IMMERSE

Implementing Mobile MEntal health Recording Strategy for Europe

H2020 - 945263

D 7.1	**Consolidated descriptions of interventions and implementation strategies for each of the participating sites**
Dissemination level[1]	**PU**
Contractual date of delivery	30.09.2022
Actual date of delivery	31.10.2022
Type[2]	R
Work package	7
Work package lead	Ulrich Reininghaus/ Michel Wensing

Author list

Organisation	**Name**	**Contact information**
2 - CIMH	Ulrich Reininghaus, Anita Schick	Ulrich.Reininghaus@zi-mannheim.de, anita.schick@zi-mannheim.de
7 - UKHD	Michel Wensing	michel.wensing@med.uni-heidelberg.de
3 - UEDIN	Matthias Schwannauer, Simona DiFolco	M.Schwannauer@ed.ac.uk; Simona.DiFolco@ed.ac.uk

[1] **Please choose the appropriate reference:**
PU = Public, fully open, e.g. web;
CO = Confidential, restricted under conditions set out in Model Grant Agreement;
CI = Classified, information as referred to in Commission Decision 2001/844/EC.

[2] **Use one of the following codes:**
R: Document, report (excluding the periodic and final reports)
DEM: Demonstrator, pilot, prototype, plan designs
DEC: Websites, patents filing, press & media actions, videos, etc.
OTHER: Software, technical diagram, etc

1 - KUL	Inez Myin-Germeys, Glenn Kiekens	inez.germeys@kuleuven.be glenn.kiekens@kuleuven.be
5 - UPJS	Iveta Nagyova Dagmar Breznoscakova	iveta.nagyova@upjs.sk dagmar.breznoscakova@upjs.sk
4 - UKBA	Anton Heretik, Michal Hajuk	anton.heretik2@uniba.sk michal.hajduk@uniba.sk

Document history

Version	Date
1	**31.10.2022**

List of abbreviations

cRCT	cluster Randomized Controlled Trial
CONSORT	Consolidated Standard of Reporting Trials
DMMH	Digital Mobile Mental Health
NASSS	Non-adoption, abandonment, scale-up, spread, and sustainability
WP	Work Package

Table of contents

1. Summary

The deliverable "Consolidated descriptions of interventions and implementation strategies for each of the participating sites" can be delivered as expected. In month 1-18, we developed the DMMH intervention in close collaboration with other Work Packages. In parallel, we drafted implementation strategies that have been informed by participatory research in phase 1 in collaboration with Work Package 5. These include i) technological implementation strategies, ii) training and support for clinicians and service users, as well as iii) organizational implementation strategies. The consolidated implementation strategies have been optimized and adapted for each of the participating sites. WP7 members have been trained to deliver the implementation strategies and everything is prepared for the start of the cluster randomized controlled trial.

2. Deliverable report

D 7.1 Consolidated descriptions of interventions and implementation strategies for each of the participating sites

2.1 Introduction and relationship with other work packages

In the scope of IMMERSE we developed implementation strategies as methods and techniques aimed at supporting and enhancing the sustainability of the DMMH intervention. In month 1-18, a detailed, factual description of the DMMH intervention and implementation strategies 'as planned' was tailored to, and optimized based on, the requirements of each site in Work Package 7 (WP7) in close collaboration with other WPs. The Template for Intervention Description and Replication (TIDieR) checklist (Hoffmann *et al.*, 2014) has been used to develop the material and promote the reporting of procedures and activities used in the intervention for future research and implementation.

In the current deliverable report, we will describe the intervention (see section 3) as well as the implementation strategies (section 4) as well as their tailoring to individual sites (section 5) before drawing conclusions from our work in M1-18.

More specifically, members of WP7 developed the following three main implementation strategies:

I) *technological implementation strategy*

As a technological implementation strategy, we advised on the creation of the information technology system adhering to prevailing standards and regulations by WP2. For this purpose we contributed to the requirements document, describing the technology system. We participated in the validation tests and provided feedback on the prototype and confirmed that it met our requirements. We participated in the Risk Management Workshop by WP2, and provided feedback on the development and visualizations of the DMMH system in collaboration with WP4.

II) training and support for clinicians and service users

We developed educational material that included a manual, workshop material, cheat sheets, support and web content. These key implementation strategies were validated by initial findings from the survey and interview study conducted in collaboration with WP5 (see D 5.1). The material has been reviewed by WP2.

III) *organizational strategies*

On the organizational level we set up regular meetings with head of departments in order to facilitate the implementation of the DMMH intervention.

These implementation strategies have been tailored to individual needs of the participating services and informed by the participatory study in collaboration with WP5. By addressing the needs of each different healthcare setting involved we aim at a smooth implementation of the intervention.

3. Description of the consolidated DMMH intervention

The "DMMH-intervention" is a Web- and App-based software system that monitors the service user's momentary mood, current symptoms, activities, context, therapy goals and key problem areas using Experience Sampling Methodology (ESM). The intervention is intended to enhance engagement with services (primary endpoint). Drawing on the results from Phase I (participatory study in collaboration with WP5), and the expertise of the wide IMMERSE consortium in conducting research projects in the field of digital mental health, a prototype of the DMMH intervention was developed. This went through an iterative process to capture the needs of services users, clinicians, and administrators and the possible barriers and facilitators to the implementation of the DMMH across the four different countries involved, acknowledging also the researchers' input to prototype. The technology system has been tested in usability tests with stakeholders (i.e. clinicians and service users) at different sites and information from this evaluation has been integrated in a refinement and adjustment of the DMMH intervention. For further information on the technology system, please refer to deliverable report D 2.1.

3.1 Intended purpose of the device

The "DMMH-intervention" is a Web- and App-based software system intended to improve engagement with mental health services, personal recovery, self-management, shared decision making, personalized therapy goal attainment, social functioning, social participation, mental health, and quality of life in service users with mental health problems through monitoring their momentary mood, current symptoms, activities, context, therapy goals, and key problem areas in daily life using ESM. The data collected through ESM monitoring forms the basis for textual and visual feedback presented to clinicians and service users to support

clinical decision making and routine outcome monitoring. It provides insights for service users and clinicians into key patterns of service users' momentary mental state in relation to their activities and social context in daily life.

3.2 Basic Technical Principle

The DMMH intervention is built with a client-server system architecture. This implies that the App is not standalone but allows for more control over the interactions between the service user and the intervention. The system uses Experience Sampling Methodology (ESM) to collect momentary data about mood, current symptoms, activities, personalized therapy goals and key problem areas of the service user in the context of daily life (as part of the core questionnaire). It also allows the clinician to configure additional ESM items to meet the service users' needs and address their symptoms. The system generates visual feedback (graphs, tables, gamification scores) based on ESM data to support clinical decision making and routine outcome monitoring. The clinician receives feedback that should be discussed with the service user together. Additionally, the service user receives visual feedback in the app that is adapted to the expected capabilities of the service user.

3.3 Implementation

We will implement the DMMH intervention in the scope of a cluster randomized controlled trial (ISRCTN15109760). The DMMH intervention will be applied in service users, who are seeking help for mental health problems, deemed sufficiently unwell to be accepted for specialist mental health treatment, and, therefore, in contact with local inpatient, outpatient or community mental health services. Service users will use the system components of the DMMH intervention with their treating clinicians providing care and being in charge of treatment for included service users in one of the 24 clinical units at the participating clinical sites. Both service users and clinicians will be provided with training and support (i.e., tailored information, counseling, and reminders for service users; support package for clinicians). Service users and clinicians do not require having prior experience with ESM-based monitoring and feedback. The DMMH intervention is based on the state-of-the-art of ESM-based monitoring/feedback and will be offered in addition to treatment as usual, which includes good standard care delivered according to local and national service guidelines (i.e., according to the state of the art in clinical care in the relevant field of application of the DMMH) and protocols by their general practitioner, psychiatrist and other members of the mental health care team. The proposed benefits of the new device include enhanced service engagement, personal recovery, self-management, shared decision making, personalized therapy goal attainment, social functioning, social participation, and quality of life as well as reduced mental health problems.

4. Description of the consolidated implementation strategies

Based on results from the participatory field study (see D 5.1), we generated an a priori assessment of anticipated barriers and facilitators that may influence implementation using the Non-adoption, Abandonment, Scale-up, Spread, and Sustainability (NASSS) framework

(Glasgow *et al.*, 1999). The NASSS framework has been specifically proposed for investigating the implementation of novel technologies and was used to optimize the DMMH intervention and implementation strategies with regard to the 7 domains:

1. the condition or illness (i.e., a mental disorder),
2. the technology,
3. the value proposition,
4. the adopter system (comprising professional staff, service users, and informal caregivers),
5. the organization(s),
6. the wider (institutional and societal) context, and
7. the interaction and mutual adaptation

The analyses of interview and survey data is still ongoing, however initial results informed the selection of implementation strategies for service users and clinicians (see section 4.1 to 4.3).

Treating clinicians and service users in clinical units allocated to the experimental condition will receive the implementation strategies after random allocation of clinical units to experimental and control condition, and after completion of the baseline assessment for the duration of the 6-month intervention period. After the 6-month intervention period, implementation strategies for service users and clinicians requiring active support by the research team will be discontinued.

All developed material went through an iteration process and received feedback from Consortium members, which embedded previous research experience in the field in this production. Moreover, feedback was also sought from some of the clinicians at the different study sites and from patients advocacy groups to allow its implementation for future use.

4.1 Technological implementation strategies

As a technological implementation strategy for shared decision-making, we created the information technology system adhering to prevailing standards and regulations in collaboration with WP2 (see section 3). Over the course of the trial, we will offer ongoing technological support to clinicians and service users. For this purpose, we will offer phone or on site support (see section 5).

4.2 Implementation strategies for clinicians

Based on results from phase 1 (see Deliverable D 5.1), a workshop was one of the preferred ways to learn how to use a new technical device. Thus, we will offer clinicians from clinical units randomized to the experimental condition to participate in a training/ workshop. The workshop will be adapted to local needs (see section 5) but the minimum content of the workshop has been agreed upon across sites. For this purpose, a slide set has been developed and translated to the languages of the Consortium. The workshop should take at least 1 hour and may be delivered in person or using a videoconference tool. The workshop may be recorded and the recording may be made available e.g. on the web page. There will be the option of refresher workshops or individual training sessions.

Although results of phase 1 indicated that a manual was not the preferred tool to use by clinicians in some countries (see D 5.1), we drafted a manual in addition to the Information For Use. From a scientific perspective it is necessary to manualize the intervention. The manual has been developed in line with the TIDieR checklist (Hoffmann *et al.*, 2014) and CONSORT guidelines. As we plan a publication of the manual, the document cannot be added to the annex of this deliverable report. While the Information For Use describes the use of both, app and dashboard, the manual focuses on the hands-on use of the dashboard and depicts screenshots of all steps for integrating the DMMH into clinical care. The manual will be provided as a pdf or printed version (see section 5). By using the search function the manual may be one option of asynchronous support, i.e. in case clinicians have questions after business hours.

In addition, we developed a quick guide or cheat sheet for clinicians. This one paged document illustrates the step-by-step procedure to start and use the DMMH (see Annex A). Using a cheat sheet has been indicated to be very important in two countries and important in the other two participating countries based on the phase 1 survey (see D 5.1).

At the workshop, clinicians will receive a support package that entails the Information For Use, the manual and the cheat sheet. In addition, this material is hosted at a dedicated section on the public website www.immerse-project.eu which also includes video instructions and frequently asked questions.

Over the course of the trial, we will provide clinicians with monthly feedback (i.e., 'key performance indicators' on use of DMMH app/dashboard by clinicians, the number of service users seen/included, the number of sessions conducted with the service users and the duration of the sessions).

Furthermore, clinicians will be offered help and support by research staff. This may be implemented by phone check-ins or via email support. As indicated in phase 1, clinicians rated help by a colleague to be a very important implementation strategy (see D 5.1).

4.3 Implementation strategies for service users

For service users we developed a well-balanced manualized package of tailored information, counseling, and reminders to motivate and enable them to use the DMMH. In addition to the Information For Use that describes the use of the DMMH intervention, further material is available on the website. This material includes frequently asked questions and videos showing the interaction with the device. In each clinical site, a named individual will be available for users to address technical questions about the DMMH intervention.

4.4 Organizational implementation strategies

The practical implementation will be carefully prepared and planned in workshops and further contacts with leading clinicians, managers and directors at each of the sites. In months 1-18,

we scheduled two meetings for clinical leads to meet with members of the Consortium. The first meeting was in June 2022 to present the finalized design of the randomized controlled trial and the second was held in September 2022 to inform about the status of receiving ethical approval.

In addition, meetings with departmental and clinical leads were scheduled to disseminate information about the study and the DMMH intervention. In total, we documented 42 contacts across sites using a multiple choice item. Most of the contacts were with clinical leads (30; 71%), followed by contacts with managers (15; 36%). There were also 3 contacts with representatives of service users and one with representatives of the public. In most cases, the contacts have been meetings, and 3 contacts have been via email communication.

Once the delivery of the DMMH intervention has been rolled out, we will send out newsletters to clinicians and heads of departments. Using the DMMH data, we will generate monthly feedback reports (with numbers on included patients and completion rates) for leading clinicians/managers, who are responsible for the implementation in order to remind and motivate them. These feedback reports may be included in a quarterly newsletter to the interested public. We prepared scripts to quickly generate and update these feedback reports.

The organizational implementation strategies will cover at least the following aspects:

1) one or two named individuals will be asked to organize the practical/logistical uptake of the DMMH intervention in clinical practice (e.g. a study nurse, research assistant);

2) the line manager/clinician who is responsible for DMMH implementation will be identified;

3) we will also explore whether there are local clinical opinion leaders for the DMMH intervention (through the workshops) and, if present, involve them in the communication and training activities.

5. Tailoring of implementation strategies to individual sites

The implementation strategies will be standardized across sites, as far as possible, but allow for some variation between sites and flexibility in their application during the intervention period. In the following, we describe the adaption and optimization of implementation strategies per country.

5.1 Germany: Investigating centers Mannheim and Wiesloch

Based on our experience with a pilot study where we also trained clinicians in the use of a dashboard, we prepared material for the workshop. We contributed to the development of the general slide deck and then translated the slide deck to German. We trained our staff in conducting the workshop and held two mock workshops with colleagues.

At the CIMH, the workshop with clinicians is conducted as an on site training for up to 10 clinicians. These clinicians may be working at different units. We may repeat the workshop in several months and provide refresher sessions if required. In addition, we offer digital workshops using videoconference tools. The advantage is that also clinicians from units that are in different clinic buildings could participate without commuting to the seminar room in the main therapy building at CIMH. Clinicians at PCN preferred an on site workshop as well. If participants agree, the workshop will be recorded and be made available on our study webpage for later use by clinicians. For the practical session in the workshop, we will use tablet computers and provide a study smartphone with the MoMent app, so that clinicians can directly work on exercises. Participants of the workshop will receive a certificate of attendance.

The supporting package for clinicians at the German sites further includes the Information For Use and the clinician manual. We translated and adapted the manual for clinicians to our local needs. For this purpose, we created screenshots of the German dashboard. In order to address local needs, we printed the manual but it is also available on the website and will be shared with participants of the workshop as a pdf file. In addition, participants at the workshop will receive a one paged cheat-sheet. The draft of the cheat-sheet has been reviewed by all WP7 contributors as well as WP2 and then translated.

We identified staff that will provide support to clinicians and service users at both sites. The contacts of this supporting staff have been made public on the website, the manual and other material. In meetings with clinical leads we introduced this staff and they introduced themselves in a welcome email to all clinicians in the experimental condition. This has also been based on results of phase 1 (see D 5.1) where across countries help and support by a colleague was rated to be very important.

5.2 Belgium: Investigating centers Leuven and Bierbeek

Based on the IMPROVE pilot study where we trained 12 Belgian clinicians in the use of an ESM-tool and a dashboard during a one-hour online training session. The training materials used in IMPROVE were revised and adapted to fit general needs for IMMERSE. The general IMMERSE material got translated to Dutch. In a subsequent period we trained our staff in conducting the workshop and held one mock workshop with colleagues and clinicians. Also based on results of phase 1 (see D 5.1) where support by a colleague was deemed very important and in response to feedback from the mock workshop and the clinician's feedback from the IMPROVE study, we extended the material for the workshop to fill 4 hours and include more hands-on sessions and live enactment of mock cases. To fit the schedules of Belgian clinicians, two to three workshops will be organized to which the participating clinical staff can subscribe. These workshops will be organized per hospital with groups consisting of personnel from the different experimental units. In this way we think to encourage clinicians for participating in the IMMERSE study, as they meet the other team members involved in the study.

5.3 Scotland: Investigating centers Lothian and Lothian CAMHS

Drawing on experiences from previous studies conducted here in the UK, we trained clinicians in the use of the DMMH intervention, including the MoMent App and the Dashboard during a MSTeams online training session which lasted approximately one hour. The training consisted in a Powerpoint slides presentation where we covered information of the DMMH, the clinical reason to use it, how to access both the MoMent App and the Dashboard, and how to deliver the feedback to the service user in the therapeutic session and to interpret data. We planned 4 workshops sessions with each unit allocated to the experimental condition (2 adults mental health, 2 children and young people). In response to the local needs of our clinicians, we offered one-to-one training sessions to those interested to participate but who could not attend the workshop. We also offered a following refresher session on the use of the DMMH to allow all participating clinicians time to go through presented material, familiarize with it, and get back to us with questions and requests for additional support should this be needed.

5.4 Slovakia

5.4.1 Investigating center: Bratislava

In cooperation with other sites we prepared materials for the workshop. We contributed to the development of the general slide deck and then translated the slide deck to Slovak. Slides were adapted to reflect more experience and knowledge of clinicians. We also translated and adapted the manual for clinicians to our local needs. The manual is available on the website and we shared it with participants of the workshop as a pdf. A one paged cheat sheet was developed and translated. It was also shared with participants at the workshop. All materials were provided as a clinician starter package.

In Bratislava, the workshop with clinicians was conducted as an on site training for 6 clinicians and took 1 hour. These clinicians worked in one large department but they differ in the their roles at the department. Prior to the workshop, we met with all involved clinicians individually and helped them to set up their Therapy Designer account in advance, so they were able to see it and familiarize themselves before we were providing instructions during the workshop.

For the practical session in the workshop we used laptops, so that clinicians could directly work on exercises. Participants of the workshop received a certificate of attendance.

5.4.2 Investigating center: Kosice

We have prepared all the necessary educational materials required for workshop conduction. Those were translated and adapted from general documents made by members of WP7. The main component of these materials was a manual for clinicians, which involved all specific information and procedures needed for efficient usage of the Moment app and Dashboard. An additional part was a cheat sheet for clinicians which summarizes the most important knowledge for usage.

We conducted the workshop for all clinicians who participated in phase II., where they were invited to use the clinicians' Dashboard and Moment app, solve the basic problems which can happen during the monitoring phases, and taught the elementary procedures. After the workshop, we also conducted individual interviews to clear possible misunderstandings.

To all clinicians, we offered follow-up meetings as long as some of them consider it is needed for the correct setting and progress in the trial.

Table 1. Overview of tailored implementation strategies per site

Site	**Tailored implementation strategy**
Mannheim	1 hour- workshop in person and remote, recording of workshop, access to slides of the workshop, IFU and pdf manual, printed cheat sheet, website, dedicated support staff,
Wiesloch	1 hour- workshop in person and remote, recording of workshop, access to slides of the workshop, IFU and pdf manual, printed manual, printed cheat sheet, website, dedicated support staff
NHS	Remote workshop (1h), refresher workshop or one to one training, IFU, clinicians manual, cheat sheet, website, service user manual, dedicated support staff
NHS-CAMSH	Remote workshop (1h), refresher workshop or one to one training, IFU, clinicians manual, cheat sheet, website, service user manual, dedicated support staff
Leuven	4h workshop, IFU, clinicians manual, cheat sheet, website, dedicated support staff
Bierbeek	4h workshop, IFU, clinicians manual, cheat sheet, website, dedicated support staff
Bratislava	1 hour workshop, IFU, pdf manual for clinicians, cheat sheet, website, dedicated support staff
Kosice	1 hour workshop, IFU, pdf manual for clinicians, cheat sheet, website, interviews after workshop, follow-up meetings with clinicians, dedicated support staff

6. Conclusions

The deliverable 7.1 has been delivered in time for the start of the cluster randomized controlled trial. All material has been developed in collaboration with other WPs, has been reviewed by the ethics committees and regulatory agencies (see D 7.2) and everything is in place by month 18 to start with the trial. Whether the intervention and the optimized implementation strategies prove to be efficient and the DMMH intervention will be adopted, and maintained, will be evaluated in the scope of the cluster randomized controlled trial.

7. References

Glasgow, R. E., Vogt, T. M. & Boles, S. M. (1999). Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health* **89**, 1322-7.
Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., Altman, D. G., Barbour, V., Macdonald, H., Johnston, M., Lamb, S. E., Dixon-Woods, M., McCulloch, P., Wyatt, J. C., Chan, A. W. & Michie, S. (2014). Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *Bmj* **348**, g1687.

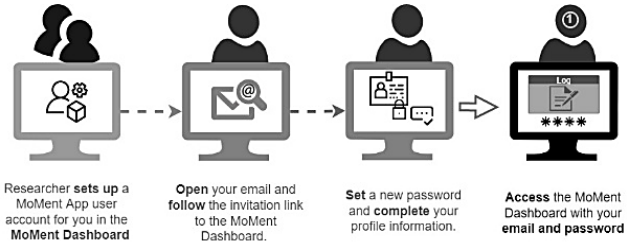
8. Annexes

Annex A. Cheat sheet for clinicians.

CHEAT SHEET Dashboard

THERAPYDESIGNER

A. Registration & Login



https://therapymanager-staging.movisens.com

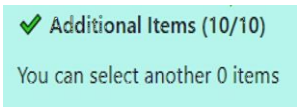
B. Configuration: Settings

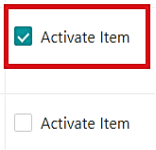
Personalise the App **together with your patient.**

Click „Configuration“ (*left side index*) and define:
1. Therapy goals, 2. Key problem areas, and
3. Time settings (first + last prompt of the day).

Click „**Edit**“ to make changes (*top right*). **Save** changes.

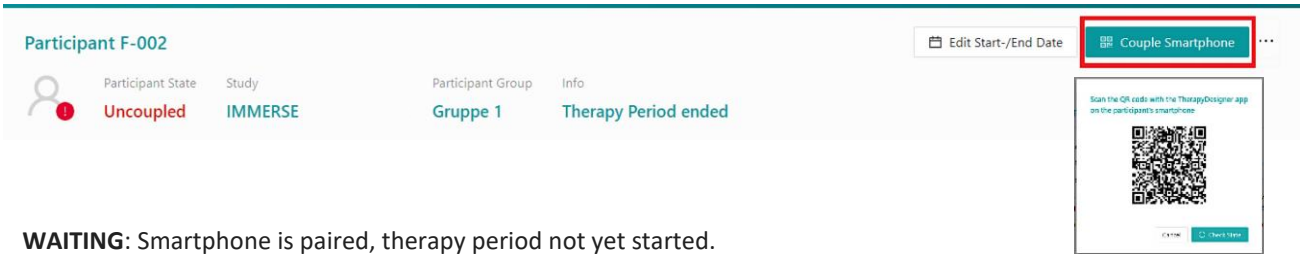
Select **up to 10 extra items** to be included in each MoMent App prompt. These will appear in addition to preset core ESM items.





C. Explanation of the Status

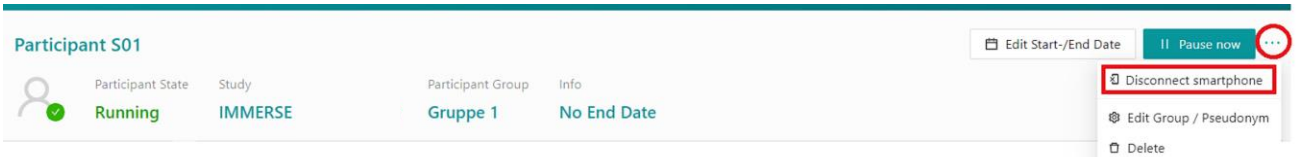
UNCOUPLED: Smartphone is not paired. Scan QR code to pair.



WAITING: Smartphone is paired, therapy period not yet started.

RUNNING: Smartphone is paired and the therapy period has begun.

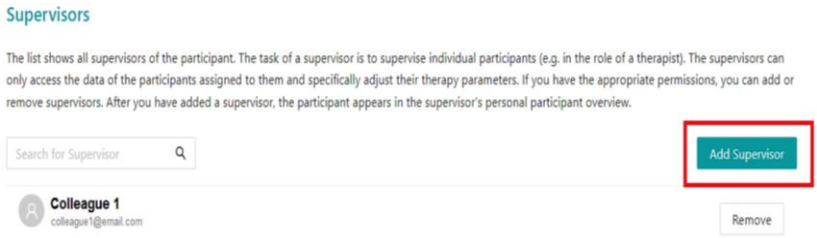
New phone? Unpair old smartphone and pair with the new smartphone:



PAUSED: Smartphone is still paired, but the last therapy period has ended.

D. Add another supervisor

1. Click „Supervisors“ (*left side index*)
2. Enter the email address of your colleague to invite them to a specific patient dashboard.

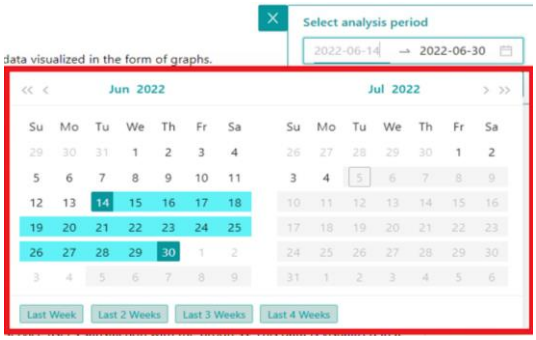


E. Visualisations: Data timeframe

1. Click „Dashboard“ (*left side index*)
2. Click „select analysis period“ to change the timeframe.
3. Edit dates in calendar view.

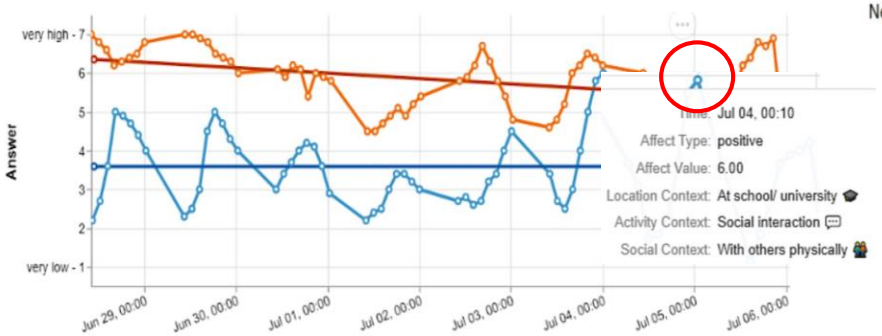
Shortcut: Select the last 1-4 weeks at the bottom of the calendar.

* Interested in a single day? Click the specific date twice.



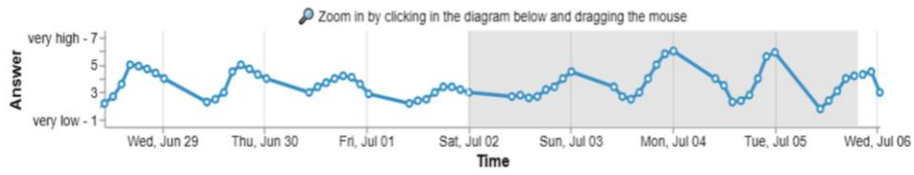
F. Visualisations: Boxplots & Linegraphs

Toggle: Activate/Deactivate constructs (click boxes):



Hover over a data point with your mouse to view social, activity, and location contexts of the response.
For example: positive affect was scored at a 6 while the service user was in a social interaction at school/university.

Click and drag to Zoom into and out of line graphs (grey):



G. Our suggestions for use

- Visit the dashboard regularly and refer to the visualisations and entries when in contact with patients.
- Encourage clients to fill out prompts.

The MoMent App and dashboard are not communication channels for crisis situations. Please discuss contact options for crisis situations with your clients and make it clear that the information entered into the app will not be accessed by you in real time.

H. Contact researchers at your site:

We are happy to support you at any time with questions and problems regarding dashboard use.

Your IMMERSE team

Contact
Name
Email:
Phone: