

How to e-mental health: a guideline for researchers and practitioners using digital technology in the context of mental health

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SUPPLEMENTARY INFORMATION

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Table S1. Do's and don'ts researchers should consider when implementing an e-mental health intervention and/or assessment.

I. DEVELOPMENT	
Where to start?	
 - Examine the context of use and identify the digital specifics to solve the problem - Involve the target group (and other important stakeholders) in the development of the application from the beginning and tailor it to it/them (i.e., selection of the features) - Get expert advice on data protection and privacy while writing the funding proposal - Obtain quotations from several external IT partners at an early stage in order to structure the budget accordingly - Check similar solutions in the field beforehand and identify well-evidence based open access material (e.g., no-code software development) - Consider budget for the support of the digital solution after completion (e.g., installing updates, fixing bugs)	 - Do not assume a priori that a digital health solution is the most appropriate approach for every problem/context of use, but explore if this approach is best (or at least better than existing ones) - Avoid developing the application purely from a researchers point of view (potential driver for low user engagement) - Avoid having a static mindset and a finished technical solution in your mind, but engage in an iterative process (guided by your objectives and the target group) - Do not discard your project timeline too easily but try to use resources proactively and continuously monitor the project to anticipate delays
Intervention content development	
 - Plan sufficient resources (i.e., financial, time, personnel) for the technical translation of therapeutic content when planning the project - Put together a transdisciplinary team (e.g. mental health professionals, software engineers, design experts) and plan time for the development of a mutual understanding and finding a common ground - Define features or content which allow for personalization of the e-mental health intervention (i.e., just-in-time adaptive interventions, self-monitoring tools, notification) - Ensure that different multimedia elements are implemented and that there is some variety across the intervention (i.e., gamification)	 - Do not take elements of existing static, text-based psychotherapeutic manuals and implement it one-to-one without considering the characteristics of the digital environment and the target group - Avoid following a linear development process, but rather an agile iterative research process - Do not adopt a 'one design fits all' approach - Avoid modifying the core principles of the evidence-based intervention, but identify possibilities to transfer them into the digital environment
User-centered design and participatory approaches	
 - Plan sufficient financial and time resources for users' inclusion throughout the study/development - Define the target groups as precisely as possible - Include the environment of your target group (e.g., professionals, therapists, relatives) - Involve the target group as early as possible	 - Do not overlook that various subgroups are represented within focus group/selected advisory group/stakeholder (i.e., equal gender, ethnic minorities, age) - Avoid neglecting awareness of who is conducting the interviews (i.e., should they be part of the development/research team and final product or do they face the risk of being biased?)

● Involve target users/ stakeholders also in decision-making processes ● Identify key needs and preferences of specific target groups ● Identify access routes and potential barriers of your target group ● Conduct focus groups and qualitative interviews ● Include advisory board with all needed stakeholders	● Do not presume what the target group might want and do not confirm assumptions on ready-made interventions ● Avoid conducting few focus groups only and do not present only finalised material
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II. STUDY SPECIFICS	
Managing Suicidality	
 ● Incorporate separate modules with specific content for people with suicidal ideation (i.e., emergency contact details) ● Routinely include a measure of suicidal thoughts and behaviours ● Assist participants with moderate to severe suicidal ideation to develop an individual crisis plan ● Train and supervise team members who provide guidance to participants to ensure qualified patient support and the well-being of the staff ● Rigorously assess reasons for dropout (i.e., include third persons to follow-up on participants who cannot be reached)	 ● Avoid excluding participants with suicidal ideation from trials ● Do not exclude suicide-related items from other scales (e.g., PHQ-8). ● Do not offer the intervention group better crisis support than the control group ● Do not prohibit co-interventions for people with suicidal thoughts or behaviours ● Do not start trials without a pre-specified crisis support plan ● Do not obtain contact information of participants and/or their general practitioners, although the study design would allow this
Data protection and data security	
 ● Pseudonymize sensitive data wherever possible ● Consider a two-factor-authentication if appropriate ● Let the app be developed under your control, avoid commercial manufacturer apps if possible ● Demand a quality-assured software development process (i.e., thorough analysis of requirements, detailed specification of data flows, data processing and data storage, precise test strategy) ● Involve your data protection officer in the project at an early stage and establish in-depth technical know-how in your own institution ● Use open source libraries in software development if possible ● Use a research database developed for this purpose which is separated from other institutional information systems ● Educate the users about dangers	 ● Do not upload data in the vendor's public cloud or in an unknown destination ● Do not save sensitive data on the smartphone permanently ● Do not rely on external IT partners only ● Do not keep the de-pseudonymization list in the same database as the e-mental data ● Avoid commercial manufacturer apps if possible ● Do not start without any risk assessment ● Do not neglect the national protection laws
Artificial intelligence in assessment and intervention	
 ● Recognise emotions in different categories, modalities and sources (i.e., clearly define input and output vocabulary/data model)	 ● Do not neglect validation and robustness test in the target population (including e.g. culture, language, age)

- Train toolkits or “engines” on target data
- Use open source AI tools (algorithms, syntax) adapted to the target task
- Validate AI for bias in your population (e.g., use model evaluation cards or similar to check for fairness issues and others)

- Do not use features of self-fulfilling predictions

Sensing and wearables



- Define device type (unisensory vs. multi-sensory, smartphone vs. wearable, operating system: e.g., iOS vs. Android)
- If possible, try to incorporate the user’s usual devices (smartphone and wearable)
- Consider evidence for the device’s reliability/validity and contact manufacturer in case of evidence is not clear
- Wearing wearables should be enjoyable, even fashionable
- Decide whether to use in-house vs. outsourced mobile-sensing platform
- Assess if you have the raw data or features
- Assess ethics of data capture
- Consider details of the back-end (e.g., reliability, geographical location, security)
- Chose a sufficient time interval for piloting and plan time to improve things after the piloting
- Prepare communication channels with participants in case of data loss/technical errors
- Assure enough time to acquire ethical study approval(s) and to design data privacy concepts in advance
- Transparently document your device choice and study setup (e.g., device firmware /software version; sources of potential biases, including study-unrelated behaviours that might influence the collected data quality; nested structure of measurements such as within days/weeks)
- Have a procedure of “sensing device hard reset” to return to default configuration
- Report the process of the data access in studies (raw data, processed data via dedicated webs, mobile platforms, APIs) and clarify the details with the manufacturer if necessary
- Watch out for dependencies: behavioural interventions (e.g., drug trials) may affect device performance due to the dependency of device accuracy on features that will change as a result of the manipulation (e.g., accelerometer, heart rate and its variability, temperature) used by these devices
- Adhere to established reporting guidelines depending on your study design (following the



- Do not assume that devices are always sufficiently charged (i.e., assure no less than a day of battery lifetime) and ‘always on’/connected
- Do not assume manual synchronisation (if required) more than once a day
- Do not use devices that are potentially unsafe (e.g., invoking an allergy), hard to use or malfunctioning (require a specific interaction to function accurately)
- Do not use devices that require participants to use large screens/laptops or PCs
- Do not use devices which costs are disproportionate with the usual devices the population is using
- If wearables: do not use obstructive or stigmatising devices
- If wearables: do not use devices that are not waterproof
- Avoid developing new software and use existing frameworks whenever possible
- Do not outsource it to locations where privacy/security laws and practices are different (EU vs. USA vs. China)
- Do not assume the data is synchronising without errors
- Avoid convenience sampling of a pilot population unrelated to the intended target population (e.g., students vs seniors)
- Do not involve team members without adequate ethical training
- If possible, avoid accepting device software updates along study duration (unless the security may be compromised)
- Avoid using pre-defined data processing pipelines / algorithms that are poorly documented
- Avoid overwhelming the study participants with large selections of own raw data presented to them

EQUATOR and/or STROBE guidelines for observational studies and for diagnostic/prognostic studies: STARD and TRIPOD) • Conduct and report reliability and validation analysis (e.g., Bland-Altman analysis if multiple devices are used simultaneously; nomological net analysis to check construct validity) • Share early your algorithms for data processing and algorithm design	
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III. EVALUATION	
Efficacy evaluation, RCTs and other methods	
 • Especially in the early stages of development, use different forms of evaluation before moving on to an RCT, including qualitative analyses, such as focus groups with target groups or short interventional studies • Before you begin an RCT, preregister your study, including all planned measurements; this avoids non-significant studies to vanish • Think about how to measure processes and to go beyond RCTs when evaluating your intervention • If you are using high-frequency assessments (e.g. EMA), consider how this might influence the effects of the intervention • Consider different study populations and control groups and also blended designs including elements of e-mental health and traditional face-to-face elements	 • Do not include variables in your study without a clear theoretical rationale for why these variables are important for the success of the intervention or as control variables • Do not just publish the measures for which you have obtained significant results in favour of your intervention while not reporting other measures that failed to produce significant results • Do not confuse correlation with causality • Do not assume that the effects of moderators and mediators in traditional settings transfer automatically to an e-mental health setting; do not automatically exclude these variables
Ecological Momentary Assessment (EMA)	
 • Choose an adequate sampling design (i.e., time-based, event-based, combined sampling schemes) • Balance the lengths (i.e., number of questions at each assessment, number of assessments per day, and the assessment epoch) • Use automatic repeated prompts/alarms and allow participants to delay alarms • Determine the order of items considering the different timeframes of items (e.g., "right now" or "since the last prompt") • Use items with good psychometric properties. In EMA, McDonald's omega is the currently most often used measure of reliability. • Consider the temporal dynamics: make sure that the sampling rate matches the temporal dynamics of the underlying target process. For example, a sampling rate that is too infrequent might miss the dynamics of interest, whereas a sampling rate that is too frequent to accurately assess the target process poses unnecessary burden on the participants	 • Do not overdo the assessments but carefully determine the length of the EMA period needed to answer the research questions • Do not be a miser. Offering monetary incentives seems to positively affect adherence rates

Transfer into (clinical) practice	
 ● Assess the long-term usage and feasibility of digital interventions ● Evaluate the implementation of the digital intervention in real-world settings ● Integrate intervention uptake, ongoing use and impact when assessing in real-world settings ● Use proven factors to improve adherence, e.g. mood monitoring or human support ● Integrate recognised international frameworks to identify relevant process evaluative indicators (acceptance, liability, functionality) ● Consider all relevant stakeholders in the conceptualization and evaluation process ● Develop a unique roll-out strategy and consider national/regional requirements such as regulatory frameworks, data safety, business models, long term technical maintenance, funding, market fit etc.	 ● Avoid efficacy studies without the consideration of process evaluation and a unique roll-out strategy ● Do not ignore relevant stakeholders in the public health system ● Do not assume that scientific evidence automatically leads to market acceptance
App evaluation frameworks	
 ● Ensure recommendations are up to date ● Assess assumptions and cultural bias in some recommendations, e.g., such as those that score “ease of use” ● Verify through your own testing that app recommendations appear accurate and in line with the needs of your populations ● Assess for any bias in app recommendation systems	 ● Do not assume app recommendations have taken into account cultural needs of your population ● Do not ignore patient preferences and needs in light of any app recommendation ● Avoid offering patients lists of ‘top’ apps without plans to discuss and/or incorporate into treatment

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sysTelios Think Tank members

Aas, Benjamin^{1,2}

Bossenbroek, Rineke^{1,3}

Bussel, Jesse van^{1,4}

Daniels-Wredenhagen, Nora¹

Gill-Schulz, Patricia¹

Goldbeck, Florens¹

Hegewald, Konstantin¹

Lichtwarck-Aschoff, Anna^{1,4}

Olthof, Merlijn^{1,3,4}

Pommerien-Becht, Florian¹

Scholz, Silvia^{1,5}

¹sysTelios Think Tank, sysTelios Health Center, Siedelsbrunn, Germany.

²Faculty of Psychology and Educational Sciences, LMU Munich, Munich, Germany.

³Faculty of Behavioural and Social Sciences, University of Groningen, Groningen, the Netherlands.

⁴Behavioural Science Institute, Radboud University, Nijmegen, The Netherlands.

⁵Department of Clinical Psychology and Psychotherapy III, Witten/Herdecke University, Witten, Germany.