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D3.2 Safety Monitoring Protocol

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Abbreviations	
AE	Adverse Event
AR	Adverse Reaction
CI	Chief Investigator
DMEC	Data Monitoring Ethics Committee
eCRF	Electronic Case Report Form
PI	Principal Investigator
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction
UAR	Unexpected Adverse Reaction

Contents

1. Executive Summary

Self-guided digital mental health solutions, while beneficial for increasing accessibility of evidence-based support among children and adolescents, should be, first and foremost, safe to use. The SMILE project will employ tried and tested procedures for monitoring, responding to and reporting of distress and harm throughout the proof-of-concept testing of the SMILE Game App and the SMILE Companion App. This deliverable comprises the safety monitoring protocol developed within the scope of *WP3 Monitoring of Ethics, Security and Privacy*, summarizing the contribution of *T3.4 Societal and Environmental Wellbeing* in preparation for *T7.3 Implementation of the case studies and data collection* and the wider activities of *WP7 Piloting and Evaluation*. The protocol will guide the efforts to safeguard young people against distress or harm during their participation in the SMILE project, ultimately allowing a reliable verdict regarding safety of the SMILE solution, contributing to achieving Milestone 12 *Pilot assessed and evaluated* of the DOA. Implementation of the protocol into the SMILE digital infrastructure will be carried out within the scope of *WP6 Digital Integrations and Data Operations*, to enable effective use throughout the lifecycle of *WP7 Piloting and evaluation*.

Upon being notified of harm or distress to a study participant (or risk thereof), it is a researcher's ethical and statutory obligation to act on it. All conduct should be consulted with the site's Principal Investigator (PI). If necessary, especially when the participant appears to be in imminent danger, relevant emergency services might also need to be notified. If the participant is under 16 years old, the participant's parent/legal guardian might be informed. All communications with participants should be documented to ensure a transparent track-record of the steps taken to manage risk is available.

Where relevant, the event should be reported as an Adverse Event (AE), via an electronic Case Report Form (eCRF), as soon as a researcher becomes aware of the event, but no later than 24 hours. Such report will include a detailed description of events and initial assessment of causality, relatedness and severity. PI reviews the report and confirms causality, severity and relatedness and then provides an interim classification of seriousness of the event. Finally, the report will be independently reviewed in accordance with the Protocol and other relevant documents by the Chief Investigator (CI) and a PI from another study site. The Data Monitoring Ethics Committee (DMEC) will periodically review the AEs, looking for possible trends, and advising on any safety issues raised by these analyses and actions required to address them.

This safety monitoring protocol will be used by researchers in Germany, Spain, Italy, Poland, Slovenia, Cyprus and the UK throughout the SMILE proof-of-concept study as a practical reference guide alongside any relevant country- or institution-specific requirements and policies.

2. Introduction

Digital mental health solutions have the potential to substantially increase the reach of evidence-based approaches (Bucci et al., 2019; Kickbusch et al., 2021). However, to fully harness this potential, digital mental health technology should not only be effective but also safe to its users (Taher et al., 2023). This is especially relevant when the users are children and adolescents (i.e., a vulnerable population).

The SMILE project intends to promote mental well-being and resilience in young people by providing a gamified platform with digital cognitive behavioural interventions in order to increase cognitive flexibility, self-efficacy, critical thinking, self-regulation and self-confidence. This digital platform (called SMILE Open Knowledge Platform) will consist of the SMILE Game App and SMILE Companion App which young people will use in their own time, at their own pace, without additional guidance. The self-guided mode of delivery may pose a challenge for monitoring and reporting of distress and harm throughout the testing phase, due to limited direct contact between the end-users and researchers (Bergin et al., 2023). As such, any procedures to safeguard young people against harm and assess the safety of the SMILE solution will be appropriately adapted to this particular mode of intervention delivery.

With this in mind, the SMILE project has put in place:

a) a set of actionable steps to safeguard children and adolescents against risk disclosure and distress while testing the SMILE Game App and SMILE Companion App;
b) a protocol to systematically identify, measure and record any adverse events, should they occur when testing of the SMILE Game App and SMILE Companion App, allowing for a reliable verdict regarding safety of these apps.

These Standard Operating Procedures (SOPs) were developed based on safety monitoring strategies that were tried and tested in previous digital mental health research (e.g., Bucci et al., 2023; Reininghaus et al., 2024). Throughout the SMILE proof-of-concept study, they are to be used as a practical reference guide alongside any relevant country- or institution-specific requirements and policies. The following report summarises the key provisions of these SOPs that will be common across all sites of the proof-of-concept study, not accounting for any site-specific procedures that may feature in the local adaptations of the SOPs.

3. Safeguarding and Risk Management

The following section outlines the procedures for managing risk disclosure and distress among young people who are participating in the SMILE proof-of-concept study. With majority of participants being children, they constitute a potentially vulnerable population, meaning that additional measures are required to safeguard them against undue harm and distress throughout the study.

3.2. During enrolment for the SMILE study

When enrolling participants for the SMILE proof-of-concept study, researchers should explain what the research is, the purpose of the research and the procedures involved. They will explain that, in principle, all information will be confidential and that information given by a young person will not be revealed to a parent/legal guardian/teacher/clinician. Researchers should explain to

young people that the exception to this would be if information was given to the researcher that indicates that the safety of the young person was at risk (e.g., a victim of physical or sexual violence). Researchers would in such circumstances explain that they are duty bound to make a decision that the information may have to be shared with someone else and that the person they may to share the information with may be someone who is outside of the research team. This information should also be included in the Participant Information Sheets and the Informed Consent Forms.

3.3. During participation in the SMILE study

Participation in the study will take place mostly in a remote format, with no active monitoring by the researchers. Therefore, the pathways through which a researcher can be notified of any harm, threat or distress experienced by the participant are limited to follow up points and active contacts with the research team, and participants are encouraged to get in touch with local researchers in any instances of concern. Independent of the pathway by which any disclosure is made, or individual distress or concerns are reported, once the researcher becomes aware of it, they must act on it as long as the young person is participating in the SMILE proof-of-concept study.

Overall, when managing and reporting disclosure of risk or distress, the researcher will notify the site Principal Investigator (PI) as soon as possible. In situations of imminent risk of direct harm to self or others[1], emergency services and/or the young person's parent/legal guardian (if under 16 years old) might need to be notified. Additionally, for participants recruited through schools or other educational institutions, it is advised that the local research staff identifies a named contact among the school staff to handle disclosure and/or distress. If circumstances call for escalating the situation further, after consulting with the PI, the researcher might need to report the situation to the named contact in the school.

3.3.1. Disclosure management

While participating in the SMILE proof-of concept study, participants could disclose:

- Concerns about their own safety and/or safety of another person
- Suicidal ideation and/or intent
- Current and/or recent self-harm
- Intention to harm another person
- Unreported abuse
- Crime
- Other

Should a researcher become aware of any of the above instances, they **must** act on it. Specific procedures to follow in each of these instances have been described in a dedicated SOP, to be adapted by each study site to align with their local context. The SOP will be used as a practical reference guide to be used alongside any site-specific safeguarding/child protection policies.

[1] In this document, imminent risk refers to risk that is immediate and direct risk to self or others and likely based on the circumstances and context of that risk. Professional/clinical judgement should be exercised when assessing whether or not risk is imminent. When a researcher is not certain of their assessment, they should consult the site PI.

In sum, once the researcher becomes aware of any of the above instances, they will notify the PI about the situation as soon as possible and discuss further conduct. Where appropriate, they should talk to the participant/contact the participant via phone call to ascertain more detail (e.g., determine if the young person is in imminent risk, if they or someone else may need medical attention). During that phone call, the researcher should specify that they may need to share this information with someone else and that the person they may share the information with may be someone who is outside of the research team. If the situation calls for it, especially when the participant appears to be in imminent danger, relevant emergency services might need to be notified - the researcher can offer to call the ambulance/police together with the young person, and if they refuse, the researcher should call the ambulance/police themselves. If the participant is under 16 years old, notify the participant's parent/legal guardian. For those over 16 years old, encourage them to disclose to their parent/legal guardian. All communications with participants and support providers should be logged/documented to ensure a transparent track-record of the steps taken to manage risk is available.

Where relevant, the event should be reported as an Adverse Event (see Section 4). Additionally, at the earliest opportunity following consultation with the PI, the researcher should circulate an email with the local SMILE team summarising:

- the risk encountered (anonymised details only) and any actions that were immediately taken to manage risk;
- the subsequent actions that were agreed during the conversation with the PI;
- the outcome of these actions (if known).

Researchers will not be in a position to actively review the incoming data from the SMILE game app or the SMILE companion app throughout the study. As such, procedures apply to scenarios where the researcher does become aware of any of the above instances during the young person's participation in the SMILE proof-of-concept study (e.g., the participant calls the researcher and discloses risk to themselves and/or others).

3.3.2. Distress management

The questionnaires participants are asked to complete and the app include topics that participants may perceive as sensitive and may provoke distress.

For this reason, the Participant Information Sheet will have an emergency contacts section in case a young person experiences distress whilst using the SMILE game app or the SMILE companion app. The contact list should include the researcher contact information relevant to the site at which they are participating, information to out-of-hours emergency contacts (e.g., A&E services; healthcare contacts; charity helplines and websites) as well as local organisations that can provide support during business hours.

Procedures to follow when the participant chooses to contact the researcher about feeling distressed due to participating in the study (e.g., due to the content of the SMILE game or any of the assessments), have been described in a dedicated SOP, to be adapted by each study site to align with their local context. In sum, the researcher should:

1) Attempt to assess the participant's mental state.
    a) Ask questions such as "How are you feeling?", "What thoughts are you having?".

b) Acknowledge that talking about how they are feeling and their experiences can be distressing.

c) Reassure the young person that their participation is voluntary and they do not need to answer questions/continue with their participation if they do not wish to do so.

2) Ask the participant if they would like to talk to another member of the research team or a named contact at their school, and provide them with the contact details of who they can contact if they feel any subsequent distress.

3) Direct participant to the Participant Information Sheet which includes contact details to any local sources of support (e.g., A&E services; healthcare contacts; charity helplines and websites) they may wish to contact.

4) Offer to phone back in a couple of days to ensure distress has not escalated.

5) If young person's distress is severe enough to raise concerns about their safety, the procedures outlined in Section 3.3.1 should be followed.

6) After contacting the participant, the researcher should discuss the situation with PI at the earliest opportunity.

7) Where relevant, the event should be reported as an Adverse Event following the procedures outlined in Section 4.

3.4. During debriefing from the SMILE study

After completing their participation in the SMILE study, participants will receive a Debriefing Sheet which will reiterate the local research team's contact detail as well as outline local sources of support should they discuss any potential future distress with someone.

4. Adverse Event Monitoring, Recording and Reporting

The following section outlines the procedures that the SMILE proof-of-concept study personnel will use to fulfil the regulatory and ethical responsibilities to identify, classify and report the spectrum of research related clinical incidents.

4.2. Definitions

4.2.1. Adverse Event (AE)

Any untoward medical or psychological occurrence in a participant which does not necessarily have a causal relationship with the study procedure or treatment (but might do). An adverse event can therefore be any unfavourable and unintended sign (including abnormal lab results, traffic accident, etc.), symptom, disease or injury in any subject in the study, whether or not considered related to the investigational psychological intervention (the SMILE serious game app and the SMILE companion app) or study procedure. This may include incidents of self-harm.

4.2.2. Serious Adverse Event (SAE)

An SAE will be defined as an AE that:

a) results in death
b) is life-threatening (see Section 4.2.2.1)
c) requires hospitalisation or prolongation of existing hospitalisation (see Section 4.2.2.2)
d) results in persistent or significant disability or incapacity, or
e) consists of a congenital anomaly or birth defect
f) other important medical event if determined to be serious based on medical judgement

4.2.2.1. Defining “life-threatening”

Life threatening in the definition of an SAE refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event that hypothetically might have caused death if it were more severe. Clinical judgement should be exercised in deciding whether an SAE is serious in other situations. AEs that are not immediately life-threatening, or do not result in death or hospitalisation but may jeopardise the participant or may require intervention to prevent one or the other outcomes listed, should be considered serious. Clinical judgement by local PIs, the CI and/or other team members with delegated responsibility for classifying AEs should be exercised in deciding whether an adverse is serious in other situations.

4.2.2.2. Planned hospitalization

Planned hospitalisation for a pre-existing condition, without a serious deterioration in health, is not considered a SAE.

4.2.2.3. Deciding whether an event is “serious” or not

To ensure no confusion or misunderstanding of the difference between the terms "serious" and "severe", which are **not** synonymous, the following note of clarification is provided. The term "severe" is often used to describe the intensity (severity) of a specific event (as in mild, moderate, or severe myocardial infarction); the event itself, however, may be of relatively minor medical significance (such as severe headache; see Section 4.2.7). This is not the same as "serious," which is based on patient/event outcome or action criteria usually associated with events that pose a threat to a participant's life or functioning. Seriousness (not severity) serves as a guide for defining regulatory reporting obligations.

Professional/clinical judgement should be exercised in deciding whether an adverse event/reaction is serious in other situations. Important adverse events/ reactions that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious.

4.2.3. Adverse Reaction (AR)

All untoward and unintended responses to an investigational psychological intervention. All adverse events judged by either the reporting investigator or other competent authority as having a reasonable causal relationship (e.g., definitely, probably or possibly related) to a psychological therapy/intervention qualify as adverse reactions.

In the SMILE study, we use the terms “Definitely not”, “Probably not”, “Possibly”, “Probably”, “Definitely” to describe the degree of certainty in relation to causality between the app/study procedures and an event (see Section 4.3).

Where there are two assessments of an event, the causality assessment made by the local investigator cannot be downgraded. In the case of a difference of opinion on causality, both assessments are recorded, and the "worst case" assessment is used for reporting purposes.

In the context of the SMILE study, the following ARs are expected:

- Mood variability and/or transient/short-lived increase in negative emotions (e.g., some distress, tearful) during/on completing an assessment, interview or reviewing app content and consequent impact on functioning
- Minor irritation with app alerts/notifications
- Non-engagement with the mobile device

Untoward and unintended responses will therefore not include these specified reactions.

For clarification, technical glitches such as periodic network outage, other minor technical hitches with the apps, phone loss, phone theft and/or a participant selling the phone are **not** counted as AEs but will be systematically logged in the study. If this does, however, result in a decline in mental state (e.g., phone theft as a result of physical assault) then this will be recorded as an AE and the phone theft coded as the trigger (as opposed to the AE itself).

Any feelings reported by participants, including the above expected ARs, should be reported as AEs, and discussed with the SMILE research team where a decision will be made regarding follow-up on a case-by-case basis.

4.2.4. Unexpected Adverse Reaction (UAR)

An adverse reaction, the nature or severity of which is not consistent with the effects or consequences of the psychological intervention being investigated.

4.2.5. Serious Adverse Reaction (SAR)

An adverse reaction that is judged to be serious, according to the definitions in Section 4.2.2 and Section 4.2.3.

4.2.6. Suspected Unexpected Serious Adverse Reaction (SUSAR)

An adverse reaction that is judged to be both serious and unexpected, according to the definitions in 4.2.2-4.2.4.

4.2.7. Severity

The term "severe" is often used to describe the intensity (clinical severity) of a specific event. This is not the same as "serious", as defined in Section 4.2.2, which is a regulatory definition based on patient/event outcome or action criteria. For example, a headache may be severe but not serious, while a minor stroke is serious but may not be severe. Criteria for grading severity should be included in the Protocol. The intensity of an adverse event will initially be assessed according to the following definitions:

> **Mild**: An event easily tolerated by the participant, causing minimal discomfort (e.g., asymptomatic or mild symptoms, diagnostic observations only, no intervention indicated). Not interfering with everyday activities/functioning.

Moderate: An event that is sufficiently discomforting to interfere with normal everyday activities. Minimal, local or non-invasive intervention indicated.

Severe: An event that prevents normal everyday activities. Medically significant but not immediately life-threatening. Hospital or prolongation of hospitalisation indicated.

4.3. Determining causality

Causality and expectedness of an AE will be assessed in a timely manner, in consideration of the regulatory reporting requirements. Causality and expectedness assessments will be carried out by a delegated, clinically qualified member of the research team. Clinical judgement shall be used and the relevant documents, such as the Protocol shall be consulted. Potential AEs include:

- Distress associated with completion of assessment measures
- Distress associated with using the SMILE apps

The presence of confounding factors, such as concomitant medication/treatment, the natural history of the underlying disease, other concurrent illness or risk factors shall also be considered. The above considerations apply also to AEs occurring in the comparison groups or control groups.

For the purpose of harmonising reports, each SAE will be classified according to five different levels of causality, which are required when completing and submitting the serious adverse event form. The investigators will use the following definitions in Table 1 to assess the relationship of the serious adverse event to the investigational therapy, intervention procedures for comparators or other study/research procedures.

Table 1. Causality definitions

Causality category	Definition
Definitely not	The relationship to the intervention or research procedures can be excluded when: • the event is not a known[2] side effect of the category the intervention belongs to or of similar interventions and procedures. • the event has no temporal relationship with the use of the intervention or the procedures. • the serious event does not follow a known response pattern to the intervention (if the response pattern is previously known) and is biologically implausible. • the discontinuation of intervention or the reduction of the level of activation/exposure - when clinically feasible - and reintroduction of its use (or increase of the level of activation/exposure), do not impact on the serious event. • the event involves a body-site, or an organ not expected to be affected by the intervention or procedure. • the serious event can be attributed to another cause (e.g., an underlying or concurrent illness/ clinical condition, an effect of another intervention, drug, treatment, or other risk factors). • In order to establish the non-relatedness, not all the criteria listed above might be met at the same time, depending on the type of intervention/procedures and the serious event. [2] When the event is not a known side effect of the category the intervention belongs to or of similar interventions and procedures, generally is considered “not related”. Yet, the unexpected effect shall not be excluded from evaluation and reporting.
Probably not	The relationship with the intervention seems not relevant and/or the event can be reasonably explained by another cause, but additional information may be obtained.
Possibly	The relationship with the intervention is weak but cannot be ruled out completely. Alternative causes are also possible (e.g., an underlying or concurrent illness/ clinical condition or/and an effect of another intervention, drug, or treatment). Cases where relatedness cannot be assessed, or no information has been obtained should also be classified as possible
Probably	The relationship with the intervention seems relevant and/or the event cannot reasonably be explained by another cause, but additional information may be obtained.

Definitely	The serious event is associated with the intervention or with procedures beyond reasonable doubt when: • the event is a known side effect of the category the intervention belongs to or of similar interventions and procedures. • the event has a temporal relationship with intervention or procedures. • the serious event follows a known response pattern to the intervention (if the response pattern is previously known). • the discontinuation of the intervention (or reduction of the level of activation/exposure) and reintroduction of its use (or increase of the level of activation/exposure), impact on the serious event (when clinically feasible). • other possible causes (e.g., an underlying or concurrent illness/ clinical condition or/and an effect of another intervention, drug, or treatment) have been adequately ruled out. In order to establish the relatedness, not all the criteria listed above might be met at the same time, depending on the type of intervention/procedures and the serious event.

The CI, a PI of a site other to the site where the event was reported ("another PI" hereafter), or other delegated and clinically qualified investigator, and any other relevant authorities (e.g., Sponsor) will distinguish between serious adverse events related to the intervention and those related to the study/research procedures (any procedure specific to the clinical investigation). An adverse event can be related both to procedures and the intervention. Complications of procedures are considered not related if the said procedures would have been applied to the patients also in the absence of intervention.

In some particular cases the event may be not adequately assessed because information is insufficient or contradictory and/or the data cannot be verified or supplemented. The Investigators will make the maximum effort to define and categorize the event and avoid these situations. Where it remains uncertain how to classify the serious event, it should not exclude the relatedness and classify the event as "possible".

4.4. Classification of AEs

The nature of the Adverse Event should be determined with reference to the flow diagram below, the definitions given in Section 4.2, the Protocol and other relevant documents.

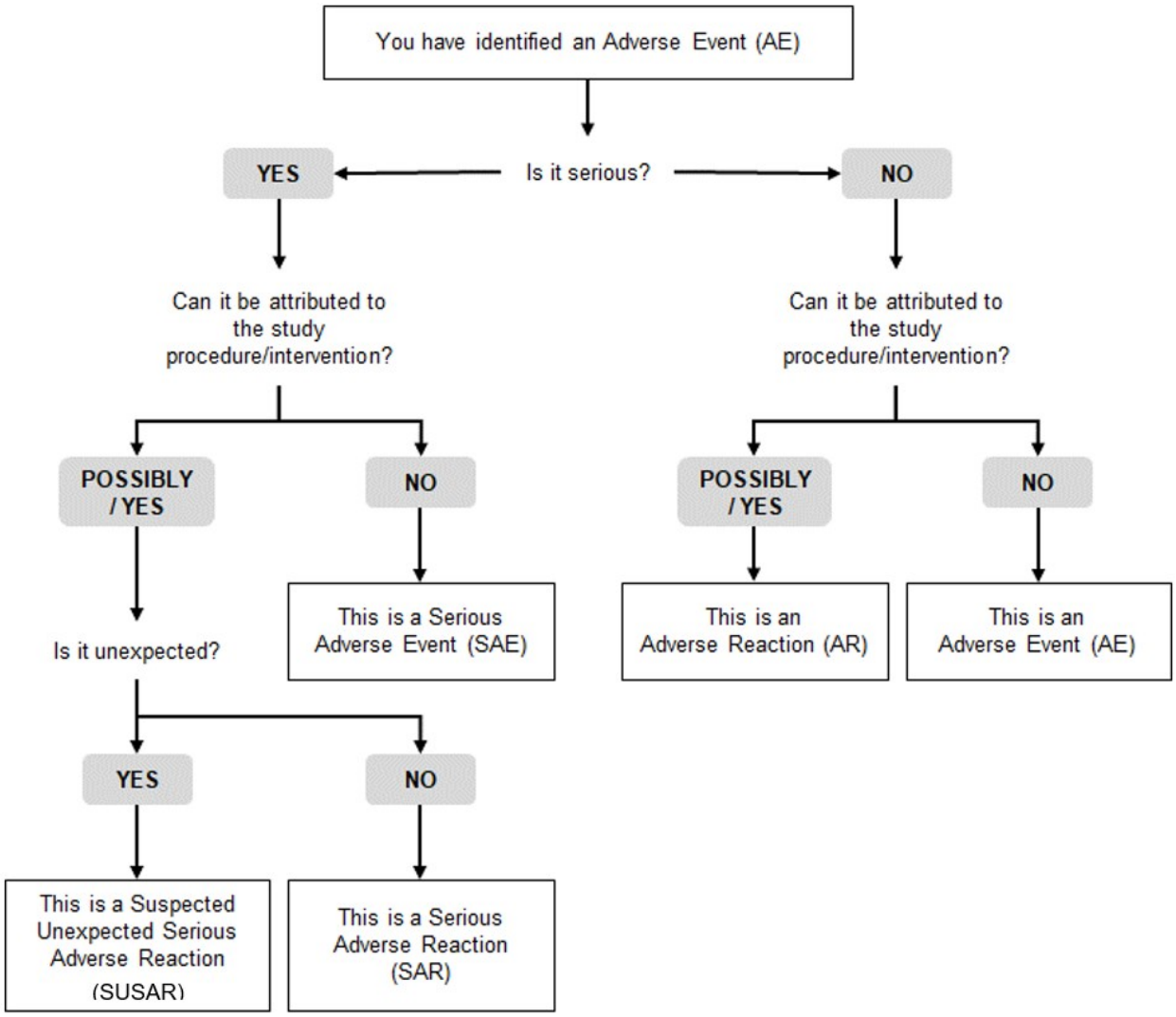

Figure 1. AE classification flowchart.

4.5. Reporting procedures and timescales

For the avoidance of doubt, **all** AEs should be collected for all trial participants from the time of their enrolment into the SMILE study onwards. The time of enrolment is defined as the time at which, following recruitment, a participant signs and dates the informed consent form. As such, these procedures also apply to events that occur after the participant's termination of the study and if a causal relationship to the intervention or study procedures is assumed. All SAEs that are ongoing after the completion of the clinical investigation will be followed up until a final assessment can be made.

All AEs and SAEs will be documented in the electronic Case Report Form (eCRF) and verified during routine monitoring visits.

In the scope of the SAE assessment, a comparison with the investigation-specific risk analysis will be performed. If the reported SAE is assessed or not assessed according to its severity regarding the risk analysis, corrective and preventive action is determined. The suspension of the investigation will be taken into consideration until the corresponding action will have completely been taken. The site PI or a delegated individual have to report SAEs to the competent authority (e.g., Sponsor) immediately (without undue delay) if a causal relationship between the SAE and the intervention or study procedures performed as part of the trial or other conditions of the trial conduct cannot be excluded.

Exact AE and SAE reporting pathways and timescales will vary across sites depending on site-specific policies and legislation. That being said, the reporting pathways that will be common for all sites are reporting to the CI and the DMEC. Procedures to follow are outlined in subsequent sections.

4.5.1. Reporting to the CI

All AEs observed during any period of a clinical trial are to be recorded, treated by the investigator as needed, and followed up. This also includes AEs that occur after the completion of the clinical investigation and are still related to the intervention or investigation procedures.

General steps for commencing the AE reporting procedure in the SMILE study are as follows:

1. Member of staff who identified the event completes the Adverse Event Report Form in eCRF as soon as they become aware of the event, but no later than 24 hours, including a detailed description of events and initial assessment of causality, relatedness and severity.
    a. Where not all information is available, the initial report must contain the following as a minimum: Identifiable Event, Participant ID & Reporter.
    b. This must be followed with a detailed follow-up report.
2. Upon completing the Adverse Event Report From via the eCRF, the PI or a delegated individual will be notified. They will review the form and make an assessment as to whether the event is defined as serious, using the definitions in Section 4.2.
3. PI reviews and confirms causality, severity and relatedness and then provides an interim classification of seriousness of the event. Alternatively, PI instructs staff to take any necessary follow-up action needed to clarify ratings (in particular relatedness and expectedness) and then provides an interim classification of the seriousness of the event. These details are updated in the Adverse Event Report Form via the eCRF for later analysis.
4. Upon finalising the Adverse Event Form via the eCRF by the PI, the CI and another PI will be notified. They will receive the form for final review, classification and assessment in accordance with the Protocol and other relevant documents.
5. If not resolved at the time of completing the Adverse Event Form via the eCRF, necessary follow-up action has to be taken by a SMILE staff member.
    a. Follow up any ongoing event or reaction documenting at each study visit until resolved, returned to baseline, stabilised. Events and reactions that are ongoing on completion of the study should be followed up for 30 days or as clinically indicated.
    b. Details of the follow-up action and its outcome are to be documented by the SMILE staff member in the Adverse Event Form via the eCRF.

c. It is recognised that determining AE resolutions may not be straightforward due to the ongoing nature of distress.

In case of the CI's planned absence (e.g., vacation), they will select a representative to fulfil their duties when reporting and handling AEs, and inform the Work Package 7 lead via email.

4.5.2. Reporting to the DMEC

The purpose of the Data Monitoring Ethics Committee (DMEC) is to safeguard the interests of study participants and assess safety of the interventions during the trial and monitor the integrity of the study. In addition, if required, the DMEC aims to assist and advice the CI in order to protect the validity and credibility of the study, without violating the concepts behind the original Protocol.

The DMEC must be informed by the CI about SAE as well as AE in preparation of the annual meetings, at least 2 weeks prior to a scheduled DMEC meeting. The DMEC must ensure that they regularly review SAEs, looking for possible trends. The review sessions must be minuted as having taken place, with a note of the attendees and the events that have been reviewed. The DMEC can advise on any safety issues raised by these analyses and actions required to address them. Recommendations by the DMEC will be discussed in the Executive Board meetings and decisions will be communicated to all investigating centres and investigators.

5. Conclusions

Implementation of a comprehensive safety monitoring framework is essential for ensuring the well-being of young users of the SMILE Open Knowledge platform. This Safety Monitoring Protocol provides a robust framework to identify and address potential risks, ensuring the safety of the SMILE Game and Companion App throughout their testing. The systematic recording and classification of risks will highlight areas for improvement and allow further enhancement of the safety features of the SMILE solution, facilitating its sustainable use beyond the lifecycle of this project. Ultimately, this proactive approach paves the way for safer, more effective digital mental health interventions.

6. References

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