFA results and the fit indices for the 3 models: (1) the first order 4-factor model in which normalization is defined by four correlated constructs, (2) the first order unidimensional model, and (3) the hierarchical model in which a second-level factor accounts for the correlations among the 4 first-order factors. Considering the number of items, all 3 models fitted the data reasonably well. Both the 4-factor model and the hierarchical model represented the observed data significantly better than the unidimensional model (respectively: χ^2_6=220.7, $p \leq .05$, and χ^2_4=198.1, $p \leq .05$). The 4-factor model performed better than the hierarchical model(χ^2_2=22.5,$p \leq .05$) with less discrepancy between the obtained and implied data(χ^2_{164}=559.7, SRMR=0.12), better fit per variable (RMSEA=0.10), and better fit relative to a baseline model (CFI=0.90, TLI=0.88). Notwithstanding the significance, the difference for the chi-square test statistic and the fit indices is small and potentially not outweighing the practical relevance of a total summary score and subscale scores combined in one measurement model. Therefore, the factor structure of the hierarchical model is displayed in Figure 4.

Table 4: Results of the confirmatory factor analysis (CFA). A fourth model is included in the CFA to explore potential improvements only.

Model	n_{par} [a]	χ^2 [b]	df [c]	CFI [d]	TLI [e]	RMSEA [f]	SRMR [g]
Four-factor	106	559.7	164	0.90	0.88	0.10	0.12
Unidimensional	100	837.3	170	0.82	0.80	0.12	0.15
Hierarchical	104	580.9	166	0.89	0.87	0.10	0.12
Hierarchical modified	101	426.1	146	0.93	0.91	0.09	0.11

[a]npar: number of parameters estimated in the CFA. [b]χ2: scaled chi-squared test. [c]df: degrees of freedom in the confirmatory factor analysis (CFA). [d]CFI: Comparative Fit Index. [e]TLI: Tucker Lewis Index. [f]RMSEA: Root Mean Square Error of Approximation. [g]SRMR: Standardized Root Mean Square Residual.

Figure 4: Factor structure of the hierarchical model including item factor loadings and residuals. CA: collective action; CO: coherence; CP: cognitive participation; NPS: normalization process scale; RM: reflexive monitoring

Potential Model Improvements

We explored possibilities to improve the measurement accuracy and reliability of the proposed hierarchical model. From evaluating the item-factor loadings, it can be concluded that item CA.2 has a weak relationship with CA (λ=0.10), indicating that less than 1% of the variance in this item is explained by this factor. This is confirmed by the "Cronbach alpha-if-item-dropped" statistic indicating an improvement in the measured internal consistency of the theorized model when this item is removed (Table 3). MIs were consulted for the 4-factor model and two error term covariances—CA.3 to CA.4 (MI=76.9, δ=0.56) and CP.3 to CP.4 (MI=51.1,

δ=0.59)—were identified as potential improvements to the model. For indicative purposes, the CFA was performed for an adapted hierarchical model in which the weakest item (CA.2) was removed and the 2 error terms were added. The modified model performed slightly better than the unmodified models (Table 4).

Convergent Validity

Following the UK study, we also explored the convergent validity of the original 20-item 4-factor model by correlating the observed mean factor scores with the mean scores for the 3 general normalization questions. Table 5 summarizes the findings. Weak correlations with the general normalization items were found for CO, CA, and RM ($-.02 \leq r \leq .27$, $0.09 \leq p \leq .81$). The CP subscale had a moderate-to-strong correlation with the normalization items ($.42 \leq r \leq .59$, $p \leq .05$).

Accurate and reliable instruments for measuring implementation factors and progress are currently few but required to improve the uptake of eMH interventions in routine care [10, 12, 43]. For this study, we translated NoMAD from English to Dutch and sought to confirm its theorized 4-factor structure in mental health care settings.

Table 5: Convergent validity: correlations of the total score and 4 factors with the general normalization items (Part B of the questionnaire).

General item	NPS[a] (95% CI)	CO[b] (95% CI)	CP[c] (95% CI)	CA[d] (95% CI)	RM[e] (95% CI)
No. 1 Feels familiar	.26 (.14 to .38)	.04[f] (-.09 to .17)	.50 (.40 to .59)	.14 (.01 to .26)	-.02[g] (.15 to .11)
No. 2 Is normal	.35 (.23 to .46)	.13 (.01 to -.26)	.42 (.31 to .52)	.27 (.15 to .39)	.18 (.05 to .30)
No. 3 Becomes normal	.32 (.21 to .42)	.10[h] (-.03 to .22)	.59 (.51 to .66)	.10[i] (-.02 to .22)	.03[j] (-.09 to .15)

[a]NPS: normalization process scale. [b]CO: coherence. [c]CP: cognitive participation. [d]CA: collective action. [e]RM: reflexive monitoring. [f]P=.52. [g]P=.81. [h]P=.12. [i]P=.09. [j]P=.63; all other correlations are significant.

Discussion

Principal findings

Our data suggests that the NoMAD can be used reliably in assessing normalization processes in Dutch mental care settings. Using structural equation modelling, the CFA showed that the 4-factor model fitted the observed data best. This finding points in the same direction as the English psychometric study (CFI=0.95, TLI=0.93, RMSEA=0.08, SRMR=0.03, estimator: maximum likelihood) [23]. The hierarchical

model might prove useful in increasing the practical utility of the NoMAD questionnaire. It offers implementation practitioners and researchers with an overall normalization score enabling comparisons across implementation projects. In addition, the subscales scores can provide a more fine-grained understanding of normalization processes and aid in identifying specific areas for improvement.

Considering the factor loadings of both the 4-factor and hierarchical models and the measured internal consistency, improvement of the theorized model seems desirable. Most notably, the explained variance in item CA.2: [the intervention] disrupts working relationships, was below validation standards (see Figure 3). Even though the extent to which people are using eMH interventions in practice might influence their perceived disruptive nature, a possible explanation might be found in the limited variance in ratings for this item as 70% of the respondents strongly disagreed with this item. This might stem from differences in linguistic interpretation by the respondents. For example, it could be that the translation of the term 'disrupt' in CA.2 has a more negative connotation among the Dutch respondents than it has among English native speakers, leading to a tendency toward negative responses in the Dutch sample. However, this is speculative, and we feel it is too early to discard the item. We suggest further deliberation on the theorized meaning of the latent and observed variables to determine the influence of sample characteristics, implementation objects, and linguistic differences in the item formulation before conclusive decisions about possible improvements to the theorized model can be made [26, 33]. In addition, we observed an increase of responses rating items in the RM scale as not applicable. Given the novelty of eMH to the care setting, it might be that the respondents have had limited exposure to the intervention to reflect on its implementation. This corresponds with a sequential interpretation of the NPT constructs but is not the only approach to the ordering of NPT mechanisms [22], and we did not measure the stage or type of implementation trajectory that respondents were currently engaged with, making it too early to draw any conclusions on the item response patterns at this stage.

Limitations
In view of the heterogeneity in implementation objects and health care settings included in current and previous NoMAD validation studies, the relevance of items should be taken in to account when administering the questionnaire to specific groups of respondents [23, 25, 44]. Although an open recruitment strategy was used for this study, it may be that the respondents had a natural inclination to partake in research or had a pioneering standpoint toward implementing eMH. This could have led to certain trends in the data that are not necessarily representative of the

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wider mental health care community involved in implementing eMH interventions. In this respect, it must be noted that sample groups one and three (mental health specialists and attendees of a national annual CBT congress, respectively) were convenience sampled. Sample two (48% of the pooled sample used in the CFA) was obtained through surveying members of a national professional association of general practice–based mental health nurse specialists [28]. We aimed to reduce selection bias by including these three sampling sources but results need to be interpreted with care because of the open design.

For the questionnaire, a 5-point Likert scale has been used for scoring the items. It goes beyond the scope of this study to discuss the consequences of this choice in depth, but it is important to note that we approached the individual responses as ordinal data because the numbers in Likert scales represent verbal statements and not numeric entities. The mean is commonly applied to summarize data allowing for calculating SDs and CIs. However, these indicators can be biased by outliers in non-normal distributions, possibly resulting in a distorted indication of the centrality of the data [45]. In addition, the approach to item nonresponse (or missingness) should be considered. Item nonresponse means that even though the respondent has participated in the study, data for certain items are unavailable for analysis [46]. In this study, respondents needed to either rate their agreement with the NoMAD items or indicate the item as not applicable.

For calculating a scale score, 2-rated items per scale were required. This approach might be limited in informing normalization processes as 50% (more for scales of more than four items) of the items in the same scale could be rated as not applicable. One possibility to reduce this nonignorable form of nonresponse is to apply a forced-choice approach by removing the option for respondents to rate an item as "not applicable" from the questionnaire. However, there is a risk that forcing a rating might lead to an artificial response when a respondent feels they do not have a choice. Another possibility is to apply theoretically defined and empirically confirmed cut-off for allowable missingness in calculating the scale scores.

A further methodological limitation of this study relates to the fit indices used to evaluate the models in the CFA. As the fit indices we used were developed for maximum likelihood–based parameter estimators, they should be interpreted with caution for ordinal data using robust Weighted Least Square estimators such as the WLSMV that we applied. It is argued that the distribution of the data and sample size have a consistent influence that might lead to overestimation of fit indices with ordinal data [47].

Future Research

With this study, we have successfully contributed to the ambition of NoMAD in delivering a generic implementation measurement instrument for measuring normalization processes across different health care settings, including mental health [11, 12, 23-25, 48, 49]. Future research should assess relative predictive value and add to the practical interpretability and utility of the questionnaire. The hierarchical model provides the added value of a singular score for situations that require comparative evaluations of different implementation processes, while retaining the possibility to assess context-specific implementation processes at the construct level for understanding where implementation challenges exist in the development of effective and efficient implementation activities.

However, and although interpretability of the sub-scale scores and the total NPS score does make sense from a mathematical perspective, the meaning and normativity of the scores in practice need to be established before these scores can serve implementation research and practice meaningfully. Future research should establish normative data and assess the implied factor structure of the hierarchical model in different datasets.

To increase comparability with the UK psychometric study, the 3 general normalization items were added to the questionnaire solely for assessing convergent validity [23-25]. Although this gives some indications of correlation of the NoMAD items with similar scales, the status of these 3 items is unclear. However, they do not constitute to the core of the questionnaire, and users are advised to disregard them. Instead, different measures of comparable constructs should be examined to establish a stronger assessment of convergent validity. Preferably, a multi-trait-multi-method matrix should be used to strengthen conclusions about construct validity by using different methods such as organizational data on normalization success [34, 50, 51].

Test-retest reliability should be assessed to examine responsiveness of the questionnaire over time, to establish the ability of the questionnaire to measure changes when they occur. Responsiveness can be considered a measure of longitudinal validity and can be assessed by testing the predefined hypothesis about expected differences in changes between known samples at different time points [27]. As the duration to achieve implementation success can vary across context implementation object and implementation activities, careful consideration is needed regarding an appropriate time frame for repeat testing to assess responsiveness of the NoMAD questionnaire [52]. Applying a large-scale,

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stepped-wedge randomized controlled trial, NoMAD is used to measure change in normalization processes over time in the ImpleMentAll project (study protocol forthcoming) to test the effectiveness of tailored implementation compared with usual implementation activities for eMH interventions.

Conclusions

Accurate and reliable assessment of implementation processes are needed to advance the implementation of eMH interventions in routine care. The translated NoMAD questionnaire proves to be a promising instrument in measuring implementation processes of innovative interventions in Dutch mental health care settings. The theorized 4-factor model approached the observed data acceptably, but there is room for improvement. The hierarchical model might prove useful in increasing the practical utility of the NoMAD questionnaire. Future research should add to the practical utility of the questionnaire by establishing normative data and assess the relative predictive value and responsiveness of the questionnaire over time.

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Chapter 6

Effectiveness of self-guided tailored implementation strategies in integrating and embedding Internet-based Cognitive Behavioural Therapy in routine mental health care. Results of the ImpleMentAll project.

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Abstract

Background. Internet-based Cognitive Behaviour Therapy (iCBT) services for common mental health disorders have been found to be effective. There is a need for effective strategies to improve implementation in routine practice. One-size-fits-all strategies are likely to be ineffective and tailored implementation is considered as a promising approach. The self-guided 'Integrated Theory-based Framework for Implementation Tailoring Strategies toolkit (ItFits-toolkit) supports local implementers with a flexible process of tailoring site-specific implementation strategies to address local contextual factors. The ItFits-toolkit was tested for its effectiveness in achieving favourable in developing tailored implementation strategies. Tailoring involves (1) identifying local barriers, (2) matching selected barriers to implementation strategies, (3) developing an actionable work plan, and (4) applying, monitoring, and adapting where necessary. We compared the effectiveness of the ItFits-toolkit with Implementation-As-Usual (IAU) in implementing iCBT in twelve routine mental health care organisations in nine countries.

Methods. A stepped-wedge cluster randomised trial design with repeated measures was applied. Repeated measures, with ten data collection waves, was chosen to assess change in implementation outcomes over time. The total trial period was 30 months. The primary outcome was normalisation of iCBT delivery by service providers (therapists, referrers, IT developers, administrators) measured with the NoMAD as a proxy for implementation success. Three-level linear mixed-effects modelling was applied to estimate the effects. iCBT uptake (referral and treatment completion rates) and implementation effort (hours) were used as secondary outcomes. Perceived satisfaction (CSQ-3), usability (SUS), and impact of the ItFits-toolkit by implementers was assessed to assesses the acceptability of the ItFits-toolkit.

Results. In total, 456 mental health service providers were included in the study. Compared to IAU, the ItFits-toolkit had a small significant positive effect on normalisation levels in service providers (M=0.09, SE=0.04, p=0.02, Cohen's d=0.12). Uptake of iCBT by patients was on par with IAU. Compared to IAU, implementers did not spent more time on implementation work when using the ItFits-toolkit and generally regarded the ItFits-toolkit as usable and were satisfied with it.

Conclusions. The ItFits-toolkit performed better than usual implementation activities in implementing iCBT services in routine practice. However, the effect on normalization levels in mental health service providers was very small. There lies practical utility in the ItFits-toolkit for supporting implementers to develop

and apply effective tailored implementation strategies. However, these findings warrant modesty about the effectiveness of self-guided tailored implementation in implementing iCBT services in routine practice.

Introduction

Common mental health disorders such as depressive disorder and anxiety account for a large proportion of the global burden of disease [1-3]. Effective evidence-based treatments exist, but access to care has become a critical issue for countries across Europe and the world. In the last two decades, effective clinical innovations that may help overcome this challenge have been developed at high rates [4]. Internet-based Cognitive Behavioural Therapy (iCBT) for common mental disorders has a wide evidence base that can potentially increase the reach and accessibility of mental health services with comparable clinical effects to face-to-face psychotherapy [5-8]. Despite the evidence base, and although examples of successful implementation exist, widespread use of iCBT services in routine mental health care lags behind expectations [9, 10].

When an organisation decides to adopt iCBT treatments, often implementation strategies are focused on the technical infrastructure or training of service providers. Commonly, service providers receive technical training that focuses on how to use the online iCBT platform. Although important, these strategies may not necessarily address the most urgent barriers to implementation. This is because successfully using a new online treatment platform in daily practice goes beyond the technical operation of the platform. Often it requires learning new communication skills [11] and reconsidering existing organisational procedures and clinical operating guidelines. Successful implementation of iCBT platforms therefore requires an integrative approach to implementation that considers a wide range of barriers.

Generally, iCBT services are not implemented and delivered in isolation. They impact and interact with various aspects of the health care service delivery system. Implementing iCBT services in routine mental health care practice is a complex process that affects multiple actors, such as service providers, clinical directors, policy makers, insurers, managers, administrators, and patients, and does so at multiple levels [12, 13]. In the complex changes required to deliver the new service, many different factors affect iCBT implementation. Promisingly, the scientific literature on implementation barriers is relatively rich and identifies factors such

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as available resources, attitudes and capabilities of service referrers [14, 15] and mental health service providers [11, 16, 17], and other barriers that exist at the system, organisational, service provider and patient level [18]. These factors are also likely to change over time. Despite this rich scientific literature, we have an incomplete understanding of how these factors interact with iCBT service delivery, and how effective different implementation strategies are in targeting implementation barriers.

Implementation, seen as a process by which people bring into operation new or modified practices [19], takes place in a dynamic context and is susceptible to barriers that vary from setting to setting and over time [20-24]. Tailored implementation is a process by which implementation work takes account of factors in the local context in which the new service is to be integrated and embedded. Examples of such factors include financial and time constraints, needs and capabilities of team members, specific organisational procedures, structures and habits, and values and beliefs of certain stakeholder groups. Innovations can be implemented more quickly and more efficiently by systematically addressing the factors that are most likely to impede and facilitate the uptake in the context of the local setting [25, 26]. Evidence of the effectiveness of tailored implementation came from a Cochrane review (n = 17 studies) of tailored implementation strategies that focused on implementing clinical guidelines in a variety of clinical settings [27]. Using health professionals' adherence to guidelines as an indicator of implementation success, the review found a pooled odds ratio (OR) of 1.56 (95% confidence interval = 1.27-1.93, $p < 0.001$) showing that tailored implementation leads to better implementation outcomes compared to doing nothing or applying implementation strategies that are not tailored to local determinants. The authors concluded that on face value, tailored implementation "can be effective, but the effect is variable and tends to be small to moderate" [27].

Up until now, mostly expert-driven models of tailored implementation have been developed and studied. In models that involve expert-driven tailoring, experienced implementation researchers or implementation practitioners have a prominent role in guiding the tailoring process, designing the implementation strategy, and in applying the strategy. Generally, these experts are external to the organisation, not involved in the development of the intervention or guideline that is to be implemented, nor are they necessarily familiar with the specific context (e.g. mental health care). Their primary field of expertise lies in implementing or systematically studying the implementation of complex interventions in various medical fields including primary and specialised health care. An example of expert-driven tailoring was applied in the Tailored Implementation for Chronic Diseases (TICD) project

[28]. In this project, the identification and matching of barriers to implementation strategies was facilitated by a team of experienced implementation researchers. It was concluded that the implementation activities resulted in "improvements on some outcomes, but they had overall little observable impact on primary or secondary [patient-level] outcomes" [28]. Studies of expert-driven tailored implementation have also been conducted in mental health settings. For example, Sinnema et al. found that an implementation program tailored to address barriers perceived by general practitioners (GP) can improve recognition of anxiety and depression in patients presenting for treatment in primary care (OR = 1.60; 95% Confidence Interval (CI) = 1.01–2.53) [29]. In this study, barriers were identified on the basis of a literature review by the research team and by trained interviewers interviewing general practitioners. The tailored implementation intervention consisted of peer group supervision, as well as periodic telephone consultations facilitated by the research team and experienced GPs, that were used to iteratively discuss the identified barriers and suggest possible solutions to address them [30].

Given the evidence base, there are limitations to the expert-driven model of tailored implementation. For example, external experts might be less adept at identifying context-specific barriers than local implementers, possibly leading to less effective implementation strategies. Also, external experts may not know or have access to relevant local stakeholders or they might be regarded as outsiders possibly limiting acceptability of specific implementation strategies by local stakeholders. Furthermore, expert-driven models of tailoring might have scalability issues and practical constraints due to the limited availability of experts to coordinate and facilitate tailoring of implementation strategies. Alternatively, tailoring more intensively to specific settings can be an alternative to improving the effectiveness of tailored implementation, but is likely to be very costly [28].

To overcome these limitations and to potentially improve the effectiveness of tailored implementation strategies, the Integrated Theory-based Framework for Intervention Tailoring Strategies toolkit (the ItFits-toolkit) was developed. As part of the Horizon2020 ImpleMentAll project (IMA, [31]), the ItFits-toolkit was specifically designed as an online self-guided tool for local implementers. The ItFits-toolkit provides a systematic and flexible approach embedded in theoretical and conceptual ideas from the field of implementation science, including Normalisation Process Theory (NPT, [32]. The toolkit does not require prior experience in, or knowledge of, implementing new clinical interventions in routine care and it supports local implementers in developing evidence-informed implementation strategies that are tailored to local needs.

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In this study, we examined the effectiveness of the ItFits-toolkit and answered the research question: does the use of the ItFits-toolkit lead to better outcomes than Implementation-as-Usual (IAU) in implementing iCBT services in routine mental health care? Implementation effectiveness was approached as the extent to which the iCBT services were regarded as being a normal part of mental health care practice by service providers. We hypothesised that ItFits-toolkit usage would be associated with increased normalisation of iCBT services into practice. Parallel to this effectiveness study, an in-depth qualitative process evaluation was conducted focusing on engagement, embedding, and integration of the ItFits-toolkit by implementers [33, 34].

Methods

A multi-centre trial was conducted in Albania, Australia, Denmark, France, Germany, Italy, Kosovo, the Netherlands, and Spain. The trial ran from March 2018 to March 2021. The study protocol is published elsewhere [31].

Study design

A Stepped Wedge cluster randomised controlled Trial (SWT) design was applied [35]. The main design principles are illustrated in Figure 1. Over a period of 30 months, the ItFits-toolkit was sequentially rolled out to six groups of 12 organisations (clusters). The clusters were randomly allocated with an interval of three months at which the clusters crossed over from the control condition (IAU) to the experimental condition (ItFits-toolkit). Data were collected in 10 waves with a three-month interval period (waves 1 – 10) to strike a balance between measuring change over time and the measurement burden imposed on study participants.

Group	Cluster (site)	Month											
		0	3	6	9	12	15	18	21	24	27	30	
1	1												
	2												
2	3												
	4												
3	5												
	6												
4	7												
	8												
5	9												
	10												
6	11												
	12												

Wave 1 Wave 2 Wave 3 Wave 4 Wave 5 Wave 6 Wave 7 Wave 8 Wave 9 Wave 10

☐ Implementation as Usual   ▨ Exposure period   ▨ Extended use
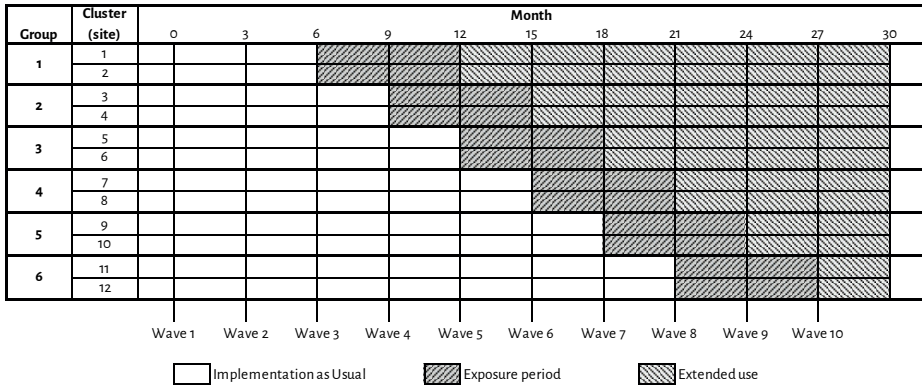
Figure 1: Stepped Wedge Cluster Randomised Controlled Trial design.

Settings

Twelve mental health service delivery organisations in nine countries were involved in the study (Table 1). All organisations embarked on implementing an iCBT-based prevention or treatment service for common mental disorders. One of the 12 organisations was not able to participate because their iCBT platform was technically not ready for implementation when the first data collection wave commenced. This organisation was replaced by a backup mental health service delivery organisation available within the ImpleMentAll consortium that was ready to implement their iCBT service. The iCBT services that were implemented targeted people with mild to severe depressive disorders, anxiety disorders, substance abuse, or somatic symptom disorders. One service included a prevention approach addressing risk profiles/symptoms for developing mental health disorders. All iCBT services were based on CBT covering four main working mechanisms: psychoeducation, techniques invoking behavioural change, a cognitive component, and relapse prevention [36]. All services were Internet-based using web-based delivery platforms, smartphone-based apps, or a combination of both technologies. Various guidance modalities were embedded in the iCBT services, ranging from unguided with minimal technological and administrative support to therapist-guided and blended treatments where online modules and face-to-face therapy were integrated into one treatment protocol [37, 38]. Patient pathways, diagnostic criteria, meaningful therapeutic exposure, and stopping rules followed local treatment manuals and clinical guidelines. The specific operationalisation differed per service in response to the local requirements and preferences (see study protocol [31] for more information).

Table 1: Overview of mental health service delivery organisations and main iCBT characteristics

Organisation	Country codes	Prevention	Primary care	Secondary care	iCBT platform/program	Unguided	Guided	Blended
IMA0101	AL			X	iFight Depression		X	
IMA0201	AU	X	X		FitMindKit	X		
IMA0301	DE		X		iFight Depression		X	
IMA0302	DE	X			Get.On / HelloBetter		X	
IMA0401	DK			X	NoDep & Fearfighter / MindDistrict		X	
IMA0501	ES			X	Super@tuDepresión		X	
IMA0502	ES		X		Super@tuDepresión		X	
IMA0601	FR			X	MoodBuster		X	X
IMA0701	IT				iFight Depression		X	
IMA0801	NL		X	X	MindWay using MindDistrict			X
IMA0802	NL		X		MySelf / Master your symptoms		X	
IMA0901	XK	X		X	iFight Depression		X	

Country codes: AL = Albania, AU = Australia, DE = Germany, DK = Denmark, ES = Spain, FR = France, IT = Italy, NL = the Netherlands, XK = Kosovo

Study participants

Two types of participants were included in the study: 1) implementers, i.e. local staff who facilitated the implementation of the iCBT service, and 2) mental health service providers, like therapists, involved in iCBT service delivery.

For each of the twelve organisations, a team of up to five staff members were appointed as implementers. One of the team members was appointed as the implementation lead. Implementers were directly involved in the development, coordination, and execution of local implementation activities such as designing and distributing iCBT information leaflets or developing training materials for referrers and therapists. Implementers were not required to have prior experience in, or specialist knowledge of, implementing iCBT services, but were expected to have working knowledge of the service they were implementing. Implementers could have different functions or roles in the organisation; i.e. manager, researcher, or clinician. Implementers were expected to have a proficient command of the English language to be able to use the ItFits-toolkit.

Mental health service providers were eligible to be included if they had a distinct role in delivering iCBT to patients. These included as clinicians, psychologists, GPs, psychiatrists, psychiatric nurses, staff in a supporting role (e.g., administrators), or Information Technology (IT) professionals involved in the operation of the technical aspects of the iCBT services.

Both implementers and service providers were recruited by the local research teams with the support of a central research team overseeing the trial. To avoid contamination between the implementation team and the target population of the toolkit, participants could not participate as both implementer and service provider at the same time.

Intervention: ItFits-toolkit

The ItFits-toolkit consists of four online modules that guide users through the tailoring process: 1) identifying and prioritising implementation goals and barriers to reaching these goals, 2) matching barriers to implementation strategies, 3) designing a work plan for carrying out the strategies, and 4) applying strategies and reviewing progress. An overview of the main components of the ItFits-toolkit are summarised in Figure 2 and Box 1. Within the respective modules, implementers work with literature-based materials, including a repository of barriers [18] and implementation strategies [39-41]. The work plan developed in module three is structured using the Template for Intervention Description and Replication (TIDieR) checklist [42]. Within the four modules, ideas from Normalisation Process Theory [32] are integrated, including stakeholder involvement. In each module, implementers work through a three-step iterative stakeholder consultation process using a number of methods (e.g., brainstorming, structured group discussions, or surveying) to reach the best possible outcome. An online surveying tool is integrated in the ItFits-toolkit to collect views from stakeholders throughout each module, and also to collect information on indicators to assess effects of the tailored implementation strategies in module four. Notes, audio recordings, and other relevant materials can be uploaded to document the decisions and progress made in each module. In developing the toolkit, a balance was sought between theoretical foundation, practical orientation, and usability. The ItFits-toolkit has been built from scratch immediately prior to the start of recruitment to the trial and undergone various rounds of conceptual and technical piloting with various user groups representing perspectives of implementers, clinical stakeholders, and researchers. More information about the toolkit is available at the project website [43] and in the study protocol [31]. The toolkit is freely accessible at www.itfits-toolkit.com.
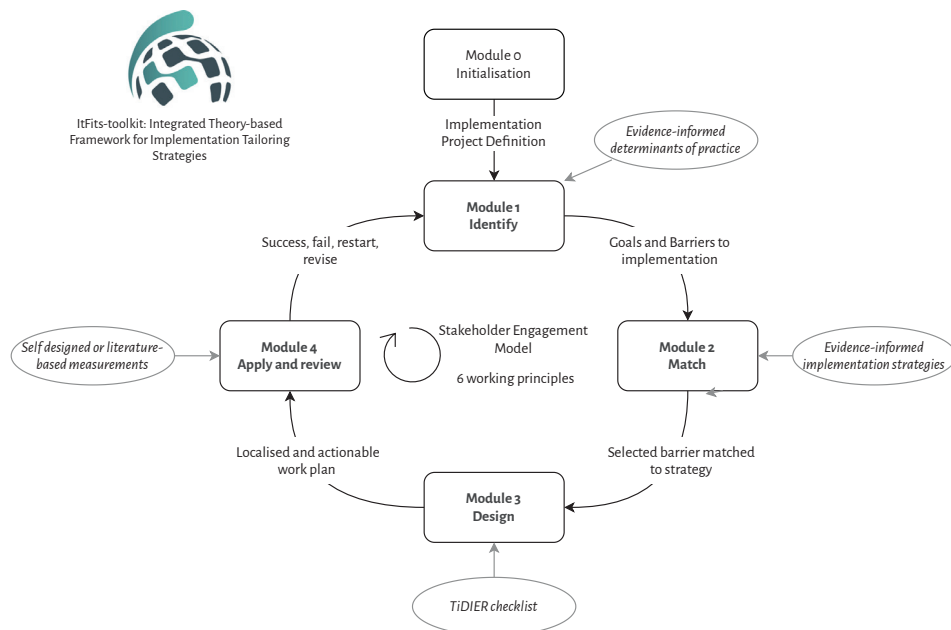
Figure 2: ItFits-toolkit process flow and main working mechanisms.

Text box 1: Core working components of the ItFits-toolkit logic model.

Core working components of the ItFits-toolkit
- Non-standardised, systematically guided step-by-step process
- Stakeholder-based co-creation
- Tools to identify local barriers, consult stakeholders, and match to suitable strategies
- Evidence-informed materials on barriers, strategies, and intervention planning
- Six working principles: pragmatic, flexible, focused, openness, organised, different

Control condition: Implementation as Usual

Implementation-as-usual functioned as the control condition in testing the effectiveness of the ItFits-toolkit. IAU referred to any existing activities the organisations were engaged in to implement the iCBT services in routine care. During the trial, IAU mostly concerned communication and dissemination activities, training, education, as well as further adapting the services to the local requirements.

Exposure to the toolkit

At cross-over (Figure 1), the implementers received access to the toolkit following an introductory training. The training covered the ItFits-toolkit working principles and technical instructions to get started. A period of six months was chosen as

the exposure period to balance practical and financial feasibility of the study with realistic opportunities for implementers to gain experience with the toolkit and being exposed to the core components of the toolkit. Adequate exposure to the ItFits-toolkit was defined as the implementers completing modules one, two, and three within the exposure period (Figure 2). Exposure was measured using the logfiles of the ItFits-toolkit in which module completion was recorded each time an implementer navigated to the next (sub)module. During the exposure period, sites received technical support in the form of monthly conference calls. As with the introductory training, the calls were limited to the technical use aspects of the toolkit and did not address any specific implementation advice such as which barriers to address or which strategy to use. The introductory training and calls were provided by members of the central research team involved in the development of the ItFits-toolkit.

Outcome measures

The primary outcome was the degree of normalisation in service providers. Normalisation, as conceptualised by NPT, concerns the actions that people engage in to integrate and embed new practices in their work so that these new practices become a normal part of their daily workflow [32]. This outcome indicator was chosen because of the prominent role service providers have in providing iCBT-services, with the expectation that they would adapt their way of working to accommodate the delivery of iCBT. The outcome of normalisation is to be understood as the degree to which service providers perceive the delivery of iCBT as a normal, integrated, well-supported and sustainable part of their work routine. Normalisation was measured using the NoMAD questionnaire [44, 45]. The NoMAD is a brief self-reported questionnaire with 20 items addressing the four generative mechanisms involved in implementation processes, as conceptualised by NPT: coherence, cognitive participation, collective action, and reflexive monitoring. Items were rated on a 5-point Likert scale (1 = completely agree to 5 = completely disagree, with 3 as neutral). The NoMAD has high internal consistency in various health care settings and languages [45, 46], including in mental health [47].

Secondary outcomes

To complement the primary outcome, we assessed the effectiveness of the ItFits-toolkit using organisation-level measures of uptake of the iCBT service by patients (referral and completed treatments with adequate exposure levels) and implementation effort (operationalised by hours spent by implementers). These were used as secondary outcomes.

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Satisfaction, usability, and impact of the ItFits-toolkit, as perceived by the implementers, were assessed to explore the extent to which the toolkit could fulfil implementers' needs and expectations in developing tailored implementation strategies. Satisfaction was measured with the short version of the Client Satisfaction Questionnaire (CSQ-3, [48-51]. CSQ has good psychometric properties and has been tested in numerous studies and diverse samples [50, 52, 53]. Usability was measured with the System Usability Scale (SUS, [54, 55]) in order to determine the degree to which the toolkit was perceived as usable. Perceived impact was assessed using a Visual Analogue Scale (VAS) to explore whether the implementation strategies developed by using the ItFits-toolkit had an impact and were helpful from the perspective of the implementers. Further details of the outcomes and measurement properties of each instrument are provided in Table 2.

Table 2: Overview of the primary, secondary and exploratory outcomes.

Outcome	Service deliverers	Organisation	Instrument	Base line	Repeated measures	End of exposure
Primary outcome						
Degree of normalisation	X		NoMAD	X	X	
Secondary outcomes						
Uptake (referral and completion)		X	iCBT platform	X	X	
Implementation effort		X	Questionnaire effort and costs	X	X	
Exploratory outcomes						
Exposure to ItFits-toolkit		X	Event-based platform log-files			
Usability		X	SUS (10 items)			X
Satisfaction		X	CSQ (3 items)			X
Perceived impact and helpfulness of ItFits		X	VAS statements			X

NoMAD: Normalisation MeAsure Development. Native language versions were developed using a standardised forward and backward translation protocol; iCBT: Internet-based Cognitive Behaviour Therapy; SUS: System Usability Scale; CSQ: Client Satisfaction Scale; VAS: Visual Analog Scale

Sample size considerations

This study had a fixed number of 12 clusters by design. Mental health service delivery organisations participated based on their commitment to implementing iCBT services. For service providers, the sample size needed for sufficient power to test the use of the ItFits-toolkit on the degree of normalisation (i.e., NoMAD) was obtained from a power analysis using data simulation. As there was no prior knowledge concerning the NoMAD in detecting change in normalisation, we assumed a 5% increase in absolute normalisation scores and an increase in three-month growth rate from 0.05 to 0.10. A cluster sample size of 15 service providers for each of the 12 mental health organisations per wave was estimated to be sufficient to achieve 80% power to detect the effect using a two-sided test with a significance level α of .05. The first two data collection waves were used to obtain a stable sample and recruitment was closed in wave three. Replacements were sought for those service providers who dropped out of the study.

Data management

Nested within the service delivery organisations, data were collected from implementers and from service providers. Some data and outcomes (demographics, satisfaction, usability) were collected once, while data on the primary and secondary outcomes were assessed every three months (see Table 2). All questionnaires were translated using a forward-backwards translation procedure [31]. All data were collected through a secure web-based central Data Collection System (DCS), which allowed for a standardised and structured data collection process. The DCS was developed specifically for this study and designed to prevent missing values or false entries and to enable automatic anonymisation.

Data analysis

Data for the primary outcome were analysed using a three-level linear mixed-effects modelling (LMM) approach [35] with normalisation as the dependent variable, and time (as a discrete variable) and intervention (i.e. the ItFits-toolkit use) as independent variables. To account for expected intervention lag effect, a fractional term for the ItFits-toolkit use parameter was used to reflect the six-month exposure time (0, 0.5 and 1). To account for a correlation structure in the outcome involving three nested levels, repeated measurements (L1) were clustered at the level of service providers (L2), and service providers were clustered at organisation level (L3). A temporal effect was assessed by testing the null hypothesis that the normalisation level was constant over time, when controlling for the effect of the ItFits-toolkit using ANOVA. Cohen's d was used as a measure of the effect by which the modelled estimate was standardised by the pooled within-organisation

standard deviation of the NoMAD scale at Wave-1. Standard cut-off levels were applied (small effect: $d \leq 0.2$, medium effect: $0.2 < d < 0.8$, and a large effect: $d \geq 0.8$). Prior to the analysis and opening the data, various potentially confounding moderators were conceptually explored by the central research team following two workshops, using preliminary information from the qualitative process evaluation [33]. The role of staff in service delivery was selected as a potential moderator. Specifically, we assumed that staff who were more directly involved in iCBT-service delivery such as psychologists and psychiatrists, were likely to go through a more extensive change process to normalise iCBT-service delivery than those at a larger distance to the service delivery process such as referrers and administrators)

For the secondary outcomes, service uptake (iCBT referral and completion) and effort (hours) were modelled following the same approach as for the primary outcome, except that a two-level LMM was applied, since these measures were collected at organisation level only (i.e. not at the level of staff members, but only waves (L1) clustered at organisation level (L2)). For exploratory purposes, measures of exposure to the ItFits-toolkit (module-based log as an indication of use), CSQ, SUS, and perceived impact and helpfulness of the ItFits-toolkit were assessed descriptively as an indication of usability, satisfaction, impact, and helpfulness of the ItFits-toolkit from the perspective of implementers. Perceived impact and helpfulness were measured using a VAS with a continuous scale with a range of 1.0 to 10.0. Scale scores for SUS and CSQ were calculated using the respective prescribed scoring systems. For CSQ, summed item rating scores were used [55]. For SUS, the summed item ratings were converted to a 0-100 scale using a curved grading scale with 68 points to be interpreted as neutral [56].

All observed data were included in the analyses following the intention-to-treat principle. We relied on the capability of linear mixed-effects models to estimate model parameters in case of missing values under the Missing at Random (MAR) assumption [57]. Data cleaning and analyses were performed using R[58] in RStudio [59] using the following packages: dplyr [60], psych [61], ggplot2 [62], and lmerTest [63].

Results

Recruitment and sample characteristics

39 implementers in 12 mental health service delivery organisations used the ItFits-toolkit to implement the iCBT services. The group had a mean age of 42.6

years (SD = 10.1) and 69% of the implementers were female. More than half of the implementers had six or more years work experience in mental health (59%) and were appointed as general project managers (33%) or clinical researchers (31%).

Table 3: Demographics of service providers included in the study.

Variable	n (%)
Gender	
N	456 (100)
female	313 (69)
male	143 (31)
Age	
Mean (years)	41.26
SD	11.08
min - max	18 - 72
Work experience	
< 1 year	56 (12)
1-2 years	79 (17)
3-5 years	84 (18)
6-10 years	75 (16)
11-15 years	75 (16)
> 15 years	87 (19)
Prior iCBT experience	
no	337 (74)
Role in iCBT delivery	
Therapist, etc	257 (56)
Referrer	159 (35)
Administrator	36 (8)
ICT	4 (1)

456 iCBT service providers were included in the study (see Table 3). The response rate to the service providers level measures was high (78% across all 10 waves) giving a total of 2,884 complete data points. Approximately 31% of the service providers were replaced due to study dropout during waves 3 to 10. The group had a mean

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age of 41 years (SD = 11) and 69% were female. Most service providers were involved as therapists (56%). 74% had no experience with iCBT delivery prior to the study.

Exposure to contents of the toolkit

Data from the online platform showed that ten out of the 12 implementation teams progressed at least one of their projects to Module 4 during the exposure period. Qualitative data informed us that two of the remaining teams were in the process of applying their strategies, without recording it on the platform. All teams continued using the toolkit after they completed the exposure period. A total of 31 projects (range = 1 - 6 per organisation) were initiated using the ItFits-toolkit. The term 'project' refers to a process initiated in the ItFits-toolkit to develop and apply a tailored strategy in relation to the iCBT service. For 12 projects, a full cycle of all four ItFits-toolkit modules was completed. A further eight projects were partially completed (up to and including Module 3, at which stage the designed strategy was being applied and monitored).

Primary outcome: Normalisation

On average, service providers ($n = 456$) scored the level of normalisation of the iCBT service slightly above neutral both during IAU ($M_{IAU} = 3.63$, SD = 0.72, $n_{observations} = 1,242$), and when the ItFits-toolkit was used ($M_{ItFits} = 3.67$, SD = 0.76, $n_{observations} = 1,642$). Figure 3 shows that mean normalisation levels were relatively stable over time, both during the IAU and when using the ItFits-toolkit. The figure also shows considerable differences between organisations, with average normalisation scores ranging from 3.11 to 4.32 on a Likert-scale of 1 to 5. Item and scale scores are included in Additional File 1.

Using the LMM, we found that overall and at the end of the study period, the ItFits-toolkit had a small positive statistically significant effect on normalisation levels ($M_{ItFits} = 0.09$, SD = 0.04, $p = 0.02$, Cohen's $d = 0.12$) when compared to IAU. Model definitions and outcomes are also included in Additional File 1. When testing levels of normalisation over time and controlling for the ItFits-intervention effect using ANOVA, a significant temporal effect was apparent (Chi^2 = 25.7, $df = 9$, $p = 0.002$). Over time, levels of normalisation decreased slightly in the IAU condition (M_{IAU} = -0.13). Tailored implementation as operationalised through the ItFits-toolkit, partially cancels out this negative trend over time. Subgroup analysis showed that the ItFits-toolkit had no statistically significant effect on normalisation in service providers that were directly involved in iCBT delivery (i.e. therapists; $M_{group 1}$ = -0.02, SD = 0.07, $p = 0.81$), or service providers that were more remote from the delivery process (i.e. referrers, IT personnel, administrators, etc.; $M_{group 2} = 0.10$, SD = 0.06, $p = 0.06$).
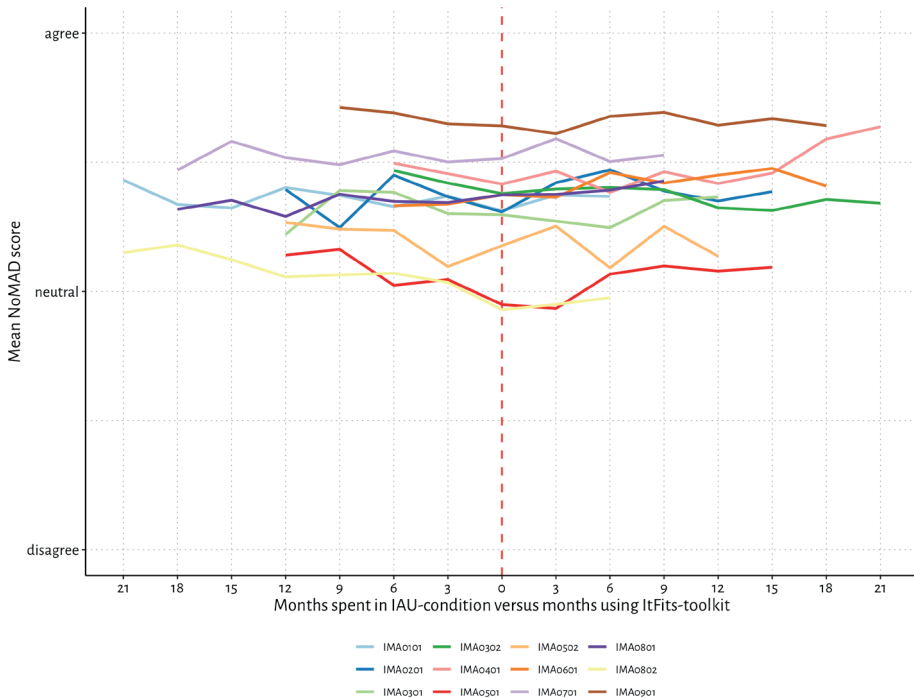
Figure 3: Mean NoMAD score per mental health service delivery organisation across time. Left of the vertical dotted red line is the time service delivery organisations were in the IAU-condition. The right side of the vertical dotted is the time service delivery organisations were in the ItFits-toolkit condition.

Secondary outcomes

Uptake

During the IAU condition, 3,256 patients were referred to the iCBT services, of whom, 18% (588) received adequate exposure to the iCBT services. During the ItFits-toolkit condition, 3,935 persons were referred to the iCBT services and 21.3% (842) received adequate exposure. Over the course of the trial period a total of 7,191 patients were referred and received login credentials to the iCBT services. Following local treatment protocols, 19.9% (1,430) patients received meaningful exposure to the iCBT services, 72.6% dropped out of the iCBT service, 5.7% were using the iCBT service, and 1.8% did not start with the iCBT service when data collection was closed. On inspecting the data, change in uptake over time followed an inconsistent and variable pattern, and there was no clear effect visible with regard to the introduction of the ItFits-toolkit. This was confirmed in our modelling, which showed that differences in referral ($M_{Referral}$ = 21.50; SD = 26.71, t = 0.81; p_t = .42) or completion rates ($M_{Completion}$ = 10.87; SD = 5.83, 21.84; t = 1.87; p = .07) between IAU and ItFits-toolkit usage were not statistically significant. For

both outcomes, no temporal effect in uptake was observed ($Chi^2_{Referral}$ = 8.27, df = 9, p = 0.51; $Chi^2_{Completion}$ = 8.34, df = 9, p = 0.50). Cumulative uptake levels and model specifications are included in Additional File 2.

Effort

As a proxy for assessing the efficiency of the ItFits-toolkit compared to IAU, the hours implementation teams spent on implementation were recorded. Over the whole study period, 20,277.5 hours were spent on implementation activities. With an assumed average of 1,650 hours for a yearly Full-Time Equivalent (FTE) position, the pooled effort corresponds to 4.9 FTE (per year, see Additional File 3) spent by the core implementation teams in total, ranging from 0.05 FTE to 2.46 FTE across the sites. Similar to uptake, the time spent on implementation activities followed an inconsistent pattern and there was no clear effect of the ItFits-toolkit. This was confirmed in our modelling, which showed that the differences in hours spent on implementation between IAU and ItFits-toolkit usage were not statistically significant ($M_{difference\ in\ Effort}$ = 45.88, SD = 41.62, t = 1.10, p = .27). Details and model specifications are included in Additional File 3.

Perceived usability, satisfaction, impact and helpfulness of the ItFits-toolkit

Implementers found the toolkit generally usable (M_{SUS-10} = 77.3 out of 100, SD = 14.2, cut-off = 68) and were satisfied with it (M_{CSQ-3} = 7.4 out of 12, SD = 0.9). Implementers graded the impact of the ItFits-toolkit in addressing the implementation objectives and barriers on average a 6.5 (SD = 1.8, 10-point VAS), with a slightly higher average rating for its ability in addressing barriers (M = 6.9, SD = 1.3) versus objectives (M = 6.1, SD = 2.5, 10-point VAS). Implementers regarded the toolkit in general as helpful, rating it with a 7.1 (SD =0.8, 10-point VAS) on average. Use and perceived added value of the ItFits-toolkit in implementation of iCBT services is the central focus of the Process Evaluation [33].

Discussion

This study sought to examine whether the ItFits-toolkit leads to better implementation outcomes than IAU in implementing iCBT services. In comparison to IAU, the ItFits-toolkit has a small statistically significant effect on normalisation levels in iCBT service providers. The toolkit did not have an effect on iCBT service uptake by patients, nor did implementers spent more time when using the toolkit. ItFits-toolkit users regarded the toolkit generally as usable

and were satisfied with it. These findings fit the general pattern across tailoring studies [27].

To our knowledge, this was the first study to investigate the effectiveness of self-guided tailored implementation supported by an online implementation toolkit using a standardised, validated, quantitative primary implementation outcome in service delivery staff. Practically, these findings and study can contribute to implementing iCBT services into routine care by delivering a functional and technically stable toolkit. The toolkit is easy to use and provides implementers flexible ways to structure and infuse their work with scientific knowledge and involve relevant stakeholders in developing and executing tailored implementation strategies. Findings of this study indicate that self-guided implementation can be improved with a toolkit that enhances implementation outcomes without extra investments of effort. Despite a small effect and a need for further research to better understand and optimise outcomes, clinical directors, managers, and implementers may consider using the current version of the toolkit for implementing iCBT services. The toolkit is freely accessible and may improve the outcome of local staff-driven implementation activities.

A temporal effect became apparent, pointing towards a small decline in normalisation scores (total and of the underlying four constructs) in the IAU condition. The ItFits-toolkit partly cancelled out this negative trend. This is surprising as, following the principles of NPT, we expected the normalisation scores to increase when implementers and service providers engaged and worked to implement the iCBT services. Approximately three quarters of the service providers were inexperienced in delivering iCBT prior to the study. Although speculative, this decline in normalisation might be related to the complexity of iCBT services for service providers to deliver iCBT to their patients. Approximately three quarters of the service deliverers were inexperienced in delivering iCBT prior to the study. As service providers started to spent more time with delivering iCBT services, they might have gained a better understanding of its complexity and the required changes to successfully integrate and embed the service in their routine practice resulting in a decline in normalisation scores. Similarly, gaining experience with providing iCBT services while at the same time be confronted with considerable patient attrition rates, might have impacted the perception of service providers towards implementing the iCBT services. Furthermore, the possibly waning enthusiasm of service providers and implementers towards the research conducted and being part of a large-scale international research project might have influenced implementation outcomes. More research and debate are required to fully understand the theoretical implications of these findings.

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For the secondary outcome, and although there are differences between organisations and the toolkit had no effect on service uptake, the high treatment drop-out rate (72.6%) is to be noted. The debate on drop-out, adherence and treatment completion is unsettled and definitions differ greatly. A systematic review of drop-out rates in research trials investigating effectiveness of guided and unguided iCBT ranges from 0 to 78% with on average 21% stopping treatment early [64]. Other reviews of adherence found that on average approximately 61 to 65% of the patients complete their guided iCBT treatment [65, 66]. Although we do not know the reasons patients in our study stopped their treatment prematurely, it might have to do with the nature of their mental health problems such as chronicity or comorbidity [64], because they experienced the treatment as less beneficial to them [67], or because they recovered earlier than expected and did not require full exposure to the treatment [68]. Also, adherence to an iCBT treatment is considered to be higher in a research setting than under routine care conditions [69]. In the current study, the iCBT services were provided following routine care procedures and guidelines, and no research was applied.

Strengths and limitations

This study is one of the first large-scale international collaborative research projects in which the primary focus was to utilise implementation science approaches to contribute to implementation of iCBT services in routine mental health care. A strength of this trial is its high ecological validity. We managed to study a diverse group of implementers and iCBT service providers that were representative of routine care in 12 mental health service organisations in eight European countries and Australia. Representing routine care mental health service delivery practice, the way in which mental health services were operationalised and delivered, including the clinical focus, guidance modalities, technical platform, and availability of mental health professionals and their experience with (i)CBT, varied amongst the mental health service delivery organisations. A number of unforeseen events, ranging from internal staff turnover, to changing legislation and reimbursement models, and natural disasters such as bush fires, earthquakes, and the COVID-19 pandemic, occurred as they did. All available data was used and by applying a pragmatic SWT study design with repeated measures and a psychometrically validated implementation outcome measure, the study allowed for these variations to provide an accurate representation of real-world implementation practice. By randomising the moment of introduction of the ItFits-toolkit in the implementing mental health organisations, both conditions had an equal chance of being exposed to the events that occurred during the trial. Another strength was the systematic execution of the multi-site study protocol within budget and time and with high

quality research teams and centralized data collection system providing high data quality [31]. Nevertheless, the findings need to be interpreted with care and are indicative of whether the conceptualisation and operationalisation of tailored implementation as packaged in the ItFits-toolkit is a feasible idea.

Some methodological limitations need to be considered in interpreting the results. One aspect is that IAU-activities cannot be undone once embarked on. The results might be influenced by carry-over and intervention-lag effects within the service delivery organisations. Therefore, it is likely that the findings originate from ItFits-toolkit plus usual implementation activities. Likewise, the effects of the ItFits-toolkit might have become apparent beyond the data collection period. A second methodological limitation relates to the outcome normalisation as measured by the NoMAD. This questionnaire is developed with great precision and methodological rigour [44, 70], and has been psychometrically validated in various studies in various settings [45-47]. However, these studies have been using cross-sectional samples, and psychometric sensitivity of NoMAD to longitudinal change is yet to be explored. In addition, and although speculative, regression to the mean in the primary outcome might have occurred as there was no option to rate items as "not applicable". Respondents might have answered neutrally whereas in reality, they experienced that some items were not relevant to their perception of the situation at that moment. Another factor which might have led to an underestimation of the effect, is that some implementers had a background in research or were practicing research, and that some had prior experience in implementing iCBT services. This experience might for example have limited adherence to some principles of the toolkit such as 'being different' in implementing the iCBT service. Similarly, partaking in a large-scale international research project that is designed to address implementation issues, might have influenced implementers in their knowledge of and setting priorities in their implementation work. The process evaluation will shed light on how implementers used the toolkit and can challenge these speculations.

Future research
The findings give rise to several new research questions. First and foremost, the effect is small. Depending on the research question and context, a small effect can be of importance to informing implementation processes. It is to be determined how this effect size is to be interpreted in terms of practical improvement of implementation outcomes. One direction of thought lies in that the toolkit supports organisational learning in systematically designing and applying evidence-informed implementation strategies over time to manage complex

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systems of change. Secondly, to optimise the effectiveness of the ItFits-toolkit, a dismantling study can be used to determine which components of self-guided tailored implementation contribute most to the outcomes of the ItFits-toolkit. A three-phase Multiphase Optimization Strategy (MOST, [71]) approach employing a factorial design, might be a good way to quantitatively identify the most economical and effective combination of tailoring components that provide the best implementation outcomes. Thirdly, implementation work is dynamic, takes time, and is context specific. The outcome measures used in the current study showed little variation over time. Moreover, normalisation levels found in this study declined over time. This requires further discussion in theory development (NPT) and verification of NoMAD with other instruments measuring implementation outcomes longitudinally and their sensitivity to change over time.

Conclusions

The ItFits-toolkit had a small significant effect on normalisation levels in mental health service providers. The toolkit did not change uptake of iCBT by patients, nor did implementers spent more time when using the toolkit in comparison with their usual ways of implementing iCBT services. Implementers generally regarded the ItFits-toolkit as usable and were satisfied with it. Although these findings are in line with expert-driven models of tailored implementation, they warrant modesty about the effectiveness of self-guided tailored implementation. Nevertheless, there lies practical utility for implementers and clinical decision makers in self-guided tailored implementation of iCBT services in routine mental health care using the ItFits-toolkit.

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Chapter 7

General Discussion

Research into the feasibility, efficacy, and cost-effectiveness of eMH services such as iCBT for depressive and anxiety disorders started two decades ago [1-4]. Numerous trials have shown that eMH services are an effective and acceptable alternative to traditional face-to-face psychotherapy [5], including when delivered in routine care conditions [6]. To leverage the clinical and cost-effectiveness, and practical utility of eMH services, successful and implementation of eMH services in routine care settings is warranted.

Drawing on implementation science approaches, the research in this dissertation focussed on understanding and improving the implementation of eMental health services in routine care settings. An organisational perspective was taken as the organisation forms the 'biotope' in which service providers individually, as a group, and in interaction with patients, create health and wellbeing. A complementary range of topics were explored related to decision-making, barriers to implementing eMH services, the organisational context, an instrument to monitor and assess implementation outcomes, and the effectiveness of tailored implementation strategies in implementing eMH services.

First the main findings will be summarised followed by a discussion of each topic separately. Then, several higher-level conceptual observations, practical implications, methodological considerations and recommendations for future research that can be learned from the results included in this dissertation will be discussed when viewed in coherence.

Summary of main findings

Successful implementation of eMH services presupposes the act of adoption; a decision made by clinical or organisational leadership that staff will use and deliver the new services to their patients [7]. Chapter 2 identified methods for systematically assessing the various aspects of eMH services and by that, enable evidence-informed decision-making prior to implementing them [8]. Various Health Technology Assessment (HTA) frameworks are adapted and used to assess complex interventions including eMH services. One example is the Model for ASsessment of Telemedicine applications (MAST) [9, 10].

Once the decision has been made, a logical next step is to identify the factors that might promote or inhibit the integration and embedding of a new practice in routine care [11]. The systematic review in Chapter 3, identified 37 barriers

(also referred to as determinants of implementation practice) that are relevant to consider when implementing eMH services in mental health care settings. Three barriers were reported most frequently: (1) acceptance of patients and professionals; (2) appropriateness of eMH and specifically, the therapeutic interaction; and (3) technological aspects, including interoperability with other existing digital technologies used in health care delivery.

Focussing on the organisational context in which the implementation of eMH services take place, the explorative study reported in Chapter 4 showed that organisational implementation climate is not only a determinant of the organisational context in which implementation takes place. It can also be shaped in such way that the outcomes of implementation strategies can be enhanced by for example systematically providing supervision and feedback, continuous monitoring progress in achieving implementation targets, and guidance in impact assessment of the eMH service that is implemented.

Reliable and valid measurement instruments are required to determine whether implementation strategies are successful in improving implementation outcomes. In Chapter 5, a Confirmatory Factor Analysis (CFA) confirmed the theoretical factor structure of the Normalization MeAsure Development Questionnaire (NoMAD) in samples of Dutch mental health service providers. NoMAD is theory-based and designed to aid identifying implementation barriers, to monitor progress, and to compare outcomes of comparable implementation trajectories and over time [12, 13].

Implementation takes place in a context and faces barriers that vary considerably from setting to setting and from time to time. Effective methods for designing implementation strategies that deliberately and effectively target specific barriers are required. Chapter 6 reports the effectiveness of a self-guided online toolkit for developing, applying and monitoring tailored implementation strategies that are infused with evidence-informed materials about barriers and strategies, and tools for stakeholder involvement. Compared to usual implementation practices, this Integrated Theory-based Framework for Intervention Tailoring Strategies (the ItFits-toolkit), had a small significant positive effect on normalisation levels in eMH service delivery staff.

Aiding the decision to implement

Health Technology Assessment (HTA) is an established systematic way of assessing the merits of a new medical practice. Traditionally, HTA focusses on pharmaceutical innovations. Besides broadening the scope of HTA to include social and ethical

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aspects, increasingly, HTA frameworks are adapted and used to also assess complex (behavioural) interventions including eHealth services and telemedicine. Although HTA frameworks such as MAST provide structure, they omit specification of standardised measurement outcomes and instruments. This stems from the requirement to balance specificity with general applicability of the assessment framework itself. Generic applicability mostly refers to being able to assess many different eHealth services with varying clinical objectives and end-points. Specificity is sacrificed to preserve generic applicability. Besides the various clinical end-points, complicating factors in assessing eMH services are the varying functional and technological properties, inherent continuous development and improvement cycles, and complexity of interventions often impacting interlocking organisational aspects, staff, and client behaviours, and their beliefs and norms [14]. To consider the functional diversity and technological maturity of eMH services, a stepped-approach tailored to the functional characteristics could be considered. This aligns with what is referred to as a mini-HTA that consists of a checklist for clinical decisionmakers to assess the prerequisites for and consequences of novel health technologies [15]. Similarly, the National Institute for Health and Care Excellence (NICE) in the United Kingdom recently introduced a method for stratifying services in proportion to the potential risk to end-users by differentiating the functional end-points of the eHealth service [16]. However, the NICE framework (still) does not provide standards for assessing the technical, organisational, or wider societal and system level impacts. Both the NICE and MAST frameworks, and mini-HTA approaches can benefit from practical guidance in assessing impacts beyond clinical and cost-effectiveness. This could include standardised indicators, criteria and methods for assessing the impact of the service on reaching the target population, impacts on service delivery pathways, organisational and economic impacts. Inspired by the RE-AIM framework [17], the potential reach of the service can be assessed as the percentage of eligible patients that engage in the clinical intervention in a given catchment area. In addition, by specifying the differences between the research environment in which the efficacy of the eMH service is determined and the real-world care settings in which the service is to be implemented, a sense of the changes and required effort to deliver the service in real world conditions can be obtained. For this purpose, Loudon and colleagues developed a taxonomy of indicators, such as the expertise and resources required to deliver the service, the measures to ensure adherence and fidelity aspects, and the organisational setting in which the research takes place [18]. As a third suggestion, a comprehensive description of the intervention logic model or theory of change of the eMH service could inform future implementation efforts as to know what can be adapted to obtain a favourable fit within a certain setting without infringing the efficacy of the service.

Determinants of implementation practice

Over 600 context-specific factors are reported in literature that are relevant to consider in implementing evidence-based interventions [19]. For implementing eMH services, acceptance, appropriateness and the technological aspects are often reported to be hindering [20]. The acceptance of eMH services by patients and professionals has, amongst others, to do with individual and collective attitudes, expectations, and preferences about mental health services. These attitudes relate to awareness and understanding of what eMH consist of and can and cannot do, as well as to the technological aspects such as usability and stability of the online delivery platform. There is ample research reporting mixed findings on the awareness and understanding of eMH services of patients and service providers. A survey amongst 168 stakeholder organisations across Europe, indicated that care providers, patients, researchers, and policy makers have moderate knowledge of eMH services, where patient organisations showed the least level of acceptance of eMH [21]. Other studies found neutral attitudes amongst general public towards eMH services [22], patients being equally positive [23], and patients more positive towards eMH than clinicians [24]. Having experience with eMH services is associated with higher levels of acceptance [24] underlining the importance of trialability of new treatments for both patients and for service providers [25]. Besides trialability, educational strategies are often used to improve awareness and knowledge of eMH amongst (potential) patients. Here, also mixed findings of effectiveness are reported. For example, targeted educational text-based materials show no effect on changing attitudes in (German speaking) general public [22], whereas other studies found that educational materials employing (digital) multimedia, can enhance acceptance amongst patients suffering from mental disorders [26-28]. For mental health service providers, training is a common method for increasing knowledge about targeted topics. Training not only can increase knowledge of service providers about eMH services, it also can provide them with insight into the limitations of these services for particular patients [29].

This relates to the second main problem area identified in the review of barriers to implementing eMH services: the appropriateness or perceived fit of these services in alleviating patients' mental health conditions. Besides efficacy, an important element of the appropriateness of any mental health service, is the flexibility to adjust treatments to individual patient needs. Evidence of personalised treatment and the effectiveness of eMH when tailored to symptomatology is growing [5]. However, personalisation of treatment goes beyond categorised symptomatology. Underlying complexity of complaints and comorbidity, treatment history, and other patient characteristics, including the social environment, differ from patient

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to patient and from time to time [30, 31]. These dynamics can conflict with the more structured nature of eMH services such as iCBT. On the one hand, mental health service providers indicate that they appreciate structure they can rely on when providing their services [32]. On the other hand, often a mix of various therapeutic principles are included in treatments with varying or no evidence of their combined efficacy [33]. Blended eMH services in which therapeutic components delivered through digital technologies are integrated with face-to-face sessions, have the potential to include best of both worlds by providing structure and personalised access, with increased adherence and therapeutic alliance [34].

Thirdly, improved interoperability of eMental health platforms with other IT systems such as electronic patient dossiers, can facilitate utilising new technologies such as artificial intelligence and big data to their full potential. By structuring the data in such a way that it can be accessed and used effectively, more effective communication of clinical performance, as well as innovative research and cooperation can be facilitated across clinical departments and scientific disciplines [35]. At the same time, incompatibility of IT systems also can pose severe practical strain on mental health service providers. Such issues relate to obvious problems with data entry in both a treatment platform and a separate electronic patient record system, multiple logins and passwords, or separate communication systems requiring additional apps and security verification checks. This is not only burdensome to patients and service providers requiring them to find 'work arounds', there is a risk that relevant clinical information is lost possibly leading to reduced quality of care and disappointing experiences with eMH services.

Organisational implementation climate

As part of the organisational context, a relevant determinant of successfully implementing eMH services in routine practice, is the climate in which the implementation takes place. Organisational implementation climate is a container term for staff members' collective understanding of and experience with the events, policies, and practices in their organisation in implementing innovations in routine care [7, 36, 37]. Organizational climates can be conducive to implementing evidence-based interventions and implementers can employ various strategies to motivate and inspire others to implement evidence-based practices [38, 39]. In implementing eMH services, organisational policies and practices can include procedures for supervision focussed on reviewing treatment performance in providing eMH services or for discussing diagnostic criteria of eMH for certain psychopathologies. Exchanging experiences and knowledge, staff members develop a collective sense of what is expected from them in delivering new eMH services,

how this can be achieved, and what possible consequences to their work the new service and its implementation might cause.

In improving organisational implementation climates in mental health organisations, the approach taken by Weiner in his theory on Organisational Readiness for Change can be considered [40]. In this theory, change commitment is a function of change valence referring to staff members' motivation to change and their perceptions of the importance, added value, and effort that is required to successfully implement the new intervention. In turn, self-efficacy, or change-efficacy in Weiner's theory, draws on a social cognitive approach related to implementation capability and includes task demands, available resources, and other situational factors such as the extent to which the internal political environment supports implementation. This corresponds to various definitions of organisational implementation climate. In further conceptualising organisational implementation climate in the context of implementing eMH services however, the relatedness to organisational culture should also be considered as organisational climate and culture are closely related concepts [37]. On the basis of these constructs, a measurement tool can be developed using an exploratory or confirmatory factor analyse approach [41]. This approach will allow developing a questionnaire with items that statistically represent the theorised constructs reliably and accurately. Such empirically validated instruments can inform design and aid testing of implementation strategies that are designed to enhance and use implementation climates for improving implementation outcomes.

Measuring implementation outcomes

Valid measurement instruments are of eminent importance in monitoring implementation progress and assess the effects of implementation strategies. Although there are many instruments developed and used in process evaluations of clinical interventions and implementation studies, most are pragmatic, study and setting specific, and lack a (generic) theoretical basis [42-45]. This is not different in implementing eMH services [46]. There are good reasons for using pragmatic measures, including the ability to address unique qualities of the service that is implemented, of the context the services are implemented in, and the purpose the instrument is used for [47, 48]. To improve the quality of the measures and at the same time ensure they are usable, the criteria and methods by which these instruments are developed are standardised. A recent set of studies developed stakeholder-informed criteria for pragmatic implementation measures addressing utility, compatibility, acceptability, and usability [49, 50]. Adding to these practical qualities, measurement instruments should also have a valid theoretical basis

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that explains the mechanisms by which eMH services become implemented. Implementation theory such as Normalisation Process Theory (NPT) can provide a heuristic tool [51] and aid the development of practical and sensible measurement instruments.

NPT starts from the proposition that normalising (i.e., embedding and integrating) innovation in routine practice is a result of the things people individually and collectively do. According to NPT, normalisation processes are driven by four generative mechanisms: 1) coherence of the innovation with the (goals of) daily routine, 2) cognitive participation as a process of enrolment and engagement of individual participants and groups, 3) collective action by individuals and groups to apply the innovation in daily routines, and 4) reflexive monitoring through which participants in the implementation process evaluate and appraise the use of the innovation in practice. In the case of implementing eMH services, the four mechanisms include for example alignment of the service with good clinical practice and perceptions of psychologists and psychiatrists of what effective psychotherapy entails (sense making), the decision to deliver eMH service (commitment), learning by e.g. following a training on how the service should be delivered or adapting habits and routines (action), and reflect on experiences with the eMH service in practice (prospective appraisal). NPT has shown good face validity and has proven its usefulness in a variety of qualitative implementation studies (n > 108) of various complex interventions in varying health care settings [52]. Using NPT as a starting point, a brief quantitative measurement instrument was developed. This questionnaire, called NoMAD (Normalization MeAsure Development Questionnaire), was designed to aid identifying normalisation specific barriers, to monitor progress of implementation projects in practice, to compare normalisation outcomes between comparable implementation trajectories and over time [12]. Various psychometric evaluations confirmed internal validity and consistency of the measurement model [13]. However, the conceptual interpretation of a NoMAD-score is subject of further learning. Secondary sources of information, such as eMH referral or completion rates by patients in relation to implementation objectives, should be considered in interpreting NoMAD scores and determining whether an implementation strategy has been effective.

Self-guided tailored implementation strategies

One-size-fits-all interventions to improve the implementation of eMental health services do most likely not exist. Three relatively simple steps can structure the development of implementation strategies that are tailored to the typical complex and dynamic nature of implementation processes:

1. Identify and select the barrier to work on that matter most in a given context at a given moment in time in the implementation of eMH service.

2. Develop an implementation strategy (or set of strategies) that addresses the selected barriers and develop accompanying concrete work plans that are feasible and fit local requirements and contextual settings.

3. Apply the strategy and monitor its effectiveness using valid outcome measures such as the NoMAD and eMH service uptake numbers.

Each step can be informed by findings from previous implementation studies that are reported in the scientific literature, such as the barriers reported in Chapter 3, the compilation of strategies by the Cochrane effective Practice and Organization of Care group (EPOC, [53]) or by the Expert Recommendations for Implementing Change (ERIC) project [54], and the repository of measurement instruments developed by members of the Society for Implementation Research Collaboration (SIRC, [43, 44]). In addition, stakeholder involvement in each step is crucial to ensure the resulting implementation strategy is aligned with local and contextual requirements, priorities, and resources, as well as to create support for the implementation by those affected by it. Various models for involving stakeholders exist, ranging from minimal consultation to co-creation [55]. Stakeholder involvement in implementation projects is a complex endeavour as often a large number and wide variety of types of stakeholders with complex relationships are involved or affected by the implementation [56]. Stakeholder involvement includes various discernible steps, including setting objectives, identification of stakeholders, and select and design methods for engagement with stakeholders to generate meaningful involvement [57].

These ideas are not new and refer to what has been defined as tailoring or tailored implementation [58-60]. What is new, besides applying it to implementing eMH services, is to drive the tailoring by non-professional implementation experts. Non-implementation experts (also regarded as implementation support practitioners, or implementers), is a relatively new concept [61-63]. Respecting the apparent complexity of the role and mechanisms by which implementers support implementation practice, and considering that implementation science training programs are emerging, implementers currently gain their experience and expertise through engaging in practical implementation work. However, they might lack overview of empirically established implementation knowledge on barriers, strategies, and theories that might guide the implementation and interpretation of

results. Also, implementation practitioners likely have an intuitive and pragmatic orientation towards their implementation work.

In the ImpleMentAll project we explored whether self-guided tailored implementation is effective in improving implementation outcomes. The Integrated Theory-based Framework for Intervention Tailoring Strategies toolkit (ItFits-toolkit) was developed. This toolkit provides an online stepped process for developing, applying and monitoring tailored implementation strategies that is infused with evidence-informed materials and tools for stakeholder involvement. The materials include a repository of barriers to implementing eMH services and implementation strategies. The toolkit does not require prior experience or knowledge of implementing eMH services in routine care and it supports local implementers in developing evidence-informed implementation strategies that are tailored to local needs.

A self-guided model was chosen for three reasons. First, local implementers might have a better view on the local needs and constraints in service delivery than external implementation experts as they are part of that local routine practice, and thus be in a better position to assess the impacts of new eMH services on routine practice and their work. Secondly, local implementers might have better access to relevant stakeholders that should be involved in designing, applying, and monitoring the tailored implementation strategy. Thirdly, a non-expert driven model might overcome issues of scalability due to the limited availability of experts. As reported in Chapter 6, the self-guided implementation toolkit had a small significant effect on normalisation levels in service delivery staff involved in eMH delivery and performs better than usual implementation practices. There was no effect on service uptake by patients. Implementers did not spend more time when using the ItFits-toolkit than under normal conditions, and they generally regarded the toolkit as usable and were satisfied with it. Although the ImpleMentAll project was the first study to investigate the effectiveness of self-guided tailored implementation, the evidence-base of expert-driven tailoring follows a similar pattern. A Cochrane review concluded that on face value, tailored implementation "can be effective, but the effect is variable and tends to be small to moderate" [58].

Scratching the surface: organisational context, individual agency, and evidence-informed implementation

When zooming out, several higher-level observations can be made from the work presented in this dissertation. First the eMH service and choosing an organisational delivery model. As introduced in Chapter 1, eMH services are complex interventions that consist of multiple therapeutic, technological, and organisational components. Organisational components include patient referral and enrolment procedures, follow-up, safety, and data protection protocols, etc. A service often grows into a centralised organisational service delivery model due to e.g., an increased science policy emphasis on knowledge valorisation. eMH services often originate from proof-of-concept research projects testing the feasibility and efficacy of the key components. Researchers are encouraged to move their invention into practice once the evidence-base grows and opportunities for application in routine practice arise. Often, a dedicated specialty organisation is setup to maintain and deliver eMH service in routine care settings.

A centralised organisational service delivery model can be advantageous over a dispersed delivery model for various reasons. For example. having a dedicated team that only provides eMH services, is likely to be more cost-efficient, as they are likely to be more motivated and more quickly become experienced and skilled in delivering eMH services. Furthermore, knowledge and experiences with eMH service delivery and applicability of the services for specific patient cases are likely to be more easily shared, enhancing group and organisational learning in optimising service delivery. It also provides single point of entry possibly adding to findability of the services by patients and referrers. However, the quality of care provided by a centralised service delivery model might be hampered by miscommunication between referrers and external service providers, notably for more complex cases with comorbidity requiring effective coordination of all services involved. In this situation, clarity on roles, responsibilities, and procedures are of eminent importance as is a well-functioning and proper use of an electronic patient data system that is accessible for all involved service providers (and the patient). Alternatively, a dispersed model in which individual mental health providers have access to the eMH service and are able to deliver it to their patients when appropriate, aligns with a more complete integration of eMH services in routine mental health care provision. However, this likely requires a change in individual providers' viewpoints towards eMH in relation to the (taught and/or habitual) perception of what constitutes good care in general and for a particular patient at a certain moment in time. Moreover, deciding on the organisational

service delivery model includes strategic considerations of many contextual and local factors, including the patient target group, compatibility with and added value to existing mental health services, and reimbursement programs. The model must align to concrete achievable objectives with a feasible business case and make sense in the given context and time frame.

Secondly and as argued in this dissertation, the organisational context is relevant to consider in implementing eMH services. However, it is a far from being a straightforward concept. Using the Consolidated Framework for Implementation Research (CFIR, [64]), the organisational context can be characterised by the structural properties of the organisation such as age, size, and management structures, the qualities of social networks and communication within the organisation, the organisational culture and the implementation climate within an organisation. These characteristics are inward looking and closely related to factors that are external to the organisation such as economic, political, legal, and social context within which an organisation resides. Changes in the outer context can affect implementation processes and outcomes and are often mediated by changes within the organisation [64, 65]. Furthermore, the boundaries between the outer and inner context of an organisation are often fluent and dynamic, and composition of organisations is often diverse, as has been the case with the various service delivery organisations that participated in the research included in this dissertation. Organisations ranged from newly formed online mental health clinics that were established separate from traditional mental health hospitals to a network of affiliated community mental health centres or contracted general practitioners, to integrated centralised service delivery lines within a large mental health institution. The organisational setting in implementing eMH services in routine care is often composed of tightly and loosely coupled entities with both tangible and intangible manifestations of structural characteristics, networks, communication, culture and climate that together, constitute a complex and dynamic whole in which health and health care are created by individuals, i.e. mental health service providers and patients.

Thirdly, organisational change required for implementing eMH services starts with individuals such as those involved with the provision of mental health services (e.g., psychologists, psychiatrists) and individuals involved in implementation processes (e.g., managers, implementers). The complex interplay between the organisational context and individuals in implementing evidence-based interventions in practice is only partly understood. Individuals have agency through which they can make choices and enactment of those choices that can

have an effect on the implementation. This corresponds to the first general assumption of the Normalisation Process Theory [51]. People make choices and work individually and collectively to implement a new service in practice. This 'work' concerns a combination of "practices, behaviours, beliefs, and operations" [66]. In implementing eMH services, this for example, can concern existing techniques therapists use to establish a therapeutic relationship with a patient and the extent to which this is possible using eMH services. Consequently, service providers experiment with new eMH services to make sense of the extent to which it aligns with their understanding of what a good mental health care entails either or not in general or for a particular patient. This aligns with one of the four generative mechanisms of NPT, coherence, through which individuals' contribution to implementation processes can be explained. Or as it has been described by Greenhalgh et al. [67]: "People are not passive recipients of innovations. Rather (and to a greater or lesser extent in different persons), they seek innovations, experiment with them, evaluate them, find (or fail to find) meaning in them, develop feelings (positive or negative) about them, challenge them, worry about them, complain about them, work around them, gain experience with them, modify them to fit particular tasks, and try to improve or redesign them—often through dialogue with other users.".

A final observation to make is the assumed linearity in improving mental health service provision by applying a mechanistic evidence-based medicine paradigm. The work presented in this dissertation started from the premises that implementation follows *after* systematic intervention development and scientific study of the safety, efficacy, and (cost-)effectiveness thereof with intermitted or incremental cycles of improvement through feasibility studies, piloting and randomised controlled trials. However, innovation in mental health care in practice does not necessarily follow a linear path. Often, novel clinical interventions emerge from practice using experiences individual therapists and patients have in treatment practice [33]. Using these experiences, new eMH services are often based on existing treatments or techniques with assumed improved therapeutic working mechanisms, that are combined with new digital technologies and delivery formats of which the efficacy is largely unknown. There are compelling reasons to be cautious with implementing and delivering untested services [33]. Similarly, this practice driven innovation possibly also sheds a different light on research into the implementation of eMH. Although often a stricter definition of implementation science is taken (scientific study of the methods of improving systematic uptake of evidence-based services in practice [68]), the focus of implementation research becomes descriptively of what was done in terms of embedding and integrating the

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service in practice as opposed to experimental; i.e. the implementation 'emerges'. Foci of implementation research is subsequently shifted towards scaling up (increase reach, spread) or scaling out (use in different settings and/or conditions) once evidence of the clinical efficacy of the particular eMH service is provided. Although these topics are relevant from an implementation research perspective, they largely skip an important step and contribute less strongly evidence-informed implementation practice, i.e. apply those implementation strategies which are empirically known to improve service, organisation, setting, and time specific implementation processes and outcomes. Though indirect, this touches upon an ethical argument: the impact of any clinical service not only is dependent on its therapeutic quality, but also on the quality of its delivery, and inherently, on the quality of its implementation. This is what this dissertation aimed to contribute to: evidence-informed implementation of evidence-based eMH services.

Practical implications

The research in this dissertation provides a number of practical implications and opportunities for further improving the implementation of eMH services in practice. All major ingredients relevant to implementing eMH services in practice are discussed, ranging from decision making, identifying barriers, to measuring implementation outcomes and developing implementation strategies that are matched to the local situation.

In deciding, whether on board room level or from a health system perspective, to implement eMH services in routine care, structured frameworks are available and should be used to aid in comparable digital health technology impact assessment. Within the scope of those frameworks, practical and usable (sets of) indicators need to be developed that (a) make sense in the setting they are to be applied in, (b) should be tailored to the technical maturity of the eMH service, and (c) should go beyond addressing clinical- and cost-effectiveness by including financial, organisational, and socio-economic aspects. These indicators should be informative to the assessment of eMH services and by that, inform decision making to either or not engage in implementing the services. A process driven by stakeholders, including decision makers in mental health hospitals, eMH service developers, mental health professionals, regulators, financers, and patients should be given the main stage in developing such indicators to make sure stakeholders are committed and assessments are useful, efficient, comparable, and agreeable.

On an organisational level, service providers' individual and collective understanding of and experience with the events, policies, and practices in their organisation can influence the implementation of eMH services in routine care. This organisational implementation climate forms the context in which service providers individually and collectively create mental health services. Implementers and leaders can and should use tools to shape and improve their organisational climate in which the implementation takes place. According to experienced implementers, feedback mechanisms, monitoring implementation progress, and impact assessment, can be useful tools to improve the organisational climate in implementing eMH services.

With the ItFits-toolkit, an effective and usable tool has become available to implementers in mental health service delivery organisations. This toolkit can be used by implementers as a self-guided method for developing evidence-informed and workable implementation strategies that are tailored to their needs and make sense in a specific setting and time. It offers a practical, flexible, and systematic way to *moving from decision making to identifying barriers to developing evidence-informed strategies* for implementing eMH services. The toolkit makes sense and is not unduly burdensome for implementers dealing daily with implementing eMH services in routine care. Clinical leadership can consider in deciding to implement a new eMH service in their clinical practice, that the subsequent implementation can be supported with practical and evidence-informed implementation tools. The ItFits-toolkit is open-access and freely accessible at www.itfits-toolkit.com.

Methodological considerations

Although the problem and study of implementation is not new, implementation research as a focal area in mental health research is relatively new [69]. Implementation research is inherently inter-disciplinary bringing together different research traditions [70]. Furthermore, eMH research focussing on implementation issues, including the research discussed in this dissertation, are often of a practical and applied nature which has profound methodological implications.

Often studies on implementing eMH services are descriptive and have an observational focus. Implementation issues, such as implementation barriers are often described and studied in process evaluations that are conducted alongside effectiveness trials. This adheres to general guidelines of intervention research

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[71], and although observational studies are typically meant to comprehend certain phenomena and behavioural patterns, the methods applied in this type of research are limited in drawing conclusions about the effectiveness of methods to improve implementation processes and outcomes. Hence, there is limited knowledge of the effectiveness of implementation strategies in addressing certain barriers. Moreover, the literature on barriers and facilitators is relatively saturated and in moving from barriers to strategies to improve implementation outcomes, a shift in methodological focus in implementation research in the field of eMH is required. Experimental research is required to test hypotheses on effective methods to improve implementation outcomes. These hypotheses should be based on existing taxonomies, models and frameworks [72] and subsequent outcome measures should make sense, and should be valid and reliable [73].

The work presented in this dissertation and specifically the psychometric study of the NoMAD reported in Chapter 5 and the effectiveness trial of tailored implementation in Chapter 6 have attempted to contribute to this transition. Notably the implementation effectiveness study has been one of the few large-scale international collaborative research projects in which the primary focus was to utilise implementation science approaches to contribute to implementation of eMH services in various mental health settings. Besides theory-based concept of tailored implementation and sociological underpinning of implementation processes (Normalisation Process Theory), also a research design (stepped-wedge RCT) that balanced scientific with practical requirements, and validated outcome measures (NoMAD, Organisational Readiness for Implementing Change (ORIC, [74]) were applied. It concerned multi-disciplinary research bringing together state of the art concepts, methods, and researchers from clinical psychology and implementation science. However, the applied nature of the study resulted in high heterogeneity in settings and conditions under which the study was conducted. Implementation sites varied considerably in the way mental health care was delivered, including clinical and diagnostic guidelines, existing treatment options as well as, service costs, funding models, and availability of medical workforce and their experience with the eMH service. Sites also differed in the clinical objective and target population for which the sites decided to implement the eMH service, ranging from prevention focussed services to treatment of mild to moderate clinical manifestations of depression, anxiety, and somatic symptom disorder in patients. On top of these differences, the involved mental health service organisations were exposed to a variety of occurrences that might have influenced priorities and local implementation work, ranging from staff turnover, to changing legislation and reimbursement models. Sites also experienced natural disasters including bush

fires, earthquakes and a pandemic (COVID-19) disrupting not only organisational and infrastructural aspects of eMH service delivery, but also (likely) led to increased group-level morbidity of depressive disorder and anxiety influencing the demand of accessible mental health services. That is, despite the research context, the implementation study took place 'in the real world'.

This touches on a complicating factor in experimenting on the implementation of eMH services: controlling and managing factors that might confound the process or outcome of and beyond the implementation strategy. These factors are contextual and often external to the implementation strategy that is subject of the study, such procedural complexity or availability of financial resources and skilled providers [75, 76]. That is, the research infrastructure required to empirically establish the effectiveness of implementation strategies, is potentially conflicting as the effectiveness of those strategies is likely to be determined by the context and those factors that are controlled for in experimental research designs. This paradoxical tension between research object and methodology is even more profound in research in the area of tailored implementation, as the need for tailoring hinges on the variance in hindering factors across organisations and settings and time. Therefore, the ability to generalise the effectiveness of implementation strategies or methods in general and the findings reported in this dissertation on tailored implementation to other settings or services is limited.

Recommendations for future research

There are three areas in which future research can help to better understand eMH implementation: (1) organisational and system level barriers and their interrelatedness, (2) improving the measurement of implementation outcomes, and (3) methods for tailored implementation.

To the extent that the review on barriers reported in Chapter 3 was comprehensive, it also exposed what is underreported. Notably factors in the organisational context and at the level of the health care system were found to be reported sparsely. Given that generalised knowledge on patient-level barriers is relatively saturated, future research on e.g., patient acceptance is mostly relevant to the extend it informs the conceptual or technical development of the specific eMH service itself and less so to inform the implementation processes in general. Future research should focus on identifying and understanding the empirical impact that organisational or system level barriers have on implementation of eMH services, and to unravel

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their interrelatedness. Empirical evidence of how these contextual factors impact implementation strategies can inform future mental health policies and organisational interventions facilitating more effective implementation of novel evidence-based eMH services. The overview of theories, models, and frameworks by Nilsen [72] and the related work on determinant frameworks in relation to context [76] are valuable resources and can provide a good starting point in this respect.

In respect to measuring implementation outcomes, it is undeniably important to have instruments that are conceptually sound, specific and reliable, and are practically usable. The NoMAD instrument ticks a number of these boxes. It underwent a detailed and thorough development process [12] and its conceptual and internal validity, consistency, and interpretability have been studied and confirmed in various settings [13, 77, 78], including in mental health (Chapter 3). However, some questions remain unanswered. Notably psychometric evidence of its criterion validity, construct validity, reproducibility, responsiveness, floor and ceiling effects, as well as its predictive value, can add to better understand the qualities of the NoMAD as a measure for implementation success [79]. Furthermore, and related to the practical relevance and utility of the questionnaire, the conceptual interpretation of a certain NoMAD score requires further explanation. That is, what does a score of 3.5 on the total Normalisation Process Scale mean in practice, and, over time, what might a change of .5 points be indicative of? When do we consider new eMH services a normal part of practice and an implementation project successful? And is this different for different eMH services and in different organisations and settings? Both psychometry and interpretability of the NoMAD can partly be answered by establishing norm data, validation with other data sources (e.g. eMH service uptake) and theory-based implementation measures (e.g. Organisational Readiness for Implementing Change (ORIC) [74]), and by performing advanced psychometric assessments (Confirmatory Factor Analysis, Path Analysis, etc.), preferably with systematic conceptual reflection with input from users of the NoMAD sharing their views and experiences in real implementation practises.

Lastly, tailored implementation. Although research on the concept and effectiveness of tailored implementation is growing [58, 80, 81], the work on tailored implementation presented in Chapter 6 is unique in that it applied a non-expert driven model of tailored implementation. The effect is small, but significant and the interpretation of the findings in relation to the qualitative understanding of the process of tailoring is subject of further scientific study. Notably, the dynamic

nature of implementation processes and taking a longitudinal perspective to normalisation processes and the fact that normalisation levels in each participating implementation site declined over time (slightly, but significantly), requires further discussion in light of instrument development such as NoMAD's longitudinal sensitivity to change as stated above, and theory development on tailoring specifically and implementation theory in more generic terms (e.g., NPT).

One explanation could be that at the start of data collection, the eMH service deliverers exerted a certain amount of enthusiasm towards the intervention. This enthusiasm naturally declined over time when the eMH services lost some of its novelty in their perception or that the initial enthusiasm diminished over time as the service delivers experienced initially unforeseen challenges. As stated in the previous paragraph, it is important to acknowledge methodological complexity and (paradoxical) limitations and of this study. For example, Implementation-as-Usual (IAU) activities cannot be undone once embarked on. Some implementation sites replaced their usual implementation activities with those developed by the toolkit. Others did not. It is likely that our findings originate from ItFits-toolkit *plus* usual implementation activities. Thus, it could be that the IAU activities were ineffective, and that these first have to be overcome to induce a positive effect in the NoMAD data. Similarly, an implementation activity embarked on during the implementation-as-usual phase, can have exerted its effect during the experimental condition. Likewise, effects of toolkit use might lie beyond the data collection period. Therefore, future research should improve our conceptual understanding of the longitudinal and dynamic nature of implementation processes of eMH services by approaching it as a set of non-linear feedback-loops and adaptive mechanisms [75], and determine whether the measurement instruments accurately can capture this complexity and the required time frames for their period of assessment.

Furthermore, the toolkit has been tested as it were a black box, i.e., a complex whole of mechanisms and factors that aim to mediate and moderate the effectiveness of self-guided tailored implementation. The underlying logic model was built from scratch and based on literature, experience in research and clinical implementation practice, and common sense. Future research should aim to unravel the contribution of specific components of the logic model of the toolkit to optimize the effectiveness of the ItFits-toolkit. Examples of existing components include the specificity of evidence-informed materials, mechanisms for stakeholder involvement, integrated impact assessment, and measurement instruments (e.g., NoMAD). Also extending the self-guided model with an implementation community-driven approach could be considered. Whereas the

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current model focused on the non-expert local implementation team, enabling the implementers to interact and exchange experiences with other implementers that are outside of their specific implementation project, might further facilitate learning processes while maintaining sensitivity to local needs and complexity. This could for example be operationalized by adding a moderated discussion forum, and area within the toolkit in which successful and unsuccessful implementation projects are showcased. For testing the effectiveness of these various components, a three-phase Multiphase Optimization Strategy (MOST, [82]) with a factorial study design could be a reasonable approach. MOST enables empirically identifying those components that provide the best expected outcome obtainable within key constraints imposed by the need for efficiency, economy, and/or scalability.

Concluding remarks

E-Mental health services such as iCBT are proven to be effective in treating depressive disorder and anxiety. eMH services come in different formats with varying degrees of guidance and technology integration, and with different organisational delivery models. Despite the strong evidence-base, widespread use of eMH services is lacking behind expectations. The mere availability of evidence-based eMH services is not enough in transforming mental health service delivery to a more accessible, cost-effective, sustainable clinical practice. There is a need for effective strategies to promote their use in routine practice. Implementation, seen as a process in which people intend to bring into operation new or modified practices, takes place in a context and faces varying barriers. Taking an organisational perspective, this dissertation aimed to contribute to moving from identifying implementation barriers to testing methods for developing implementation strategies that are tailored to the local context in which the eMH service is to be implemented.

Prior to any implementation, a well-founded decision should be made on *if, what, and why* to implement. Various Health Technology Assessment frameworks reported in the scientific literature, are specifically designed to assess the unique features and impacts of eMH services. Clinical leadership can use these assessments to *inform their decision making*, and by doing so, increase the likelihood of successful implementation. Once the decision to implement has been made, *barriers to implementation* should be identified so that effective implementation strategies can be applied. The acceptance of eMH services by patients and professionals, (2) the appropriateness of eMH services in addressing patients' needs, and (3) the

availability, reliability, and interoperability with other technologies are important factors to consider when implementing eMH services in routine care. Another implementation barrier highlighted in this dissertation is the *organisational implementation climate.* From the perspectives of implementers and mental health service deliverers, the organisational implementation climate is not only an inherent characteristic of the context in which implementation takes place, it can also be intentionally shaped to improve implementation of eMH services. An important step in moving from barriers to strategies is the availability of *valid and reliable measurement instruments*. The theory-based NoMAD questionnaire proves to be valid and useful to assess processes and measure outcomes of implementing eMH services in mental health settings. Finally, a self-guided tailoring method specifically designed to facilitate implementers in developing and applying *tailored implementation strategies,* the ItFits-toolkit, can improve the implementation of eMH services. The ItFits-toolkit includes a flexible work process with four modules that implementers can work through. Tailoring involves developing context-specific implementation strategies that address local objectives and barriers. In each of these modules, evidence-informed materials, such as literature-based implementation barriers and implementation strategies, are included as well as methods for engaging with stakeholders.

Learning from the work presented in this dissertation, there are new lines of enquiry to be pursued. First, the dynamic and longitudinal nature of implementation processes should be explored in more depth, both conceptually as well as in terms of measurements. Secondly, the inner workings of self-guided tailored implementation should be better understood to obtain a more effective combination of components that drive tailored implementation and improves implementation outcomes.

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Chapter 8

Summaries

Summary

Background
One in four people will suffer from a common mental health disorder in their life. Common mental health disorders such as depression and anxiety have severe negative impact on mental wellbeing, quality of life and social and work-related functioning. E-Mental health (eMH) services such as Internet-based Cognitive Behaviour Therapy (iCBT), are proven to be effective in treating common mental health disorders. Despite the rich evidence-base, eMH services do not enter routine care as expected and their uptake in practice remains low, slow, and costly. The difference between what is known about effective treatments and what is delivered in routine care, is one of the most critical issues in achieving effective, sustainable, and equitable mental health care. Building on approaches in implementation science, this dissertation aimed to contribute to understanding and ultimately reducing the research-to-practice gap in clinical mental health care.

This thesis focussed on five research questions related to: decision-making in implementing eMH services (Chapter 2), a taxonomy of barriers (Chapter 3) and a characterisation of organisational implementation climate as a specific barrier to implementing eMH services in routine care (Chapter 4), the validity of NoMAD as an instrument to measure and monitor implementation outcomes and processes (Chapter 5), and the effectiveness of a toolkit for developing and applying tailored implementation strategies for implementing eMH services (Chapter 6). Combined, this research contributes to moving from barriers to implementing eMH services to overcoming those barriers by developing and applying effective implementation strategies. An organisational perspective was taken because the organisation forms the 'biotope' in which service providers together with patients, create health.

Various methods were applied, including systematic reviews of existing literature, qualitative research using a concept mapping approach, a psychometric Confirmatory Factor Analysis, and an implementation effectiveness trial employing a Stepped Wedge cluster randomised study design with Linear Mixed Modelling with repeated measures. A substantial part of the research was carried out in an international context.

Main findings
Implementation is preceded by a decision-making process. The review in Chapter 2 found that various Health Technology Assessment (HTA) frameworks are adapted and used to assess various aspects of eMH services and by that, support systematic

and evidence-informed decision making. One example of such framework is the Model for ASsessment of Telemedicine applications (MAST). Besides the health problem, and technical and therapeutic, the clinical effectiveness, patient perspectives, as well as economic, organisational, and socio-cultural, ethical, and legal aspects of the eMH service are included in the assessment model. However, and in general, outcomes and instruments are not specified by the framework potentially limiting the applicability and comparability of assessments.

Once the decision has been made, a logical next step is to identify the barriers that hinder implementation of the eMH service in routine care. The systematic review of the scientific literature presented in Chapter 3 lists 37 barriers. Three barriers were reported most frequently: (1) acceptance of patients and professionals, (2) appropriateness of the eMH service and specifically in relation to the therapeutic interaction, and (3) technological aspects of eMH services, including interoperability with other digital technologies. Furthermore, the review indicated that mostly barriers on patient and professional level were reported whereas the scientific knowledge of organisational and system level determinants of implementation practice seems less rich.

Focussing on the organisational context, the explorative study with implementers and mental health service deliverers in Chapter 4, showed that organisational implementation is a relevant factor in implementing eMH services in routine care. Important elements include roles and skills of implementers, implementation targets, and the availability of a dedicated implementation team. Moreover, the implementation climate within a mental health care organisation not only is a (set of) static determinants, it can also be shaped in such way that the implementation of eMH services can be improved. Examples of practical strategies related to the organisational implementation climate implementers can use include providing systematic supervision and feedback to service providers, continuous monitoring progress in achieving implementation targets, and providing guidance in assessing the impact of the eMH service that is implemented.

Once one or a set of barriers are identified to be hindering the implementation, targeted strategies can be employed to overcome the issue and enhance the delivery of eMH services as a normal part of routine care. To determine whether an implementation strategy is effective, reliable and valid measurement instruments are required. The Confirmatory Factor Analysis (CFA) reported in Chapter 5, confirmed the validity of the Normalization MeAsure Development Questionnaire (NoMAD) in samples of Dutch mental health service providers. NoMAD is theory-

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based and supports implementers in monitoring progress, and to compare outcomes of implementation strategies.

One-size-fits-all implementation strategies most likely do not exist. Implementation takes place in a context and faces barriers that vary considerably from setting to setting and from time to time. Chapter 6 reports the effectiveness of a self-guided online toolkit (the ItFits-toolkit) that supports implementers in developing, applying and monitoring tailored implementation strategies for eMH services. The toolkit includes evidence-informed materials about barriers and strategies, and tools for stakeholder involvement. Compared to usual implementation activities, the ItFits-toolkit has a small significant positive effect on normalisation levels in service delivery staff involved in eMH delivery.

In Chapter 7, a general reflection on the main findings is provided as well as possible practical implications and recommendations for future research. At least four overarching observations can be made from this dissertation related to the organisational delivery model, the organisational context, organisational change, and the presumed linearity in bridging the gap between research and practice.

Conclusions
The work presented in this dissertation touches upon four major topics relevant to implementing eMH services in practice: technology assessment and decision making, identifying barriers to implementation, measuring implementation outcomes, and developing effective implementation strategies that are matched to the local situation.

It can be concluded that it is possible to move from observational research identifying barriers to developing and applying effective implementation strategies for eMH services that are tailored to the local context. Practical tools are available and more research is warranted to further understand and improve the effectiveness of tailored implementation.

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Samenvatting

Achtergrond

Een op de vier mensen krijgt te maken met een veel voorkomende psychische aandoening. Veel voorkomende psychische aandoeningen zoals depressie en angst, hebben een ernstige negatieve impact op het mentaal welzijn, kwaliteit van leven, en het sociaal en werk-gerelateerd functioneren. Digitale psychotherapie zoals cognitieve gedragstherapie via het internet (iCBT), ook wel eMental health (eMH) genoemd, zijn effectief gebleken bij de behandeling van veel voorkomende geestelijke gezondheidsstoornissen. Ondanks de rijke evidentie, vinden veel eMH diensten niet de weg naar de zorgpraktijk en blijft het gebruik ervan laag, traag en kostbaar. Het verschil tussen wat bekend is over effectieve behandelingen en wat daadwerkelijk in de praktijk aan zorg wordt geleverd, is een van de meest kritische kwesties in het bereiken van effectieve, duurzame en rechtvaardige geestelijke gezondheidszorg. Voortbouwend op inzichten in de implementatiewetenschap, beoogt het onderzoek in deze dissertatie bij te dragen aan een beter begrip en het verkleinen van de kloof tussen onderzoek en praktijk in de geestelijke gezondheidszorg.

Dit proefschrift richtte zich op vijf onderzoeksvragen die betrekking hebben op de besluitvorming bij het implementeren van eMH diensten (Hoofdstuk 2), een taxonomie van barrières (Hoofdstuk 3), karakterisering van organisatorisch implementatieklimaat als een specifieke barrière voor het implementeren van eMH diensten in de reguliere zorg (Hoofdstuk 4), de validiteit van NoMAD als een instrument om implementatie uitkomsten te meten en processen te monitoren (Hoofdstuk 5), en de effectiviteit van een toolkit voor het ontwikkelen en toepassen van op maat gemaakte implementatiestrategieën voor het implementeren van eMH diensten (Hoofdstuk 6). Gecombineerd draagt dit onderzoek bij aan de overgang van belemmeringen voor het implementeren van eMH diensten naar het overwinnen van die belemmeringen door het ontwikkelen en toepassen van effectieve implementatiestrategieën. Er is gekozen voor een organisatorisch perspectief omdat de organisatie de 'biotoop' vormt waarin dienstverleners samen met patiënten gezondheid creëren.

In de beantwoording van de onderzoeksvragen zijn verschillende methoden toegepast, waaronder systematisch literatuuronderzoek, kwalitatief onderzoek met gebruikmaking van concept mapping, een psychometrische Confirmatory Factor Analysis, en een implementatie effectiviteitsonderzoek met gebruikmaking van een Stepped Wedge cluster gerandomiseerd studieopzet met herhaalde metingen in 12

organisaties in 9 verschillende landen. Een aanzienlijk deel van het onderzoek is in internationale context en in samenwerking met verschillende academische en klinische instellingen uitgevoerd.

Belangrijkste bevindingen

Aan implementatie gaat besluitvorming vooraf. Uit het literatuuronderzoek in hoofdstuk 2 bleek dat verschillende raamwerken voor Health Technology Assessment (HTA), veelal in aangepaste vorm, worden gebruikt om verschillende aspecten van eMH te beoordelen. Daarmee wordt op systematische en wetenschappelijk gefundeerde wijze de besluitvorming om eMH te implementeren ondersteund. Een voorbeeld van een dergelijk wijze is het Model for ASsessment of Telemedicine applications (MAST). Naast het gezondheidsprobleem en de technische en therapeutische aspecten worden ook de klinische effectiviteit, de perspectieven van de patiënt, alsmede de economische, organisatorische, en sociaal-culturele, ethische en juridische aspecten van eMH in het beoordelingsmodel opgenomen. Echter, in veel van de gevonden modellen zijn de uitkomstmaten en meetinstrumenten niet gespecificeerd, hetgeen de toepasbaarheid en vergelijkbaarheid van de beoordelingen kan beperken.

Als de beslissing eenmaal is gemaakt, is een logische volgende stap het identificeren van de barrières die de implementatie van eMH diensten in de zorgpraktijk belemmeren. Het literatuuronderzoek in hoofdstuk 3, benoemt 37 barrières waarvan drie barrières het vaakst worden gerapporteerd: (1) acceptatie van patiënten en professionals, (2) geschiktheid van eMH, met name in relatie tot de therapeutische interactie, en (3) technologische aspecten van eMH, inclusief interoperabiliteit met andere digitale technologieën. Uit de review bleek ook dat vooral barrières op patiënten- en beroepsniveau werden gerapporteerd en dat daarmee de wetenschappelijke kennis over de determinanten op organisatie- en systeemniveau van de implementatiepraktijk minder rijk lijkt.

Met betrekking tot de organisatorische implementatiecontext, toonde de verkennende studie met implementatieondersteuners en zorgverleners in de geestelijke gezondheidszorg in hoofdstuk 4 aan dat organisatorische implementatie een relevante factor is bij het implementeren van eMH in de zorgpraktijk. Belangrijke elementen hierin zijn de rollen en vaardigheden van de uitvoerders, de implementatiedoelen, en de beschikbaarheid van een toegewijd implementatieteam. Bovendien is het implementatieklimaat binnen een zorgorganisatie niet alleen een (set van) statische factoren, het kan ook zodanig worden vormgegeven dat de implementatie van eMH kan worden

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verbeterd. Voorbeelden hiervan zijn het bieden van systematische supervisie en feedback aan zorgverleners, het monitoren van de voortgang in het bereiken van implementatiedoelen, en het bieden van begeleiding bij het beoordelen van de impact van eMH.

Zodra specifieke belemmeringen zijn geïdentificeerd kunnen gerichte strategieën worden ontworpen en toegepast om de implementatie van eMH te bevorderen. Om te bepalen of een implementatiestrategie effectief is, zijn betrouwbare en valide meetinstrumenten nodig. De Confirmatory Factor Analysis (CFA) in hoofdstuk 5 bevestigde de validiteit van de Normalization MeAsure Development Questionnaire (NoMAD) in steekproeven van Nederlandse GGZ-zorgverleners. NoMAD heeft een theoretische onderbouwing en kan worden ingezet om implementatieprocessen te monitoren en bij het vergelijken van de effectiviteit van implementatiestrategieën.

'One-size-fits-all' implementatiestrategieën bestaan hoogstwaarschijnlijk niet. Implementatie vindt plaats in een context en stuit op belemmeringen die per setting en per tijdperk aanzienlijk verschillen. Hoofdstuk 6 rapporteert de effectiviteit van een online toolkit (de ItFits-toolkit) die implementatieondersteuners helpt in het ontwikkelen, toepassen en monitoren van op maat gemaakte implementatiestrategieën voor eMH. De ItFits-toolkit bevat op de onderzoek gebaseerde informatie over barrières en strategieën, en methoden voor het betrekken van stakeholders. In vergelijking met de gebruikelijke manier van implementeren heeft de ItFits-toolkit een klein significant positief effect op zorgpersoneel dat is betrokken is bij eMH.

In hoofdstuk 7 wordt een algemene reflectie op de belangrijkste bevindingen gegeven, evenals mogelijke praktische implicaties en aanbevelingen voor toekomstig onderzoek. Tenminste vier overkoepelende observaties kunnen worden gemaakt van dit proefschrift met betrekking tot het organisatorische leveringsmodel, de organisatorische context, organisatorische verandering, en de veronderstelde lineariteit in het overbruggen van de kloof tussen onderzoek en praktijk.

Conclusies

Het in dit proefschrift gepresenteerde werk raakt aan vier onderwerpen die relevant zijn voor het implementeren van eMH in de praktijk: technologiebeoordeling en besluitvorming, het identificeren van belemmeringen van succesvolle implementatie, het monitoren en meten van implementatieprocessen en uitkomsten, en het ontwikkelen van effectieve implementatiestrategieën die zijn afgestemd op de specifieke situaties.

Uit het proefschrift blijkt dat het mogelijk is om van observationele identificatie van barrières die implementatie belemmeren, over te gaan naar het ontwikkelen en toepassen van effectieve context specifieke implementatiestrategieën voor eMH. Praktische kennis en methoden zijn beschikbaar, en meer onderzoek is gerechtvaardigd om de effectiviteit van deze tools verder te begrijpen en te verbeteren.

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Chapter 4: Organisational Implementation Climate in implementing internet-based Cognitive Behaviour Therapy for depression

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Additional files

Chapter 3: Improving Implementation of eMental Health for Mood Disorders in Routine Practice: Systematic Review of Barriers and Facilitating Factors

- Multimedia Appendix 1: Benchmark definitions, definitions of RE-AIM, and the actual search strings that were applied in the search and analysis strategy. PDF File (Adobe PDF File)

- Multimedia Appendix 2: Data file with two sheets. Sheet 1 contains the aims, designs, settings, participants, and clinical and implementation-related interventions of the studies that were included in this review. Sheet 2 lists the determinants and supporting excerpts of texts retrieved from the articles that were included in the thematic analysis. XLSX File (Microsoft Excel File)

Chapter 4: Organisational Implementation Climate in implementing internet-based Cognitive Behaviour Therapy for depression
- Additional file 1: Results brainstorming workshop, ranked clusters and items. DOCX File (Microsoft Word File)

- Additional file 2: Survey items and results. DOCX File (Microsoft Word File)

Chapter 5: Toward an Objective Assessment of Implementation Processes for Innovations in Health Care: Psychometric Evaluation of the Normalization Measure Development (NoMAD) Questionnaire Among Mental Health Care Professionals
- Multimedia Appendix 1: Translated Normalization MeAsure Development-NL Questionnaire. DOCX File (Microsoft Word File)

Chapter 6: Effectiveness of self-guided tailored implementation strategies in integrating and embedding Internet-based Cognitive Behavioural Therapy in routine mental health care. Results of the ImpleMentAll project. **Note: manuscript under review**

- Additional File 1: Detailed information on the primary outcome (NoMAD) and modelling results. DOCX File (Microsoft Word File)

- Additional File 2: Detailed information on the secondary outcome (uptake) and modelling results. DOCX File (Microsoft Word File)

- Additional File 3: Detailed information on the secondary outcome (effort) and modelling results. DOCX File (Microsoft Word File)