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ImpleMentAll

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Deliverable D5.2

*Final implementation
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AUTHORS (name and organization):	<p>Anne Etzelmüller (GET.ON) David Daniel Ebert (GET.ON) Isabelle Wenck (GET.ON) Elena Heber (GET.ON) Margot Fleuren (VU) Leah Buhrmann (VU) Annika Montag (GET.ON) Tracy Finch (UNN) Tim Rapley (UNN) Sebastian Potthoff (UNN) Neil Perkins (UNN) Christiaan Vis (VU) Josien Schurmans (GiG) Claire van Genugten (GiG) The ImpleMentAll Consortium</p>

This document contains the final evaluation of the implementation efforts and knowledge exchange within Work Package 5 on “Implementation management and knowledge transfer”

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D5.2 Final Implementation and Knowledge Exchange Report

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Statement of originality

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EXECUTIVE SUMMARY

Implementation-as-usual (IAU) constitutes the control condition in the main effectiveness trial of the IMA project. This report summarises the monitoring of routine implementation determinants and activities as well as influence of the first wave of the COVID-19 pandemic on IAU. It also includes the project's knowledge exchange activities and overall lessons learned of the implementation sites.

Determinants (barriers and facilitators to IAU) included the limited uptake of the service (in comparison to what was expected or planned), individual characteristics and attitudes of stakeholders involved and intervention-related obstacles (including participant identification and diagnostic procedures). Summarising IAU activities highlights communication and dissemination activities, training, education, as well as adaptation of the services to the local context.

We matched relevant IAU determinants and activities with "Stages of implementation" (Exploration, Preparation, Implementation, Sustainment). As expected in the project setup, all sites mainly reported determinants and activities on Stages 2 and 3. Stage 2 "Preparation" includes nearly half of the activities and determinants mentioned and addresses equally the aspect of readiness planning for the implementation and hiring and training staff. The other half is included in stage 3 "Service Implementation", which addresses activities and determinants during the actual implementation process. Matching IAU determinants and activities revealed a great number of mentioned determinants without also mentioning a related activity and vice versa. This highlights the potential of a structured matching between determinants and strategies as offered by the ItFits-toolkit.

Within the IAU condition, the knowledge exchange activities focussed on topics related to the iCBT interventions themselves and general topics surrounding eMental health.

Main lessons learned at the implementation sites in the IAU condition of the IMA project include "working with stakeholders and referrers", "team organisation", "measures to increase reach", "timeliness of implementation activities", and the importance of "knowledge exchange".

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1. INTRODUCTION

1.1 Purpose of this document

This document summarises all information on the monitoring of the Implementation-as-usual (IAU) condition of the ImpleMentAll project. This concerns the determinants of the implementation of the iCBT solutions relevant to the implementation. Furthermore, the monitoring includes a summary of the activities undertaken by the sites to implement the services in the local contexts. This report solely includes activities undertaken independently of the use of the ItFits-toolkit. Additionally, we summarised the information on knowledge exchange between partners on relevant topics such as the iCBT services and lessons learned within the IAU processes.

The first wave of the COVID-19 pandemic influences the last months of the IAU monitoring. This document therefore includes a section on changes within the implementation sites regarding the implementation of their iCBT services during the COVID-19 pandemic.

1.2 Structure of document

This document contains deliverable D5.2 and provides the summary of the IAU monitoring. The document provides an overview of relevant implementation aspects within the sites.

In the first section, the objective is presented in detail. The rationale behind focussing on determinants of iCBT implementation and activities executed by the sites is given and the aim of the monitoring is presented. Following, the methods used for the monitoring process are described. The main results are clustered around the presented aims and discussed.

Separately, a summary of the influences of the first wave of the COVID-19 pandemic is provided. The document then provides a summary of the knowledge exchange topics, divided into the topics discussed with the knowledge exchange processes and lessons learned reported by the implementation sites. The document closes with an overall discussion.

1.3 Glossary

ANU	Australian National University
ASLTO3	Azienda Sanitaria Locale TO3, Italy
BDI	Black Dog Institute
BSA	Badalona Serveis Assistencials SA
CBT	Cognitive Behavioural Therapy
CM	Consortium Meeting
CMHC	Community Mental Health Center
CMHTir	Community Centre for Health and Wellbeing

COVID-19	Corona Virus Disease 2019
DF	German Depression Foundation
EAAD	European Alliance Against Depression
EPIS	Exploration, Preparation, Implementation, Sustainment framework
EPOC	Effective Practice and Organisation of Care
FFM	Fondation FondaMental
F2f	Face-to-Face
GET.ON	GET.ON Institut
GiG	STICHTING GGZinGeest
GP	General Practitioner
IAU	Implementation-as-usual
IMA	ImpleMentAll
iCBT	Internet-based Cognitive Behavioural Therapy
MDD	Major Depression Disorder
MHCPriz	Community Based Mental Health Center and House for Integration PRIZREN
n.a.	Not available
OTM	Online treatment module defined as one thematic entity of the treatment delivered internet- or mobile-based
RSD	Region of Southern Denmark
SWT	stepped wedge cluster randomised controlled trial
t.b.d.	To be decided
UMCG	University Medical Center Groningen
WP	Work Package

2. IMPLEMENTATION-AS-USUAL REPORT - OBJECTIVE

Implementation-as-usual (IAU) constitutes the control condition in the main effectiveness trial of the IMA project (Bühmann et al., 2020). The effectiveness trial tests whether the ItFits-toolkit is more effective in obtaining favourable implementation outcomes (normalisation and uptake of the services) compared to usual implementation activities in routine care settings. The IAU condition “refers to any existing activities the implementation sites are engaged in to embed and integrate the local iCBT programme within routine care” (Bühmann et al., 2020). This process was started no later than 3 months prior to baseline (T0) with the goal of continuously improving the utilization of the services (Bühmann et al., 2020).

Initially, the IAU condition informed the design process of the ItFits-toolkit as well as the study design. The monitoring process was planned to ensure the stability of the control condition of the trial. In this sense, the IAU monitoring was also used as a risk management instrument. The tasks of WP5 include:

1. the monitoring of IAU activities of the involved implementation sites to assess risks to the project
2. the description of implementation sites and services over the course of the project to inform the design process of the ItFits-toolkit as well as the study design
3. foster knowledge exchange between partners on relevant topics such as the iCBT services

The WP5 tasks are described in **Figure 1**. The tasks were executed by gathering information via a) project documentation, b) monthly implementation questionnaires, and c) telephone conference (monthly group calls in the IAU phase and additional bilateral calls when necessary).

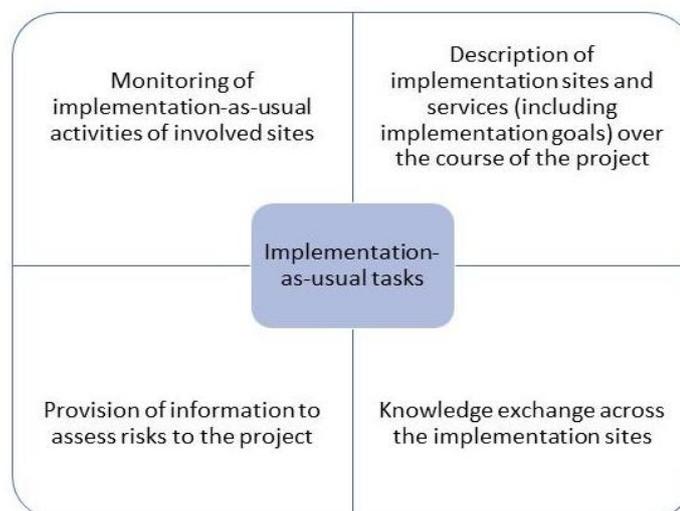


Figure 1. WP5 Implementation management and knowledge transfer tasks

The information gathering and reporting assured the smooth management of sites at the start of the project and at the start of the research trial. Also, it facilitated the assessment of the project risks with regards to them fulfilling all trial requirements at trial start. Furthermore, all information gathered fed directly into:

- a) the project’s work on data collection and management (WP1 and WP3),
- b) the planning and execution of the ItFits-toolkit process evaluation (WP2),
- c) the IAU process evaluation feeding into the guidelines for further deployment of eMental health interventions (task 5.4 “Guidelines for further deployment of iCBT” and the accompanying deliverable D5.3 “Guidelines for further deployment”), as well as
- d) the overall management of the project.

These project interdependencies are described in **Figure 2**.

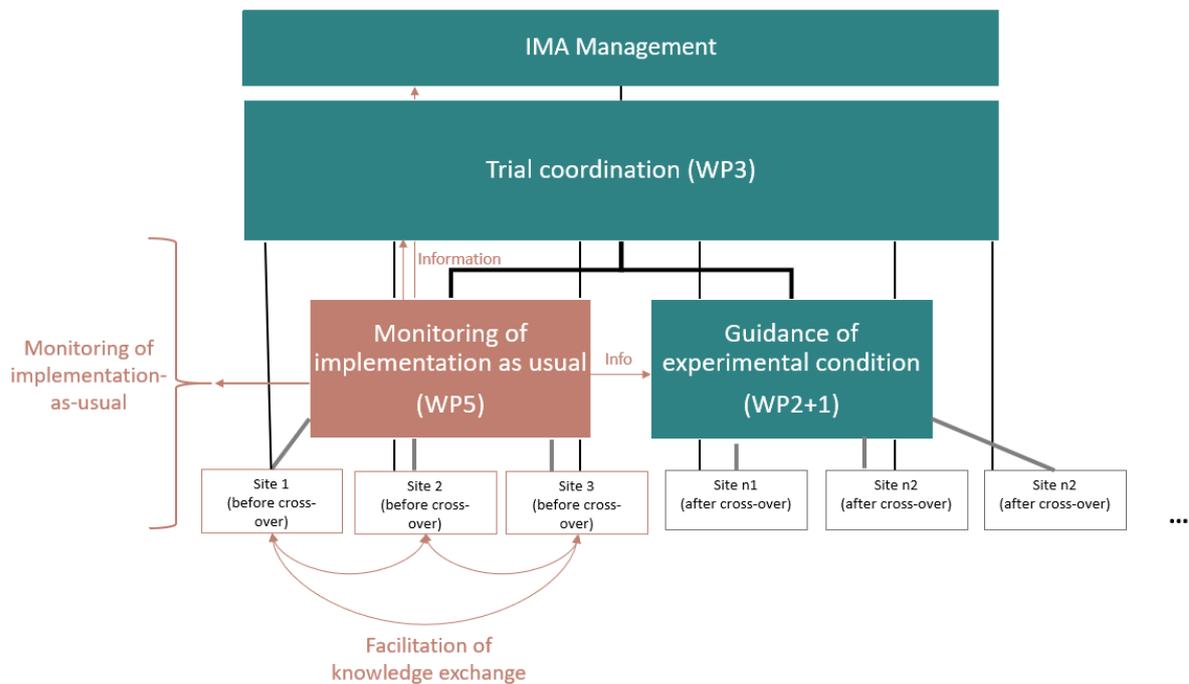


Figure 2. WP5 tasks in the scope of the IMA project: Responsibilities and information flow

In this document, we summarised all information on the IAU condition with regards to determinants of the implementation of the iCBT solutions as well as the activities undertaken at the sites to implement the services in the local contexts independent of the use of the toolkit. We also summarised all information on knowledge exchange between partners on relevant topics such as the iCBT services and lessons learned within the IAU processes. We are extending this section with a summary of changes in sites regarding the implementation of iCBT during the COVID-19 pandemic.

This deliverable is accompanied by the first WP5 D5.1 on “Implementation plans” in its updated version and well as the D5.3 “The Guidelines for further deployment of iCBT”.

2.1 Background and theoretical Framework

Common mental health problems such as depression and anxiety do not only cause significant suffering, impairment, and reduction in quality of life (Kessler et al., 2003; Kessler & Bromet, 2013), but also lead to considerable socioeconomic cost through decreased work productivity and higher utilisation of healthcare services (Donohue & Pincus, 2007). Over the past decades, research has identified several effective psychotherapeutic treatments for depression and anxiety (Cuijpers et al., 2020). Despite the proven effectiveness of psychotherapy in the treatment of depression and anxiety, the provision of evidence-based treatments is challenging, and the implementation of these services is lagging behind (Andersson et al., 2019). Using the internet to provide guided and unguided Internet-based Cognitive Behavioural Therapy (iCBT) may help overcome some of the limitations of traditional treatment services (Andersson, 2009).

Recent research suggests iCBT to be effective for the treatment of a wide variety of mental health conditions (Cuijpers et al., 2020) and studies were also able to show comparable effects to face-to-face treatments in adults (Carlbring et al., 2018; Cuijpers et al., 2019; Olthuis et al., 2016). Recently, a meta-analysis summarised results of iCBT interventions for the treatment of depression and anxiety in routine care indicating that iCBT interventions also show the acceptability and effectiveness of such interventions in routine health care contexts (Etzelmueller et al., 2020).

iCBT interventions depict complex healthcare interventions being implemented into complex healthcare contexts (Craig et al., 2008). Systematically studying implementation contexts, system processes, and determinants of practice can help to understand and subsequently facilitate the implementation process.

Current implementation efforts are often slow and costly (Grol et al., 2013) and there is no “one-size-fits-all” approach to successful iCBT implementation. One promising approach is the structured tailoring of implementation activities to specific contexts. Therefore, the IMA project aims to develop a toolkit to apply tailored implementation strategies in various mental health contexts and iCBT services. This ItFits-toolkit provides implementers with guidance in using tailored implementation strategies. Within the IMA project, a closed cohort stepped wedge cluster randomised controlled trial (SWT) design is applied, in which the implementation sites (clusters) cross over from the control condition (IAU) to the experimental condition (ItFits-toolkit) (Bührmann et al., 2020).

2.1.1 Determinants of practice

The IAU monitoring focused on identification of determinants of routine iCBT implementation practice to describe the IAU landscape within the implementation sites over the course of the project. This will also help to understand why specific implementation activities have been executed within IAU. This work includes the identification of barriers, facilitators, and implementation goals outside of the ItFits-toolkit use.

Recently, the systematic identification of determinants influencing the successful implementation of iCBT services has been examined (Titzler et al., 2018; Vis et al., 2018). Both studies identified the lack of coherent implementation actions and strategies as a possible hindering factor for the implementation of internet-based interventions.

This literature did not inform the information collection directly (e.g. in form of questionnaire items), as the information collection should not influence the implementers' thinking of such determinants in the IAU phase. In contrast, the questionnaires rather asked for influences on the implementation process, obstacles and risks, as well as lessons learned.

Subsequently, the aforementioned studies founded the basis for our IAU questionnaire summary regarding determinants (see section "Procedure").

2.1.2 Implementation activities

Within the monitoring of the IAU condition, we put a specific focus on the identification of implementation activities within multiple implementation sites. IAU refers to "any existing activities the implementation sites are engaged in to embed and integrate the local iCBT programme within routine care"; Bührmann et al., 2020).

Understanding activities promoting successful implementation might not only bridge the gap between innovations and their delivery in routine care practice but also improve the quality of care delivered by optimising the fit between services and the context they are implemented into (Powell et al., 2012).

2.2 Aim

During the IMA project, WP5 "Implementation management and knowledge transfer" was responsible for monitoring the implementation processes at the implementation sites before using the ItFits-toolkit. All existing activities the implementation sites are engaged in to embed and integrate the local iCBT programme within routine care (Bührmann et al., 2020) were called "Implementation-as-usual" (IAU). Furthermore, this Work Package fostered knowledge exchange between partners on relevant topics, e.g. regarding the iCBT services.

3. IMPLEMENTATION-AS-USUAL MONITORING METHODS

All terms used in this deliverable follow the ImpleMentAll working definitions laid out in Annex 1 “Lexicon of implementation terms” of D2.1 “Protocol for identifying and contextualising determinants”.

3.1 The implementation-as-usual questionnaire

To evaluate and monitor relevant determinants (barriers, facilitators, and implementation goals) of the ongoing iCBT implementation as well as activities executed, a questionnaire was developed and distributed over the IAU period (November 2017 until October 2020).

Determinants of iCBT implementation and actions executed at the sites were monitored via a bespoke IAU-questionnaire (see Appendix A).

The development of the IAU questionnaire was a common endeavour of the IMA Work Package leaders to establish an IAU monitoring mechanism. This mechanism assured

- a. risk mitigation throughout the project by identifying changes in IAU and risks to the implementation project, such as discontinuation or severe changes in the contextual setting influencing IAU,
- b. provision of information to other Work Packages for their planning of data acquisition, and
- c. provision of information on routine IAU contexts and activities across Europe.

The IAU questionnaire assessed:

1. The reach and uptake of the iCBT service (before the trial assessment on inclusion numbers was in place)
2. New implementation activities started
3. Alterations and adaptations to the iCBT programme
4. Implementation activities stopped
5. Determinants relevant to the iCBT implementation and actions taken
6. Risks to the project

The questionnaire was distributed via an online surveying tool and completed by the local implementation teams (mainly the implementation leads). It was distributed throughout the IMA project time. Once a site had crossed over and started to use the toolkit, they were asked to only report on ongoing activities outside of the toolkit use. If they, in the beginning, still reported on a toolkit-related activity, they were reminded of the purpose of the IAU questionnaire. Two sites still used the questionnaire as a monitoring tool for both activities related to IAU and the toolkit. This was clearly indicated and toolkit related activities were excluded from the summary.

While the initial plan was to monitor the IAU condition by sending out the questionnaire bi-monthly, it became clear that in some sites the information provision in this time frame was quite saturated. As the information was given retrospectively to cover a period of time (in contrast to stating a ‘snapshot’ of the current situation), it was decided to give the sites the freedom to skip questionnaires if there was nothing new to report. If sites had not filled out the questionnaires twice, they were contacted by the WP5 team to ensure that IAU processes were still running smoothly. Additionally, to reduce the workload the IAU questionnaire might impose on the sites, questionnaires could be skipped in December, during the local summer break, and at cross-over.

In the IAU period between November 2017 and October 2020, 151 IAU questionnaires were collected across the 13 sites.

Table 1 shows the number of questionnaires per site. After all sites had crossed over, the IAU questionnaire was paused due to the burden posed on the implementation sites by the onset of the COVID-19 pandemic. The last IAU questionnaire sent out in September 2020 asked about routine IAU determinants with regards to the last six months.

Questions regarding the influence of the COVID-19 pandemic were included in a separate chapter of this questionnaire. These COVID-19-specific questions included topics on the influence of the pandemic on IAU activities, on the running service, and legal changes in the country.

Table 1. Provision of IAU questionnaire per site

Site	Number of IAU questionnaires
ANU	10
ASLTO3	14
BDI	9
BSA	12
BSA 2	12
CMHTIR	9
DF	14
FFM	7
GET.ON	13
GIG	14
MHCPRIZ	10
RSD	11
UMCG	16

3.2 Process of summarising information

A content summary was conducted, drawing on inductive and deductive approaches and using standardised methodical steps in qualitative research (Mayring, 2010). Codes based on the literature on determinants of eMental Health implementation and relevant to addressing the research question were combined with ones developed from the raw data. Similarly, based on the literature (Michie et al., 2005; Powell et al., 2015; Proctor et al., 2013; Titzler et al., 2018; Vis et al., 2018; Waltz et al., 2015; Effective Practice and Organisation of Care (EPOC), 2015) and enhanced by common implementation methods in iCBT implementation (e.g. a strong focus on online marketing or diagnostic and referral procedures specific to iCBT implementation) relevant concepts were identified and discussed within the WP5 team. From these actions, an initial list of codes on implementation activities was compiled. Afterwards, a working-code list was developed after taking the data of the first months of the project into account.

In the process of identifying emerging (sub-)themes and discussing excerpts within WP5 team discussions, it was decided to cluster the emerging themes by “phases within the implementation process”. Different clusters became clear within the implementation sites; some had more experience with the implementation of their services than others and had been active in their local mental health context for longer. The question of “how to scientifically underpin the clustering of data along implementation phases” was presented to the ImpleMentAll External Advisory Board. The integration of the “Stages of Implementation Completion” framework (Chamberlain et al., 2011; Saldana, 2014; Saldana et al., 2014) was suggested. For a more detailed description, please consider the section on “Stages of implementation” below.

The coding framework, organisation of the categories, and the possible meanings of text frames were discussed during consultative meetings within WP5 throughout the summary process. Following this, all IAU questionnaire material was read, codes were applied to all relevant text passages, and new emerging themes were added to the list of codes. During this coding process, new categories emerged and old ones were changed or deleted to reflect the data. A sentence or paragraph could be coded as containing aspects from one or more categories.

3.2.1 Stages of Implementation

We categorised determinants and activities according to the “Exploration, Preparation, Implementation, Sustainment (EPIS) framework” (Aarons et al., 2011). The model describes that, in an implementation process, four main stages of implementation exist (**Figure 3**). For the summary we divided the information from stage 2 *Preparation* into two subgroups, *Readiness planning* and *Staff hired & trained* (retaining our original coding structure here).

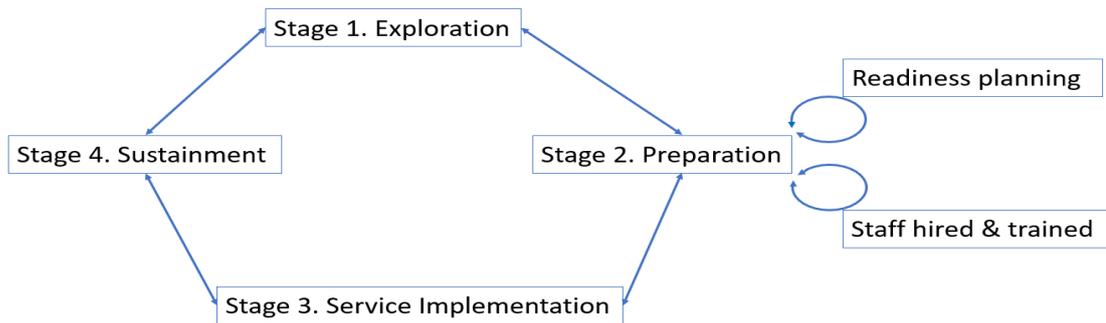


Figure 3. Stages of implementation from the EPIS Model.

A specific set of activities and determinants was assigned to each stage of implementation. The assignment was based on a literature review on implementation stages, a cognitive mapping exercise in the WP5 team, as well as a short session collecting input/information from the consortium during the CM6.

To summarise the IAU questionnaires regarding this structure, a pre-defined set of codes was derived from combining the literature mentioned above and team discussions before considering the data. While summarising the data, a code system was then extended as additional themes were included in the coding process. Appendix B depicts all initial codes and codes that were later included into the code system. This appendix also lays out which codes were being used in the end and which codes were dropped in the coding process.

All qualitative summaries were conducted with the software tool dedoose (Consultants, 2018).

3.3 Summary of IAU implementation

This following section summarises the initial findings of the Implementation-as-usual (IAU) questionnaires from November 2017 until October 2020. The summary includes the activities that sites have executed as well as determinants of practice. No information regarding the activities promoted by the toolkit use have been included in the summary. Sites were engaged in IAU activities, which they did not stop during the toolkit use. Feedback from the implementers indicated that they were able to differentiate between IAU and toolkit activities.

3.3.1 Summary of information on iCBT services and implementation contexts

Thirteen implementation sites provided information on their mental health service contexts and iCBT services. A more detailed description of the iCBT solutions being implemented, the clinical context, as well as implementation goals and plans of the participating implementation sites is provided in deliverable D5.1.

All services follow the principles of Cognitive Behavioural Therapy (CBT) and can thereby be considered evidence-informed, internet-based CBT treatments (iCBT), which ensure high-quality treatment. They have been adapted to the local needs and restraints regarding the form of guidance, number of online treatment modules (OTMs), and duration of the treatment. These clinical contexts differ by their economic parameters, mental health care systems, and legislative frameworks regarding eMental Health (for details see D5.1).

All implementation sites took decisions regarding where in the local clinical context to implement the service (primary or secondary care) based on reasons relevant to the local implementing organisation. Involved parties (persons and organisations) in service delivery and implementation can best describe the clinical contexts. Most sites are involving psychologists in their services, some also psychotherapists and psychiatrists as well as specialised nurses in the service delivery. Referral is heavily based on either GP networks, self-referral, or the support of health insurance companies. Within the implementation process, most trial sites' implementation teams consist of managers and project employees within not only the participating organisations themselves, but also their GP network, local governments, insurance companies, and universities.

Regarding the target groups of the clinical service, all implementation sites targeted adults suffering from either depression or anxiety (including somatic symptom disorders). Additionally, deliverable D5.1 and its update highlight potential risks (e.g. contextual changes influencing the conduct of IAU), which are identified and analysed elsewhere, as this analysis goes beyond the scope of the implementation plans as such.

There is a high heterogeneity in all three described areas, the clinical treatment modality, the clinical context, and the implementation goals and plans. The variety in services implemented will allow the project to assess determinants of implementation practice and activities for multiple iCBT services. Likewise, the diversity of clinical contexts will allow for the observation of determinants of practice and implementation activities under multiple conditions.

At the same time, this diversity complicated that comparability and pooling of information on implementation determinants and activities. Using the EPIS framework as described above and deriving pre-defined set of codes from the literature mentioned above was used to enhance comparability.

4. MAIN RESULTS

The main results are depicted in **Table 2**. The table lists all determinants of iCBT implementation and activities identified within the IAU questionnaires, including their respective descriptions. They are clustered by the stages of implementation.

Main barriers to the implementation of the iCBT interventions were related to the continuous limited uptake of the iCBT service. Across sites, the theme of not reaching as many participants as expected or planned to include into the service, not reaching the right participants or having interested individuals dropping out before even starting the use of the iCBT tool were prominent among all sites and across most time points during the IMA project.

Furthermore, low uptake was related to the limited engagement of referrers regularly needed in the service processes to include users of the iCBT service. Activities were therefore heavily focused on the “active engagement in measures to increase reach”, such as activities on a contextual level (including building a new network and motivating stakeholders to use iCBT), providing information, actions on a political level (efforts in making the intervention part of clinical care standard), and improving organisational workflows by trying to “reduce bureaucracy”.

Another determinant was the individual stakeholder characteristics. While acceptance and trust towards the iCBT intervention as well as experience and interest in innovations can be considered facilitating factors for the implementation, most sites described some form of negative attitudes towards innovations in general or the iCBT intervention in particular. It was repeatedly reported that stakeholders (referrers, mental health workers, therapists, GPs, etc.) did not trust or did not accept the iCBT, were hindered by their lack of experience with the tool, or lacked the motivation to implement innovations in general or the implemented iCBT interventions specifically. While there were no activities mentioned specifically to influence the attitudes of stakeholders towards iCBT interventions directly, mainly the activity “providing information” was mentioned when reporting on how to overcome this obstacle. Providing information included communication, dissemination, and education activities.

Table 2. Determinants of implementation and activities in the four different stages of implementation

Stage 1: Exploration			
Description	Activities	Determinants of practice	Description
Different stakeholders approve of the idea of implementing the service	Seeking agreement to consider implementation	NA	
Implementation site's stakeholders expresses interest in implementing the intervention	Express motivation to implement the iCBT program	NA	
Stage 2.1: Preparation (readiness planning)			
Adapting iCBT interventions to the local contexts and needs	Adapting the intervention (programme)	NA	
Making the treatment process leaner and more efficient, involving patients earlier into the process, collecting feedback from participants	Adapting service components	NA	
Developing and sharing a business plan, planning long-term financing	Developing a business plan	NA	
Stakeholders/implementers are identifying determinants of their current implementation, e.g. by conducting focus groups and talking to experts	Identifying barriers and facilitators (determinants of practice) of implementation	NA	
Specification of service processes. Including recruitment and referral pathways (How to transfer participants to the intervention, how referrers can test the service)	Planning out service processes	NA	
Stakeholders/implementers are working out implementation plans,	Writing an implementation plan	Creating an Implementation plan is time consuming and difficult to finish	

e.g. an overview of all implementation activities, how the service will be implemented, including governance structures and referral/recruitment pathways			
Some routine implementation processes required a local ethical application process. Those have been managed by site stakeholders/implementers	Applying for ethical approval	Problems in achieving ethical approval	The process of applying for ethical approval is time consuming. Waiting for clearance is long and hindering implementation progress
Working towards an alignment with local legal requirements, including consultation with national law and legal department, e.g. regarding the user agreement and the governance structure	Seeking alignment with legal requirements	NA	
All activities of stakeholders regarding supporting staff in developing their competencies, doing their work	Providing necessary staff-related requirements and resources	NA	
Stage 2.2: Preparation (staff hired & trained)			
Description	Activities	Determinants	Description
The act of hiring and engaging new staff or shifting staff within the organisation to the iCBT service	Hiring and engaging staff	Staff restrictions due to staff turnover	Difficulties to hire adequate staff, fluctuation of staff
Measures to increase reach, including actions to widen the geographical reach, raising awareness, and adding new referrers and participant pathways	Actively engaging in measures to increase reach	Difficulties in increasing reach, including finding enough active referrers to refer to the iCBT service	
Training and informing stakeholders and staff, e.g. how to use the tool,	Training stakeholders/staff	NA	

giving information about preventive strategies			
Making sure that roles and responsibilities are clear in the project, determine team and working structures	Determine roles and responsibilities	NA	
Being in close contact with referrers and staff to discuss challenges, getting feedback through surveys and meetings	Getting feedback from referrers/staff	NA	
Stage 3: Service Implementation			
Description	Activities	Determinants	Description
The iCBT service staff is ready to provide the service with confidence	Staff is offering the service with confidence	Low uptake of participants	There are not enough referrals, not enough participants being included into or starting the service
All actions regarding implementation activities on contextual level, including building a new network and motivating stakeholders to use iCBT	Acting on contextual level	NA	
Activities and determinants of practice, which are also happening in other stages			
Distributing information via different channels and media	Providing information		
Communicating information about the service at health-related events to increase awareness about the service. Creating public awareness and enhancing the visibility of your project results, consortium, and the research programme. Encouraging people to use the results, increasing the chances research will make an impact	Communication		

Disseminate information about the service among participants and referrers e.g. with flyers or an article	Dissemination	NA	
Educate referrers and participants about the service and develop educational material, let referrers test/use the service	Education	NA	
Actions to make intervention part of clinical care standard (e.g. "lobbying")	Acting on political level	NA	
Improve work processes between stakeholders	Improving organisational workflow	Increase in administrative work	A lot of bureaucracy, including longer user agreement, difficult to plan meetings among many stakeholders
Regular gathering of change information and evaluation	Monitoring of change progress	NA	
	NA	Time issues	Delay, long waiting periods
	NA	Barriers on inner contextual level	Problems financing the project, problems because iCBT is not part of the organisational structure, the implementation was stopped
	NA	Barriers on outer contextual level	Restricted level of control over implementation process outside the organisation
	NA	Individual stakeholder characteristics	Attitudes of stakeholders towards innovations in general or the implemented iCBT interventions specifically; perceived differences to their usual ways of working; personality traits
	NA	Acceptance/ Trust of professionals	Stakeholders do not trust or do not accept the iCBT

	NA	Lack of (time) resources	Stakeholder have too much work and not enough time to engage with the iCBT service or promote its implementation
	NA	Lack of experience	Stakeholders lack experience with iCBT
	NA	Lack of interest	Stakeholders lack motivation to implement innovations in general or the implemented iCBT interventions specifically
	NA	Intervention-related obstacles	The technical or content side of the iCBT intervention does not work properly; the intervention does not fit the organisational structure
	NA	Difficulties in the identification of participants	Difficulties in identifying participants to be included into the services (reasons might include the different levels of accreditation of staff); Difficulties in reaching eligible patients
Stage 4: Sustainment			
Description	Activities	Determinants	Description
Process of certifying their product has been started (according to national or EU standards). The certification process might be necessary due to national or EU law.	Engaging in the process of getting the iCBT service certified	NA	

Notes. NA = not specifically mentioned in the IAU questionnaire. Activities mainly conducted in Stage 3, but also executed in other stages are reported under Stage 3.

Table 2 shows that Stage 1. “Exploration” and Stage 4. “Sustainment” have nearly no activities or determinants listed. We conclude that most of the sites were already in the process of preparing their service, but it was too early in the project for many of them to deal with sustaining their service. Nearly all activities and determinants can be categorised into stage 2. Preparation and stage 3. Service implementation.

As mentioned above, Stage 2 “Preparation” is divided into two different subgroups: Stage 2.1 “Readiness planning” and Stage 2.2 “Staff hired & trained”. In Stage 2.1 “Readiness planning”, sites are creating the service process and are making sure that the implementation process fulfils e.g. legal and ethical requirements. Hence, this stage includes activities like writing an implementation plan or planning service processes. Stage 2.2 “Staff hired & trained” focusses on the individuals involved in the service and implementation process. This includes activities like hiring and training staff, e.g. referrers to iCBT, and determining roles and responsibilities in the project. Often, Stage 2.2 “Staff hired & trained” activities begin when activities in Stage 2.1 “Readiness planning” have started.

In this project, most determinants and activities can be assigned to Stage 3 “Service implementation” across all sites. These activities and determinants can be divided into two sections. The first section describes the activities and determinants that are unique to Stage 3 “Service implementation”, including the activity “The staff is offering the service with confidence”. The second section includes activities and determinants that are mainly happening in Stage 3 but are indicative of involvement of the site in other stages. For example, “Providing information” is an activity executed mainly in the service implementation phase (e.g. giving referrers monthly updates of (technical) changes in the system/tool). At the same time, “Providing information” constitutes an action also executed at other stages, e.g. Stage 2.2 “Publishing an article in a magazine to include more referrers”.

Table 2 also shows that there are some activities and determinants that are commonly mentioned together, e.g. many sites had problems finding enough active referrers to refer to the iCBT service. Therefore, the activities executed at those sites focussed on action towards “Increase reach to include more referrers”. Other activities had no direct determinant mentioned in relation to them and vice versa.

4.1 Determinants and activities by implementation sites

Table 3 gives the count of codes applied regarding determinants and activities per site. If one site mentioned the exact same activity multiple times, then this activity was only coded once. For example, the repeated mentioning of “Presenting the intervention on one specific event to increase reach” was coded once as “Communication” (Definition: Creating public awareness and enhancing the visibility of your project results, consortium, and the research programme. Encouraging people to use the results, increasing the chances research will make an impact). But if another event was mentioned, then the code “Communication” was given again. Hence, the number assigned to the code usage reflects the number of categories of activities, but not identical activities. Table 3 is meant as a heat map. The redder the colour and the higher the

number, the more this kind of determinant or activity was mentioned by the implementation site. The table description (row 1) depicts the stages in dark green colour and the activities in lighter green colour. The determinants of practice of each stage are marked in red. For Stages 2.1 and 2.2, determinants (in accordance with Table 2) are summarised into “Determinants”. For Stage 3, all determinants are shown separately with their count.

Table 3 shows that the activities that were mentioned the most were “Actively engaging in measures to increase reach” and “Providing information”. The determinant that was mentioned most was individual stakeholder characteristics, which includes e.g. lack of acceptance or trust of stakeholders regarding iCBT interventions. Some activities and determinants are only mentioned by some of the sites, e.g. developing a business plan.

It is important to mention that this overview does not depict a saturated summary of all determinants and activities executed at a specific time point. Rather, it gives an indication of what the sites found “noteworthy” at this moment.

Table 3. Quantitative summary of code appearance.

	Stages of implementation																			Stage 4. Sustainment																	
	Stage 1. Exploration Agreement ¹	Motivation ²	Stage 2.1 Preparation ³	Adaptation of intervention Service adaptation ⁴	Developing Business plan	Barriers and facilitators ⁵	Planning out service processes	Implementation plan ⁶	Ethical approval ⁷	Legal requirements ⁸	Staff related requirements ⁹	Determinants	Stage 2.2 Preparation ¹⁰	Measures to increase reach ¹¹	Training stakeholders/staff	Determine roles ¹²	Getting feedback ¹³	Hiring and engaging staff	Determinants	Stage 3. Implementation ¹⁴	Staff is offering the service ¹⁵	Acting on contextual level	Providing information	Acting on political level	Improving workflow ¹⁶	Monitoring of change progress	Low uptake	Identification of participants ¹⁷	Increase in administrative	Time issues	Barriers on contextual level	Stakeholder characteristics ¹⁸	Intervention related obstacles	Stage 4. Sustainment	Getting iCBT service certified ¹⁹		
Site 1	0	0	0	0	7	1	0	0	0	1	1	0	0	0	6	4	1	4	0	0	0	3	9	0	0	0	1	0	0	1	0	7	2	0	0		
Site 2	0	1	0	0	0	0	0	0	0	0	0	0	0	0	6	1	0	2	0	2	0	1	3	0	1	1	1	0	1	0	0	3	1	0	0		
Site 3	0	0	0	0	0	0	0	1	0	1	1	0	0	1	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	3	0	3	1	0	0		
Site 4	1	1	1	2	0	2	0	0	2	0	1	1	2	0	1	1	3	0	3	0	1	7	0	0	3	3	0	1	0	2	2	0	1	3	8	0	0
Site 5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	2	0	0	1	0	1	2	0	1	0	4	1	1	0	0	5	0	0		
Site 6	1	0	0	0	0	4	0	0	1	0	2	2	0	0	2	0	2	0	0	0	0	3	1	0	0	0	1	0	0	0	1	5	1	0	0		
Site 7	0	0	0	0	0	1	0	0	0	0	1	0	0	1	14	3	0	1	0	2	0	2	17	0	0	0	1	0	0	4	3	1	0	0	3		
Site 8	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	3	1	0	0	0	0		
Site 9	1	0	0	0	0	0	0	0	4	2	0	0	0	2	0	0	6	0	1	0	1	4	23	0	4	3	3	1	0	2	5	3	1	0	0		
Site 10	0	0	0	0	1	1	0	1	2	0	2	0	2	0	12	0	0	0	0	2	0	2	12	1	0	0	1	0	1	1	1	7	3	0	0		
Site 11	0	0	0	0	0	6	1	4	1	0	2	0	2	0	12	0	0	0	0	0	0	2	12	0	0	1	0	0	0	1	7	0	0	0			
Site 12	1	0	0	0	1	2	0	0	0	0	1	1	0	0	3	0	0	0	0	0	0	1	4	0	0	1	0	0	0	0	1	4	0	0	0		
Site 13	0	0	0	0	0	3	1	1	0	0	0	0	1	0	3	0	0	0	1	0	0	0	0	0	0	3	0	0	0	0	1	2	2	0	0	0	

Notes: ¹ Seeking agreement to consider implementation, ² Express motivation to implement the iCBT program, ³ Stage 2.1 Preparation (Readiness planning), ⁴ Adapting service components, ⁵ Identifying barriers and facilitators of implementation, ⁶ Writing an implementation plan, ⁷ Applying for ethical approval, ⁸ Seeking alignment with legal requirements, ⁹ Providing necessary staff related requirements and resources, ¹⁰ Stage 2.2 Preparation (Staff Hired & trained), ¹¹ Actively engaging in measures to increase reach, ¹² Determine roles and responsibilities, ¹³ Getting feedback from referrers/staff, ¹⁴ Stage 3. Service Implementation, ¹⁵ Staff is offering the service with confidence, ¹⁶ Improving organisational workflow, ¹⁷ Difficulties in the identification of participants, ¹⁸ Individual stakeholder characteristics, ¹⁹ Engaging in the process of getting the iCBT service certified

Table 4. Percentage of activities per stage per site.

Stages of implementation	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Site 7	Site 8	Site 9	Site 10	Site 11	Site 12	Site 13	% activities and determinants per stage
Stage 1. Exploration	0	4%	0	10%	0	0	0	0	0	0	0	0	0	1.1%
Stage 2.1 Preparation (Readiness planning)	21%	0	30%	18%	0	41%	6%	17%	10%	12%	26%	26%	33%	16.6%
Stage 2.2: Preparation (staff hired & trained)	31%	46%	15%	28%	20%	15%	37%	17%	29%	41%	21%	16%	22%	26.9%
Stage 3. Service Implementation	48%	50%	54%	44%	80%	44%	66%	66%	61%	47%	53%	58%	45%	54.8%
Stage 4. Sustainment	0	0	0	0	0	0	5%	0	0	0	0	0	0	0.4%
	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

4.2 Average activities per site per stage and stages of implementation across sites and the project lifetime

Table 4 comprises the quantitative results of **Table 3**. It shows all the sites and the percentage of activities they have engaged in for each stage. This is an indicator for how many activities the sites have engaged in on average at each of the stages. It is visible that only the two sites mentioned *Stage 1* activities and that only one site engaged in the *Stage 4*. “*Sustainment*” activities. In the case of this site, this means that they were starting the process of getting their service certified. The other sites show a similar distribution of percentages in *Stage 2*. “*Preparation*” and *Stage 3*. “*Service implementation*”. The last column of **Table 4** displays the mean percentage of activities that all sites have mentioned.

Figure 4 illustrates these mean percentages visually. More than half of all activities (54.8%) were executed at *Stage 3* “*Service implementation*”. In total, 43.5% of all activities were executed on *Stages 2.1* (16.6%) and *2.2* (26.9%). *Stage 1*. “*Exploration*” and *Stage 4*. “*Sustainment*” make up a very small percentage: 1.1% and 0.4%, respectively.

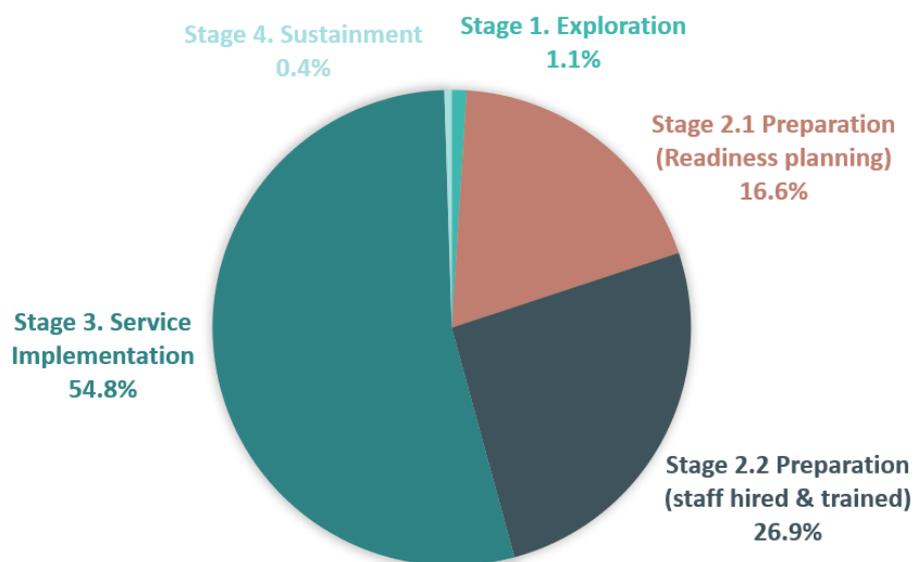


Figure 4. Segmentation of codes in stages.

4.3 Discussion of IAU monitoring results

To give a complete picture of the IAU activities executed during the project, we decided to include the information collected from the sites after they started to use the toolkit in this report. It should be noted that, once the sites started to use the ItFits-toolkit, they started to report significantly less IAU activities. We observed that this was due to the focus they put on the toolkit use, which was desirable for the IMA project.

During the coding process, the initial code system developed from the mentioned literature was adapted based on the interview information. Literature-based codes from the original coding frame concerned all stages of implementation.

In Stage 1. “Engagement”, we expected to see activities like “Establishing the benefit of the iCBT program” and in Stage 4. “Sustainment”, we were initially looking for how sites sustain their service process and their competencies. None of these activities were mentioned in the IAU questionnaires.

In Stage 2.1 “Readiness planning”, we were expecting activities like “Creating a communication plan” or “Define resources required to run the service”. In Stage 2.2 “Staff hired & trained”, “Establishing a process for fidelity monitoring or measurement of treatment effectiveness” was not mentioned.

Finally, in Stage 3. “Service implementation”, sites did not refer e.g. to “Having an ongoing fidelity monitoring”. In the end, many activities and determinants that were expected to occur based on the literature were not mentioned in the IAU questionnaires. All codes that were in the initial literature-informed code system but were not mentioned by the sites are marked red in Appendix B. initial and final code system.

The results from the IAU summary show that sites reported on many different determinants and engaged in many activities throughout the project. These activities and determinants were assigned to different stages of implementation. Stage 2. “Preparation” includes nearly half of the activities and determinants mentioned and addresses equally the aspect of readiness planning for the implementation and hiring and training staff. The other half is included in stage 3. “Service Implementation”, which addresses activities and determinants during the actual implementation process. Since the project was concerned with ongoing implementation, almost no activities were reported on Stage 1 “Exploration”. Furthermore, only one site was engaged in Stage 4 “Sustainment”. While many activities on stages 2 and 3 are obviously also concerned with the sustainment of the interventions, the IAU summary indicated that sites were not yet in the maintenance and sustainment phase of the implementation. Such activities include certification and reimbursement procedures. Most sites were still in a “project status” within their healthcare context and not yet truly integrated into routine care.

As described above, it is important to keep in mind that this analysis only includes information that sites mentioned in their questionnaire. Therefore, the quantitative analysis must be interpreted with caution.

5. INFLUENCES OF COVID-19 ON IMPLEMENTATION-AS-USUAL (IAU)

The last IAU questionnaire was distributed in September 2020 and covered the timeframe after the last site had crossed over to the toolkit use. This timeframe coincides with the beginning of the COVID-19 pandemic up to the delivery of this report. In the last IAU questionnaire, we therefore also focused on the influences of COVID-19 on the IAU condition. All influences on the experimental condition are described in Deliverable D2.3. For the description of influences of COVID-19 on the IAU condition, we focused on the monitoring of context and legal factors, barriers and obstacles to the service implementation, and activities the implementation sites were engaged in to embed and integrate the local iCBT programme within routine care.

We asked the sites if they had observed or were expecting a change in the number of participants in their service. None of the sites referred to specific numbers (statistics on uptake, intake numbers, or referrals), but rather the implementers' impression of the intake numbers. Of the 12 sites answering the COVID-19 specific questions within the IAU questionnaire, five sites expected and observed a decrease in the number of participants in the service due to COVID-19. Four sites expected an increase, and three sites did not expect any changes in any direction. Three sites observed an increase in participants, while four did not identify any changes.

Sites observing a decrease in participants due to COVID-19 mention that *“Face-to-face visits have been reduced and doctors and nurses are focused on solving more urgent health problems and especially on detecting possible cases of COVID-19”, “activity has been reduced during the pandemic. Doctors and nurses could not make face-to-face visits and they were dedicated to COVID-19 patients”, the “significant reduction in the clinical activity and abrupt discontinuation of face-to-face [contacts]”, as well as “fewer patients visiting primary care” (as iCBT participants were recruited in this setting), and “less willingness to engage with screening on tablets” during the pandemic.*

Sites observing an increase in participants due to COVID-19 mentioned that their *“organisation replaced most of the Face-to-Face sessions by videoconferencing during the lockdown, that was a boost for the use of the [intervention] platform and blended treatment. After the lockdown [they] started to see patients again face-to-face, and also replaced the video-services on the [intervention] platform by Google meet (our IT system). The number of participants of our services seems to diminish again, but overall, more therapists are now familiar with the possibilities of the platform”¹. Another site noticing an increase in participants in their iCBT service notices that the increase was “... especially strong at the beginning of the pandemic and then came back to ‘normal’”. Another site “observed an increased number of uptake patients during the lockdown period (March and April) and then a normalisation of the uptake numbers in the following months”.*

¹ Please note that this is not based on actual numbers, but on observations.

One site reported that they “observe an increase in patients and projects. In the [local IMA] project, the numbers are rather consistently low. From our point of view, there is currently an increased demand for online services, on the one hand to respond to the current crisis, on the other hand to substitute therapy that could not be carried out at the height of the crisis. However, implementation activities are also limited”.

Three sites observed changes in the group of people using the service during the COVID-19 pandemic, namely that “clients come with different topics” and “clients experience elevated symptoms”. Two sites could not say as they do not have direct contact to participants and seven sites did not observe any changes².

Five sites did notice that people were more open-minded to using the iCBT services due to the COVID-19 pandemic, six could not say, and one site observed that people were more unwilling to use the services.

The five sites noticing that people were more open-minded to using the iCBT services mentioned that “[the] reason is because visits have been reduced and it is an option to receive non-face-to-face therapy”, that it “is the easy way to get in touch with the health service”, that the intervention “seem to be a valuable alternative to f2f offers”, and that there was a “need for online therapy during the COVID-19 outbreak”. It was also mentioned that “many therapists used the time where they could not see patients face to face to research online opportunities and were open to trying them out. Patients were also inquiring about options when other care systems were temporarily closed. Overall, during the pandemic it became ‘the norm’ to do things online that were formerly done offline, and I think that increased the acceptance of iCBT”.

The sites that could not say if people were more open-minded to using the iCBT service elaborated that they had “a mixed observation: some therapists are enthusiastic and open-minded, others are disappointed and struggling a lot. They want to go back to the old situation as soon as possible”, “on the one hand, we would expect that GPs and patients are more willing to use eHealth because of the COVID-19 pandemic; on the other hand, GPs have been very busy because of COVID-19, which could be the reason why they don’t use it more often in practice” and that “there may be greater need for services, and people may be more aware of tele/digital health services. But having clinical services as the point of contact/referral limits the ability of people to engage with the service (if it was delivered directly to end-users through online marketing, I think we would see an increase in use and greater acceptability)”.

The site reporting that they perceived people as less open-minded to using the iCBT services elaborated that “people during the pandemic were more concerned with managing fear of contagion and social isolation. Furthermore, isolation has led people to seek another type of

² One service mentioned that they have “very few participants (patients) that are using our eHealth system”

help based more on contact, even just by telephone, and not on a self-help tool via the internet”.

IAU activities introduced due to COVID-19

One implementation site discontinued the service delivery during the lockdown in their country. Seven of the sites reported to not having started any new IAU activities (activities independent of the toolkit use) because of COVID-19.

Two sites started working with the digitisation of informed consent procedures. Also, two sites started to *“facilitate [...] medical video consultation processes”*.

One site stated that, *“while most of the planned events, exhibitions, and lectures to promote the online trainings have been cancelled since March”, they “tried to focus more on mailing campaigns to specific target groups (e.g. chronic pain patients, caring relatives) and the expansion of digital recruitment channels, more PR activities and webinars for employees”*.

Two sites opened *“... up a new pathway for unguided use (temporarily, it is now closed, and the numbers are not counted in the IMA trial). [...] through opening [the service] for unguided use”, one site “got a massive media coverage that also helped the guided version and [this] boosted [...] uptake”*.

The other site cannot evaluate any changes in uptake at this moment.

Alterations to the iCBT services due to COVID-19

Five sites stated that they did not alter or adapt their services due to COVID-19. One site tried to *“alter the iCBT program to implement the video calls and more questions relating to the COVID-19 pandemic. However, it was not technologically possible”*.

Two sites provided their services now *“completely online”* (in comparison to previous procedures).

One site reported that the built-in *“videoconferencing services within [their] platform were activated during the lockdown period. The CBT is still the same format, [they] replaced face-to-face contact with videoconferencing.”*

One site *“added a new video on the landing page after login that addresses the corona pandemic and its special challenges for patients suffering from depression. The rest of the intervention remained unchanged”*.

Implementation-as-usual activities stopped due to COVID-19

Three sites stated that all IAU activities could go on as planned. One site stated that they did not stop any IAU activities but postponed the start of new planned ones.

In contrast, three sites reported that all implementation activity was halted, and all health system resources were directed to the care of COVID-19 patients. They state that COVID-19 still has consequences for their implementation as of today, as patient visits to primary care centres, on which the recruitment processes rely, are restricted and therefore, the entire implementation strategy stopped working.

Other sites reported restrictions in communication, dissemination, and training activities. Since all *“events, exhibitions, and lectures to promote the online trainings have been cancelled since March 2020”* and *“[...] several talks planned to inform [...] [referrers]. All of them were cancelled due to the Corona pandemic. As this is one of [the] reliable pathways to increase awareness about [the] intervention and to find new [referrers], [potential referrers were] probably “lost” [...] here.”* Other implementation and treatment activities were hindered as they were planned as face-to-face settings and only some could be transferred to an online setting.

In some settings, the provision of tele-based support or videoconferencing was hindered, for some time or permanently, due to technical difficulties.

One site stated that the introduction of video-based consultations outside of the iCBT tool used for treatment seemed to diminish the use of the iCBT tool now.

One site stated that they had to decide to *“stop making phone calls to GPs. From our [organisation] it was no longer allowed to approach general practitioners for the reason of scientific research, to prevent overburdening of GPs.”* After stopping to call the GPs, the site did not experience a decrease in referrals.

Obstacles to the iCBT services and their implementation due to COVID-19

▪ Obstacles to the service provision and actions to overcome them

Six sites stated that they did not experience any specific obstacles within their service due to the COVID-19 pandemic other than mentioned above.

Most sites stated that during the first wave of the pandemic, the regular healthcare service was only open to emergencies or severely depressed patients. One site stated that they *“worked only with emergency cases because nonessential services stopped, so possibility of face to face meetings [to introduce the iCBT service] was low.”* They further stated that the plan was to continue completely online, using videoconferencing, but that most patients do not have the technological means for this. Another site stated that the *“access to [the] services was only possible for emergencies, so it was necessary to find another way to reach patients. [They] have given patients the opportunity to choose to be able to start the process through a video call or skype interview.”*

Another site mentioned that the *“initial closing of practices and hospitals hindered the contact of patients with their guiding healthcare professionals, [...] but this was overcome quite rapidly through a wider use of telepsychiatry”*.

Other sites mentioned the *“limited access to sites (GP clinics, pharmacies) for several months, [and the] removal of tablets (for screening and referral into the service) at many of [the] sites.”* Therefore, the recruitment processes had to shift towards *“focusing on posters/flyers with links to [the] screening and the iCBT service [...]”*.

One site mentioned the *“fear of contamination of patients and health workers”* as one hindering factor for service provision.

▪ **Obstacles to the implementation processes and actions to overcome them**

As mentioned above, the implementation and recruitment to the services was hindered by the fact that participants could not be informed about the service during their regular face-to-face consultations with their caregivers.

One site stated that *“the therapists were very tired, partly because of the forced use of videoconferencing. A perceived misconception by the therapists is that videoconferencing equals blended treatment, and they might think now that blended treatment is very tiring, which it is not in normal circumstances. That [constitutes] a bit of a setback in the implementation efforts”*. This site tries to *“keep on training and informing [the] therapists [about] the benefits of blended CBT. [Their] team of early adopters are playing a key part in this”*.

One site stated that when their organisation *“... decided that it was not allowed to contact GPs in the context of scientific research because of the COVID-19 pandemic, [their] main implementation strategy, keeping in touch with the GPs, was not allowed anymore.”* The only thing they could do was to wait *“until [they] got permission again to contact general practitioners.”* Another site experiencing a similar problem stated that they now have regained access to their referrers.

Context-related changes to the IAU due to COVID-19

Seven of the sites with commercial customers (such as businesses or healthcare insurances) stated that no additional customers approached them with regards to their services due to the COVID-19 pandemic.

Two sites stated that they had been approached. One stated that *“few additional customers approached [them]. There was an intensified interest both by healthcare practitioners as well as by organisations. Also, [they] received donations from two companies to support [their] service especially during the pandemic. That greatly helped [them] to make the unguided version possible.”* They also stated that *“there was an increase in interest in our*

service. They demanded special services due to the COVID-19 pandemic. New funding opportunities arose or might arise from this special situation”.

This also holds true for a second implementation site, which closed deals to develop COVID-19-specific treatments together with other organisations receiving specific funding. This campaign helped offer a crisis hotline, a guided Facebook group, and a COVID-19 programme for free. This also promoted the site’s existing services and opened new dissemination channels.

Legal changes to the IAU context due to COVID-19

One site reported a legal change concerning the *“utilisation of teleconsultation for the most severely depressed [patients]”*.

Three sites mentioned a temporary change in the legal system that allows a greater proportion of psychotherapies to be conducted as video conferences. One of those sites, for example, stated that *“during the pandemic, it was easier to use telemedicine tools. The issue of data confidentiality was placed in second place with respect to people's safety. There was no change in the law but in some regulations. However, in the [COVID-19 specific regulations] provided by the central government, remote communications have been encouraged. At the health level, regional guidelines provide for increased use of remote tools including telephone, video chat, e-mail, WhatsApp, etc”*.

The remaining sites did not mention any (temporary) changes in national law prompting the implementation or delivery of their services.

The COVID-19 pandemic had very different influences on the sites. Some sites benefited as participants and professionals showed higher interest in iCBT, which led to increasing participant numbers and funding for additional COVID-19 related services. Other sites had to stop all their IAU activities, their professionals could only concentrate on COVID-19 patients, referral processes came to a stop, and the sites had a very low uptake. Sites tried to overcome these obstacles by a wider use of telecommunication and online marketing. Changes in legal regulations also helped some sites in introducing more telemedicine.

6. KNOWLEDGE EXCHANGE

While there is a huge heterogeneity across the implementation sites regarding the healthcare contexts and implemented iCBT services, the fostering of knowledge exchange in WP5 was planned to focus on the exchange of previous experiences with iCBT implementation and lessons learned. We strived to blind as much as we could to ensure the integrity of the trial, by which the knowledge exchange was limited. This was agreed by the consortium. As discussing implementation plans across the sites could confound the effect of the ItFits-toolkit under investigation, such topics have been left out of the WP5 discussions. Therefore, knowledge exchange events, networking tables, marketplaces, discussion forums (online and offline), and Socratic discussion meetings were not realised during the project lifetime. The main knowledge exchange activities were distributed to Work Package 8 “Project Management and Communication”.

IAU knowledge exchange was therefore focused on the iCBT interventions themselves and more general topics surrounding eMental health. Implementation activities as well as barriers and obstacles were presented by the sites, but solutions could not be discussed.

Monthly calls between the sites who did not yet have access to the ItFits-toolkit were administered. Topics for the WP5 meetings were gathered in the IAU questionnaires completed by the implementation leads prior to the call and redirected if they were relevant to other Work Packages.

6.1 Knowledge exchange topics

Sites wanted to obtain more information about two main aspects. First, all sites wanted to get a periodic update on the other implementation sites’ implementation contexts and progress. This should facilitate the exchange of experiences with iCBT and mutual learning about iCBT solutions. Second, sites wanted to get information about the project itself, like the study protocol, progress and content of the ItFits-toolkit, and ImpleMentAll planning. This was to provide a better understanding of the project phase requirements and what the sites were supposed to do with the toolkit.

With regards to getting updates from the other sites, one main interest was how to facilitate the adherence and involvement of professionals, referrers, guides, and clinical management. Also, sites were interested in sharing ideas about how to motivate staff to participate in the trial. Sites were also interested in different implementation strategies depending on the different clinical settings and the different professionals e.g. psychologists or GPs, involved. For example, sites with self-guided interventions were interested in how other sites with a similar approach involve professionals. Other sites mentioned that it was hard to work with various professionals in different ways and wanted to know if other sites had the same problem. One site also wanted to know if linking all participating local sites to

share results and ensure all sites have consistent information and approach to implementation would be beneficial. With regards to WP5 topics, sites were interested in how to implement novel iCBT interventions in developing countries.

In addition to that, sites were interested in strategies to motivate professionals to include more participants and generally in recruitment strategies. There was one other question on how other sites find time to do meetings with professionals in the middle of their routine.

There were also some comments regarding the trial itself. Some sites asked how other sites achieve staff participation in the three-monthly trial surveys. Also, sites wanted to know if others are collecting the informed consent form online or written. Sites were likewise interested in how other sites collect their data and how they keep their data safe. Those questions were tackled by WP3. Additionally, sites were interested in information about the study protocol, e.g. incentives planned and recruitment procedures. Also, sites wanted to exchange common problems and solutions related to the IMA protocol. At the beginning of the project, some sites also asked for at least a draft version of the IMA study protocol to adapt their activities to the objectives of the general study. Those questions were tackled by WP3.

Before starting to use the ItFits-toolkit, sites wanted further details about the toolkit, including how to engage and use the toolkit. Only a high-level overview of what to expect on a conceptual level as well as an estimation of effort (including workload of ItFits-toolkit use) was provided by WP2, as providing too much detail about the content and tasks of ItFits-toolkit was considered a risk to the experimental condition of the trial.

6.2 Lessons learned in WP5

The lessons learned mentioned by the implementation sites can be clustered in topics of working with stakeholders, team organisation, increasing reach, implementation strategies, and knowledge exchange.

Working with stakeholders/referrers

Many sites mention that it is important to include health professionals (and individuals who could potentially become one) as an active and meaningful part of the implementation process from the beginning. Furthermore, staying in close contact with the referrers and meeting them in person seemed to improve their commitment. In this context, sending emails to the sites was way less effective than a face-to-face meeting.

Another site mentioned that presentations of successful iCBT interventions can improve acceptance and engagement of the referrers. Furthermore, meetings with referrers to talk about their challenges are beneficial. In addition to that, clear roles and responsibilities for GPs using the new iCBT tool need to be established.

The training of professionals regarding the use of iCBT is also relevant to understand the status of their patients and to improve the credibility of the information provided by the

tool. Moreover, it is necessary that professionals accept the information about the tool. Finally, referrers must know whom they can talk to if they are having problems with the intervention.

Team organisation

Also in IAU, implementers considered constant project team meetings important. Explaining the process in person is very beneficial as well as talking about challenges. Being in close contact with different groups that are involved in the implementation process is also very important. Furthermore, it is necessary that every site has its own implementation team that is ready to implement.

Increase reach

It was mentioned that it is important to co-operate with the communication department or something similar, from a very early stage on to increase awareness. Also, “giving talks” is an effective way to recruit additional referrers. Moreover, a press conference is a good start to build awareness about e.g. iCBT in depression. But increased attention also leads to more telephone calls and emails and therefore takes up time resources. Sites also mentioned that convincing partners outside of the own organisation to spread the sites’ ideas especially as a non-commercial organisation is very helpful.

In addition to that, as the compatibility of iCBT with the existing organisational structures of healthcare is often low, it is important to convince politicians with the ‘good story’ about iCBT to change such structures. This includes arguments like being modern, empowering, and independent of geography and time. One learning of note was that it would have been easier to start with only a few referrers (centres) and then to extend the working processes to other centres in comparison to starting the implementation on a large scale.

Timeliness of IAU activities

One site mentioned that it is important to focus on both short- and long-term implementation. One site emphasised that you should not forget about the long-term activities in your implementation process. In general, many sites mention that it is important to stay optimistic in implementing iCBT as it is a long and slow process, and it takes a lot of time to build a network. One other lesson was that asking for feedback from current users of the system leads to new ideas for implementation activities.

Knowledge exchange

Exchanging experiences with other sites who are already involved in iCBT was considered helpful and can be a key factor for implementing the new tool at local level. Also, collaborating with other sites or associations was mentioned as useful. But information exchange with other sites about how they solve their problems is not always as beneficial as each site is very different and adapting their solutions is not always that simple.

7. OVERALL CONCLUSION

While Implementation-as-usual (IAU) constitutes the control condition in the main effectiveness trial of the IMA project (Bührmann et al., 2020), the monitoring of routine implementation determinants and activities has not been much reported on in literature on iCBT implementation. We summarised the relevant determinants and activities in IAU, reflected on the influences of the first wave of COVID-19 on the IAU condition, and reflected on knowledge exchange topics and overall lessons learned in IAU.

Determinants (barriers and facilitators to IAU) included the limited uptake of the service (in comparison to what was expected or planned), individual characteristics and attitudes of stakeholders involved, and intervention-related obstacles (including participant identification and diagnostic procedures). The summary of IAU activities highlights communication and dissemination activities, training and education, as well as adaptation of the services to the local context.

A comparison to implementation activities based on the literature reveals that many theoretically potent strategies have not been mentioned by the implementers. It can be assumed that the potential of implementation science knowledge on effective implementation strategies has not been exhausted before they started to use the ItFits-toolkit. Furthermore, we tried to match determinants and activities (e.g. which activity was initiated to overcome which barrier), but this matching process revealed a great number of mentioned determinants without also mentioning a related activity and vice versa. This also highlights the potential of a structured matching between determinants and strategies as offered by the ItFits-toolkit.

We matched mentioned IAU activities to “Stages of implementation”. This process allows for a classification of activities but also could help categorise implementation sites or projects with regards to their progress. In the IMA project, activities mainly related to the second and third implementation stage (“Preparation” and “Service implementation”). This was expected due to the project setup. Further analysis of the IAU data could focus on the transition of the sites through the stages during IAU, but also during toolkit use.

The first wave of the COVID-19 pandemic took place during the last quarter of the IMA project. It had very different influences on the sites. Many implementation sites had to stop all their IAU activities. Some sites reported to have benefited from the situation in the sense that participants and professionals showed higher interest in iCBT, which lead to an increased uptake and funding opportunities. Furthermore, contextual changes also helped some sites in introducing more telemedicine. It would be interesting to monitor the influence of the pandemic on IAU processes further.

Implementers were frequently asked to share their most important lessons learned concerning IAU with the consortium.

Themes identified concerned “working with stakeholders and referrers”, “team organisation”, “measures to increase reach”, “timeliness of implementation activities”, and the importance of “knowledge exchange”. All these topics have also been mentioned as important IAU activities.

Further research on iCBT implementation should investigate the processes around these important topics.

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APPENDICES

Appendix A: ImpleMentAll WP5 – Monthly “Implementation-As-Usual” (IAU) Questionnaire

What is your name?

Which site do you represent?

Did you start any new implementation activities? Which implementation activities did you start? Why did you start those new implementation activities?

How would you rate the effectiveness of those new implementation activities?

- (1) Very ineffective
- (2) Somewhat ineffective
- (3) Neither effective nor ineffective
- (4) Somewhat effective
- (5) Very effective

Please elaborate

Did you alter the iCBT program since the project start (e.g. number of sessions, form of guidance, technical features, smaller changes to the modules)? If so, please indicate how and why?

Did you stop any implementation activities? Which implementation activities did you stop? Why did you stop those new implementation activities?

With which result would you rate their effectiveness?

- (1) Very ineffective
- (2) Somewhat ineffective
- (3) Neither effective nor ineffective
- (4) Somewhat effective
- (5) Very effective

Please elaborate

What did you learn that might be beneficial to other sites?

Have you experienced any obstacles to implementation? Which obstacles to implementation are you dealing with right now?

Have any new obstacles to implementation come up in the last four weeks? (Describe if yes)

How are you planning to overcome those obstacles?
Conference call to discuss fears and reduce them with our knowledge.

Did you identify any uncertainties or risks to the course of the IMA project which emerged at your site?

Please describe the uncertainties or risks:

Which issues would you like discuss/learn about during the IMA monthly telco - either from the other implementation sites or the participating WP Leaders?

Is there anything else you would like to add?

You can also use this field to describe the change in a specific field you are interested in, which has not been mentioned in this survey. This could include refferals or adherence to the treatment.

Thank you!

Thank you very much for participating in this WP5 survey.

The WP5 Team

APPENDIX B: Initial and final coding scheme

Code	Sub-code	Sub-sub-code
Seeking agreement to consider implementation		
Express motivation to implement the iCBT program		
Establish the benefit of the iCBT program		
Understanding the iCBT program		
<i>Determinants</i>		
Stage 2.1: Preparation (readiness planning)		
Adapting of intervention (programme)		
Adapting service components		
Developing a business plan		
Identifying barriers and facilitators (determinants of practice) of implementation		
Planning out service processes		
Writing an implementation plan		
Applying for ethical approval		
Seeking alignment with legal requirements		
Providing necessary staff related requirements and resources		
<i>Determinants</i>		
define resources for Implementation		
define resources required to run the service		
Communication plan		
Plan for (implementation) time-plan		
Plan for staff hiring		
Stakeholder meeting		
Stage 2.2: Preparation (staff hired & trained)		
Hiring and engaging staff		
Actively engaging in measures to increase reach		
Training stakeholders/staff		
Determine roles and responsibilities		
Getting feedback from referrers/staff		
<i>Staff restrictions due to personnel turnover</i>		
<i>difficulties finding enough referrers for the implementation</i>		
<i>No adequate personnel</i>		
Fidelity measure/checklist implemented		
Measurement of treatment effectiveness established		
Process for success monitoring		
Stage 3: Service Implementation		
Staff is offering the service with confidence		
Acting on contextual level	building a new network motivate stakeholders working with stakeholders	

Activities and determinants of practice, which are also happening in other stages		
Providing information	Communication	
	Dissemination	among participants among referrers
	Education	educate potential participants develop educational material educate referrers
Acting on political level Improving organizational workflow Monitoring of change progress <i>Low uptake of participants</i> <i>Increase in administrative work</i> <i>Time issues</i>		
<i>Barriers on inner contextual level</i>	<i>Implementation stopped</i> <i>financial issues</i> <i>not being part of the organizational structure</i>	
<i>Barriers on outer contextual level</i>	<i>restricted level of control over implementation process</i>	
<i>Individual stakeholder characteristics</i>	<i>Acceptance/ Trust of professionals</i> <i>Lack of (time) resources</i> <i>Lack of experience</i> <i>Lack of interest</i>	
<i>Intervention related obstacles</i> <i>Difficulties in the identification of participants</i>		
Ongoing consultations Ongoing feedback Ongoing fidelity monitoring Ongoing services		
Stage 4: Sustainment		
Engaging in the process of getting the iCBT service certified		
<i>Determinants</i> Sustainment of competencies Sustainment of processes		

Note: all codes used in the analysis are green, all initial codes from literature that were not used are in red, barriers/determinants of implementation are written in cursive characters