ImpleMentAll

"Towards evidence-based tailored implementation strategies for eHealth" GA no. 733025

Deliverable D1.3

Integrated Implementation Framework: the ItFits-toolkit

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AUTHORS (name and organization):	Søren Lange Nielsen (RSD) Kim Mathiasen (RSD) Mette Atipei Craggs (RSD) Heleen Riper (VUA)

Short description of the Deliverable (as in the DoA):

This document provides a high-level overview of the ready to disseminate (generalised) ItFits-toolkit, detailing its development, trial, evaluation, and future use and dissemination.

REVISION HISTORY			
REVISION	**DATE**	**COMMENTS**	**AUTHOR (NAME AND ORGANISATION)**
V0.1	17/05/2021	First draft	Søren Lange Nielsen (RSD)
V0.2	21/05/2021	Second draft incorporating feedback from management team	Søren Lange Nielsen (RSD) Kim Mathiasen (RSD) Mette Atipei Craggs (RSD)
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This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

Executive Summary

This document provides an overview and examination of the ItFits-toolkit, a key contribution from the EU-funded ImpleMentAll project (IMA). The IMA project set out with an ambitious goal of developing, evaluating, and delivering a generic Integrated Theory-based Framework for Intervention Tailoring Strategies (the ItFits-toolkit). The overall purpose of this work was to test if tailored implementation strategies can make the implementation and upscaling of new interventions more efficient, in a large-scale multisite trial. Accordingly, the extensive work carried out to realise the ItFits-toolkit can be divided into three phases:

1) Develop the ItFits-toolkit and prepare for the trial:
   Within the first phase of the project, the toolkit's theoretical and conceptual foundation was established, providing a sound theoretical embedding of the toolkit. This included the necessary scientific evidence, tools, and methods for tailored implementation, which were developed, combined, and integrated into the toolkit. Moreover, the toolkit was operationalised and embedded in an easy-to-use web-based version.

2) Apply and validate the toolkit in a large-scale multisite implementation trial:
   The second phase of the project focused on testing the toolkit in a large-scale trial, using the natural laboratory of on-going implementation projects across Europe and Australia. During this phase, the toolkit was trialled at 12 sites, following a stepped-wedge trial design, sequentially introducing the sites to the ItFits-toolkit. This meant that the sites acted as both the control (implementation-as-usual, IAU) and experimental condition (ItFits-toolkit). Throughout this phase, data were continuously collected to enable a comprehensive evaluation of the toolkit.

3) Analyse, improve, and deliver the ItFits-toolkit:
   In the third phase of the project, the trial results were analysed and reported in an in-depth effectiveness study and process evaluation, establishing the toolkit's effectiveness and validity. The findings and lessons learned from the large-scale trial were also used for further refinements of the toolkit, which were embedded in a finalised version, ready for public dissemination (www.itfits-toolkit.com)

Throughout these phases, the IMA project has successfully developed, validated, and delivered a conceptually and technically innovative and sound framework for facilitating tailored implementation. In itself, this has been an ambitious endeavour, *"…pushing the boundaries of implementation science and practice in the field of eMental health."* (D3.2).

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1   Introduction

In recent years, large amounts of time and money have been invested in the development, testing, and implementation of innovative and effective eHealth interventions. Yet, their uptake into routine practice remains low and costly, as only a limited number of such eHealth interventions manage to make it into routine care, often requiring several years to get there. Consequently, in January 2017, the EU funded ImpleMentAll (IMA) project set out to address this need for effective implementation strategies, promoting the uptake of evidence-based innovative clinical practices and interventions in routine practice.

The objectives of the IMA project were three-fold:

1) To develop a generic Integrated Theory-based Framework for Intervention Tailoring Strategies (the ItFits-toolkit) for data-driven tailored implementation of evidence-based eHealth services.

2) To demonstrate the impact of the ItFits-toolkit on the implementation of eHealth for common mental disorders, in nine European countries, including two Low-and-Middle-Income countries, and Australia.

3) To disseminate the validated toolkit for tailored implementation to various healthcare contexts and interventions across Europe.

Accordingly, a central element of this effort has been the Integrated Theory-based Framework for Intervention Tailoring Strategies (ItFits-toolkit) and its development, trial, and evaluation. This document provides a high-level overview of this process and the toolkit, drawing on the extensive work carried out across the work packages (WPs) of the project. The WPs include:

- WP1: Integrated Implementation Framework: ItFits
- WP2: Implementation Interventions (tailoring)
- WP3: Evaluation of Implementation Interventions
- WP4: Utilisation platform
- WP5: Implementation management and knowledge transfer
- WP6: Stakeholder and expert participation
- WP7: Innovation and dissemination management
- WP8: Project management and communication
- WP9: Ethics requirements

In particular, this deliverable is based on the findings, discussions, and recommendations from WP1, WP2, WP3 and WP4, as reported in Deliverables D1.1, D2.1, D2.2, D2.3, D3.2, D4.2, and D4.3.

1.1   Purpose of this document

The purpose of this document is to provide a high-level overview of the ItFits-toolkit, detailing its development, trial, evaluation, and delivery, as part of the EU funded ImpleMentAll (IMA) project.

1.2   Structure of document

Section 1 provides a general introduction, which is followed by an overview of how the ItFits-toolkit came to be, detailing its initial scope and development phase as well as its trial and impact (section 2). Section 3 focuses on the toolkit's future, examining potentials for using the toolkit in new projects and initiatives within and outside of the IMA project consortium.

1.3   Glossary

DCS	Data Collection System
D	Deliverable
IaU	Implementation-as-Usual
iCBT	Internet-based Cognitive Behavioural Therapy
IMA	ImpleMentAll
ItFits toolkit	Integrated Theory-based Framework for Intervention Tailoring
MoU	Memorandum of Understanding
NPT	Normalization Process Theory
WP	Work Package

2   The ItFits-toolkit

2.1   Overview of the ItFits-toolkit

Tailored implementation is a systematic process, which includes the identification of determinants hindering or facilitating implementation and specifically choosing implementation strategies that address those determinants. As an approach, tailored implementation is perceived as a promising and effective way to implement new interventions, as studies have shown that it is associated with better uptake in comparison to non-tailored implementation or no implementation (Baker et al., 2015). However, the approach is still emerging within implementation science and further advancements and evidence are required in terms of large-scale trials of tailored implementation, providing conclusive evidence of its relative effectiveness. Furthermore, the lack of a standardised framework has been identified as a possible reason for the varied outcomes of past tailored implementation projects (Ibid.).

In view of that, the IMA project set out to test if tailored implementation strategies can make the implementation and upscaling of new interventions more efficient, in a large-scale multisite trial. To realise this, the project covers the development, validation, and delivery of a theory-based framework for the development and evaluation of context-specific implementation strategies (the ItFits-toolkit). The toolkit itself was operationalised as a web-based platform with evidence-informed methods and materials, offering step-by-step guidance towards tailored implementation to enable more efficient implementation of evidence-based clinical services in routine practice. Accordingly, the toolkit consists of a combination of local assessments of implementation barriers and the selection, application, and assessment of strategies to counter such barriers.

Subsequently, the conceptualised ItFits-toolkit was trialled and evaluated in on-going implementation and up-scaling projects throughout Europe and Australia, testing if tailored implementation strategies can make the process of implementation more efficient. The comprehensive work undertaken to develop, evaluate, and finalise the toolkit will be further examined in the following sections.

2.2   How it came to be

To accomplish the ambitious goal of developing, validating, and delivering the ItFits-toolkit, a group of international key experts in clinical practice, health, innovation, clinical research, and implementation science were brought together, establishing a multidisciplinary international collaboration in the IMA consortium. The underlying process for reaching the project's goals was divided into three main phases, corresponding with the established objectives. The phases cover the following, during the project period of 51 months:

1) Develop the ItFits-toolkit and prepare for the trial (January 2017 – May 2018).

2) Apply and validate the toolkit in a large-scale multisite implementation trial (June 2018 – September 2020).

3) Analyse, improve, and deliver the ItFits-toolkit (October 2020 – March 2021).

Each of these phases required extensive work from the IMA consortium and the different WPs of the project, as covered throughout the following sections.

2.2.1 Phase 1: development of the ItFits-toolkit and trial preparation

The first phase of the project commenced in January 2017, primarily focusing on the development of the ItFits-toolkit and the preparatory work for phase 2. During this phase, the required scientific evidence, tools, and methods for tailored implementation were developed and combined into one integrated implementation framework, the ItFits-toolkit. Throughout this work, emphasis was put on providing a sound theoretical embedding of the toolkit, securing its generalisability and transferability to other settings and eHealth in general. In addition, a comprehensive evaluation protocol was developed and the necessary infrastructure for conducting the trial in phase 2 was prepared. The work conducted in phase 1 resulted in six main achievements:

1. A detailed understanding of the settings and context in which the implementation takes place, including the clinical service, its provision modalities, and usual implementation activities in the participating sites.

2. A first and triable ItFits-toolkit, establishing its theoretical and conceptual foundation including a comprehensive repository of determinants and strategies for implementing iCBT interventions.

3. Development of an online utilisation platform, operationalising and embedding the ItFits-toolkit in an easy-to-use web-based version.

4. Preparation of the trial sites.

5. A comprehensive evaluation framework (study protocols) designed to test the effectiveness and perform a process evaluation of the toolkit.

6. Establishment of the project's measures to maximise impact.

This was achieved through a collaborative and iterative process with strong collaboration between the work packages (WPs) of the IMA project. Through this process, the toolkit's theoretical, conceptual, and technical foundation was developed, and initial piloting and laboratory testing were carried out, ensuring the toolkit's workflow and technical stability. This development and the resulting ItFits-toolkit will be further examined below.

2.2.1.1 *Development of the ItFits-toolkit*

To develop the underlying process and tools of the ItFits-toolkit, a theory-based approach was deployed in WP1 and WP2, organising and combining scientific outputs and theories in the field of implementation science. This process involved extensive reviews of relevant literature, which were carried out to establish a detailed understanding of the mechanisms of effective tailored implementation, the determinants of practice, and relevant implementation strategies. Through these reviews, a repository of 37 determinants for implementing iCBT interventions was compiled, refined and clustered into six main themes: acceptance, appropriateness, engagement, resources, work processes, and leadership (Vis et al., 2018). Subsequently, these determinants were formulated in terms of barriers hindering successful implementation and were adapted to fit the purpose of the toolkit. Moreover, a taxonomy of 73 implementation strategies was identified and adapted to the purposes of the ItFits-toolkit and iCBT (Powell et al., 2015). The identified barriers and implementation strategies were matched and combined into one repository, providing the basis for the ItFits-toolkit. This combined repository was further supplemented with supporting information, examples of application, links to associated tools, guidance on use, and more.

Another equally important output from this initial development phase is the six core principles, guiding the users in working with the ItFits-toolkit. These guiding principles are based on Normalization Process Theory (NPT) and the combined academic experience of working with implementers, alongside the knowledge collected from the scientific literature. The six principles can be seen Figure 1 and are all embedded within the step-by-step process of the toolkit along with ten key implementation strategies from Powell's taxonomy of strategies (Powell et al., 2015).
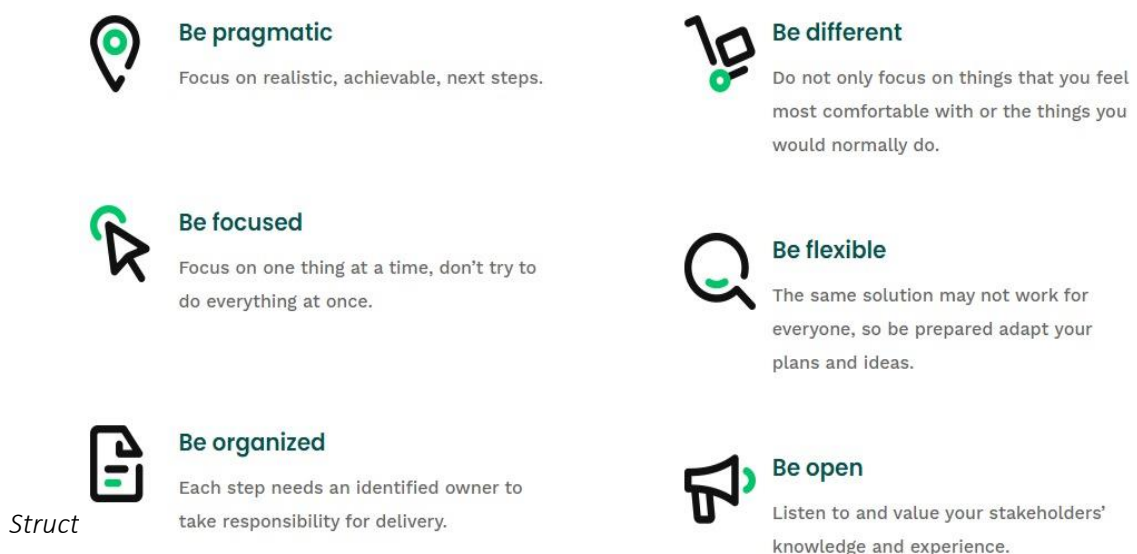
Be pragmatic
Focus on realistic, achievable, next steps.

Be different
Do not only focus on things that you feel most comfortable with or the things you would normally do.

Be focused
Focus on one thing at a time, don't try to do everything at once.

Be flexible
The same solution may not work for everyone, so be prepared adapt your plans and ideas.

Be organized
Struct Each step needs an identified owner to take responsibility for delivery.

Be open
Listen to and value your stakeholders' knowledge and experience.

Figure 1: Principles of the ItFits-toolkit

2.2.1.2   *Structure of the ItFits-toolkit*

The conceptualised structure of the ItFits-toolkit was developed as a systematic and flexible step-by-step model with four substantive modules, designed to guide users consecutively through the modules. When working through the toolkit, implementation teams are advised on choosing appropriate methods for developing knowledge and understanding of tailored implementation within their local context. Across the four modules, users are presented with supporting evidence-informed materials, including the identified barriers and implementation strategies. Moreover, they are introduced to several consensus techniques for consulting with relevant stakeholders, as iterative cycles of stakeholder engagement is a core feature of the toolkit. Accordingly, users are aided in identifying local barriers to implementation (Module 1), matching evidence-based strategies to these barriers (Module 2), designing a detailed action plan operationalising the chosen strategies (Module 3), and reviewing and modifying their progress and approaches where appropriate (Module 4). The overall structure, workflow, and underlying modules of the first triable version of the toolkit can be seen in figure 2 below.
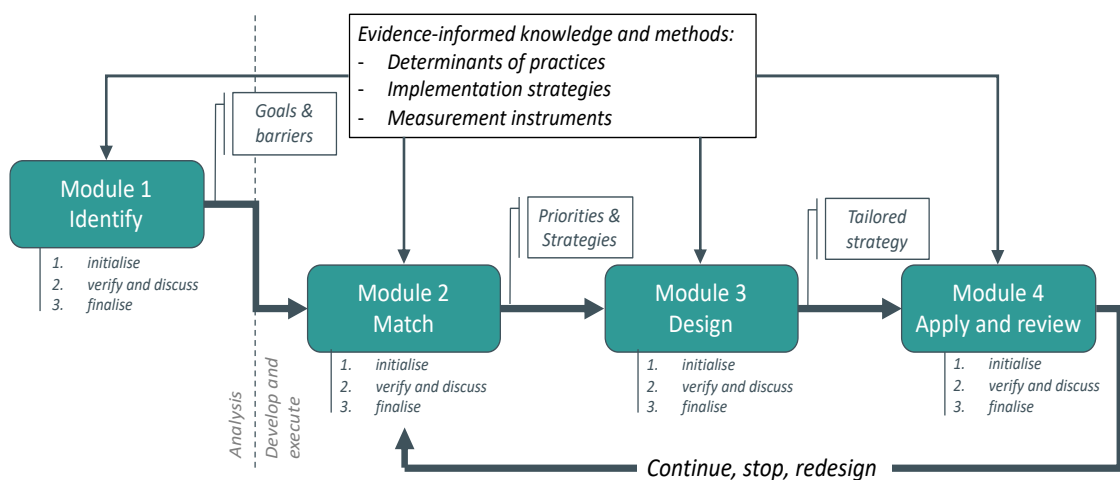
Figure 2: ItFits-toolkit: a standardised stepped approach for developing evidence-informed implementation strategies. Modules 1, 2, and 3 extensively draw on scientific evidence, including determinants of practice and implementation strategies (e.g. behavioural change techniques)

Before the large-scale trial, the toolkit's concept, structure, and underlying information underwent iterative cycles of testing and refinement. Initially, the toolkit was pilot tested in a pen and paper version to inform, improve, and refine the process, materials, and instructions of the toolkit. The testing involved relevant stakeholders including implementation scientists, health service researchers, and clinical teams, all working through the modules of the toolkit. All in all, the results of this conceptual piloting confirmed overall acceptability and confidence in the process, tasks, and materials of the toolkit.

2.2.1.3   *Utilisation platform – operationalising the ItFits-toolkit*

As the toolkit had been developed, piloted, and refined in WP1 and WP2, an online utilisation platform was developed in WP4 ahead of the trial, operationalising and embedding the ItFits-toolkit in an easy-to-use web-based version. It was initially planned to develop the web-based utilisation platform at the end of the project, building upon the outcomes of the trial. However, the technical development of the utilisation platform was advanced in December 2017, so it could *"…be used in the context of the trial, thus taking the chance to validate it instead of having a non-tested version by the end of the project."* (D4.1). Consequently, the technical development process was shortened and carried out much earlier in the project, yet with significant effort, still following the planned approach for creating the platform.

To ensure the functionality and user satisfaction of the utilisation platform, a comprehensive requirements elicitation phase was initially carried out to identify the functional needs and to understand the needs and expectations of potential users. Building upon this knowledge, WP4 designed and developed the platform from scratch in an iterative and intense co-design process, involving relevant stakeholders. Two separate pilot tests were performed, testing the platform's technical reliability, usability, and workflow to verify and ensure the quality of the developed software. The resulting utilisation platform embeds the conceptual structure of the ItFits-toolkit along with surveying functionalities and written, audio, and video guidance for working through the modules.
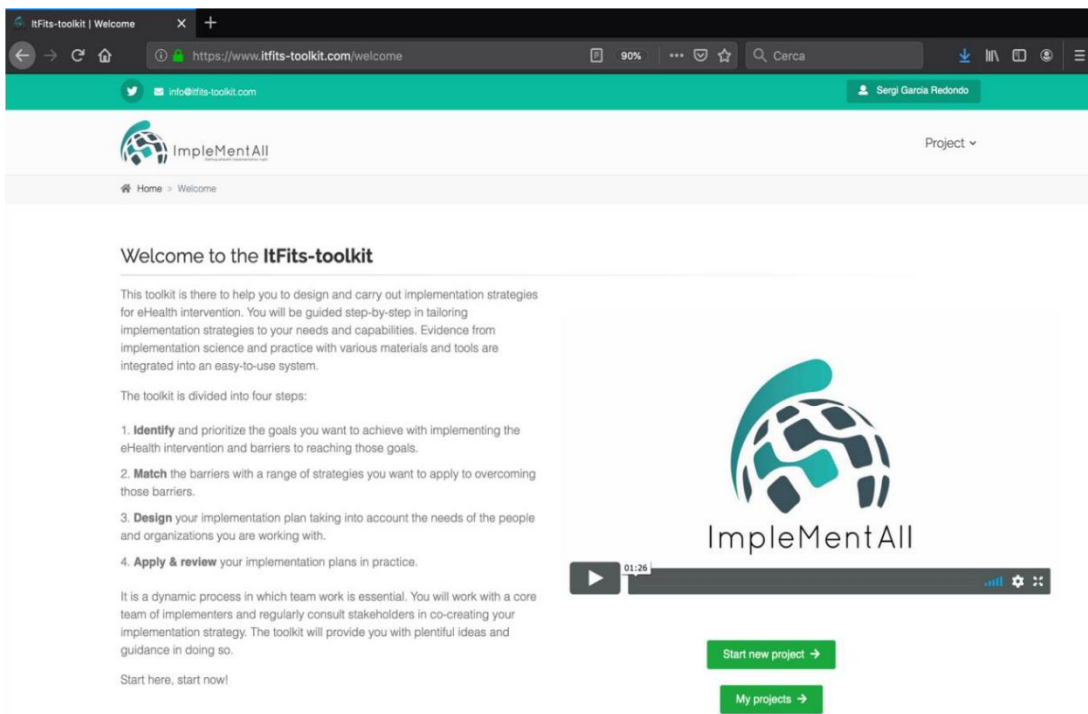

Figure 3: Initial screen of the ItFits-toolkit once logged in as implementation lead

To prepare for the large-scale trial, this development and operationalisation of the ItFits-toolkit was a key contribution of phase 1. However, numerous noteworthy contributions took place in a combined effort across work packages to plan and organise the necessary infrastructure and procedures in preparation for the trial. This includes the development of a comprehensive evaluation framework, training materials for the toolkit, a dedicated data collection system, and much more. These will be covered further in the following sections, as they were applied in phase 2 and phase 3.

2.2.2 Phase 2: validation of the ItFits-toolkit in a large-scale trial

The second phase of the project commenced in June 2018 and ran until September 2020. This phase primarily focused on executing the trial and continuously implementing iCBT services in and by the trial sites, while collecting data for the comprehensive evaluation. Thus, the large-scale multisite implementation trial commenced, following a stepped-wedge trial design, sequentially introducing the trial sites to the toolkit in a pre-randomised order. The trial sites were introduced to the toolkit in six waves, crossing over from implementation-as-usual (IAU) to the experimental condition in which they received the ItFits-toolkit to develop and apply tailored implementation strategies. During the trial period, both qualitative and quantitative data were regularly collected from all 12 sites to understand how the ItFits-toolkit works in practice and to evaluate the effectiveness of the toolkit in comparison to IAU. Overall, the work conducted in phase 2 resulted in the following five achievements:

1. A successful start, execution, and management of the multisite trial, introducing and training 12 sites in working with the toolkit to develop, apply, and assess the impact of implementation strategies tailored to the local settings, needs, and constraints.

2. Consistent data collection, gathering both quantitative and qualitative data for the effectiveness study and process evaluation with regular data monitoring, ensuring high data quality.

3. Despite various challenges faced by the trial sites, all sites managed to continuously implement the iCBT services into routine practice. These challenges included staff turnover, local legislative changes, earthquakes, bush fires, and the emergence of COVID-19.

4. From a technical point of view, the online ItFits-toolkit and data collection systems worked as designed and expected; no technical issues occurred.

5. Data analysis scripts for the effectiveness study were developed, tested, and refined using synthetic data, so that the analysis could be performed efficiently in phase 3.

The trial sites, the trial execution, and the overall work of phase 2 will be examined further in the following sections.

2.2.2.1 *Trial sites*

To evaluate and validate the ItFits-toolkit, it was tested in the natural laboratory of on-going implementation projects across 12 organisations, providing mental health services in Albania, Australia, Denmark, France, Germany, Italy, Kosovo, the Netherlands, and Spain. Prior to the trial start, all of the sites were engaged in implementing a variety of iCBT services that targeted adults suffering from depression or anxiety disorders. These various services all followed the evidence-informed principles of iCBT, safeguarding a high quality treatment, which was adapted to their local context and needs. This also meant that the services varied to a high degree in terms of the guidance and support provided to patients and the extent, duration, and provision of the treatment. The variations between the trial sites allowed the project to evaluate and validate the toolkit *"…in multiple conditions, therefore enhancing the external validity of the tool."* (D5.1).

2.2.2.2 *Trial execution*

The trial started in June 2018, following a stepped-wedge trial design, which meant that the trial sites were sequentially introduced to the ItFits-toolkit during the trial period, acting as both the control (IAU) and experimental condition (ItFits-toolkit), as illustrated in figure 4. Data were collected in a pre-rollout period of six months to provide the control condition for the trial while ensuring stable and reliable data collection measures. Following the pre-rollout period, the first two sites were introduced to the toolkit in December 2018, receiving introductory training, guidance, and ongoing technical support in applying the toolkit. The remaining sites followed suit in five waves, with two randomly chosen sites being introduced to the toolkit every three months. During the trial period, each site was expected to use the toolkit for at least six months, although encouraged to continue their use after the six-month exposure period.
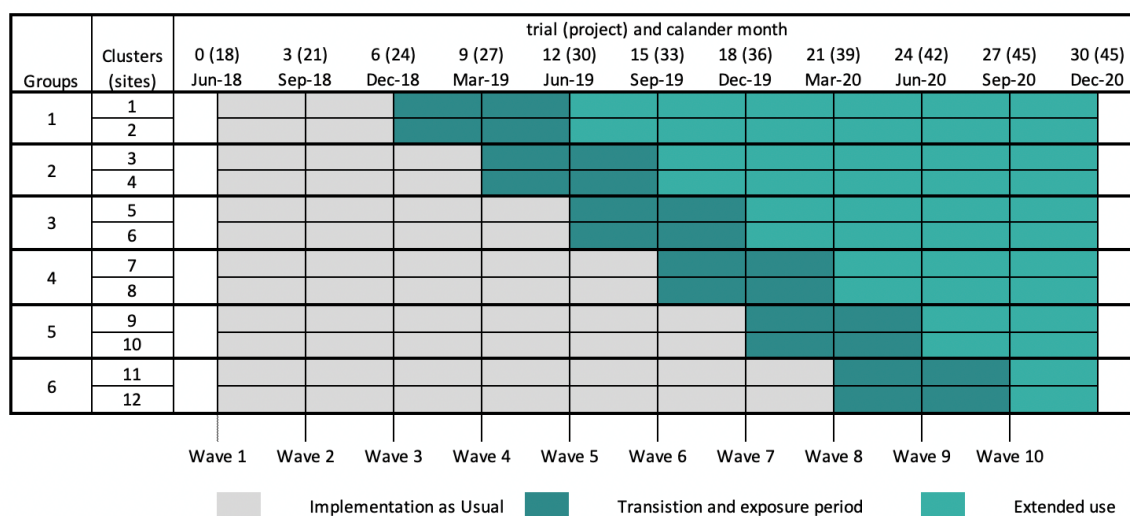

Figure 4: Stepped-Wedge Trial design applied in the ImpleMentAll study

To evaluate the ItFits-toolkit and the trial sites' usage of the toolkit, a comprehensive evaluation framework had been prepared in phase 1 through the combined efforts of WP1, WP2, WP3, WP4, and WP5, integrating both quantitative and qualitative study protocols. This included a quantitative effectiveness study, testing the effectiveness of the toolkit for implementing iCBT and a qualitative process evaluation, focusing on the implementation teams' engagement, usage, and integration of the toolkit.

For the purpose of the effectiveness study, quantitative data were regularly and repeatedly collected to assess potential changes throughout the trial period. These data were collected from event-based log files, detailing the various trial sites' usage of the toolkit as well as regular surveys, using two validated measurement instruments: the Normalisation MeAsure Development questionnaire (NoMAD) and the Organizational Readiness for Implementing Change (ORIC). The NoMAD was used to assess *"…staff perceptions of factors relevant to embedding interventions that change their work practices."* (Finch et al., 2018, p. 1), measuring the constructs of NPT. The ORIC measured the organisational readiness for implementing change (Shea et al., 2014). To facilitate a standardised and structured collection of this data, WP4 developed a secure web-based data collection system (DCS) in phase 1, specifically for the IMA project. Along with a dedicated data management team and several other data collection and monitoring measures, this system promoted a consistent data collection during the trial to ensure the data quality, a vital aspect of the advanced statistical modelling applied to establish the toolkit's effectiveness in phase 3.

Alongside the data collection for the effectiveness study, data were collected for the process evaluation to account for the activities undertaken by the trial sites prior to and after the introduction of the ItFits-toolkit. Accordingly, the aim of this process evaluation was to understand how the sites engaged with the toolkit and how it worked in practice across different settings. To enable this examination, user-generated data were collected from all trial sites, detailing *"data relating to activities undertaken in using the ItFits-toolkit (process data) and decisions made by the implementation core teams (content data)"* (D2.3). These data were recorded on and by the online utilisation platform. Moreover, qualitative data were collected throughout the trial to further examine how the trial sites used the toolkit. This included both observational data from guidance and support meetings and other events related to the sites' use of the toolkit and individual interviews with the involved implementation team members. The in-depth interviews were conducted using a theory-informed topic guide, which had been conceptually informed *"…by three theories relevant to technology implementation (Normalization Process Theory; Self-determination theory; organisational routines theory)."* (D2.3).

Throughout phase 2, the comprehensive amount of data collected for the effectiveness study and process evaluation were continuously and collectively interpreted and analysed to prepare for phase 3. The collective results of this evaluation framework were analysed and concluded in phase 3, providing valuable inputs for the finalised version of the ItFits-toolkit.

2.2.3 Phase 3: analysing, improving, and delivering the ItFits-toolkit

The third phase of the project commenced in October 2020 and ran for six months, until the end of March 2021, at which the IMA project concluded. The phase primarily focused on concluding the project, and analysing and reporting the data collected, laying the basis for further refinements of the ItFits-toolkit. During this phase, the in-depth effectiveness study and process evaluation were completed, establishing the toolkit's effectiveness and validity. Furthermore, a finalised and refined version of the toolkit was devised, incorporating changes based on the findings from the effectiveness study, the process evaluation, and the lessons learned from carrying out the large-scale trial. Attention was also paid to the dissemination of the trial findings and the toolkit, culminating in the project's final conference in March 2021. Overall, the work conducted in phase 3 resulted in the following five achievements:

- The completion of a comprehensive effectiveness study, evaluating the effectiveness of the ItFits-toolkit.
- The completion of an in-depth process evaluation, detailing the activities undertaken to apply the ItFits-toolkit in and by the trial sites.
- A finalised and refined version of the ItFits-toolkit ready for dissemination, incorporating the findings and lessons learned from the large-scale trial.
- Successful two-day virtual conference, disseminating the ItFits-toolkit and the scientific outcomes of the trial to a broad audience.
- Potential plans for sustaining the toolkit and its further use and dissemination, after the IMA project ends.

The work undertaken to evaluate, finalise, and disseminate the toolkit will be further examined in the following sections.

2.2.3.1 *Evaluation and validation of the ItFits-toolkit*

A central part of phase 3 was the analysis and reporting of the effectiveness study (D3.2) and process evaluation (D2.3), detailing the findings of the comprehensive amount of data collected in phase 2. Accordingly, *"…the effectiveness of the ItFits-toolkit in achieving favourable implementation outcomes was compared with the effectiveness of usual implementation activities…"* (D3.2). To accomplish this comparison, the effectiveness study applied a repeated measures design, involving multiple and repeated measurements of the study participants, providing data for the control condition (IAU) and the experimental condition (ItFits-toolkit). This approach allowed the research team to assess changes over time, measuring how trial sites responded to the experimental condition against their previously measured control condition. The primary outcome measure for this examination was *"…the degree of normalisation of the iCBT services as perceived by service delivery staff (i.e. therapists, referrers such as general practitioners, IT developers, administrators) measured by the NoMAD questionnaire."* (D3.2). The reasoning for measuring the perceptions of service delivery staff was based on their prominent role in the delivery of iCBT, which meant that they would be either directly or indirectly influenced by the related implementation activities. In addition to the primary outcome, secondary outcome measures were applied to measure the

"…effectiveness of the ItFits-toolkit on organisational level by means of uptake of the iCBT service by patients (referred and completed treatments with adequate exposure levels) and efficiency of implementing the service (measured by hours spent by implementers on the implementation)." (D3.2). Both the primary and secondary outcomes were measured every three months throughout the trial period, providing a comprehensive data set with 2,884 data points (fully completed questionnaires) from 39 implementers and 456 service deliverers. This allowed the research team with sufficient "*…power to detect significant differences with regard to the primary outcome measure…"* (D3.2).

The collected data for the primary and secondary outcomes were statistically analysed by using a three-level linear mixed-effects modelling method (LMM). The resulting statistical modelling showed that the *"…ItFits-toolkit has a small but significant effect on normalisation levels in mental health service delivery staff involved in iCBT delivery."* (D3.2). Moreover, the toolkit was perceived as usable and implementation teams were generally satisfied with it. The results of the effectiveness study will be further reported and published in a forthcoming scientific paper for a peer-reviewed journal. Consequently, the discussed findings and results are preliminary and sparingly covered within this document to prevent future publishing issues.

In parallel with the effectiveness study, the process evaluation was carried out to *"…understand how tailored implementation as operationalised by the ItFits-toolkit works for users and to formulate improvements for the toolkit."* (D2.3). To that end, the process evaluation explored three central research questions:

- How do IMA implementation teams *engage* with the ItFits-toolkit?
- How is the ItFits-toolkit *reconfigured and adapted* within and across settings?
- What *factors shape implementation* of the ItFits-toolkit?

To answer these questions, a mixed-methods study design was applied, using two kinds of data: *"…user-generated data from the ItFits-toolkit via the online platform; and qualitative data from interviews and observational fieldwork."* (D2.3). Accordingly, extensive user-generated data were collected, detailing how implementation teams engaged with and used the toolkit. These data were descriptively summarised and reported, providing a comprehensive account of their progress and the most common goals, barriers, and strategies applied. Additionally, this was combined with qualitative data in the form of 19 observations and 55 interviews conducted with members of the implementation teams during the trial period. The qualitative data was interpreted and analysed through a team-based approach, applying a *"…rigorous qualitative analysis, including pre-coding, open and focused coding, constant comparison, memoing, tables, diagrams, and deviant case analysis…"* (D2.3).

With reference to the research questions, the results showed that implementation teams *engaged* with the overall logic of the ItFits-toolkit and *"...saw value in the ItFits-toolkit to support and enhance the implementation work they were undertaking."* (D2.3). This also led to their continued usage of the toolkit, after the required six-month trial period. As the implementation teams engaged and worked with the toolkit, they *reconfigured and adapted* the toolkit, *"...as teams found ways to adapt how they worked with it within their existing*

organisational norms, logics, and routines." (D2.3). In terms of the *factors shaping the implementation* of the toolkit, the ease of use and workability of the toolkit was central, as *"...implementers could find their own ways of working with the structure and process the toolkit set out: that they could 'make it at home'."* (D2.3). However, it was also noted that some aspects of the toolkit were perceived as constraining. For one, the operationalised toolkit was configured with specific design features, which limited the implementation teams' ability to *"...go back and change or adapt any of the prior work they had undertaken in relation to a specific project."* (D2.3). Though as with the effectiveness study, these findings and results will be further reported in a forthcoming scientific paper.

2.2.3.2 *Finalisation and dissemination of the ItFits-toolkit*

Based on feedback from the trial sites and the findings and lessons learned during the trial, a finalised and refined version of the ItFits-toolkit was devised and disseminated. Accordingly, a list of technical adaptations and improvements for the toolkit were developed and ranked through a series of workshops with members of WP1, WP2, WP3, and WP4. The suggested improvements were ranked according to their priority and feasibility. The highly prioritised and feasible improvements were incorporated to improve the overall usability and user experience of the web-based toolkit. These improvements were primarily focused on the navigation and workflow of the platform, increasing its flexibility and usability to better accommodate usage outside of a trial setting. Furthermore, a case study and a library of resources was added to better support and orientate new users to the toolkit, including its structure and workflow. Technical measures were also taken in this phase to make the toolkit accessible to the public as an open resource. To realise this, a separate accessible website was created (Figure 5), at which anyone interested in using the toolkit can register and start using the toolkit without external guidance or coaching. To reinsure the technical stability of the adapted toolkit, a technical pilot test was performed.
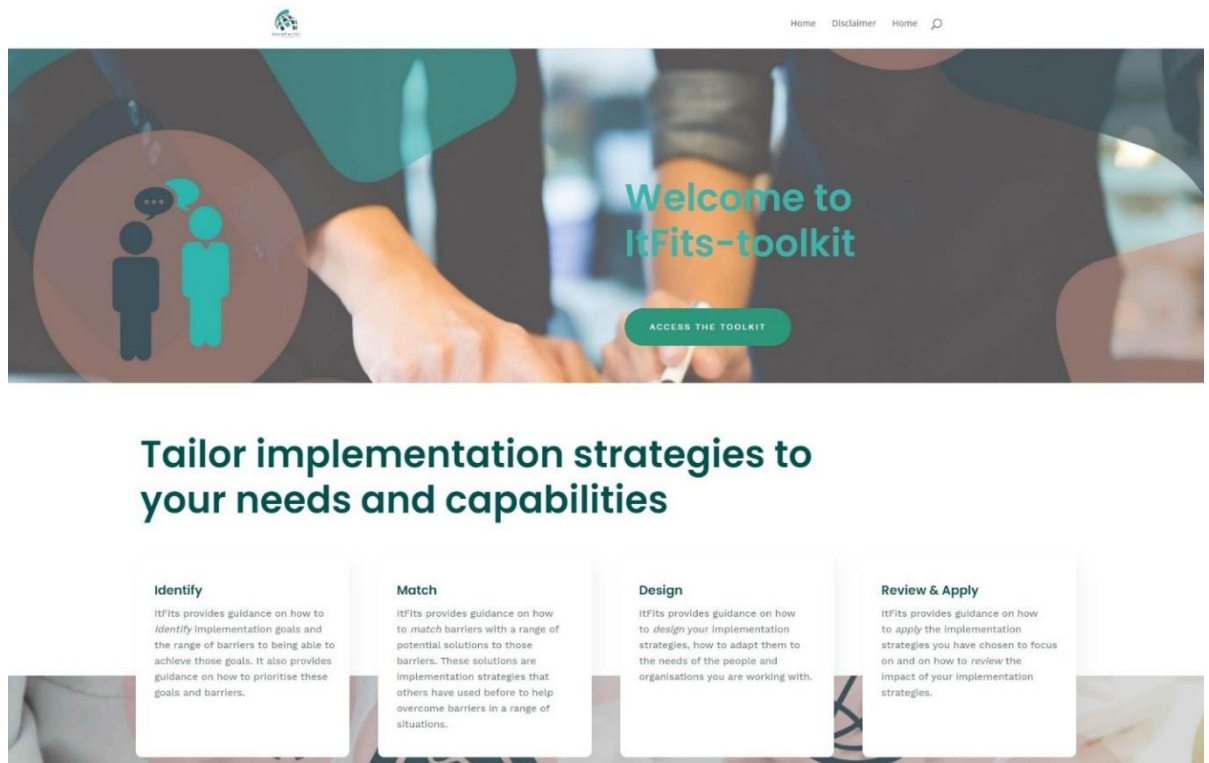
Figure 5: ItFits-toolkit landing page (www.itfits-toolkit.com)

With the finalised and accessible ItFits-toolkit in place, measures have been put in place to further disseminate the finalised toolkit and the outputs of the IMA project. This includes a snapshot document, developed by WP7, which acts as an accessible guide for potentially interested stakeholders, providing a brief overview of the toolkit, common implementation challenges, key recommendations, and more. Moreover, an explanatory video was created to introduce and demonstrate the toolkit and its underlying modules and principles. Both of these dissemination measures were released in connection with the final conference carried out online in March 2021, which showcased the toolkit and the trial results to a wide audience with 180 participants across 23 countries. The conference was successfully planned and delivered by the consortium with WP7 in the lead and all of the presentations were recorded and published for future reference and further dissemination of the toolkit and project results.

3 The future of the ItFits-toolkit

As covered within previous sections, the IMA project has successfully developed, validated, and delivered a conceptually and technically innovative and sound framework for facilitating tailored implementation. In itself, this has been an ambitious endeavour, *"…pushing the boundaries of implementation science and practice in the field of eMental health."* (D3.2). Furthermore, the unprecedented large-scale trial of the toolkit has led to the implementation of numerous iCBT interventions, benefitting patients across Europe and Australia. During this trial, the toolkit has been well received by the involved trial sites and several have already expressed interest and specific plans for using the toolkit in current and future projects. This interest has also resulted in four memorandums of understanding (MoU) with affiliated organisations that are interested in future collaborations in relation to the toolkit, two of which have already made concrete plans to utilise the toolkit in their implementation work.

Accordingly, it becomes increasingly important to look towards the future of the ItFits-toolkit, ensuring the continued use, dissemination, and development of the toolkit. To address this, relevant aspects of the ItFits toolkit's sustainability and its potential future pathways have been examined in D4.3, involving the consortium and the external advisory board. Within these discussions, four potential scenarios have been recurring in terms of establishing the necessary governance and maintenance structure around the toolkit.

- **Establishing a research community:**

  Many prefer the scenario of forming a research community around the toolkit, focused on sustaining and developing it further. This is due to the toolkit still being in its early stages, with many arguing that it requires further validation in other settings. A research community would also be a good foundation for pursuing other scenarios.

- **Establishing a separate legal entity:**

  A separate entity has also been a prevalent scenario, establishing a non-profit entity around the toolkit. Such an entity could provide a formalised structure, which supports the toolkit's further development, maintenance, and possibly guidance.

- **Hosting the toolkit within existing entities:**

  Several have voiced their preference for hosting the toolkit in one or more existing entities, which could then provide the necessary structure and resources to sustain and further develop the toolkit. To this end, some consortium members have already expressed potential interest, in terms of embedding the toolkit within their respective organisations and professional networks.

- **Open release of the toolkit for public dissemination**:

  Some have also argued for an open release of the toolkit, potentially releasing the underlying source code and content, enabling individuals and organisations to make their own version of the toolkit. To maintain some control over the toolkit and its content, a differentiated licencing agreement has been suggested.

For now, the scenario of an open release has been chosen, as the finalised and refined ItFits-toolkit has been made publicly available (https://itfits-toolkit.com/) *"…as an open resource to guide implementation processes of eHealth interventions in service organisations."* (D4.2). However, this does not exclude the pursuit of other scenarios. Accordingly, a working group has been established to continue this work to sustain the ItFits-toolkit, taking the necessary steps towards the further use, dissemination, and development of the toolkit. To that end, the first steps towards sustaining the toolkit have already been taken, securing the toolkit and its hosting and technical maintenance for the next five years.

References

ImpleMentAll Deliverable 1.1: Repository of determinants of practice and implementation interventions

ImpleMentAll Deliverable 2.1: Protocol for identification, contextualisation and implementation of determinants of practice

ImpleMentAll Deliverable 2.2: Protocol for identification and development of implementation activities

ImpleMentAll Deliverable 2.3: Final progress report on tailored implementation activities undertaken using the ItFits-toolkit

ImpleMentAll Deliverable 3.2: Final Trial Report

ImpleMentAll Deliverable 4.1: Report on specifications and requirements for optimal utilisation of the ItFits-toolkit

ImpleMentAll Deliverable D4.2: Final version of the ItFits-toolkit utilisation platform

ImpleMentAll Deliverable 4.3: Report on potential plans for the use and further dissemination of the ItFits-toolkit

ImpleMentAll Deliverable 5.1: Implementation plans

ImpleMentAll Deliverable 7.2: Implementation practices guidelines

ImpleMentAll Deliverable 7.4: Final Report on Dissemination Activities

Baker, R., Camosso-Stefinovic, J., Gillies, C., Shaw, E. J., Cheater, F., Flottorp, S., Robertson, N., Wensing, M., Fiander, M., Eccles, M. P., Godycki-Cwirko, M., Lieshout, J. van, & Jäger, C. (2015). Tailored interventions to address determinants of practice. *Cochrane Database of Systematic Reviews*, *4*. https://doi.org/10.1002/14651858.CD005470.pub3

Finch, T. L., Girling, M., May, C. R., Mair, F. S., Murray, E., Treweek, S., McColl, E., Steen, I. N., Cook, C., Vernazza, C. R., Mackintosh, N., Sharma, S., Barbery, G., Steele, J., & Rapley, T. (2018). Improving the normalization of complex interventions: Part 2 - validation of the NoMAD instrument for assessing implementation work based on normalization process theory (NPT). *BMC Medical Research Methodology*, *18*(1), 135. https://doi.org/10.1186/s12874-018-0591-x

Hussey, M. A., & Hughes, J. P. (2007). Design and analysis of stepped wedge cluster randomized trials. *Contemporary Clinical Trials*, *28*(2), 182–191. https://doi.org/10.1016/j.cct.2006.05.007

Powell, B. J., Waltz, T. J., Chinman, M. J., Damschroder, L. J., Smith, J. L., Matthieu, M. M., Proctor, E. K., & Kirchner, J. E. (2015). A refined compilation of implementation strategies: Results from the Expert Recommendations for Implementing Change (ERIC) project. *Implementation Science*, *10*(1), 21. https://doi.org/10.1186/s13012-015-0209-1

Shea, C. M., Jacobs, S. R., Esserman, D. A., Bruce, K., & Weiner, B. J. (2014). Organizational readiness for implementing change: A psychometric assessment of a new measure. *Implementation Science*, *9*(1), 7. https://doi.org/10.1186/1748-5908-9-7

Vis, C., Mol, M., Kleiboer, A., Bührmann, L., Finch, T., Smit, J., & Riper, H. (2018). Improving Implementation of eMental Health for Mood Disorders in Routine Practice: Systematic Review of Barriers and Facilitating Factors. *JMIR Mental Health*, *5*(1), e9769. https://doi.org/10.2196/mental.9769