IMMERSE

Implementing Mobile MEntal health Recording Strategy for Europe

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[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

List of abbreviations

N/A

Table of contents

1. Summary……..[3]
2. Deliverable report……..[3]
3. References……..[4]

1. Summary

This deliverable provides a preliminary risk assessment of the proposed Digital Mobile Mental Health (DMMH) device, and outlines which procedures will be followed to carry out continuous risk assessment throughout the various phases of the IMMERSE project.

2. Deliverable report

A risk assessment must be provided as a deliverable to describe how the DMMH device could adversely affect the lives of the patients, particularly the risk of causing distress, disrupting their lives and the dependence on mobile devices.

Preliminary risk assessment of DMMH device uptake

In general terms, there is strong evidence from over two decades of research into the use of Experience Sampling Methodology (ESM) that the DMMH can be used in a safe and reliable way in people with mental health problems (including in those with severe mental disorder) with regard to three levels of risk: 1) symptom exacerbation, side effects and severe adverse events (clinical safety), 2) distress, interference, burden, and any other effects related to DMMH usage (mHealth safety), 3) unusual activity patterns of the DMMH App (system/privacy protection). [1, 2, 3, 4-12]

These levels of risk will be rigorously monitored in the proposed implementation trial. More to the point, the consortium has discussed and agreed a **risk-management process** as depicted in Figure 1. This process is highly dependent on the specific requirements and implementation strategy of the DMMH - which are currently in discussion within the consortium. Thus, as of now it is still premature to precisely identify possible and concrete (as opposed to theoretical) risks deriving from uptake of the device, and it is only possible to outline how the risk-management process will be conducted.

During the phase of requirement analysis we will define our risk policy stating what risks are acceptable and which are unacceptable. Then we will do an initial Risk-Analysis with a Preliminary Hazard Analysis (PHA) solely based on the requirements defined for the DMMH.
Afterwards during the development phase we will conduct a more structured risk analysis by leveraging different methods, like Fault-Tree-Analysis (FTA) and Failure Mode Effect Analysis (FMEA). For those methods more details about the architecture and how the DMMH will be used are necessary thus we can only conduct them during development. After analysing all the risks we come up with measures in order to mitigate these risks. Here we will mitigate all risks, even the acceptable ones, following the principle of reducing the risk as reasonably as possible. During development we then implement those mitigations and verify them. After development has finished and the mitigations have been verified we evaluate the expected benefit of the DMMH against the overall risk.

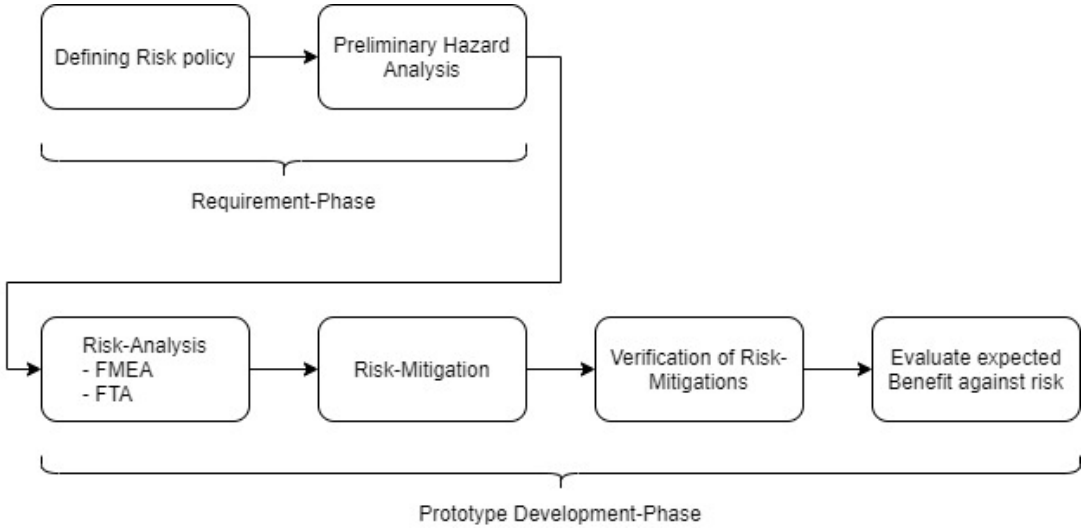

Figure 1: The Risk-Management process as it will be conducted for the DMMH-App during the project.

Benefit to research participants and avoidance of therapeutic misconception

The Declaration of Helsinki of the World Medical Association (Fortaleza revision, 2013), and notably its provisions on participation of vulnerable groups and individuals (such as those that will be recruited for the study), provides that *medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research* (article 20). In line with this requirement, all vulnerable participants are expected to benefit from participation in this study (which is directly geared to address their health needs), and stand to benefit as well from the resulting DMMH intervention. The risk-benefit assessment for participation in research is thus considered to be highly favorable, in line with the **principle of beneficence** underpinning ethical requirement for enrollment of research subjects.

Moreover, to **avoid therapeutic misconception** and make clear that DMMH will not substitute clinical judgement and joint decision-making by participants in the study and their clinicians, all information about DMMH – on the web site, on recruitment flyers, in the information about the DMMH embedded in the app itself, in the participant information sheet, in patient and clinician instruction manuals and leaflets – will clearly outline that the DMMH is intended to help patients collect information about their own symptoms, and that this information is intended for discussion with the clinical team. In addition, in order to be able to use the DMMH app, patients need to be paired with a supervising clinician first.

3. References

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