



## IMMERSE

### Implementing Mobile MEntal health Recording Strategy for Europe

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# 1 Summary

This report describes the development process and the development activities carried out on the DMMH prototype. The DMMH prototype was developed using the TherapyDesigner platform and consists of the following system components:

- MoMent-App - a smartphone app for patient
  - Including visualizations
- MoMent-Dashboard / Management-Console - a webfrontend for clinicians
  - Including visualizations
- TherapyManager - a webfrontend for researchers to administer the study
  - Including a data export interface
- TherapyExecutor - a server backend that is responsible for the execution of the DMMH intervention as well as the data persistence

The development took place under consideration of the applicable standards for the Medical Device Regulation (MDR) compliant development, which requires compliance and documentation of prescribed processes (see chapter 2.1). In order to enable the project partners to participate continuously in the process, meetings / workshops were organised by movisens and mock-ups and functional prototypes were regularly provided to them.

## 2 Deliverable report – DMMH prototype for study

### 2.1 Process model for developing the DMMH-Prototype

In order to fulfill the requirements imposed by the MDR on a medical device prototype used in a so called ‘other clinical investigation’ a development process model was put in place. This ensures that all requirements by the researchers are correctly implemented and that the final prototype is as safe as reasonably possible to be used in the study. Figure 1 and Figure 2. show this process including the required input for each of the stages as well as produced content for the technical documentation.

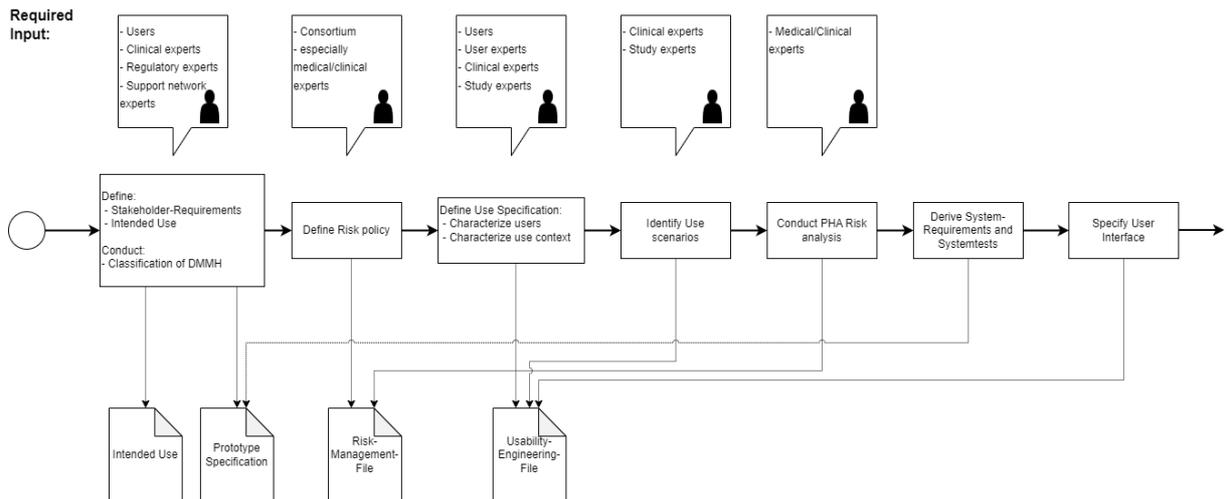


Figure 1 First part of the development process diagram depicting the stages from defining requirements over defining the risk policy as well as the user interface.

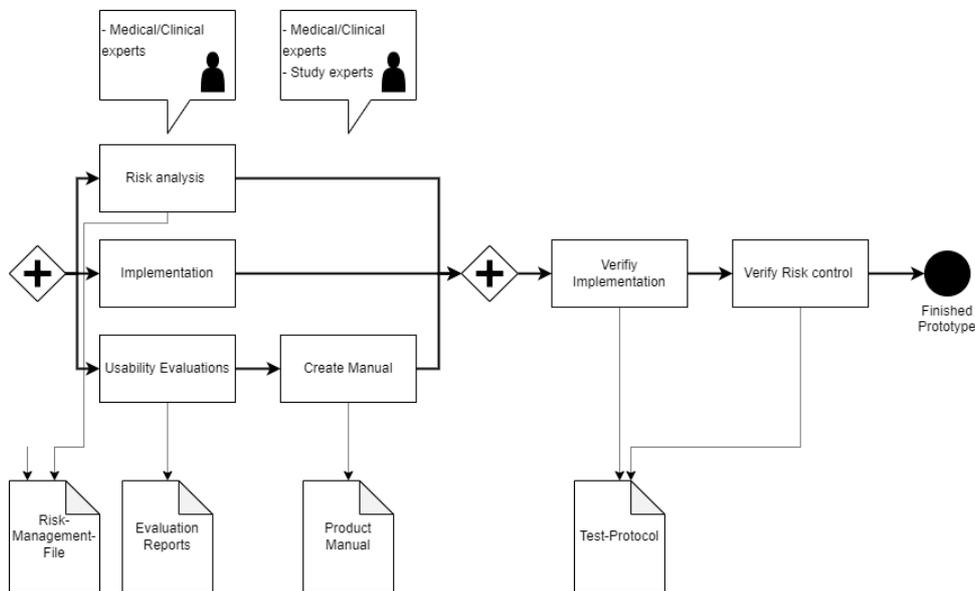


Figure 2 Second part of the development process diagram focusing on the actual implementation of the prototype as well as the parallel activities and final testing

The first part of the process starts with the definition of the intended use to define the objective intent of the DMMH-Intervention, its medical purpose, its users, its indications and contra-indications and its use context. The intended use is the foundation for further process steps, e.g. classification, risk analysis, usability and development. Based on the intended use together with the classification rules of the MDR (Annex VIII) the device was classified as an *active medical device intended for diagnosis and monitoring* of class *Ila* according to rule 11. The stakeholder requirements are also based on the intended use and are critical to later decide if the correct DMMH-Intervention was developed. Details of this will be discussed in chapter 2.2. The three documents, intended use, classification and

stakeholder requirements were created in close collaboration with WP7, WP5, WP4 and WP3 representing the stakeholders.

Afterwards the risk policy together with WP7 was defined specific for the DMMH-Intervention. Details are discussed in chapter 2.3. The next two process steps come from usability engineering and play an important role in identifying potential risks as well as providing user requirements emerging from special use contexts or user needs. The use scenarios help identifying potential hazardous functionality of the DMMH-Intervention which should then be tested as part of the usability evaluations (chapter 2.4.5).

The next step was conducting the Preliminary Hazard Analysis (PHA) as described in chapter 2.3.3. This was done in a workshop format together with WP7 and WP5 as domain experts are needed to assess situations and identify possible hazards. The PHA is done early in the lifecycle of the DMMH-Intervention as it allows for easier integration of risk mitigations compared to later on when development already started.

Afterwards system requirements and system tests were derived from the stakeholder requirements. This was done by movisens. System tests were tailored to test the fulfilment of stakeholder requirements to allow later the verification of the implementation. The last step is to define specific user interfaces. For IMMERSE these were the visualizations for the clinicians and patients all other interfaces are part of the standard interface that comes with using the TherapyDesigner-Platform. Together with WP4 and WP7 drafts of the visualizations were created so that these could be tested in the usability evaluations.

These initial process steps were all part of defining the prototype and its users. The second part of the process in Figure 2 is concerned with the actual development work, i.e. the implementation of the DMMH-Intervention with the TherapyDesigner as well as implementing the visualizations and the data export interface for the big data system. The development is guided by the defined stakeholder and software requirements. In parallel an in-depth risk analysis, requiring knowledge of the systems architecture as well as usability testing together with WP7 and WP5 was done. Results of these parallel tasks feed back into the development in the form of risk mitigations or usability issues that were translated into respective stakeholder or software requirements. After the usability tests the manual can be finalized with final screenshots helping the users to understand operating the prototype better.

After development work has been finished the implementation and risk mitigations were verified, i.e. the implementation and the risk mitigations are correctly implemented. This was done through conducting the system tests that were defined in an earlier process step. The tests that were carried out are described in more detail in chapter 2.4.5.

In order to determine if each process step was finished properly a manual review of the created documents assisted by a process specific checklist was conducted. Changes that occurred after a step was finished resulted in an additional review and analysis of the impact on later steps.

During each process step either a complete document or parts of a document were generated. Some of these documents are required for the ethics application (Risk-Management File and Test-Protocol) others are just part of the technical documentation of the prototype.

## 2.2 Requirements-Engineering

Requirements engineering is about identifying the correct requirements for the DMMH-Intervention from the stakeholders. As described in chapter 2.1 different process steps are needed to gather the all required input starting with the intended use to identify which stakeholders are relevant for the DMMH-Intervention and how they will be using the prototype under which circumstances. After the stakeholder requirements were identified the software requirements were derived from them. Lastly, the system tests were prepared in order to verify each stakeholder requirement.

### 2.2.1 Stakeholder-Requirements

After the stakeholders, clinicians, researcher, service user and movisens technician were identified we started to gather stakeholder requirements from the respective groups. The researchers were solely represented by WP7 whereas clinicians and service users were represented by WP5 and WP7 together. WP3 and WP4 contributed requirements on an organisational level, e.g. which calculations are needed for simple statistics as well as how data needs to be handled and exported. In order to gather the requirements a structured document was set up that allowed non-technical partners to formulate requirements in a way that is more familiar to them. To start with requirements an initial meeting was done with all relevant parties explaining the document and answering open questions. After the initial round of gathering information in the document a first draft of requirements, consisting of core tasks for each user group and user requirements were derived by movisens. Unclear or undefined points were flagged in the document. In a second round of collaboration on the document these open questions were clarified by the consortium partners. Points that could not be clarified at that point were collected and discussed in a separate meeting. Afterwards the stakeholder requirements were updated accordingly resulting in the deletion or replacement of some requirements.

This process led to the following list of core tasks:

- **Clinicians:**
  - Personalization of intervention
  - Discuss feedback with service user

- Export data for documentation
- Onboard service user
- **Service user:**
  - Answering ESM Questions
  - Discuss feedback with clinician
  - Personalization of configuration
- **Researcher:**
  - User management (clinician and service users)
  - First-level support
- **Technician movisens**
  - Maintenance activities
  - Technical support

Here is an example for a stakeholder requirement for clinicians, service users and researcher:

#### Researcher Requirement

<b>Title</b>	<b>Assign service user supervisor</b>
Description	A researcher must be able to assign a supervisor to an existing service user.
Id	056 Assignserviceusersupervisor
Status	Active
Requires Specification	true
Is safety relevant	false
Category	User

*Table 1 Stakeholder requirement for the “researcher” user group*

#### Service user Requirement

<b>Title</b>	<b>Notify Service user</b>
Description	The service user must be notified if an ESM questionnaire is due to be answered.
Id	008 NotifyServiceuser
Status	Active

Requires Specification	true
Is safety relevant	false
Category	User

Table 2 Stakeholder requirement for the "service user" user group

### Clinicians Requirement

Title	Intervention Customization - Clinician
Description	<p>The clinician must be able to customize parts of the intervention for a service user that they treat. They must be able to select additional items for the core module as well as for the evening module. For the core module the add-on questions will be available regarding the following topics:</p> <ul style="list-style-type: none"> <li>• Psychosis</li> <li>• Suicide</li> <li>• Substance use</li> <li>• Mania</li> <li>• Distress/Trauma</li> <li>• Eating Difficulties</li> <li>• Somatic</li> <li>• OCD</li> <li>• Emotion regulation</li> <li>• Self/Thoughts</li> <li>• Behaviour</li> </ul>
Id	003 InterventionCustomization
Status	Active
Requires Specification	true
Is safety relevant	true
Category	User

Table 3 Stakeholder requirement for the "clinician" user group

Each stakeholder requirement had a descriptive title and a unique Id in order to unambiguously identify that specific requirement. Additionally, a description for each requirement clearly states what a user must be able to do with the system. The status indicates during the creation in which status the requirement resides: “draft”, “active”, “accepted”, “deleted”. The other elements define whether the requirement needs a more detailed specification in the form of software requirements or not (Requires specification) and if it is part of a potential hazardous use scenario.

## 2.2.2 Software-Requirements

In the next step, software requirements were derived from the stakeholder requirements. Here, especially the details of the interventions were defined, i.e. which questions and variables should be recorded according to which query logic. This was the foundation work for a later implementation of the intervention with the TherapyDesigner DSL.

Following is an example of the Software requirements for the Morning Module:

### SW-001 MorningModuleSleepQuality

<b>Title</b>	<b>Morning Module Sleep Quality</b>
Description	The Morning Module asks the user to rate his sleep quality on a 7-Point Likert Scale.
Id	SW-001 MorningModuleSleepQuality
Status	Active
Linked stakeholder requirement	018 MorningModule

*Table 4 Software requirement SW-001*

### SW-002 MorningModuleTriggerTimeWeekday

<b>Title</b>	<b>Morning Module Trigger Time Weekday</b>
Description	The MorningModule must trigger at the beginning of the notification period for weekdays on weekdays.
Id	SW-002 MorningModuleTriggerTimeWeekday
Status	Active

Linked Stakeholder	018 MorningModule
--------------------	-------------------

Table 5 Software requirement SW-002

### SW-003 MorningModuleTriggerTimeSaturday

<b>Title</b>	<b>Morning Module Trigger Time Saturday</b>
Description	The MorningModule must trigger at the beginning of the notification period for Saturday on Saturday.
Id	SW-003 MorningModuleTriggerTimeSaturday
Status	Active
Linked stakeholder requirement	018 MorningModule

Table 6 Software requirement SW-003

### SW-004 MorningModuleTriggerTimeSunday

<b>Title</b>	<b>Morning Module Trigger Time Sunday</b>
Description	The MorningModule must trigger at the beginning of the notification period for Sunday on Sunday.
Id	SW-004 MorningModuleTriggerTimeSunday
Status	Active
Linked stakeholder requirement	018 MorningModule

Table 7 Software requirement SW-004

## 2.2.3 System Tests

To verify that stakeholder requirements were implemented correctly we derived system tests. For each system test we defined the following properties:

- ID
- Title
- Success criteria
- Test goal(s) and their respective acceptance criteria(s)

- Preparation
- Test steps
- Test results (documenting success of the test)

### Example of a system test

Title	Reminder
Id	Test-DMMH-11
Success criteria	<p><b>MoMent App:</b></p> <p>A reminder is triggered if:</p> <ul style="list-style-type: none"> <li>- the service user did not interact with the initial beep 10 minutes after the initial time of the beep</li> <li>- a service user stops responding in the middle of completion</li> </ul>
Linked Stakeholder	<ul style="list-style-type: none"> <li>- 025 BeepReminder</li> <li>- 036 Reminderafterinterruption</li> </ul>
Preparation	<ul style="list-style-type: none"> <li>- Login in into manager- staging.therapydesigner.com / https://manager.therapydesigner.com /</li> <li>- Open study Immerse (movisens)</li> <li>- Open the participants Overview page by clicking on the “Participants” menu item</li> <li>- Add new participant or use existing</li> <li>- Open participant</li> <li>- With app tester download and install TherapyDesigner 1.0.0 (1)</li> <li>- Couple App</li> <li>- Use screenshots to record the results</li> </ul>
Test steps	<ul style="list-style-type: none"> <li>- After a initial beep, wait 10min. A reminder notification is shown.</li> <li>- After a initial beep, enter app, start entering answer, stop in the middle.</li> </ul>

	<p>Wait for 10min. reminder notification is shown</p> <p>-</p>
Results	<p>Reminder 10 min after initial beep:</p>  <p>Reminder when stopping responding in the middle of interaction:</p>

Table 8 Example System test

We then created a traceability chart, mapping each stakeholder requirement to one of the system tests in order to make sure that all stakeholder requirements are covered by at least one system test. For the initial release of the 1.0.0 version of the DMMH-intervention we created a system verification report for which we conducted all system test and documented their results. This system verification report acts as a quality gate to release only versions of the DMMH-Intervention that satisfy all stakeholder requirements.

Stakeholder Requirement	Test
012 CreateServiceuser	TEST-DMMH-1
056 Assignserviceusersupervisor	TEST-DMMH-1
057 Createclinicianaccount	TEST-DMMH-1
003 InterventionCustomization	TEST-DMMH-3
016 KeyProblemAreas	TEST-DMMH-2
017 TherapyGoal	TEST-DMMH-2
034 Add-OnSubstanceAbuseValidation	TEST-DMMH-4
055 Exportdata	TEST-DMMH-5
007 DiscussFeedback-Clinician	TEST-DMMH-6
010 ViewFeedback-Clinician	TEST-DMMH-6
027 DaterangeforVisualization	TEST-DMMH-6
028 SelectDataforVisualization	TEST-DMMH-6
044 Displayadditionaldatavisualization	TEST-DMMH-6
008 NotifyServiceuser	TEST-DMMH 10
025 BeepReminder	TEST-DMMH-11
036 Reminderafterinterruption	TEST-DMMH-11

009 ViewFeedback-Serviceuser	TEST-DMMH-16
011 DiscussFeedback-Serviceuser	TEST-DMMH-16
002 ServiceuserOnboarding	TEST-DMMH-17
006 ChangeSupervisor-Clinician	TEST-DMMH-15
005 ChangeSupervisor-Serviceuser	TEST-DMMH-14

*Table 9 Excerpt from traceability chart between system tests and stakeholder requirements*

## 2.3 Risk-Management

An important part of the development of the DMMH intervention was the implementation of a risk management system that accompanies the software life cycle from the beginning to ensure that the developed intervention is as safe as possible for the participants. The risk management started with the definition of the risk policy, which then sets priorities in the subsequent steps of risk analysis, assessment and control. The respective steps can also be found in the process overview in Figure 1 and Figure 2. In the following sections, the risk associated process steps are presented in more detail.

### 2.3.1 Risk policy

The risk policy was defined specifically for the intervention in order to assess and manage the resulting risks as effectively as possible. The risk policy defines which of the risk classes (combination of a probability class and a damage class) are classified as acceptable and which as unacceptable. For this purpose, the probability classes and the damage class must first be derived.

To derive the probability classes, the prototypes duration of life, the number of potential users and the average number of usages of the DMMH-Intervention was defined. This was done in close collaboration with WP7 and specific numbers for each country involved in the trial was asked to provide respective information. This resulted in the 1.692.675 users in the 4 participating countries distributed as follows for each country:

- 1.292.107 (Germany)
- 161.285 (Belgium)
- 125.834 (Scotland)
- 113.449 (Slovakia)

The number of usages per person was estimated to be 722 usages per year with a life duration of 5 years for the intervention. From these numbers the total amount of uses of the intervention was calculated as 6.137.000.000. The number of users and uses in the trial are a lot smaller still to estimate the risk properly and not under- or overestimate a risk the number were taken as if the DMMH-intervention would be a product available to everyone.

From the number of uses over the whole lifespan of the prototype the probability class “Unthinkable” was defined in such a way that is actually mathematically “Unthinkable” of happening during the entire life span of the prototype. The other probability classes were defined accordingly with a distance by a factor of 1000 from each other. Studies have shown that people can best estimate probabilities when these differ by a factor of 1000.

Similarly, together with WP7, corresponding damage classes and associated binary decision criteria were derived. With the help of the binary decision criteria, damage can be clearly assigned to one of the damage classes and assignments are not open for interpretation.

The resulting probability and damage classes are as follows:

Probability category (P)		Probability*	
		[%]	
		from .....	to less then .....
<b>Frequent</b>	<b>1</b>	10%	...
<b>Occasional</b>	<b>2</b>	0,012%	10%
<b>Rare</b>	<b>3</b>	0,000014%	0,012%
<b>Unlikely</b>	<b>4</b>	0,000000016%	0,000014%
<b>Unthinkable</b>	<b>5</b>	...	0,000000016%

*Table 10 Probability classes of DMMH-Interventions risk policy.  
\*Numbers have been rounded for this report.*

Severity category (S)		According to the product
		Definition
<b>Marginal</b>	<b>1</b>	No medical/psychological intervention needed
<b>Minor</b>	<b>2</b>	Simple medical/ psychological intervention needed (e.g. contact with clinician / temporary change in medication)
<b>Moderate</b>	<b>3</b>	Complex medical/ psychological intervention needed (e.g. more intensive psychological care needed) OR Hospitalization/intensive home treatment needed
<b>Serious</b>	<b>4</b>	Long-stay residential care or supported housing
<b>Catastrophic</b>	<b>5</b>	Death of patient, user, third parties or environment damage

*Table 11 Severity classes of DMMH-Interventions risk policy*

Subsequently, from the comparison with the gold standard, it was derived which combinations of damage and probability classes are classified as acceptable. The resulting risk policy can be seen in Table 12.

Probability category's	1 - Marginal	2 - Minor	3 - Moderate	4 - Serious	5 - Catastrophic
1 - Frequent	P1S1	P1S2	P1S3	P1S4	P1S5
2 - Occasional	P2S1	P2S2	P2S3	P2S4	P2S5
3 - Rare	P3S1	P3S2	P3S3	P3S4	P3S5
4 - Unlikely	P4S1	P4S2	P4S3	P4S4	P4S5
5 - Unthinkable	P5S1	P5S2	P5S3	P5S4	P5S5

Table 12 Final risk policy for the DMMH-Intervention

### 2.3.2 Risk-Analysis

The risk analysis was carried out in different levels of detail parallel to the development. It was started during the requirements analysis with the help of the Preliminary Hazard Analysis (PHA). During the actual development and implementation of the DMMH intervention, more detailed chains of events were analysed using Fault Tree Analysis (FTA). The implementation and results of the two methods are described in the following sections.

### 2.3.3 Preliminary-Hazard-Analysis

The PHA is about identifying potential hazards as early as possible so that changes can be done early and thus cost-effective. For conducting the PHA several workshops were done with WP7 and WP5. During these workshops different techniques were used to identify potential hazards of the DMMH-Intervention. First a use-case led brainstorming was conducted in which we presented the different use cases involving either clinician and service users. For each use cases different sequences were discussed and each sequence was then scanned for potential hazards. At the end of each use case foreseeable misuse was discussed as well.

In order to think about all aspects of the prototypes lifecycle as well as applying best practices we also used the checklist from ISO EN 14971 that covers all aspects of a device's lifecycle. The potential hazards that were identified were then grouped into the categories which can be seen in Table 13.

Source	Type of Hazard	Category of hazard
PHA	Information	Notification

PHA	Information	potentially triggering Information
PHA	Performance	Treatment
ISO 14971 Table Annex C.1 + PHA	Performance	Data
ISO 14971 Table Annex C.1 + PHA	Performance	Data
ISO 14971 Table Annex C.1	Performance	Function
ISO 14971 Table Annex E.1	Operational	Function

Table 13 Identified Hazard during PHA

### 2.3.4 Fault-Tree-Analysis

During the FTA we analysed which events and especially which combinations of events could lead to the hazards identified in the PHA. This was done together with WP7 and WP5 in two workshops. These results were recorded in a mind map during the workshop and later transferred to the risk table which is part of the technical documentation.

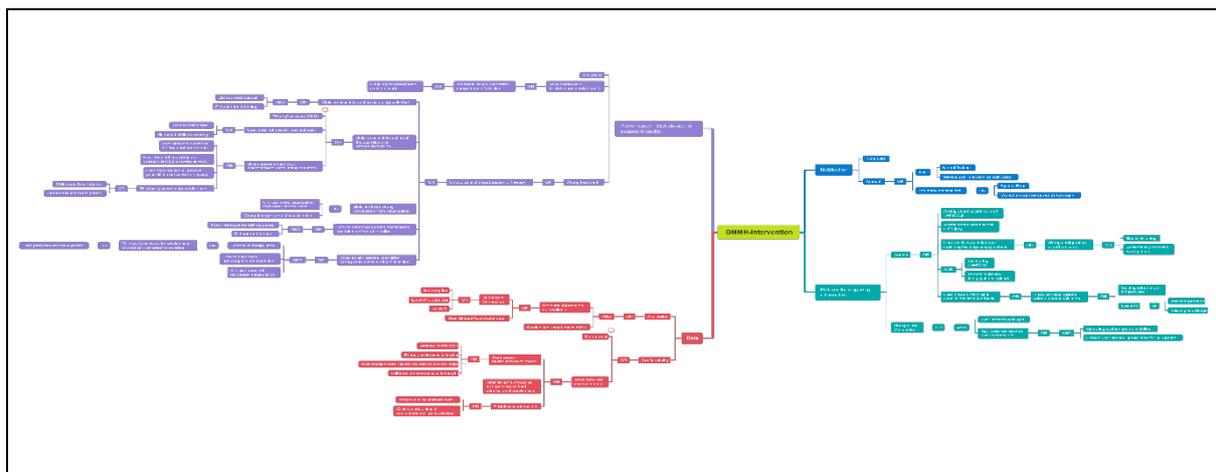


Figure 3 FTA Mindmap for documenting events and chain of events leading to hazards during the FTA-workshop

In the risk table the columns "Misconduct", "Outer chain of causes" and "Explanation of Hazard" were filled out as part of transferring the FTA results into the table. Following is an example:

External misconduct	Outer chain of causes	Explanation of Hazard
Coupling of Smartphone and Dashboard not working	1. service user observes clinician failing to couple smartphone with Intervention 2. Service user loses trust in clinician 3. Service user hesitates to respond honestly to clinicians questions	Disturbance of treatment quality - Trust relationship

Table 14 Example of FTA finding transferred to the risk table

The missing columns were filled as part of the assessment as well as defining the risk mitigation measures.

### 2.3.5 Risk assessment

Following the risk analysis, the risks were assessed by clinical practitioners from WP7 with guidance from movisens, i.e. each identified hazard was assigned a probability and damage class. Often times multiple combinations of probability and risk class were assigned to a hazard. In this way, risks can be modelled for which different harms with different probabilities can occur. The example from Table 14 was assessed like that:

Probability (DropDown)	Explanation of harm	Severity (DropDown)	Risk class	Risk acceptance
3 - Rare	Breach of trust leading to service user not feeling comfortable disclosing information anymore	1 - Marginal	P3S1	acceptable

Table 15 Assessment of an example FTA finding in the risk table

The resulting risk table before the introduction of control measures can be seen in Table 16.

Probability Classes	1 - Marginal	2 - Minor	3 - Moderate	4 - Serious	5 - Catastrophic
1 - Frequent	0	0	0	0	0
2 - Occasional	4	0	0	0	0
3 - Rare	4	9	3	0	0
4 - Unlikely	1	7	5	0	0
5 - Unthinkable	0	1	0	0	0

*Table 16 Number of risks per risk class **before** risk control measure*

The measures to minimise the identified risks are described in the next section. A final risk table after the introduction of the risk control measures can be seen in Table 18.

### 2.3.6 Risk control measures

Next, the identified risks and possible risk control measures were defined together with WP7. The goal of that action is to eliminate all unacceptable risks. A large number of measures were defined and included in the requirements. For the example in Table 14 the following measures were defined:

- Missing internet connection should be visible in the app
- Display information along QR-Code that internet connection is necessary

The measures were then checked if they introduce new hazards or risks. After that has been done all risks were reassessed and the risk table was adjusted accordingly. So the example risk from above was reassessed after mitigations to:

Probability (DropDown)	Severity (DropDown)	Risk class	Risk acceptance (DropDown)
4 - Unlikely	1 - Marginal	P4S1	acceptable

Table 17 Assessment of an example FTA finding in the risk table after mitigations

Reassessing all risks after risk mitigation measure have been defined result in the final risk table that can be seen in Table 18.

Probability Classes	1 - Marginal	2 - Minor	3 - Moderate	4 - Serious	5 - Catastrophic
1 - Frequent	0	0	0	0	0
2 - Occasional	4	0	0	0	0
3 - Rare	2	3	0	0	0
4 - Unlikely	3	14	7	0	0
5 - Unthinkable	0	1	0	0	0

Table 18 Number of risks per risk class **after** risk control measures

## 2.4 Prototype Development and Testing

### 2.4.1 Implementation of the MoMent Dashboard

The purpose of the MoMent Dashboard is to process the data of a service user (smartphone user) and to visualise it for the clinician in the form of comprehensible representations. For this the visualisation examples prototypically defined in WP4 were transferred into JavaScript with the help of Vega (a grammar for creating interactive graphics, see <https://vega.github.io/vega-lite/>) in order to integrate them into the web frontend of the TherapyDesigner platform. Furthermore, a visualisation service was implemented on the server side, which retrieves the required data from the TherapyDesigner database, prepares them according to the respective visualisations and embeds them into the Vega visualisation. For the data preparation, the following statistical analysis methods, among others, were implemented:

- Kruskal Wallis Test
- Mann Kendall Test
- Spearman Rhos
- Linear Regression

Since not all requirements for the visualisations defined in Immerse could be implemented with Vega, a proprietary container format (see Appendix) was further defined and corresponding rendering functions implemented for the TherapyDesigner webfrontend. Among other things, this container format allows individual signals to be shown or hidden and warnings or the results of statistical evaluations to be displayed.

To enable the project partners to participate in the development process, a staging server was set up and various generators for dummy data were integrated. In this way, continuous feedback could be obtained from the partners.

The following pictures show the final version of the visualizations in the MoMent Dashboard:

### Personal Therapy Goals

Below you can visualize the perceived progress in service users' personal treatment goals. This is assessed once per day, as a part of the evening questionnaire.

For each goal, two items assess the perceived progress made that day and the service user's satisfaction with the progress. This data is visualized in a line graph, in which a trend line can be added.

Test MoMent System  Original Data  Calculated Trendline  
 Mehr Sport  Original Data  Calculated Trendline

Test MoMent System  
 Calculated trend - there is **no evidence** of an increase or decrease over time. (Mann-Kendall-Test p-Value=0.8227).



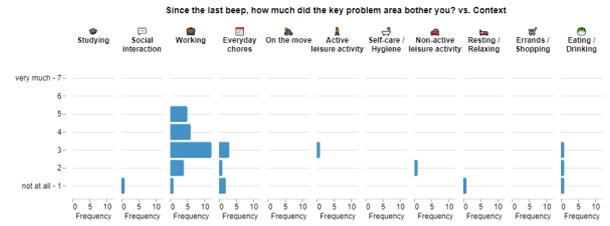
### Key Problems / Key Problems in Context

#### Key Problems in Context

Here you can visualize service-users' key problem areas, assessed throughout the day, as a part of the core module.

This data can also be visualized using vertical bar charts that show the distribution of the problem areas in the selected contexts.

Key Problem  Bugs in MoMent System



### Key Problems / Key Problems Line Chart

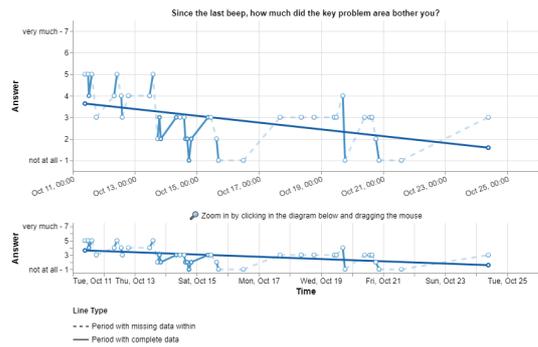
#### Key Problems Line Chart

Here you can visualize service-users' key problem areas, assessed throughout the day, as a part of the core module.

This data can be visualized using line graphs.

Bugs in MoMent System  Original Data  Calculated Trendline

Bugs in MoMent System  
 Calculated trend - there is considerable evidence showing an **decrease** over time. (Mann-Kendall-Test p-Value=0.0002).



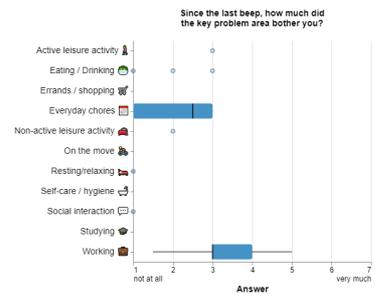
### Key Problems / Key Problems in Context Boxplot

#### Key Problems in Context Boxplot

This boxplot chart shows the distribution of the key problems within the context of each selected activity.

Key Problem  Bugs in MoMent System

Significant difference between the contexts  
 The Kruskal-Wallis test shows that there are significant differences between the contexts. The most prominent difference is observed between Working and Everyday chores.

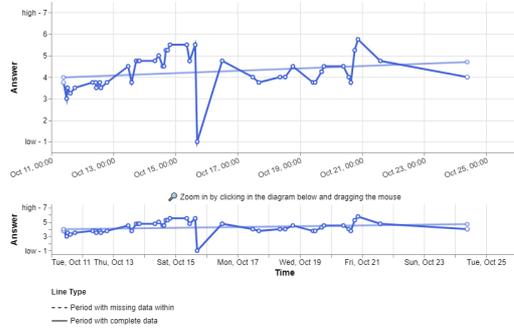


### Affects

Momentary mood is assessed continuously throughout the day, using ten different affect items, including both positive and negative affect items. In the mood graph below, the average momentary positive and negative affect is summarised for each moment. Data is displayed as line graphs showing moment to moment fluctuations in service users' mood. The graph is particularly helpful for identifying timely trends (rapid shifts or slow built ups) as well as peaks and valleys on service users' momentary mood. Specific timepoints can be explored in depth by hovering on the point of interest. A text box will then be displayed providing more information about this specific moment in time (context, activity, social context, related appraisal etc).

Positive Affect  Original Data  Calculated Trendline  
 Negative Affect  Original Data  Calculated Trendline

Positive Affect  
 Calculated trend - there is considerable evidence showing an **increase** over time (Mann-Kendall-Test p-Value=0.0057).



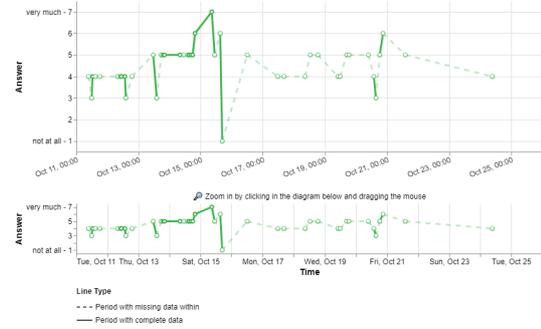
The Spearman correlation coefficient **does not** indicate a significant correlation between positive and negative affect

### Moods Line Chart

Momentary mood is assessed continuously throughout the day, using different mood items. Data is displayed as line graphs showing moment to moment fluctuations in service users' mood. The graph is particularly helpful for identifying timely trends (rapid shifts or slow built ups) as well as peaks and valleys on service users' momentary mood. Specific timepoints can be explored in depth by hovering on the point of interest. A text box will then be displayed providing more information about this specific moment in time (context, activity, social context, related appraisal etc).

Core Moods  Happy  Enthusiastic  Relaxed  Content  Anxious  Irritated  Sad  Insecure  
 Optional Moods  Tired  Stressed  Lonely  Exhilarated  Angry  Bored

Happy  
 Calculated trend - there is considerable evidence showing an **increase** over time (Mann-Kendall-Test p-Value=0.0465).



Significant correlations between core mood items  
 The Spearman correlation coefficient indicates a **significant correlation** between core mood items

#### Significant positive correlations:

- Happy and Enthusiastic
- Happy and Relaxed
- Happy and Content
- Enthusiastic and Relaxed

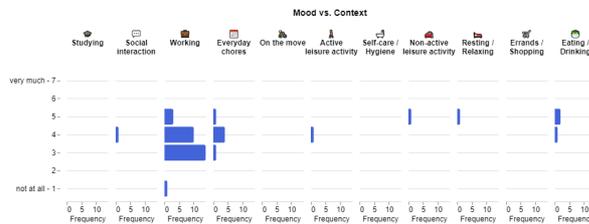
### Mood in Context

Service-users' moods often depend on the context in which the person finds themselves. The visualization below displays the mood in context graph and it can be used to examine relationships between specific moods and specific contexts. This is done by selecting (toggling) the moods and context (activity, social or location) of interest. Vertical bar charts will show the mood distribution in the selected contexts, together with a mean mood score for each context.

The visualization provided below refers both to positive and negative affect experienced by service users throughout the day and the two most frequent moods experienced by the service users and established with their clinician at the start of the DMMH intervention

Affects  Positive Affect  Negative Affect

Core Moods  Happy  Enthusiastic  Relaxed  Content  Anxious  Irritated  Sad  Insecure  
 Optional Moods  Tired  Stressed  Lonely  Exhilarated  Angry  Bored



### Mood in Context Boxplot

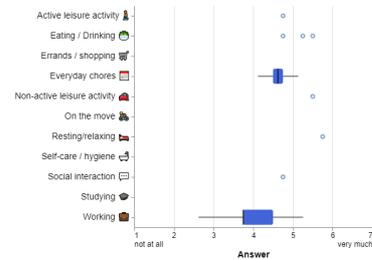
This boxplot chart shows the distribution of the affects (positive and negative) within the context of each selected activity.

By clicking on "moods" you can also visualize the specific mood experienced by the service user when engaging in each one of them.

Affects  Positive Affect  Negative Affect

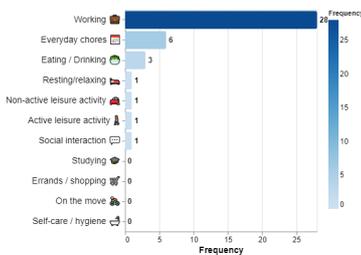
Core Moods  Happy  Enthusiastic  Relaxed  Content  Anxious  
 Moods  Irritated  Sad  Insecure  
 Optional Moods  Tired  Stressed  Lonely  Exhilarated  Angry  Bored

No significant difference between the contexts  
 The Kruskal-Wallis test shows no significant differences between contexts.



### Activity Context

An overview of the service-user's daily activities can be obtained from a ranked bar chart, summarizing and displaying the distribution of the different reported activities.



### Social Context

An overview of the service-user's daily social context can be obtained from the social context ranked bar chart, summarizing and displaying the distribution of the different reported social contexts the service-user found themselves in.

Summarized ranking of social contexts with highest appraisal is also displayed.

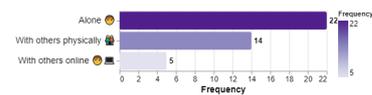




Figure 4 Visualizations of the MoMent Dashboard.

## 2.4.2 Implementation of the MoMent Management Console

Like the MoMent Dashboard, the MoMent Management Console is part of the TherapyDesigner web frontend. It allows the clinician to configure the DMMH-Intervention individually for a patient, e.g. adapt it to the patient's symptoms and/or diagnosis. The configuration options were defined by the project partner in the requirements. They include:

- The definition of up to 3 therapy goals
- The definition of up to 3 key problem areas
- The adaptation of the scheduling specifically for weekdays Saturdays and Sundays
- The activation / deactivation of approx. 80 different question items on 22 different areas such as substance abuse, self-injury, eating-difficulties, etc.

These configuration options were described declaratively in the DMMH-Intervention using the TherapyDesigner DSL [see chapter 2.4.4] and are rendered automatically on the MoMent Management

console according to the declaration. In turn, corresponding render functions had to be implemented in the TherapyDesigner web frontend.

In addition, the configuration must be validated before saving. For the DMMH intervention, the following validation rules were defined in the requirements.

- A maximum of 10 additional question items may be selected
- The scheduling period must be at least 12 hours per day.

For the validation, a service and a corresponding web interface were implemented on the server side. This enables live validation when changes are made in the DMMH-Intervention configuration. Thus, possible errors are displayed to the physician directly in the MoMent Management Console when editing the configuration and saving an invalid configuration is prevented. The following images show parts of the MoMent Management Console:

### Therapy Goals

Define up to three therapy goals for the participant. They can refer to thoughts, feelings, and/or behaviours. Each personal goal is linked to two questions that come every evening:

[Display therapy goal]

1. I feel that I made progress towards this goal today
2. I am satisfied with the progress I made attaining this goal today

Parameter	Description	Parameter Value for Participant
Therapy Goal 1	Define the 1st therapy goal	Test MoMent System
Therapy Goal 2	Define the 2nd therapy goal	Mehr Sport
Therapy Goal 3	Define the 3rd therapy goal	

### Scheduling

Schedule the time periods during which the DMMH app should interact with the service user. These should be based on the patient's **sleeping hours**. Ideally, the app should start shortly after the service user gets up and end shortly before the service user goes to bed.

Parameter	Description	Parameter Value for Participant
Scheduling Monday - Friday	Define start and end of the DMMH intervention for weekday	08:00 → 19:00 The interval is too short, there must be at least 12h in between.
Scheduling Saturday	Define start and end of the DMMH intervention for saturday	08:01 → 21:00
Scheduling Sunday	Define start and end of the DMMH intervention for sunday	08:00 → 22:00

AddOn Modules / Psychopathology / Psychosis / Positive symptoms

### Positive symptoms

This module contains items assessing psychosis (hallucinations and paranoia).

Parameter	Description	Parameter Value for Participant
Auditory hallucinations	I hear things or voices (that other people can't hear)	<input type="checkbox"/> Activate Item
Visual hallucinations	I see things (that other people can't see)	<input checked="" type="checkbox"/> Activate Item Too many items selected, please remove 2
Paranoia	I feel suspicious	<input checked="" type="checkbox"/> Activate Item Too many items selected, please remove 2
Delusion 1	I feel that others dislike me	<input checked="" type="checkbox"/> Activate Item Too many items selected, please remove 2
Delusion 2	I feel that others might hurt me	<input type="checkbox"/> Activate Item
Delusion 3 (reverse)	I feel safe	<input type="checkbox"/> Activate Item

Figure 5 A small snippet of the configuration options of the MoMent Management Console

### 2.4.3 Implementation of the MoMent App

The MoMent App serves as a user interface for the patient. It interacts automatically with the patient in the form of a chatbot according to the individual DMMH-Intervention configuration (see MoMent Management Console). For this purpose, the app offers various input and output items, such as text messages, Likert scales, multiple choice, visual analogue scale, which are presented to the patient in the form of an intuitive chat conversation. The app was developed as a cross-platform app using the Flutter framework and is available for iOS and Android. In the course of adapting the TherapyDesigner basic app to the DMMH intervention, major changes were made. This includes, among other things:

- The visualisation of graphs and diagrams in the app.
- The administration of access rights to a patient's MoMent Dashboard / Management Console via the app.
- The integration of gamification elements

Analogous to the Moment Dashboard, the visualisations for the app were also implemented using Vega. For this purpose, the interface to the server's visualisation service was extended and the service was supplemented with the necessary functionalities for specific data preparation for these visualisations. In contrast to the dashboard, however, no proprietary container format is used here, as the visualisations are embedded directly in an HTML file that is rendered by the app in a web view. In

total, 8 different visualisations were designed and implemented. The following pictures show an excerpt:

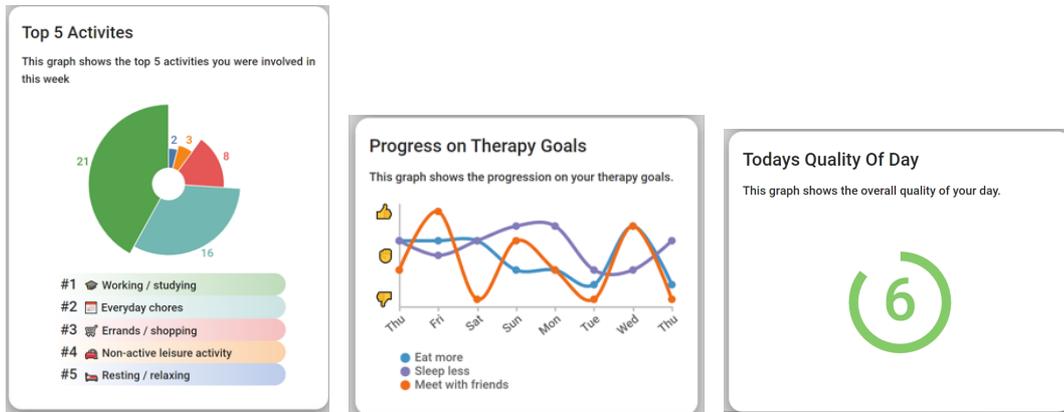


Figure 6 Visualisations for the MoMent App

Another requirement for the DMMH system was that the patients (service users) themselves can decide which clinicians have access to their personal MoMent Dashboard / Management Console. The settings of the app as well as the server-side interfaces were extended accordingly to include this functionality. The patient can now give the clinician access by scanning the clinician's personal QR code. Access can be revoked at any time in the app by deleting the user from the list.

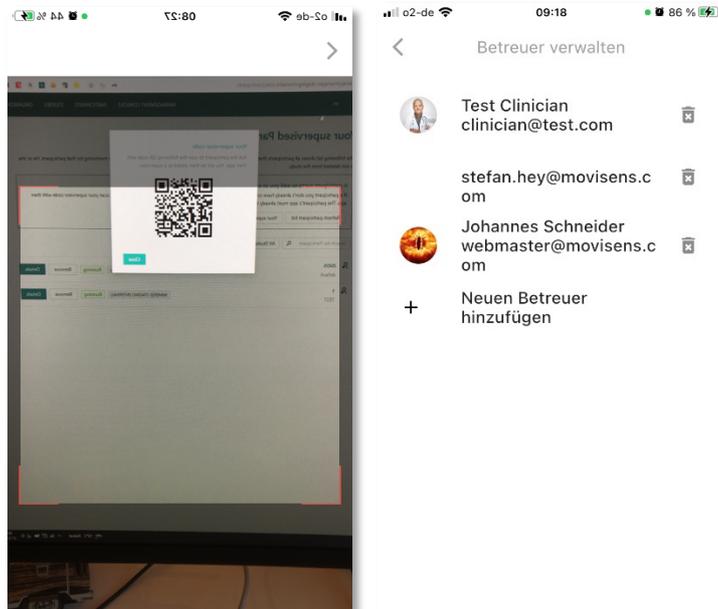


Figure 7 Administration of access rights to personal data via the app

Gamification elements were designed and implemented to improve patient compliance. The user collects points for completed questionnaires. When a certain number of points is reached, the user advances to the next level. The individual levels are represented by the growth stages of a tree. The user promotes the growth of the tree by answering the question items; the more question items he

answers, the larger the tree becomes. The graphic is displayed and animated using Lottie, a file format for vector graphics animation. For this, on the one hand a service had to be implemented on the server side, which continuously monitors the achieved score of each patient and transfers it into an animated graphic, and on the other hand the interface of the server had to be extended. In addition, corresponding functionalities had to be implemented in the app to display these animated Lottie files. The following image shows the design layout of the gamification levels:

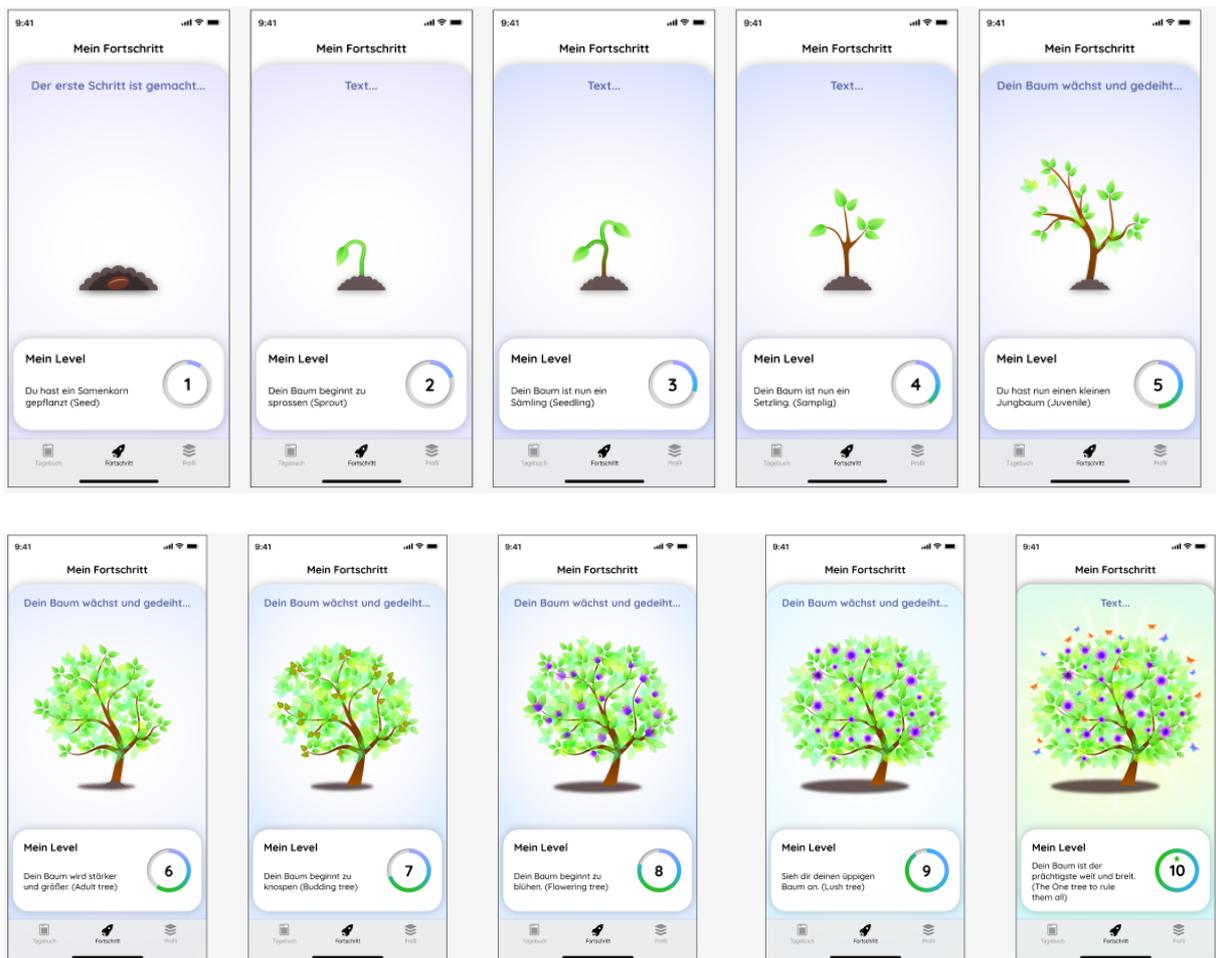


Figure 8 Gamification Levels

#### 2.4.4 Implementation of DMMH-Intervention with TherapyDesigner DSL

The main functionality of the DMMH-Intervention was realised through creating a configuration for TherapyDesigner using a domain specific language (DSL) created for that purpose. The use of the DSL allows for faster development and reduces the possibility for unwanted bugs besides providing enough flexibility to implement the DMMH-Intervention. Additionally, the DSL is open for extension which in the case of the DMMH-Intervention was used to provide a rich set of feedback via the dashboard as well as the app.

Figure 9 show the high-level overview of the DMMH-Intervention using the components provided by the TherapyDesigner DSL. The starting point of the configuration is the ImmerseTherapy where one can define different default configurations used by the other components of the Intervention (e.g. TherapyGoals, CoreModule etc.). Besides the configuration one does define which Modules to include in the therapy.

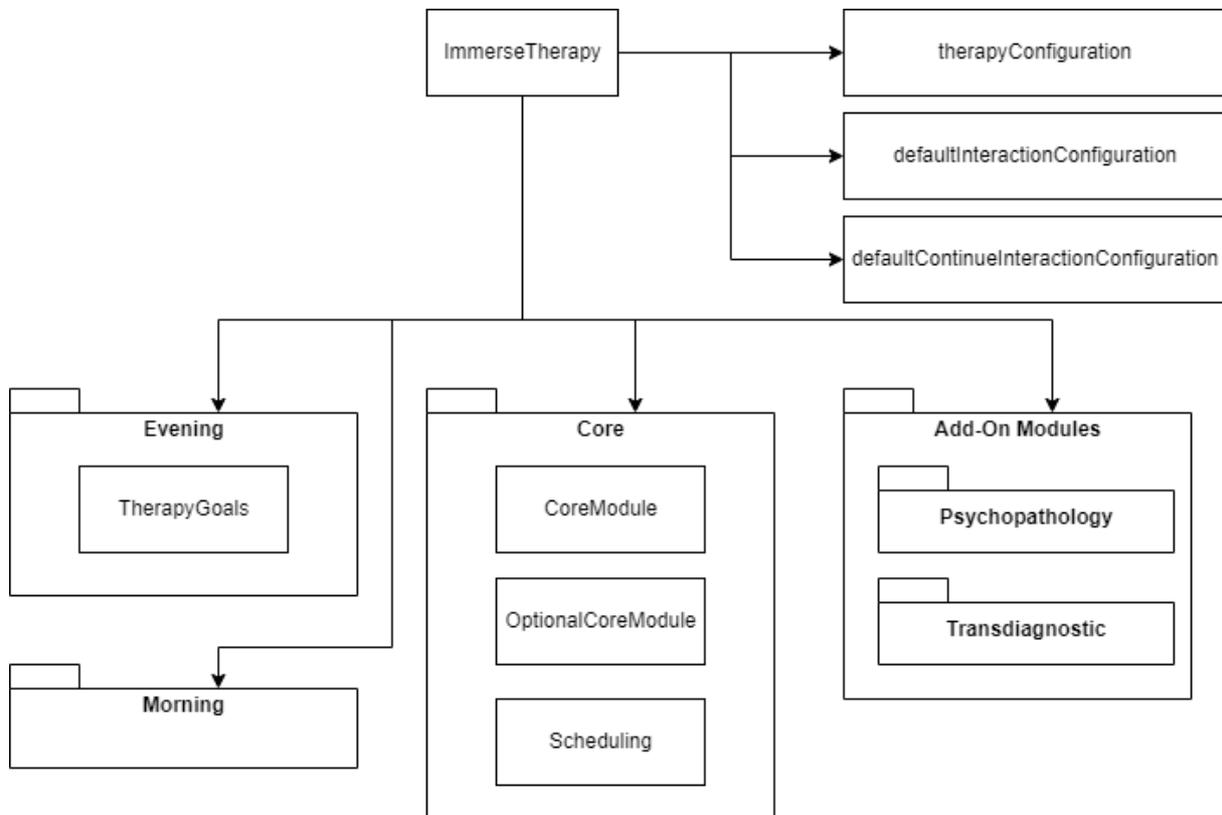


Figure 9 Overview of the DMMH-Intervention realisation using the TherapyDesigner DSL.

#### 2.4.4.1 Interaction configurations

In the interaction configuration one defines the push-notification messages and respective answers with which the participant can respond to the notification as well as the number of reminders and the validity time of a beep/questionnaire/module. Closely connected is the continue interaction configuration which defines the reminders if the participant stopped answering or missed the initial notification.

#### 2.4.4.2 Therapy configuration

More general information is defined in the therapy configuration. Here the contact and emergency information as well as initial greeting messages that are displayed during first coupling can be defined. The labelling information for the intervention are defined here too. At last the all modules are added to the therapy so they are part of the execution.

### 2.4.4.3 Interactions

The general idea of the TherapyDesigner DSL is that interactions are executed based on triggers and connected conditions. The DMMH-Intervention can be divided into three main interactions: Evening, Morning and Core. As a utility three additional interactions have been implemented to give the participant the opportunity to alter the time range in which the interactions are sent.

The DMMH-Intervention is supposed to be used with a variety of different symptoms and as not every question fits all symptoms the intervention is highly customizable via an interface with the MoMent-Dashboard. This capability of customization is achieved through the definition of the Add-On Modules which define additional questions or set of questions that can be activated by the treating clinician to match the participants needs.

The definition of an interaction consists of the definition of a set of variables, a list of triggers and an interaction consisting of different questions and displays of text. For a better understanding Figure 10 shows a snippet of the definition of the core module and its connection with other interactions.

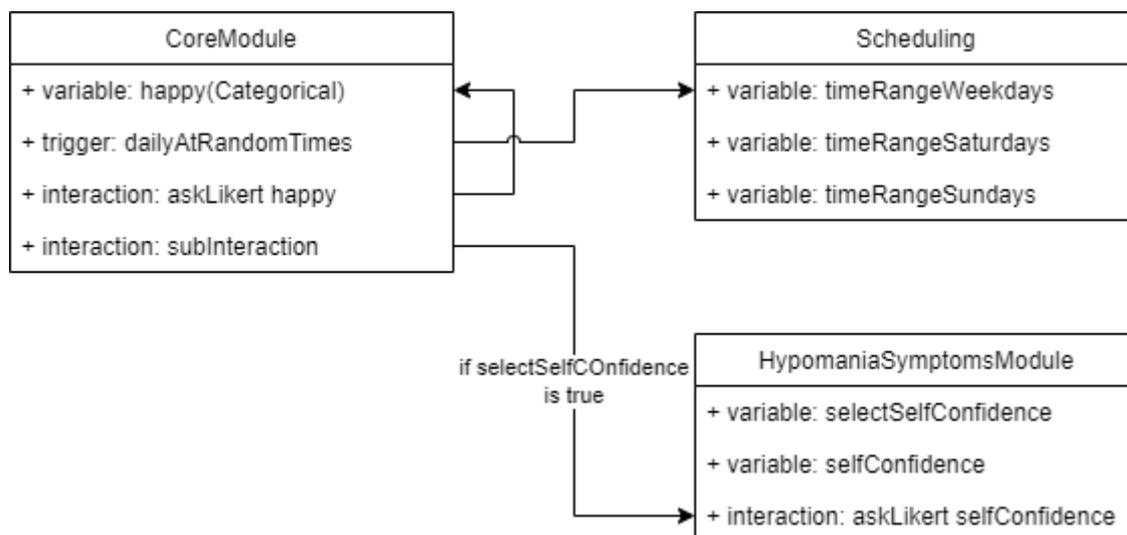


Figure 10 Small Snippet of definition of the core module and its connection to other interactions.

The Scheduling interaction defines three time-ranges for the notification periods of the DMMH-Intervention. With that definition the participant can adjust the notification period for the weekdays as well as Saturdays and Sunday separately. The triggers of the Core Module reference those variables when scheduling the beeps for the interaction. The Core Module itself defines in this snippet a categorical variable named happy and, in the interaction, it asks the participant a question and defines that the answer should be given on a Likert scale and will be saved in the happy variable. The customization of the DMMH-Intervention heavily relies on the possibility to call another interaction from within an existing interaction through a special interaction component called sub interaction. In

the snippet the sub interaction references the Hypomania symptoms module. This module itself defines a set of variables and an interaction. The “selectSelfConfidence” variable can be set via the MoMent-Dashboard. If a clinician sets the variable to true the interaction of the Hypomania symptoms module will ask the user about their self-confidence which they should estimate using a Likert scale.

## **2.4.5 Testing**

In order to meet the requirements of MDR-compliant development, extensive testing activities were carried out. This includes automated unit-, integration- and end2end testing via CICD as well as manual testing activities such as usability tests. For the Usability evaluations, movisens defined use scenarios and provided functional prototypes to the project partners. The tests were then carried out with the respective user group, evaluated and documented. Suggestions for improvement were discussed and implemented for any usability issues found. The usability tests that were carried out are briefly explained below.

### *2.4.5.1 Usability test MoMent Management Console*

This formative usability test was conducted based on the Think Aloud method at the ZI Mannheim with four clinicians. The focus of the test was the administration of the MoMent App via the MoMent Management Console. Scenarios that were tested were: Coupling / recoupling the patient's smartphone, adjusting the therapy period, adjusting the parameters (defining therapy goals and main problem areas, adjusting beep times, activating / deactivating add on items), adding additional clinicians. The test revealed minor usability issues of individual UI components, but these did not lead to critical situations that would have affected the safety of the system. However, to improve usability, improvement measures were derived and implemented where appropriate.

### *2.4.5.2 Usability test MoMent Dashboard*

This test was also conducted based on the Think Aloud method at ZI Mannheim with 3 clinicians. The focus of the test was on the visualizations of the MoMent dashboard for the clinician, which display the answers given by the patient via the MoMent App and also derived statistical parameters. It was tested if the clinicians can understand / interpret the different types of visualizations and if they are able to use the interactive charts. No serious usage errors were observed that would have affected the safety of the system. However, individual improvement measures were again derived to improve usability.

### *2.4.5.3 Usability test study administration via the Therapydesigner platform*

The focus of the test was on the account and rights management for patients and clinicians performed by researchers using the TherapyDesigner platform. The test was conducted with 4 subjects based on the Think Aloud method. Scenarios that were tested included: Creating patient accounts, assigning

patients to clinician accounts, editing patient settings, adding / removing study editors. No serious usage errors were also observed that would have compromised the security of the system. Individual improvement measures were also derived here

#### *2.4.5.4 Usability Test App*

This formative usability test was conducted based on the Think Aloud method at the university of Edinburgh with 3 students. The focus of the test was the interaction of users with the app, the initial setup and administration of supervisors, the answering of questionnaires and accessing contact information. Concrete scenarios that were part of the test were: coupling a smartphone, answering a questionnaire via notification, access emergency information, configuration of intervention, administer supervisors and Access contact resource. The test revealed minor usability issues, which did not lead to critical situations that would have affected the safety of the system. However, to improve usability, improvement measures were derived and implemented where appropriate.

#### *2.4.5.5 System Verification Test*

System verification testing has been carried out to ensure that the DMMH intervention meets stakeholder requirements. A combination of automated unit, integration and end-to-end testing as well as manual testing and document review (e.g. user manuals) was used. To ensure that all stakeholder requirements have been taken into account, a mapping from stakeholder requirements to tests and vice versa was created.

## **2.5 Screenshots**

In the following, some screenshots of the developed system from different user perspectives are shown:

1. Study administration by researchers
2. MoMent Dashboard / Management Console for clinicians
3. MoMent App for participants

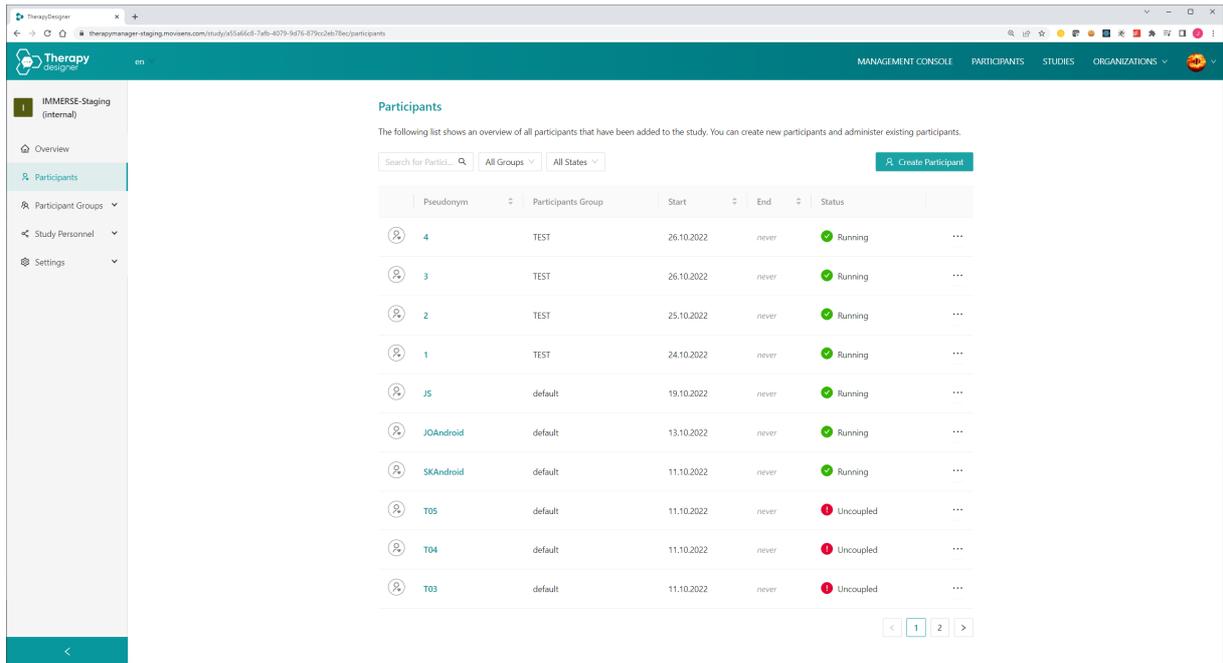


Figure 11 Study administration: administration of study participants

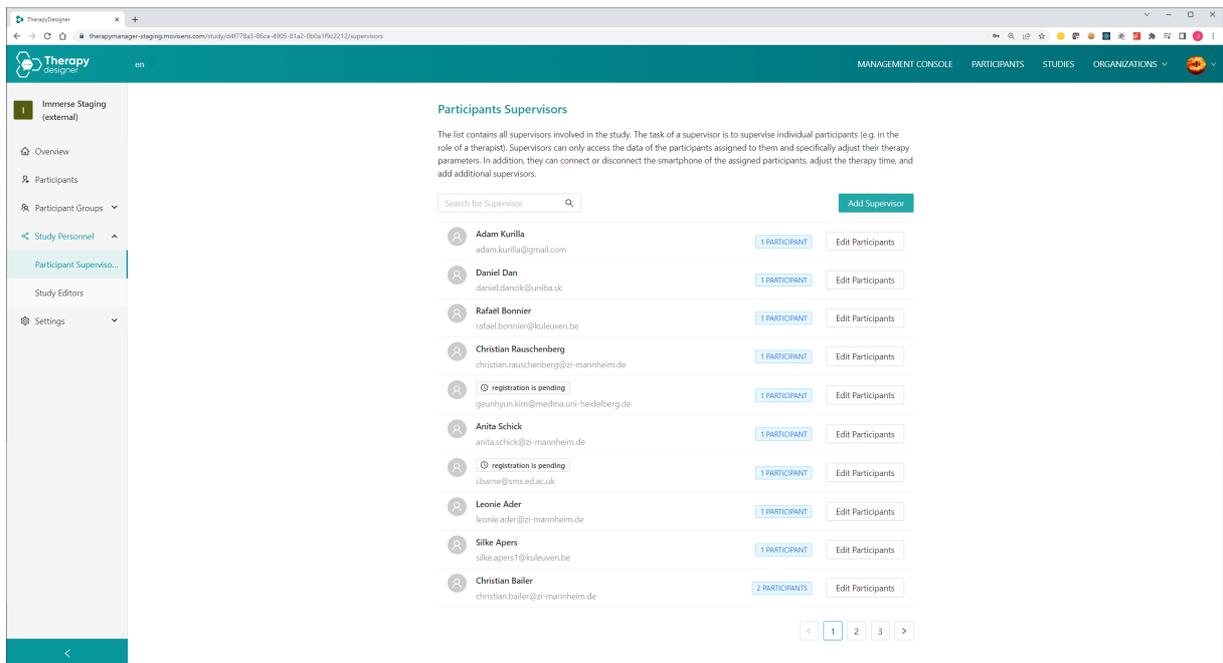


Figure 12 Study administration: administration of the study staff (clinicians, researchers) and their rights.

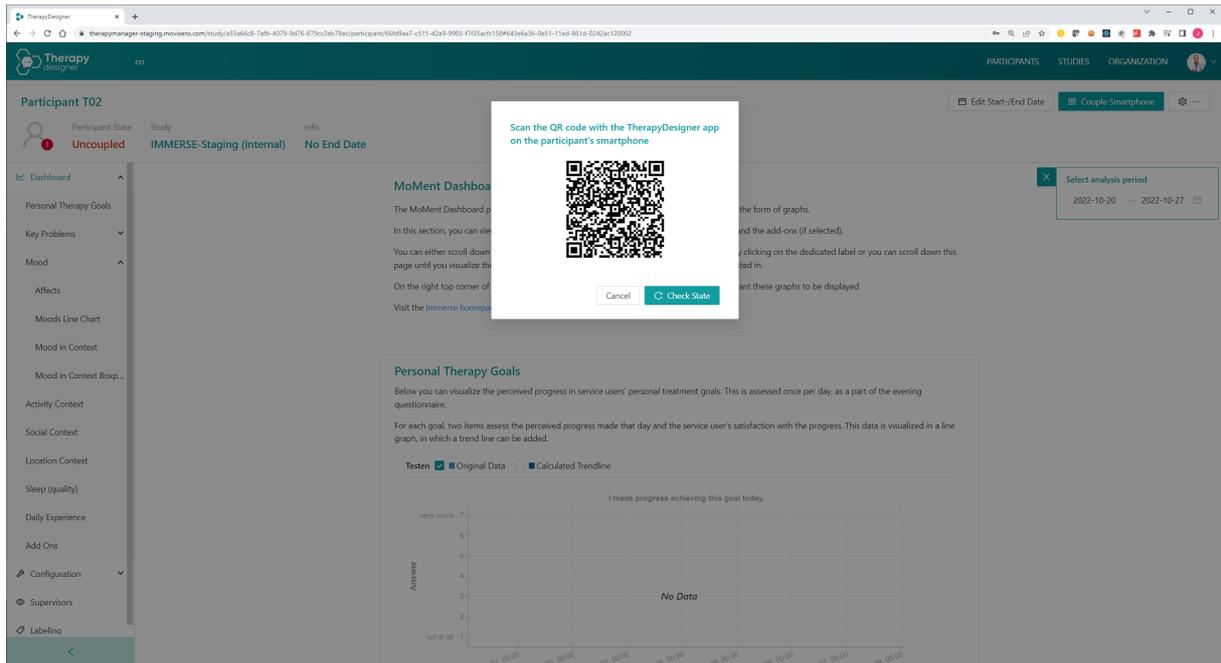


Figure 13 MoMent Dashboard / Management Console: Coupling of the participant's smartphone via QR-Code.

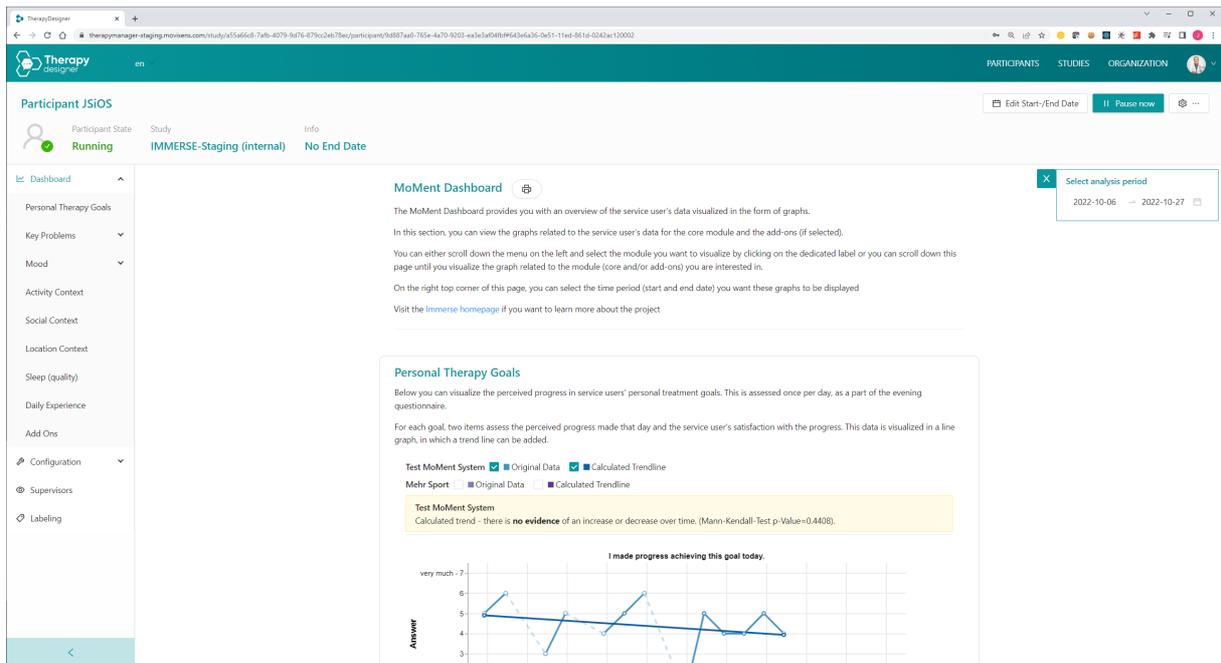


Figure 14 MoMent Dashboard / Management Console: Visualisations

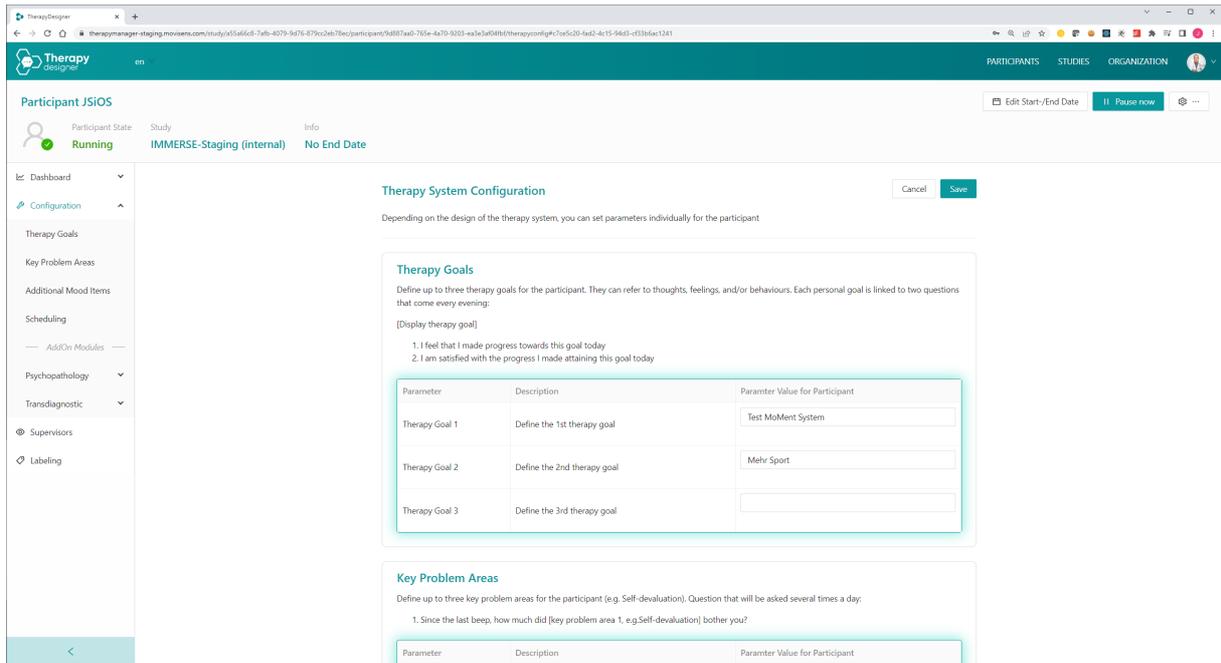


Figure 15 MoMent Dashboard / Management Console: Configuring the DMM-Intervention.

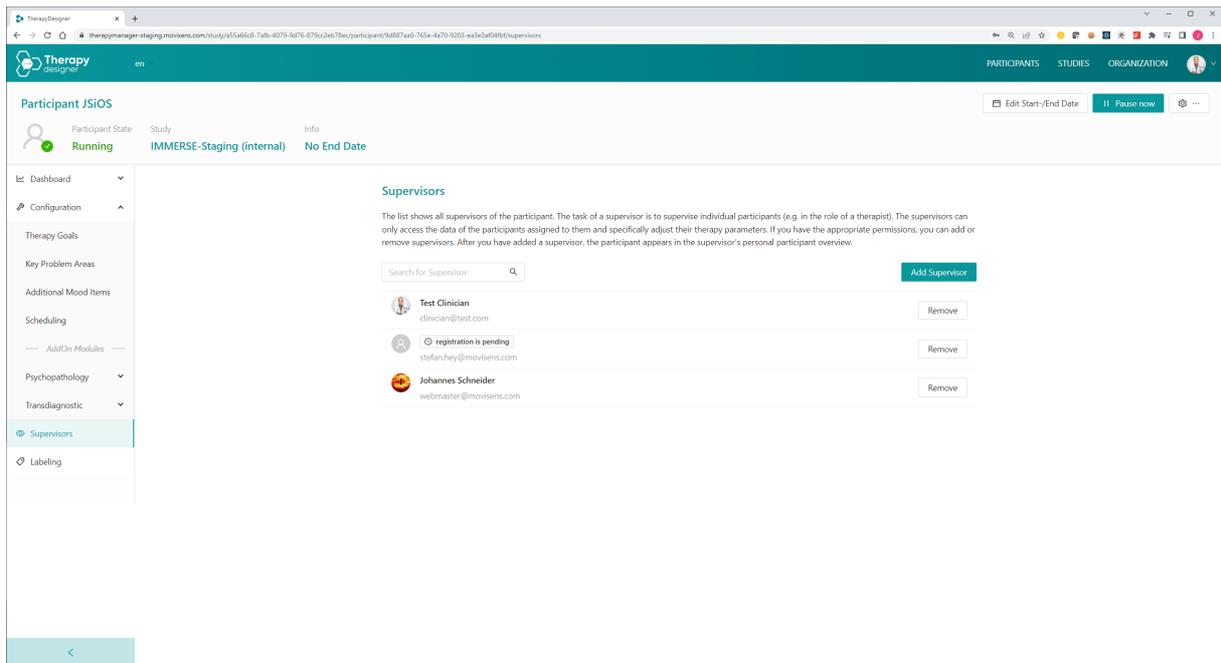


Figure 16 MoMent Dashboard / Management Console: Managing access rights to the participant dashboard

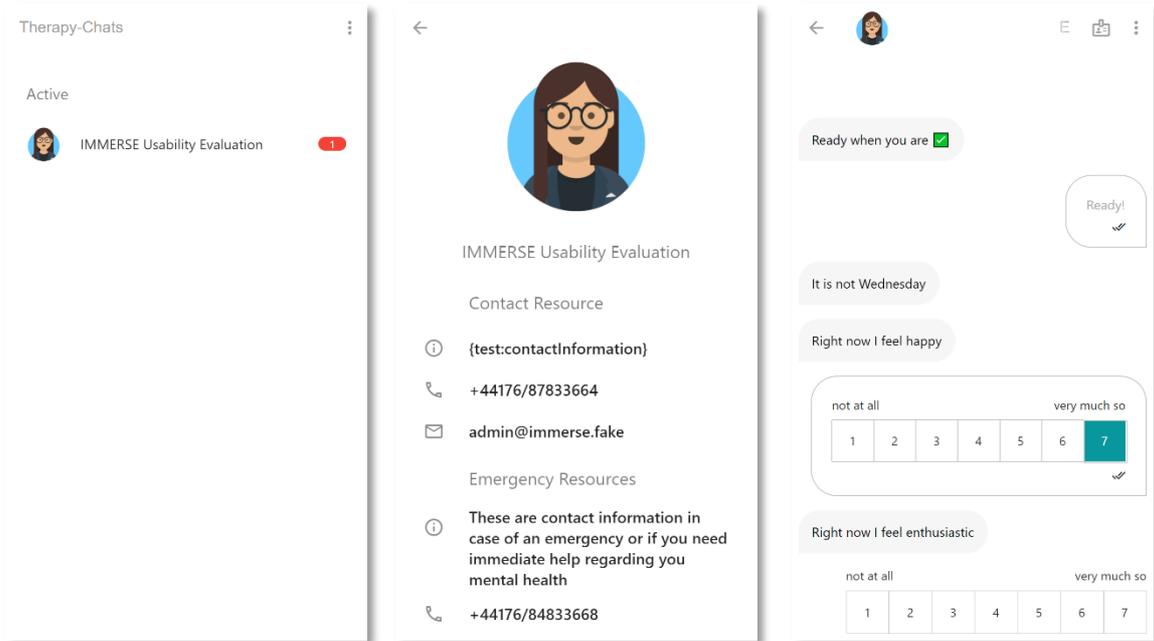


Figure 17 Screenshots of the MoMent App

### 3 Appendix

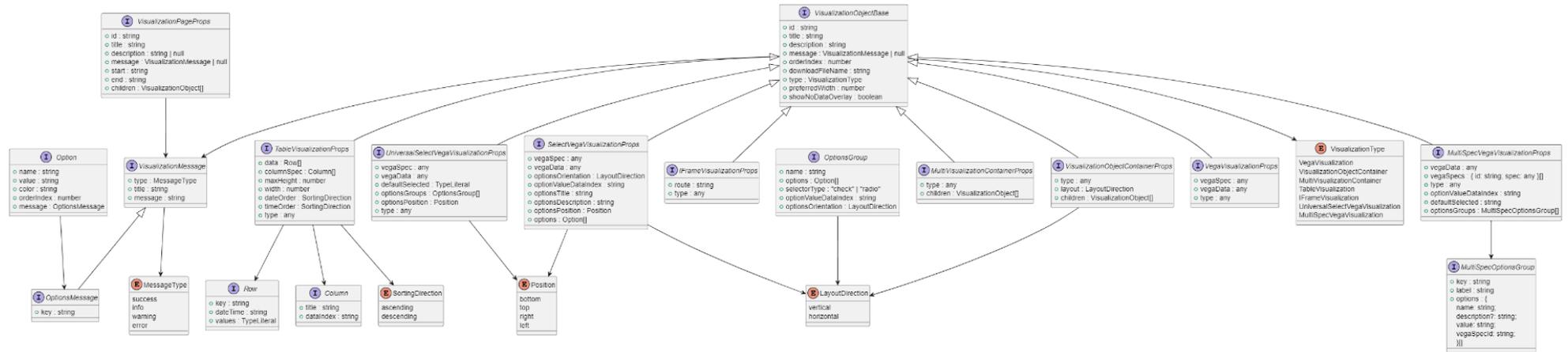


Figure 18 Container definition for visualisations