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The Evolution of Research Procedures for Internet-Based Interventions in Switzerland: Challenges and Recommendations

OPINION

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ABSTRACT

The number of Internet-based interventions (IBIs) are rapidly increasing – particularly since the advent of the COVID-19 pandemic – partly because of increased technological possibilities and the population's access to these technologies, as well as the limited availability of face-to-face psychotherapies (known as the treatment gap). Research is necessary to ensure the security and validity of such interventions. This implies significant changes in procedure not only in research, but also in the corresponding legal and ethical frameworks. The current paper highlights four main issues researchers in clinical psychology are currently facing in Switzerland in relation to these adaptations: 1) the question whether IBIs should be considered to be medical devices, 2) the discrepancies between outdated policies, current practices and new technological possibilities, 3) the unsuitability of mandatory training for the specific challenges faced by IBI psychology researchers, and 4) the heterogeneity of ethical practices throughout the country. These issues have substantial financial and temporal consequences. We conclude by discussing recommendations and possible solutions in order to improve the conditions for IBI researchers.

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The COVID-19 pandemic has accelerated the already rapidly expanding use of psychological Internet-based interventions (IBI; Rauschenberg et al., 2021; Wind et al., 2020). Recent studies (e.g., Stoll et al., 2019) have reviewed the benefits and clinical limitations with the use of online psychotherapy. The use and dissemination of IBIs are a matter of public health choices but also of patients' and health professionals' attitudes towards them. Scientific literature has examined these issues but has not given much consideration to the impact of these new methods on psychological intervention research practices. Indeed, technological innovations, legislations, and ethical practices as well as the training for researchers are rapidly evolving but are not always in adequacy with one another.

Based on the authors' experience in implementing a two-phase research project assessing the efficacy of an IBI (Berthoud et al., 2021; Debrot, Berthoud et al., 2022; Debrot, Kheyar et al., 2022; Efinger et al., 2022), this paper aims (1) to present the main issues researchers may currently be faced with when working with IBIs in Switzerland, and (2) to discuss and share possible solutions at different levels to meet these requirements in order to aid future researchers to anticipate some obstacles.

MAIN ISSUES WHEN IMPLEMENTING AN EVALUATION STUDY OF AN IBI

The implementation of IBIs requires several specificities that differ from other clinical trials. Below, we summarize the issues that we were confronted with in our project. A summary of the addressed issues can be found in Table 1.

1. ARE IBIS MEDICAL DEVICES?

An important legal change in Switzerland came into effect in May 2021, when the ordinance on clinical trials with medical devices (ClinO-MD; RS 810.306) was adapted to match EU rulings. These now deem that products used without a medical purpose will be considered medical devices if they are used as such or are associated with similar risks (e.g., coloured contact lenses that do not correct vision). Therefore, the Swiss Federal Office of Public Health has defined medical devices in a broad sense as products "which are intended to have, or are presented as having, a medical use and whose principal effect is not obtained with a medicinal product" (Therapeutic Products Act; AS 2001 2790). As a result, Ethics Committees may be prompted to inquire whether IBIs are medical devices. The main issue here for IBI researchers is the definition of what a medical device is—and it appears that IBIs are in a grey area. In our case, we submitted a request for approval for a clinical trial on an IBI at the same time that this new ordinance came into effect in Switzerland (Debrot, Kheyar et al., 2022). To the best of our knowledge, we were the first researchers to submit a request for approval for a psychological IBI to the cantonal ethics committee after the implementation of the new law. The committee asked us to clarify whether our intervention should be considered a medical device—without telling us whether this was the case. After several discussions with them and consultations with other Swiss researchers conducting clinical trials on IBIs as well as with research from other clinical fields, the IBI was considered a medical device (MedDO; RS 812.813) as 1) an IT programme could use the collected data for other purposes, 2) it will include a clinical population (even if a diagnosis was not an inclusion criteria), 3) the objectives of the IBI fall within the aim of "helping,

CHALLENGES	EXAMPLES	RECOMMENDATIONS
IBIs as medical devices, necessitating the approval of Swissmedic	– Additional laws, guidelines and norms to consider – Difficulty to find reliable information on how to comply with the rules and norms	– Reassess and clarify the nature of IBIs as medical devices – Assess the relevance of each IBI as a medical device, based on specific criteria – Compile the reliable information in one easy-to-find place (e.g., resource bank)
Outdated policies	– Lack of clear guidelines on procedures for online recruitment – Confronted with ill-suited procedures limiting greatly recruitment (e.g., forbidden to recruit abroad, handwritten consent for online studies)	– Develop clear guidelines for online recruitment – Adapt procedures to current technology (e.g., possibility to sign or send online consent forms)
Inadequate research training	– Mandatory 3-day pharmacology-oriented training – Only and occasionally in biomedical faculties throughout the country	– Make training more relevant and specific for the field studied by the researchers in training (e.g., psychology, social sciences, internet interventions) – Increase the frequency and diversify the settings of trainings (incl. online training)
Different ethical practices	– Swiss legal framework interpreted differently from one ethics committee to another	– Ensure better coherence between committees and across time through better coordination

Table 1 Summary of the challenges encountered and the resulting recommendations, with examples.

curing or mitigating diseases", and 4) it concerns "health measures". All medical devices require the approval of Swissmedic, the Swiss surveillance authority for medicines and medical devices. This involves considering an important number of laws, guidelines and norms (e.g., ISO norm 14155, CEI/IEC 62304) and providing several additional documents, forms and information. This affected our research schedule significantly. In our experience, it was challenging and time consuming to find reliable information regarding the way to comply with the rules and norms because neither the Ethics Committees nor Swissmedic were able to provide us guidance (e.g., where to find the information needed, what to put in the required documents, how to ensure data security, etc.).

2. FACING OUTDATED POLICIES

As Looijmans et al. (2022) pointed out, clear guidelines on procedures for online recruitment are lacking, especially regarding international recruitment. In our case, the local Ethics Committees forbade us to recruit abroad, hence greatly limiting recruitment possibilities. This defeats an important purpose of developing internet interventions which have the potential to reach people around the globe; this has significant consequences for research in a small multilingual country such as Switzerland (i.e., limiting the recruitment pool) compared to a large country with one national language. Another example illustrating the current difficulty to reconcile research carried out through the Internet with the current legislation is the fact that, to date, only *handwritten* signatures are accepted. Thus, mandatory written consent forms must be printed out by participants, who then physically have to sign them and then send the original signed form by mail. This slows the process down significantly, contrasts with the rest of the procedure, which can be entirely completed online, and is often not understood by participants who are used to providing consent online.

3. UNSUITABLE RESEARCH TRAINING

A three-day training course on Good Clinical Practice is mandatory in order to apply for approval for a Clinical Trial in Switzerland (see ClinO; RS 810.305). Such courses take place only and occasionally in biomedical faculties throughout the country, which can sometimes make them difficult to coordinate with a project schedule. Moreover, they are mainly pharmacology-oriented and therefore little suited for social and psychological sciences; no expert was able to reliably answer our questions regarding specific issues related to internet interventions (e.g., regarding the possibility to obtain electronic consent). Consequently, researchers are left with many open questions that they have to take time to clarify themselves, even after having completed the training.

4. DIFFERENT ETHICAL PRACTICES DEPENDING ON TIME AND PLACE

Switzerland possesses an important number of ethics committees and commissions with ethics-related mandates. This requires a complex strategy and a set of legal provisions drawn up to coordinate the work, operation, and organisation of these commissions. Realistically, and after discussion with colleagues from other cantons, requirements from ethics committees vary not only depending on legislation changes, but also among ethics committees and across time. This indicates that the interpretation of the Swiss legal framework (Federal Act of on Research involving Human Beings, HRA; RS 810.30) differs from one place to another and at various times. For example, there are differences across ethics committees of whether IBIs are medical devices or not. This leaves researchers perplexed regarding the procedures and complicates the planning of the time and cost of obtaining approval.

In sum, the issues encountered and the new procedures mentioned above required substantial adjustments to our project. First, significant complexity was introduced into the research protocol (e.g., the definition of safety procedures, the actions to be taken). Second, many additional, very detailed appendixes had to be provided (e.g., an investigator's brochure, the completion of numerous additional forms, proof of compliance with ISO and IEC standards). Third, an insurance not available at our university for this type of project was requested by the external monitoring instance; this also required additional time, as the proof of insurance had to be produced by the rectorate and signed by the Head of the University. Unsurprisingly, all these unforeseen steps considerably increased the financial and time cost of the project, representing about 20% of the initial funding received and six additional months. The lack of available resources necessary to comply with these requirements might discourage researchers from pursuing such projects because the standard research time and money allocated to researchers and PhD candidates might not allow them to deal with such long and complex procedures. For instance, local state ethics committees now require external monitoring for some clinical trials on medical devices (i.e., an authority that controls that the study will do what it said it would do). Many universities do not (yet) have such monitoring instances; hence, it might be necessary (as in our case) to outsource such monitoring, which entails a high financial cost.

WHAT CAN WE LEARN FROM SUCH AN EXPERIENCE? SEVERAL RECOMMENDATIONS

In sum, the safety of participants in IBIs is taken very seriously in Switzerland. The numerous steps required

to obtain approval push researchers to think in detail about how to ensure participant safety both in terms of health and data protection. On the downside, this paper has underlined that recent changes in research procedures (laws, standards, concerns, practices) have made the process of testing an IBI in Switzerland more laborious, time-consuming, and expensive. They indeed necessitate highly specialised skills and knowledge which ordinary researchers do not have (or lack easy access to). Therefore, conducting clinical trials on psychological IBIs involves several prerequisites in terms of training, funding, legal and practical knowledge, and monitoring that not all Swiss universities currently have. One particularly striking central issue is the failure to specify clearly the line between what is considered medical and what is not. It seems at best vague and at worst absent. Medical devices are so broadly defined that they cover a very wide variety of interventions. There should be some coordination at the federal level and clear guidance on how researchers may comply with the requirements.

This has led us to devise several possible recommendations. First, more support mechanisms are necessary not only in terms of information resources, but also in terms of training that is more specific to social sciences in general and to psychological internet interventions in particular. On top of specific training courses, this could include the creation of a resource bank (e.g., containing approved protocols, links to useful contacts and websites, information on available training) that better suits the needs of psychology researchers. Furthermore, setting up internal monitoring instances within universities would avoid delegating this to biomedical researchers (and having to pay them).

TRANSPARENCY STATEMENT

Given that this is an Opinion paper, there is no information to report regarding data collection and analysis.

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COMPETING INTERESTS

The authors have no competing interests to declare.

AUTHOR CONTRIBUTIONS

LB and AD conceived the manuscript and wrote the initial draft. MK, LE, JC and VP revised it critically for important intellectual content. All authors provided final approval of the version to be published.

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