Clinical trials of psychological interventions cancelled due to the COVID-19 outbreak: how should we respond?

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To the Editor:

The measures to contain the spread of the COVID-19 outbreak have no precedent in the recent history of many countries. Around 2,000 million people in the world are in isolation or quarantine, and gatherings of people have been expressly banned in many countries. In Spain, this prohibition affects workplaces, schools, and the national health system, where most of the healthcare is being provided either on the phone or online.

These measures hardly change most ongoing clinical trials, as drugs are available in the pharmacies and can be home delivered, prescriptions are often in electronic format and assessments can be performed via telephone. Neither the interventions nor the study designs are significantly affected. However, clinical trials of psychological interventions can be massively disrupted, especially when the interventions have a group format. Although participants can still provide self-reports and the evaluators can do phone interviews, the interventions require a much more challenging adaptation. Furthermore, the participants of these trials are often more vulnerable not only to the infection itself, but also to the "parallel epidemic of fear, anxiety, and depression"[1]. An abrupt stop of what sometimes is their only psychological therapy can make them even more vulnerable.

We had to stop the third randomization of our ongoing clinical trial[2] on the second week of March 2020. It means that 25 people with a first episode of psychosis suddenly ceased to receive their weekly sessions of group psychotherapy. Some of them said that after 5 weekly sessions they had just started to get "attached" to the intervention arm they were allocated to. For many, the trial was the only safe environment for sharing their thoughts and feelings with their peers. Additionally, they pointed out a striking fact about clinical trials, namely that the clinicians are more accessible than usual. In light of this reality, we adopted a set of measures. First, the therapists of both intervention arms launched on-line adaptations of the interventions (a mindfulness-based intervention and a psychoeducational program). Second, a research assistant is making weekly phone calls to provide basic psychosocial support and to remind the participants about the on-line sessions. Last, the phoneline is open 24/7, and participants can still access the practices and materials on the website.

These psychotherapy groups may be avoidable gatherings in the context of a public health emergency. The services they provide, on the other hand, are often essential. It is our duty as researchers to accept the fact of losing valuable information, but it is our more important duty as clinicians not to let anyone go without psychological support in such a difficult time.

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