

and biomarker-based diagnosis<sup>3</sup>.

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## Digital interventions in severe mental health problems: lessons from the Actissist development and trial

Severe mental health problems are characterized by repeated relapse, yet timely access to treatment remains problematic<sup>1</sup>. Within current health care systems, the delivery of treatment by scheduled appointment can result in warning signs being missed or treated too late. Recognizing the need for innovative, timely and efficient solutions to improve the speed and quality of treatment delivery, digital strategies are being developed worldwide<sup>2</sup>.

Grounded in the cognitive model of psychosis, and following an extensive period of co-design with patients and stakeholders, we developed Actissist<sup>3</sup>, a theory-informed smartphone app targeting areas of distress in early psychosis. Actissist uses question and answer dialogues with a branched design to provide cognitive or behavioral-informed feedback to participants, based on the information they input into the app. The app also contains a menu of multi-media options (e.g., links to external sites, patient stories, relaxation sessions) designed to complement and support the feedback from the intervention domains.

In a proof-of-concept, single-blind, randomized controlled trial, 36 early psychosis patients were randomly allocated to receive either Actissist plus treatment as usual (N=24) or Clin-Touch<sup>4</sup>, a symptom monitoring app, plus treatment as usual (N=12) over 12 weeks, with blind assessor follow-up at 12 and 22 weeks<sup>3</sup>. Participants were recruited over 7 months from several early intervention for psychosis services in the North West of England.

Nearly two thirds (38/59; 64.4%) of referred people participated in the study. We found that Actissist was feasible (75% participants used it at least once a day over the 12-week intervention period; 97% participants remained in the trial until the end), acceptable (90% participants declared they would recommend Actissist to others in a similar position), and safe (no serious adverse events related to the study). The treatment effects at 12 weeks favoured the Actissist group, with a Cohen's D standardized effect size of -0.85 (95% CI: -1.44 to -0.25) for the total score on the Positive and Negative Syndrome Scale, and of -0.65 (95% CI: -1.28 to -0.02) for the total score on the Calgary Depression Scale for Schizophrenia.

The next stage of Actissist is being tested in a powered randomized controlled trial (RCT). However, there are at present several clear challenges to both the conduction of standard

RCTs in this area and the implementation of digital health interventions in ordinary practice.

In standard RCTs, the intervention is fixed at the onset of the trial and is not permitted to evolve during the trial. For many drugs under investigation or complex interventions, this is reasonable. However, this is problematic for digital health interventions due to the pace of change in technology. Fixing the intervention at trial onset can render the technology outdated or even obsolete by the time the trial results are available. Adaptive interventions, which are designed to systematically and efficiently optimize behavioural interventions, might be one possible solution to this problem<sup>5</sup>.

Furthermore, the success of digital health interventions is not merely determined by patient uptake; it will ultimately be determined by patients *and* staff, both of whom are key end-users. We have found that mental health professionals and patients often express concerns about data security, safety and risk information being robustly handled<sup>6</sup>. However, given reassurances from reputable and trusted organizations, patients recognize the value of digital health interventions in enhancing their connection with services, and perceive digital approaches as not only destigmatizing but also a relevant way of receiving health care. Perhaps most importantly, patients view these interventions as empowering, affording them meaningful choice and the opportunity to take active control of their health care.

Staff attitudes, however, are a potentially major barrier to digital health care implementation<sup>6</sup>. In our work, staff often expressed the opinion that resources would be better spent on professionals' training than on technology development. Integrating a steady stream of data into patients' records was sometimes perceived as overwhelming, adding to already stretched workloads and professional responsibilities. Without considering issues around implementation during the early stages of the development and delivery of digital health interventions, it is unlikely that these approaches will be disseminated beyond research studies and into the service setting.

Moreover, a clear set of strategies regarding closer involvement of patients in the development of digital innovations as well as engagement of stakeholders with digitally-enabled services is lacking. More research is needed worldwide to under-

stand patients' and stakeholders' perspectives on digital health systems, to maximize implementation. We achieved this in Actissist<sup>3</sup> by holding quarterly meetings with an expert reference group comprising patient representatives and other stakeholders, who were actively involved in all aspects of trial design and app development. We also integrated extensive qualitative work with patients and other stakeholders from before the trial commenced right through to trial exit interviews post follow-up.

Finally, from a global perspective, there is a need to address the exclusion of low-income individuals who cannot access the technology necessary to run digital health tools. Evidence-based digital systems should be a health care cost covered by routine processes, rather than billed to patients. The digital divide also relates to staff using digital systems in the health care context. In our qualitative work, staff often described concerns about their own ability to use technology as well as lack of confidence in the ability of health services to successfully implement a coherent and fully integrated digital system, highlighting the need for all individuals using mental health services and those delivering services to be fully trained and supported<sup>6</sup>.

One final consideration is the lack of theory-driven work underpinning apps being developed across the health setting. It is through theoretical development and innovation that we advance our discipline.

Each of the challenges set out above will need significant programmes of research, considering not only methods of evaluating digital health interventions, but also drawing on implementation science principles. Taken together, these challenges define a prioritized research agenda for digital health interventions for mental health. The promise shown in this field will only be turned into significant progress through multi-disciplinary working.

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## Rethinking progress and challenges of mental health care in China

The rapid socio-economic development and extensive public health reform in China has led to considerable changes in the mental health service system, as previously described<sup>1,2</sup>. However, an update on the recent progress and challenges is now warranted.

Due to various reasons, China has faced major deficits in mental health resources in the past decades. For example, in 2004 there were only 16,103 licensed psychiatrists and psychiatric registrars (1.24 per 100,000 population), 24,793 psychiatric nurses (1.91 per 100,000), and 557 psychiatric hospitals with 129,314 psychiatric beds (9.95 per 100,000) nationwide<sup>1</sup>. Through strengthening the mental health service and education systems nationally, by 2015, there were 27,733 psychiatrists and psychiatric registrars (2.02 per 100,000 population), 57,591 psychiatric nurses (4.19 per 100,000) and 2,936 mental health services with approximately 433,000 psychiatric beds (31.5 per 100,000)<sup>3</sup>. In contrast, based on the World Health Organization (WHO)'s Mental Health Atlas<sup>4</sup>, the proportion of psychiatrists in 2014 was 0.3 per 100,000 in India, 0.87 per 100,000 in Thailand, and 20.1 per 100,000 in Japan.

Although the number of mental health professionals has increased in China, there remains a comparative shortage in human resources. Furthermore, these resources are mostly located in urban psychiatric hospitals, making services far less accessible for at least half of China's 1.39 billion people living

in rural areas. Moreover, the lack of qualified community mental health professionals, which applies to many urban areas even today, remains a major barrier.

To effectively manage millions of community-dwelling patients with severe psychiatric disorders, a national community-based model named "The management and treatment program for severe mental illness with subsidy from the central government" or the "686 Program" was initiated in 2004. We were involved in the development and training components of this program, which integrates the resources of hospital services, community case management, neighborhood committees and the police to provide comprehensive monitoring, treatment, rehabilitation and prevention services. The program prioritized patients with psychiatric disorders and relatively high risk of violent behaviours, namely those with schizophrenia, schizoaffective disorder, paranoid psychosis, bipolar disorder, and epilepsy and mental retardation associated with mental disorders.

Since 2004, the central and local governments have so far invested CNY 2.24 billion (US\$ 325 million) in this program. By 2015, a total of 5.4 million patients with severe mental illness (of which around three quarters with schizophrenia) have been registered at 2,774 districts/counties in 31 provinces, municipalities and autonomous regions. Of the registered patients, 88.7% received regular services and follow-up monitoring<sup>3</sup>. Despite these large figures, the treatment coverage is