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## Contents

## Review

Editorial

# Teaching Telepsychiatry Skills: Building on the Lessons of the COVID-19 Pandemic to Enhance Mental Health Care in the Future

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## Abstract

COVID-19 has accelerated the use of telehealth and technology in mental health care, creating new avenues to increase both access to and quality of care. As video visits and synchronous telehealth become more routine, the field is now on the verge of embracing asynchronous telehealth, with the potential to radically transform mental health. However, sustaining the use of basic synchronous telehealth, let alone embracing asynchronous telehealth, requires new and immediate effort. Programs to increase digital literacy and competencies among both clinicians and patients are now critical to ensure all parties have the knowledge, confidence, and ability to equitably benefit from emerging innovations. This editorial outlines the immediate potential as well as concrete steps toward realizing the potential of a new, more personalized, scalable mental health system.

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**KEYWORDS**

mHealth; mental health; smartphones; telehealth; telepsychiatry; COVID-19

During the COVID-19 pandemic, telepsychiatry—a "virtually perfect" solution to the immediate crisis of a global pandemic [1]—has provided an effective way to deliver care while maintaining social (or, more accurately, physical) distancing. Although remote assessments were novel to many real-world clinicians, telepsychiatry is not a new discipline. There is a well-established evidence base of effectiveness in different patient populations and demographics [2]. Established guidance on telepsychiatry is available and has been synthesized into a user-friendly format, updated to include COVID-19–specific strategies [3,4]. There are additional advantages over in-person treatment in terms of convenience, privacy, reduced stigma, and ease of integration with multidisciplinary viewpoints and specialized care, as well as with other digital technologies [5-7]. Feedback from patients is also positive [8,9] and a majority want to continue to use it after the pandemic [10]—but can the same be said for clinicians? To use fully the wide range of modalities for treatment delivery including telepsychiatry and digital approaches, and to feel confident and competent in offering a truly hybrid service, clinicians will need training to build on the immediate experience they gained during the COVID-19 pandemic [9,11].

At the beginning of the pandemic, there was an almost overnight transition to video- and telephone-based assessments in mental health in many countries [12,13]. Immediate challenges were related to technology and access issues. These included access to both sufficient broadband speed and to a software solution compliant with local and national guidance, which varies across regions and countries. For example, in the United States, software must be compliant with the Health Insurance Portability and Accountability Act (HIPAA) [14], whereas in other countries such as the United Kingdom, commonly available tools such as Skype, WhatsApp, and FaceTime are deemed acceptable, assuming an appropriate local risk assessment. Audio and video transmission also need to be encrypted (according to national guidance) and the device used needs security features (such as passphrases, two-factor authentication, and the latest antivirus, antimalware, and firewall software with updates) [5].

Licensing and legislation also initially provided a barrier, especially in the United States, as prior to the COVID-19 pandemic, physicians in telemedicine were required to be licensed in the state in which the patient was located. In the context of the pandemic, these barriers were quickly overcome (eg, by emergency waivers) to allow telepsychiatry to proceed. Clinicians quickly modified their in-person skills to using telephone and video, learning to a large extent by "doing" [15]. Still, not all were able to adapt easily, and a lack of digital competency has been suggested to be a major source of burnout and stress in these clinicians [16].

However, there is much more to telepsychiatry than just video visits and phone calls. Video and telephone approaches are often classed as "synchronous" telepsychiatry because the interaction, although distanced, is delivered in real time. Asynchronous telepsychiatry, by contrast, occurs when the clinician and patient interaction is separated by time as well as distance. Examples include use of apps for monitoring or delivering treatment, and use of smartphones and other mobile health apps [17]. These technologies can all add rich data and modes of communication to the clinical consultation, but clinicians need to be aware of potential pitfalls as well as advantages. During the pandemic, clinicians have focused almost invariably on video and telephone consultations only [13]. Even after more than two years of pandemic restrictions, clinicians continue to have less experience around asynchronous telehealth, despite its potential to exponentially increase access to care.

Going forward, it is clear that telepsychiatry has the potential to offer much more than a simple replacement of face-to-face care, as a short-term solution to an immediate crisis. Telepsychiatry can now be used toward its true potential in radically increasing access to care as well as quality through an artful combination of synchronous and asynchronous technologies [18], but to realize this, the art of telepsychiatry requires investments in teaching the knowledge, skills, and competencies necessary to use the full range of these technologies. This extension of skills is key, as telepsychiatry will be needed more and more in the future, not only as an essential element of planning for the next crisis but also as the most efficient and effective approach to move psychiatry toward personalized and preventive care that serves the entire population.

Retraining the workforce need not start from scratch. Synchronous telepsychiatry [19], mobile technologies and apps [17,20], social media [21,22], and digital informatics [23] already have proposed competency frameworks. Many are aligned with pre-existing medical education frameworks (see Multimedia Appendix 1 for examples) and use levels of skill attainment: Novice, Competent/Proficient, and Expert. These proposed competencies focus on acquiring and developing skills rather than pure knowledge acquisition [24], and skills development is monitored through ongoing assessment during patient care [25]. Telehealth curricula have been proposed for medical students and for residents (Multimedia Appendix 1). There are examples of programs for teaching telehealth [26-37] (Multimedia Appendix 2), and some psychiatry residency programs in the United States for example are also offering informatics tracks [38]. Novel approaches, such as identifying a care team member (a "digital navigator") to promote and model digital health within clinical teams [39] also show great promise. However, there are important challenges with training the current workforce in telepsychiatry:

1. Enthusiasm may vary and individual clinicians differ in their openness to training. Many already feel they are competent enough, given their experience during the COVID-19 pandemic. The focus of their immediate management has used synchronous techniques, and clinicians may assume that skills can be translated directly from the in-person to virtual setting. Digital literacy among clinicians can also vary [40] and depends to some extent on age [41]. Younger staff and students are often considered as "digital natives" who have grown up with widespread digital technologies, compared to so-called "digital immigrants" who did not encounter these until adulthood [12,21]. However, these are broad categories, with individual variation in skills and enthusiasm for digital literacy, and significant differences for people in their use of and comfort with technologies. Teaching must be targeted and tailored, taking these baseline differences into account.
2. Clinicians are only part of the equation; we also need to improve access to technology for patients. A successful virtual or hybrid clinical interaction can only occur if both clinician and patient are able to access and navigate the tools being used. Access to devices and adequate connectivity represents one significant digital divide, but there is also a second barrier, in which patients have access to technologies but do not have the digital literacy, competence, or confidence to use them to their full potential. Offering training and skills building to patients to strengthen their competence and autonomy in using digital technology to support their health and their therapeutic relationship is critical to ensure access to help for those who need it the most [18]. There are successful examples of schemes for those with serious mental illness, with skills and competencies that are shareable for other groups to modify or expand on as needed [42], and those for community stakeholders to enable remote participation in research studies or community engagement initiatives [43].
3. Existing competency frameworks are comprehensive and detailed, but many have not actually been implemented. This makes them ideally suited for further testing, but less appropriate for broad implementation today. These competencies that have been outlined already could be adapted and amalgamated into a pragmatic time-limited approach that is acceptable to all levels of pre-existing skill and interest [19].
4. Synchronous and asynchronous telepsychiatry have many similarities. For example, their common goal is to enable a clear and therapeutic exchange of information, while preserving professional boundaries [20]. However, there are also a number of key differences, which may require slightly different skill sets. This is partly because asynchronous interactions are often spontaneous and unstructured, and may occur outside health settings and their associated platforms such as the electronic health record. This generates more potential boundary, legal, and ethical issues, which clinicians will need to actively manage.

Clinicians and patients need to be aware of both the advantages and potential pitfalls of these different modes of communication (eg, email, portals, messaging), and successfully navigate any potential overlap between personal and professional life. Social media is another aspect where specific training is critical, especially as younger patients are likely to be influenced by it. Increased digitalization has expanded the boundaries and tools available in medical practice, but specific training has not kept up with increased use of technology. Potential hazards include breaches of confidentiality, privacy, and professional boundaries [44], but these need to be balanced against the potential benefits, such as increased opportunities for professional networking, collaboration, and education and training, and increased patient engagement, education, and health promotion [21,44]. Organizations have developed professional guidelines, standards, and consensus statements regarding responsible physician use of social media and the internet (see Multimedia Appendix 3 for examples), but given the wide variety of guidance documents, in practice it has been difficult for clinicians to absorb the knowledge, competence, and skills required to use social media, apps, and wearables in clinical interactions [20,22]. Novice and more advanced learners alike require competency-based education in this area. Experienced clinicians may be less confident than trainees in digital literacy and may require more training in the benefits and potential pitfalls of different digital media [21], but all aspects of skills will need to be addressed during training to achieve a level of competence to safely blend a range of techniques.

To meet these challenges, training will need to be evidence-based, relevant for the challenges of a post–COVID-19 world, and also engaging for clinicians. Competencies will need to measurable to assess change and there will need to be ongoing evaluation, including feedback from patients. Appetite and interest will vary, and practicing clinicians will already have gained sufficient experience during the pandemic to have progressed beyond the “Novice” stage; therefore, a two-level process aiming for the competency levels of “Competent/Proficient” and “Expert” (for those who wish) would be a helpful model. There is no doubt that developing a telepsychiatry teaching program is warranted, but it will be a challenging process. However, much of the hard work has been completed in developing guidance and a range of competencies. The pandemic has accelerated telepsychiatry into a commonly used, effective, and acceptable route for mental health consultation. Now is the time to complete the translational pathway and allocate dedicated research funding. We need to grasp this impetus and extend skills and competencies into the full range available, so we can offer the very best combination of approaches and treatments to our patients.

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## Conflicts of Interest

AC has received research and consultancy fees from INCiPiT (Italian Network for Paediatric Trials), CARIPLO Foundation, and Angelini Pharma, outside the submitted work. KS has no conflicts to declare. JT is cofounder of a mental health company called Precision Mental Wellness and Editor-in-Chief of *JMIR Mental Health*.

Multimedia Appendix 1
Examples of medical education frameworks.
[DOCX File , 15 KB - mental_v9i10e37939_app1.docx ]

Multimedia Appendix 2
Examples of teaching telehealth.
[DOCX File , 25 KB - mental_v9i10e37939_app2.docx ]

Multimedia Appendix 3
Examples of guidelines for professionalism, social media, and the internet.
[DOCX File , 15 KB - mental_v9i10e37939_app3.docx ]

## References

1. Hollander JE, Carr BG. Virtually Perfect? Telemedicine for Covid-19. N Engl J Med 2020 Apr 30;382(18):1679-1681. [doi: 10.1056/NEJMp2003539] [Medline: 32160451]

2. Melcher J, Hays R, Torous J. Digital phenotyping for mental health of college students: a clinical review. Evid Based Ment Health 2020 Nov;23(4):161-166. [doi: 10.1136/ebmental-2020-300180] [Medline: 32998937]
3. Smith K, Ostinelli E, Macdonald O, Cipriani A. COVID-19 and Telepsychiatry: Development of Evidence-Based Guidance for Clinicians. JMIR Ment Health 2020 Aug 28;7(8):e21108 [FREE Full text] [doi: 10.2196/21108] [Medline: 32658857]
4. Smith K, Ostinelli E, Cipriani A. Covid-19 and mental health: a transformational opportunity to apply an evidence-based approach to clinical practice and research. Evid Based Ment Health 2020 May;23(2):45-46. [doi: 10.1136/ebmental-2020-300155] [Medline: 32317345]
5. Telepsychiatry toolkit. American Psychiatric Association. URL: https://www.psychiatry.org/psychiatrists/practice/telepsychiatry/toolkit [accessed 2022-04-29]
6. Shore JH, Yellowlees P, Caudill R, Johnston B, Turvey C, Mishkind M, et al. Best Practices in Videoconferencing-Based Telemental Health April 2018. Telemed J E Health 2018 Nov;24(11):827-832. [doi: 10.1089/tmj.2018.0237] [Medline: 30358514]
7. Hilty DM, Ferrer DC, Parish MB, Johnston B, Callahan EJ, Yellowlees PM. The effectiveness of telemental health: a 2013 review. Telemed J E Health 2013 Jun;19(6):444-454 [FREE Full text] [doi: 10.1089/tmj.2013.0075] [Medline: 23697504]
8. Guinart D, Marcy P, Hauser M, Dwyer M, Kane J. Patient Attitudes Toward Telepsychiatry During the COVID-19 Pandemic: A Nationwide, Multisite Survey. JMIR Ment Health 2020 Dec 22;7(12):e24761 [FREE Full text] [doi: 10.2196/24761] [Medline: 33302254]
9. Appleton R, Williams J, Vera San Juan N, Needle J, Schlief M, Jordan H, et al. Implementation, Adoption, and Perceptions of Telemental Health During the COVID-19 Pandemic: Systematic Review. J Med Internet Res 2021 Dec 09;23(12):e31746 [FREE Full text] [doi: 10.2196/31746] [Medline: 34709179]
10. Predmore ZS, Roth E, Breslau J, Fischer SH, Uscher-Pines L. Assessment of Patient Preferences for Telehealth in Post-COVID-19 Pandemic Health Care. JAMA Netw Open 2021 Dec 01;4(12):e2136405 [FREE Full text] [doi: 10.1001/jamanetworkopen.2021.36405] [Medline: 34851400]
11. Preparing the healthcare workforce to deliver the digital future. An independent report on behalf of the Secretary of State for Health and Social Care - February 2019. The Topol Review. URL: https://topol.hee.nhs.uk/ [accessed 2022-04-29]
12. Shore JH, Schneck CD, Mishkind MC. Telepsychiatry and the Coronavirus Disease 2019 Pandemic-Current and Future Outcomes of the Rapid Virtualization of Psychiatric Care. JAMA Psychiatry 2020 Dec 01;77(12):1211-1212. [doi: 10.1001/jamapsychiatry.2020.1643] [Medline: 32391861]
13. Hong JS, Sheriff R, Smith K, Tomlinson A, Saad F, Smith T, et al. Impact of COVID-19 on telepsychiatry at the service and individual patient level across two UK NHS mental health Trusts. Evid Based Ment Health 2021 Nov;24(4):161-166 [FREE Full text] [doi: 10.1136/ebmental-2021-300287] [Medline: 34583940]
14. Health Insurance Portability and Accountability Act of 1996 (HIPAA). Centers for Disease Control and Prevention. URL: https://www.cdc.gov/phlp/publications/topic/hipaa.html [accessed 2022-04-29]
15. Wright S, Spaulding R, Henley W. A Multipronged Digital Response to Increased Demand for Telehealth Support and Training During the COVID-19 Pandemic. J Technol Behav Sci 2021 Oct 21:1-8 [FREE Full text] [doi: 10.1007/s41347-021-00224-4] [Medline: 34703876]
16. Golz C, Peter KA, Müller TJ, Mutschler J, Zwakhalen SM, Hahn S. Technostress and Digital Competence Among Health Professionals in Swiss Psychiatric Hospitals: Cross-sectional Study. JMIR Ment Health 2021 Nov 04;8(11):e31408 [FREE Full text] [doi: 10.2196/31408] [Medline: 34734840]
17. Hilty DM, Chan S, Torous J, Luo J, Boland RJ. A Telehealth Framework for Mobile Health, Smartphones, and Apps: Competencies, Training, and Faculty Development. J Technol Behav Sci 2019 Apr 15;4(2):106-123. [doi: 10.1007/s41347-019-00091-0]
18. Torous J, Jän Myrick K, Rauseo-Ricupero N, Firth J. Digital Mental Health and COVID-19: Using Technology Today to Accelerate the Curve on Access and Quality Tomorrow. JMIR Ment Health 2020 Mar 26;7(3):e18848 [FREE Full text] [doi: 10.2196/18848] [Medline: 32213476]
19. Hilty DM, Maheu MM, Drude KP, Hertlein KM. The Need to Implement and Evaluate Telehealth Competency Frameworks to Ensure Quality Care across Behavioral Health Professions. Acad Psychiatry 2018 Dec;42(6):818-824. [doi: 10.1007/s40596-018-0992-5] [Medline: 30426453]
20. Hilty D, Chan S, Torous J, Luo J, Boland R. A Framework for Competencies for the Use of Mobile Technologies in Psychiatry and Medicine: Scoping Review. JMIR Mhealth Uhealth 2020 Feb 21;8(2):e12229 [FREE Full text] [doi: 10.2196/12229] [Medline: 32130153]
21. Zalpuri I, Liu HY, Stubbe D, Wrzosek M, Sadhu J, Hilty D. Social Media and Networking Competencies for Psychiatric Education: Skills, Teaching Methods, and Implications. Acad Psychiatry 2018 Dec;42(6):808-817. [doi: 10.1007/s40596-018-0983-6] [Medline: 30284148]
22. Hilty DM, Zalpuri I, Stubbe D, Snowdy CE, Shoemaker EZ, Joshi SV, et al. Social media/networking as part of e-behavioral health and psychiatric education: Competencies, teaching methods, and implications. J Tech Behav Sci 2018;3(4):268-293. [doi: 10.1007/s41347-018-0061-7]

23. Torous J, Chan S, Luo J, Boland R, Hilty D. Clinical Informatics in Psychiatric Training: Preparing Today's Trainees for the Already Present Future. Acad Psychiatry 2018 Oct;42(5):694-697 [FREE Full text] [doi: 10.1007/s40596-017-0811-4] [Medline: 29047074]
24. Frank JR, Mungroo R, Ahmad Y, Wang M, De Rossi S, Horsley T. Toward a definition of competency-based education in medicine: a systematic review of published definitions. Med Teach 2010;32(8):631-637. [doi: 10.3109/0142159X.2010.500898] [Medline: 20662573]
25. Iobst WF, Sherbino J, Cate OT, Richardson DL, Dath D, Swing SR, et al. Competency-based medical education in postgraduate medical education. Med Teach 2010;32(8):651-656. [doi: 10.3109/0142159X.2010.500709] [Medline: 20662576]
26. Waseh S, Dicker AP. Telemedicine Training in Undergraduate Medical Education: Mixed-Methods Review. JMIR Med Educ 2019 Apr 08;5(1):e12515. [doi: 10.2196/12515] [Medline: 30958269]
27. Edirippulige S, Armfield NR. Education and training to support the use of clinical telehealth: A review of the literature. J Telemed Telecare 2017 Mar;23(2):273-282. [doi: 10.1177/1357633X16632968] [Medline: 26892005]
28. Wamsley M, Cornejo L, Kryzhanovskaya I, Lin B, Sullivan J, Yoder J, et al. Best Practices for Integrating Medical Students Into Telehealth Visits. JMIR Med Educ 2021 Apr 21;7(2):e27877 [FREE Full text] [doi: 10.2196/27877] [Medline: 33881407]
29. Jonas CE, Durning SJ, Zebrowski C, Cimino F. An Interdisciplinary, Multi-Institution Telehealth Course for Third-Year Medical Students. Acad Med 2019 Jun;94(6):833-837. [doi: 10.1097/ACM.0000000000002701] [Medline: 30870152]
30. Rienits H, Teuss G, Bonney A. Teaching telehealth consultation skills. Clin Teach 2016 Apr;13(2):119-123. [doi: 10.1111/tct.12378] [Medline: 26016733]
31. Poncette A, Glauert DL, Mosch L, Braune K, Balzer F, Back D. Undergraduate Medical Competencies in Digital Health and Curricular Module Development: Mixed Methods Study. J Med Internet Res 2020 Oct 29;22(10):e22161 [FREE Full text] [doi: 10.2196/22161] [Medline: 33118935]
32. Abraham HN, Opara IN, Dwaihy RL, Acuff C, Brauer B, Nabaty R, et al. Engaging Third-Year Medical Students on Their Internal Medicine Clerkship in Telehealth During COVID-19. Cureus 2020 Jun 24;12(6):e8791 [FREE Full text] [doi: 10.7759/cureus.8791] [Medline: 32724740]
33. Flickinger TE, O'Hagan T, Chisolm MS. Developing a Curriculum to Promote Professionalism for Medical Students Using Social Media: Pilot of a Workshop and Blog-Based Intervention. JMIR Med Educ 2015 Dec 01;1(2):e17 [FREE Full text] [doi: 10.2196/mededu.4886] [Medline: 27731846]
34. Crawford A, Sunderji N, López J, Soklaridis S. Defining competencies for the practice of telepsychiatry through an assessment of resident learning needs. BMC Med Educ 2016 Jan 26;16:28 [FREE Full text] [doi: 10.1186/s12909-016-0529-0] [Medline: 26813286]
35. Zalpuri I, Domakonda M, Wrzosek M, DeJong S. Trainees on Technological Terrain: a Video Vignette-Based Tool to Teach E-Professionalism. Acad Psychiatry 2021 Apr;45(2):224-230. [doi: 10.1007/s40596-020-01325-7] [Medline: 33058052]
36. Afshari M, Witek NP, Galifianakis NB. Education Research: An experiential outpatient teleneurology curriculum for residents. Neurology 2019 Jul 23;93(4):170-175. [doi: 10.1212/WNL.0000000000007848] [Medline: 31332085]
37. Kirkland EB, DuBose-Morris R, Duckett A. Telehealth for the internal medicine resident: A 3-year longitudinal curriculum. J Telemed Telecare 2021 Oct;27(9):599-605. [doi: 10.1177/1357633X19896683] [Medline: 31888396]
38. Vitiello E, Kane M, Hutto A, Hall A. Building for the future: the creation of a residency training track to foster innovation through clinical informatics in psychiatry. J Am Med Inform Assoc 2020 Nov 01;27(11):1747-1751 [FREE Full text] [doi: 10.1093/jamia/ocaa160] [Medline: 33020847]
39. Wisniewski H, Torous J. Digital navigators to implement smartphone and digital tools in care. Acta Psychiatr Scand 2020 Apr;141(4):350-355 [FREE Full text] [doi: 10.1111/acps.13149] [Medline: 31930477]
40. An L, Bacon E, Hawley S, Yang P, Russell D, Huffman S, et al. Relationship Between Coronavirus-Related eHealth Literacy and COVID-19 Knowledge, Attitudes, and Practices among US Adults: Web-Based Survey Study. J Med Internet Res 2021 Mar 29;23(3):e25042 [FREE Full text] [doi: 10.2196/25042] [Medline: 33626015]
41. Oh SS, Kim K, Kim M, Oh J, Chu SH, Choi J. Measurement of Digital Literacy Among Older Adults: Systematic Review [published correction appears in J Med Internet Res. 2021 Jun 15;23(6):e30828]. J Med Internet Res 2021 Feb 3;23(2):e26145 [FREE Full text] [doi: 10.2196/26145] [Medline: 34129513]
42. Hoffman L, Wisniewski H, Hays R, Henson P, Vaidyam A, Hendel V, et al. Digital Opportunities for Outcomes in Recovery Services (DOORS): A Pragmatic Hands-On Group Approach Toward Increasing Digital Health and Smartphone Competencies, Autonomy, Relatedness, and Alliance for Those With Serious Mental Illness. J Psychiatr Pract 2020 Mar;26(2):80-88 [FREE Full text] [doi: 10.1097/PRA.0000000000000450] [Medline: 32134881]
43. Drazich B, Nyikadzino Y, Gleason K. A Program to Improve Digital Access and Literacy Among Community Stakeholders: Cohort Study. JMIR Form Res 2021 Nov 10;5(11):e30605 [FREE Full text] [doi: 10.2196/30605] [Medline: 34757316]
44. Vukušić Rukavina T, Viskić J, Machala Poplašen L, Relić D, Marelić M, Jokic D, et al. Dangers and Benefits of Social Media on E-Professionalism of Health Care Professionals: Scoping Review. J Med Internet Res 2021 Nov 17;23(11):e25770 [FREE Full text] [doi: 10.2196/25770] [Medline: 34662284]

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Viewpoint

# The Best Predictor of the Future—the Metaverse, Mental Health, and Lessons Learned From Current Technologies

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## Abstract

The metaverse—a virtual world accessed via virtual reality technology—has been heralded as the next key digital experience. It is meant to provide the next evolution of human interaction after social media and telework. However, in the context of the growing awareness of the risks to mental health posed by current social media technologies, there is a great deal of uncertainty as to the potential effects of this new technology on mental health. This uncertainty is compounded by a lack of clarity regarding what form the metaverse will ultimately take and how widespread its application will be. Despite this, given the nascent state of the metaverse, there is an opportunity to plan the research and regulatory approaches needed to understand it and promote its positive effects while protecting vulnerable groups. In this viewpoint, we examine the following three current technologies whose functions comprise a portion of what the metaverse seeks to accomplish: teleworking, virtual reality, and social media. We attempted to understand in what ways the metaverse may have similar benefits and pitfalls to these technologies but also how it may fundamentally differ from them. These differences suggest potential research questions to be addressed in future work. We found that current technologies have enabled tools such as virtual reality–assisted therapy, avatar therapy, and teletherapy, which have had positive effects on mental health care, and that the metaverse may provide meaningful improvements to these tools. However, given its similarities to social media and its expansion upon the social media experience, the metaverse raises some of the same concerns that we have with social media, such as the possible exacerbation of certain mental health problems. These concerns led us to consider questions such as how the users will be protected and what regulatory mechanisms will be put in place to ensure user safety. Although clear answers to these questions are challenging in this early phase of metaverse research, in this viewpoint, we use the context provided by comparator technologies to provide recommendations to maximize the potential benefits and limit the putative harms of the metaverse. We hope that this paper encourages discussions among researchers and policy makers.

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**KEYWORDS**

metaverse; mental health; social media; virtual reality; VR; digital experience; human interaction; mental health risk; teleworking; assisted therapy; teletherapy; benefits; safety; mental health problems; data security; privacy; protection; user safety; safety regulations; mobile phone

## Introduction

It is 8 AM on Tuesday, and you are in your therapist's office for your weekly session. You listen to your therapist while enjoying the calming sound of the small water fountain in her office. Suddenly, you remember—today is the important meeting with your boss at 9 AM. Your therapist's office is an hour away from your workplace—there is no way to get there on time. You almost have a panic attack. Just as suddenly, you remember—you are not really in her office. Owing to the strikingly authentic look of the surroundings, you forgot that

you were attending your weekly session in the *metaverse*. You finish the session at 8:50 AM, remove your virtual reality (VR) headgear, and walk around the house to stretch your legs. It is 8:55 AM. You put the headset back on, choose your office avatar, and enter the meeting 5 minutes early. You sigh and think, "Thank goodness for technology!"

The term "metaverse" was coined by writer Neal Stephenson in his 1992 science fiction novel, *Snow Crash*, in which characters used digital avatars of themselves as a way of escaping a dystopian reality. However, since then, the term has evolved to refer to a technology that encompasses more than just a digital escape. Today, the metaverse is a virtual world that exists beyond the physical world, equipped with means for the creation of digital locations for work, play, and socializing. This virtual world is accessed using VR hardware plugged into the next iteration of major social networks and collaboration software.

Despite the definition, the fact is that what *precisely* the metaverse will be and how it will evolve over time remain unknown. Experience has taught us that it is easy to both over- and underestimate the impacts of new technologies and often impossible to predict their diverse applications. Decoding the human genome has not led to the widespread adoption of gene therapy for most diseases; by contrast, the myriad uses of the internet likely go far beyond what its progenitors would have imagined. It is not even clear, despite the posturing of large companies in this space, whether the metaverse will become a truly pervasive phenomenon, such as the social media that precedes it, or whether it will become a niche experience, relevant in only some industries and consumer segments. The pace of development and deployment of the metaverse also remains unclear, and the question of who gains access first will certainly have potential effects in terms of what kinds of mental and physical health concerns the metaverse may be able to help alleviate or exacerbate. We also are unlikely to be able to draw meaningful and generalizable conclusions based on the data collected from current users of the nascent metaverse as this group is unlikely to be representative of the general population. However, it remains possible that the metaverse will be restricted, at least initially, to specific subpopulations; should this be the case, research may need to be focused on those populations to reduce harms and maximize benefits of the new technology.

Having acknowledged these uncertainties, in this viewpoint, we will adopt the following as our guiding question: "What will the effects of the metaverse be on mental health?" We use this frame to consider some initial questions that researchers can address. We begin with the following question while drawing on the existing literature on social media, teleworking, and VR technologies: "In what ways might the metaverse differ from existing technologies?" We selected these 3 technologies as comparators to inform this viewpoint given their relevance to the likely uses of the metaverse.

## Comparator Technologies

Our 3 chosen comparator technologies (telework, VR, and social media) exist at varying levels of adoption and maturity. Especially in the context of the COVID-19 pandemic, many people—including providers of mental health care—have become familiar with working from home and conversing with team members through technology. As such, teleworking technologies can be said to be at a more advanced stage of adoption and maturity in both the consumer and medical realms.

A subset of video gamers has adopted VR technologies, although the numbers are limited compared with traditional platforms owing to cost and concerns with motion sickness [1]. VR programs have been proven to be of value in treating some mental health conditions such as phobias and posttraumatic stress disorder [2,3], although a 2019 meta-analysis concluded that VR may be equivalent to active comparators for posttraumatic stress disorder (with the caveat that this was based on a limited number of trials focusing mostly on male military service members) [4]. VR has also recently been used to reduce agoraphobia in people with psychosis; this therapy was automated and required minimal intervention from staff, although staff with varying degrees of training were present in the room, helped review homework assigned during VR therapy, and encouraged patients to apply what they learned in the real world [5]. Although VR has seen some adoption in consumer and clinical contexts, its maturity and use are perhaps the lowest of the 3 technologies.

Social media has a ubiquitous influence on the lives of billions of people [6], but research on social media continues to present significant challenges, including data access and quality [7,8]. Despite these challenges, there is growing and consistent evidence of potential negative effects of social media use and misuse on mental health, particularly in children and adolescents. In a recent large study, higher amounts of social media use has been shown to predict later reductions in life satisfaction [9]. It is worth noting from recent reports that social media companies were aware of the negative impacts on the mental health of adolescents based on research conducted internally, including worsening body image issues, increased feelings of depression and anxiety, and suicidal ideation, but chose to keep these data private [10]. Despite these findings, it must be acknowledged that research on social media is still a rapidly changing field that is continuously providing new nuances to our understanding. For example, some studies have found that passive social media use (eg, monitoring social media feeds and passively consuming content by others) has been associated with worsened well-being, whereas active use (ie, using social media for the purpose of connecting with others or making posts) is associated with improved well-being; however, in a recent review, these findings were not shown to be consistent across studies, potentially as the benchmarks used to measure active versus passive use, such as time, were not precise enough [11]. The authors further discussed the possibility that future research needs to consider the profiles of users as well as the type of engagement in social media, highlighting the potential importance of taking a nuanced approach that accounts for both the technology and individual differences in this kind of research. Social media has the most advanced adoption and maturity from a consumer standpoint, although it currently seems to be rather limited with respect to both metrics in terms of clinical application. Research on each of these

technologies has something to teach us about the metaverse's potential effect on mental health. While exploring this, let us also clarify some potential distinctions between these technologies and the metaverse.

## Telework

In the case of telework, the purpose of relevant technologies (such as team management applications and videoconferencing) is to enable workers to continue working *from* home. The mental health effects of telework are known to be complex and depend on variables such as available organizational support, social connections available outside of work, and work-family conflict (see the review by Oakman et al [12] and the study by De Sio et al [13]). We argue that the metaverse is qualitatively different, as its effect would be to enable workers to *be* at work while they are at home. The psychological effect this will have is unclear, but one might imagine that being able to interact with colleagues in a VR space may reduce the isolation that some teleworkers experience [14] while at the same time further eroding the separation between work and home life and potentially increasing the work-family conflict, which can reduce well-being during telework. We believe that the potential impact on people with anxiety disorders, such as social anxiety, should also be considered. On the one hand, we might imagine that coming to work as an avatar whose physical reactions are limited and likely controlled by the user may reduce anxiety and facilitate workplace integration for people with anxiety who fear that they might show symptoms of panic or tension publicly. On the other hand, we (speaking as therapists and psychiatrists who treat anxiety) might argue that this may also facilitate avoidance, leading to therapy-interfering avoidance behaviors or fewer people seeking care as they are able to support themselves while remaining isolated. Indeed, avoiding exposure during anxiety treatment is a common therapy-interfering behavior that can hinder treatment outcomes and that therapists associate with worsened outcomes [15]. Furthermore, other aspects of telework, such as social isolation, a perceived lack of support, poor sleep, or the need to sort through technical difficulties, could all contribute to increasing anxiety and reducing well-being [16-18], and as such, it is difficult to know without further empirical work which aspects of telework in the metaverse may drive or reduce anxiety and how this might interact with individual differences. Indeed, in line with the discussions by Valkenburg et al [11,19] and Oakman et al [12], we argue that an understanding of individual differences in responses to the metaverse will be as key to its future study as it may be to the study of social media and telework. In addition, although research on working in the metaverse is in its nascent stages, a recent study did find reduced subjective productivity and well-being as well as physical side effects such as nausea and migraine after a week of office work in VR [20]. This is certainly preliminary work, and it is possible that advances in technology and software application design will reduce some of these effects, but it does indicate that the metaverse is far from ready to positively transform work at present.

## Teletherapy and VR

A particular aspect of telework that intersects with mental health is the provision of teletherapy. There is already evidence that internet and videoconferencing–based psychotherapy seems to be as effective as in-person therapy for a number of indications, such as anxiety and depression [21,22], although there remains a need for more rigorous research in this area, especially considering the reduced tendency to recruit patients who are more severely ill or suicidal in teletherapy studies [23]. The metaverse could allow for easier integration of VR elements into traditional therapy (imagine a teletherapy session that transitions to a VR environment for exposure work). However, the question remains as to whether the metaverse will present significant advantages over in-person or existing VR and teleconferencing technologies. Should the metaverse become widely used, it may increase access to VR and teletherapy, which would be a significant benefit but which, we argue, would not in and of itself change the therapeutic process. However, we can also imagine that the metaverse may also present entirely new therapeutic opportunities. If it becomes truly trivial to take a session from a traditional (though virtual) therapist's office to a crowded street or a public speaking engagement, it may make the treatment of anxiety disorders, such as social anxiety or panic disorder, more effective (given the importance of exposure in these conditions and the aforementioned evidence of the value of VR in treating anxiety disorders) and reduce disparities in care quality for those in rural areas. By providing more virtual environments in which a patient and therapist may move around safely, we believe that a host of functional assessments, novel behavioral tests, and new approaches to the therapeutic process become possible. Indeed, a parallel can be seen in the extensive literature examining the use of data captured by smartphones to better diagnose and "digitally phenotype" patients (see the review by Huckvale et al [24] for a discussion). We foresee that challenges are likely to present themselves; for example, conducting therapy when both participants are "avatars" may reduce key nonverbal cues that are still present to some extent during teleconferences and that are traditionally considered to be an important part of therapy [25]. As such, we might argue that VR approaches that better approximate real movement and reproduce the participants' faces with high fidelity may be necessary to make full use of this technology. However, these are technological challenges that could realistically be solved.

Teletherapy did not *improve* therapy; it improved its availability and the ease of engagement for those who otherwise would have avoided the therapy or been unable to access services. For the metaverse to provide anything more than an incremental improvement over teletherapy, we argue that therapists and patients will need to be given tools and the capacity to create and manipulate content in the metaverse. This can be thought of as being similar to the map editors one might find in popular video games, where players can create new levels or "maps" to play on and share them with the community. Researchers and commercial interests may also generate standardized testing environments or scenarios, similar to the aforementioned current

VR simulations used for therapy, which therapists may choose to integrate into their practice.

A key point of VR therapy as it currently exists is that, as noted previously, it is generally an extension of existing therapeutic practices guided by trained staff. This suggests that for full benefit and potentially to avoid harm, professionally guided use of metaverse-enabled therapy may be necessary.

The metaverse may also provide a useful adjunct in other areas where technology has been used to try to improve mental health. Let us take avatar therapy as an example. In this novel therapy, which has been used in psychotic disorders and has shown promise in treating persistent verbal hallucinations, patients construct a virtual representation of the persecutor and then engage in a dialogue with this "avatar," who is voiced by the therapist [26]. Access to this therapy might be facilitated by the metaverse given the ease with which avatars can be created in virtual worlds. The metaverse may also pose challenges specific to those with psychosis; however, a digital world in which movements are tracked, environments can be controlled, and reality can be altered on a whim may, speculatively, worsen paranoid feelings or further entrench delusional beliefs.

In addition, the metaverse may be a useful tool for measurement-based care, a gold standard in the treatment of conditions such as depression. Measurement-based care entails the use of frequent standardized assessments to guide treatment. Within the metaverse, clinical researchers may find new and relevant measurements derived from social interaction, work habits, and other behaviors that could serve as more naturalistic markers of function and illness or act as predictors of treatment response or guides for the modification of treatment. However, as will be discussed in the following sections, concerns regarding privacy and the manner in which the metaverse will be monetized will pose a challenge to this use.

## Social Media

Having considered VR, teletherapy, and telework, let us turn to social media. Despite the aforementioned dangers, social media is very popular because it meets the human need to connect and share, and it can have positive effects on human connections [27]. The metaverse will include, as a key element, the experience of social media in VR. This means that the same concerns we currently have regarding social media can be applied to the metaverse. This raises a number of questions. Can people become addicted to the metaverse as some have argued people can become addicted to social media [28]? Can it exacerbate underlying symptoms of eating disorders, anxiety, and depression in a manner similar to social media? Will it, similar to social media, lead to a reinforcement of maladaptive sleep or physical activity patterns in some users [29]? Will it provide even more opportunities for bullying and abuse, especially now that people will have (virtual) bodies available to attack in addition to their social media profiles? There has already been evidence of the potential for virtual sexual harassment. A number of people, from researchers to metaverse beta testers, have reported being groped, pinched, and sexually and verbally assaulted in the metaverse by perpetrators who feel especially emboldened by the anonymity it provides [30].

In addition, the development of haptic technology, where a user can feel the stimulus of virtual punches or kicks on their physical body, opens doors for users now being exposed to physical assault along with virtual assault. As discussed previously, the effects of social media are complex and likely depend a great deal on the way in which people use it and on individual differences between users, and social media clearly has significant utility for a large segment of the population. There is no reason to expect that this will be different for the metaverse; therefore, the focus on negative aspects in this section is not intended to paint all social media as negative but rather to demonstrate areas of concern that likely need to be carried forward into metaverse research. Indeed, in our view, the social elements of the metaverse, which become amenable to measurement and research in their digital form, may prove to be rich avenues for research into social interactions as markers of function or measures for measurement-based care, as described previously.

Aside from existing concerns, we must also consider in what way the metaverse will represent a qualitative evolution of current social media. To address this, it is necessary to speculate to a certain extent, given that the metaverse is not yet available for meaningful empirical testing. Currently, social media is accessed *through* an interface—a phone or computer. This has not stopped it from being a powerful force in the lives of many. However, we ask how this might change when the interface (the VR headset) provides access to a virtual world that the user *inhabits* and this world itself *is, to a large extent*, social media. How will our relationship with social media evolve when what we identify as our bodies is subjected to the pressures of this virtual world? Indeed, as discussed in the study by Fardouly and Vartanian [31], it has already been demonstrated that social media use, especially prolonged use, can lead to more negative body image. If someone can morph and control their avatar to fit in with expectations, what kind of dissonance will be created when they emerge into the real world and remember that their real bodies cannot be altered with the same ease? This perhaps is the qualitative difference between the metaverse and current social media—one may create a persona for social media, whereas, in the metaverse, one may be able to create a new *person*. What this will mean for conditions in which self-esteem and identity are already deeply affected—such as personality and eating disorders—is unclear, but we argue that what is clear is the need for careful and concerted research in this area. Indeed, there is research demonstrating that teenage girls craft their personas on the web and often hide feelings while on the internet and, furthermore, that the nature of the persona they craft depends on the social media site they use and the environment it creates [32], and adolescents are known to use the internet to experiment with their identities [19]. As the metaverse offers a new platform for social interaction on the web, one with additional features beyond the existing social media platforms, it will be both interesting and important to consider how people, and young people especially, interact with it while forming their identities.

## Discussion and Initial Recommendations

In this brief and incomplete discussion, we have compared and contrasted the metaverse with existing technologies. It is our view that the existing benefits and harms that these technologies provide are likely to continue into the age of the metaverse, should it materialize. However, we also believe that there are qualitative differences between this novel technology and existing technologies that provide us with new questions to ask, new potential harms to anticipate and mitigate, and opportunities for improving mental health services and developing new therapies and measures.

Research and policy directions will depend on our ability to predict the direction that the metaverse will take. We posit that this, in turn, depends on the answer to the following question: *cui bono* (who benefits)? Relevant to the public health perspective of this technology is this need to understand how metaverse architects will profit from it. For example, as social media networks are free to access, their business model focuses on driving user engagement to increase advertising revenue [33]. This is concerning, as the passive use of social media (eg, scrolling through news or content as presented by the site in its effort to drive engagement) was linked to reduced well-being in some studies, whereas active use (eg, messaging friends) was not [34]; although, as discussed previously, this is not a consistent finding in the literature. Similarly, the business models underlying the metaverse will drive how it is built and the behaviors it encourages, which in turn will drive its mental health effects. We believe that it is critical for researchers to consider this when designing studies and hypotheses as we cannot rely on companies to share data on worrying trends. Indeed, in a recent commentary on the private regulation of neurotechnology [35], the authors note that paying out settlements when harm is done is something that has simply become part of the "cost of doing business."

Hence, we as users must question how we will be protected from the potential harms of the metaverse and who will be responsible for regulating it. The argument for the regulation of technologies related to social media and, as such, social media companies is easier to make in light of recent events described previously. However, to date, we have not been able to resolve the question of who should regulate these platforms and if regulation were to occur, how to balance the need to protect the public with the right to free expression and participation in public spaces.

Governments often lack the technical knowledge required to create and enforce regulations of technologies and can move slowly, and given the rising need for mental health services, there is an argument for making sure that the benefits of the metaverse to mental health can be realized quickly. In addition, governments are susceptible to lobbying, bribery, and collusion. By contrast, if companies are given free rein to self-regulate, the situation we currently face where social media companies put their bottom line above user safety will simply repeat in the metaverse. If we consider the past to be a good predictor of the future, then, in our opinion, early involvement of government regulation (in jurisdictions where there is adequate protection for freedom of speech) will be necessary to avoid a repeat of the status quo.

Then there is the question of what kind of regulation these platforms should be subject to. Although a full treatment of this subject is beyond the scope of this paper, we make some recommendations based on our view of the current and likely future situation for consideration by relevant authorities. First, we differentiate between those applications that are designed as treatments or diagnostic tools that are implemented in the metaverse and the metaverse more broadly. In the former, narrow case, our recommendations are outlined in Textbox 1.

This would be in line with existing regulations regarding devices designed to diagnose or treat illness in the United States, Europe, and Canada [36-38], and the argument for equivalent regulatory practices has been made for similar novel technologies such as artificial intelligence–powered medical products [39,40]. As such, the recommendation is not meant to change the status quo but rather to serve as a reminder that the creators of novel technologies continue to have responsibilities laid out in current regulations and that regulators, in turn, must not only be vigilant with respect to the unregulated deployment of new technologies but also, as the Food and Drug Administration has done in their new draft guidance on artificial intelligence devices [39], be innovative to ensure that their regulations and guidance evolve to best address novel technologies. In addition, we believe that care must be taken to streamline regulatory processes and provide templates and materials that can be used by smaller firms and start-ups, so that their entry into the market is not blocked by the cost of regulatory compliance. This is relevant not just from an economic standpoint because if smaller, newer firms cannot enter the market, then it will necessarily be dominated by existing social media giants, reducing the chance that the development of the metaverse could proceed in a different manner to the recent development of social media.

With respect to the metaverse more generally, we make the recommendations outlined in Textbox 2.

**Textbox 1.** Recommendations regarding applications designed as treatments or diagnostic tools.

**Classification as medical devices**

- Any application developed in the metaverse ecosystem designed specifically as a treatment or diagnostic tool for mental health should come under regulations governing medical devices and require appropriate validation and evidence of safety and utility.

**Textbox 2.** Recommendations regarding the metaverse more broadly.

**Increased transparency and control for users**

- Companies should be required to make available user-friendly suites of data to consumers describing how long they spend in the metaverse, what activities they engage in, how their data are being used, what kinds of targeted elements (eg, advertisements) they interact with, and how these were targeted. Users should be able to easily set limits on time, targeted marketing, and uses of their data. Although there is some evidence that most users do currently use tools such as advanced privacy settings on social media [41], their overall effectiveness in enhancing privacy and well-being is understudied and often questioned (see the study by Mondal et al [42], who discuss this in the case of Twitter). As such, this recommendation is included as a "baseline" of sorts that we believe, on ethical grounds, to be necessary though likely not sufficient for the mitigation of potential harms.

**Active moderation**

- We argue that from the start, companies must put in place measures to limit sexual and other forms of harassment and remove offending users from the platform. Users must be given tools to limit harassment, for example, being able to exclude other users from their personal space. In addition, effective reporting mechanisms should be put in place. One case study of the deplatforming (a form of moderation where controversial figures are removed from social media platforms) of 3 well-known influencers demonstrated that, at least on the platforms from which they were removed, the overall toxicity and activity of their supporters dropped after deplatforming [43], although some supporters may simply move to other less-moderated platforms, and the effectiveness of different moderation approaches—only some of which focus on the experience of individuals being subjected to harassment—remains an area of active research [44]. There are, of course, concerns regarding the open exchange of ideas and freedom of speech that must also be addressed when it comes to moderation. Although this is perhaps less of an issue in the case of clear interpersonal harassment, the many forms that harassment and intimidation can take and their ability to be directed to both groups and individuals will require careful legal and ethical analysis that is outside the scope of this paper. As such, we conclude that the precise form that active moderation should take in the metaverse is a question that will require experimentation, ethical debate, and research; therefore, a key element of this recommendation is that active and both prospective and retrospective analysis of the effectiveness and ethics of different moderation techniques be undertaken as the metaverse is implemented. During this research, care will be needed to differentiate between moderation that targets the macrolevel experience (ie, moderating popular figures that can influence the tone of discourse in the metaverse) and microlevel experiences of harassment between individual users [44]. This prospective approach to shaping moderation practices would be in contrast to what is arguably the more reactive approach to moderation taken in social media in recent years.

**Compulsory after-market research**

- Companies should be required to collect data, in aggregate form using a format mandated by regulators, on user mental health and share this with relevant authorities and the research community, very similar to how pharmaceutical companies are required to complete after-market studies.

**Compulsory beta testing and data sharing**

- Companies should be required to extensively beta test the metaverse and collect data on health outcomes in a prespecified manner by regulators and in representative populations, and this beta testing should be required for major application updates. This information should be submitted to regulators who may then take appropriate actions. This information should also be made public and available to researchers. This and the previous recommendation are based on the consistent findings in the literature, discussed previously [7,8], that the quality of and access to data has been a challenge in social media research. As such, creating programs for structured beta testing as well as postmarketing research, the data for which are intended to be generated in a format meant for sharing with researchers and regulators, should help accelerate the pace and increase the quality of metaverse-related research. It would also help avoid situations such as those described previously in connection with social media, where evidence of potential harms experiences significant delays before being made public.

**Taking privacy protection seriously**

- Social media companies and data aggregators are currently exempt from health data privacy regulations such as the Health Insurance Portability and Accountability Act (HIPAA), as they are not considered creators or custodians of health care data. However, the data they aggregate can contain detailed information about an individual, and the behavioral measures available in the metaverse may exacerbate this situation [45]. Steps could be taken to bring any company that controls or collects data that can be used to generate a profile of a person's health status under relevant regulations such as HIPAA. However, defining which data come under this definition will be a challenging exercise, and as noted previously, care must be taken to streamline requirements such that smaller, innovative firms are not frozen out of the market to the benefit of existing major players in the space.

It should be noted that, to properly regulate the metaverse, a clear operationalization of the metaverse is necessary to allow regulators to know what to regulate and in which contexts. If an application, regardless of its precise implementation, is generated with a clearly medical purpose and makes medical claims, it would be relatively easy to argue that it should be regulated as a medical device (as we do in Textbox 1). However, the precise definition of what is part of the metaverse becomes more important when the application in question is not clearly medical in nature. The description of the metaverse as a virtual environment where people work, play, interact, and receive services using VR is a starting point for a definition but one that will need to evolve as the metaverse takes shape. We posit that the question for regulators will then become *which* elements of this space and its construction may have health impacts that require regulatory oversight. We believe that this may be, in essence, an empirical question, one that could be answered by the compulsory after-market research and data sharing we described in Textbox 2. Once sufficient data have been collected and scrutinized by regulators, researchers, and the public, it may become easier to see which nonmedical elements of the metaverse are most deserving of health-related regulation. We

argue that this would have been a helpful approach in the original deployment of social media, helping to maximize benefits and minimize harms; there is now an opportunity to approach the nascent metaverse in this manner.

In terms of the limitations of this work, one area of technology that we have not addressed is digital gaming, an area with a rich research literature. This is because, to date, in the opinion of the authors, the metaverse has been focused on the union of digital work and social media in a VR space, and it is not yet clear to us what transformative impact they will have on the experience of digital gaming. However, such impacts may occur and should be the subject of future research.

## Conclusions

The challenges and potential uses of the metaverse and similar VR communities merit meaningful discussion to maximize the benefits and limit harm. In summary, our viewpoint is as follows: the metaverse is a tool that can facilitate mental health care and treatment and that has vast potential to provide innovative approaches to the measurement, detection, and treatment of mental illness, so long as it is used appropriately. We can best ensure that this occurs through research, proper prospective data collection, and proper use of the data collected. Governments and other regulators should become involved now, before it is too late, to protect the metaverse from becoming just another commercial space devoid of standards to protect users. This is particularly relevant to mental health after the COVID-19 pandemic, where virtual care is already a standard of care, as the metaverse is poised to become the next platform for virtual mental health care delivery.

### Conflicts of Interest

DB is a founder, shareholder, and officer of Aifred Health, a digital mental health company whose work is unrelated to the content of this work. HCM has received honoraria, sponsorship, or grants for participation in speaker bureaus, consultations, advisory board meetings, or clinical research from AbbVie, HLS Therapeutics, Janssen, Lundbeck, Otsuka, Sunovion, SyneuRx International, and Teva.

### References


1. Rebenitsch L, Owen C. Review on cybersickness in applications and visual displays. Virtual Reality 2016 Apr 26;20(2):101-125 [FREE Full text] [doi: 10.1007/s10055-016-0285-9]
2. Park MJ, Kim DJ, Lee U, Na EJ, Jeon HJ. A literature overview of virtual reality (VR) in treatment of psychiatric disorders: recent advances and limitations. Front Psychiatry 2019 Jul 19;10:505 [FREE Full text] [doi: 10.3389/fpsyt.2019.00505] [Medline: 31379623]
3. Baghaei N, Chitale V, Hlasnik A, Stemmet L, Liang HN, Porter R. Virtual reality for supporting the treatment of depression and anxiety: scoping review. JMIR Ment Health 2021 Sep 23;8(9):e29681 [FREE Full text] [doi: 10.2196/29681] [Medline: 34554097]
4. Kothgassner OD, Goreis A, Kafka JX, Van Eickels RL, Plener PL, Felnhofer A. Virtual reality exposure therapy for posttraumatic stress disorder (PTSD): a meta-analysis. Eur J Psychotraumatol 2019 Aug 19;10(1):1654782 [FREE Full text] [doi: 10.1080/20008198.2019.1654782] [Medline: 31489138]
5. Freeman D, Lambe S, Kabir T, Petit A, Rosebrock L, Yu LM, gameChange Trial Group. Automated virtual reality therapy to treat agoraphobic avoidance and distress in patients with psychosis (gameChange): a multicentre, parallel-group, single-blind, randomised, controlled trial in England with mediation and moderation analyses. Lancet Psychiatry 2022 May;9(5):375-388 [FREE Full text] [doi: 10.1016/S2215-0366(22)00060-8] [Medline: 35395204]
6. Number of social media users worldwide from 2018 to 2027. Statista. 2022. URL: https://www.statista.com/statistics/278414/number-of-worldwide-social-network-users/ [accessed 2022-03-28]
7. Weller K. Accepting the challenges of social media research. Online Inf Rev 2015;39(3):281-289 [FREE Full text] [doi: 10.1108/oir-03-2015-0069]
8. Persily N, Tucker J. The Challenges and Opportunities for Social Media Research. Stanford Cyber Policy Center. 2020. URL: https://cyber.fsi.stanford.edu/publication/challenges-and-opportunities-social-media-research [accessed 2022-10-24]
9. Orben A, Przybylski AK, Blakemore SJ, Kievit RA. Windows of developmental sensitivity to social media. Nat Commun 2022 Mar 28;13(1):1649 [FREE Full text] [doi: 10.1038/s41467-022-29296-3] [Medline: 35347142]
10. Gayle D. Facebook aware of Instagram's harmful effect on teenage girls, leak reveals. The Guardian. 2021 Sep 14. URL: https://www.theguardian.com/technology/2021/sep/14/facebook-aware-instagram-harmful-effect-teenage-girls-leak-reveals [accessed 2022-10-24]
11. Valkenburg PM, van Driel II, Beyens I. The associations of active and passive social media use with well-being: a critical scoping review. New Media Soc 2021 Dec 31;24(2):530-549 [FREE Full text] [doi: 10.1177/14614448211065425]
12. Oakman J, Kinsman N, Stuckey R, Graham M, Weale V. A rapid review of mental and physical health effects of working at home: how do we optimise health? BMC Public Health 2020 Nov 30;20(1):1825 [FREE Full text] [doi: 10.1186/s12889-020-09875-z] [Medline: 33256652]

13. De Sio S, Cedrone F, Nieto HA, Lapteva E, Perri R, Greco E, et al. Telework and its effects on mental health during the COVID-19 lockdown. Eur Rev Med Pharmacol Sci 2021 May;25(10):3914-3922 [FREE Full text] [doi: 10.26355/eurrev_202105_25961] [Medline: 34109606]
14. Van Zoonen W, Sivunen AE. The impact of remote work and mediated communication frequency on isolation and psychological distress. Eur J Work Organ Psychol 2022;31(4):610-621 [FREE Full text] [doi: 10.1080/1359432x.2021.2002299]
15. Davis ML, Fletcher T, McIngvale E, Cepeda SL, Schneider SC, La Buissonnière Ariza V, et al. Clinicians' perspectives of interfering behaviors in the treatment of anxiety and obsessive-compulsive disorders in adults and children. Cogn Behav Ther 2020 Jan;49(1):81-96. [doi: 10.1080/16506073.2019.1579857] [Medline: 30862251]
16. Mann S, Holdsworth L. The psychological impact of teleworking: stress, emotions and health. New Technol Work Employ 2003 Nov;18(3):196-211 [FREE Full text] [doi: 10.1111/1468-005x.00121]
17. Pelissier C, Paredes J, Moulin M, Bitot T, Fakra E, Fontana L. Telework and psychological health in hospital staff during the first wave of the COVID-19 epidemic in France. Int J Environ Res Public Health 2021 Oct 03;18(19):10433 [FREE Full text] [doi: 10.3390/ijerph181910433] [Medline: 34639732]
18. Afonso P, Fonseca M, Teodoro T. Evaluation of anxiety, depression and sleep quality in full-time teleworkers. J Public Health (Oxf) (forthcoming) 2021 May 25:fdab164 [FREE Full text] [doi: 10.1093/pubmed/fdab164] [Medline: 34036369]
19. Valkenburg PM, Schouten AP, Peter J. Adolescents' identity experiments on the internet. New Media Soc 2005 Jun;7(3):383-402 [FREE Full text] [doi: 10.1177/1461444805052282]
20. Biener V, Kalamkar S, Nouri N, Ofek E, Pahud M, Dudley JJ, et al. Quantifying the effects of working in VR for one week. arXiv. Preprint posted online on June 8, 2022 2022 [FREE Full text]
21. Berryhill MB, Culmer N, Williams N, Halli-Tierney A, Betancourt A, Roberts H, et al. Videoconferencing psychotherapy and depression: a systematic review. Telemed J E Health 2019 Jun;25(6):435-446. [doi: 10.1089/tmj.2018.0058] [Medline: 30048211]
22. Berryhill MB, Halli-Tierney A, Culmer N, Williams N, Betancourt A, King M, et al. Videoconferencing psychological therapy and anxiety: a systematic review. Fam Pract 2019 Jan 25;36(1):53-63. [doi: 10.1093/fampra/cmy072] [Medline: 30188992]
23. Markowitz JC, Milrod B, Heckman TG, Bergman M, Amsalem D, Zalman H, et al. Psychotherapy at a distance. Am J Psychiatry 2021 Mar 01;178(3):240-246. [doi: 10.1176/appi.ajp.2020.20050557] [Medline: 32972202]
24. Huckvale K, Venkatesh S, Christensen H. Toward clinical digital phenotyping: a timely opportunity to consider purpose, quality, and safety. NPJ Digit Med 2019 Sep 6;2:88 [FREE Full text] [doi: 10.1038/s41746-019-0166-1] [Medline: 31508498]
25. Foley GN, Gentile JP. Nonverbal communication in psychotherapy. Psychiatry (Edgmont) 2010 Jun;7(6):38-44 [FREE Full text] [Medline: 20622944]
26. Craig TK, Rus-Calafell M, Ward T, Leff JP, Huckvale M, Howarth E, et al. AVATAR therapy for auditory verbal hallucinations in people with psychosis: a single-blind, randomised controlled trial. Lancet Psychiatry 2018 Jan;5(1):31-40 [FREE Full text] [doi: 10.1016/S2215-0366(17)30427-3] [Medline: 29175276]
27. Valkenburg PM, Peter J. Preadolescents' and adolescents' online communication and their closeness to friends. Dev Psychol 2007 Mar;43(2):267-277. [doi: 10.1037/0012-1649.43.2.267] [Medline: 17352538]
28. Sun Y, Zhang Y. A review of theories and models applied in studies of social media addiction and implications for future research. Addict Behav 2021 Mar;114:106699. [doi: 10.1016/j.addbeh.2020.106699] [Medline: 33268185]
29. Shimoga SV, Erlyana E, Rebello V. Associations of social media use with physical activity and sleep adequacy among adolescents: cross-sectional survey. J Med Internet Res 2019 Jun 18;21(6):e14290 [FREE Full text] [doi: 10.2196/14290] [Medline: 31215512]
30. Wong JC. Sexual harassment in virtual reality feels all too real – 'it's creepy beyond creepy'. The Guardian. 2016 Oct 26. URL: https://www.theguardian.com/technology/2016/oct/26/virtual-reality-sexual-harassment-online-groping-quivr [accessed 2022-04-15]
31. Fardouly J, Vartanian LR. Social media and body image concerns: current research and future directions. Curr Opin Psychol 2016 Jun;9:1-5 [FREE Full text] [doi: 10.1016/j.copsyc.2015.09.005]
32. Binns A. Twitter City and Facebook Village: teenage girls' personas and experiences influenced by choice architecture in social networking sites. J Media Pract 2014 Nov 12;15(2):71-91 [FREE Full text] [doi: 10.1080/14682753.2014.960763]
33. Edelman G. Social media CEOs can't defend their business model. Wired. 2021 Mar 25. URL: https://www.wired.com/story/social-media-ceo-hearing-cant-defend-business-model/ [accessed 2022-03-29]
34. Verduyn P, Lee DS, Park J, Shablack H, Orvell A, Bayer J, et al. Passive Facebook usage undermines affective well-being: experimental and longitudinal evidence. J Exp Psychol Gen 2015 Apr;144(2):480-488. [doi: 10.1037/xge0000057] [Medline: 25706656]
35. Pfotenhauer SM, Frahm N, Winickoff D, Benrimoh D, Illes J, Marchant G. Mobilizing the private sector for responsible innovation in neurotechnology. Nat Biotechnol 2021 Jun;39(6):661-664. [doi: 10.1038/s41587-021-00947-y] [Medline: 34099907]

36. Office of the Commissioner, Office of Clinical Policy and Programs, Office of Combination Products. Classification of Products as Drugs and Devices and Additional Product Classification Issues. U.S. Food & Drug Administration. 2017 Sep. URL: https://tinyurl.com/y6b7hxt5 [accessed 2022-10-24]
37. Medical devices regulations. Justice Laws Website. 2022 Mar 2. URL: https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/page-1.html#h-1021337 [accessed 2022-10-24]
38. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance. ). European Union. 2020 Apr 24. URL: http://data.europa.eu/eli/reg/2017/745/oj/eng [accessed 2022-10-24]
39. Center for Devices and Radiological Health's Digital Health. Artificial Intelligence and Machine Learning in Software as a Medical Device. U.S. Food & Drug Administration. 2021 Sep 22. URL: https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device [accessed 2022-10-24]
40. Benrimoh D, Israel S, Perlman K, Fratila R, Krause M. Meticulous transparency—an evaluation process for an agile AI regulatory scheme. In: Proceedings of the 31st International Conference on Recent Trends and Future Technology in Applied Intelligence. 2018 Presented at: IEA/AIE '18; June 25-28, 2018; Montreal, Canada p. 869-880 URL: https://doi.org/10.1007/978-3-319-92058-0_83 [doi: 10.1007/978-3-319-92058-0_83]
41. Wachtor L. Are more people public or private on social media? Viasat. 2020 May 27. URL: https://www.viasatsavings.com/news/blog/are-more-people-public-or-private-on-social-media/ [accessed 2022-10-24]
42. Mondal M, Messias J, Ghosh S, Gummadi K, Kate A. Longitudinal privacy management in social media: the need for better controls. IEEE Internet Comput (forthcoming) 2017 Jun 16:1-1 [FREE Full text] [doi: 10.1109/MIC.2017.265102818]
43. Jhaver S, Boylston C, Yang D, Bruckman A. Evaluating the effectiveness of deplatforming as a moderation strategy on Twitter. Proc ACM Hum Comput Interact 2021 Oct 13;5(CSCW2):1-30 [FREE Full text] [doi: 10.1145/3479525]
44. Singhal M, Ling C, Kumarswamy N, Stringhini G, Nilizadeh S. SoK: content moderation in social media, from guidelines to enforcement, and research to practice. arXiv. Preprint posted online on June 29, 2022 2022 [FREE Full text]
45. Cosgrove L, Karter JM, Morrill Z, McGinley M. Psychology and surveillance capitalism: the risk of pushing mental health apps during the COVID-19 pandemic. J Humanist Psychol 2020 Jun 29;60(5):611-625 [FREE Full text] [doi: 10.1177/0022167820937498]


## Abbreviations

**VR:** virtual reality


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Short Paper

# A Digital Intervention Using Daily Financial Incentives to Increase Medication Adherence in Severe Mental Illness: Single-Arm Longitudinal Pilot Study

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## Abstract

**Background:** Medication nonadherence is prevalent in severe mental illness and is associated with multiple negative outcomes. Mobile technology and financial incentives show promise to improve medication adherence; however, studies in mental health, especially with oral medications, are lacking.

**Objective:** The aim of this paper is to assess the feasibility and effectiveness of offering financial incentives through a mobile app based on behavioral economics principles to improve medication adherence in severe mental illness.

**Methods:** A 10-week, single-arm longitudinal pilot study was conducted. Patients earned rewards in the context of app-based adherence incentives. The reward was split into biweekly payments made in increments of US $15, minus any US $2 per day penalties for missed check-ins. Time-varying effect modeling was used to summarize the patients' response during the study.

**Results:** A total of 25 patients were enrolled in this pilot study, of which 72% (n=18) were female, and 48% (n=12) were of a White racial background. Median age was 24 (Q1-Q3: 20.5-30) years. Participants were more frequently diagnosed with schizophrenia and related disorders (n=9, 36%), followed by major depressive disorder (n=8, 32%). App engagement and medication adherence in the first 2 weeks were higher than in the last 8 weeks of the study. At study endpoint, app engagement remained high (n=24, Z=–3.17; *P*<.001), but medication adherence was not different from baseline (n=24, Z=–0.59; *P*=.28).

**Conclusions:** Financial incentives were effectively delivered using an app and led to high engagement throughout the study and a significantly increased medication adherence for 2 weeks. Leveraging behavioral economics and mobile health technology can increase medication adherence in the short term.

**Trial Registration:** ClinicalTrials.gov NCT04191876; https://clinicaltrials.gov/ct2/show/NCT04191876

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**KEYWORDS**

antipsychotic; adherence; digital; mobile health; mHealth; financial incentives

## Introduction

Medication adherence is a challenge in all of medicine, as only an average of 50% of individuals affected by a chronic condition follow their care plan as prescribed [1]. In mental health, poor adherence is a significant public health challenge, fueled by chronicity, lack of insight, significant medication side effects, and other factors such as stigma and poor access to care [2-4]. Neuropsychiatric medication reduces the severity of serious mental illness and improves patient outcomes [5-9], but only for as long as the patient is adherent. Unfortunately, the rates of adherence to neuropsychiatric medication are far from optimal, which has been estimated to average 40%-50% for schizophrenia and bipolar disorder [10-13]. Similar rates are reported for major depressive disorder [14,15], with some studies reporting rates as low as 21% at 12 months, albeit with variations by drug type [16].

Medication nonadherence has been associated with increased risk of relapse, violence, and legal problems; increased risk of suicide attempts; use of emergency services; and poor social and occupational functioning [17-23]. Recently, financial reinforcement interventions based on behavioral economic principles have emerged as a potential tool to enhance medication adherence in severe mental illness [24,25]. A very recent study explored the use of financial incentives to increase oral antidepressant adherence [26], and 2 studies have focused on antipsychotic medication [27,28], both limited to long-acting injectables. To our knowledge, no study to date has examined the effects of financial incentives on adherence to neuropsychiatric treatments including oral antipsychotic medication.

For this project, we used an app that takes advantage of behavioral economics principles to increase adherence for patients with chronic diseases [29]. Mobile health technology can be designed to be persuasive and potentially increase medication adherence when coupled with incentives contingent on behavior [30,31]. The aim of this study was to assess the feasibility and effectiveness of offering financial incentives through an app to help improve adherence to oral medication in severe mental illness.

## Methods

### Ethics Approval

This study was carried out in accordance with the Declaration of Helsinki [32], and all participants provided written informed consent as approved by the local Institutional Review Board (IRB#190739).

### Study Design

A 10-week, single-arm longitudinal pilot study was conducted (NCT04191876). Included were English-speaking patients 18-80 years old owning a smartphone and receiving treatment with psychotropic medication, with suspected or confirmed poor oral medication adherence. Patients were recruited from inpatient and outpatient units from a semiurban tertiary care facility that draws a representative racial or ethnic and sociodemographic mixture of eligible patients.

After consent, patients were instructed to download the study app, assisted by a digital navigator when necessary. The app automatically prompts the participant to take their medication by generating a reminder at a preset time of day. Patients were instructed to take a photo of the medication in their hand, as prescribed by their doctor, and submit it through the app, which was considered as a check-in or engagement. Engagement was defined as the number of app check-ins. Additionally, all photo check-ins were manually reviewed and verified by the study personnel to ensure accuracy and estimate reliability. Adherence was calculated by dividing the number of pills collected by the app at every check-in by the total number of pills required to be taken and was monitored throughout the study. Baseline adherence in relation to the number of pills required to be taken was determined by subject self-reports at the time of enrollment, which were then confirmed on the health care system's electronic medical records as well as administrative data from the Medicaid claims database when available. Medication changes occurring during the study period were taken into account, and the number of pills to be taken was adjusted accordingly.

Patients were not compensated for participation in this project. They earned rewards in the context of adherence incentives based on successful check-ins. The reward was split into 5 biweekly payouts made in increments of US $15, minus any US $2 per day penalties for missed check-ins, up to a maximum reward of US $75 per participant over the study period. This incentive design is based on the loss aversion strategy, which has shown to be more powerful than gain-framed incentives in daily health behaviors such as physical activity [33] and smoking cessation [34].

### Data Analysis

Measures of mean engagement and adherence were used to summarize patient's response over the 10 weeks of the study using intercept-only time-varying effect modelling (TVEM) [35,36]. We selected intercept-only TVEM to summarize longitudinal trends with 95% confidence intervals. This approach uses a spline function to approximate the average change in engagement and adherence over time [37]. Wilcoxon signed-rank test were used to compare baseline adherence to 10-week engagement and 10-week adherence. Pearson correlations were conducted to assess the relationship between baseline adherence and number of prescribed pills. All statistical analyses were performed using the R software, version 4.0.5 (The R Foundation).

## Results

A total of 25 patients were enrolled in this pilot study between January and July 2020 (Figure 1); 72% (n=18) were female, and a majority were of a White racial background (n=12, 48%), followed by Black (n=6, 24%) and Asian (n=4, 16%). Median age was 24 years (Q1-Q3: 20.5-30). The participants were diagnosed with schizophrenia and related disorders (n=9, 36%), followed by major depressive disorder (n=8, 32%). Detailed characteristics of the patient sample are included in Table 1.

Treatment regime for each study participant is described in Multimedia Appendix 1. Study participants received treatment with a variety of oral antipsychotics, antidepressants, and mood stabilizers. The number of prescribed pills taken per day per subject varied from a minimum of 1 per day to a maximum of 9 per day (mean 2.82, SD 1.99). This measure did not correlate with baseline adherence ($r$=0.01).

Engagement and adherence were generally higher than baseline adherence but fluctuated throughout the study period (Figure 2). At study endpoint, engagement was higher compared to baseline (n=24, $Z$=–3.17; $P$<.001) but adherence was not different from baseline (n=24, $Z$=–0.59; $P$=.28). One study participant was removed from this analysis as the app was not downloaded. We conducted an additional sensitivity analysis including only those who finished participation (n=16), but the results remained unchanged for engagement (n=16, $Z$=–2.22; $P$=.01) and adherence (n=16, $Z$=–0.66; $P$=.25).

We additionally conducted a TVEM to understand how engagement and adherence change over time, showing significantly higher engagement and adherence in the first 2 weeks compared with the last 8 weeks of the study (Figure 3).

**Figure 1.** CONSORT (Consolidated Standards of Reporting Trials) flow diagram.

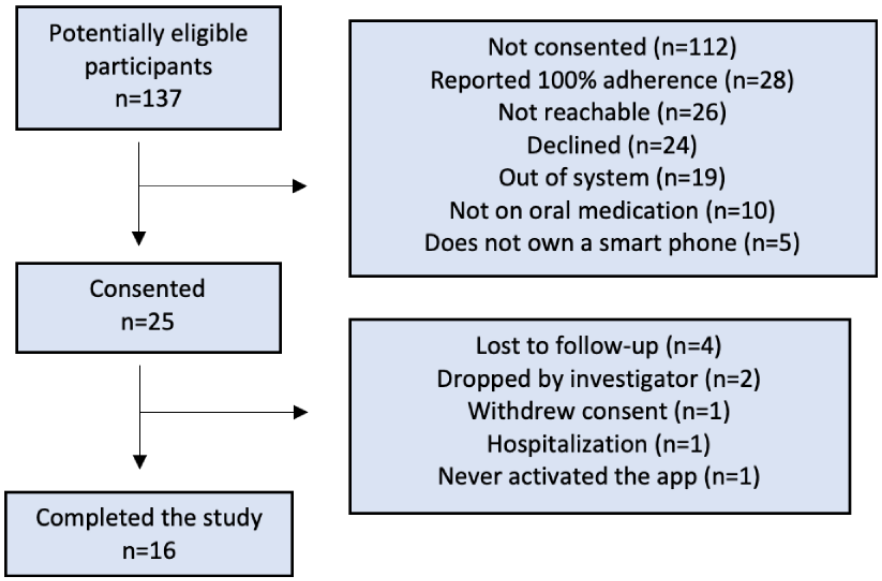


**Table 1.** Sociodemographic characteristics of the patient sample (N=25).

| Variable | Value |
|---|---|
| Age (years), mean (Q1-Q3) | 24 (20.5-30) |
| **Sex, n (%)** | |
| Female | 18 (72) |
| Male | 7 (28) |
| **Race, n (%)** | |
| White | 12 (48) |
| Black or African American | 6 (24) |
| Asian | 4 (16) |
| Mixed or other | 3 (12) |
| **Primary diagnosis, n (%)** | |
| Schizophrenia and related disorders | 9 (36) |
| Major depressive disorder | 8 (32) |
| Bipolar disorder | 4 (16) |
| Schizoaffective disorder | 2 (8) |
| Other | 2 (8) |
| **Marital status, n (%)** | |
| Single | 20 (80) |
| Married | 4 (16) |
| Divorced or separated | 1 (4) |
| **Education status, n (%)** | |
| Some college | 11 (44) |
| High school | 5 (20) |
| College graduate | 3 (12) |
| Master’s degree | 2 (8) |
| Some master’s | 2 (8) |
| Unfinished high school | 2 (8) |
| **Employment status, n (%)** | |
| Unemployed | 15 (60) |
| Employed | 10 (40) |
| Retired | 0 (0) |
| Disabled | 0 (0) |
| **Insurance type, n (%)** | |
| Private | 16 (64) |
| Medicaid or Medicare | 9 (36) |

**Figure 2.** Summary measures of adherence and engagement throughout the 10-week study period. Blue dotted line represents mean baseline adherence of the sample.

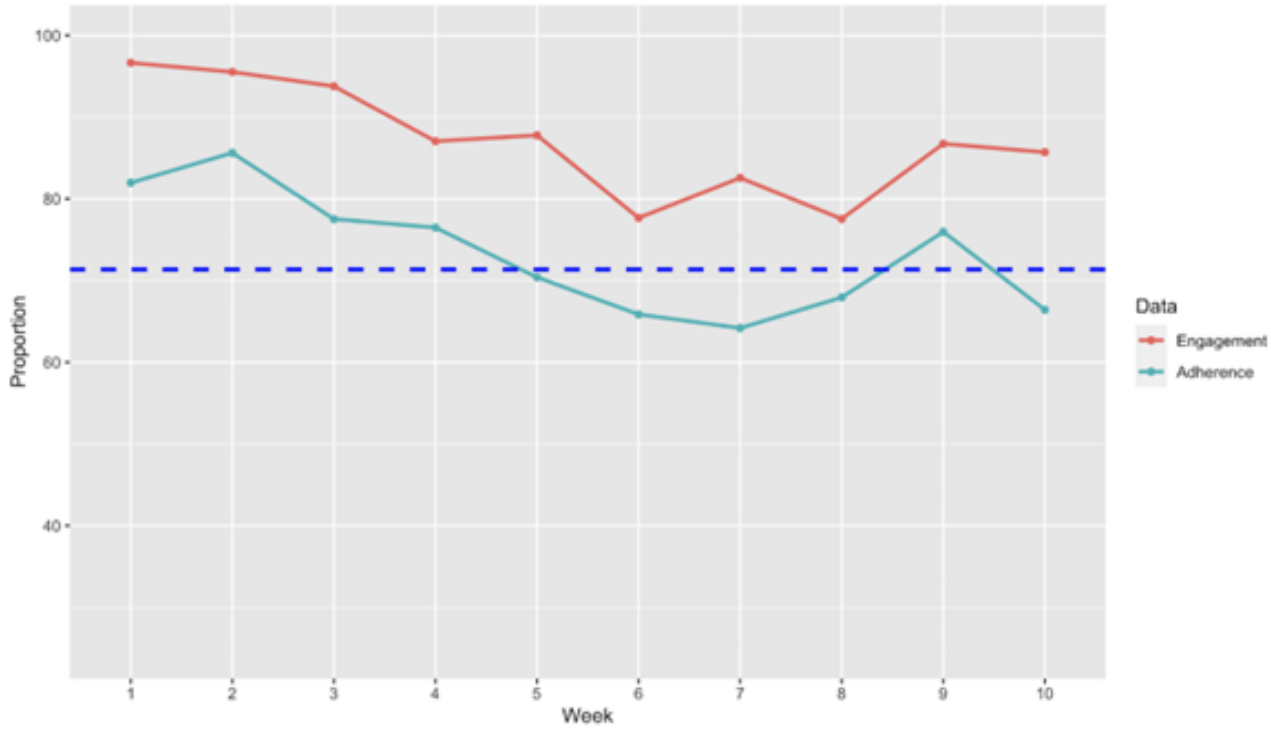
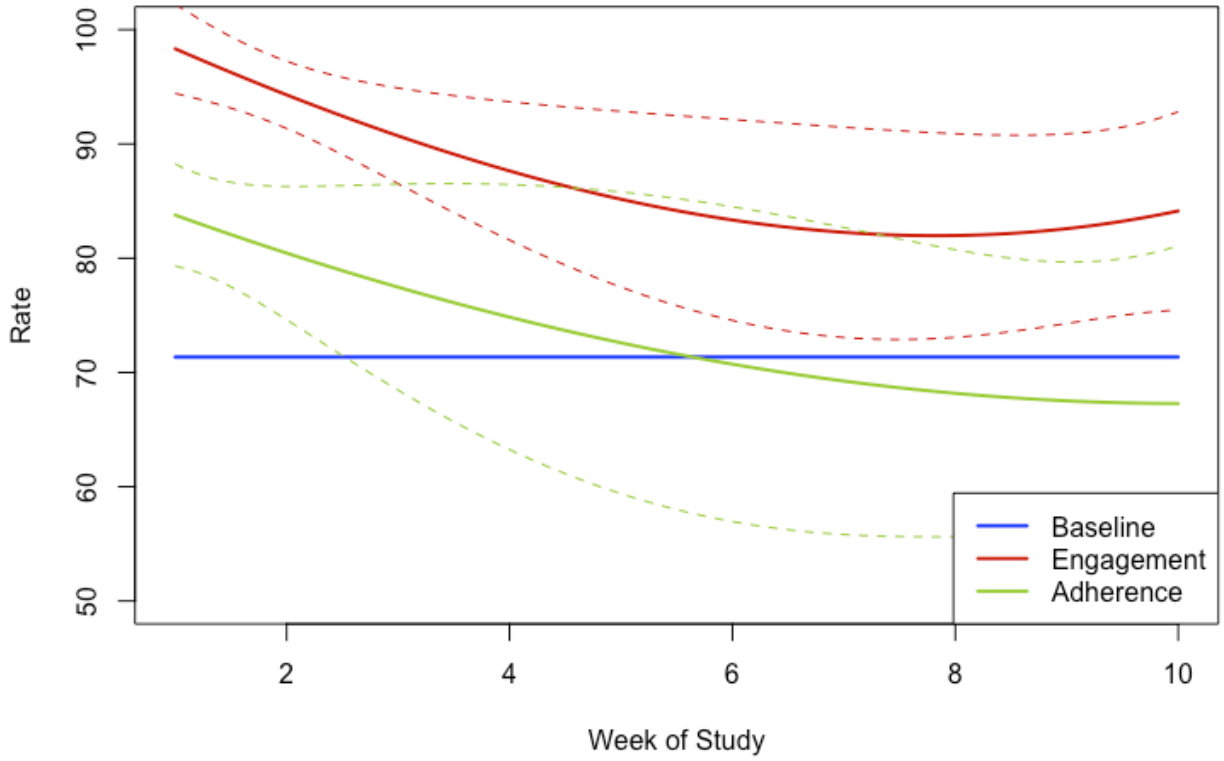



**Figure 3.** Time-varying effect model (TVEM) of engagement and adherence over time, plotting the estimated coefficient function for both engagement and adherence (solid line) with approximation of 95% confidence interval (dotted line) for the proportion at each time point (week).




## Discussion

In this pilot study, we show that financial incentives can be effectively delivered through an app in severe mental illness. We found that small financial incentives increased medication adherence during the initial 2 weeks of our follow-up period, yet this increase was not maintained at study endpoint.

Our findings add to previous studies showing great potential for behavioral economics-based financial incentives to impact patient outcomes in severe mental illness including medication

adherence [24,25]; however, we additionally show that such incentives can be remotely delivered through an app, which allows real-time measures of engagement and adherence, thus paving the way for future studies to evaluate the efficacy different types of incentives or incentive combinations but also for clinicians to access daily adherence data, which could prompt specific interventions if nonadherence is detected.

Despite this study involving financial incentives, attrition was relatively high. This finding could relate to the amount of the incentive, lower than other recently published meta-analysis exploring strategies to incentivize medication adherence in the context of substance use disorders, reporting mean maximum daily earnings of over US $10 [38]. Alternatively, perhaps loss aversion strategies may be less effective in severe mental illness compared with traditional gain-framed incentives. Recent studies evaluating financial incentives to enhance adherence to oral treatment in depression show that escalating amounts up to US 7$ a day was more effective than de-escalating incentives or control groups [26]. Nonetheless, it is also possible that participants took some medications outside of their specific check-in window; therefore, pill count in each check-in photo may not truly capture all the medications an individual took that day, underestimating incentive effects. Lastly, specific app features could have influenced the results as well. Future study designs should include higher or escalating incentives, a larger sample size, an active control group, and additional measures of adherence.

The results should be interpreted with caution, as a pre-post single-arm study lacks control group and randomization, and factors unrelated to the intervention itself could be partially responsible for the differences detected. Nonetheless, this design can inform about the feasibility of offering financial incentives via an app to enhance medication adherence in severe mental illness. Engagement remained high during the initial 2 weeks of the study and was stable afterward, improving generally reported mental health app engagement rates [39]. Second, baseline measures of adherence were self-reported and thus subject to possible inaccuracies. However, chart and database reviews were conducted to confirm patient reports. Lastly, clinical outcomes were not measured, which is relevant as enhanced adherence may not necessarily reflect improved clinical outcomes [40].

In summary, financial incentives can be effectively delivered using an app. Leveraging behavioral economics and mobile health technology can increase medication adherence in the short term while maintaining high app engagement.

## Acknowledgments

We thank the patients who took the time to participate in our study in such challenging times.

## Conflicts of Interest

DG has been a consultant for and has received speaker honoraria from Otsuka America Pharmaceuticals, Janssen Pharmaceuticals, Lundbeck and Teva. JMK has been a consultant and advisor for or has received honoraria from Alkermes, Allergan, LB Pharmaceuticals, H Lundbeck, Intracellular Therapies, Janssen Pharmaceuticals, Johnson and Johnson, Merck, Minerva, Neurocrine, Newron, Otsuka, Pierre Fabre, Reviva, Roche, Sumitomo Dainippon, Sunovion, Takeda, Teva, and UpToDate, and is a shareholder in LB Pharmaceuticals and Vanguard Research Group. MS, BP, and MW declare no conflicts of interest.

Multimedia Appendix 1
Supplementary Table 1.
[DOCX File , 25 KB - mental_v9i10e37184_app1.docx ]

## References

1. Sabaté E, editor. Adherence to Long-Term Therapies: Evidence for Action. Geneva, Switzerland: World Health Organization; 2003.
2. Dell'Osso B, Albert U, Carrà G, Pompili M, Nanni MG, Pasquini M, et al. How to improve adherence to antidepressant treatments in patients with major depression: a psychoeducational consensus checklist. Ann Gen Psychiatry 2020 Oct 12;19(1):61 [FREE Full text] [doi: 10.1186/s12991-020-00306-2] [Medline: 33062034]
3. Leclerc E, Mansur RB, Brietzke E. Determinants of adherence to treatment in bipolar disorder: a comprehensive review. J Affect Disord 2013 Jul;149(1-3):247-252. [doi: 10.1016/j.jad.2013.01.036] [Medline: 23489403]
4. Sendt K, Tracy DK, Bhattacharyya S. A systematic review of factors influencing adherence to antipsychotic medication in schizophrenia-spectrum disorders. Psychiatry Res 2015 Jan 30;225(1-2):14-30. [doi: 10.1016/j.psychres.2014.11.002] [Medline: 25466227]
5. Leucht S, Tardy M, Komossa K, Heres S, Kissling W, Salanti G, et al. Antipsychotic drugs versus placebo for relapse prevention in schizophrenia: a systematic review and meta-analysis. The Lancet 2012 Jun;379(9831):2063-2071. [doi: 10.1016/s0140-6736(12)60239-6]
6. Furukawa TA, Levine SZ, Tanaka S, Goldberg Y, Samara M, Davis JM, et al. Initial severity of schizophrenia and efficacy of antipsychotics: participant-level meta-analysis of 6 placebo-controlled studies. JAMA Psychiatry 2015 Jan 01;72(1):14-21. [doi: 10.1001/jamapsychiatry.2014.2127] [Medline: 25372935]

7. Park LT, Zarate CA. Depression in the Primary Care Setting. N Engl J Med 2019 Feb 07;380(6):559-568. [doi: 10.1056/nejmcp1712493]
8. Fournier JC, DeRubeis RJ, Hollon SD, Dimidjian S, Amsterdam JD, Shelton RC, et al. Antidepressant drug effects and depression severity: a patient-level meta-analysis. JAMA 2010 Jan 06;303(1):47-53 [FREE Full text] [doi: 10.1001/jama.2009.1943] [Medline: 20051569]
9. Krivoy A, Balicer RD, Feldman B, Hoshen M, Zalsman G, Weizman A, et al. Adherence to Antidepressants Is Associated With Lower Mortality. J. Clin. Psychiatry 2016 Apr 12;77(05):e566-e572. [doi: 10.4088/jcp.14m09531]
10. Cramer JA, Rosenheck R. Compliance with medication regimens for mental and physical disorders. Psychiatr Serv 1998 Feb;49(2):196-201. [doi: 10.1176/ps.49.2.196] [Medline: 9575004]
11. Lacro JP, Dunn LB, Dolder CR, Leckband SG, Jeste DV. Prevalence of and risk factors for medication nonadherence in patients with schizophrenia: a comprehensive review of recent literature. J Clin Psychiatry 2002 Oct;63(10):892-909. [doi: 10.4088/jcp.v63n1007] [Medline: 12416599]
12. Lingam R, Scott J. Treatment non-adherence in affective disorders. Acta Psychiatr Scand 2002 Mar;105(3):164-172. [doi: 10.1034/j.1600-0447.2002.1r084.x] [Medline: 11939969]
13. Sajatovic M, Valenstein M, Blow FC, Ganoczy D, Ignacio RV. Treatment adherence with antipsychotic medications in bipolar disorder. Bipolar Disord 2006 Jun;8(3):232-241. [doi: 10.1111/j.1399-5618.2006.00314.x] [Medline: 16696824]
14. Sawada N, Uchida H, Suzuki T, Watanabe K, Kikuchi T, Handa T, et al. Persistence and compliance to antidepressant treatment in patients with depression: A chart review. BMC Psychiatry 2009 Jun 16;9(1):1-10. [doi: 10.1186/1471-244x-9-38]
15. Sheehan DV, Keene MS, Eaddy M, Krulewicz S, Kraus JE, Carpenter DJ. Differences in medication adherence and healthcare resource utilization patterns: older versus newer antidepressant agents in patients with depression and/or anxiety disorders. CNS Drugs 2008;22(11):963-973. [doi: 10.2165/00023210-200822110-00005] [Medline: 18840035]
16. Keyloun KR, Hansen RN, Hepp Z, Gillard P, Thase ME, Devine EB. Adherence and Persistence Across Antidepressant Therapeutic Classes: A Retrospective Claims Analysis Among Insured US Patients with Major Depressive Disorder (MDD). CNS Drugs 2017 May 4;31(5):421-432 [FREE Full text] [doi: 10.1007/s40263-017-0417-0] [Medline: 28378157]
17. Robinson D, Woerner MG, Alvir JMJ, Bilder R, Goldman R, Geisler S, et al. Predictors of relapse following response from a first episode of schizophrenia or schizoaffective disorder. Arch Gen Psychiatry 1999 Mar 01;56(3):241-247. [doi: 10.1001/archpsyc.56.3.241] [Medline: 10078501]
18. Ascher-Svanum H, Faries DE, Zhu B, Ernst FR, Swartz MS, Swanson JW. Medication adherence and long-term functional outcomes in the treatment of schizophrenia in usual care. J Clin Psychiatry 2006 Mar;67(3):453-460. [doi: 10.4088/jcp.v67n0317] [Medline: 16649833]
19. Law MR, Soumerai SB, Ross-Degnan D, Adams AS. A longitudinal study of medication nonadherence and hospitalization risk in schizophrenia. J Clin Psychiatry 2008 Jan 15;69(1):47-53. [doi: 10.4088/jcp.v69n0107] [Medline: 18312037]
20. Novick D, Haro JM, Suarez D, Perez V, Dittmann RW, Haddad PM. Predictors and clinical consequences of non-adherence with antipsychotic medication in the outpatient treatment of schizophrenia. Psychiatry Res 2010 Apr 30;176(2-3):109-113. [doi: 10.1016/j.psychres.2009.05.004] [Medline: 20185182]
21. Hong J, Reed C, Novick D, Haro JM, Aguado J. Clinical and economic consequences of medication non-adherence in the treatment of patients with a manic/mixed episode of bipolar disorder: results from the European Mania in Bipolar Longitudinal Evaluation of Medication (EMBLEM) study. Psychiatry Res 2011 Nov 30;190(1):110-114. [doi: 10.1016/j.psychres.2011.04.016] [Medline: 21571375]
22. Akerblad AC, Bengtsson F, von Knorring L, Ekselius L. Response, remission and relapse in relation to adherence in primary care treatment of depression: a 2-year outcome study. Int Clin Psychopharmacol 2006 Mar;21(2):117-124. [doi: 10.1097/01.yic.0000199452.16682.b8] [Medline: 16421464]
23. Weiden PJ, Kozma C, Grogg A, Locklear J. Partial compliance and risk of rehospitalization among California Medicaid patients with schizophrenia. Psychiatr Serv 2004 Aug;55(8):886-891. [doi: 10.1176/appi.ps.55.8.886] [Medline: 15292538]
24. Guinart D, Kane JM. Use of Behavioral Economics to Improve Medication Adherence in Severe Mental Illness. Psychiatr Serv 2019 Oct 01;70(10):955-957. [doi: 10.1176/appi.ps.201900116] [Medline: 31215352]
25. Guinart D, Kane JM. Incentivizing Is Not Coercing: A Commentary. Psychiatr Serv 2020 Mar 01;71(3):301-302. [doi: 10.1176/appi.ps.201900543] [Medline: 31896340]
26. Marcus SC, Reilly ME, Zentgraf K, Volpp KG, Olfson M. Effect of Escalating and Deescalating Financial Incentives vs Usual Care to Improve Antidepressant Adherence: A Pilot Randomized Clinical Trial. JAMA Psychiatry 2021 Feb 01;78(2):222-224 [FREE Full text] [doi: 10.1001/jamapsychiatry.2020.3000] [Medline: 32965464]
27. Priebe S, Yeeles K, Bremner S, Lauber C, Eldridge S, Ashby D, et al. Effectiveness of financial incentives to improve adherence to maintenance treatment with antipsychotics: cluster randomised controlled trial. BMJ 2013 Oct 07;347(oct07 3):f5847-f5847 [FREE Full text] [doi: 10.1136/bmj.f5847] [Medline: 24100934]
28. Noordraven EL, Wierdsma AI, Blanken P, Bloemendaal AFT, Staring ABP, Mulder CL. Financial incentives for improving adherence to maintenance treatment in patients with psychotic disorders (Money for Medication): a multicentre, open-label, randomised controlled trial. Lancet Psychiatry 2017 Mar;4(3):199-207. [doi: 10.1016/S2215-0366(17)30045-7] [Medline: 28236956]
29. Wellth Solution. Wellth. URL: https://www.wellthapp.com/solution [accessed 2022-07-08]

30. Ahmed I, Ahmad NS, Ali S, Ali S, George A, Saleem Danish H, et al. Medication Adherence Apps: Review and Content Analysis. JMIR Mhealth Uhealth 2018 Mar 16;6(3):e62 [FREE Full text] [doi: 10.2196/mhealth.6432] [Medline: 29549075]
31. Sobolev M. Digital Nudging: Using Technology to Nudge for Good. SSRN Journal 2021 Mar 24:1-7. [doi: 10.2139/ssrn.3889831]
32. World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA 2013 Nov 27;310(20):2191-2194. [doi: 10.1001/jama.2013.281053] [Medline: 24141714]
33. Patel MS, Asch DA, Rosin R, Small DS, Bellamy SL, Heuer J, et al. Framing Financial Incentives to Increase Physical Activity Among Overweight and Obese Adults: A Randomized, Controlled Trial. Ann Intern Med 2016 Mar 15;164(6):385-394 [FREE Full text] [doi: 10.7326/M15-1635] [Medline: 26881417]
34. Halpern SD, French B, Small DS, Saulsgiver K, Harhay MO, Audrain-McGovern J, et al. Randomized Trial of Four Financial-Incentive Programs for Smoking Cessation. N Engl J Med 2015 May 28;372(22):2108-2117. [doi: 10.1056/NEJMoa1414293]
35. Matthews JN, Altman DG, Campbell MJ, Royston P. Analysis of serial measurements in medical research. BMJ 1990 Jan 27;300(6719):230-235 [FREE Full text] [doi: 10.1136/bmj.300.6719.230] [Medline: 2106931]
36. Tan X, Shiyko MP, Li R, Li Y, Dierker L. A time-varying effect model for intensive longitudinal data. Psychol Methods 2012 Mar;17(1):61-77 [FREE Full text] [doi: 10.1037/a0025814] [Medline: 22103434]
37. Dziak J, Coffman DL, Li R, Litson K, Chakraborti Y. Package 'tvem'. R Project. URL: https://cran.r-project.org/web/packages/tvem/tvem.pdf [accessed 2022-09-07]
38. Bolívar HA, Klemperer EM, Coleman SRM, DeSarno M, Skelly JM, Higgins ST. Contingency Management for Patients Receiving Medication for Opioid Use Disorder: A Systematic Review and Meta-analysis. JAMA Psychiatry 2021 Oct 01;78(10):1092-1102 [FREE Full text] [doi: 10.1001/jamapsychiatry.2021.1969] [Medline: 34347030]
39. Baumel A, Muench F, Edan S, Kane JM. Objective User Engagement With Mental Health Apps: Systematic Search and Panel-Based Usage Analysis. J Med Internet Res 2019 Sep 25;21(9):e14567 [FREE Full text] [doi: 10.2196/14567] [Medline: 31573916]
40. Barankay I, Reese PP, Putt ME, Russell LB, Loewenstein G, Pagnotti D, et al. Effect of Patient Financial Incentives on Statin Adherence and Lipid Control: A Randomized Clinical Trial. JAMA Netw Open 2020 Oct 01;3(10):e2019429 [FREE Full text] [doi: 10.1001/jamanetworkopen.2020.19429] [Medline: 33034639]

## Abbreviations

**TVEM:** time-varying effect modeling

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Original Paper

# An App-Based Digit Symbol Substitution Test for Assessment of Cognitive Deficits in Adults With Major Depressive Disorder: Evaluation Study

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## Abstract

**Background:** Cognitive dysfunction is an impairing core symptom of depression. Among adults with major depressive disorder (MDD) treated with antidepressants, residual cognitive symptoms interfere with patient-reported outcomes. The foregoing characterization of cognitive symptoms provides the rationale for screening and assessing the severity of cognitive symptoms at point of care. However, clinical neurocognitive assessments are time-consuming and difficult, and they require specialist expertise to interpret them. A smartphone-delivered neurocognitive test may offer an effective and accessible tool that can be readily implemented into a measurement-based care framework.

**Objective:** We aimed to evaluate the use of a smartphone-delivered app-based version of the established Cognition Kit Digit Symbol Substitution Test (DSST) neurocognitive assessment compared to a traditional paper-and-pencil version.

**Methods:** Convergent validity and test-retest reliability of the 2 versions were evaluated. Patient satisfaction with the app was also assessed.

**Results:** Assessments made using the app-based Cognition Kit DSST were highly correlated with the standard paper-and-pencil version of the test, both at the baseline visit ($r$=0.69, $df$=27; $P$<.001) and at the end-of-study visit ($r$=0.82, $df$=27; $P$<.001), and they were positively evaluated by 30 patients as being user-friendly, easy to navigate, and preferable over the paper-and-pencil version of the DSST. However, although the app-based Cognition Kit DSST was validated in patients with MDD, it still needs to be evaluated in healthy controls.

**Conclusions:** App-based DSST may facilitate a more personalized, convenient, and cost-effective method of cognitive assessment, helping to guide measurement-based care and psychotherapeutic and pharmacologic treatment options for patients with MDD.

**Trial Registration:** ClinicalTrials.gov NCT03999567; https://tinyurl.com/2p8pnyv7

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**KEYWORDS**

depression; DSST; Digit Symbol Substitution Test; smartphone; technology; measurement-based care; cognition

## Introduction

Major depressive disorder (MDD) is an episodic illness characterized by a persistently depressed mood or loss of interest in activities that causes significant impairment in daily life [1,2]. Cognitive impairment is a core domain disturbance in MDD, with disturbances in cognitive function being listed among the criteria that define a major depressive episode [2].

Approximately 90%-95% of adults with MDD experience cognitive symptoms during a depressive episode [3], including impairments in executive function, attention, learning and memory, and processing speed [4,5]. The foregoing cognitive deficits have been demonstrated to mediate social, functional, and work-related disability associated with MDD and have a long-term impact that often persists when depressive symptoms have abated [5,6]. Indeed, during periods of remission, approximately half of all depressed patients will continue to experience cognitive deficits, which presage patient-reported outcomes (PROs) in adults with MDD [3,7].

Addressing cognitive symptoms can be a clinical priority when treating some patients with MDD, particularly those whose MDD appears to be significantly impairing their daily functioning and treatment has failed to resolve these symptoms [8]. Impaired cognitive functioning is also progressive in some patients with MDD [5,9], and there is evidence to suggest that cognitive function deteriorates further with each major depressive episode [4]. Accordingly, there is a need to address cognitive dysfunction in patients with MDD, as it substantially interferes with daily psychosocial functioning and can lead to adverse long-term outcomes. For example, patients with MDD may have poorer workplace performance, which is a result of impaired cognitive functioning [5,6,10]. Cognitive deficits, therefore, influence PROs and reduce individuals' quality of life and functioning [11].

The critical and pervasive role that cognitive deficits play in the functioning PROs in patients with MDD invites the need for accessible, convenient, and effective measurement-based care (MBC) assessment tools that offer more than a simple evaluation of the presence or absence of symptoms. Tools that collect valuable information about symptoms and potential changes that could impact general well-being may provide greater insight into a patient's condition, supporting individualized care that can improve overall treatment outcomes. Guiding principles of MBC are more likely to be implemented at the point of care as tools that are brief and patient administered, provide actionable information, and are preferably digitalized in keeping with busy office practices [12].

Many commonly used comprehensive neurocognitive tests are effective MBC assessment tools, but they are lengthy and cumbersome to administer and complete and often require professional interpretation, limiting their implementation outside of a clinical environment [13,14]. Web-based tools integrate both subjective and objective measures of cognition, are typically free of charge for the patient, digitalized, implemented remotely (ie, using a tablet), and require less time to complete (ie, approximately 10 minutes) [12,15]. However, web-based tools may not be accessible for all patients if a paid software subscription is required or the test has not been optimized for smartphone delivery and must be delivered using a computer or tablet with a large screen [16]. Recent progress in smartphone technology and mobile apps presents a unique prospect in this scenario. Several health-related smartphone apps have already been implemented in other chronic diseases (eg, diabetes mellitus), where it has been shown to be acceptable to end users, provide actionable data, and facilitate health outcomes [17]. The ubiquity of smartphones provides an opportunity to screen and measure the presence of cognitive functions in patients with MDD via smartphone-based neurocognitive assessments. Similar to web-based tools, smartphone-based neurocognitive assessments can also be free of charge for the patient, easy to administer, and may require even less time to complete.

The Digit Symbol Substitution Test (DSST) is an MBC assessment tool that provides multidomain assessment of neurocognitive functions and has been extensively validated in psychiatric, medical, and general populations [16]. This study was designed to evaluate an app-based Cognition Kit DSST as a screening and assessment tool for cognition in MDD that can be delivered via a smartphone.

## Methods

### Ethics Approval

This study was approved by the institutional review board of Advarra (Pro00037042) prior to initiation of the study. All participants provided written informed consent prior to enrollment.

### Study Design and Participants

Patients enrolled at the Canadian Rapid Treatment Center of Excellence were approached and asked to participate. Adult patients (aged 18-65 years) experiencing a moderate-to-severe major depressive episode (based on the Montgomery-Åsberg Depression Rating Scale [MADRS] with a total score ≥20) in the context of MDD were enrolled in this prospective, longitudinal validation study (Clinical Trial Identifier NCT03999567). Patients were not under treatment during participation and could not have had a change in their medication up to 2 weeks prior to participation. Participants were recruited by 2 research coordinators who were not responsible for patient care at the center.

The diagnosis of MDD was ascertained clinically and confirmed using the Mini-International Neuropsychiatric Interview (MINI). Patients were excluded if they had a comorbid psychiatric condition primary to MDD, used benzodiazepines within 12 hours of cognitive assessment, consumed alcohol within 8 hours of cognitive assessment, or used marijuana in an inconsistent or abusive manner. Patients were also excluded if they had current alcohol or substance use disorder confirmed by the MINI; physical, cognitive, or language impairments; diagnosed reading disability; dyslexia; or a clinically significant learning disorder. Use of electroconvulsive therapy in the past 6 months or a history of moderate-to-severe head trauma, neurological disorders, or unstable medical conditions that affect the central nervous system were criteria for exclusion from the study. If patients had a previous history or were currently experiencing

symptoms of mania or hypomania or had a history of seizures and epilepsy, they were not eligible to participate. Patients were asked not to change medications 1 week prior to the baseline study visit and in the week between the baseline and end-of-study visits.

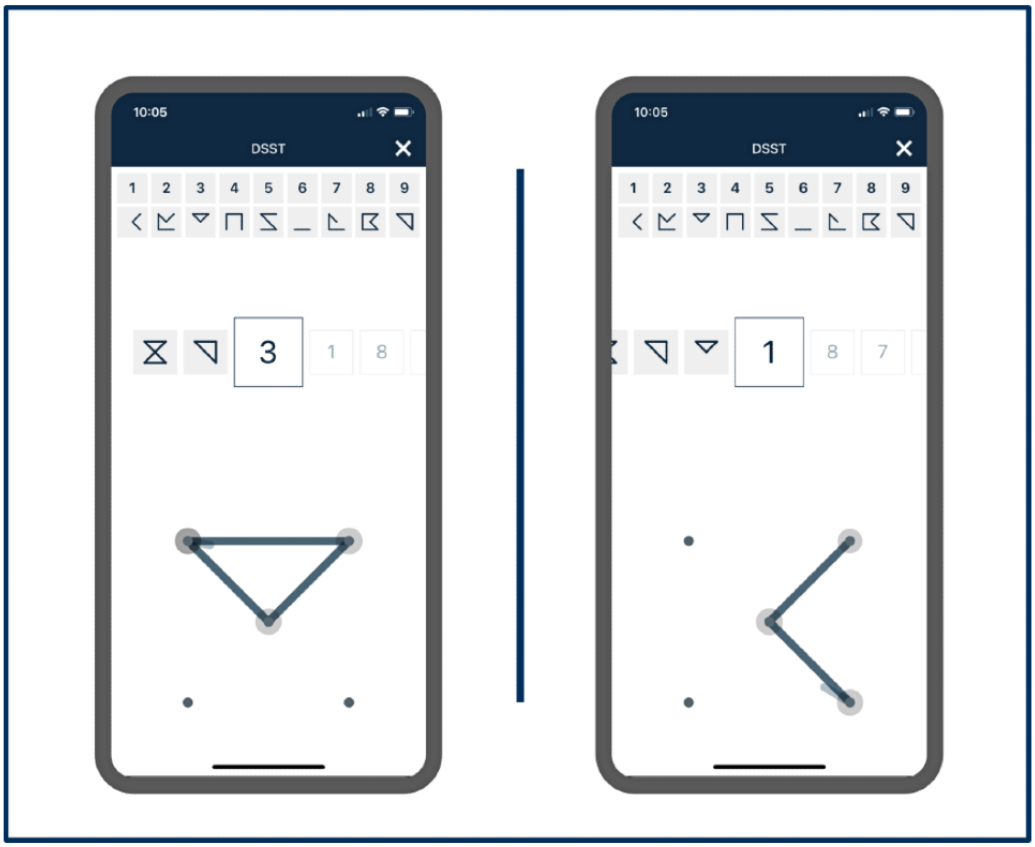
### Procedure

Participants completed both the app-based Cognition Kit DSST (Cognition Kit Ltd; Figure 1) on an Apple iPhone with finger-screen interaction and the paper-and-pencil DSST at 2 study visits: first at the baseline visit and then 1 week later at the end-of-study visit. The order of the app-based and paper-and-pencil assessments was counterbalanced between the 2 visits and between study participants. The DSST was based on the Wechsler Adult Intelligence Scale–Revised version [16]. Data from each app-based Cognition Kit DSST was stored in a system compliant with the Health Insurance Portability and Accountability Act to ensure data privacy.

Overall, depressive symptom severity (based on MADRS), consummatory anhedonia (based on Snaith-Hamilton Pleasure Scale [SHAPS]) [18], and anxiety (based on Hamilton Anxiety Rating Scale [HAM-A]) [19] were assessed at each visit. At the end-of-study visit, patients completed a 10-item app satisfaction survey. Each item of this survey was scored on a 5-point Likert scale, where 1 indicated “strongly disagree” and 5 indicated “strongly agree.”

Convergent validity of the app-based Cognition Kit DSST versus the paper-and-pencil DSST and the test-retest reliability of each instrument were assessed by calculating the Pearson correlation coefficient (partial correlation) using SPSS (version 23.0; IBM Corp), controlling for age.

**Figure 1.** App-based Cognition Kit Digit Symbol Substitution Test (DSST) screenshots.




## Results

### Patient Demographic and Clinical Characteristics

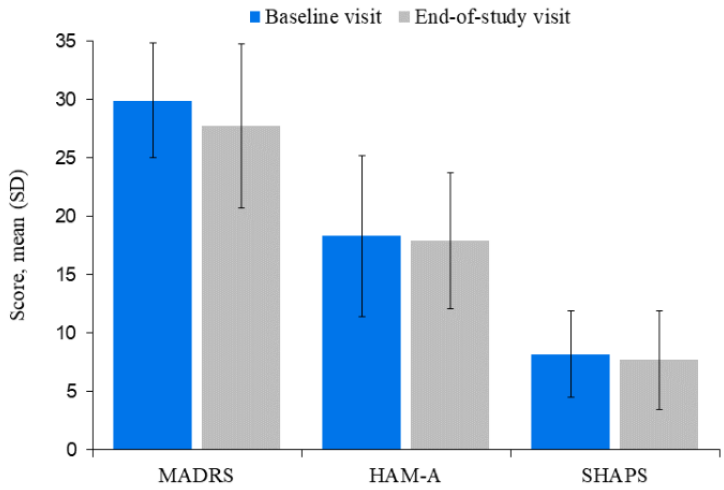
Prescreening was performed for 47 potential patients, of which a total of 30 patients were eligible for inclusion (Multimedia Appendix 1). All patients completed both study visits; 17 (57%) were female, and the mean age was 42 (SD 13) years. Approximately two-thirds (19/30, 63%) of patients had completed a college or university education. At baseline, 57% (17/30) of patients were currently taking an antidepressant medication (Table 1). Patients had a mean MADRS total score of 29.9 (SD 4.9) at baseline. Mean MADRS, HAM-A, and SHAPS scores did not differ greatly between the baseline and end-of-study visits (Figure 2).

**Table 1.** Patient demographic and clinical characteristics at baseline.

| Demographics or clinical characteristics | All study participants (N=30) |
|---|---|
| Age (years), mean (SD) | 42 (13) |
| **Sex, n (%)** | |
| Female | 17 (57) |
| Male | 13 (43) |
| **Race, n (%)** | |
| White | 25 (83) |
| Asian | 2 (6.7) |
| Multiracial | 2 (6.7) |
| Latin American | 1 (3.3) |
| **Highest level of education completed, n (%)** | |
| High school | 7 (23) |
| College or university | 19 (63) |
| Graduate school | 4 (13) |
| **Antidepressant medication** | |
| Taking antidepressant medication, n (%) | 19 (63) |
| Current antidepressants, mean (SD) | 1.0 (0.98) |
| Lifetime antidepressants[a], mean (SD) | 7 (7) |

[a]Number of antidepressants used throughout the patient's lifetime.

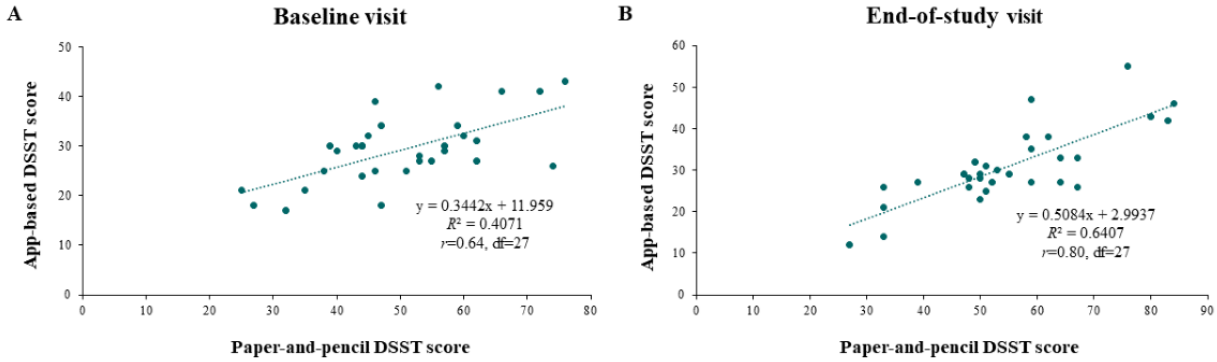
**Figure 2.** Clinical measures at baseline and end-of-study (N=30). HAM-A: Hamilton Anxiety Rating Scale; MADRS: Montgomery-Åsberg Depression Rating Scale; SHAPS: Snaith-Hamilton Pleasure Scale.




## Convergent Validity

Patients had mean DSST scores of 29 (SD 7) and 50 (SD 13) at baseline for the app-based and paper-and-pencil DSST, respectively. At the end of the study, the mean DSST scores were 31 (SD 9) and 55 (SD 14), respectively, for the app-based and paper-and-pencil DSST. The app-based Cognition Kit DSST and the paper-and-pencil DSST were positively correlated at both the baseline visit ($r$=0.64, $df$=27; Figure 3A) and the end-of-study visit ($r$=0.80, $df$=27; Figure 3B). The corresponding partial correlations after adjusting for age were $r$=0.69 ($df$=27; $P$<.001) and $r$=0.82 ($df$=27; $P$<.001) at baseline and end-of-study visits, respectively. Differences in the Cognition Kit DSST score from the baseline visit to the end-of-study visit versus the corresponding differences in the paper-and-pencil DSST score trended toward positive correlation ($r$=0.24, $df$=27; $P$=.21).

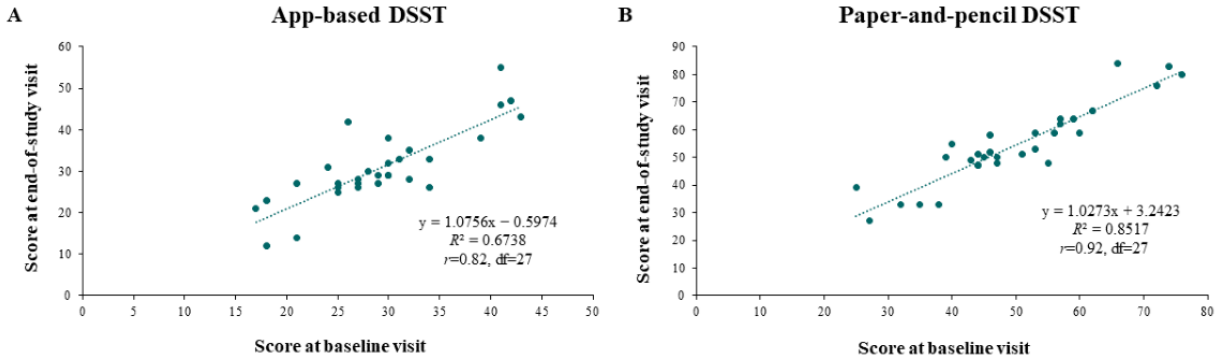
**Figure 3.** Correlation between app-based DSST and paper-and-pencil DSST scores at (A) baseline visit and (B) end-of-study visit (N=30). The correlation is not adjusted for age. DSST: Digit Symbol Substitution Test.




## Test-Retest Reliability

A positive correlation was found between scores at the baseline visit and scores at the end-of-study visit for both the app-based Cognition Kit DSST ($r$=0.82, $df$=27; Figure 4A) and the paper-and-pencil DSST ($r$=0.92, $df$=27; Figure 4B). The corresponding partial correlations after adjusting for age were $r$=0.75 ($df$=27; $P$<.001) and $r$=0.92 ($df$=27; $P$<.001) for the app-based Cognition Kit DSST and the paper-and-pencil DSST, respectively.

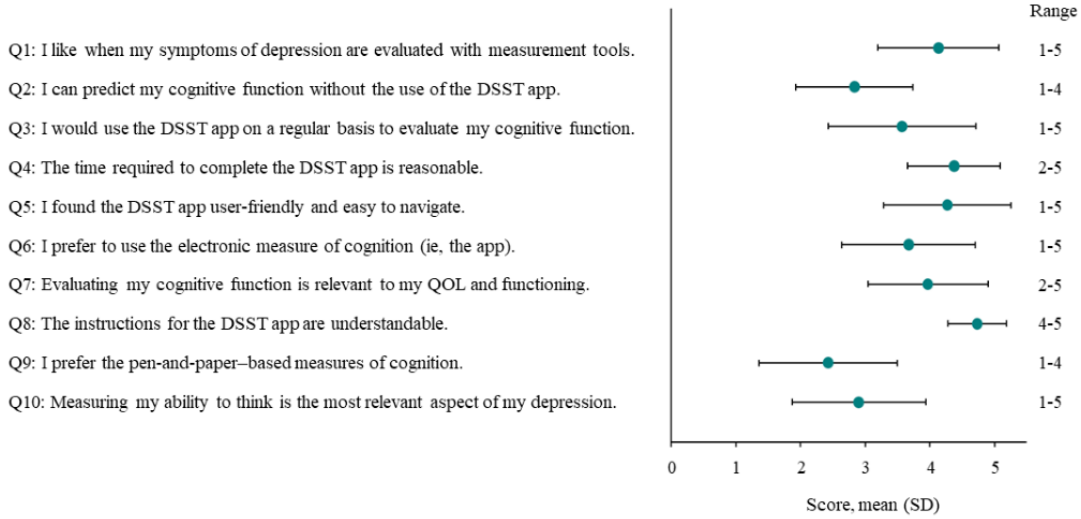
**Figure 4.** Test-retest reliability of (A) app-based DSST and (B) paper-and-pencil DSST (N=30). Results are not adjusted for age. DSST: Digit Symbol Substitution Test.




## Cognition Kit DSST App Satisfaction

In the app satisfaction survey, 87% (26/30) of patients reported that they agreed or strongly agreed that the Cognition Kit DSST app was user-friendly and easy to navigate. Overall, patients reported the highest levels of agreement with the following statements, each of which received a mean score >4 on the 5-point Likert scale (where a score of 4 indicated “agree” and a score of 5 indicated “strongly agree”): “I like when my symptoms of depression are evaluated with measurement tools”; “The time required to complete the DSST app is reasonable”; “I found the DSST app user-friendly and easy to navigate”; and “The instructions for the DSST app are understandable” (Figure 5). Additionally, 57% (17/30) of patients reported that they preferred to use the Cognition Kit DSST over the paper-and-pencil DSST.

**Figure 5.** App satisfaction survey mean scores (N=30). Each question was scored on a 5-point Likert scale where 1=strongly disagree and 5=strongly agree. DSST: Digit Symbol Substitution Test; QOL: quality of life.




## Discussion

### Principal Results

The Cognition Kit DSST was capable of detecting cognitive deficits in adults with MDD. The app-based DSST was highly correlated with the standard paper-and-pencil version of the test and was positively evaluated by 30 patients as being user-friendly, easy to navigate, and preferable to the paper-and-pencil version of the DSST. The change in mean DSST scores from baseline to end of the study observed in both the paper-and-pencil and app-based DSST may be due to intervention effects, random effects, regression to mean, or practice effects [16,20].

### Comparison With Prior Work

Antidepressant therapy may relieve depressive symptoms, but resolution of these symptoms is not well correlated with functional recovery and quality of life, which are often higher priority outcomes for patients with MDD [21]. Therefore, regular assessment of functional outcomes using validated measures, such as the DSST, may assist health care professionals in optimizing treatment for patients with MDD [21].

MBC has been highly evaluated in clinical practice in adult patients with MDD [22], but uptake remains low (<20%) in mental health settings [21]. Therefore, it is important that a convenient and accessible method of assessment is made available to patients with MDD, especially those who may be experiencing a degree of cognitive impairment. Indeed, the National Institute of Mental Health's public health trial—Sequenced Treatment Alternatives to Relieve Depression—demonstrated the usefulness of MBC for guiding psychotherapeutic and pharmacologic treatment approaches in patients with depression [22]. Strategies to reduce barriers to MBC and appropriately implement it as part of routine practice should be prioritized.

Neurocognitive tests via smartphones offer an effective and accessible tool that can be readily implemented into an MBC framework. In particular, individual tests such as the Cognition Kit DSST can be integrated into a suite of clinical measures within a single app, allowing multiple clinically relevant assessments to be performed. For example, depressive symptom, functioning, and quality of life measures may be offered alongside medication adherence and adverse event reporting, as well as reminders.

The THINC-it Tool has been previously validated as a screening tool and as a repeat measure for cognitive function in adults with MDD [12,23]. A variant of the DSST was included in the THINC-it Tool and accounted for significant variance in the tool's overall performance, suggesting that the DSST alone may provide sufficient conceptual coverage [12,23,24]. This study demonstrated the validity of the app-based Cognition Kit DSST to assess cognitive impairment in patients with MDD and represents a personalized assessment approach that may help guide MBC to inform psychotherapeutic and pharmacologic treatment options.

Moreover, applying smartphone technology may help clinicians to more fully understand the mediational role of cognition in MDD, particularly the extent to which it interferes with daily life in patients with persistent psychosocial and workplace impairment [6]. Integrating cognitive functions as part of the assessment of MDD may inform suicide risk, as suicidality in some cases may be linked to cognitive function [25]. Therefore, there is a need to assess cognition in these patients and in patients who do not functionally recover and will continue to exhibit cognitive impairment despite treatment. Deploying an easily accessible smartphone-based testing regimen that can be completed outside the clinical environment at no cost and with limited inconvenience to the patient may help remove barriers to routine assessment.

There is a risk, however, that assessments performed using a paper-and-pencil approach may differ compared with a smartphone-based assessment. The DSST is a polyfactorial test that assesses motor speed, attention, and visuoperceptual functions, all of which may be subject to subtle inter- and intraindividual differences when evaluated using a paper-and-pencil approach versus a smartphone-based approach [16]. However, high test-retest reliability has previously been

demonstrated with the paper-and-pencil version [26]. DSST performance is known to be reduced with increasing age and may be negatively influenced by physical impairments relating to vision or motor skills, but level of education does not appear to significantly influence performance [27]. Women may also perform better than men [28]. Therefore, additional neurocognitive testing may be required alongside the DSST to confirm any deficit.

Preliminary evidence suggests that there are differences among antidepressants in their ability to affect cognitive function in patients with MDD [5], indicating that cognitive function assessment is highly relevant when initiating pharmacologic therapy. In fact, DSST has been effectively used to assess improved performance in patients with MDD when comparing 2 different antidepressants [5,29]. That the Cognition Kit DSST was able to detect cognitive dysfunction in patients with MDD demonstrates that it may be implemented into an MBC framework because it is capable of guiding treatment decision-making for clinicians.

Implementing the Cognition Kit DSST in routine clinical practice has several benefits for both clinicians and patients. Enabling patients to complete neurocognitive assessment tools on their smartphones conserves clinical resources and streamlines the assessment process. For example, having a preassessed electronic record of cognitive symptom status can improve testing accuracy and consistency, while enabling clinicians to focus appointment time on treatment as opposed to administering and interpreting paper-and-pencil versions of cognitive assessments [30]. Furthermore, patients can easily and privately access app-based assessments at their convenience. Currently, assessment is recommended every 2-4 weeks if clinically appropriate, but patients could complete the Cognition Kit DSST more frequently, if required, to build a rich longitudinal picture of their cognition during a clinical study or as part of a health care pathway. However, when deploying these electronic assessments, consideration needs to be given to applying appropriate data protection measures to ensure patient privacy [30], especially given that individuals with depression may be concerned about employers, for example, becoming aware of a diagnosis of MDD or a degree of cognitive impairment [30].

This study had several strengths, including the patient population being representative of patients with MDD based on MADRS score, diagnosis confirmed by the MINI, and anxiety and anhedonia assessed by HAM-A and SHAPS, respectively. Furthermore, patients with heterogeneous illness presentation and course were eligible, including those receiving psychotropic medications in combination with medications for concurrent comorbidities.

### Limitations and Future Directions

Although the app-based Cognition Kit DSST was validated in patients with MDD, it still needs to be evaluated in healthy controls and individuals with MDD in other settings (eg, primary care). Additionally, Cognition Kit DSST sensitivity to change remains to be assessed. Our study excluded patients whose principal diagnosis was not MDD, which was another limitation. Further, only one standardized measure of cognitive function was validated in a relatively small sample, and patients were recruited from treatment-resistant depression centers. These factors may limit the generalizability of study results to a broader patient population, including those with treatment-responsive MDD or those who are treatment naive. Likewise, these results may not be generalizable to individuals with neurological disorders other than MDD, such as dementia, or those with learning differences, such as dyslexia.

The DSST has been extensively studied and is well regarded as a multidomain assessment of cognitive function [16]; however, it may disproportionately evaluate processing speed, and therefore, may not provide adequate conceptual coverage of other subdomains of neurocognition. Furthermore, the Cognition Kit DSST does not contain any self-reported measures of cognitive function, and we acknowledge that self-reported cognitive function does not correlate with objective cognitive function.

### Conclusions

This study demonstrated that cognitive function assessments performed using the Cognition Kit DSST app correlated with the paper-and-pencil version of the test, detecting cognitive deficits in adults with MDD. Future research efforts should focus on validating the Cognition Kit DSST in a healthy control population and in a larger MDD patient population. Research is needed into the Cognition Kit DSST app's sensitivity to change with treatment, the cost-effectiveness and impact on therapeutic outcomes of implementing the app, as well as the app's implications for health outcomes.

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## Authors' Contributions

RSM, OL, NBR, MS, FN, YL, BF, JK, LC, KK, SU, JDR, RBM, and MM contributed to the design and implementation of the study, the analysis of results, and the writing of the manuscript. All authors reviewed and approved the final manuscript for submission.

## Conflicts of Interest

MM, LC, and SU are employees of Takeda Pharmaceuticals U.S.A., Inc. RSM has received research grant support from the Canadian Institutes of Health Research (CIHR), Global Alliance for Chronic Diseases (GADC), and the National Natural Science Foundation of China and the Milken Institute; he has received speaker or consultation fees from Lundbeck, Janssen, Alkermes, Neumora Therapeutics, Boehringer Ingelheim, Sage, Biogen, Mitsubishi Tanabe, Purdue, Pfizer, Otsuka, Takeda, Neurocrine, Sunovion, Bausch Health, Axsome, Novo Nordisk, Kris Pharma, Sanofi, Eisai, Intra-Cellular, NewBridge Pharmaceuticals, Viatris, AbbVie, and Atai Life Sciences; and he is CEO of Braxia Scientific Corp. JDR has received research grant support from the Canadian Cancer Society, Canadian Psychiatric Association, American Psychiatric Association, American Society of Psychopharmacology, University of Toronto, University Health Network Centre for Mental Health, Joseph M. West Family Memorial Fund, and Timeposters Fellowship, as well as industry funding for speaker, consultation, or research fees from Janssen, Allergan, Lundbeck, Sunovion, and COMPASS. JDR is also the medical director of a private clinic providing intravenous ketamine infusions and intranasal esketamine for depression. KK is an employee of the Canadian Rapid Treatment Center of Excellence in Mississauga, ON, Canada. JK is an employee of Ctrl Group. BF is an employee of Ctrl Group and director of Cognition Kit. YL received a personal fee from Champignon Brand Inc. OL, MS, NBR, RBM, and FN have no conflicts of interest related to this study.

Multimedia Appendix 1
Evaluation of an app-based Digit Symbol Substitution Test for assessment of cognitive deficits in adults with major depressive disorder.
[PDF File (Adobe PDF File), 232 KB - mental_v9i10e33871_app1.pdf ]

## References


1. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders (DSM-5®). 5th ed. Washington, DC: American Psychiatric Association; 2013.
2. Practice guideline for the treatment of patients with major depressive disorder. American Psychiatric Association. 2010. URL: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf [accessed 2021-09-21]
3. Conradi HJ, Ormel J, de Jonge P. Presence of individual (residual) symptoms during depressive episodes and periods of remission: a 3-year prospective study. Psychol Med 2011 Jun;41(6):1165-1174. [doi: 10.1017/S0033291710001911] [Medline: 20932356]
4. Harrison JE, Lophaven S, Olsen CK. Which cognitive domains are improved by treatment with vortioxetine? Int J Neuropsychopharmacol 2016 May 26;19(10):1-6 [FREE Full text] [doi: 10.1093/ijnp/pyw054] [Medline: 27231256]
5. McIntyre RS, Harrison J, Loft H, Jacobson W, Olsen CK. The effects of vortioxetine on cognitive function in patients with major depressive disorder: a meta-analysis of three randomized controlled trials. Int J Neuropsychopharmacol 2016 Jun 15;19(10):1-9 [FREE Full text] [doi: 10.1093/ijnp/pyw055] [Medline: 27312740]
6. McIntyre RS, Soczynska JZ, Woldeyohannes HO, Alsuwaidan MT, Cha DS, Carvalho AF, et al. The impact of cognitive impairment on perceived workforce performance: results from the International Mood Disorders Collaborative Project. Compr Psychiatry 2015 Jan;56:279-282. [doi: 10.1016/j.comppsych.2014.08.051] [Medline: 25439523]
7. McIntyre RS, Cha DS, Soczynska JK, Woldeyohannes HO, Gallaugher LA, Kudlow P, et al. Cognitive deficits and functional outcomes in major depressive disorder: determinants, substrates, and treatment interventions. Depress Anxiety 2013 Jun;30(6):515-527. [doi: 10.1002/da.22063] [Medline: 23468126]
8. Chiauzzi E, Drahos J, Sarkey S, Curran C, Wang V, Tomori D. Patient perspective of cognitive symptoms in major depressive disorder: retrospective database and prospective survey analyses. J Particip Med 2019 May 16;11(2):e11167 [FREE Full text] [doi: 10.2196/11167] [Medline: 33055062]
9. Gorwood P, Corruble E, Falissard B, Goodwin GM. Toxic effects of depression on brain function: impairment of delayed recall and the cumulative length of depressive disorder in a large sample of depressed outpatients. Am J Psychiatry 2008 Jun;165(6):731-739. [doi: 10.1176/appi.ajp.2008.07040574] [Medline: 18381906]
10. Lee Y, Smofsky A, Nykoliation P, Allain SJ, Lewis-Daly L, Schwartz J, et al. Cognitive impairment mediates workplace impairment in adults with type 2 diabetes mellitus: results from the motivaction study. Can J Diabetes 2018 Jun;42(3):289-295. [doi: 10.1016/j.jcjd.2017.06.013] [Medline: 28958785]
11. Knight MJ, Lyrtzis E, Baune BT. The association of cognitive deficits with mental and physical quality of life in major depressive disorder. Compr Psychiatry 2020 Feb;97:152147 [FREE Full text] [doi: 10.1016/j.comppsych.2019.152147] [Medline: 31838296]

12. McIntyre RS, Lee Y, Mansur RB. Treating to target in major depressive disorder: response to remission to functional recovery. CNS Spectr 2015 Dec;20 Suppl 1:20-30; quiz 31. [doi: 10.1017/S1092852915000826] [Medline: 26683526]
13. McIntyre RS, Best MW, Bowie CR, Carmona NE, Cha DS, Lee Y, et al. The THINC-Integrated Tool (THINC-it) screening assessment for cognitive dysfunction: validation in patients with major depressive disorder. J Clin Psychiatry 2017 Jul;78(7):873-881. [doi: 10.4088/JCP.16m11329] [Medline: 28858441]
14. Lee Y, Brietzke E, Cao B, Chen Y, Linnaranta O, Mansur RB, Global Alliance for Chronic Diseases (GACD) Mental Health Guidelines Working Group. Development and implementation of guidelines for the management of depression: a systematic review. Bull World Health Organ 2020 Oct 01;98(10):683-697H [FREE Full text] [doi: 10.2471/BLT.20.251405] [Medline: 33177758]
15. McIntyre RS, Anderson N, Baune BT, Brietzke E, Burdick K, Fossati P, et al. Expert consensus on screening and assessment of cognition in psychiatry. CNS Spectr 2019 Feb;24(1):154-162. [doi: 10.1017/S1092852918001189] [Medline: 30642417]
16. Jaeger J. Digit symbol substitution test: the case for sensitivity over specificity in neuropsychological testing. J Clin Psychopharmacol 2018 Oct;38(5):513-519 [FREE Full text] [doi: 10.1097/JCP.0000000000000941] [Medline: 30124583]
17. Doupis J, Festas G, Tsilivigos C, Efthymiou V, Kokkinos A. Smartphone-Based Technology in Diabetes Management. Diabetes Ther 2020 Mar;11(3):607-619 [FREE Full text] [doi: 10.1007/s13300-020-00768-3] [Medline: 31983028]
18. Nakonezny PA, Morris DW, Greer TL, Byerly MJ, Carmody TJ, Grannemann BD, et al. Evaluation of anhedonia with the Snaith-Hamilton Pleasure Scale (SHAPS) in adult outpatients with major depressive disorder. J Psychiatr Res 2015 Jun;65:124-130 [FREE Full text] [doi: 10.1016/j.jpsychires.2015.03.010] [Medline: 25864641]
19. Baldwin DS, Florea I, Jacobsen PL, Zhong W, Nomikos GG. A meta-analysis of the efficacy of vortioxetine in patients with major depressive disorder (MDD) and high levels of anxiety symptoms. J Affect Disord 2016 Dec;206:140-150 [FREE Full text] [doi: 10.1016/j.jad.2016.07.015] [Medline: 27474960]
20. Morton V, Torgerson DJ. Effect of regression to the mean on decision making in health care. BMJ 2003 May 17;326(7398):1083-1084 [FREE Full text] [doi: 10.1136/bmj.326.7398.1083] [Medline: 12750214]
21. Hong RH, Murphy JK, Michalak EE, Chakrabarty T, Wang Z, Parikh SV, et al. Implementing measurement-based care for depression: practical solutions for psychiatrists and primary care physicians. Neuropsychiatr Dis Treat 2021;17:79-90 [FREE Full text] [doi: 10.2147/NDT.S283731] [Medline: 33469295]
22. Lewis CC, Scott K, Marti CN, Marriott BR, Kroenke K, Putz JW, et al. Implementing measurement-based care (iMBC) for depression in community mental health: a dynamic cluster randomized trial study protocol. Implement Sci 2015 Sep 07;10:127 [FREE Full text] [doi: 10.1186/s13012-015-0313-2] [Medline: 26345270]
23. Harrison JE, Barry H, Baune BT, Best MW, Bowie CR, Cha DS, et al. Stability, reliability, and validity of the THINC-it screening tool for cognitive impairment in depression: A psychometric exploration in healthy volunteers. Int J Methods Psychiatr Res 2018 Dec;27(3):e1736 [FREE Full text] [doi: 10.1002/mpr.1736] [Medline: 30088298]
24. McIntyre RS, Subramaniapillai M, Park C, Zuckerman H, Cao B, Lee Y, et al. The THINC-it tool for cognitive assessment and measurement in major depressive disorder: sensitivity to change. Front Psychiatry 2020;11:546 [FREE Full text] [doi: 10.3389/fpsyt.2020.00546] [Medline: 32670103]
25. Lee Y, Syeda K, Maruschak NA, Cha DS, Mansur RB, Wium-Andersen IK, et al. A new perspective on the anti-suicide effects with ketamine treatment: a procognitive effect. J Clin Psychopharmacol 2016 Feb;36(1):50-56. [doi: 10.1097/JCP.0000000000000441] [Medline: 26658082]
26. Matarazzo JD, Herman DO. Base rate data for the WAIS-R: test-retest stability and VIQ-PIQ differences. J Clin Neuropsychol 1984 Nov;6(4):351-366. [doi: 10.1080/01688638408401227] [Medline: 6501578]
27. Hoyer WJ, Stawski RS, Wasylyshyn C, Verhaeghen P. Adult age and digit symbol substitution performance: a meta-analysis. Psychol Aging 2004 Mar;19(1):211-214. [doi: 10.1037/0882-7974.19.1.211] [Medline: 15065945]
28. Kertzman S, Ben-Nahum Z, Gotzlav I, Grinspan H, Birger M, Kotler M. Digit Symbol Substitution test performance: sex differences in a Hebrew-readers' health population. Percept Mot Skills 2006 Aug;103(1):121-130. [doi: 10.2466/pms.103.1.121-130] [Medline: 17037653]
29. Rosenblat JD, Kakar R, McIntyre RS. The cognitive effects of antidepressants in major depressive disorder: a systematic review and meta-analysis of randomized clinical trials. Int J Neuropsychopharmacol 2015 Jul 25;19(2):1-13 [FREE Full text] [doi: 10.1093/ijnp/pyv082] [Medline: 26209859]
30. Gold M, Amatniek J, Carrillo MC, Cedarbaum JM, Hendrix JA, Miller BB, et al. Digital technologies as biomarkers, clinical outcomes assessment, and recruitment tools in Alzheimer's disease clinical trials. Alzheimers Dement (N Y) 2018;4:234-242 [FREE Full text] [doi: 10.1016/j.trci.2018.04.003] [Medline: 29955666]


## Abbreviations

**DSST:** Digit Symbol Substitution Test
**HAM-A:** Hamilton Anxiety Rating Scale
**MADRS:** Montgomery-Åsberg Depression Rating Scale
**MBC:** measurement-based care
**MDD:** major depressive disorder

**MINI:** Mini-International Neuropsychiatric Interview
**PROs:** patient-reported outcomes
**SHAPS:** Snaith-Hamilton Pleasure Scale

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Review

# Guided Internet-Delivered Treatment for Depression: Scoping Review

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## Abstract

**Background:** Studies on guided internet-delivered treatment have demonstrated promising results for patients with depressive disorder.

**Objective:** The aim of this study was to provide an overview of this research area and identify potential gaps in the research.

**Methods:** In this scoping review, web-based databases were used to identify research papers published between 2010 and 2022 where guided internet-delivered treatment was administered to participants with depressive disorders, a standardized rating scale of depressive symptoms was used as the primary outcome measure, and the treatment was compared with a control condition.

**Results:** A total of 111 studies were included, and an overview of the studies was provided. Several gaps in the research were identified regarding the design of the studies, treatments delivered, participant representation, and treatment completion.

**Conclusions:** This review provides a comprehensive overview of the research area, and several research gaps were identified. The use of other designs and active control conditions is recommended. Future studies should provide access to treatment manuals, and more replications should be conducted. Researchers should aim to include underrepresented populations and provide reports of comorbidities. Definitions of adequate dosage, reports of completion rates, and reasons for treatment dropout are recommended for future studies.

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**KEYWORDS**

web-based therapy; computer-assisted therapy; internet; digital interventions; major depression; mental health; mobile phone

## Introduction

### Depressive Disorder and Treatment Over the Internet

The number of people with access to the internet is considerable and increasing also in low-income countries [1]. As the number of people with access to the internet is sizable, internet-delivered treatment has the potential to reach more patients, be easily accessible, and be less time-consuming for the therapist per patient than more resource-intensive face-to-face therapies [2-4]. The COVID-19 pandemic has also demonstrated that situations might arise when face-to-face therapy can be less available, thus suggesting the benefits of internet-delivered treatments [5].

Depressive disorders, or clinical depression, are associated with great personal distress and high societal costs [6]. Common features of depressive disorders according to the Diagnostic and Statistical Manual of Mental Disorders [7] are sad, empty, or irritable mood and somatic and cognitive changes that decrease the ability to function at work and at home. As the number of people with clinical depression is increasing, there is a demand for effective and accessible treatments [8]. Meta-studies on internet-delivered psychological treatment show promising results for adults with mild or moderate depressive disorder [9-12], and this treatment option could be an accessible and less resource-intensive alternative to traditional face-to-face treatment [10].

Internet-delivered treatments typically involve working with different modules composed of reading assignments and tasks in a self-help format [13]. Treatments are often based on evidence-based treatment for depressive disorder; *cognitive behavioral therapy* (CBT); or other psychological treatments such as *acceptance and commitment therapy*, *problem-solving therapy*, positive psychology, or psychodynamic therapy [10,11,14]. These treatment options are accessible digitally through web-based programs such as web pages and phone apps and are available to the patient wherever there is internet access.

In *therapist-guided internet-delivered treatment*, additional guidance and support are provided by therapists, coaches, or other professionals over the internet via chats, emails, and telephone [14-16]. In unguided treatment programs, the patients usually have access to the treatment content, and some programs provide automated prewritten feedback. In guided treatment programs, a therapist often plays an active role in the treatment and guides the patient (or research participant) through the program. Studies have shown that both treatment formats could be effective and that a guided program is not necessarily superior to an unguided program [17,18] but that the inclusion of guidance could have an impact on treatment adherence [19].

A few recent meta-studies have focused primarily on guided treatments. Karyotaki et al [11] found guided internet-delivered treatments to have positive treatment effects, especially for patients with more severe depressive symptoms at baseline. Chan et al [12] found effectiveness in reducing depression and anxiety and lower attrition rates than previously reported for guided internet-delivered CBT. Carlbring et al [20] compared guided internet-delivered CBT with face-to-face therapy and concluded that the 2 treatments were equally effective for depression and several other psychiatric and somatic disorders.

To our knowledge, no recent review aimed at providing an overview and identifying potential research gaps focusing on guided treatments for patients with depressive disorder has been conducted.

## Scoping Review

A scoping review is a method used to provide an overview of a research area. The *PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews*) provides a framework with guidelines for conducting and reporting scoping reviews [21,22]. A key capacity of a scoping review is that it can synthesize research and describe what evidence is known and available in a confined area of research in the form of publicized empirical accounts. However, another important aspect of a scoping review is that it can inform and contribute to a research field by identifying potential gaps in knowledge.

In this scoping review, we focused on 4 overarching aspects of the included studies. We focused on (1) the design (and methods), (2) the treatments delivered, (3) the characteristics of the participants, and (4) how treatment completion was reported in the studies. We then considered potential gaps in the literature that should be taken into account in future research on internet-delivered treatment for depression.

## Type of Design

In previously published reviews and meta-analyses on internet-delivered treatment for depression, *randomized controlled trials* (RCTs) have been the most prevalent methodological design [11,14-16]. Etzelmueller et al [10] reviewed guided internet-delivered CBT focusing only on nonrandomized pre-post designs to evaluate the intervention effectiveness in a clinical setting and found evidence of both acceptability and effectiveness. Effectiveness studies investigating potential effects of treatment programs in a *real world* clinical setting could provide stronger conclusions about expected treatment outcomes than efficacy studies conducted in a controlled environment with more "ideal settings." In their systematic review of the implementation of internet-delivered treatments for depression in public health primary care settings, Rodriguez-Pulido et al [23] concluded that there were few studies outside the United Kingdom where this was investigated. Given the high prevalence of depression and the need for clinical evidence on the effectiveness of known treatment programs, it is of high relevance that a review of the available research and an evaluation of the study setting are warranted. Other factors regarding how studies are designed are also recommended for inclusion in a scoping review. These factors include descriptions of the comparator or control conditions (if used) in the intervention, the aims of the study, and the outcome measures used [24]. Including a variety of designs in a scoping review has the benefit of providing a more comprehensive overview of the research area [25]. At the same time, it is recommended to limit the inclusion of studies using designs related to answering the research questions (RQs) in the review [24]. In some research areas, the number of studies published can be quite extensive. Hence, some type of exclusion criterion is needed. This scoping review focused on efficacy or effectiveness studies that presuppose experimental and quasi-experimental designs, and therefore, studies with at least one control condition were included.

## Type of Treatment

Reports on the properties of the treatment, duration, and other methodological choices are recommended for inclusion in scoping reviews [25]. These factors could provide a useful overview of the treatments delivered and contribute to the identification of potential research gaps. Internet-delivered treatments based on CBT have been the principal subject matter of several newer reviews [10,12,20,26,27] and have even been the most prevalent treatment approach in reviews where other

treatment approaches were also considered [11,14,16]. For example, Karyotaki et al [11], who focused exclusively on guided internet-delivered treatment for depression, showed that most treatments tested were based on CBT (>70%) or problem-solving therapy. Tokgöz et al [16] and Garrido et al [14] reported similar findings as well.

When reviewing treatments, easy accessibility to treatment manuals is beneficial for transparency purposes and for making comparisons between studies feasible [28]. In addition, access to manuals is beneficial for future replication studies as well as for developing new treatments in which content from previously tested treatment programs is used. A review of trials in which psychological treatments were delivered for common mental disorders showed lower rates of access to the treatment manuals [28], and similar results were found in a review of internet-delivered CBT for adults in treatment for depression and anxiety [10]. There are, to our knowledge, no recently published reviews where the accessibility of treatment manuals in studies on guided internet-delivered treatment for depression is investigated.

### Participant Characteristics

In highly tailored treatments with relevant content directed at patients with depression, detailed descriptions of the participants are important. Many recently published reviews and meta-analyses on internet-delivered treatment have focused on treatments directed at adults with depression [10,11,16,20], and several have focused on 1 particular population group (eg, perinatal women with anxiety and depression [15], young people with anxiety or depression or a combination of both [14], participants aged >50 years [29], or participants living in lower-income countries [30]). Given the focus on specific populations, these reviews provide limited insight into the area of guided internet-delivered treatment for depression as a whole. In this review, we wanted to provide an overview of sex, age, and location (country) representation in the studies to investigate whether some populations are over- or underrepresented.

Participants from Western countries have been overrepresented in previous reviews [10-12,14,15,20,26], with few or none of the included studies recruiting participants from countries outside the Western world. Martínez et al [30] reviewed studies with participants from lower-income countries and found only 6 studies.

There is a high prevalence of comorbid disorders to depression [31] as well as of comorbid anxiety disorder [32-34]. If the goal is to create effective treatments for the general population, it would also be advantageous to report whether the treatments were tested on participants with other diagnoses or additional comorbidities.

A synthesis including all studies regardless of the participant group in focus could contribute to the identification of potential research gaps in the represented populations.

### Reports of Treatment Completion

Nonadherence and dropout rates have been reported to range from 0% to 75% in digital CBT treatments for depression [35], and the challenges of nonadherence have been discussed in several meta-studies [36-39]. Discontinuation of treatment hinders its effective delivery. First, patients not receiving an "adequate dose" of the therapy might not improve or may even experience a worsening of symptoms. Furthermore, limited resources (eg, therapy appointments) go to waste if patients discontinue treatment before an adequate dose is delivered, which could affect the ability of others to receive access to needed services and treatment [40,41]. With internet-delivered treatments, adherence has been defined as the extent to which individuals experience or engage with the content of the treatment [36,42]. Measures of adherence have included reports on the number of log-ins to the program, modules completed, time spent on the web, completion of different activities or use of web-based tools, posts made, pages viewed, replies to emails, forum visits, self-reports of completion of offline activities, and print requests made [43]. The adherence rate is commonly defined as the percentage of participants who complete treatment [39], which could include those participants who complete either the entire treatment or a specified amount of the lessons, modules, or exposure [44].

Completion of treatment as a measure of treatment adherence has been discussed as a problematic measure as treatment drop out might be the result of improvement [45], and "exposure" to a higher dosage of treatment does not necessarily mean better results [46]. In addition, participants might also use the technology in other ways than the developers intended [46], which can thus further skew the measured outcomes and interpretation of the results. The reasons or motivation for choosing the internet-delivered treatment could be of more importance for the results than the frequency or duration of exposure [46]. The adequate dose necessary to experience improvement could also vary among the different participants and user groups [45].

There is a lack of consensus on how to report treatment adherence [43,44]. Given that completion of treatment is described as a commonly used measure of adherence [39], this was also a focus of this scoping review. Reasons given (if reported) by participants for treatment discontinuation were also charted, which has often been described as not reported in many studies [39,44]. Understanding treatment discontinuation can provide useful information for treatment development and patient care and guide the design of future studies.

### Aim and RQs

The aims of this scoping review were to analyze and describe currently available quantitative research on guided internet-delivered treatment for participants with depressive disorder, provide insight into this research area, and identify potential gaps in research.

We posed the following four RQs: (1) How are the studies designed? (RQ 1), (2) What types of treatments are delivered? (RQ 2), (3) What are the characteristics of the participants in the studies? (RQ 3), and (4) What is the treatment completion in the various studies? (RQ 4).

# Methods

## Scoping Review

The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines [21] for conducting systematic scoping reviews, described by Peters et al [24], were followed. Given that the aims of this scoping review were to describe the research and identify the potential research gaps, no quality assessment of the included studies was conducted.

## Eligibility Criteria

Quantitative studies published in peer-reviewed journals between January 1, 2010, and June 4, 2022, were eligible for inclusion. Full-text accessible publications in the English or Scandinavian languages were included.

Even though this scoping review could have included noncontrolled studies, we restricted the inclusion criteria to controlled experimental studies where at least one condition stipulated that participants received guided internet-delivered treatment to reduce the potential extensiveness of this review. Reviews, meta-analyses, conceptual articles, and nonempirical articles were excluded.

A standardized rating scale for depressive symptoms (eg, Center for Epidemiological Studies-Depression [48], Patient Health Questionnaire-9 [49], and Montgomery-Åsberg Depression Rating Scale [50]) had to be used as the primary outcome measure throughout the study. To secure a comparable group of participants and limit the focus of the review, only studies in which the participants initially scored mild or moderate for depression were eligible for inclusion. Studies focused on preventing depressive disorder or promoting psychological well-being were excluded. Studies including participants with comorbid disorders were accepted as long as depressive symptoms were a primary outcome measure. We implemented no limitations regarding participant age, which typically has been the case in previous reviews [10,11,16,20,51]. We included studies with treatments directed at children as well as teenagers and young adults, thus allowing for comparisons between age groups, providing insight into age representation in the studies, and identifying potential studies that were previously excluded. We also assumed that younger people were more adept at using digital solutions, and therefore, there would be a vast number of studies with treatments directed at this subpopulation.

For this scoping review, treatments had to be delivered over the internet and accessible wherever the participants had access to the internet (the device used by the participants was not decisive, and both phone apps and web page–available interventions were included). Studies in which the participants were required to be in a specific location to have access to the treatment (eg, at home, in school, or at the psychologist's office) were excluded. The guided internet treatments had to be a stand-alone treatment and not a supplement to face-to-face treatments. Only treatments in which the participants received guidance from a *trained* guide during the treatment were eligible. To be *trained* was defined as having a degree in psychology, social work, or nursing or other relevant education or being a student, in training, or a layperson and receiving special courses or training in the methods and supervision from a trained professional. The guidance had to be implemented during the entire treatment and not limited to measures and testing or reminders to complete web-based tasks.

See Multimedia Appendix 1 for the coding manual used.

## Information Sources

The second author (AD) conducted a systematic search on June 4, 2022. The scientific databases PubMed, Scopus, PsycINFO, MEDLINE, and ERIC were searched. See Multimedia Appendix 2 for details about the search.

A total of 28 published systematic reviews on internet-delivered treatment (Multimedia Appendix 3 [10,11,14-16,20,27,29,30,51-69]) were hand searched by LB for relevant studies not identified in the literature search. The identified studies were screened using the same criteria applied when screening the database records.

## Selection of Sources of Evidence

After removal of duplicates using the EndNote (version 20; Clarivate Analytics) duplicate finder followed by manual removal, the results were imported into the systematic review research tool Rayyan (Rayyan Systems Inc) [70] and screened by the first author (LB) for inclusion. Screening was performed by first reading the title and abstract and thereafter by screening the full-text articles. For studies where the eligibility was unclear, the fifth author (ANH) was consulted, and an agreement was reached after discussion between the 2 authors.

## Data Items

### *Overview*

The data were extracted and charted by LB. Author names, title of the article, journal, and year of publication were extracted as well as the items described in the following sections related to the 4 RQs. A detailed description of the extraction and charting of the data is provided in Multimedia Appendix 4 [7,71,72].

### *RQ 1: How Are the Studies Designed?*

To answer this question, information about research design, control conditions, whether the studies were considered to be efficacy or effectiveness studies, and the outcome measures collected in the studies was charted.

### *RQ 2: What Types of Treatments Are Delivered?*

To answer this question, information about the treatments, including treatment approaches, accessibility of treatment manuals, names of the treatments, by whom the guidance was delivered, and the duration of the treatment, was charted.

### *RQ 3: What Are the Characteristics of the Participants in the Studies?*

To answer this question, information about the participants was charted. This included the number of participants, sex, mean age, age group in focus, reports of comorbid disorders, and the countries from which the participants were recruited.

### *RQ 4: What Is the Treatment Completion in the Various Studies?*

To answer this question, information about treatment completion was charted, including if a definition of treatment completion was provided, the number of participants defined as completers, and reasons for discontinuation of treatment (if provided).

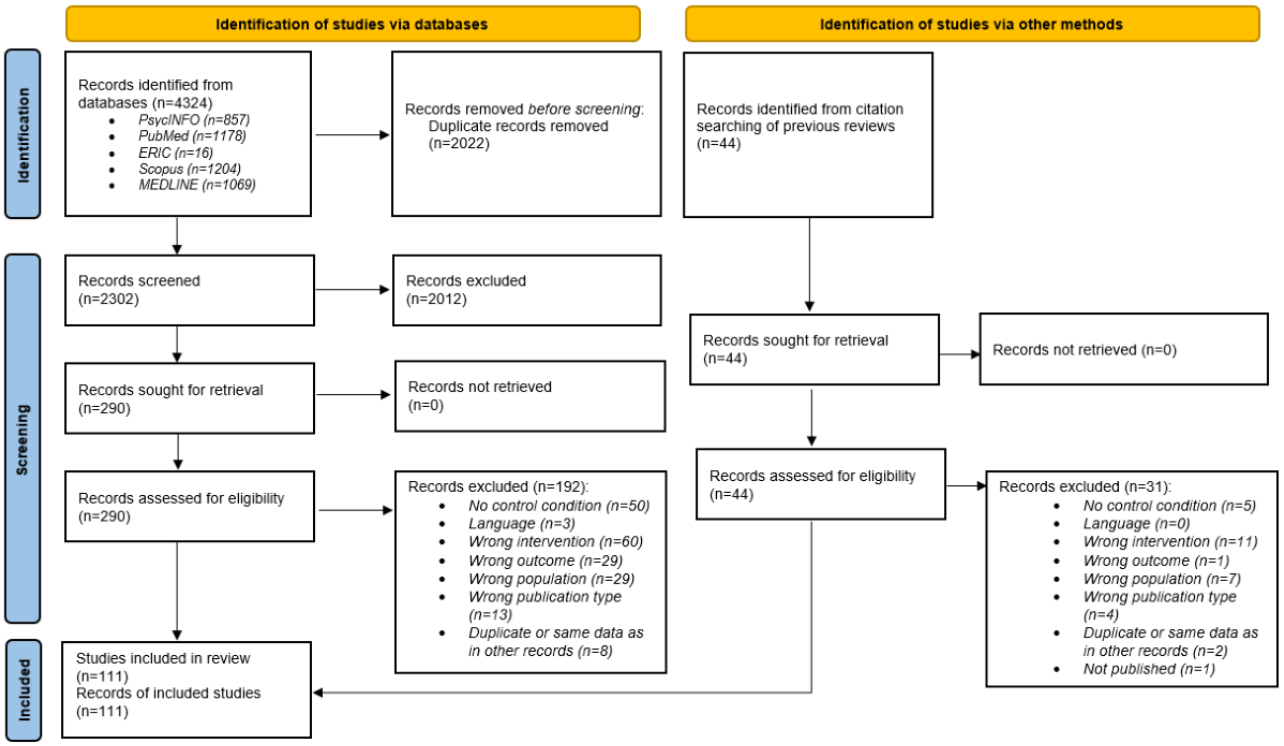
## Results

### Selection of Sources of Evidence

The results of the screening process are presented in Figure 1. The literature search resulted in 4324 records, of which 98 (2.27%) were included in this scoping review.

The hand search of 28 published reviews yielded 13 additional studies. Thus, the total number of studies included in this review was 111.

**Figure 1.** Results from the screening process and literature search. Flow diagram showing inclusion and exclusion strategy.




### Synthesis of Results

In Multimedia Appendix 5 [17,73-182], the data charted from and the characteristics of the different sources of evidence are presented. Multimedia Appendix 5 provides an overview of the 111 included studies.

### *Study Design and Methods*

The first RQ—"How are the studies designed?"—was related to what types of study designs and methods that were applied in the studies.

#### Study Design

Most publications (110/111, 99.1%) were RCTs. A total of 0.9% (1/111) were prospective cohort studies.

#### Control Condition

A total of 52.3% (58/111) of the studies included at least one active control condition (eg, access to other treatments or variations of the treatment). Of the 58 studies considered, 38 (66%) solely had active controls, whereas the other 20 (34%) used a combination of active and inactive controls. In addition, 47.7% (53/111) of the included studies had exclusively inactive control conditions (eg, no treatment, waitlist, attention control, or treatment as usual).

#### Efficacy and Effectiveness

A total of 81.1% (90/111) of the studies were defined as effectiveness (43/111, 38.7%) or efficacy studies (47/111, 42.3%). The remaining 18.9% (21/111) did not provide a definition.

#### Outcome Measure

A total of 14 different psychometric scales were used to measure depressive symptoms in the studies. In 17.1% (19/111) of the studies, a combination of different measurement scales was used as a primary outcome measure. In Multimedia Appendix 5, all relevant measurement scales used in the studies are charted. The 3 most applied outcome measurement scales for depressive symptoms were the Patient Health Questionnaire-9 [49], Beck's Depression Inventory [183], and the Center for Epidemiological Studies-Depression scale [48].

#### Research Gaps in Study Design and Methods

Table 1 provides an overview of the identified research gaps with regard to how the studies were designed.

**Table 1.** Identified gaps in the reviewed literature regarding design.

| Identified gap | Reason | Report | Percentage of studies reporting |
|---|---|---|---|
| Lack of diversity in research design | Few studies with designs other than RCT[a] | Only 1 study with other design (<1%) | 100% of the studies reported the design used |
| Need for more studies with an active control condition | Relatively many studies with an inactive control condition | 47.7% of the studies had only an inactive control condition | 100% of the studies described the control condition |
| Large variations in the outcome measure used | Several different measurement scales and combinations of these were used | 14 different measurement scales were used; 19 studies where combinations of different measurement scales were used | 100% of the studies reported the outcome measure used |

[a]RCT: randomized controlled trial.

## *Treatment Characteristics*

The second RQ—"What types of treatments are delivered?"—focused on what types of treatments were delivered and how the treatments were designed.

### Treatment Approaches

Table 2 provides an overview of all the approaches used. A total of 123 treatments were tested. In 6.3% (7/111) of the studies, treatments were based on a combination of different approaches (eg, behavioral activation and physical activity [73] or problem-solving therapy and cognitive therapy [74]). A total of 1.8% (2/111) of the studies included several experimental arms that received treatments based on different approaches. In Kladnitski et al [75], one group received CBT, one group received CBT in combination with mindfulness, and one group received mindfulness exclusively. In the study by Stiles-Shields et al [76], one group received behavioral activation, and one group received CBT. For an overview of the treatment approaches used in the different studies, please see Multimedia Appendix 5.

**Table 2.** Treatments tested as stand-alone approaches, in combination, or as one of several arms in the studies (n=123).

| Treatment approaches | Tests, n (%) |
|---|---|
| Acceptance and commitment therapy | 4 (3.3) |
| Behavioral activation | 9 (7.3) |
| Cognitive behavioral therapy | 82 (66.7) |
| Information | 1 (0.8) |
| IPDT[a]: affect-focused psychodynamic psychotherapy | 2 (1.6) |
| Life review therapy | 1 (0.8) |
| Mindfulness | 4 (3.3) |
| Physical activity | 3 (2.4) |
| Problem-solving therapy | 13 (10.6) |
| Psychodynamic treatment | 1 (0.8) |
| Sleep diary | 1 (0.8) |
| Social cognitive theory | 1 (0.8) |
| Stress process model | 1 (0.8) |

[a]IPDT: internet-based psychodynamic therapy.

### Treatment Manual

None of the studies provided easy access to the entire treatment manual. Many studies included brief descriptions of the treatment, such as a table describing the treatment content. Several studies referred to previous publications for a more detailed description of the treatment, but even in those cases, the manuals were not accessible. In all, 2.7% (3/111) of the studies provided more extensive treatment descriptions in the study protocol [77] or in the supplementary material or appendix [78,79].

### Name of Treatment

In all, 71.2% (79/111) of the studies referenced a named treatment program. The most frequently identified treatment programs were different versions of The Wellbeing Course (8/111, 7.2%) [80] and The Sadness Program (7/111, 6.3%; including culturally adapted versions) [184].

### Guidance

Only 0.9% (1/111) of the studies [81] did not report the background or training of the guides. Trained professionals delivered the guidance in 67.6% (75/111) of the studies. Most of the guidance was delivered by psychologists, social workers, and nurses, but there were also studies where guidance support

was delivered by lay counselors [82] and nonprofessional volunteering telephone counselors [83] who did receive some training beforehand. A total of 6.3% (7/111) of the studies had research staff and authors providing the guidance, and 25.2% (28/111) of the studies had students or professionals in training supporting the participants.

### Duration

Most studies (101/111, 91%) described the duration of the treatment in weeks, months, or years, and often the participants had to complete 1 module or session per week. A total of 3.6% (4/111) of the studies described the number of sessions or modules that should be completed without reference to time [84-87]. In total, 5.4% (6/111) of the studies did not describe the duration of the treatment [88-93]. The longest treatment lasted for 52 weeks [78], and the shortest lasted for 3 weeks [94]. For the 91% (101/111) of the studies where it was possible to chart duration in weeks, the mean treatment duration was 9.3 (SD 5.6) weeks with the range being 3 to 52 weeks, and the median was 8 weeks.

### Research Gaps Regarding the Treatments Delivered

In total, 2 research gaps regarding types of treatments delivered were identified in the included studies. First, none of the studies provided easy access to a treatment manual.

Second, there was large variation in the treatment programs used. Only 47.7% (53/111) of the studies tested treatments that were used in at least one other study included in this review. This points to a lack of replications. However, only 71.2% (79/111) of the included studies reported the name of the treatment program, and unidentified replication studies are possible.

## *Participant Characteristics*

The third RQ—"What are the characteristics of the participants in the studies?"—was related to the participants in the included studies.

### Number of Participants

There were a total of 11,851 participants across all studies. Not all participants from all studies were included as some study arms did not fulfill the inclusion criteria (eg, studies where a comparison group did not receive web-based treatment or had a diagnosis other than depression). The mean number of participants with relevant conditions was 106.8 (SD 151.83, median 52, range 9-949).

### Sex of Participants

Table 3 summarizes the representation of sex in the studies. The studies had an average of 74% female participants (median 76.6%, range 12.4%-100%). In 7.2% (8/111) of the studies, sex was not reported [76,95,96] or was reported for the total sample but not separated for the different conditions [97-101]. In total, 8.1% (9/111) of the studies included only women and had treatments directed at maternal depression [84,87,88,102-105], patients with breast cancer [106], or female adolescents [107].

A total of 7.2% (8/111) of the studies included <50% women. Of these 8 studies, 6 (75%) had participants with comorbid disorders (heart problems [108-111], HIV [112], and kidney diseases [113]), 1 (12%) was directed at a Kurdish population in Sweden [114], and 1 (12%) was directed specifically at army Veterans [115].

**Table 3.** Female participants (N=111).

| Percentage of female participants | Publications, n (%) |
|---|---|
| 0% to 20% | 2 (1.8) |
| 21% to 40% | 4 (3.6) |
| 41% to 60% | 7 (6.3) |
| 61% to 80% | 60 (54.1) |
| 81% to 100% | 35 (31.5) |
| NR[a] | 3 (2.7) |

[a]NR: not reported.

### Age of Participants

A total of 5.4% (6/111) of the studies did not report the participants' ages [76,85,88,101,104,116]. The mean age across the remaining 94.6% (105/111) of the studies was 40.9 (SD 11.6, median 42.3, range 15.8-69.6) years.

### Age Group in Focus

None of the included studies had treatments directed at children. A total of 9.9% (11/111) of the studies included teenagers or young adults. Most studies (96/111, 86.5%) had treatments directed at adults. A total of 3.6% (4/111) of the studies included solely older adults [117-120].

### Comorbid Disorders

In 24.3% (27/111) of the studies, comorbidities or secondary diagnoses besides depressive disorder were not reported. In 26% (7/27) of these studies, comorbidities were stated as being included, but no description of these comorbidities was provided. Most studies (68/111, 61.3%) included participants with other Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV), Axis I disorders [7] (eg, anxiety disorders, posttraumatic stress disorder, and eating disorders) in combination with depression.

In all, 19.8% (22/111) of the studies included participants diagnosed with both depression and a physical disease (eg, renal diseases [78,113], breast cancer [106], and multiple sclerosis

[121]). In 5.4% (6/111) of the studies, participants were diagnosed with a combination of physical diseases and mental disorders or other DSM-IV Axis I disorders in addition to depression (eg, cancer, anxiety and stress [95,122], or diabetes and anxiety [123].

### Countries of Recruitment

See Table 4 for an overview of all the countries in which the participants were recruited. Most studies (104/111, 93.7%) were conducted in and included participants from Western countries, but non-Western countries such as Iran [107], Colombia [126], and Indonesia [82] were also represented. In total, 2.7% (3/111) of the studies included a population that was considered to have a culturally different background than most participants recruited. These culturally different populations were Turkish migrants in the Netherlands [124], the Kurdish population in Sweden [114], and Chinese Australians [127].

**Table 4.** Countries where participants were recruited (N=111).

| Countries | Publications, n (%) |
|---|---|
| Australia | 20 (18) |
| Brazil and Peru | 1 (0.9) |
| Canada | 6 (5.4) |
| China | 1 (0.9) |
| Colombia | 1 (0.9) |
| Finland | 2 (1.8) |
| Germany | 7 (6.3) |
| Indonesia | 1 (0.9) |
| Iran | 1 (0.9) |
| Ireland | 1 (0.9) |
| Netherlands | 15 (13.5) |
| Norway | 1 (0.9) |
| Romania | 1 (0.9) |
| Spain | 2 (1.8) |
| South Korea | 1 (0.9) |
| Sweden | 26 (23.4) |
| Switzerland | 2 (1.8) |
| Switzerland and Germany | 1 (0.9) |
| United Kingdom | 6 (5.4) |
| United States | 15 (13.5) |

### Research Gaps Regarding the Participants in the Studies

In Table 5, research gaps with regard to the participants in the studies are identified.

**Table 5.** Identified gaps in the reviewed literature regarding characteristics of the participants.

| Identified gap | Reason | Report | Percentage of studies reporting |
|---|---|---|---|
| Female participants overrepresented | More female than male participants in the studies | The studies had an average of 74.1% female participants | Sex was reported in 97.3% of the studies |
| Lack of studies directed at teenagers and young adults | Few studies of treatments directed at teenagers or young adults | 11 studies directed at teenagers or young adults | 100% of the studies reported or provided sufficient information to draw conclusions about age group in focus |
| Lack of studies directed at older adults | Few studies of treatments directed at older adults | 4 studies included solely older adults | 100% of the studies reported or provided sufficient information to draw conclusions about age group in focus |
| Lack of reports of comorbid disorders | Several studies where comorbid disorders were not described in detail or reported | 24.3% of the studies did not include reports of comorbid disorders | 75.7% of the studies reported comorbidity |
| Non-Western participants underrepresented | Few studies with participants from non-Western countries | 6.3% of the studies recruited participants from non-Western countries | 100% of the studies reported or provided sufficient information for conclusions about origin |

### *Treatment Completion*

The fourth RQ—"What is the treatment completion in the various studies?"—was related to treatment completion in the studies, including if the researchers provided a definition of adequate dosage for the treatment to be considered completed, the number of participants completing the treatment, and reasons provided for treatment dropout.

#### Definitions of Treatment Completion

Of the 111 studies, 22 (19.8%) provided a clearly stated definition of treatment completion.

Completion was often defined as completing all modules or sessions [77,87,128] or a majority of the modules (eg, 5 of 8 modules [82]). A total of 0.9% (1/111) of the studies defined completion as having started in the last module [129].

#### Number of Completers

Overall, 80.2% (89/111) of the studies provided information about the number of participants who completed all the treatment modules or lessons or fulfilled a stated definition of treatment completion. See Table 6 for an overview of the percentage treatment completers in the 80.2% (89/111) of studies. In 34% (30/89) of these studies, <50% of the participants completed the treatment. In 66% (59/89) of these studies, >51% of the participants completed the treatment; of these 59 studies, there were 5 (8%) with >90% of the participants completing the treatment [118,130-133].

**Table 6.** Treatment completers (N=89).

| Percentage of treatment completers | Publications, n (%) |
|---|---|
| 0% to 20% | 10 (11) |
| 21% to 40% | 14 (16) |
| 41% to 60% | 21 (24) |
| 61% to 80% | 26 (29) |
| 81% to 100% | 18 (20) |

#### Reasons for Noncompletion

A total of 15.3% (17/111) of the studies clearly stated reasons why participants did not complete the treatment. In 100% (17/17) of these studies, several reasons for noncompletion were reported. The most reported reason was that some of the patients lacked time to complete the treatment, as reported in 71% (12/17) of these studies. Treatment not meeting personal needs (10/111, 9%) and personal problems or sickness (10/111, 9%) were also described by patients as reasons for not completing.

In 8.1% (9/111) of the studies, some of the participants dropped out without providing reasons for noncompletion. See Table 7 for details from the 15.3% (17/111) of the studies.

In the remaining studies (94/111, 84.7%), reasons for noncompletion were either not stated (88/94, 94%) or not clearly stated (6/94, 6%). During coding, we noted that several studies provided reasons for attrition (dropout from the study; eg, failure to complete follow-up questionnaires), but these data were not charted in this review.

**Table 7.** Reasons participants provided for noncompletion of the treatment in the 17 studies where this information was described.

| Reason | Study | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Boele et al [139], 2018 | Boeschoten et al [121], 2017 | Geraedts et al [74], 2014 | Heller et al [87], 2020 | Høifødt et al [138], 2013 | Karyotaki et al [144], 2022 | Kenter et al [137], 2016 | Kleiboer et al [136], 2015 | Lappalainen et al [132], 2015 | Nadort et al [113], 2022 | O'mahen et al [88], 2014 | Pots et al [145], 2016 | Preschl et al [134], 2011 | Ström et al [81], 2013 | Van der Zweerde et al [98], 2019 | Wagner et al [135], 2014 | Westerhof et al [79], 2019 |
| No reason provided | ✓[a] | | ✓ | ✓ | ✓ | | ✓ | ✓ | | | | | | ✓ | ✓ | ✓ | |
| Not meeting personal needs | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ | | | | ✓ | | ✓ | |
| Recovery | ✓ | | | ✓ | ✓ | | ✓ | ✓ | | | ✓ | | ✓ | | | ✓ | |
| Preferred other treatment or part of the treatment | ✓ | ✓ | | ✓ | ✓ | | | ✓ | | | | | | | | ✓ | |
| Technical difficulties | ✓ | ✓ | | | | ✓ | ✓ | ✓ | | | | | | | | ✓ | |
| Lack of time | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ | | | ✓ | ✓ | ✓ | ✓ | ✓ | | |
| Motivation | | | | ✓ | | ✓ | ✓ | ✓ | | ✓ | ✓ | | ✓ | | | ✓ | ✓ |
| Personal problems or sickness | ✓ | ✓ | | | ✓ | | ✓ | | ✓ | ✓ | | ✓ | | ✓ | ✓ | | ✓ |

[a]✓: indicates that at least one participant in the study stated the reason as a cause for treatment noncompletion.

### Research Gaps Regarding Completion of Treatment

In Table 8, research gaps regarding the definition of treatment completion, the rate of completion, and the reasons provided for treatment dropout are presented.

**Table 8.** Identified gaps in the reviewed literature regarding treatment completion.

| Identified gap | Reason | Report | Percentage of studies reporting |
|---|---|---|---|
| Lack of clear definitions of treatment completion | Few studies where completion was defined | A minority (n=22) of the studies provided a clearly stated definition of adequate or necessary dosage of the treatment for it to be considered completed | 19.8% of the studies provided definitions of treatment completion or adequate dosage |
| Lack of reports of treatment completion | Several studies without reports of the number of participants who completed the treatment | 89 studies provided information about the number of completers (completed all the treatment modules or fulfilled a stated definition) | 80.2% of the studies reported the number of participants who completed the treatment |
| Lack of reports on reasons for treatment dropout | Most studies did not provide reasons for participants dropping out of treatment | 17 studies clearly stated reasons for noncompletion of the treatment | 15.3% of the studies reported reasons for discontinuation of treatment |

# Discussion

## Summary of Evidence

In this scoping review, we identified 111 studies published between 2010 and 2022 on guided internet-delivered treatment for participants diagnosed with depression.

### *Study Design and Methods*

There was a high degree of uniformity regarding research designs, with 99.1% (110/111) of the studies using RCTs; these results are similar to results from previously published reviews on internet-delivered treatment for depression [11,14-16]. We anticipated to identify controlled experimental studies without randomization (eg, comparing the effects for men vs women), including studies with multiple single-case designs with within-person control or other variations of research designs. Even though we did not exclude nonrandomized studies, our findings might still be a result of the quite strict inclusion criteria, such as the studies needing to include at least one control condition. A scoping review including noncontrolled studies might produce results in which further information about the treatments is identified [47] and could be useful for updating treatments in an applied setting [10].

There were an equal number of efficacy and effectiveness studies in the part of our sample where this was reported. Given that one of the inclusion criteria stipulated that participants should have depressive disorder, one might expect the identification of a higher number of effectiveness studies conducted with patients in clinical settings. However, the criteria that the studies had to have at least one control condition may have indirectly led to the exclusion of these types of studies. In a clinical setting, it might have been viewed as impractical or even unethical to not offer the same conditions to all patients. This might also explain why a large amount of the studies had an active control condition or a combination of active and inactive control conditions.

Even though most studies (58/111, 52.3%) had at least one active control condition, 47.7% (53/111) had an inactive control condition. As active control is preferable [185], this represents a gap in the research, and future studies should aim to be designed with an active control condition.

There was quite a large variation regarding outcome measures considering that only standardized measurement scales were accepted. Many studies used combinations of various scales. A possible reason might be that studies were conducted by a variety of research teams in different countries and that personal preferences and traditions could influence such decisions. The use of different outcome measures might not be problematic, and treatment effects could still be compared, but it could represent a possible scaling issue if there are large variations in how depression is defined. There is a risk that different phenomena were measured in the different studies, where some behaviors defined as depressive symptoms in one study might not be considered so in another study. In addition, what is used as primary outcome measures varies and in many instances, is not specifically mentioned or defined as the primary outcome in the trial.

### *Treatment Characteristics*

We identified several different treatment approaches, but most studies (81/111, 73%) used some variation of CBT. This might represent the standard treatments recommended for patients with depression [186] and is also similar to the findings of a previous review on guided internet-delivered treatment for depression [11]. This could be an indicator that the treatments were implemented based on evidence-based studies and results.

With no publications where the treatment manual was easily accessible, the results are weaker than in previous reviews [10,28], and this gap in research should be addressed in future studies. The lack of accessibility to treatment manuals makes the studies less transparent as well as making comparisons and replications more difficult.

A large variety of treatment programs was used, which could indicate that more studies using the same programs would be beneficial as opposed to every research team investigating a new program. However, lack of accessible treatment manuals and with several unnamed treatments used in the included studies, it is possible that some studies used the same treatment programs without it being identified in this review.

Trained professionals accounted for most of the guidance, which was expected for studies with participants diagnosed with clinical depression, and these findings were in line with previously published reviews [10,11]. However, research staff and students were also used as guides in several studies (35/111, 31.5%).

In line with the common duration of face-to-face sessions in CBT for depression [187,188], most treatments in our sample lasted between 5 and 12 weeks.

### *Participant Characteristics*

There were large variations in the number of participants included in the studies. This scoping review evaluated studies with a combined total of >11,000 participants and thus provided a large demographic profile of the participants studied.

Female participants were overrepresented in the studies, with an average of 74%. Although this might indicate a sex prevalence of depression, treatments should be tested for all potential target populations. Those studies directed at participants diagnosed with both depression and a comorbidity or physical disease (eg, heart failure [108]) had more male participants. Our review also identified 8.1% (9/111) of the studies directed at women only, mostly with the aim of reducing maternal depression. Studies on treatments directed at maternal depression have often been excluded from previous reviews [52] or reviewed separately [15].

Participants from non-Western countries were also underrepresented in the studies. Given the increasing access to internet-connected devices and the steady rise in the number of people in need of treatment in these countries [189], more studies with non-Western participants would be advantageous.

Studies with treatments specifically directed at teenagers or young adults and older adults were underrepresented in the research. However, there was some overlap in some of the included studies in which several studies recruited and enrolled participants aged <30 years and >60 years. The prevalence of depressive disorders is higher in young adults than in any other age group in high-income countries [189], and providing and testing treatments for this targeted group should be prioritized.

We identified several studies with computerized treatments directed at children. However, treatments directed at children often involved working together with a therapist or coach at school or in a therapist's office, and these studies were excluded from our review because of the limited accessibility and requirement to be in a specific location. A future review aiming to include treatments for this age group could focus on computerized program treatments rather than internet-delivered treatments.

This review revealed deficient reporting of comorbid conditions experienced by the participants, which is problematic because of the high prevalence in the patient group [31]. It is reasonable to assume that there were participants with comorbidities or secondary diagnoses in most of the studies as long as these comorbid conditions were not used as an exclusion criterion. Reports on this should be included in future studies. In the studies where this was reported (84/111, 75.7%), DSM-IV Axis I disorders, especially anxiety disorders, were the most prevalent. Given the high prevalence of comorbid anxiety with depressive disorder [32-34], this was as expected. A total of 0.9% (1/111) of the studies [134] excluded participants with symptoms of anxiety disorders or posttraumatic stress disorder, which could limit the ability to generalize the findings. Testing treatments directed at patients without other comorbid DSM-IV Axis I disorders could, by contrast, lead to highly targeted treatments. Specialized and individualized treatment programs could potentially reduce the problem of treatment dropout, that is, assuming that the participant continues to deem all modules or lessons as highly relevant for treatment success. Further research on how comorbid conditions affect the response to treatment and how treatment programs should be amended is needed.

This scoping review led to the identification of several studies (22/111, 19.8%) in which participants had physical diseases or disorders. For patients with chronic pain, diabetes, cancer, or renal disease or kidney failure, the flexibility and accessibility of the internet-delivered format could be crucial for implementation of the treatment.

### *Treatment Completion*

A minority of the studies (22/111, 19.8%) provided a clearly stated definition of what was considered an adequate dosage of the treatment for it to be considered completed. It is problematic if treatment programs are not evaluated with the aim of ensuring access to effective treatment components. If it is expected that participants will not interact with all the modules or lessons in the program, it could be argued that the treatments should be made shorter and only include the most effective components. It is also problematic if most studies make conclusions regarding treatment efficacy or effectiveness based on a study sample where dosage or interaction with treatment were not evaluated.

Most studies provided information about the number of participants who completed all modules or lessons in the program. As a result, we synthesized this information although these data could be a somewhat problematic measure of treatment adherence [45,46]. Several studies included optional modules that were directed at specific problems (eg, insomnia) that might not have been applicable to all participants. Treatment adherence is considered a challenge for both psychotherapy in general [41] and digital psychotherapeutic treatments [36-39]. Thus, it would be advantageous to have some consensus when reporting nonadherence to treatment to be able to effectively target the challenging areas of nonadherence. To compare across studies, an operationalization of treatment completion and reporting of the number of participants considered completers are needed in future studies.

A minority of the studies (17/111, 15.3%) provided reasons for noncompletion of the treatment; this is in line with previous findings [39,44]. The most reported reasons were primarily associated with the participants' personal experiences and everyday challenges. These reasons might be expected from all participants. Other reasons such as reports of technical difficulties and the treatment not meeting personal needs and preferences were provided as rationales for nonadherence to treatment programs. This information could be of high value when developing and refining digital treatments. Dropout rates because of aspects of the treatment should be addressed, and the collection of data from participants who drop out is a necessary future step in this line of research.

In 47% (8/17) of these studies, treatment dropout as a consequence of recovery was reported [87,88,134-139]. It would

be highly interesting to assess whether dropout as a result of recovery was also reported in 100% (111/111) of the studies. This lack of reporting is a problem that is discussed in other reviews [44]. If a large number of participants drop out because of recovery early in treatment, it could indicate that some of the components were highly effective or that the participants were misdiagnosed. Furthermore, dropout because of recovery could also indicate that it would be advantageous to deliver the treatment program in a stepped care model where treatment and data collection are conducted with the expectation that participants will recover during the treatment and therefore, should be considered treatment completers. A stepped care model would also make it possible to reduce the resources spent on each patient, and guidance by a therapist could be delivered only to participants who do not recover when the treatment is delivered unguided.

### Limitations

The first author screened the results from the literature search and extracted and charted the data without reliability measures being conducted. The fifth author (ANH) was consulted when the eligibility of a study was unclear, but the studies discussed were selected by the first author. This is a limitation of this scoping review. It is possible that screening, extraction, and charting would have led to different results if conducted by several researchers.

In an effort to make the treatments included in the scoping review comparable, only guided treatments were included. However, it is important to acknowledge that there is variation in the guidance offered in the different studies. In addition to differences in who delivered the guidance, the frequency, modality, and content of the guidance also varied across the studies. In some studies, guidance was available exclusively upon request (eg, the study by Beiwinkel et al [140]) and, in other studies, guidance was initially delivered to all participants and thereafter available only upon request (eg, the studies by Kladnitski et al [75] and Smith et al [141]). Other studies included weekly feedback with brief emails (eg, the study by Ünlü Ince et al [124]), 5- to 10-minute therapist contact (eg, the study by Mullin et al [142]), or phone calls or instant messaging (eg, the study by Dear et al [143]). The large variation in guidance and the therapist's role in the treatment make the methods used in the different studies less comparable. It is possible that participants in studies with guidance solely upon request completed the entire treatment unguided.

The comprehensiveness of the study was also reduced owing to our restrictions on the year of publication. However, previous years have been thoroughly covered in other reviews. Despite this limitation, we attempted to provide an extensive and large sample of studies in our review. There are also a limited number of studies on internet-delivered treatments in the initial years of the internet, which could also be related to participants' limited availability and access to the internet in general.

Other limitations of our findings are the exclusion of studies published in languages other than English or one of the Scandinavian languages and the exclusion of gray literature or literature pieces that were not formally published. By excluding gray literature, there is a chance of publication bias in that studies considered to have novel or significant results will have a greater chance of being published [190].

### Future Review Studies

A scoping review where inclusion is not limited to controlled studies could potentially provide a comprehensive overview of the research area. Studies investigating how a treatment works could lead to a lot of additional and important information [47]. Therefore, inclusion of these types of studies in future reviews would be beneficial.

Given our restriction to only include stand-alone internet-delivered treatments in this scoping review, several studies were consequently excluded. Therapies in which internet-delivered treatment is provided in combination with other treatments could lead to efficient and effective outcomes for participants with reduced costs and use of resources. This cost-effectiveness of treatment and reduction in use of resources could allow for an increase in participants' access to needed services and treatment therapies. For example, patients with more severe symptoms of depression could have greater access to needed therapy in combination with the already existing treatment practices. In future reviews, the inclusion of studies in which the internet-delivered treatment is used as a supplement to other treatments would be beneficial to assess. Comparisons between stand-alone and supplemental treatments could also be an area of interest.

A potential interesting item to investigate could be how the treatments were made available to the participants. As we included all studies independent of how the treatment was accessed by the participants (as long as it was delivered over the internet), all formats were included in this review but not described in detail. We believe that treatment delivery via web-based programs, websites, or apps might not represent vastly different user experiences (eg, the difference between opening an app on a smartphone and visiting a website on the same device could be minimal). At the same time, usability, design, user interface, and functionality of the treatment program could be of great importance, and this could be an interesting topic to investigate for a future study.

Studies examining the preventive effect of internet-delivered treatment for depressive symptoms would also make a highly relevant and interesting area for a future review. If cases of depression could be prevented using low-cost and highly accessible methods of treatment delivered over the internet, this would be both ethically and economically beneficial, and research on this area should be prioritized.

## Conclusions

A total of 111 studies on guided internet-delivered treatment were suitable for inclusion in this scoping review. The RCT design was the most prevalent, and the use of other designs and active control conditions is recommended for future studies. Variations in the outcome measurement scales applied were identified, and more consistency could be beneficial. Lack of accessibility to treatment manuals and few replications where the same treatment program was tested were also discovered and discussed. In future research, underrepresented populations (men, teenagers or young adults, older adults, and non-Western

populations) should be included to a greater extent. Given the high prevalence of comorbidities in participants with depressive disorder, the reports of comorbidities in the included studies were somewhat deficient, and future research should investigate this further. Few studies provided definitions of when the treatments were considered completed (22/111, 19.8%) and reasons for treatment dropout (17/111, 15.3%). Most studies (89/111, 80.2%) provided information about the number of participants who completed all treatment modules or lessons or fulfilled a stated definition of treatment completion. There were more studies identified in which >51% of the participants completed the treatment compared with studies in which <50% of the participants completed the treatment. Finally, in only 4.5% (5/111) of the studies, >90% of the participants completed the treatment.

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## Data Availability

The original contributions presented in this study are included in the paper and appendixes. Further inquiries can be directed to the corresponding author.

## Authors' Contributions

LB, AD, ANH, TN, and SS collectively contributed to the conception and design of the study. LB reviewed the literature. AD designed the strategy and conducted the search. Screening and data extraction were conducted by LB in consultation with ANH. Analysis and manuscript drafting were carried out by LB with support from ANH, TN, AD, and SS. All authors participated in the interpretation of the results and reviewed, edited, and approved the final version of the manuscript.

## Conflicts of Interest

None declared.

Multimedia Appendix 1
Coding manual.
[DOCX File , 21 KB - mental_v9i10e37342_app1.docx ]

Multimedia Appendix 2
Search terms and Boolean operators.
[DOCX File , 20 KB - mental_v9i10e37342_app2.docx ]

Multimedia Appendix 3
Screened reviews.
[DOCX File , 25 KB - mental_v9i10e37342_app3.docx ]

Multimedia Appendix 4
Data items extracted and charted from the included studies.
[DOCX File , 25 KB - mental_v9i10e37342_app4.docx ]

Multimedia Appendix 5
All the included studies.
[XLSX File (Microsoft Excel File), 60 KB - mental_v9i10e37342_app5.xlsx ]

## References

1. Individuals using the internet (% of population). The World Bank. URL: https://data.worldbank.org/indicator/IT.NET.USER.ZS [accessed 2020-12-18]
2. Kazdin AE. Addressing the treatment gap: a key challenge for extending evidence-based psychosocial interventions. Behav Res Ther 2017 Jan;88:7-18. [doi: 10.1016/j.brat.2016.06.004] [Medline: 28110678]
3. Kazdin AE, Blase SL. Rebooting psychotherapy research and practice to reduce the burden of mental illness. Perspect Psychol Sci 2011 Jan 03;6(1):21-37 [FREE Full text] [doi: 10.1177/1745691610393527] [Medline: 26162113]
4. Nordgreen T, Repål A. Veiledet internettbehandling: digitale verktøy for psykisk helsehjelp. Oslo: Gyldendal; 2019.

5. Wind TR, Rijkeboer M, Andersson G, Riper H. The COVID-19 pandemic: the 'black swan' for mental health care and a turning point for e-health. Internet Interv 2020 Apr;20:100317 [FREE Full text] [doi: 10.1016/j.invent.2020.100317] [Medline: 32289019]
6. Kessler RC. The costs of depression. Psychiatr Clin North Am 2012 Mar;35(1):1-14 [FREE Full text] [doi: 10.1016/j.psc.2011.11.005] [Medline: 22370487]
7. Diagnostic and Statistical Manual of Mental Disorders, 5th edition. Washington, DC: American Psychiatric Publishing; 2013.
8. Carey TA, Tai SJ, Mansell W, Huddy V, Griffiths R, Marken RS. Improving professional psychological practice through an increased repertoire of research methodologies: illustrated by the development of MOL. Prof Psychol Res Practice 2017 Jun;48(3):175-182. [doi: 10.1037/pro0000132]
9. Cuijpers P, Riper H, Andersson G. Internet-based treatment of depression. Current Opinion Psychol 2015 Aug;4:131-135. [doi: 10.1016/j.copsyc.2014.12.026]
10. Etzelmueller A, Vis C, Karyotaki E, Baumeister H, Titov N, Berking M, et al. Effects of internet-based cognitive behavioral therapy in routine care for adults in treatment for depression and anxiety: systematic review and meta-analysis. J Med Internet Res 2020 Aug 31;22(8):e18100 [FREE Full text] [doi: 10.2196/18100] [Medline: 32865497]
11. Karyotaki E, Ebert DD, Donkin L, Riper H, Twisk J, Burger S, et al. Do guided internet-based interventions result in clinically relevant changes for patients with depression? An individual participant data meta-analysis. Clin Psychol Rev 2018 Jul;63:80-92. [doi: 10.1016/j.cpr.2018.06.007] [Medline: 29940401]
12. Chan M, Jiang Y, Lee CY, Ramachandran HJ, Teo JY, Seah CW, et al. Effectiveness of eHealth-based cognitive behavioural therapy on depression: a systematic review and meta-analysis. J Clin Nurs 2022 Jan 20 (forthcoming). [doi: 10.1111/jocn.16212] [Medline: 35060252]
13. Schröder J, Berger T, Westermann S, Klein JP, Moritz S. Internet interventions for depression: new developments. Dialogues Clin Neurosci 2016 Jun;18(2):203-212 [FREE Full text] [Medline: 27489460]
14. Garrido S, Millington C, Cheers D, Boydell K, Schubert E, Meade T, et al. What works and what doesn't work? A systematic review of digital mental health interventions for depression and anxiety in young people. Front Psychiatry 2019 Nov 13;10:759 [FREE Full text] [doi: 10.3389/fpsyt.2019.00759] [Medline: 31798468]
15. Loughnan SA, Joubert AE, Grierson A, Andrews G, Newby JM. Internet-delivered psychological interventions for clinical anxiety and depression in perinatal women: a systematic review and meta-analysis. Arch Womens Ment Health 2019 Dec 17;22(6):737-750. [doi: 10.1007/s00737-019-00961-9] [Medline: 31101993]
16. Tokgöz P, Hrynyschyn R, Hafner J, Schönfeld S, Dockweiler C. Digital health interventions in prevention, relapse, and therapy of mild and moderate depression: scoping review. JMIR Ment Health 2021 Apr 16;8(4):e26268 [FREE Full text] [doi: 10.2196/26268] [Medline: 33861201]
17. Berger T, Hämmerli K, Gubser N, Andersson G, Caspar F. Internet-based treatment of depression: a randomized controlled trial comparing guided with unguided self-help. Cogn Behav Ther 2011;40(4):251-266. [doi: 10.1080/16506073.2011.616531] [Medline: 22060248]
18. Krämer R, Köhne-Volland L, Schumacher A, Köhler S. Efficacy of a web-based intervention for depressive disorders: three-arm randomized controlled trial comparing guided and unguided self-help with waitlist control. JMIR Form Res 2022 Apr 04;6(4):e34330 [FREE Full text] [doi: 10.2196/34330] [Medline: 35105536]
19. Musiat P, Johnson C, Atkinson M, Wilksch S, Wade T. Impact of guidance on intervention adherence in computerised interventions for mental health problems: a meta-analysis. Psychol Med 2022 Jan;52(2):229-240. [doi: 10.1017/S0033291721004621] [Medline: 34802474]
20. Carlbring P, Andersson G, Cuijpers P, Riper H, Hedman-Lagerlöf E. Internet-based vs. face-to-face cognitive behavior therapy for psychiatric and somatic disorders: an updated systematic review and meta-analysis. Cogn Behav Ther 2018 Jan 07;47(1):1-18. [doi: 10.1080/16506073.2017.1401115] [Medline: 29215315]
21. Moher D, Liberati A, Tetzlaff J, Altman DG, PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. BMJ 2009 Jul 21;339(jul21 1):b2535 [FREE Full text] [doi: 10.1136/bmj.b2535] [Medline: 19622551]
22. Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA extension for scoping reviews (PRISMA-ScR): checklist and explanation. Ann Intern Med 2018 Oct 02;169(7):467-473 [FREE Full text] [doi: 10.7326/M18-0850] [Medline: 30178033]
23. Rodriguez-Pulido F, Castillo G, Hamrioui S, Martin LD, Vazquez-Beltrán P, de la Torre-Díez I, et al. Treatment of depression in primary care with computerized psychological therapies: systematic reviews. J Med Syst 2020 Feb 13;44(3):67. [doi: 10.1007/s10916-020-1543-7] [Medline: 32060635]
24. Peters MD, Marnie C, Tricco AC, Pollock D, Munn Z, Alexander L, et al. Updated methodological guidance for the conduct of scoping reviews. JBI Evid Synth 2020 Oct;18(10):2119-2126. [doi: 10.11124/JBIES-20-00167] [Medline: 33038124]
25. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. Int J Soc Res Methodol 2005 Feb;8(1):19-32. [doi: 10.1080/1364557032000119616]

26. Andersson G, Carlbring P, Rozental A. Response and remission rates in internet-based cognitive behavior therapy: an individual patient data meta-analysis. Front Psychiatry 2019 Oct 25;10:749 [FREE Full text] [doi: 10.3389/fpsyt.2019.00749] [Medline: 31708813]
27. Andersson G, Cuijpers P, Carlbring P, Riper H, Hedman E. Guided internet-based vs. face-to-face cognitive behavior therapy for psychiatric and somatic disorders: a systematic review and meta-analysis. World Psychiatry 2014 Oct 01;13(3):288-295 [FREE Full text] [doi: 10.1002/wps.20151] [Medline: 25273302]
28. Watts S, van Ommeren M, Cuijpers P. Open access of psychological intervention manuals. World Psychiatry 2020 Jun 11;19(2):251-252 [FREE Full text] [doi: 10.1002/wps.20756] [Medline: 32394577]
29. Xiang X, Wu S, Zuverink A, Tomasino KN, An R, Himle JA. Internet-delivered cognitive behavioral therapies for late-life depressive symptoms: a systematic review and meta-analysis. Aging Ment Health 2020 Aug 27;24(8):1196-1206 [FREE Full text] [doi: 10.1080/13607863.2019.1590309] [Medline: 30913898]
30. Martínez P, Rojas G, Martínez V, Lara MA, Pérez JC. Internet-based interventions for the prevention and treatment of depression in people living in developing countries: a systematic review. J Affect Disord 2018 Jul;234:193-200. [doi: 10.1016/j.jad.2018.02.079] [Medline: 29529553]
31. Steffen A, Nübel J, Jacobi F, Bätzing J, Holstiege J. Mental and somatic comorbidity of depression: a comprehensive cross-sectional analysis of 202 diagnosis groups using German nationwide ambulatory claims data. BMC Psychiatry 2020 Mar 30;20(1):142 [FREE Full text] [doi: 10.1186/s12888-020-02546-8] [Medline: 32228541]
32. Kaufman J, Charney D. Comorbidity of mood and anxiety disorders. Depression and Anxiety 2020;12(S1):69-76 [FREE Full text] [doi: 10.1002/1520-6394(2000)12:1+<69::AID-DA9>3.0.CO;2-K]
33. Kalin NH. The critical relationship between anxiety and depression. Am J Psychiatry 2020 May 01;177(5):365-367. [doi: 10.1176/appi.ajp.2020.20030305] [Medline: 32354270]
34. Rogers A, Wieman S, Baker A. Anxiety comorbidities: mood disorders, substance use disorders, and chronic medical illness. In: Clinical Handbook of Anxiety Disorders. Cham: Humana; 2020.
35. Schmidt ID, Forand NR, Strunk DR. Predictors of dropout in internet-based cognitive behavioral therapy for depression. Cognit Ther Res 2019 Jun 16;43(3):620-630 [FREE Full text] [doi: 10.1007/s10608-018-9979-5] [Medline: 32879540]
36. Christensen H, Griffiths KM, Farrer L. Adherence in internet interventions for anxiety and depression. J Med Internet Res 2009 Apr 24;11(2):e13 [FREE Full text] [doi: 10.2196/jmir.1194] [Medline: 19403466]
37. Johansson O, Michel T, Andersson G, Paxling B. Experiences of non-adherence to Internet-delivered cognitive behavior therapy: a qualitative study. Internet Interv 2015 May;2(2):137-142 [FREE Full text] [doi: 10.1016/j.invent.2015.02.006]
38. Kaltenthaler E, Parry G, Beverley C, Ferriter M. Computerised cognitive-behavioural therapy for depression: systematic review. Br J Psychiatry 2008 Sep;193(3):181-184. [doi: 10.1192/bjp.bp.106.025981] [Medline: 18757972]
39. van Ballegooijen W, Cuijpers P, van Straten A, Karyotaki E, Andersson G, Smit JH, et al. Adherence to Internet-based and face-to-face cognitive behavioural therapy for depression: a meta-analysis. PLoS One 2014;9(7):e100674 [FREE Full text] [doi: 10.1371/journal.pone.0100674] [Medline: 25029507]
40. Barrett MS, Chua W, Crits-Christoph P, Gibbons MB, Casiano D, Thompson D. Early withdrawal from mental health treatment: implications for psychotherapy practice. Psychotherapy (Chic) 2008 Jun 01;45(2):247-267 [FREE Full text] [doi: 10.1037/0033-3204.45.2.247] [Medline: 19838318]
41. Swift JK, Greenberg RP. Premature discontinuation in adult psychotherapy: a meta-analysis. J Consult Clin Psychol 2012 Aug;80(4):547-559. [doi: 10.1037/a0028226] [Medline: 22506792]
42. Beintner I, Vollert B, Zarski A, Bolinski F, Musiat P, Görlich D, et al. Adherence reporting in randomized controlled trials examining manualized multisession online interventions: systematic review of practices and proposal for reporting standards. J Med Internet Res 2019 Aug 15;21(8):e14181 [FREE Full text] [doi: 10.2196/14181] [Medline: 31414664]
43. Donkin L, Christensen H, Naismith SL, Neal B, Hickie IB, Glozier N. A systematic review of the impact of adherence on the effectiveness of e-therapies. J Med Internet Res 2011 Aug 05;13(3):e52 [FREE Full text] [doi: 10.2196/jmir.1772] [Medline: 21821503]
44. Treanor C, Kouvonen A, Lallukka T, Donnelly M. Acceptability of computerized cognitive behavioral therapy for adults: umbrella review. JMIR Ment Health 2021 Jul 06;8(7):e23091 [FREE Full text] [doi: 10.2196/23091] [Medline: 34255714]
45. Sieverink F, Kelders SM, van Gemert-Pijnen JE. Clarifying the concept of adherence to eHealth technology: systematic review on when usage becomes adherence. J Med Internet Res 2017 Dec 06;19(12):e402 [FREE Full text] [doi: 10.2196/jmir.8578] [Medline: 29212630]
46. Kelders SM, van Zyl LE, Ludden GD. The concept and components of engagement in different domains applied to ehealth: a systematic scoping review. Front Psychol 2020;11:926 [FREE Full text] [doi: 10.3389/fpsyg.2020.00926] [Medline: 32536888]
47. Anjum RL, Copeland S, Rocca E. Medical scientists and philosophers worldwide appeal to to expand the notion of 'evidence'. BMJ Evid Based Med 2020 Feb 14;25(1):6-8. [doi: 10.1136/bmjebm-2018-111092] [Medline: 30429163]
48. Radloff LS. The CES-D Scale: a self-report depression scale for research in the general population. Applied Psychol Measure 2016 Jul 26;1(3):385-401. [doi: 10.1177/014662167700100306]

49. Spitzer R, Kroenke K, Williams JB. Validation and utility of a self-report version of PRIME-MD: the PHQ primary care study. Primary Care Evaluation of Mental Disorders. Patient Health Questionnaire. JAMA 1999 Nov 10;282(18):1737-1744. [doi: 10.1001/jama.282.18.1737] [Medline: 10568646]
50. Montgomery SA, Asberg M. A new depression scale designed to be sensitive to change. Br J Psychiatry 1979 Apr;134:382-389. [doi: 10.1192/bjp.134.4.382] [Medline: 444788]
51. Sztein DM, Koransky CE, Fegan L, Himelhoch S. Efficacy of cognitive behavioural therapy delivered over the Internet for depressive symptoms: a systematic review and meta-analysis. J Telemed Telecare 2017 Jul 11;24(8):527-539. [doi: 10.1177/1357633x17717402]
52. Huguet A, Rao S, McGrath PJ, Wozney L, Wheaton M, Conrod J, et al. A systematic review of cognitive behavioral therapy and behavioral activation apps for depression. PLoS One 2016;11(5):e0154248 [FREE Full text] [doi: 10.1371/journal.pone.0154248] [Medline: 27135410]
53. Arnberg F, Linton SJ, Hultcrantz M, Heintz E, Jonsson U. Internet-delivered psychological treatments for mood and anxiety disorders: a systematic review of their efficacy, safety, and cost-effectiveness. PLoS One 2014;9(5):e98118 [FREE Full text] [doi: 10.1371/journal.pone.0098118] [Medline: 24844847]
54. Baumeister H, Reichler L, Munzinger M, Lin J. The impact of guidance on internet-based mental health interventions — a systematic review. Internet Interv 2014 Oct;1(4):205-215 [FREE Full text] [doi: 10.1016/j.invent.2014.08.003]
55. Davies E, Morriss R, Glazebrook C. Computer-delivered and web-based interventions to improve depression, anxiety, and psychological well-being of university students: a systematic review and meta-analysis. J Med Internet Res 2014 May 16;16(5):e130 [FREE Full text] [doi: 10.2196/jmir.3142] [Medline: 24836465]
56. Dowling M, Rickwood D. Online counseling and therapy for mental health problems: a systematic review of individual synchronous interventions using chat. J Technol Hum Serv 2013 Jan;31(1):1-21 [FREE Full text] [doi: 10.1080/15228835.2012.728508]
57. Fleming T, Cheek C, Merry SN, Thabrew H, Bridgman H, Stasiak K, et al. Juegos serios para el tratamiento o la prevención de la depresión: una revisión sistemática. Revista de Psicopatología y Psicología Clínica 2015 Jan 15;19(3):227 [FREE Full text] [doi: 10.5944/rppc.vol.19.num.3.2014.13904]
58. Hedman E, Ljótsson B, Lindefors N. Cognitive behavior therapy via the Internet: a systematic review of applications, clinical efficacy and cost-effectiveness. Expert Rev Pharmacoecon Outcomes Res 2012 Dec;12(6):745-764 [FREE Full text] [doi: 10.1586/erp.12.67] [Medline: 23252357]
59. Königbauer J, Letsch J, Doebler P, Ebert D, Baumeister H. Internet- and mobile-based depression interventions for people with diagnosed depression: a systematic review and meta-analysis. J Affect Disord 2017 Dec 01;223:28-40 [FREE Full text] [doi: 10.1016/j.jad.2017.07.021] [Medline: 28715726]
60. Lee E, Denison FC, Hor K, Reynolds RM. Web-based interventions for prevention and treatment of perinatal mood disorders: a systematic review. BMC Pregnancy Childbirth 2016 Feb 29;16:38 [FREE Full text] [doi: 10.1186/s12884-016-0831-1] [Medline: 26928898]
61. Li J, Theng YL, Foo S. Game-based digital interventions for depression therapy: a systematic review and meta-analysis. Cyberpsychol Behav Soc Netw 2014 Aug;17(8):519-527 [FREE Full text] [doi: 10.1089/cyber.2013.0481] [Medline: 24810933]
62. Paganini S, Teigelkötter W, Buntrock C, Baumeister H. Economic evaluations of internet- and mobile-based interventions for the treatment and prevention of depression: a systematic review. J Affect Disord 2018 Jan 01;225:733-755 [FREE Full text] [doi: 10.1016/j.jad.2017.07.018] [Medline: 28922737]
63. Păsărelu CR, Andersson G, Bergman Nordgren L, Dobrean A. Internet-delivered transdiagnostic and tailored cognitive behavioral therapy for anxiety and depression: a systematic review and meta-analysis of randomized controlled trials. Cogn Behav Ther 2017 Jan;46(1):1-28 [FREE Full text] [doi: 10.1080/16506073.2016.1231219] [Medline: 27712544]
64. Pennant M, Loucas CE, Whittington C, Creswell C, Fonagy P, Fuggle P, Expert Advisory Group. Computerised therapies for anxiety and depression in children and young people: a systematic review and meta-analysis. Behav Res Ther 2015 Apr;67:1-18 [FREE Full text] [doi: 10.1016/j.brat.2015.01.009] [Medline: 25727678]
65. Rice S, Goodall J, Hetrick SE, Parker AG, Gilbertson T, Amminger GP, et al. Online and social networking interventions for the treatment of depression in young people: a systematic review. J Med Internet Res 2014 Sep 16;16(9):e206 [FREE Full text] [doi: 10.2196/jmir.3304] [Medline: 25226790]
66. Richards D, Richardson T. Computer-based psychological treatments for depression: a systematic review and meta-analysis. Clin Psychol Rev 2012 Jun;32(4):329-342 [FREE Full text] [doi: 10.1016/j.cpr.2012.02.004] [Medline: 22466510]
67. Rosenbaum S, Newby JM, Steel Z, Andrews G, Ward PB. Online physical activity interventions for mental disorders: a systematic review. Internet Interv 2015 May;2(2):214-220 [FREE Full text] [doi: 10.1016/j.invent.2015.04.001]
68. Saddichha S, Al-Desouki M, Lamia A, Linden IA, Krausz M. Online interventions for depression and anxiety - a systematic review. Health Psychol Behav Med 2014 Jan 01;2(1):841-881 [FREE Full text] [doi: 10.1080/21642850.2014.945934] [Medline: 25750823]
69. Ye X, Bapuji SB, Winters SE, Struthers A, Raynard M, Metge C, et al. Effectiveness of internet-based interventions for children, youth, and young adults with anxiety and/or depression: a systematic review and meta-analysis. BMC Health Serv Res 2014 Jul 18;14:313-319 [FREE Full text] [doi: 10.1186/1472-6963-14-313] [Medline: 25037951]

70. Ouzzani M, Hammady H, Fedorowicz Z, Elmagarmid A. Rayyan-a web and mobile app for systematic reviews. Syst Rev 2016 Dec 05;5(1):210 [FREE Full text] [doi: 10.1186/s13643-016-0384-4] [Medline: 27919275]
71. Cochrane Handbook for Systematic Reviews of Interventions. Hoboken, New Jersey, United States: John Wiley & Sons; 2019.
72. Lindquist R, Wyman J, Talley K, Findorff M, Gross C. Design of control-group conditions in clinical trials of behavioral interventions. J Nurs Scholarsh 2007;39(3):214-221 [FREE Full text] [doi: 10.1111/j.1547-5069.2007.00171.x] [Medline: 17760793]
73. Lambert JD, Greaves CJ, Farrand P, Price L, Haase AM, Taylor AH. Web-based intervention using behavioral activation and physical activity for adults with depression (the eMotion study): pilot randomized controlled trial. J Med Internet Res 2018 Jul 16;20(7):e10112 [FREE Full text] [doi: 10.2196/10112] [Medline: 30012547]
74. Geraedts AS, Kleiboer AM, Twisk J, Wiezer NM, van Mechelen W, Cuijpers P. Long-term results of a web-based guided self-help intervention for employees with depressive symptoms: randomized controlled trial. J Med Internet Res 2014 Jul 09;16(7):e168 [FREE Full text] [doi: 10.2196/jmir.3539] [Medline: 25008127]
75. Kladnitski N, Smith J, Uppal S, James MA, Allen AR, Andrews G, et al. Transdiagnostic internet-delivered CBT and mindfulness-based treatment for depression and anxiety: a randomised controlled trial. Internet Interv 2020 Apr;20:100310 [FREE Full text] [doi: 10.1016/j.invent.2020.100310] [Medline: 32140427]
76. Stiles-Shields C, Montague E, Kwasny MJ, Mohr DC. Behavioral and cognitive intervention strategies delivered via coached apps for depression: pilot trial. Psychol Serv 2019 May;16(2):233-238 [FREE Full text] [doi: 10.1037/ser0000261] [Medline: 30407055]
77. Hoek W, Schuurmans J, Koot HM, Cuijpers P. Effects of internet-based guided self-help problem-solving therapy for adolescents with depression and anxiety: a randomized controlled trial. PLoS One 2012 Aug 31;7(8):e43485 [FREE Full text] [doi: 10.1371/journal.pone.0043485] [Medline: 22952691]
78. Hunkeler EM, Hargreaves WA, Fireman B, Terdiman J, Meresman JF, Porterfield Y, et al. A web-delivered care management and patient self-management program for recurrent depression: a randomized trial. Psychiatr Serv 2012 Nov;63(11):1063-1071. [doi: 10.1176/appi.ps.005332011] [Medline: 22983558]
79. Westerhof G, Lamers S, Postel M, Bohlmeijer E. Online therapy for depressive symptoms: an evaluation of counselor-led and peer-supported life review therapy. Gerontologist 2019 Jan 09;59(1):135-146. [doi: 10.1093/geront/gnx140] [Medline: 28961958]
80. Titov N, Dear BF, Schwencke G, Andrews G, Johnston L, Craske MG, et al. Transdiagnostic internet treatment for anxiety and depression: a randomised controlled trial. Behav Res Ther 2011 Aug;49(8):441-452. [doi: 10.1016/j.brat.2011.03.007] [Medline: 21679925]
81. Ström M, Uckelstam C, Andersson G, Hassmén P, Umefjord G, Carlbring P. Internet-delivered therapist-guided physical activity for mild to moderate depression: a randomized controlled trial. Peer J 2013;1:e178 [FREE Full text] [doi: 10.7717/peerj.178] [Medline: 24109561]
82. Arjadi R, Nauta MH, Scholte WF, Hollon SD, Chowdhary N, Suryani AO, et al. Internet-based behavioural activation with lay counsellor support versus online minimal psychoeducation without support for treatment of depression: a randomised controlled trial in Indonesia. Lancet Psychiatry 2018 Sep;5(9):707-716. [doi: 10.1016/s2215-0366(18)30223-2]
83. Farrer L, Christensen H, Griffiths KM, Mackinnon A. Internet-based CBT for depression with and without telephone tracking in a national helpline: randomised controlled trial. PLoS One 2011 Nov 30;6(11):e28099 [FREE Full text] [doi: 10.1371/journal.pone.0028099] [Medline: 22140514]
84. Sheeber LB, Seeley JR, Feil EG, Davis B, Sorensen E, Kosty DB, et al. Development and pilot evaluation of an internet-facilitated cognitive-behavioral intervention for maternal depression. J Consult Clin Psychol 2012 Oct;80(5):739-749 [FREE Full text] [doi: 10.1037/a0028820] [Medline: 22663903]
85. Wade S, Cassedy A, McNally K, Kurowski B, Kirkwood M, Stancin T, et al. A randomized comparative effectiveness trial of family-problem-solving treatment for adolescent brain injury: parent outcomes from the coping with head injury through problem solving (CHIPS) study. J Head Trauma Rehabil 2019;34(6):E1-E9. [doi: 10.1097/HTR.0000000000000487] [Medline: 31033747]
86. van der Zanden R, Kramer J, Gerrits R, Cuijpers P. Effectiveness of an online group course for depression in adolescents and young adults: a randomized trial. J Med Internet Res 2012 Jun 07;14(3):e86 [FREE Full text] [doi: 10.2196/jmir.2033] [Medline: 22677437]
87. Heller HM, Hoogendoorn AW, Honig A, Broekman BF, van Straten A. The effectiveness of a guided internet-based tool for the treatment of depression and anxiety in pregnancy (MamaKits online): randomized controlled trial. J Med Internet Res 2020 Mar 23;22(3):e15172 [FREE Full text] [doi: 10.2196/15172] [Medline: 32202505]
88. O'Mahen HA, Richards DA, Woodford J, Wilkinson E, McGinley J, Taylor RS, et al. Netmums: a phase II randomized controlled trial of a guided Internet behavioural activation treatment for postpartum depression. Psychol Med 2014 Jun;44(8):1675-1689 [FREE Full text] [doi: 10.1017/S0033291713002092] [Medline: 24148703]
89. Ebert D, Nobis S, Lehr D, Baumeister H, Riper H, Auerbach R, et al. The 6-month effectiveness of Internet-based guided self-help for depression in adults with Type 1 and 2 diabetes mellitus. Diabet Med 2017 Jan;34(1):99-107 [FREE Full text] [doi: 10.1111/dme.13173] [Medline: 27334444]

90. Fletcher S, Chondros P, Densley K, Murray E, Dowrick C, Coe A, et al. Matching depression management to severity prognosis in primary care: results of the Target-D randomised controlled trial. Br J Gen Pract 2021;71(703):e85-e94 [FREE Full text] [doi: 10.3399/BJGP.2020.0783] [Medline: 33431380]
91. Montero-Marín J, Araya R, Pérez-Yus MC, Mayoral F, Gili M, Botella C, et al. An internet-based intervention for depression in primary care in Spain: a randomized controlled trial. J Med Internet Res 2016 Aug 26;18(8):e231 [FREE Full text] [doi: 10.2196/jmir.5695] [Medline: 27565118]
92. Tulbure BT, Andersson G, Sălăgean N, Pearce M, Koenig HG. Religious versus conventional internet-based cognitive behavioral therapy for depression. J Relig Health 2018 Oct 24;57(5):1634-1648. [doi: 10.1007/s10943-017-0503-0] [Medline: 29067598]
93. Wilson M, Hewes C, Barbosa-Leiker C, Mason A, Wuestney KA, Shuen JA, et al. Engaging adults with chronic disease in online depressive symptom self-management. West J Nurs Res 2018 Jun 30;40(6):834-853. [doi: 10.1177/0193945916689068] [Medline: 28322662]
94. Sethi S, Campbell AJ, Ellis LA. The use of computerized self-help packages to treat adolescent depression and anxiety. J Technol Hum Serv 2010 Aug 31;28(3):144-160. [doi: 10.1080/15228835.2010.508317]
95. Hauffman A, Alfonsson S, Bill-Axelson A, Bergkvist L, Forslund M, Mattsson S, et al. Cocreated internet-based stepped care for individuals with cancer and concurrent symptoms of anxiety and depression: results from the U-CARE AdultCan randomized controlled trial. Psychooncology 2020 Dec 22;29(12):2012-2018 [FREE Full text] [doi: 10.1002/pon.5489] [Medline: 32691455]
96. Kivi M, Eriksson MC, Hange D, Petersson E, Vernmark K, Johansson B, et al. Internet-based therapy for mild to moderate depression in Swedish primary care: short term results from the PRIM-NET randomized controlled trial. Cogn Behav Ther 2014;43(4):289-298 [FREE Full text] [doi: 10.1080/16506073.2014.921834] [Medline: 24911260]
97. Hallgren M, Kraepelien M, Öjehagen A, Lindefors N, Zeebari Z, Kaldo V, et al. Physical exercise and internet-based cognitive-behavioural therapy in the treatment of depression: randomised controlled trial. Br J Psychiatry 2015 Sep 02;207(3):227-234. [doi: 10.1192/bjp.bp.114.160101] [Medline: 26089305]
98. van der Zweerde T, van Straten A, Effting M, Kyle SD, Lancee J. Does online insomnia treatment reduce depressive symptoms? A randomized controlled trial in individuals with both insomnia and depressive symptoms. Psychol Med 2018 May 11;49(3):501-509. [doi: 10.1017/s0033291718001149]
99. Thompson NJ, Walker ER, Obolensky N, Winning A, Barmon C, Diiorio C, et al. Distance delivery of mindfulness-based cognitive therapy for depression: project UPLIFT. Epilepsy Behav 2010 Nov;19(3):247-254. [doi: 10.1016/j.yebeh.2010.07.031] [Medline: 20851055]
100. Gilbody S, Brabyn S, Lovell K, Kessler D, Devlin T, Smith L, REEACT collaborative. Telephone-supported computerised cognitive-behavioural therapy: REEACT-2 large-scale pragmatic randomised controlled trial. Br J Psychiatry 2017 May;210(5):362-367. [doi: 10.1192/bjp.bp.116.192435] [Medline: 28254959]
101. Do R, Lee S, Kim J, Cho M, Shin H, Jang M, et al. Effectiveness and dissemination of computer-based cognitive behavioral therapy for depressed adolescents: effective and accessible to whom? J Affect Disord 2021 Mar 01;282:885-893 [FREE Full text] [doi: 10.1016/j.jad.2020.12.177] [Medline: 33601732]
102. Milgrom J, Danaher BG, Gemmill AW, Holt C, Holt CJ, Seeley JR, et al. Internet cognitive behavioral therapy for women with postnatal depression: a randomized controlled trial of MumMoodBooster. J Med Internet Res 2016 Mar 07;18(3):e54 [FREE Full text] [doi: 10.2196/jmir.4993] [Medline: 26952645]
103. Yang M, Jia G, Sun S, Ye C, Zhang R, Yu X. Effects of an online mindfulness intervention focusing on attention monitoring and acceptance in pregnant women: a randomized controlled trial. J Midwifery Womens Health 2019 Jan 29;64(1):68-77. [doi: 10.1111/jmwh.12944] [Medline: 30695166]
104. Pugh NE, Hadjistavropoulos HD, Dirkse D. A randomised controlled trial of therapist-assisted, internet-delivered cognitive behavior therapy for women with maternal depression. PLoS One 2016;11(3):e0149186 [FREE Full text] [doi: 10.1371/journal.pone.0149186] [Medline: 26930488]
105. Milgrom J, Danaher BG, Seeley JR, Holt CJ, Holt C, Ericksen J, et al. Internet and face-to-face cognitive behavioral therapy for postnatal depression compared with treatment as usual: randomized controlled trial of MumMoodBooster. J Med Internet Res 2021 Dec 08;23(12):e17185 [FREE Full text] [doi: 10.2196/17185] [Medline: 34889742]
106. Kim SC, Shaw BR, Shah DV, Hawkins RP, Pingree S, McTavish FM, et al. Interactivity, presence, and targeted patient care: mapping e-health intervention effects over time for cancer patients with depression. Health Commun 2019 Feb 14;34(2):162-171 [FREE Full text] [doi: 10.1080/10410236.2017.1399504] [Medline: 29135321]
107. Moeini B, Bashirian S, Soltanian A, Ghaleiha A, Taheri M. Examining the effectiveness of a web-based intervention for depressive symptoms in female adolescents: applying social cognitive theory. J Res Health Sci 2019 Aug 19;19(3):e00454 [FREE Full text] [Medline: 31586376]
108. Hudson JL, Moss-Morris R, Norton S, Picariello F, Game D, Carroll A, et al. Tailored online cognitive behavioural therapy with or without therapist support calls to target psychological distress in adults receiving haemodialysis: a feasibility randomised controlled trial. J Psychosom Res 2017 Nov;102:61-70. [doi: 10.1016/j.jpsychores.2017.09.009] [Medline: 28992899]

109. Norlund F, Wallin E, Olsson EM, Wallert J, Burell G, von Essen L, et al. Internet-based cognitive behavioral therapy for symptoms of depression and anxiety among patients with a recent myocardial infarction: the U-CARE heart randomized controlled trial. J Med Internet Res 2018 Mar 08;20(3):e88 [FREE Full text] [doi: 10.2196/jmir.9710] [Medline: 29519777]
110. Lundgren JG, Dahlström Ö, Andersson G, Jaarsma T, Kärner Köhler A, Johansson P. The effect of guided web-based cognitive behavioral therapy on patients with depressive symptoms and heart failure: a pilot randomized controlled trial. J Med Internet Res 2016 Aug 03;18(8):e194 [FREE Full text] [doi: 10.2196/jmir.5556] [Medline: 27489077]
111. Johansson P, Westas M, Andersson G, Alehagen U, Broström A, Jaarsma T, et al. An internet-based cognitive behavioral therapy program adapted to patients with cardiovascular disease and depression: randomized controlled trial. JMIR Ment Health 2019 Oct 03;6(10):e14648 [FREE Full text] [doi: 10.2196/14648] [Medline: 31584000]
112. van Luenen S, Garnefski N, Spinhoven P, Kraaij V. Guided internet-based intervention for people with HIV and depressive symptoms: a randomised controlled trial in the Netherlands. Lancet HIV 2018 Sep;5(9):e488-e497. [doi: 10.1016/s2352-3018(18)30133-4]
113. Nadort E, Schouten R, Boeschoten R, Smets Y, Chandie Shaw P, Vleming L, et al. Internet-based treatment for depressive symptoms in hemodialysis patients: a cluster randomized controlled trial. Gen Hosp Psychiatry 2022;75:46-53 [FREE Full text] [doi: 10.1016/j.genhosppsych.2022.01.008] [Medline: 35134703]
114. Nygren T, Brohede D, Koshnaw K, Osman SS, Johansson R, Andersson G. Internet-based treatment of depressive symptoms in a Kurdish population: a randomized controlled trial. J Clin Psychol 2019 Jun 31;75(6):985-998. [doi: 10.1002/jclp.22753] [Medline: 30702758]
115. Hobfoll SE, Blais RK, Stevens NR, Walt L, Gengler R. Vets prevail online intervention reduces PTSD and depression in veterans with mild-to-moderate symptoms. J Consult Clin Psychol 2016 Jan;84(1):31-42. [doi: 10.1037/ccp0000041] [Medline: 26322788]
116. Palacios JE, Richards D, Palmer R, Coudray C, Hofmann SG, Palmieri PA, et al. Supported internet-delivered cognitive behavioral therapy programs for depression, anxiety, and stress in university students: open, non-randomised trial of acceptability, effectiveness, and satisfaction. JMIR Ment Health 2018 Dec 14;5(4):e11467 [FREE Full text] [doi: 10.2196/11467] [Medline: 30552076]
117. Staples LG, Fogliati VJ, Dear BF, Nielssen O, Titov N. Internet-delivered treatment for older adults with anxiety and depression: implementation of the Wellbeing Plus Course in routine clinical care and comparison with research trial outcomes. BJPsych Open 2016 Sep;2(5):307-313 [FREE Full text] [doi: 10.1192/bjpo.bp.116.003400] [Medline: 27703794]
118. Titov N, Fogliati VJ, Staples LG, Gandy M, Johnston L, Wootton B, et al. Treating anxiety and depression in older adults: randomised controlled trial comparing guided v. self-guided internet-delivered cognitive-behavioural therapy. BJPsych Open 2016 Jan;2(1):50-58 [FREE Full text] [doi: 10.1192/bjpo.bp.115.002139] [Medline: 27703754]
119. Titov N, Dear B, Ali S, Zou J, Lorian C, Johnston L, et al. Clinical and cost-effectiveness of therapist-guided internet-delivered cognitive behavior therapy for older adults with symptoms of depression: a randomized controlled trial. Behav Ther 2015 Mar;46(2):193-205 [FREE Full text] [doi: 10.1016/j.beth.2014.09.008] [Medline: 25645168]
120. Tomasino K, Lattie E, Ho J, Palac H, Kaiser S, Mohr D. Harnessing peer support in an online intervention for older adults with depression. Am J Geriatr Psychiatry 2017 Oct;25(10):1109-1119 [FREE Full text] [doi: 10.1016/j.jagp.2017.04.015] [Medline: 28571785]
121. Boeschoten RE, Dekker J, Uitdehaag BM, Beekman AT, Hoogendoorn AW, Collette EH, et al. Internet-based treatment for depression in multiple sclerosis: a randomized controlled trial. Mult Scler 2017 Jul;23(8):1112-1122. [doi: 10.1177/1352458516671820] [Medline: 27682229]
122. Murphy M, Newby J, Butow P, Loughnan S, Joubert A, Kirsten L, et al. Randomised controlled trial of internet-delivered cognitive behaviour therapy for clinical depression and/or anxiety in cancer survivors (iCanADAPT Early). Psychooncology 2020 Jan;29(1):76-85 [FREE Full text] [doi: 10.1002/pon.5267] [Medline: 31659822]
123. Braun L, Titzler I, Terhorst Y, Freund J, Thielecke J, Ebert D, et al. Effectiveness of guided internet-based interventions in the indicated prevention of depression in green professions (PROD-A): results of a pragmatic randomized controlled trial. J Affect Disord 2021 Jan 01;278:658-671 [FREE Full text] [doi: 10.1016/j.jad.2020.09.066] [Medline: 33096333]
124. Ünlü Ince B, Cuijpers P, van 't Hof E, van Ballegooijen W, Christensen H, Riper H. Internet-based, culturally sensitive, problem-solving therapy for Turkish migrants with depression: randomized controlled trial. J Med Internet Res 2013 Oct 11;15(10):e227 [FREE Full text] [doi: 10.2196/jmir.2853] [Medline: 24121307]
125. Buhrman M, Syk M, Burvall O, Hartig T, Gordh T, Andersson G. Individualized guided internet-delivered cognitive-behavior therapy for chronic pain patients with comorbid depression and anxiety: a randomized controlled trial. Clin J Pain 2015 Jun;31(6):504-516. [doi: 10.1097/AJP.0000000000000176] [Medline: 25380222]
126. Salamanca-Sanabria A, Richards D, Timulak L, Connell S, Mojica Perilla M, Parra-Villa Y, et al. A culturally adapted cognitive behavioral internet-delivered intervention for depressive symptoms: randomized controlled trial. JMIR Ment Health 2020 Jan 31;7(1):e13392 [FREE Full text] [doi: 10.2196/13392] [Medline: 32003749]
127. Choi I, Zou J, Titov N, Dear B, Li S, Johnston L, et al. Culturally attuned Internet treatment for depression amongst Chinese Australians: a randomised controlled trial. J Affect Disord 2012 Feb;136(3):459-468 [FREE Full text] [doi: 10.1016/j.jad.2011.11.003] [Medline: 22177742]

128. Newby J, Robins L, Wilhelm K, Smith J, Fletcher T, Gillis I, et al. Web-based cognitive behavior therapy for depression in people with diabetes mellitus: a randomized controlled trial. J Med Internet Res 2017 May 15;19(5):e157 [FREE Full text] [doi: 10.2196/jmir.7274] [Medline: 28506956]
129. Zagorscak P, Heinrich M, Sommer D, Wagner B, Knaevelsrud C. Benefits of individualized feedback in internet-based interventions for depression: a randomized controlled trial. Psychother Psychosom 2018 Jan 6;87(1):32-45. [doi: 10.1159/000481515] [Medline: 29306945]
130. Andersson G, Hesser H, Veilord A, Svedling L, Andersson F, Sleman O, et al. Randomised controlled non-inferiority trial with 3-year follow-up of internet-delivered versus face-to-face group cognitive behavioural therapy for depression. J Affect Disord 2013 Dec;151(3):986-994 [FREE Full text] [doi: 10.1016/j.jad.2013.08.022] [Medline: 24035673]
131. Rosso I, Killgore W, Olson E, Webb C, Fukunaga R, Auerbach R, et al. Internet-based cognitive behavior therapy for major depressive disorder: a randomized controlled trial. Depress Anxiety 2017 Mar;34(3):236-245 [FREE Full text] [doi: 10.1002/da.22590] [Medline: 28009467]
132. Lappalainen P, Langrial S, Oinas-Kukkonen H, Tolvanen A, Lappalainen R. Web-based acceptance and commitment therapy for depressive symptoms with minimal support: a randomized controlled trial. Behav Modif 2015 Nov;39(6):805-834. [doi: 10.1177/0145445515598142] [Medline: 26253644]
133. Blom K, Jernelöv S, Kraepelien M, Bergdahl M, Jungmarker K, Ankartjärn L, et al. Internet treatment addressing either insomnia or depression, for patients with both diagnoses: a randomized trial. Sleep 2015 Feb 01;38(2):267-277 [FREE Full text] [doi: 10.5665/sleep.4412] [Medline: 25337948]
134. Preschl B, Maercker A, Wagner B. The working alliance in a randomized controlled trial comparing online with face-to-face cognitive-behavioral therapy for depression. BMC Psychiatry 2011 Dec 06;11(1):189. [doi: 10.1186/1471-244x-11-189]
135. Wagner B, Horn A, Maercker A. Internet-based versus face-to-face cognitive-behavioral intervention for depression: a randomized controlled non-inferiority trial. J Affect Disord 2014 Jan;152-154:113-121 [FREE Full text] [doi: 10.1016/j.jad.2013.06.032] [Medline: 23886401]
136. Kleiboer A, Donker T, Seekles W, van Straten A, Riper H, Cuijpers P. A randomized controlled trial on the role of support in Internet-based problem solving therapy for depression and anxiety. Behav Res Ther 2015 Sep;72:63-71 [FREE Full text] [doi: 10.1016/j.brat.2015.06.013] [Medline: 26188373]
137. Kenter RM, Cuijpers P, Beekman A, van Straten A. Effectiveness of a web-based guided self-help intervention for outpatients with a depressive disorder: short-term results from a randomized controlled trial. J Med Internet Res 2016 Mar 31;18(3):e80 [FREE Full text] [doi: 10.2196/jmir.4861] [Medline: 27032449]
138. Høifødt RS, Lillevoll KR, Griffiths KM, Wilsgaard T, Eisemann M, Waterloo K, et al. The clinical effectiveness of web-based cognitive behavioral therapy with face-to-face therapist support for depressed primary care patients: randomized controlled trial. J Med Internet Res 2013 Aug 05;15(8):e153 [FREE Full text] [doi: 10.2196/jmir.2714] [Medline: 23916965]
139. Boele FW, Klein M, Verdonck-de Leeuw IM, Cuijpers P, Heimans JJ, Snijders TJ, Dutch Society for Neuro-Oncology (LWNO). Internet-based guided self-help for glioma patients with depressive symptoms: a randomized controlled trial. J Neurooncol 2018 Mar 13;137(1):191-203 [FREE Full text] [doi: 10.1007/s11060-017-2712-5] [Medline: 29236238]
140. Beiwinkel T, Eißing T, Telle N, Siegmund-Schultze E, Rössler W. Effectiveness of a web-based intervention in reducing depression and sickness absence: randomized controlled trial. J Med Internet Res 2017 Jun 15;19(6):e213 [FREE Full text] [doi: 10.2196/jmir.6546] [Medline: 28619701]
141. Smith J, Newby J, Burston N, Murphy M, Michael S, Mackenzie A, et al. Help from home for depression: a randomised controlled trial comparing internet-delivered cognitive behaviour therapy with bibliotherapy for depression. Internet Interv 2017 Sep;9:25-37 [FREE Full text] [doi: 10.1016/j.invent.2017.05.001] [Medline: 30135834]
142. Mullin A, Dear B, Karin E, Wootton B, Staples L, Johnston L, et al. The UniWellbeing course: a randomised controlled trial of a transdiagnostic internet-delivered cognitive behavioural therapy (CBT) programme for university students with symptoms of anxiety and depression. Internet Interv 2015 May;2(2):128-136 [FREE Full text] [doi: 10.1016/j.invent.2015.02.002]
143. Dear B, Titov N, Schwencke G, Andrews G, Johnston L, Craske M, et al. An open trial of a brief transdiagnostic internet treatment for anxiety and depression. Behav Res Ther 2011 Dec;49(12):830-837 [FREE Full text] [doi: 10.1016/j.brat.2011.09.007] [Medline: 21993153]
144. Karyotaki E, Klein AM, Ciharova M, Bolinski F, Krijnen L, de Koning L, et al. Guided internet-based transdiagnostic individually tailored Cognitive Behavioral Therapy for symptoms of depression and/or anxiety in college students: a randomized controlled trial. Behav Res Ther 2022 Mar;150:104028 [FREE Full text] [doi: 10.1016/j.brat.2021.104028] [Medline: 35066365]
145. Pots WT, Fledderus M, Meulenbeek PA, ten Klooster PM, Schreurs KM, Bohlmeijer ET. Acceptance and commitment therapy as a web-based intervention for depressive symptoms: randomised controlled trial. Br J Psychiatry 2016 Jan;208(1):69-77. [doi: 10.1192/bjp.bp.114.146068] [Medline: 26250745]
146. Araya R, Menezes PR, Claro HG, Brandt LR, Daley KL, Quayle J, et al. Effect of a digital intervention on depressive symptoms in patients with comorbid hypertension or diabetes in Brazil and Peru: two randomized clinical trials. JAMA 2021 May 11;325(18):1852-1862 [FREE Full text] [doi: 10.1001/jama.2021.4348] [Medline: 33974019]

147. Boersma K, Södermark M, Hesser H, Flink IK, Gerdle B, Linton SJ. Efficacy of a transdiagnostic emotion-focused exposure treatment for chronic pain patients with comorbid anxiety and depression: a randomized controlled trial. Pain 2019 Aug;160(8):1708-1718 [FREE Full text] [doi: 10.1097/j.pain.0000000000001575] [Medline: 31335641]
148. Brabyn S, Araya R, Barkham M, Bower P, Cooper C, Duarte A, et al. The second randomised evaluation of the effectiveness, cost-effectiveness and acceptability of computerised therapy (REEACT-2) trial: does the provision of telephone support enhance the effectiveness of computer-delivered cognitive behaviour therapy? A randomised controlled trial. Health Technol Assess 2016 Nov;20(89):1-64 [FREE Full text] [doi: 10.3310/hta20890] [Medline: 27922448]
149. Carlbring P, Hägglund M, Luthström A, Dahlin M, Kadowaki A, Vernmark K, et al. Internet-based behavioral activation and acceptance-based treatment for depression: a randomized controlled trial. J Affect Disord 2013 Jun;148(2-3):331-337. [doi: 10.1016/j.jad.2012.12.020] [Medline: 23357657]
150. Day V, McGrath PJ, Wojtowicz M. Internet-based guided self-help for university students with anxiety, depression and stress: a randomized controlled clinical trial. Behav Res Ther 2013 Jul;51(7):344-351. [doi: 10.1016/j.brat.2013.03.003] [Medline: 23639300]
151. Eriksson MC, Kivi M, Hange D, Petersson EL, Ariai N, Häggblad P, et al. Long-term effects of internet-delivered cognitive behavioral therapy for depression in primary care - the PRIM-NET controlled trial. Scand J Prim Health Care 2017 Jun;35(2):126-136 [FREE Full text] [doi: 10.1080/02813432.2017.1333299] [Medline: 28585868]
152. Flygare AL, Engström I, Hasselgren M, Jansson-Fröjmark M, Frejgrim R, Andersson G, et al. Internet-based CBT for patients with depressive disorders in primary and psychiatric care: is it effective and does comorbidity affect outcome? Internet Interv 2020 Mar;19:100303 [FREE Full text] [doi: 10.1016/j.invent.2019.100303] [Medline: 32055451]
153. Forand NR, Barnett JG, Strunk DR, Hindiyeh MU, Feinberg JE, Keefe JR. Efficacy of guided iCBT for depression and mediation of change by cognitive skill acquisition. Behav Ther 2018 Mar;49(2):295-307 [FREE Full text] [doi: 10.1016/j.beth.2017.04.004] [Medline: 29530267]
154. Hadjistavropoulos HD, Peynenburg V, Nugent M, Karin E, Titov N, Dear BF. Transdiagnostic internet-delivered cognitive behaviour therapy with therapist support offered once-weekly or once-weekly supplemented with therapist support within one-business-day: pragmatic randomized controlled trial. Internet Interv 2020 Dec;22:100347 [FREE Full text] [doi: 10.1016/j.invent.2020.100347] [Medline: 32995303]
155. Hadjistavropoulos HD, Peynenburg V, Thiessen DL, Nugent M, Adlam K, Owens KM, et al. A pragmatic factorial randomized controlled trial of transdiagnostic internet-delivered cognitive behavioural therapy: exploring benefits of homework reflection questionnaires and twice-weekly therapist support. Internet Interv 2020 Dec;22:100357 [FREE Full text] [doi: 10.1016/j.invent.2020.100357] [Medline: 33335846]
156. Hadjistavropoulos HD, Schneider LH, Edmonds M, Karin E, Nugent MN, Dirkse D, et al. Randomized controlled trial of internet-delivered cognitive behaviour therapy comparing standard weekly versus optional weekly therapist support. J Anxiety Disord 2017 Dec;52:15-24 [FREE Full text] [doi: 10.1016/j.janxdis.2017.09.006] [Medline: 28964994]
157. Johansson O, Bjärehed J, Andersson G, Carlbring P, Lundh LG. Effectiveness of guided internet-delivered cognitive behavior therapy for depression in routine psychiatry: a randomized controlled trial. Internet Interv 2019 Sep;17:100247 [FREE Full text] [doi: 10.1016/j.invent.2019.100247] [Medline: 31249791]
158. Johansson R, Björklund M, Hornborg C, Karlsson S, Hesser H, Ljótsson B, et al. Affect-focused psychodynamic psychotherapy for depression and anxiety through the internet: a randomized controlled trial. PeerJ 2013;1:e102 [FREE Full text] [doi: 10.7717/peerj.102] [Medline: 23862104]
159. Johansson R, Ekbladh S, Hebert A, Lindström M, Möller S, Petitt E, et al. Psychodynamic guided self-help for adult depression through the internet: a randomised controlled trial. PLoS One 2012;7(5):e38021 [FREE Full text] [doi: 10.1371/journal.pone.0038021] [Medline: 22741027]
160. Johansson R, Sjöberg E, Sjögren M, Johnsson E, Carlbring P, Andersson T, et al. Tailored vs. standardized internet-based cognitive behavior therapy for depression and comorbid symptoms: a randomized controlled trial. PLoS One 2012;7(5):e36905 [FREE Full text] [doi: 10.1371/journal.pone.0036905] [Medline: 22615841]
161. Lappalainen P, Granlund A, Siltanen S, Ahonen S, Vitikainen M, Tolvanen A, et al. ACT internet-based vs face-to-face? A randomized controlled trial of two ways to deliver Acceptance and Commitment Therapy for depressive symptoms: an 18-month follow-up. Behav Res Ther 2014 Oct;61:43-54. [doi: 10.1016/j.brat.2014.07.006] [Medline: 25127179]
162. Lindner P, Olsson EL, Johnsson A, Dahlin M, Andersson G, Carlbring P. The impact of telephone versus e-mail therapist guidance on treatment outcomes, therapeutic alliance and treatment engagement in internet-delivered CBT for depression: a randomised pilot trial. Internet Interv 2014 Oct;1(4):182-187. [doi: 10.1016/j.invent.2014.09.001]
163. Lindqvist K, Mechler J, Carlbring P, Lilliengren P, Falkenström F, Andersson G, et al. Affect-focused psychodynamic internet-based therapy for adolescent depression: randomized controlled trial. J Med Internet Res 2020 Mar 30;22(3):e18047 [FREE Full text] [doi: 10.2196/18047] [Medline: 32224489]
164. MacLean S, Corsi DJ, Litchfield S, Kucharski J, Genise K, Selaman Z, et al. Coach-facilitated web-based therapy compared with information about web-based resources in patients referred to secondary mental health care for depression: randomized controlled trial. J Med Internet Res 2020 Jun 09;22(6):e15001 [FREE Full text] [doi: 10.2196/15001] [Medline: 32515740]

165. Mira A, Bretón-López J, García-Palacios A, Quero S, Baños RM, Botella C. An Internet-based program for depressive symptoms using human and automated support: a randomized controlled trial. Neuropsychiatr Dis Treat 2017;13:987-1006 [FREE Full text] [doi: 10.2147/NDT.S130994] [Medline: 28408833]
166. Mohr DC, Duffecy J, Ho J, Kwasny M, Cai X, Burns MN, et al. A randomized controlled trial evaluating a manualized TeleCoaching protocol for improving adherence to a web-based intervention for the treatment of depression. PLoS One 2013;8(8):e70086 [FREE Full text] [doi: 10.1371/journal.pone.0070086] [Medline: 23990896]
167. Newby JM, Mackenzie A, Williams AD, McIntyre K, Watts S, Wong N, et al. Internet cognitive behavioural therapy for mixed anxiety and depression: a randomized controlled trial and evidence of effectiveness in primary care. Psychol Med 2013 Dec;43(12):2635-2648. [doi: 10.1017/S0033291713000111] [Medline: 23419552]
168. Niles AN, Axelsson E, Andersson E, Hedman-Lagerlöf E, Carlbring P, Andersson G, et al. Internet-based cognitive behavior therapy for depression, social anxiety disorder, and panic disorder: effectiveness and predictors of response in a teaching clinic. Behav Res Ther 2021 Jan;136:103767. [doi: 10.1016/j.brat.2020.103767] [Medline: 33249272]
169. Nobis S, Lehr D, Ebert DD, Baumeister H, Snoek F, Riper H, et al. Efficacy of a web-based intervention with mobile phone support in treating depressive symptoms in adults with type 1 and type 2 diabetes: a randomized controlled trial. Diabetes Care 2015 May;38(5):776-783. [doi: 10.2337/dc14-1728] [Medline: 25710923]
170. Nyström MB, Stenling A, Sjöström E, Neely G, Lindner P, Hassmén P, et al. Behavioral activation versus physical activity via the internet: a randomized controlled trial. J Affect Disord 2017 Jun;215:85-93 [FREE Full text] [doi: 10.1016/j.jad.2017.03.018] [Medline: 28319696]
171. Oehler C, Görges F, Rogalla M, Rummel-Kluge C, Hegerl U. Efficacy of a guided web-based self-management intervention for depression or dysthymia: randomized controlled trial with a 12-month follow-up using an active control condition. J Med Internet Res 2020 Jul 14;22(7):e15361 [FREE Full text] [doi: 10.2196/15361] [Medline: 32673233]
172. Reins JA, Boß L, Lehr D, Berking M, Ebert DD. The more I got, the less I need? Efficacy of internet-based guided self-help compared to online psychoeducation for major depressive disorder. J Affect Disord 2019 Mar 01;246:695-705. [doi: 10.1016/j.jad.2018.12.065] [Medline: 30611913]
173. Richards D, Enrique A, Eilert N, Franklin M, Palacios J, Duffy D, et al. A pragmatic randomized waitlist-controlled effectiveness and cost-effectiveness trial of digital interventions for depression and anxiety. NPJ Digit Med 2020;3:85 [FREE Full text] [doi: 10.1038/s41746-020-0293-8] [Medline: 32566763]
174. Richards D, Timulak L, O'Brien E, Hayes C, Vigano N, Sharry J, et al. A randomized controlled trial of an internet-delivered treatment: its potential as a low-intensity community intervention for adults with symptoms of depression. Behav Res Ther 2015 Dec;75:20-31. [doi: 10.1016/j.brat.2015.10.005] [Medline: 26523885]
175. Rollman BL, Herbeck Belnap B, Abebe KZ, Spring MB, Rotondi AJ, Rothenberger SD, et al. Effectiveness of online collaborative care for treating mood and anxiety disorders in primary care: a randomized clinical trial. JAMA Psychiatry 2018 Jan 01;75(1):56-64 [FREE Full text] [doi: 10.1001/jamapsychiatry.2017.3379] [Medline: 29117275]
176. Smith GC, Egbert N, Dellman-Jenkins M, Nanna K, Palmieri PA. Reducing depression in stroke survivors and their informal caregivers: a randomized clinical trial of a web-based intervention. Rehabil Psychol 2012 Aug;57(3):196-206 [FREE Full text] [doi: 10.1037/a0029587] [Medline: 22946607]
177. Titov N, Andrews G, Davies M, McIntyre K, Robinson E, Solley K. Internet treatment for depression: a randomized controlled trial comparing clinician vs. technician assistance. PLoS One 2010 Jun 08;5(6):e10939 [FREE Full text] [doi: 10.1371/journal.pone.0010939] [Medline: 20544030]
178. Topooco N, Berg M, Johansson S, Liljethörn L, Radvogin E, Vlaescu G, et al. Chat- and internet-based cognitive-behavioural therapy in treatment of adolescent depression: randomised controlled trial. BJPsych Open 2018 Jul;4(4):199-207 [FREE Full text] [doi: 10.1192/bjo.2018.18] [Medline: 29988969]
179. Topooco N, Byléhn S, Dahlström Nysäter E, Holmlund J, Lindegaard J, Johansson S, et al. Evaluating the efficacy of internet-delivered cognitive behavioral therapy blended with synchronous chat sessions to treat adolescent depression: randomized controlled trial. J Med Internet Res 2019 Nov 01;21(11):e13393 [FREE Full text] [doi: 10.2196/13393] [Medline: 31682572]
180. Vernmark K, Lenndin J, Bjärehed J, Carlsson M, Karlsson J, Oberg J, et al. Internet administered guided self-help versus individualized e-mail therapy: a randomized trial of two versions of CBT for major depression. Behav Res Ther 2010 May;48(5):368-376. [doi: 10.1016/j.brat.2010.01.005] [Medline: 20152960]
181. Dear BF, Fogliati VJ, Fogliati R, Johnson B, Boyle O, Karin E, et al. Treating anxiety and depression in young adults: A randomised controlled trial comparing clinician-guided versus self-guided Internet-delivered cognitive behavioural therapy. Aust N Z J Psychiatry 2018 Jul;52(7):668-679. [doi: 10.1177/0004867417738055] [Medline: 29064283]
182. Watts S, Mackenzie A, Thomas C, Griskaitis A, Mewton L, Williams A, et al. CBT for depression: a pilot RCT comparing mobile phone vs. computer. BMC Psychiatry 2013 Mar 07;13:49 [FREE Full text] [doi: 10.1186/1471-244X-13-49] [Medline: 23391304]
183. Beck A, Steer R, Brown G. Beck depression inventory-II. Am Psychol Assoc 1996. [doi: 10.1037/t00742-000]
184. Perini S, Titov N, Andrews G. The climate sadness program of internet-based treatment for depression: a pilot study. E J Applied Psychol 2008 Dec 23;4(2):18-24. [doi: 10.7790/ejap.v4i2.135]

185. Boot WR, Simons DJ, Stothart C, Stutts C. The pervasive problem with placebos in psychology: why active control groups are not sufficient to rule out placebo effects. Perspect Psychol Sci 2013 Jul;8(4):445-454. [doi: 10.1177/1745691613491271] [Medline: 26173122]
186. Depression in adults: recognition and management. National Institute for Health and Clinical Excellence. 2009 Oct 28. URL: https://www.nice.org.uk/guidance/cg90 [accessed 2021-10-05]
187. Keles S, Idsoe T. A meta-analysis of group Cognitive Behavioral Therapy (CBT) interventions for adolescents with depression. J Adolesc 2018 Aug;67:129-139 [FREE Full text] [doi: 10.1016/j.adolescence.2018.05.011] [Medline: 29957492]
188. Li J, Zhang Y, Su W, Liu L, Gong H, Peng W, et al. Cognitive behavioral therapy for treatment-resistant depression: a systematic review and meta-analysis. Psychiatry Res 2018 Oct;268:243-250 [FREE Full text] [doi: 10.1016/j.psychres.2018.07.020] [Medline: 30071387]
189. Kessler RC, Birnbaum HG, Shahly V, Bromet E, Hwang I, McLaughlin KA, et al. Age differences in the prevalence and co-morbidity of DSM-IV major depressive episodes: results from the WHO World Mental Health Survey Initiative. Depress Anxiety 2010 Apr;27(4):351-364 [FREE Full text] [doi: 10.1002/da.20634] [Medline: 20037917]
190. Rosenthal R. The file drawer problem and tolerance for null results. Psychol Bull 1979 May;86(3):638-641. [doi: 10.1037/0033-2909.86.3.638]

## Abbreviations

**CBT:** cognitive behavioral therapy
**DSM-IV:** Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition
**PRISMA:** Preferred Reporting Items for Systematic Reviews and Meta-Analyses
**PRISMA-ScR:** Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews
**RCT:** randomized controlled trial
**RQ:** research question

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Original Paper

# A Social Media Website (Supporting Our Valued Adolescents) to Support Treatment Uptake for Adolescents With Depression or Anxiety: Pilot Randomized Controlled Trial

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## Abstract

**Background:** Adolescents with depression or anxiety initiate mental health treatment in low numbers. Supporting Our Valued Adolescents (SOVA) is a peer support website intervention for adolescents seen in primary care settings and their parents with the goal of increasing treatment uptake through changing negative health beliefs, enhancing knowledge, offering peer emotional support, and increasing parent-adolescent communication about mental health.

**Objective:** This pilot study aimed to refine recruitment and retention strategies, refine document intervention fidelity, and explore changes in study outcomes (the primary outcome being treatment uptake).

**Methods:** We conducted a 2-group, single-blind, pilot randomized controlled trial in a single adolescent medicine clinic. Participants were aged 12 to 19 years with clinician-identified symptoms of depression or anxiety for which a health care provider recommended treatment. The patient and parent, if interested, were randomized to receive the SOVA websites and enhanced usual care (EUC) compared with EUC alone. Baseline, 6-week, and 3-month measures were collected using a web-based self-report survey and blinded electronic health record review. The main pilot outcomes assessed were the feasibility of recruitment and retention strategies. Implementation outcomes, intervention fidelity, missingness, and adequacy of safety protocols were documented. Descriptive statistics were used to summarize mental health service use and target measures with 2-sample *t* tests to compare differences between arms.

**Results:** Less than half of the adolescents who were offered patient education material (195/461, 42.2%) were referred by their clinician to the study. Of 146 adolescents meeting the inclusion criteria, 38 completed the baseline survey, qualifying them for randomization, and 25 (66%, 95% CI 51%-81%) completed the 6-week measures. There was limited engagement in the treatment arm, with 45% (5/11) of adolescents who completed 6-week measures reporting accessing SOVA, and most of those who did not access cited forgetting as the reason. Changes were found in target factors at 6 weeks but not in per-protocol analyses. At 12 weeks, 83% (15/18) of adolescents randomized to SOVA received mental health treatment as compared with 50% (10/20) of adolescents randomized to EUC (*P*=.03).

**Conclusions:** In this pilot trial of a peer support website intervention for adolescents with depression or anxiety, we found lower-than-expected study enrollment after recruitment. Although generalizability may be enhanced by not requiring parental

permission for adolescent participation in the trials of mental health interventions, this may limit study recruitment and retention. We found that implementing education introducing the study into provider workflow was feasible and acceptable, resulting in almost 500 study referrals. Finally, although not the primary outcome, we found a signal for greater uptake of mental health treatment in the arm using the SOVA intervention than in the usual care arm.

**Trial Registration:** ClinicalTrials.gov NCT03318666; https://clinicaltrials.gov/ct2/show/NCT03318666

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**KEYWORDS**

adolescent; adolescent health services; technology; depression; anxiety

## Introduction

### Background

Adolescent depression and anxiety are rapidly increasing public health problems in the United States, with serious clinical and societal consequences [1-3]. One-third of adolescents with depression experience suicidality and 11% attempt suicide [4], resulting in US $12 billion in hospital costs [5], but only one-third receive treatment [6]. An estimated 30% to 70% of children with mental health disorders do not receive counseling from a mental health professional [7]. Routine adolescent depression screening has been widely implemented in pediatric primary care settings to increase the identification of depression in early adolescence [8,9]; however, initiation of treatment is low with screening without subsequent efforts to increase engagement [10-12]. There is a need for feasible and scalable additional interventions that can be implemented in busy primary care settings, which can accompany screening and address attitudinal factors in both parents and adolescents, which may enhance treatment engagement.

Supporting Our Valued Adolescents (SOVA) [13] is a moderated website (with an accompanying separate parent website, wiseSOVA) [14] with the overall goal of increasing the uptake of and engagement with mental health treatment in adolescents referred to treatment. SOVA is designed to target (1) increasing mental health literacy, (2) prevailing over negative health beliefs toward depression or anxiety diagnosis and treatment, and (3) growing an anonymous online support community. The conceptual model and rationale for the design of the SOVA intervention are described in a previous protocol paper [15]. The SOVA Peer Ambassador program scaffolds websites by engaging youths (age 14-21 years) who have already experienced symptoms of depression or anxiety, mostly those who have already been in treatment and are willing to write monthly blog posts and comment weekly on others' posts to share their experiences with mental health, with the goal of encouraging others to find support. One-third of the posts are written by SOVA Peer Ambassadors, and two-thirds, by the research team.

### Aims and Objectives

The aims of this pilot randomized controlled trial of SOVA as compared with enhanced usual care (EUC) were as follows:

Aim 1: examine the feasibility of and refine recruitment and retention strategies with the goal of recruiting 150 adolescents with 75 per arm and that 90% of the sample would complete 6-week follow-up measures.

Aim 2: document implementation outcomes and intervention fidelity.

Exploratory aim 3: describe changes in and between-arm comparisons for the following:

1. Health beliefs and knowledge
2. Emotional and informational social support
3. Adolescent and parent communication quality
4. Perceived need for treatment
5. Mental health service use
6. Symptoms of depression and anxiety

Aim 4: examine the appropriateness of effectiveness and implementation measures, rates of missing data, and adequacy of safety protocols.

## Methods

A detailed description of the protocol and design of this study is available in a prior publication [15].

### Trial Design

This was a parallel-arm, single-blind, pilot randomized controlled trial with 1:1 allocation and 6-week and 12-week follow-up by self-report and electronic health record (EHR) review.

### Participants

The trial participants included adolescents and their parents, if interested. Adolescent health care providers (AHCPs) included medical providers (physicians and advanced practice practitioners) seeing adolescent patients for physical health visits and were interviewed at study conclusion. Adolescents were eligible if they were between the ages of 12 and 19 years inclusive, their AHCP identified that they have symptoms of anxiety or depression, and the AHCP recommended that the adolescent initiate a new treatment episode (no treatment in the past 3 months). Adolescents were excluded if they were already engaged in treatment, meaning they were currently on a psychiatric medication—defined as filling a prescription and starting to and currently taking a medication—or currently engaged in psychotherapy—defined as attending at least 3 therapy sessions in the past 2 months—for depression or anxiety. The purpose of this was to measure specifically treatment initiation in adolescents not currently in treatment, as the goal

of SOVA is to serve as an intervention that promotes psychotherapy treatment initiation and engagement. Adolescents were not excluded if they were newly being prescribed a medication or referred to psychotherapy at the AHCP visit. Adolescents were required to have at least mild depressive symptoms (≥5 on the Patient Health Questionnaire-9 [PHQ-9] screener [16]) or mild anxiety symptoms (≥5 on the Generalized Anxiety Disorder Questionnaire-7 [GAD-7] screener [17]). Adolescents were excluded if they were actively suicidal, requiring crisis intervention or hospitalization, defined as current suicidal thoughts and plans or AHCP determination. Adolescents were excluded if they had no access to the internet, no active email account, could not read and write in English, or had not completed sixth grade. Initially, adolescents aged 14 to 19 years were recruited because of concerns about a waiver of parental permission but given the minimal risk of the study and the goal to increase earlier engagement in mental health treatment, the age range was expanded to 12 to 19 years.

Parents were included if their child met the study criteria and agreed to enroll in the study, could read and write in English, and had completed sixth grade. Parents were excluded if they had no access to the internet or no active email account. At the start of the study, we initially required adolescents and parents to enroll as a dyad, but as clinical recruitment proceeded, we learned that some adolescents refused to participate in the study because of this requirement, as they were uncomfortable discussing their mental health symptoms with their parents. As the aim of the intervention is partly to enhance communication between an adolescent and their support person, we amended our protocol to not require parents to enroll in the study and were granted a waiver of parental permission. We encouraged adolescents randomized to the SOVA intervention to share the parent website (wiseSOVA) containing publicly accessible articles with a support person, even if the support person was not enrolled in the study. This change occurred after the initial 17 dyads were consented.

AHCPs were included if they were a health care provider (eg, physician, nurse practitioner, or physician assistant) providing clinical services at the 2 participating clinics.

## Procedure

Potential participants were identified by within-clinic research assistants (RAs) reviewing the EHR to determine those who may meet eligibility criteria and approaching patients during clinic visits, as well as self-referral through research advertisements and contact cards placed in clinic spaces. Participants were recruited from 2 clinics providing care to adolescents at an academic medical center, one being general primary care and another being adolescent primary and subspecialty care. RAs prompted AHCPs and other clinical staff including team social workers to introduce the study to the adolescent. Typically, AHCPs would see patients for medical visits for physical health complaints and involve social workers to assist when a mental health referral is indicated. For potentially eligible adolescents (being referred for an initial treatment episode), AHCPs asked the adolescent's permission to be approached by a research team member available in the clinic or to be contacted after the appointment. RAs then prescreened the EHR to determine if the eligibility criteria were met (specifically, no prior treatment and a referral for a new treatment episode), and if not, they contacted the AHCP to verify. If the individual met the criteria, the RA contacted them to conduct a screen using the PHQ-9 and GAD-7. AHCPs were notified if a potential adolescent participant scored in the severe range or endorsed suicidality. If the eligibility criteria were met, the RA proceeded to obtain consent. Adolescents provided assent, and if their parents were joining the study, the parents provided consent. Then, the RA emailed the adolescent and parent (if participating) an electronic baseline survey using the secure database REDCap (Research Electronic Data Capture; Vanderbilt University) [18]. Randomization was performed after baseline survey completion to either SOVA+EUC or EUC alone. All participants were sent a self-report web-based survey at 6 and 12 weeks, and the research team obtained EHR data at baseline, 6 weeks, and 12 weeks.

## Ethics Approval

Approval was obtained from the University of Pittsburgh Human Research Protection Office (STUDY19120034), including a waiver of parental permission, a waiver of informed consent to review medical records only for the identification of potential participants, and a waiver to obtain a written signed consent form (ie, verbal consent was obtained without a signature). All the participants were emailed a copy of the consent form. The study was registered with the National Institute of Health trials registry, ClinicalTrials.gov (NCT03318666), before participant enrollment. The office did not request an independent data safety monitoring board because, as an adjunct to treatment intervention, the study was deemed as minimal risk.

## Intervention Arm

Several publications describe the SOVA intervention design [19], initial usability testing [20], and evaluation of the moderation process [21]. Briefly, there are 2 separate websites, SOVA for adolescents and young adults and wiseSOVA for parents. All article content is publicly available, but participating in interactive components (ie, comments and discussion boards) requires logging in. Discussion boards are available for any topic. Every weekday, there are new articles, approximately one-third written by SOVA Peer Ambassadors, or young people receiving small compensation for contributing blog article content. This content is reviewed by the research team, providing guidance around factuality before publication. Adolescents randomized to SOVA (and their parent if included) received a welcome email to the sites with log-in information and a phone call or an in-person appointment from an RA to explain site use rules and assist with any log-in technical difficulties. The site use rules included asking participants to not share identifying information, not meet with other participants, avoid bullying, and take a break if they feel upset by using the site. Site moderation (that all comments are reviewed within 24 hours of being posted and removed if they did not meet ground rules) was reviewed. Even if a parent was not enrolled with their adolescent child, adolescents were provided information about the parent website to provide to a parent or guardian or support person if they wished. Adolescents and enrolled parents received a weekly digest email alerting them to new articles published

on the site. An Android-only mobile app version of the site, rendering the website in an app form, was also available to the participants. All adolescents in the intervention arm also received EUC.

## Control Arm

As described in detail in a previous publication [22], individuals in the EUC arm and enrolled parents received an email from the research team containing information from the AHCP's documentation (eg, instructions to follow-up at a certain time interval with the AHCP or instruction to contact an outside therapist or to schedule a follow-up with the clinic therapist) that the research team obtained from the EHR, along with a list of psychoeducational materials and crisis resources. Psychoeducational materials were a list of website materials from US national organizations' patient-friendly materials on mental health and help seeking; none were connecting to an online peer support community, and none were specific to addressing negative health beliefs about help seeking (Multimedia Appendix 1). The email also included information on how to contact the AHCP and clinic social worker. The clinic social worker conducted their typical duties of assisting with mental health referrals for patients referred by the AHCP.

## Measures

### *Aim 1: Pilot Outcomes*

Measures are described in detail in the research protocol manuscript [15] with measure characteristics and reliability and validity metrics included in the research protocol's accompanying Multimedia Appendix 1, and they are also summarized here in Table 1.

The main pilot study outcome was the study retention rate, measured by the proportion of enrolled adolescents completing the 6-week survey.

**Table 1.** Measures obtained from adolescents and parents at baseline and 6-week follow-up.

| | Measure[a] |
|---|---|
| **Health beliefs** | |
| Stigma | Depression Stigma Scale [23] |
| Beliefs about antidepressants | Resistance to Antidepressant Use Questionnaire—higher score indicates more acceptance of antidepressant use; Antidepressant Meanings Scale [24] |
| Beliefs about psychotherapy | Adolescent: barriers to adolescents seeking help [25]; Parent: Parental Barriers to Help Seeking Scale |
| **Mental health knowledge** | |
| Depression knowledge | Depression Literacy Questionnaire [26] |
| Anxiety knowledge | Anxiety Literacy Questionnaire [26] |
| Peer emotional and informational social support | Emotional or Informational subscale from the Medical Outcomes Study Social Support Survey [27] |
| Parent-adolescent communication quality | Parent-Adolescent Communication Scale [28] |
| Perceived need for treatment | Single-item yes or no question about need for mental health service [29]; General-Practice Users Perceived-Need Inventory [30] |
| **Symptoms** | |
| Depressive symptoms | Adolescent: Patient Health Questionnaire-9 [31] |
| Anxiety symptoms | Adolescent: Generalized Anxiety Disorder Questionnaire-7 [17] |
| Functioning | Adolescent: Multidimensional Adolescent Functioning Scale [32]; Parent: Columbia Impairment Scale-Parent [33] |
| Relationship quality | Parent-child connectedness [34] |

[a]All measures were asked of both adolescents and parents with regard to the adolescents unless specified in the table.

### *Aim 2: Implementation and Fidelity Outcomes*

To understand potential strategies to measure future implementation outcomes such as adoption (use of the provider patient education), we gathered data for the number of adolescent patients seen in the clinic where recruitment was taking place and who received information about the study, as measured by a "Stress and Worry" patient education handout inserted into their end-of-visit depart summary during the study timeframe. The depart summary is paperwork that is routinely provided to all patients when they are leaving after their appointment. This helps to determine the feasibility of using patient education to introduce the study. We calculated the proportion of adolescents provided that information who showed an interest in the study to understand the adoption of the trial from those who provided information about it. We also asked AHCP's to complete a poststudy survey inquiring about whether the provider used the "Stress and Worry" patient education and if so, to what extent on a 4-point Likert scale (0=not at all, 3=to a very great extent) did they think this patient education was clinically useful, intuitively appealing, made sense, used because it was required, and thought colleagues were happy using it and

to what extent patients or the social worker brought up the "Stress and Worry" study to the AHCP. AHCPs were also asked open-ended questions about how the study could be improved.

### *Aim 3: Changes in Clinical Outcomes*

The proposed main clinical outcome was the use of mental health services. As one of the pilot trial's goals was to inform measurement selection, mental health service use was measured in multiple ways, per a single-item question combined with EHR data extraction [11], as well as measured by the Actual Help Seeking Questionnaire [35]. Mental health service use was dichotomized into treatment received or not received and assessed at the 6- and 12-week follow-up. Treatment was defined as received if any of the following were true: (1) the adolescent reported yes when asked, "Have you received any treatment for depression or anxiety since the start of this study (this could include starting a new medication, seeing a professional to talk to, or follow up with your adolescent health care provider to talk about depression or anxiety)?"; (2) the adolescent's parent, if enrolled, reported yes to that same question; or (3) the EHR showed evidence that a new antidepressant medication prescription was filled, an appointment with a mental health professional was attended, or there was a mental health follow-up visit with an AHCP or primary care provider at the time after the baseline assessment. Mental health service use was also measured more stringently, excluding follow-up with the AHCP or primary care provider for a mental health concern, but no differences were found. The Actual Help-Seeking Questionnaire lists people who the adolescent may have sought help from for a personal or emotional problem and asks yes or no whether help was sought and to describe the problem it was sought for. The scale was modified to ask about the past 6 weeks. The original scale was also modified for clarity in a US health care setting as (3c) parent or guardian, (3e) mental health professional (counselor or social worker or psychologist or psychiatrist), (3f) helpline (phone number to call or text in crisis), and (3g) doctor or health care provider (doctor or provider you see for yearly physicals). In addition, 2 categories were added for coaches and religious persons (eg, priest, imam, and rabbi). At baseline, the General Help-Seeking Questionnaire [36] was used to ask about the intention to seek help from individuals on the aforementioned list, with a likelihood to seek help or advice for a personal or emotional problem from each individual on a 7-point Likert scale.

Other measures examined in adolescents and participating adults are shown in Table 1.

At baseline, both adolescents and parents were asked about their age, gender (male, female, transgender, and other with free text option), race, ethnicity, education (last grade level completed and any postgraduate education completed), and history of the adolescent ever receiving prior prescription medication or help from a mental health professional (eg, counselor or psychologist) for a personal or emotional problem [37]. If they answered yes to a prior visit with a mental health professional, they were asked what type of mental health professional, how many visits were completed, and how helpful the visits were on a Likert scale of 1 to 5. If prescribed a medication, they were asked about the helpfulness of the medication. Parents reporting a prior visit to a mental health professional were asked comparable questions. Socioeconomic status was assessed by asking yes or no questions about transportation (ease of finding transportation, own a car, or easy access to a car) and using the MacArthur socioeconomic ladder [38], comparing oneself with their community and the United States. Adolescents were asked about their sexuality with regards to identity, attraction, and behaviors. At baseline, there was an EHR review to assess what treatment was recommended at the patient visit. There were no changes to pilot trial assessments or measurements after the pilot trial commenced. There were no prespecified criteria used to judge whether to proceed with a future definitive trial.

### *Aim 4: Safety Protocols*

We examined the appropriateness of the aforementioned implementation and effectiveness measures and kept the notation of any concerns for safety. The research team met weekly to ensure the data integrity and safety of the research participants. This included any concerns with regards to recruitment procedures, confidentiality, web data security, or safety. All identifiable and sensitive data were obtained through a secure database. All information stored on the intervention website was anonymous, except for the participants' emails, which were stored on the back end (not visible to other participants). The participants were asked to agree to the ground rules as described earlier. Emergency contact information was obtained for all users even if they enrolled without their parents. The principal investigator, a physician with subspecialization in adolescent medicine, and the research team, consisting of RAs and graduate students with training in social work, underwent a 2-hour training session with regard to moderating the websites. Site moderation (reviewing any new users and new content, which only consisted of updates to a profile or comments posted to a blogpost) occurred at least every 3 hours during the day by reviewing a study email notifying the moderator on their mobile phone. If the participant were to make a reference to harming themselves, the moderator was to contact the participant or their emergency contact to gather more information, and in the event of the participant confirming suicidal thinking, history of an attempt, or plans to make an attempt in the future, the moderator was to contact the PI for further guidance as well as provide crisis resources and call emergency services as needed. This process is described in more detail in a separate publication [21].

## Sample Size

The sample size was determined based on the main pilot outcome, retention rate, which we determined would be at least 90%. This percentage was the goal to enhance trial efficiency with regard to budget and resources and to ensure that the study procedures were appropriate to achieve this retention rate. Our goal was to recruit sufficient adolescents to increase the likelihood of spontaneous peer-to-peer interactions occurring on the SOVA websites. For this goal, we desired a sample of 150 adolescents with 75 per arm and calculated a 95% CI for the retention rate to be between 85.2% and 94.8%. The study was terminated early after 38 adolescents were recruited because

of meeting the pilot study goals, as described further in the *Discussion* section.

### Randomization and Blinding

Before study initiation, a statistician generated a permuted block randomization scheme and entered it into the REDCap database. Randomization was stratified by gender to account for anticipated low numbers of individuals specifying as cisgender male because of the clinic's focus on providing contraception and reproductive health and to have even distribution between arms. The research team enrolled and consented participants, and if the criteria were met, the baseline survey was distributed. Once the baseline survey was completed by the adolescents, individuals were randomized by the research team using a REDCap module. AHCPs were blinded to the patients' study arm. Separate research team members, who did not participate in enrollment and were limited from viewing enrollment or self-report survey data, conducted EHR extractions and were blinded to participant allocation to the study arm.

### Statistical Analysis Plan

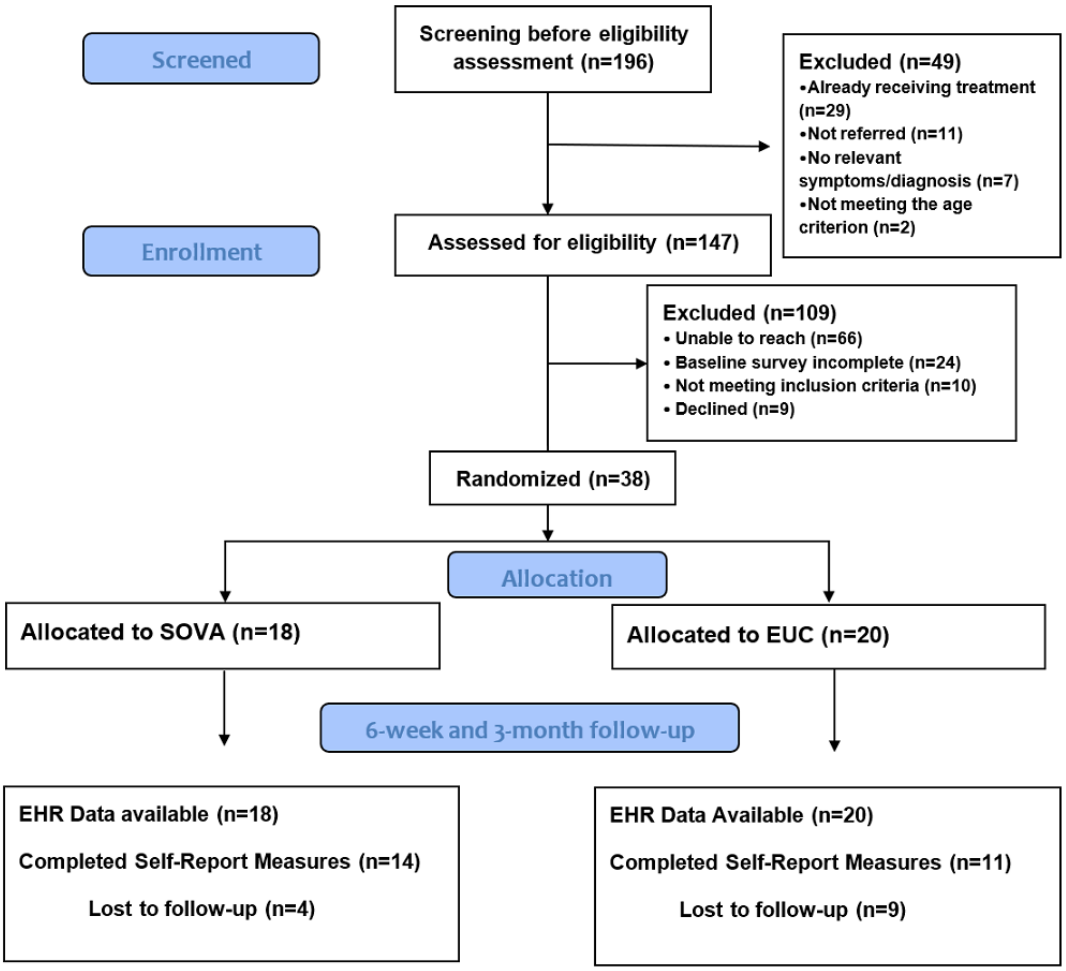
Descriptive statistics (percentage for proportions and means and SDs for continuous measures) were used for all measures. We calculated the main pilot outcome, retention rate, and 95% CI. The baseline measures for covariate balance and outcome measures were summarized by the study arm. Each measure was examined by the study arm for changes from baseline to 6 weeks using 2 samples separately for adolescents and parents. Change scores versus mixed models were considered at 1 time point, 6 weeks, because that was the time point determined a priori to be of the highest clinical significance. A chi-square test was used to compare proportions for dichotomous outcomes. A *P* value of .05 was considered significant.

## Results

### Aim 1: Feasibility of Recruitment and Retention Strategies

The CONSORT (Consolidated Standards of Reporting Trials) diagram of the study flow is shown in Figure 1 (Multimedia Appendix 2). A total of 196 adolescents were referred to the study by their health care providers. Of these 196 adolescents, 49 (25%) were excluded after the EHR chart review uncovered that they did not meet the study criteria. Of the 147 remaining participants, 66 (44.8%) could not be reached, 24 (16.3%) did not complete the baseline survey, 10 (6.8%) did not meet the inclusion criteria, and 9 (6.1%) declined study participation. The remaining 38 adolescents were randomized, of which 26 (68%) were recruited as a dyad with their parent and 12 (32%) were individually enrolled. Of the full sample (N=38), 18 (47%) were allocated to SOVA and 20 (53%) were allocated to EUC. Adolescents enrolling without a parent were equally distributed between SOVA (5/18, 28%) and EUC (7/20, 35%) arms. Of the 38 participants, 25 (66%, 95% CI 51%-81%) completed the 6-week measures. There were few differences between those at baseline who completed and those who did not complete the 6-week measures. Study participants who did not complete the 6-week measures were more likely to, at baseline, say they had a depressed mood on most days in the last year (12/13, 92%) compared with those who completed the 6-week measures (15/25, 60%; *P*=.04), but there were no differences between total PHQ-9 scores; have lower anxiety literacy (mean 7.8, SD 3.5 vs mean 9.7, SD 2.4, *P*=.05); and report that asking for but not getting help had occurred to them in the past few weeks (3/13, 23% vs 0/25, 0%; *P*=.01). There were 65 adolescents who consented to but did not enter the study either because they did not complete the baseline or they were recruited earlier in the study when parental enrollment was required, but their parents could not be reached. There were no statistically significant differences between the group that consented but did not enter the study and the group that entered the study (N=38) in terms of patient age, depressive symptom score, or anxiety symptom score. They were less likely to have a parent who desired to enroll in the study (21/65, 36%) compared with those entering the study (26/38, 68%; *P*=.002), although some adolescents (before the first 17 were enrolled) were not offered entry into the study because of earlier study entry requirements requiring parental enrollment. When comparing based on condition, 55% (11/20) of the EUC arm sample completed the 6-week measures as compared with 78% (14/18) of the SOVA arm, *P*=.14, $\chi^2_1$=2.2.

**Figure 1.** CONSORT (Consolidated Standards of Reporting Trials) diagram. EUC: enhanced usual care; SOVA: Supporting Our Valued Adolescents. EHR: electronic health record.




## Baseline Characteristics

The baseline characteristics of the sample are available in Table 2 briefly and in detail in Tables S1 and S2 in Multimedia Appendix 3. On average, adolescents were approximately aged 16 years, and their parents were approximately aged 44 years in the SOVA arm and 47 years in the EUC arm. Most adolescents in the EUC arm were identified as female (17/20, 85%), while in SOVA, there were also 33% (6/20) who identified as transgender or other gender. Approximately half of each sample (60% in EUC and 50% in SOVA) identified as 100% heterosexual. The adolescent sample was about three-fourths White, and none were Hispanic or Latino. A substantial number of adolescents had prior history of receiving psychotherapy (70% in EUC and 50% in SOVA), and few had received medication before (30% in EUC and 17% in SOVA). The parents were all female and mostly White.

**Table 2.** Baseline characteristics for the adolescent and parent study samples.

| Baseline characteristic | Adolescent | | Parent | |
|---|---|---|---|---|
| | EUC[a] (n=20) | SOVA[b] (n=18) | EUC (n=13) | SOVA (n=13) |
| Age (years), mean (SEM[c]) | 15.9 (1.7) | 16.1 (1.6) | 47.2 (5.2) | 43.8 (6.1) |
| **Gender identity, n (%)** | | | | |
| Male | 2 (10) | 0 (0) | 0 (0) | 0 (0) |
| Female | 17 (85) | 12 (67) | 13 (100) | 13 (100) |
| Transgender | 0 (0) | 2 (11) | 0 (0) | 0 (0) |
| Other or >1 | 1 (5) | 4 (22) | 0 (0) | 0 (0) |
| **Sexual identity, n (%)** | | | | |
| Heterosexual (straight) | 12 (60) | 9 (50) | N/A[d] | N/A |
| Mostly heterosexual | 4 (20) | 2 (11) | N/A | N/A |
| Bisexual | 2 (10) | 4 (22) | N/A | N/A |
| Mostly homosexual | 1 (5) | 2 (11) | N/A | N/A |
| Homosexual (gay) | 1 (5) | 1 (6) | N/A | N/A |
| **Race, n (%)** | | | | |
| White | 15 (75) | 13 (72) | 11 (85) | 13 (100) |
| Black or African American | 2 (10) | 1 (6) | 2 (15) | 0 (0) |
| >1 race | 1 (5) | 4 (22) | 0 (0) | 0 (0) |
| Asian | 1 (5) | 0 (0) | 0 (0) | 0 (0) |
| American Indian or Alaska native | 1 (5) | 0 (0) | 0 (0) | 0 (0) |
| **Ethnicity, n (%)** | | | | |
| Hispanic or Latino | 0 (0) | 0 (0) | 1 (8) | 0 (0) |
| **Symptoms, mean (SEM)** | | | | |
| Depressive symptoms (0-27) | 11.8 (5.5) | 10.8 (3.5) | N/A | N/A |
| Anxiety symptoms (0-21) | 11.0 (5.8) | 8.9 (4.2) | N/A | N/A |

[a]EUC: enhanced usual care.

[b]SOVA: Supporting Our Valued Adolescents.

[c]SEM: SE of the mean.

[d]N/A: not applicable.

## Aim 2: Implementation Outcomes and Intervention Fidelity

We found limited self-reported engagement in the treatment arm, with only 43% (6/14) of the adolescents who completed the 6-week measures and were randomized to SOVA reporting they ever accessed the intervention. While 14% (2/14) thought they were in the EUC arm, the 6 who knew they were in the SOVA arm cited free text reasons for not looking at the site, which were mostly due to forgetting (2/14, 14%) and not having time (2/14, 14%; 1 individual cited both forgetting and not having time), 7% (1/14) were not sure and 14% (2/14) said they did not know how or "it's confusing" but did not specify whether the study or the intervention was confusing. There were few differences at baseline between adolescents who visited the site and those who did not. A few notable differences were that those visiting the site in the first 6 weeks experienced higher perceived stigma (mean 27, SD 6.1 vs mean 15.7, SD 6.1; *P*=.01) and fewer negative feelings toward antidepressants (mean 6.4, SD 5.1 vs mean 13.3, SD 5.1; *P*=.05). At 6 weeks, we asked all adolescents if they were in the arm with the website (without providing the link or name), and if they answered yes, they were asked how often they accessed it; 2 (18%) adolescents in the EUC arm reported they had accessed the site at that time. At 12 weeks, study end, we asked all the users if they had accessed the sites. In the EUC arm, 27% (3/11) of adolescents and in the SOVA arm, 45% (6/14) of adolescents reported accessing the site, showing evidence of some crossover, although out of the 3 accessing SOVA in the EUC arm, only 1 accessed the site more than once. Of the adolescents reporting accessing the site, 22% (2/9) self-reported accessing it once, 56% (5/9) accessed it 2 to 5 times, and 22% (2/9) accessed it 5 to 10 times. Among parents, at 6 weeks, 60% (6/10) reported having accessed the site in the SOVA arm and 20% (2/10) in the EUC arm reported accessing it. At 12 weeks, 30% (3/10) of the parents in the SOVA arm and 11% (1/9) of the parents

in the EUC arm said they had accessed the parent sites. Parents reported reasons for not accessing the site because of forgetting and prioritizing other aspects of their lives, as evident in these example free text responses: “I have been curious to visit the website but have not made it a priority and I probably should” and “I have a son with autism and just don’t have time.” Of note, no one used the mobile app option.

During the study timeframe (March 7, 2018, to June 5, 2020), 461 unique adolescents were provided with the “Stress and Worry” patient education handout. The proportion of those who were initially interested in the study and were screened was 42.2% (195/461). Out of 11 AHCPs answering the poststudy survey, 7 (63%) reported including the “Stress and Worry” patient education for end-of-visit depart summaries. Of the 37% (4/11) who did not use it, they cited forgetting its existence and a workflow concern with switching to a new EHR three-fourths of the way through the trial. Of the 6 respondents answering follow-up questions about the patient education material, on the 0 to 3 scale, most found it clinically useful (mean 2.8, SD 0.4), intuitively appealing (mean 2.8, SD 0.4), and made sense (mean 2.7, SD 0.8). When asked if they thought colleagues were happy using the “Stress and Worry” patient education, 67% (4/6) of participants noted to a very great extent, 17% (1/6) to a moderate extent, and 17% (1/6) not at all (mean 2.33, SD 0.49). The majority reported that using education was not something they did only because they thought it was required (mean 0.5, SD 0.8). Most noted that patients did not bring the study up to them (mean 0.7, SD 0.8), but social workers did to a moderate extent (mean 2.0, SD 1.0). Suggestions for improvement included setting reminders to use the patient education or automating its inclusion in yearly visit depart summaries, increasing advertising, and periodically providing updates about the form, as well as having information in the EHR denoting which patients were in the study.

### Exploratory Aim 3: Between-Arm Comparisons of Clinical Outcomes

At 6 weeks, 61% (11/18) of adolescents randomized to SOVA received mental health treatment compared with 50% (10/20) of adolescents randomized to EUC ($P$=.53), and at 12 weeks, 83% (15/18) of adolescents randomized to SOVA received mental health treatment compared with 50% (10/20) of adolescents randomized to EUC ($P$=.03), where receipt of treatment was measured by a combination of either adolescent or parent self-report and a blinded manual EHR extraction. Blinded manual EHR extraction included individuals who did not complete the 6-week measures, making it possible to examine the full sample despite their survey nonresponse.

It is important to note that these were exploratory comparisons. For the most part, we found no difference in the between-arm comparisons of 6-week outcomes in an intention-to-treat analysis between those randomized to the SOVA intervention and those randomized to the EUC arm (Table 3). Some noted differences included a decrease in total stigma, increase in social support, and decrease in anxiety in the EUC group as compared with the SOVA group for adolescents, and a decrease in stigma as compared with baseline for the EUC group as compared with the SOVA group for parents. In both SOVA and EUC, 1 adolescent who at baseline did not perceive a need for services, at 6 weeks said they did need services, and there was no statistically significant difference for changes in perceived need (0.47), although on the General-Practice Users Perceived-Need Inventory scale, adolescents in EUC were more likely (8/11, 73%) compared with those in SOVA (3/14, 57%; $P$=.02) to not want help because of a preference for self-management.

As there was significant crossover between arms, as well as lack of engagement within the treatment arm, we conducted a per-protocol analysis for adolescents to see if any between-arm differences would remain. We compared those who self-reported that they accessed SOVA (8/25, 32%) at least once (including 2 in the EUC arm) with those who did not (17/25, 68%). We found no clinically or statistically significant differences, except an increase in peer functioning in the SOVA group versus EUC (mean 2.0, SD 1.3 vs mean −0.2, SD 2.3; $P$=.02; Table 4).

**Table 3.** Six-week exploratory comparison in change scores between SOVA[a] and EUC[b].

| Change in scores | Adolescents | | | Parents | | |
|---|---|---|---|---|---|---|
| | EUC (n=11), mean (SD) | SOVA (n=14), mean (SD) | *P* value | EUC (n=11), mean (SD) | SOVA (n=10), mean (SD) | *P* value |
| **Stigma** | −5.6 (8.1) | 0.4 (5.7) | .04 | −2.3 (5.8) | 4.1 (6.8) | .03 |
| Personal stigma | −2.3 (4.3) | 0.2 (2.9) | .10 | 1.2 (3.9) | 2.7 (2.9) | .33 |
| Perceived stigma | −3.4 (5.8) | 0.2 (3.8) | .08 | −3.4 (4.6) | 1.4 (7.0) | .07 |
| Acceptance of antidepressant use | −0.6 (4.0) | −0.6 (2.8) | 1 | 0.8 (2.8) | 0.6 (4.7) | .90 |
| Worry about antidepressant | −1.6 (4.8) | 0.1 (6.0) | .45 | .45 (3.5) | 0.8 (8.8) | .91 |
| Barriers to adolescent seeking help from a therapist | 1.3 (19.9) | −6.3 (20.5) | .36 | −22.2 (10.1) | −10.2 (18.7) | .08 |
| **Knowledge** | | | | | | |
| Depression knowledge | 0 (4.4) | −1.4 (2.8) | .35 | −6.0 (2.4) | −4.9 (2.7) | .34 |
| Anxiety knowledge | 0.6 (4.2) | 0.4 (2.4) | .88 | 1.6 (2.0) | 0.6 (3.0) | .36 |
| Social support | 13.1 (14.2) | −10.5 (29.2) | .02 | 3.1 (12.7) | −2.5 (10.9) | .30 |
| **Parent-adolescent communication quality (20-100)** | 0.9 (7.0) | −0.7 (4.8) | .50 | 1.9 (6.0) | 0.3 (9.6) | .65 |
| Openness of communication | 1.7 (6.5) | −1.0 (6.2) | .30 | −0.2 (6.5) | −0.3 (4.6) | .96 |
| Extent of communication | −0.8 (4.5) | 0.3 (7.4) | .67 | 2.1 (7.3) | 0.6 (5.8) | .61 |
| **Symptoms** | | | | | | |
| Depressive symptoms | −3.2 (3.7) | 0.8 (6.8) | .09 | N/A[c] | N/A | N/A |
| Anxiety symptoms | −4.0 (5.6) | −0.1 (3.6) | .04 | N/A | N/A | N/A |
| **Adolescent functioning** | | | | | | |
| (Parent: Columbia Scale) | N/A | N/A | N/A | −1.4 (6.2) | 0.9 (3.8) | .32 |
| General functioning | 0.0 (5.8) | −0.1 (5.0) | .95 | N/A | N/A | N/A |
| Family functioning | −0.3 (2.7) | −0.4 (3.3) | .95 | N/A | N/A | N/A |
| Peer functioning | 0.3 (1.9) | 0.6 (2.6) | .70 | N/A | N/A | N/A |
| Parent-adolescent relationship quality | 15.3 (4.6) | 13.7 (4.2) | .38 | 16.6 (4.3) | 14.4 (4.7) | .28 |

[a]SOVA: Supporting Our Valued Adolescents.

[b]EUC: enhanced usual care.

[c]N/A: not applicable.

**Table 4.** Six-week per-protocol analysis, comparing change scores between adolescents accessing the SOVA[a] intervention and those who did not access it (N=25).

| Change in scores | Did not access SOVA (n=17), mean (SD) | Accessed SOVA (n=8), mean (SD) | *P* value |
|---|---|---|---|
| **Stigma (total)** | −2.6 (8.1) | −1.5 (6.1) | .74 |
| Personal stigma | −0.8 (4.4) | −1.1 (2.0) | .83 |
| Perceived stigma | −1.8 (5.1) | −0.4 (4.9) | .51 |
| Acceptance of antidepressant use | −1.1 (3.6) | 0.4 (2.3) | .30 |
| Worry about antidepressant | −1.9 (5.2) | 2.0 (5.2) | .09 |
| Barriers to adolescent seeking help from a therapist | −1.7 (18.6) | −5.7 (24.4) | .65 |
| **Knowledge** | | | |
| Depression knowledge | −0.6 (4.0) | −1.1 (2.7) | .73 |
| Anxiety knowledge | 0.7 (3.7) | 0.1 (2.2) | .69 |
| Social support | −0.2 (28.4) | 0.0 (22.7) | .99 |
| **Parent-adolescent communication quality** | 1.4 (5.8) | −2.9 (5.0) | .09 |
| Openness of communication | 0.8 (6.7) | −1.1 (5.9) | .49 |
| Extent of communication | 0.5 (6.0) | −1.8 (6.8) | .40 |
| **Symptoms** | | | |
| Depressive symptoms | −0.7 (6.8) | −1.6 (3.3) | .71 |
| Anxiety symptoms | −2.4 (5.5) | −0.6 (3.2) | .42 |
| **Adolescent functioning** | | | |
| General functioning | −0.8 (5.4) | 1.5 (4.8) | .31 |
| Family functioning | −0.6 (3.3) | 0.2 (2.4) | .53 |
| Peer functioning | −0.2 (2.3) | 2.0 (1.3) | .02 |
| Parent-adolescent relationship quality | 0.3 (3.1) | −0.9 (3.0) | .39 |

[a]SOVA: Supporting Our Valued Adolescents.

### Aim 4: Safety and Follow-up

The safety protocol was found to be adequate as there were no events indicative of safety concerns or breaches of data integrity or confidentiality. No posts were removed because of safety issues. No harm or unintended effects were noted in either group. Recruitment began in March 2018 and the last follow-up time point for the last participant was April 2020. The pilot trial was ended because of expiration in funding, ceasing in-person recruitment because of the start of the COVID-19 pandemic and the Pennsylvania Governor's stay-at-home order, as well as because of obtaining enough data to determine the feasibility of recruitment and retention findings.

## Discussion

### Principal Findings

The main findings of this pilot trial highlight the difficulties in conducting research with adolescents for technology-based mental health studies in the primary care setting. We met 25% of our sample size goal. The goal of 150 adolescents was based on the desire to observe spontaneous peer-peer interaction on the web and was not necessary to meet our pilot outcomes, which were to examine the feasibility of and refine recruitment and retention strategies; therefore, the study was terminated before reaching that goal. This termination was also contributed to by the prohibition of in-person recruitment during the start of the COVID-19 pandemic and budgetary constraints. We found that implementing patient education by introducing the study into the provider workflow was feasible and acceptable. This likely contributed to the ease of referral to the study, as we observed a large number of referrals (almost 500). Had everyone who had consented completed the baseline survey, we would have met 85% of our sample size goal. This led us to understand that the main challenge of this pilot study was retention to study initiation after completing consent. To increase the reach of this mental health intervention to youth, especially those whose parents may be unaware of their need for mental health referral—as parental perceived need is one of the intervention targets but may limit enrollment—we amended the study design to not require parental enrollment or permission. We found that this was detrimental to initial retention because participants enrolling without a parent were more difficult to reach and less likely to complete the baseline survey. We found that only approximately half of the participants in the intervention arm reported ever viewing the sites. Similarly, less than half of the parents reported accessing the site. Our parent stakeholder group expressed that some parents desire to use the site only when their child is symptomatic as a resource when they need information but not on a routine basis.

We found a signal for greater mental health service use at 12 weeks but not at 6 weeks. At 6 weeks, half of those randomized to EUC had accessed mental health treatment as compared with approximately 60% of those randomized to SOVA, but at 12 weeks, EUC remained at half, while 83% of those randomized to SOVA accessed treatment. Despite an approximately two-thirds survey response rate, we were able to supplement our data for mental health service use from the EHR to examine the full sample. Much of the sample had had prior mental health treatment, and so their perceived need for further treatment may have been tempered by whether they felt prior treatment was helpful. This factor may be important to measure in a future trial. This finding of greater uptake of mental health treatment is tempered as the study was not powered to examine this main outcome, the arms were not balanced especially with regard to gender minorities, and the study was limited by less than expected intervention engagement as well as some crossover. Finding this difference does suggest that SOVA warrants further study to understand its potential benefit on mental health service use in adequately powered samples. Examining outcomes at 12 weeks may be more meaningful than at 6 weeks, as even if mental health services are desired, multiple nonattitudinal barriers may influence difficulty with timely use of services, such as insurance, timing, appointment availability, and scheduling barriers. An intervention such as SOVA, which continues to be available during these difficulties, may help maintain the motivation to and perceived need to seek treatment. Although in this trial, we examined the uptake of treatment in individuals whose medical provider recommended they initiate treatment and had not been in treatment for the previous 3 months, a secondary outcome of interest in future trials would be reinitiation of treatment and continued adherence to treatment.

In this pilot sample, we did not find statistically significant differences in changes in target outcomes, which were only examined at 6 weeks, for the most part, and for those we did find (ie, stigma, social support, and anxiety), they appeared to go in the opposite of the proposed hypothesized direction. It is important to note that examining differences in these clinical outcomes was preliminary and very exploratory. The differential effects in the 2 groups were likely random because of the small sample size in this pilot study and less likely because of the intervention, as when a per-protocol analysis was performed, those differences disappeared. Some differences that were seen may have had more to do with the likelihood of finding a difference based on the number of tests done and that randomization was not successful because of the small sample size. In addition, these differences disappeared in a per-protocol analysis comparing adolescents who accessed SOVA with those who did not at 6 weeks. In this analysis, there was only a small increase in peer functioning in SOVA as compared with that in EUC. Because of the small sample size and exploratory nature of the study, we did not have the power to detect differences. A lack of finding these differences may be due to a lack of intervention engagement, lack of power to detect them, or intervention crossover or that the intervention mechanism is not explained by these targets.

For this study, we deemed the training procedures for safety protocols to be adequate and feasible as we were able to train multiple social work graduate students to take on this role and split its demands, including managing the website, totaling about the equivalent of 1 part-time employee per week. We did not have any safety concerns. As participants were all patients of the same clinic, providers were available to contact if, at screening, participants were noted to have high scores for depression or anxiety symptoms. There were low rates of data missingness for those who responded, the main concern being study initiation and retention after consent.

## Strengths and Limitations

There are a few notable strengths of this study. First, despite its pilot nature, because we had already done a preimplementation study [39], we were able to gather further data on parts of an implementation strategy during this trial. We were not able to test the full strategy, as it would have risked crossover for participants not randomized to the intervention. Another strength is the pragmatic nature of this trial with regard to testing a technology intervention in a real-world setting, relying on clinicians and social workers to introduce the study, and maintaining adolescent autonomy in decision-making about their mental health by allowing them to autonomously enter the study with a waiver of parental permission. The same strengths of the study design contributed to consequences that resulted in limitations. Owing to its testing in a real-world setting and the main goal being treatment uptake, the timing of introducing the intervention immediately after referral to treatment is important. If delayed, understanding whether the intervention directly contributes to treatment initiation is difficult. When factoring in the busyness of clinic flow, recruitment can be difficult. Despite this, we were able to receive almost 500 referrals, and the main limitation of this study was a reduced sample size because of the failure of those who consented to the study to initiate the baseline survey and subsequently be randomized. We found that 1 factor influencing this was the waiver of parental permission. Although waiving parental permission facilitated reaching the target population—adolescents who may not initiate mental health treatment because of lack of parental involvement, engagement, or awareness of symptoms—it limited the final sample size. Although we stratified arms based on gender to ensure that an equal number of the anticipated low number of cisgender males would be equally distributed, we had unbalanced arms with regard to gender minorities, with 6 individuals who were transgender or other>1 gender in the SOVA arm and 1 individual who was other or >1 gender in the usual care arm. During the time of the study, the clinic began a new program for gender and sexual development, and the number of gender minority individuals increased; therefore, this was not planned for in the original study design. An exploratory logistic regression with 3-month mental health treatment as the outcome when controlling for gender found a small decrease in the statistical significance found in the full sample by 0.02. This informs to stratify by all genders in future studies to ensure equal balance across arms.

Furthermore, about half of the sample recruited to the SOVA intervention reported not viewing the intervention. There was

some crossover reported between arms, but this was minimal, as only 1 participant in the control arm accessed the site more than once. We were limited in the technology used for this study to measure user engagement as individuals could view site content without logging in or blurbs about articles in an email newsletter, limiting our ability to capture their use if they never logged in. We instead relied on self-report for both reports of site use and crossover, and hence, we cannot be sure of the accuracy of site use and, therefore, intervention engagement. Throughout most of the study, participants received emails notifying them of new website content, as SMS text messaging research participants was not yet a standard communication because of privacy concerns. Toward the end of the study, as texting participants became more of a research norm, we began a protocol for increasing intervention engagement by tracking user log-ins and sending SMS text message suggestions to view articles to participants who did not log in. Future iterations will further personalize article recommendations to participants based on baseline survey data (eg, someone who lists cost as a barrier will be sent an article about the cost of mental health care). Future studies should seek opportunities for increased funding to enable the use of more sophisticated user metrics. These metrics also become more accessible to researchers with advancements in technology. However, in our initial usability study, user engagement was higher than the typical rates in similar studies [20]. We believe that the individual randomization design and not introducing participants to the intervention from the start may have also contributed to low engagement. One factor to consider in efforts to increase intervention engagement is that, although not significant, we did find that less of the EUC group (55%) completed the 6-week measures as compared with the SOVA (78%) group, suggesting that having an attention control that also has some ongoing engagement may decrease retention differences between arms.

Another limitation is we did not adjust for multiple comparisons. As this was a pilot trial, analyses of comparisons were solely exploratory and, although adjusting for multiple comparisons would avoid type I error, we were more interested in not inflating type II error for the purposes of informing which measures may be the most important to examine in a future fully powered trial. In addition, currently, the SOVA intervention is only in English, and therefore, we had to exclude any non–English-speaking participants. This did not lead to any exclusion in this study, and if we find effectiveness in a fully powered trial, we will pursue language and cultural adaptations of the intervention.

### Implications for Future Research

Although referrals to this pilot study were adequate, retention and engagement were lacking. For adolescents with mental health concerns, some of the same barriers to initiating mental health care, such as lack of motivation or lack of parental support, may also act as barriers to enrolling in research. For example, adolescents considering participation in HIV research may choose not to enroll because of stigma and requirements for parental consent [40]. For some sensitive issues, adolescent participation in research may not be possible without waiving parental permission [41]. During the trial, the recruitment rate actually increased after passing a waiver for parental permission and not requiring adolescents to enter the study as a dyad. This change is conceptually consistent, as adolescents who have poor communication with their parents are a SOVA target population but may be more difficult to recruit if parental permission is required. In addition, including a parental waiver more closely simulates real-world scenarios, as in almost half of the states of the United States [42] and about one-third of countries responding to a World Health Organization child policy survey [43], adolescents may provide consent for their own mental health care. We found during our study that, in fact, the research procedures were of minimal risk, which may help influence other ethics boards to approve similar waivers. On the contrary, a lack of parental enrollment may have negatively influenced retention and engagement.

The limitations of retention and engagement in this pilot trial are not necessarily a reflection of the intervention itself being difficult to engage with. Recently, we found that adolescents and young adults have been very interested in contributing content to SOVA sites [44,45], especially during the COVID-19 pandemic, during which social isolation increased in adolescents.

A different study design that does not require individual randomization would improve retention and engagement, as we would have the freedom to expose individuals to the intervention from the point of study recruitment, instead of requiring them to complete an initial lengthy survey before learning about whether they would be randomized to the intervention. Although a cluster trial design is more complex and resource intense, it would allow for clustering based on the primary care clinic as a unit. This clinic-based recruitment could have the added benefit of onboarding an entire primary care clinic with additional implementation strategies, as recommended by primary care providers participating in our preimplementation study [39]. In particular, this would include distributing materials about the intervention to all adolescents presenting to the practice, regardless of whether they enroll in the study. Viewing the intervention before enrollment may increase interest in the study and enhance engagement. Our target population included adolescents and parents who may be resistant to speaking to their primary care provider about mental health symptoms and answer a screen falsely to avoid such a conversation. Because of the study inclusion criteria necessitating referral to therapy, these adolescents may never be exposed to the intervention if there is individual randomization. Instead, in a cluster design, all adolescents and parents visiting the practice site would be provided information about SOVA. Recruitment and study initiation rates may be enhanced if all adolescents and parents know they will receive the intervention. We hypothesize that prior pilot trial recruitment would have been more successful if all knew they would receive the intervention, as during the recruitment and consent process, it was evident that they perceived the site as a potential benefit and were excited about using it but were disappointed when they knew they may not initially receive it. However, this design may limit evaluating immediate before and after changes in potential target mechanisms (ie, stigma and other barriers) if participant data are difficult to capture before the initial viewing of the site. However, we may still be able to capture a dose effect, and, importantly, we would be able to understand whether

practices in the intervention arm have improved the uptake of mental health treatment in adolescents with depression or anxiety as compared with treatment as usual.

## Conclusions

In conclusion, in this pilot trial of a peer support website intervention for adolescents with depression or anxiety, we found lower-than-expected study enrollment after recruitment. Although study retention may be limited by not requiring parental enrollment and parental permission, the tradeoff of enrolling adolescents who may have more difficulty seeking mental health services because of a lack of parental support may enhance generalizability and reach to the target population. Therefore, future trials will continue to waive parental permission but account for expected attrition from consent to randomization. We will also plan to use more engaging methods to reach adolescents, such as SMS text messaging as opposed to email, and incorporate automatic notifications. We will use a cluster trial design to increase the initial interest in the study intervention, as this may enhance intervention engagement from the start as compared with individual randomization. In addition, we found a signal for greater uptake of mental health treatment in adolescents using SOVA, a peer support website intervention for adolescents with depression or anxiety and their parents. We determined that our safety protocols were adequate and that no adverse events occurred. This pilot study informs a larger trial in planning for attrition, pairing-down salient measures, waiving parental permission, informing a protocol for increasing website engagement, and refining parameters for an automated EHR extraction.

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## Conflicts of Interest

EM receives royalties from Wolters Kluwer Inc for writing content for UpToDate not related to this work. AR serves on the scientific advisory board of Appa Health, which provided them with stock options. Their work and the work in this paper do not overlap and the author does not conduct research for them.

Multimedia Appendix 1
"Stress and Worry" Patient Handout.
[DOCX File , 14 KB - mental_v9i10e35313_app1.docx ]

Multimedia Appendix 2
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 3928 KB - mental_v9i10e35313_app2.pdf ]

Multimedia Appendix 3
Supplemental tables.
[DOCX File , 29 KB - mental_v9i10e35313_app3.docx ]

## References

1. Naicker K, Galambos NL, Zeng Y, Senthilselvan A, Colman I. Social, demographic, and health outcomes in the 10 years following adolescent depression. J Adolesc Health 2013 May;52(5):533-538. [doi: 10.1016/j.jadohealth.2012.12.016] [Medline: 23499382]
2. Keenan-Miller D, Hammen CL, Brennan PA. Health outcomes related to early adolescent depression. J Adolesc Health 2007 Sep;41(3):256-262 [FREE Full text] [doi: 10.1016/j.jadohealth.2007.03.015] [Medline: 17707295]
3. Katon W, Richardson L, Russo J, McCarty CA, Rockhill C, McCauley E, et al. Depressive symptoms in adolescence: the association with multiple health risk behaviors. Gen Hosp Psychiatry 2010;32(3):233-239 [FREE Full text] [doi: 10.1016/j.genhosppsych.2010.01.008] [Medline: 20430225]
4. Avenevoli S, Swendsen J, He JP, Burstein M, Merikangas KR. Major depression in the national comorbidity survey-adolescent supplement: prevalence, correlates, and treatment. J Am Acad Child Adolesc Psychiatry 2015 Jan;54(1):37-44.e2 [FREE Full text] [doi: 10.1016/j.jaac.2014.10.010] [Medline: 25524788]

5. Torio CM, Encinosa W, Berdahl T, McCormick MC, Simpson LA. Annual report on health care for children and youth in the United States: national estimates of cost, utilization and expenditures for children with mental health conditions. Acad Pediatr 2015;15(1):19-35. [doi: 10.1016/j.acap.2014.07.007] [Medline: 25444653]
6. National Survey on Drug Use and Health, 2016 and 2017. Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. 2018. URL: https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHDetailedTabs2017/NSDUHDetailedTabs2017.pdf [accessed 2021-10-12]
7. Whitney DG, Peterson MD. US national and state-level prevalence of mental health disorders and disparities of mental health care use in children. JAMA Pediatr 2019 Apr 01;173(4):389-391 [FREE Full text] [doi: 10.1001/jamapediatrics.2018.5399] [Medline: 30742204]
8. Fallucco EM, James L, Smotherman C, Greco P. Impact of experiential training with standardized patients on screening and diagnosis of adolescent depression in primary care. J Adolesc Health 2019 Jul;65(1):57-62. [doi: 10.1016/j.jadohealth.2018.12.022] [Medline: 30879884]
9. Hacker KA, Penfold R, Arsenault L, Zhang F, Murphy M, Wissow L. Screening for behavioral health issues in children enrolled in Massachusetts Medicaid. Pediatrics 2014 Jan;133(1):46-54 [FREE Full text] [doi: 10.1542/peds.2013-1180] [Medline: 24298005]
10. O'Connor BC, Lewandowski RE, Rodriguez S, Tinoco A, Gardner W, Hoagwood K, et al. Usual care for adolescent depression from symptom identification through treatment initiation. JAMA Pediatr 2016 Apr;170(4):373-380 [FREE Full text] [doi: 10.1001/jamapediatrics.2015.4158] [Medline: 26832387]
11. Breland DJ, McCarty CA, Zhou C, McCauley E, Rockhill C, Katon W, et al. Determinants of mental health service use among depressed adolescents. Gen Hosp Psychiatry 2014;36(3):296-301 [FREE Full text] [doi: 10.1016/j.genhosppsych.2013.12.003] [Medline: 24417955]
12. Hacker K, Arsenault L, Franco I, Shaligram D, Sidor M, Olfson M, et al. Referral and follow-up after mental health screening in commercially insured adolescents. J Adolesc Health 2014 Jul;55(1):17-23. [doi: 10.1016/j.jadohealth.2013.12.012] [Medline: 24525226]
13. SOVA - Supporting Our Valued Adolescents: A place to learn, share your strength, be positive, and grow. SOVA. URL: http://sova.pitt.edu/ [accessed 2021-11-30]
14. Parents Supporting Our Valued Adolescents: A place to learn, get your questions answered, share your strength, and be positive. WiseSOVA. URL: https://wisesova.pitt.edu/ [accessed 2021-11-30]
15. Radovic A, Li Y, Landsittel D, Stein BD, Miller E. A social media website (supporting our valued adolescents) to support treatment uptake for adolescents with depression and/or anxiety and their parents: protocol for a pilot randomized controlled trial. JMIR Res Protoc 2019 Jan 23;8(1):e12117 [FREE Full text] [doi: 10.2196/12117] [Medline: 30672741]
16. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med 2001 Sep;16(9):606-613 [FREE Full text] [doi: 10.1046/j.1525-1497.2001.016009606.x] [Medline: 11556941]
17. Mossman SA, Luft MJ, Schroeder HK, Varney ST, Fleck DE, Barzman DH, et al. The Generalized Anxiety Disorder 7-item scale in adolescents with generalized anxiety disorder: signal detection and validation. Ann Clin Psychiatry 2017 Nov;29(4):227-34A [FREE Full text] [Medline: 29069107]
18. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009 Apr;42(2):377-381 [FREE Full text] [doi: 10.1016/j.jbi.2008.08.010] [Medline: 18929686]
19. Radovic A, DeMand AL, Gmelin T, Stein BD, Miller E. SOVA: design of a stakeholder informed social media website for depressed adolescents and their parents. J Technol Hum Serv 2018;35(3):169-182 [FREE Full text] [doi: 10.1080/15228835.2017.1347552] [Medline: 29743822]
20. Radovic A, Gmelin T, Hua J, Long C, Stein BD, Miller E. Supporting Our Valued Adolescents (SOVA), a social media website for adolescents with depression and/or anxiety: technological feasibility, usability, and acceptability study. JMIR Ment Health 2018 Feb 26;5(1):e17 [FREE Full text] [doi: 10.2196/mental.9441] [Medline: 29483067]
21. Windler C, Clair M, Long C, Boyle L, Radovic A. Role of moderators on engagement of adolescents with depression or anxiety in a social media intervention: content analysis of Web-based interactions. JMIR Ment Health 2019 Sep 26;6(9):e13467 [FREE Full text] [doi: 10.2196/13467] [Medline: 31573923]
22. Peters KM, Sadler G, Miller E, Radovic A. An electronic referral and social work protocol to improve access to mental health services. Pediatrics 2018 Nov;142(5):e20172417. [doi: 10.1542/peds.2017-2417] [Medline: 30282783]
23. Griffiths KM, Christensen H, Jorm AF, Evans K, Groves C. Effect of Web-based depression literacy and cognitive-behavioural therapy interventions on stigmatising attitudes to depression: randomised controlled trial. Br J Psychiatry 2004 Oct;185:342-349. [doi: 10.1192/bjp.185.4.342] [Medline: 15458995]
24. Cohane GH. Psychological barriers to antidepressant use in adolescents. Clark University. 2008 Oct. URL: https://www.proquest.com/openview/a7426c186edd01eab72d358407cf6407/1.pdf?pq-origsite=gscholar&cbl=18750&diss=y [accessed 2022-10-03]
25. Kuhl J, Jarkon-Horlick L, Morrissey RF. Measuring barriers to help-seeking behavior in adolescents. J Youth Adolesc 1997 Dec;26(6):637-650. [doi: 10.1023/A:1022367807715]

26. Gulliver A, Griffiths KM, Christensen H, Mackinnon A, Calear AL, Parsons A, et al. Internet-based interventions to promote mental health help-seeking in elite athletes: an exploratory randomized controlled trial. J Med Internet Res 2012 Jun 29;14(3):e69 [FREE Full text] [doi: 10.2196/jmir.1864] [Medline: 22743352]
27. Sherbourne CD, Stewart AL. The MOS social support survey. Soc Sci Med 1991;32(6):705-714. [doi: 10.1016/0277-9536(91)90150-b] [Medline: 2035047]
28. Barnes H, Olson DH. Parent-adolescent communication scale. In: Olson DH, McCubbin HI, Barnes HL, Larsen A, Muxen M, Wilson M, editors. Family Inventories : Inventories Used in a National Survey of Families Across The Family Life Cycle. St. Paul, MN, USA: Family Social Science, University of Minnesota; 1982:33-48.
29. Wu P, Hoven CW, Cohen P, Liu X, Moore RE, Tiet Q, et al. Factors associated with use of mental health services for depression by children and adolescents. Psychiatr Serv 2001 Feb;52(2):189-195. [doi: 10.1176/appi.ps.52.2.189] [Medline: 11157117]
30. McNab C, Meadows G. Brief assessment of perceived need for mental health care - development of an instrument for primary care use. Monash University. 2004. URL: http://www.med.monash.edu.au/assets/docs/scs/psychiatry/gupi-report.pdf [accessed 2021-10-12]
31. Richardson LP, McCauley E, Grossman DC, McCarty CA, Richards J, Russo JE, et al. Evaluation of the Patient Health Questionnaire-9 Item for detecting major depression among adolescents. Pediatrics 2010 Dec;126(6):1117-1123 [FREE Full text] [doi: 10.1542/peds.2010-0852] [Medline: 21041282]
32. Wardenaar KJ, Wigman JT, Lin A, Killackey E, Collip D, Wood SJ, et al. Development and validation of a new measure of everyday adolescent functioning: the multidimensional adolescent functioning scale. J Adolesc Health 2013 Feb;52(2):195-200. [doi: 10.1016/j.jadohealth.2012.06.021] [Medline: 23332484]
33. Bird HR, Shaffer D, Fisher P, Gould MS. The Columbia Impairment Scale (CIS): pilot findings on a measure of global impairment for children and adolescents. Int J Methods Psychiatr Res 1993;3(3):167-176.
34. Williams KA, Chapman MV. Unmet health and mental health need among adolescents: the roles of sexual minority status and child-parent connectedness. Am J Orthopsychiatry 2012 Oct;82(4):473-481. [doi: 10.1111/j.1939-0025.2012.01182.x] [Medline: 23039345]
35. Rickwood DJ, Braithwaite VA. Social-psychological factors affecting help-seeking for emotional problems. Soc Sci Med 1994 Aug;39(4):563-572. [doi: 10.1016/0277-9536(94)90099-x] [Medline: 7973856]
36. Wilson CJ, Deane FP, Ciarrochi JV, Rickwood D. Measuring help seeking intentions: properties of the General Help Seeking Questionnaire. University of Wollongong. 2005. URL: https://ro.uow.edu.au/cgi/viewcontent.cgi?referer=&httpsredir=1&article=2580&context=hbspapers [accessed 2021-10-12]
37. Carlton PA, Deane FP. Impact of attitudes and suicidal ideation on adolescents' intentions to seek professional psychological help. J Adolesc 2000 Feb;23(1):35-45. [doi: 10.1006/jado.1999.0299] [Medline: 10700370]
38. Adler N, Stewart J, Group PW. Research/psychosocial notebook: Research Network on SES and Health. MacArthur SES & Health Network. 2007. URL: https://publications.aap.org/pediatrics/article-abstract/108/2/e31/63665/Adolescents-Perceptions-of-Social-Status?redirectedFrom=fulltext [accessed 2018-01-24]
39. Radovic A, Odenthal K, Flores AT, Miller E, Stein BD. Prescribing technology to increase uptake of depression treatment in primary care: a pre-implementation focus group study of SOVA (Supporting Our Valued Adolescents). J Clin Psychol Med Settings 2020 Dec;27(4):766-782 [FREE Full text] [doi: 10.1007/s10880-019-09669-5] [Medline: 31630347]
40. DiClemente RJ, Ruiz MS, Sales JM. Barriers to adolescents' participation in HIV biomedical prevention research. J Acquir Immune Defic Syndr 2010 Jul;54 Suppl 1:S12-S17 [FREE Full text] [doi: 10.1097/QAI.0b013e3181e1e2c0] [Medline: 20571418]
41. Macapagal K, Coventry R, Arbeit MR, Fisher CB, Mustanski B. "I won't out myself just to do a survey": sexual and gender minority adolescents' perspectives on the risks and benefits of sex research. Arch Sex Behav 2017 Jul;46(5):1393-1409 [FREE Full text] [doi: 10.1007/s10508-016-0784-5] [Medline: 27469352]
42. Boonstra HD, Nash E. Minors and the Right to Consent to Health Care. Guttmacher Institute. 2000 Aug 1. URL: https://www.guttmacher.org/gpr/2000/08/minors-and-right-consent-health-care [accessed 2021-10-12]
43. Legal age for unmarried adolescents to provide consent for mental health services without parental/legal guardian consent. World Health Organization. URL: https://www.who.int/data/gho/indicator-metadata-registry/imr-details/legal-age-for-unmarried-adolescents-to-provide-consent-for-mental-health-services-without-parental-legal-guardian-consent [accessed 2021-10-12]
44. Bickerstaff JM, Karim S, Whitman RK, Cypher A, Wiener S, Radovic A. "You have people here to help you, people like me." A qualitative analysis of a blogging intervention for adolescents and young adults with depression or anxiety. J Technol Behav Sci 2021 Dec;6(4):578-588. [doi: 10.1007/s41347-021-00210-w] [Medline: 34926793]
45. Karim S, Hsiung K, Symonds M, Radovic A. Experience of peer bloggers using a social media website for adolescents with depression or anxiety: proof-of-concept study. JMIR Form Res 2021 Jul 22;5(7):e26183 [FREE Full text] [doi: 10.2196/26183] [Medline: 34292161]

## Abbreviations

**AHCP:** adolescent health care provider
**CONSORT:** Consolidated Standards of Reporting Trials
**EHR:** electronic health record
**EUC:** enhanced usual care
**GAD-7:** Generalized Anxiety Disorder Questionnaire-7
**PHQ-9:** Patient Health Questionnaire-9
**RA:** research assistant
**REDCap:** Research Electronic Data Capture
**SOVA:** Supporting Our Valued Adolescents

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Original Paper

# A Digital Mental Health Intervention (Inuka) for Common Mental Health Disorders in Zimbabwean Adults in Response to the COVID-19 Pandemic: Feasibility and Acceptability Pilot Study

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## Abstract

**Background:** Common mental health disorders (CMDs) are leading causes of disability globally. The ongoing COVID-19 pandemic has further exacerbated the burden of CMDs. COVID-19 containment measures, including lockdowns, have disrupted access to in-person mental health care. It is therefore imperative to explore the utility of digital mental health interventions to bridge the treatment gap. Mobile health technologies are effective tools for increasing access to treatment at a lower cost. This study explores the utility of Inuka, a chat-based app hinged on the Friendship Bench problem-solving therapy intervention. The Inuka app offers double anonymity, and clients can book or cancel a session at their convenience. Inuka services can be accessed either through a mobile app or the web.

**Objective:** We aimed to explore the feasibility of conducting a future clinical trial. Additionally, we evaluated the feasibility, acceptability, appropriateness, scalability, and preliminary effectiveness of Inuka.

**Methods:** Data were collected using concurrent mixed methods. We used a pragmatic quasiexperimental design to compare the feasibility, acceptability, and preliminary clinical effectiveness of Inuka (experimental group) and WhatsApp chat-based counseling (control). Participants received 6 problem-solving therapy sessions delivered by lay counselors. A reduction in CMDs was the primary clinical outcome. The secondary outcomes were health-related quality of life (HRQoL), disability and functioning, and social support. Quantitative outcomes were analyzed using descriptive and bivariate statistics. Finally, we used administrative data and semistructured interviews to gather data on acceptability and feasibility; this was analyzed using thematic analysis.

**Results:** Altogether, 258 participants were screened over 6 months, with 202 assessed for eligibility, and 176 participants were included in the study (recruitment ratio of 29 participants/month). The participants' mean age was 24.4 (SD 5.3) years, and most participants were female and had tertiary education. The mean daily smartphone usage was 8 (SD 3.5) hours. Eighty-three users signed up and completed at least one session. The average completion rate was 3 out of 4 sessions. Inuka was deemed feasible and acceptable in the local context, with connectivity challenges, app instability, expensive mobile data, and power outages cited

as potential barriers to scale up. Generally, there was a decline in CMDs ($F_{2,73}$=2.63; $P$=.08), depression ($F_{2,73}$=7.67; $P$<.001), and anxiety ($F_{2,73}$=2.95; $P$=.06) and a corresponding increase in HRQoL ($F_{2,73}$=7.287; $P$<.001) in both groups.

**Conclusions:** Study outcomes showed that it is feasible to run a future large-scale randomized clinical trial (RCT) and lend support to the feasibility and acceptability of Inuka, including evidence of preliminary effectiveness. The app's double anonymity and structured support were the most salient features. There is a great need for iterative app updates before scaling up. Finally, a large-scale hybrid RCT with a longer follow-up to evaluate the clinical implementation and cost-effectiveness of the app is needed.

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**KEYWORDS**

acceptability; COVID-19; feasibility; Friendship Bench; Inuka; pilot; task-shifting; Zimbabwe

## Introduction

Common mental health disorders (CMDs) are leading causes of disability-adjusted life years, with more than a billion people having mental disorders globally [1,2]. The burden of CMDs is disproportionately large in low-resourced settings, with 1 in every 4 people at risk of having a CMD in a lifetime [3]. Globally, the burden of mental disorders has invariably increased due to the ongoing COVID-19 pandemic [4]. The absence of social safety nets, and the presence of poverty, food insecurity, impairment of social and occupational functioning (eg, loss of income and recreation opportunities), and uncertainty have predisposed the Zimbabwean population to poor mental health as in other low-resourced settings [5,6]. The World Bank projects a global recession after the COVID-19 pandemic [7]. The economic effects could further shrink the Zimbabwean economy, predisposing the majority of the population to greater poverty [5]. Poverty has been linked to poor mental health functioning, thus creating a vicious cycle [7]. Unfortunately, if untreated, CMDs may lead to poor daily functioning, economic losses due to lost productivity at work, risky sexual behaviors, substance misuse, relationship instability, suicidal ideation, and increased health care resource use, which can further pressure fragile health care systems [8-10].

Despite the high burden of CMDs, a vast gap in mental health care exists in low-resourced settings. The general population is unlikely to seek mental health services due to various environmental and personal factors [8,10-12]. First, the stigmatization of mental health services is a salient barrier to mental health seeking and use behaviors [10-13]. Second, the general population may not inherently recognize the need for mental health care [10,11]. For example, due to low mental health literacy, the general population may perceive CMD symptoms as normal pressure associated with adulthood and thus may not actively seek treatment [10,11]. Third, not all communities have functional mechanisms for the early screening, detection, referral, and treatment of CMDs [11]. Like other low-income countries, mental health care has not been prioritized in Zimbabwe, leading to a substantial care gap further exacerbated by COVID-19 [14]. Fourth, numerous competing health and social needs (eg, COVID-19, HIV/AIDS, and maternal and child health programs) coupled with a shortage of trained mental health professionals (eg, clinical psychologists, occupational therapists, and psychiatrists) are salient barriers to the provision of mental health services [14,15]. Considering these inhibitive factors, it is important to explore alternative ways to provide mental health services to the general population, which address public stigma and increase access at a lower cost.

The Friendship Bench, a task shifting–based intervention, evolved as an innovation to reduce the mental health care gap in resource-constrained settings [14]. Task shifting entails redistributing less complicated tasks to less-qualified cadres to increase care coverage and mitigate human resource gaps [16]. For instance, in the absence of trained mental health care practitioners, the World Health Organization (WHO) recommends the assignment of lay counselors to provide mental health care services under the supervision of higher-level cadres (eg, psychiatrists) [16]. The Friendship Bench uses lay counselors who are primarily community volunteers without expert training in health care; they are trained to provide basic health promotion, including immunizations [14,15]. Trained lay counselors provide mental health services using 6 sessions of problem-solving therapy (PST). The Friendship Bench intervention is a proven evidence-based intervention found to reduce CMDs among adults attending primary health care clinics and has been adopted internationally and as a Zimbabwean national treatment/care model [14,15]. As part of efforts to scale up the intervention, the Friendship Bench is exploring the utility of multiple modal intervention delivery methods. For example, Friendship Bench uses the WhatsApp platform and telephone calls to deliver therapy sessions. Exploring alternatives to physical (in-person) psychosocial interventions is paramount, given the ongoing COVID-19 pandemic. The impending public health catastrophe requires a proactive approach to mental health service provision.

Systematic reviews have demonstrated the effectiveness of mobile- and web-based applications for treating CMDs in the general population [9,10,13,17]. Zimbabwe has recently seen an exponential increase in digital penetration. The general population has access to digital devices (eg, smartphones, tablet devices, and personal laptops) and the internet, and up to 90% of Zimbabweans own a smartphone [7]. High digital penetration is an essential predictor of the utility of digital mental health services [9-11,13,17]. Considering the potential reach of digital mental health interventions, it is vital to identify and evaluate the feasibility and scalability of mobile health (mHealth) technologies, given resource limitations in low-to-middle income countries. Inuka, a digital-based mental well-being service, is potentially low-hanging fruit for increasing mental health care coverage. The Inuka app transferred the Friendship Bench

intervention to a digital setting to make the service more accessible and scalable [18]. Chat-based mental health care services have been found to lower barriers to seeking support from the general population and increase active/effective help-seeking behavior [12]. Like physical Friendship Bench sessions, in Inuka, therapy is provided by lay counselors using PST. Unlike physical Friendship Bench sessions, in Inuka, clients can book or cancel appointments at their convenience. Further, the Inuka app requires low bandwidth, offers prospective users complete anonymity, and has been tested in Kenya, a country with an almost similar sociodemographic profile to Zimbabwe [18]. In the Kenyan pilot cohort study (N=60), participants showed significantly declined psychiatric morbidity after 4 sessions [18]. Further, most participants perceived the Inuka app to be very helpful in dealing with stressful conditions (n=38, 69%), reported that sessions met their needs (n=27, 49%), and rated the program as excellent (n=36, 66%) [18]. Although preliminary evidence is promising, there is a need to explore the multilevel factors influencing the feasibility of implementing Inuka in a different context [19]. For instance, connectivity challenges, power outages, and local perceptions of mental health interventions may affect the uptake, feasibility, and acceptability of mHealth solutions in Zimbabwe. Moreover, the Kenyan pilot study was clinic based, limiting our understanding of the implementability of the services outside primary health care settings. It is also vital to glean data on users' experiences to inform the digital intervention's feasibility and acceptability, using qualitative and quantitative methods. Finally, there is a great need to evaluate the effectiveness of mHealth interventions in low-resource settings using randomized clinical trials (RCTs) [20]. However, mHealth interventions are still in infancy in low-resource settings, and pilot studies are required to assess the feasibility of conducting future clinical trials. Therefore, the study sought to address the following objectives: (1) to assess the feasibility of a large-scale clinical trial by exploring the feasibility of randomization, recruitment rate, and retention rate; (2) to explore the feasibility, acceptability, appropriateness, and scalability of the Inuka intervention for providing mental health care in the Zimbabwean general population; (3) to evaluate the preliminary clinical effectiveness of the Inuka app for improving the general population's mental health compared with the WhatsApp intervention.

## Methods

### Design

Concurrent mixed methods were used to simultaneously glean data on implementation-related parameters (feasibility and acceptability) and preliminary clinical effectiveness [21]. A pragmatic nonequivalent control group quasiexperimental design [22] was used, with the Inuka intervention arm being the experimental group and the WhatsApp intervention arm being the control group. In line with the pragmatic design adopted, participants were assigned to either Inuka or WhatsApp PST counseling sessions, depending on preference and bandwidth/connectivity stability. In response to physical/social distancing measures to mitigate the effects of the COVID-19 pandemic, this study aims to pilot test digital Friendship Bench interventions (Inuka and WhatsApp) in the general population under realistic conditions. We want to understand how the 2 interventions may best be implemented. The "classical/in-person" Friendship Bench intervention has demonstrated effectiveness. It was assumed that both Inuka and WhatsApp counseling would be equally effective in improving the mental health of the general population. Semistructured interviews were used to gather data on aspects of implementation.

### Participants

The inclusion criteria for participation were as follows: age of 18 years or older; score of 9 or more on the Shona Symptoms Questionnaire (SSQ), a locally validated screening tool for CMDs with good psychometric properties [14]; and access to a smartphone/tablet or a laptop/desktop computer. People were excluded from the study if they were receiving specialist mental health care at the point of recruitment and had known psychiatric conditions such as major depression.

### Interventions

There were 2 treatment arms. The experimental intervention consisted of the Inuka intervention, a digital chat-based mental health application [18]. The control intervention consisted of the Friendship Bench WhatsApp intervention (see Multimedia Appendix 1 for more information on the Inuka intervention). Both interventions consisted of 6 PST sessions. Session 1 involves identifying possible stressors and ranking them in the order of priority. Sessions 2 to 5 involve developing context-specific and need-driven solutions. Finally, session 6 involves reviewing the client's progress. Interventions across both arms were delivered by nonspecialist lay counselors/peers trained to deliver PST. Lay counselors consisted of young adults aged 18 to 25 years. Sessions across both interventions were chat based. However, those allocated to the control arm also had an option of voice notes on WhatsApp. For quality assurances, trained clinical psychologists and psychiatrists supervised lay counselors from both arms to ensure fidelity to the therapy/intervention.

### Procedure

We advertised the pilot study through the Friendship Bench website [23] and social media (ie, Facebook, WhatsApp, Instagram, and Twitter). Prospective participants filled out a sign-up form by entering their email address and phone number or sending a text or WhatsApp message to the Friendship Bench customer care number. All contact details were forwarded to the principal investigator (PI) to initiate contact with potential participants. Two research assistants (RAs) followed up with all prospective participants within 30 minutes of receiving an inquiry through a phone call. The RAs briefly described the study and assessed clients for eligibility. Eligible participants were then sent consent forms, and return was expected within 48 hours. The RAs followed up with nonresponders 48 hours from when consent forms were sent out. After consenting to participation, clients were given the option to choose the Inuka or WhatsApp intervention depending on their preference and the stability of the internet connection. Participants choosing WhatsApp were asked their preferred date and time for their

first session. The preferred times were relayed to the Friendship Bench customer care unit. Bookings were only finalized after cross-checking with the client.

For participants choosing Inuka, the RAs briefly explained the sign-up process and thereafter sent the client a registration link and step-by-step guide for the signing-up process. Participants could either sign-up independently or be assisted by the RAs. For Inuka, clients only enter their phone number and email address. The system creates a pseudonym to enable anonymity. The phone number is captured for follow-ups, with only the administrators accessing the client credentials. Both the client and the counselor are blinded to the other entities' phone numbers, and communication is only done through the app. Clients can, however, send offline messages between sessions. Upon signing up, the system sends a client an email confirming the date, time, and name of the counselor; the session calendar file; and a link to download the app. Participants were encouraged to download and install the app, and sign in using their sign-up details. Inuka can either be accessed through a browser or the app. The app is currently available for Android users only; an iOS app version is under development. Upon consulting various stakeholders (clinicians, lay counselors, service users, and app developers), it was deemed essential to first develop the Android version of the Inuka app. The Android platform dominates the smartphone market in low-income countries. From the administrative back end, the PI had access to the list of all clients who had signed up. The list was shared with RAs who followed up with clients to book an appointment to collect baseline measures. Please refer to Multimedia Appendix 1 for a graphic illustration of the Inuka app. Finally, all baseline data collection was performed before the first session across the groups.

## Outcomes

### *Future Clinical Trial Feasibility*

To measure the feasibility of a future clinical trial, we collected data on the following feasibility indicators: (1) willingness to be randomized, (2) recruitment rate and source, (3) recruitment fidelity, (4) eligibility and consent rates, and (5) attrition rates.

### *Implementation Parameters*

We used the Consolidated Framework for Implementation Research (CFIR) [24] to identify and conceptualize the implementation parameters. We assessed the feasibility, acceptability, appropriateness, adoption/uptake, and fidelity of Inuka services. Additionally, we used the mHealth App Usability Questionnaire (MAUQ) to measure lay counselors' satisfaction with the Inuka app. The MAUQ is a psychometrically robust 20-item tool for assessing user experiences with mHealth technologies [25]. User experiences and perceptions are evaluated under 4 domains (ie, engagement/interactivity, ease of use, esthetics, and information quality). Items are scored on a 5-point Likert scale, giving scores in the range of 20 to 100, with higher scores indicating greater usability and usefulness [25]. Table 1 outlines the definitions and operationalization of implementation indicators, including the evaluation methodology.

**Table 1.** Implementation parameters.

| Domain | Working definition | Operationalization/indicators | Methods | Stage |
|---|---|---|---|---|
| Feasibility of implementation | The extent to which an innovation (Inuka) can be successfully used to provide mental health services in the Zimbabwean general population. | ● Patients' experiences with the Inuka platform (ie, ease of use of the platform).<br>● Administrators' and lay counselors' experiences in rolling out the digital app. | ● Semistructured interviews with the general population, lay counselors, and administrators<br>● Mobile Application Rating Scale (MAUQ) scores [25]<br>● Administrative data | Postimplementation |
| Acceptability | The extent of satisfaction with the complexity, comfort, and delivery of digital mental health care through Inuka. | ● General population's degree of comfort in receiving mental health care through Inuka.<br>● The quality of the session and user satisfaction are automatically measured inside the app. After every session, users are asked to rate the session's quality on a scale of 0 to 5 stars (commonly used in online and app settings).<br>● The perceptions of lay counselors toward providing mental health services to the general population digitally.<br>● The perceived complexity of digital mental health provision (Inuka) by administrators and lay counselors. | ● Semistructured interviews with the general population, lay counselors, and administrators<br>● MAUQ scores [25] | Preimplementation and postimplementation |
| Appropriateness | The perceived fit, relevance, or compatibility of digital mental services in the Zimbabwean context to address the huge burden of common mental health disorders in the Zimbabwean general population. | ● Is Inuka consummate with lay counselors' roles or job expectations?<br>● Is accessing mental services through Inuka appropriate given the differences in technology familiarity and access by the Zimbabwean general population? | ● Semistructured interviews with the general population<br>● Semistructured interviews or focus group discussions with administrators<br>● MAUQ scores [25] | Preimplementation and postimplementation |
| Fidelity | The extent to which the Inuka intervention (ie, problem-solving approach) protocol is adhered to. | ● Are the same procedures being followed in providing mental health services through Inuka?<br>● Is the treatment algorithm being followed as per the protocol? | ● Semistructured interviews with lay counselors, administrators, and supervisors<br>● Interviews with the general population<br>● Review of session transcripts<br>● Review of lay counselors' ratings | Midimplementation and postimplementation |

### *Mental Health Outcomes*

#### Primary Clinical Outcomes

A reduction in CMDs was the primary clinical outcome, and this was measured using the SSQ [14], Patient Health Questionnaire-9 (PHQ-9) [26], and Generalized Anxiety Disorder-7 scale (GAD-7) [27]. All outcome measures have been validated and used extensively in Zimbabwe. The SSQ is a binary (yes/no), 14-item, native Zimbabwean anxiety and depression screener [14]. Scores range from 0 to 14, with scores ≥9 regarded as indicating psychiatric morbidity. The PHQ-9 (9 items) and GAD-7 (7 items) are generic depression and anxiety screeners, respectively [27,28]. On both scales, respondents rate the frequency of the experience of enlisted depressive or anxiety symptoms in the previous 2 weeks on a 4-point Likert scale, ranging from "not at all" (0) to "all the time" (3) to give a cumulative score ranging from 0 to 27 and 0 to 21 for the PHQ-9 and GAD-7, respectively. PHQ-9 scores of 0-9, 15-19, and 20-27 are considered to indicate minor, moderate, and severe

depression, respectively [26]. For GAD-7, the criteria values for low, moderate, and severe anxiety are 5, 10, and 15, respectively [27].

### Secondary Clinical Outcomes

Health-related quality of life **(**HRQoL), disability and functioning, and social support were the secondary outcomes, and these were measured using the EuroQol-5 dimensions (EQ-5D), WHO Disability Assessment Schedule (WHODAS), and multidimensional scale of perceived social support (MSPSS), respectively. The EQ-5D is a generic self-report HRQoL outcome measure [29]. Respondents rate challenges with mobility, self-care, usual activities, pain/discomfort, and anxiety/depression on a 3-point scale. Participants also rate their health on a visual analog scale that ranges from 0 to 100, with higher scores indicating higher perceived HRQoL. Normative utility scores are available for the Zimbabwean population [29]. The WHODAS 2.0 is a brief (12 items) and extensively used generic disability and function outcome measure [30]. It consists of 6 domains (ie, cognition, mobility, self-care, socialization ability, life activities, and community participation), with higher scores indicating greater disability [30]. The MSPSS is an extensively used and psychometrically robust social support outcome measure. Social support sources are categorized as family, friends, and significant others, with 4 items per domain [31]. The scores range from 12 to 36, with higher scores indicating greater social support [32].

### Sample Size

Although formal sample size calculations are not obligatory for pilot studies [33], we sought to recruit 102 participants. Based on the Friendship Bench intervention efficacy evaluation study [14], assuming a 6.7 reduction in SSQ scores after the intervention ($\mu_0$=10.5, SD 1.4 and $\mu_1$=3.8, 95% CI 3.3-4.3), the expected minimum number of cases per group was 51 at 95% CI, 90% goal power (β), and anticipated 9% loss to follow-up.

### Analytical Methods

We used descriptive statistics to report the sociodemographic characteristics of the study population. The Shapiro-Wilks test was used to test for the normality of all data before using either parametric tests (eg, *t* tests) or nonparametric tests (eg, Mann-Whitney *U* test). We used the chi-squared test for binary outcomes and the *t* test for continuous outcomes. For all tests, the level was set at $\alpha \leq .005$. Quantitative analyses were performed using SPSS (Version 25.2; IBM Corp) and Stata (Version 16; StataCorp). Implementation parameters were assessed at the cluster and individual levels using mixed methods. Acceptability and appropriateness were assessed preimplementation and postimplementation. Feasibility, adoption/uptake, and fidelity were assessed postimplementation (Table 1). Qualitative data were analyzed using an inductive thematic analysis with the CFIR as a reference frame [24].

### Ethical Considerations

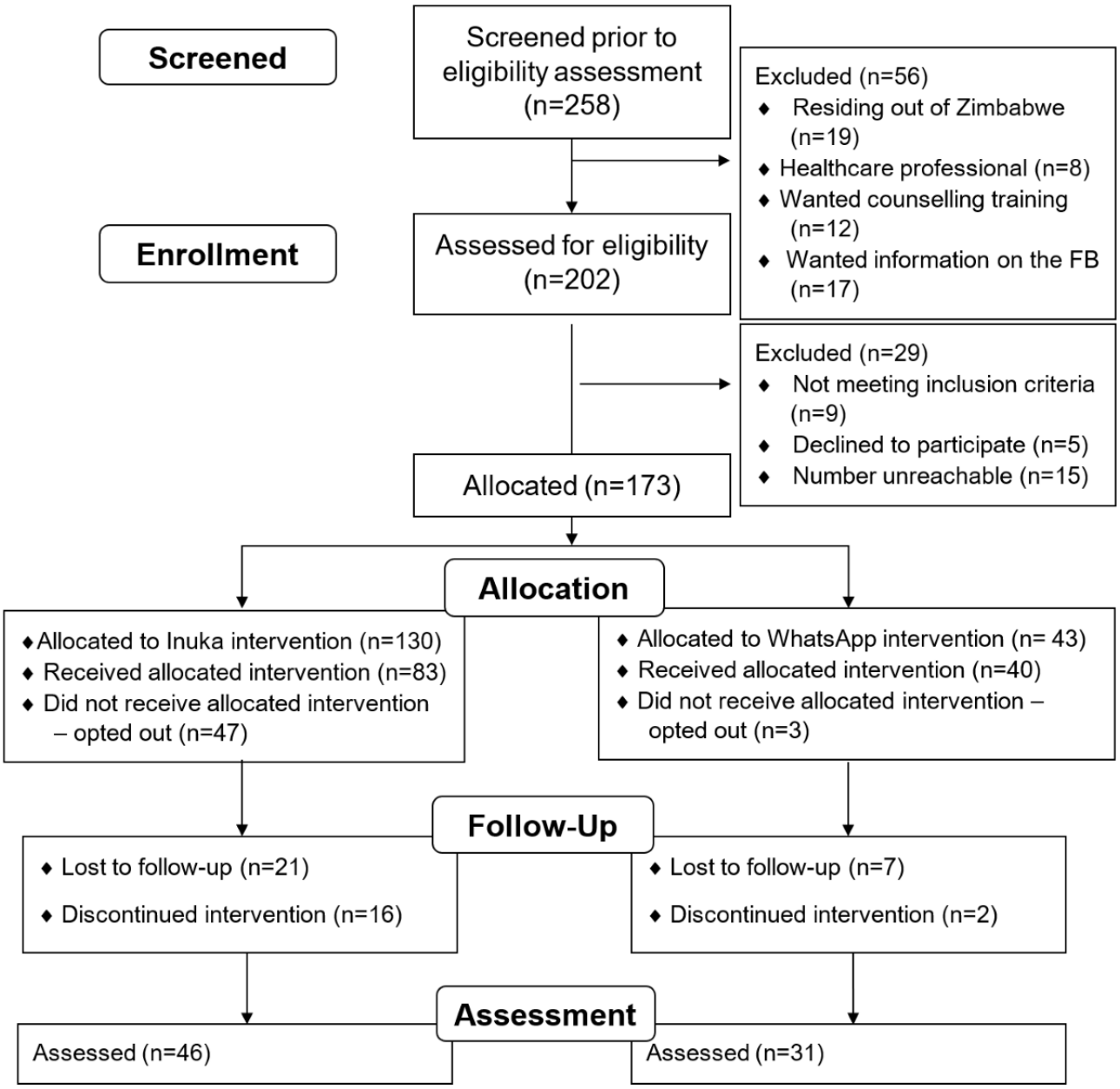
The study was approved by the Medical Research Council of Zimbabwe (MRCZ/A/2566). Participants were treated as autonomous agents and participated in the study voluntarily. Participants either gave written or verbal consent before participating in the study. All participants were assigned a numeric code, and data were deidentified before analysis. Only the PI and technical support staff had access to the database with identifiable information that included contact numbers and email addresses. Moreover, participants were appropriately referred for further clinical management whenever necessary. Cases reporting suicidal ideation or hallucinations were immediately referred for further evaluation and treatment by clinical psychologists and psychiatrists.

## Results

### Participant Flowchart

Figure 1 shows the participant flowchart, that is, the number of participants screened, enrolled, allocated to interventions, lost to follow-up, and analyzed. Altogether, 258 participants were screened over 6 months, with 202 assessed for eligibility, and 173 people who met the inclusion criteria were assigned to either the experimental arm (n=130) or the control arm (n=43), resulting in the recruitment of 29 participants per month (Figure 1). Eventually, 76 participants were assessed.

**Figure 1.** Participants' characteristics.




## Participant Characteristics

As seen in Table 2, the mean age of the participants was 24.4 (SD 5.3) years. Most participants were female (50/76, 66%), were enrolled in or had completed tertiary education (42/76, 55%), never married (53/76, 70%), were unemployed/students (49/76, 64%), and reported financial inadequacy (33/76, 43%) and food insecurity (32/76, 42%). Moreover, most participants had not been hospitalized in the past month (65/76, 86%) and did not experience an adverse event (42/76, 55%). The mean daily smartphone usage was 8 (SD 3.5) hours. Smartphones were mainly used for social media (75/76, 99%), communication (74/76, 97%), and academic work (56/76, 74%). Overall, the groups were comparable at baseline, except for employment status ($\chi^2_3$=7.80; *P*=.05). There were more students in the WhatsApp group than in the Inuka group (17/31, 55% vs 11/45, 24%).

**Table 2.** Participant characteristics (N=76).

| Variable | Inuka group (n=45) | WhatsApp group (n=31) | Total (N=76) | Statistic, $\chi^2$ or *t* value (df) | *P* value |
|---|---|---|---|---|---|
| **Gender, n (%)** | | | | 0.296[a,b] (1) | .59 |
| Female | 28 (62) | 22 (71) | 50 (66) | | |
| Male | 17 (38) | 9 (29) | 26 (34) | | |
| Age, mean (SD) | 25.2 (6.0) | 23.2 (4.0) | 24 (5) | 1.629[c] (74) | .11 |
| **Educational level, n (%)** | | | | 0.587[a,b] (1) | .44 |
| Secondary | 18 (40) | 16 (52) | 34 (45) | | |
| Tertiary | 27 (60) | 15 (48) | 42 (55) | | |
| **Marital status, n (%)** | | | | 1.762[a] (2) | .41 |
| Currently married | 8 (18) | 5 (16) | 13 (17) | | |
| Never married | 33 (73) | 20 (65) | 53 (70) | | |
| Other | 4 (9) | 6 (19) | 10 (13) | | |
| **Employment status, n (%)** | | | | 7.799[a] (3) | .05 |
| Formal | 9 (20) | 5 (16) | 14 (18) | | |
| Informal | 9 (20) | 4 (13) | 13 (17) | | |
| Student | 11 (24) | 17 (55) | 28 (37) | | |
| Unemployed | 16 (36) | 5 (16) | 21 (28) | | |
| **Financial adequacy, n (%)** | | | | 1.646 (4)[a] | .88 |
| Very inadequate | 2 (4) | 0 (0) | 2 (3) | | |
| Inadequate | 18 (40) | 13 (42) | 31 (41) | | |
| Somewhat adequate | 17 (38) | 11 (36) | 28 (37) | | |
| Adequate | 7 (16) | 6 (19) | 13 (17) | | |
| Very adequate | 1 (2) | 1 (3) | 2 (3) | | |
| **Food security, n (%)** | | | | 3.984[a] (3) | .26 |
| Inadequate | 3 (7) | 5 (16) | 8 (11) | | |
| Somewhat adequate | 13 (29) | 11 (36) | 24 (32) | | |
| Adequate | 19 (42) | 7 (23) | 26 (34) | | |
| Very adequate | 10 (22) | 8 (26) | 18 (24) | | |
| **Hospital admission, n (%)** | | | | 0.000[a,b] (1) | .99 |
| No | 39 (87) | 26 (84) | 65 (86) | | |
| Yes | 6 (13) | 5 (16) | 11 (15) | | |
| **Adverse event, n (%)** | | | | 0.088[a,b] (1) | .77 |
| No | 26 (58) | 16 (52) | 42 (55) | | |
| Yes | 19 (42) | 15 (48) | 34 (45) | | |
| Smartphone usage in hours, mean (SD) | 8.7 (4.0) | 8.8 (2.6) | 8.8 (3.5) | −0.130[c] (74) | .90 |
| **Main smartphone usage function, n (%)** | | | | 1.027[a] (3) | .80 |
| Social media | 44 (98) | 31 (100) | 75 (99) | | |
| Academic work | 37 (82) | 19 (61) | 56 (74) | | |
| Communication | 43 (96) | 31 (100) | 74 (97) | | |
| Other | 10 (22) | 7 (23) | 17 (22) | | |

[a]$\chi^2$ value.
[b]With Yates' correction of continuity.
[c]*t* value.

## Inuka Session Analysis

Table 3 summarizes the number of completed sessions, cancellation rate, and reasons for incomplete sessions. Eighty-three users signed up and completed at least one session. The average completion rate was 3 sessions per participant. Among the scheduled sessions, the nonattendance proportions for participants and lay counselors were 22.4% (95/424) and 5.9% (25/424), respectively, and 9.2% (39/424) of sessions were cancelled.

**Table 3.** Inuka session overview.

| Session status | Value (N=424), n (%) |
|---|---|
| The user did not show up | 95 (22.4) |
| Session completed | 240 (56.6) |
| The lay counselor did not show up | 25 (5.9) |
| Session cancelled | 39 (9.2) |
| No one showed up for the session | 25 (5.9) |

## Qualitative Implementation Outcomes

Below are the key findings from the qualitative analysis of the implementation outcomes. The subthemes and additional vivid verbatim quotes are presented in Multimedia Appendix 2.

### *Acceptability*

Both users and lay counselors revealed that Inuka was an acceptable model for mental health provision. The ability to access mental health care remotely was the most salient feature. Remote access was highly valued as it enabled access to mental health care during the COVID-19 total lockdowns, with a lay counselor saying the following:

> *In the wake of the COVID-19 restrictions; the Inuka app makes it very easy to connect with clients since we are not able to conduct physical sessions.* [Counselor #2]

Moreover, the double anonymity offered by the Inuka app and data security were viewed as vital features. Anonymity increased accessibility to mental health care services and increased patients' ability to open up to their therapists. One patient made the following statement:

> *…it is enjoyable and helpful at once…the hiding of identity part is brilliant and encouraging… [Patient #7]*

### *Feasibility*

Users and lay counselors pointed out that Inuka could be successfully used to provide mental health services in Zimbabwe. One patient commented as follows:

> *The application is very easy to use…* [Patient #1]

A lay counselor made the following statement:

> *It was very easy to use the app… It took me three days to learn how to use the app.* [Counselor #5]

However, the app users raised concerns about the app's stability, which affected usability. Challenges in connectivity were reported as a potential impediment to digital mental health care services in the Zimbabwean context. One lay counselor made the following statement:

> *At times, it is difficult to complete sessions due to connectivity challenges…*

Connectivity challenges negatively affected some of the clients' experiences. Further, the app's responsiveness and stability were also seen as areas of improvement. Technical glitches were prevalent, and these negatively affected therapy progression. Patients said the following:

> *My counselor's network was bad…she was late replying always, and I ended up losing focus…* [Patient #2]
>
> *The app was laggy and disconnected frequently…* [Patient #7]

### *Appropriateness*

Lay counselors expressed that the Inuka app was congruent with their roles or job expectations, with the app offering a structured way of delivering services. Clients expressed the ability to connect or form a therapeutic alliance with their counselors over the digital sessions. One patient made the following statement:

> *Yeah, it was great. I felt like I was talking to a real friend...* [Patient #5]

### *Adoption/Uptake*

Both administrators and lay counselors concurred that Inuka could be integrated within the Friendship Bench to complement physical sessions. The ubiquity of digital innovations was viewed as a low-hanging fruit to increase mental health coverage in low-resource settings. One lay counselor made the following statement:

> *…digital mental health innovations are the future…we definitely need to embrace changes in times…Inuka offers that…* [Counselor #7]

However, technical glitches, usability (eg, navigation), and connectivity challenges were viewed as potential barriers to integrating Inuka into routine care. One lay counselor revealed

challenges in navigation that may negatively affect user experience:

> *…it was slow in that I struggle to navigate from the action card to the actual chat platform … it took a bit time than it should…* [Counselor #5]

### *Fidelity*

The lead psychologist's audit checks revealed that lay counselors adhered to the PST protocol. The structured PST steps on the app made it easier for lay counselors to follow through with the sessions with fidelity. A lay counselor made the following statement:

> *There is no way you can forget all the necessary PST steps as the information is all included in the app…* [Counselor #4]

## Inuka Usability

### *MAUQ Outcomes*

Table 4 shows lay counselors' usability ratings of Inuka regarding ease of use, esthetics, and usefulness. The lay counselors assigned the highest ratings for ease of use and the lowest ratings for satisfaction and esthetics. The mean MAUQ score was 78.5 (SD 13.2), denoting high perceived usability. The frequencies of responses on the MAUQ are presented in Multimedia Appendix 3.

**Table 4.** Lay counselors' mHealth App Usability Questionnaire scores (N=8).

| mHealth App Usability Questionnaire (MAUQ) variable | Mean score (SD) | Median score (Q1-Q3) | Score range (min-max) |
|---|---|---|---|
| Ease of use and satisfaction (40 points) | 27.5 (6.2) | 29.0 (24.0-31.5) | 19.0 (16-35) |
| System information arrangement (30 points) | 25.1 (3.4) | 24.0 (24.0-25.0) | 11.0 (22-33) |
| Usefulness (35 points) | 25.9 (5.1) | 27.0 (22.5-29.0) | 16.0 (17-33) |
| MAUQ total score (105 points) | 78.5 (13.2) | 80.5 (70.0-83.5) | 42.0 (59-101) |

### *In-App Ratings*

Participants were satisfied with the Inuka app. The mean app and session ratings were 4.2 (SD 1.2) and 4.5 (SD 1.1), respectively. The descriptive statistics are displayed in Table 5.

**Table 5.** Clients' in-app ratings (N=83).

| Rating | Mean value (SD) | Range (min-max) | Median value (Q1-Q3) |
|---|---|---|---|
| App rating | 4.2 (1.2) | 4 (1-5) | 5 (3-5) |
| Session rating | 4.5 (1.1) | 4 (1-5) | 5 (4-5) |

## Mental Health Outcomes

Table 6 compares the mental health outcomes of the 2 groups at baseline and follow-up. The table shows changes in depression, anxiety, disability and functioning, social support, and HRQoL over the follow-up period. Both groups were comparable at baseline, except for depression scores. PHQ-9 scores were higher in the WhatsApp group than in the Inuka group ($t_{74}$=−2.725; $P$=.008). Generally, there were declines in depression, anxiety, and disability and functioning, and corresponding increases in social support and HRQoL in both groups (Table 6). A 1-way ANOVA was performed to test for changes in the mean PHQ-9 scores at baseline and follow-up. It yielded statistically significant differences between the 2 groups ($F_{2,73}$=7.67; $P$<.001), with the WhatsApp group exhibiting a great decline in depression scores. A 1-way ANOVA was also performed to test for changes in the mean EQ-5D visual analog scale scores at baseline and follow-up. It yielded a statistically significant difference between the 2 groups ($F_{2,73}$=7.287; $P$=.001), with the Inuka group exhibiting great gains in HRQoL scores.

**Table 6.** Mental health outcomes (N=76).

| Construct- outcome measure | Baseline | | | | Follow-up | | Between-group comparisons | |
|---|---|---|---|---|---|---|---|---|
| | Inuka group (n=45), mean (SD) | WhatsApp group (n=31), mean (SD) | *t* (df) | *P* value | Inuka group (n=45), mean (SD) | WhatsApp group (n=31), mean (SD) | *F* (df) | *P* value |
| Common mental disorders (Shona Symptoms Questionnaire) | 8.0 (2.6) | 8.1 (2.0) | 10.116 (74) | .91 | 5.4 (2.1) | 6.48 (1.6) | 2.63 (2,73) | .08 |
| Depression (Patient Health Questionnaire-9) | 10.4 (5.5) | 13.2 (2.3) | −2.725 (74) | .008 | 6.9 (4.0) | 9.7 (2.8) | 7.67 (2,73) | <.001 |
| Anxiety (Generalized Anxiety Disorder-7) | 10.5 (5.8) | 12.1 (2.7) | −1.630 (74) | .15 | 7.2 (4.4) | 9.1 (2.7) | 2.95 (2,73) | .06 |
| Disability and functioning (WHO[a] Disability Assessment Schedule) | 23.1 (9.0) | 22.1 (5.4) | −1.766 (74) | .08 | 18.4 (5.1) | 17.8 (2.1) | 0.273 (2,73) | .76 |
| Social support (multidimensional scale of perceived social support) | 25.9 (5.2) | 27.7 (3.1) | −1.766 (74) | .08 | 28.2 (4.5) | 28.4 (3.3) | 1.545 (2,73) | .22 |
| HRQoL[b] (EQ-5D[c] utility score) | 0.807 (0.139) | 0.745 (1.69) | 1.735 (74) | .09 | 0.859 (0.124) | 0.850 (0.077) | 1.49 (2,73) | .23 |
| HRQoL (EQ-5D visual analog scale score) | 62.1 (20.2) | 58.6 (12.5) | 0.870 (74) | .39 | 73.2 (11.5) | 63.6 (10.4) | 7.287 (2,73) | .001 |

[a]WHO: World Health Organization.

[b]HRQoL: health-related quality of life.

[c]EQ-5D: EuroQol-5 dimensions.

### Data Dissemination

We will communicate the study findings to the health care professionals and relevant groups associated with the study through policy briefs, and oral and conference presentations. As for the participants, we will summarize the study findings in simplified language, and information will be disseminated using leaflets with summarized findings.

## Discussion

### General Findings

This study used a pragmatic nonequivalent control group quasiexperimental design to explore the feasibility of running a future RCT. The study also examined the feasibility, acceptability, and preliminary clinical effectiveness of Inuka compared with the Friendship Bench intervention delivered via WhatsApp. Overall, study outcomes showed that it is feasible to run a future large-scale RCT and lend support to the feasibility and acceptability of Inuka, including evidence of preliminary effectiveness. However, connectivity and usability challenges are potential impediments to the scale-up of Inuka.

### Feasibility of a Future Clinical Trial

An optimal recruitment rate demonstrated the feasibility of a future RCT. We screened 258 participants over 6 months (43 participants per month). The recruitment rate is comparable to that in an almost similar local study [34]. A pilot trial exploring the feasibility and acceptability of a task-shifted PST intervention to improve adherence in HIV care in Harare, Zimbabwe, yielded a recruitment rate of 27 participants per month [34]. The high recruitment rate may be attributable to the increased awareness and acceptability of mHealth interventions in the study setting [35-37]. The ongoing COVID-19 pandemic has brought the importance of mental health to the forefront [38]. COVID-19 containment measures, such as lockdowns, have resulted in an exponential increase in mental health issues; hence, there is an impetus to increase service coverage [38,39]. Another possible reason for the increased uptake could be the campaign of the Zimbabwean Ministry of Health and Child Care and the WHO to increase the awareness and coverage of mental health services in Zimbabwe [40].

The high recruitment rate could be credited to our multimodal dissemination strategy. We publicized the pilot study through social media, the Friendship Bench website [23], and radio channels. The study sensitization was engrafted in the Friendship Bench's broader community engagement strategy to increase awareness of the mental health effects of the COVID-19 pandemic, including signposting clients to care [35]. The COVID-19 pandemic has led to an exponential increase in social media usage, and this coupled with high mobile penetration [37,39] increased our social media reach.

We had initially planned to randomize clients to interventions; however, this was impractical. Most clients meeting the inclusion criteria preferred Inuka (n=130) to WhatsApp (n=43). The double anonymity offered by the app was the major pull factor, and this is consistent with other studies [13]. Anonymity decreases stigmatization, which enhances the uptake of mental

health care services [13,41]. Unfortunately, there was a high loss to follow-up in the Inuka group. Around 36.1% of clients in the Inuka group did not receive the allocated intervention, while this rate was 7.0% in the WhatsApp group. Connectivity challenges were cited as the main barriers to accessing the Inuka intervention. Poor connectivity and high data costs are salient barriers to the scale up of mHealth innovations in low-resource settings [36,37]. There is a need to iteratively improve the Inuka platform to a data-lite version. Methodologically, future RCTs should consider a large sample and block randomization enrollment, with 5 participants randomized to the Inuka group for every participant assigned to the control group. Moreover, consideration may be made to compare Inuka to the in-person Friendship Bench intervention. This was impossible owing to the ongoing COVID-19 pandemic. Overall, the loss to follow-up for both groups was 25.3%, which is comparable to a similar study evaluating the feasibility of using lay counselors for improving HIV care adherence [34]. Loss to follow-up is inevitable; however, we employed several retention strategies, including texting reminders and encouraging clients to activate in-app reminders. The Inuka app sends reminders to both lay counselors and clients an hour and 30 minutes before the session. Moreover, upon signing up, the system sends an automated confirmatory email with a calendar file that can be added to the client's digital calendar. However, clients rarely used this feature, necessitating multiple retention strategies such as reminder text messages and phone calls. Taken together, this pilot study shows the feasibility of a future trial. However, there need to be considerations for the allocation mechanism and efforts to increase adherence to scheduled sessions.

### Feasibility and Acceptability of Inuka

This pilot study also demonstrated the feasibility and acceptability of implementing Inuka, a digital mental health intervention in Zimbabwe, a low-resource country. The ongoing COVID-19 pandemic has increased the utility of digital mental health interventions [39]. To the best of our knowledge, this is the first study to explore the utility of digital mental health solutions in Zimbabwe and one of the few studies in Africa [18,36,39]. Digital mental health solutions can alleviate access barriers, including destigmatizing access to mental health care and offering convenience compared with physical sessions [12,42]. For example, the double anonymity offered by Inuka was highly valued by both participants and lay counselors. However, connectivity and usability challenges are potential impediments to the feasibility of mHealth interventions in low-income settings [42]. The beta version used during the pilot required a much more stable internet connection than WhatsApp. Internet speeds in Zimbabwe depend much on geographical location. For example, connection speeds are faster and more stable in low-density areas than in high-density areas, with rural areas having poorer connectivity than urban areas [40]. Such disparity affects the feasibility of an equitable roll out of mHealth interventions in low-resource settings, necessitating the exploration of reasonable alternatives. During the early phases of the study, we received several complaints from both clients and lay counselors about the app's connectivity and stability. The developers reconfigured the app by changing to an Angular framework that is data lite and is compatible with unreliable internet speeds in low-resource settings such as Zimbabwe. Moreover, users suggested that offline access to some key features (eg, chat user interface), voice calls/messages, and push notifications of new messages could improve the utility of Inuka further. The piloting phase indicated a stern need to elicit constant feedback and troubleshooting to optimize mHealth service delivery [42,43].

Despite the predictable challenges with mHealth technologies, both lay counselors and clients were highly satisfied with the Inuka app. The satisfaction rate is comparable to that in other studies and is vital for enhancing adherence and improving treatment effectiveness and efficiency [9,10,13,17]. As in other settings [13], our preliminary outcomes suggest that Inuka can offer PST sessions with increased fidelity as it offers lay counselors essential reminders of all critical steps. Supervisors consisting of experienced clinical psychologists and psychiatrists could remotely access the session transcripts. The ability to remotely access transcripts is time-saving, increases user satisfaction and quality control, and is a salient feature of mHealth technologies compared with in-person sessions [13]. Moreover, the Inuka platform enables real-time tracking of session attendance and changes in client well-being scores, and enables clients to submit anonymized feedback on the quality of the service received. These salient features collectively enhance quality control, including strengthening the clinical supervision process, which is essential for optimal treatment outcomes.

### Preliminary Clinical Effectiveness

Although our study was not powered to demonstrate clinical effectiveness, study outcomes provided evidence of preliminary effectiveness. Participants showed improvements in anxiety and depression, and increased functioning and HRQoL. Systematic reviews have demonstrated that mHealth apps are clinically effective as face-to-face therapies [13,41]. Inuka can be an alternative or complimentary delivery model to the original in-person Friendship Bench intervention to improve mental health outcomes due to the relative advantage of enabling greater access to care. Across both arms, lay counselors provided counseling, which is a more sustainable care provision in low-resource settings that lack human resources and capital investment in mental health care [14]. However, the lack of in-person contact between a client and coach is a potential drawback for therapeutic alliance in mHealth interventions [44]. There is a greater need to explore ways to optimize client experiences to increase the utility and engagement of mHealth technologies [13,41]. Optimization of mHealth technologies is crucial in low-income countries where mHealth technologies could help close the sizeable mental health care gap [12].

### Limitations and Strengths

Several methodological limitations warrant a cautious interpretation of the findings. First, participants were conveniently assigned to intervention groups, which may have introduced selection bias. Randomization was impractical given the differences in smartphones and high-speed stable internet access among participants. Second, there was a considerable loss to follow-up in the Inuka intervention arm. Network changes, power outages, and forgetting were the primary reasons

for nonattendance. Beyond the pilot study, the Inuka team has iteratively reconfigured the app to a data-lite Angular framework, including WhatsApp integration. The iterations will increase coverage and mitigate connectivity challenges. The new app requires rigorous testing before scaling up. Moreover, future studies should explore the effectiveness of implementation strategies (eg, text reminders) to enhance adherence to scheduled sessions. A strength of this study was that lay counselors successfully implemented the intervention. Task-shifting is a cost-effective mental health care service delivery model [14]. Moreover, the Inuka app enables full access to session transcripts for fidelity assessment, and all interventionists highly adhered to the PST steps.

## Conclusion

The findings of our study suggest that the Inuka intervention is feasible and acceptable in the Zimbabwean context. The high perceived ease of use and satisfaction by clients and lay counselors, the comparable level of uptake of the Inuka intervention when compared with the in-person Friendship Bench intervention, the positive perceptions around the use of technology in mental health care, and the desirability of the anonymity provided by the intervention/app increase the app's utility. Our findings also provide preliminary evidence of the clinical effectiveness of the Inuka intervention. However, significant barriers to implementation were identified, primarily concerning internet connectivity and mobile app stability. There is a need for iterative app upgrades to increase usability, which will, in turn, improve the scaling up of the mHealth solution. The Friendship Bench and other clinicians should consider using mHealth solutions, such as Inuka, to complement in-person therapies to close the mental health care gap in low-resource settings. Future research should use our findings to optimize the intervention and investigate the clinical implementation and cost-effectiveness of the Inuka intervention using a hybrid RCT design.

## Acknowledgments

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## Conflicts of Interest

None declared.

Multimedia Appendix 1
Description of the Inuka app.
[PPTX File , 1473 KB - mental_v9i10e37968_app1.pptx ]

Multimedia Appendix 2
Qualitative analysis of implementation outcomes.
[DOCX File , 20 KB - mental_v9i10e37968_app2.docx ]

Multimedia Appendix 3
Mobile App Rating Scale responses.
[DOCX File , 22 KB - mental_v9i10e37968_app3.docx ]

## References

1. Rehm J, Shield KD. Global burden of disease and the impact of mental and addictive disorders. Curr Psychiatry Rep 2019 Feb 07;21(2):10. [doi: 10.1007/s11920-019-0997-0] [Medline: 30729322]
2. GBD 2016 DALYsHALE Collaborators. Global, regional, and national disability-adjusted life-years (DALYs) for 333 diseases and injuries and healthy life expectancy (HALE) for 195 countries and territories, 1990-2016: a systematic analysis for the Global Burden of Disease Study 2016. Lancet 2017 Sep 16;390(10100):1260-1344 [FREE Full text] [doi: 10.1016/S0140-6736(17)32130-X] [Medline: 28919118]
3. Steel Z, Marnane C, Iranpour C, Chey T, Jackson JW, Patel V, et al. The global prevalence of common mental disorders: a systematic review and meta-analysis 1980-2013. Int J Epidemiol 2014 Apr;43(2):476-493 [FREE Full text] [doi: 10.1093/ije/dyu038] [Medline: 24648481]
4. Holmes EA, O'Connor RC, Perry VH, Tracey I, Wessely S, Arseneault L, et al. Multidisciplinary research priorities for the COVID-19 pandemic: a call for action for mental health science. Lancet Psychiatry 2020 Jun;7(6):547-560 [FREE Full text] [doi: 10.1016/S2215-0366(20)30168-1] [Medline: 32304649]
5. Watzke B, Haller E, Steinmann M, Heddaeus D, Härter M, König HH, et al. Effectiveness and cost-effectiveness of telephone-based cognitive-behavioural therapy in primary care: study protocol of TIDe - telephone intervention for depression. BMC Psychiatry 2017 Jul 19;17(1):263 [FREE Full text] [doi: 10.1186/s12888-017-1429-5] [Medline: 28724423]
6. Huang Y, Zhao N. Mental health burden for the public affected by the COVID-19 outbreak in China: Who will be the high-risk group? Psychol Health Med 2021 Jan;26(1):23-34. [doi: 10.1080/13548506.2020.1754438] [Medline: 32286091]

7. Patel V, Burns JK, Dhingra M, Tarver L, Kohrt BA, Lund C. Income inequality and depression: a systematic review and meta-analysis of the association and a scoping review of mechanisms. World Psychiatry 2018 Feb;17(1):76-89 [FREE Full text] [doi: 10.1002/wps.20492] [Medline: 29352539]
8. Ibrahim AK, Kelly SJ, Adams CE, Glazebrook C. A systematic review of studies of depression prevalence in university students. J Psychiatr Res 2013 Mar;47(3):391-400. [doi: 10.1016/j.jpsychires.2012.11.015] [Medline: 23260171]
9. Huang J, Nigatu YT, Smail-Crevier R, Zhang X, Wang J. Interventions for common mental health problems among university and college students: A systematic review and meta-analysis of randomized controlled trials. J Psychiatr Res 2018 Dec;107:1-10. [doi: 10.1016/j.jpsychires.2018.09.018] [Medline: 30300732]
10. Davies EB, Morriss R, Glazebrook C. Computer-delivered and web-based interventions to improve depression, anxiety, and psychological well-being of university students: a systematic review and meta-analysis. J Med Internet Res 2014 May 16;16(5):e130 [FREE Full text] [doi: 10.2196/jmir.3142] [Medline: 24836465]
11. Lattie EG, Lipson SK, Eisenberg D. Technology and college student mental health: Challenges and opportunities. Front Psychiatry 2019;10:246 [FREE Full text] [doi: 10.3389/fpsyt.2019.00246] [Medline: 31037061]
12. Gulliver A, Griffiths KM, Christensen H. Perceived barriers and facilitators to mental health help-seeking in young people: a systematic review. BMC Psychiatry 2010 Dec 30;10:113 [FREE Full text] [doi: 10.1186/1471-244X-10-113] [Medline: 21192795]
13. Lattie EG, Adkins EC, Winquist N, Stiles-Shields C, Wafford QE, Graham AK. Digital mental health interventions for depression, anxiety, and enhancement of psychological well-being among college students: Systematic review. J Med Internet Res 2019 Jul 22;21(7):e12869 [FREE Full text] [doi: 10.2196/12869] [Medline: 31333198]
14. Chibanda D, Weiss HA, Verhey R, Simms V, Munjoma R, Rusakaniko S, et al. Effect of a primary care-based psychological intervention on symptoms of common mental disorders in Zimbabwe: A randomized clinical trial. JAMA 2016 Dec 27;316(24):2618-2626. [doi: 10.1001/jama.2016.19102] [Medline: 28027368]
15. Patel V, Saxena S, Lund C, Thornicroft G, Baingana F, Bolton P, et al. The Lancet Commission on global mental health and sustainable development. Lancet 2018 Oct 27;392(10157):1553-1598. [doi: 10.1016/S0140-6736(18)31612-X] [Medline: 30314863]
16. Shahid N, Malik TA, Hussain A, Ahmed S. Unmet psycho-social needs, coping strategies and psychological distress among people with cancer: Evidence from Pakistan. J Pak Med Assoc 2021 May;71(5):1373-1378 [FREE Full text] [doi: 10.47391/JPMA.1117] [Medline: 34091617]
17. Farrer L, Gulliver A, Chan JKY, Batterham PJ, Reynolds J, Calear A, et al. Technology-based interventions for mental health in tertiary students: systematic review. J Med Internet Res 2013 May 27;15(5):e101 [FREE Full text] [doi: 10.2196/jmir.2639] [Medline: 23711740]
18. Doukani A, van Dalen R, Valev H, Njenga A, Sera F, Chibanda D. A community health volunteer delivered problem-solving therapy mobile application based on the Friendship Bench 'Inuka Coaching' in Kenya: A pilot cohort study. Glob Ment Health (Camb) 2021;8:e9 [FREE Full text] [doi: 10.1017/gmh.2021.3] [Medline: 34026239]
19. Kirk MA, Kelley C, Yankey N, Birken SA, Abadie B, Damschroder L. A systematic review of the use of the Consolidated Framework for Implementation Research. Implement Sci 2016 May 17;11:72 [FREE Full text] [doi: 10.1186/s13012-016-0437-z] [Medline: 27189233]
20. Batra S, Baker RA, Wang T, Forma F, DiBiasi F, Peters-Strickland T. Digital health technology for use in patients with serious mental illness: a systematic review of the literature. Med Devices (Auckl) 2017;10:237-251 [FREE Full text] [doi: 10.2147/MDER.S144158] [Medline: 29042823]
21. Landes SJ, McBain SA, Curran GM. An introduction to effectiveness-implementation hybrid designs. Psychiatry Res 2019 Oct;280:112513 [FREE Full text] [doi: 10.1016/j.psychres.2019.112513] [Medline: 31434011]
22. Harris AD, McGregor JC, Perencevich EN, Furuno JP, Zhu J, Peterson DE, et al. The use and interpretation of quasi-experimental studies in medical informatics. J Am Med Inform Assoc 2006;13(1):16-23 [FREE Full text] [doi: 10.1197/jamia.M1749] [Medline: 16221933]
23. Research Trial. Friendship Bench. URL: https://www.friendshipbenchzimbabwe.org/digital-trial [accessed 2022-07-21]
24. Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health 2011 Mar;38(2):65-76 [FREE Full text] [doi: 10.1007/s10488-010-0319-7] [Medline: 20957426]
25. Stoyanov SR, Hides L, Kavanagh DJ, Wilson H. Development and validation of the user version of the Mobile Application Rating Scale (uMARS). JMIR Mhealth Uhealth 2016 Jun 10;4(2):e72 [FREE Full text] [doi: 10.2196/mhealth.5849] [Medline: 27287964]
26. Chibanda D, Verhey R, Gibson LJ, Munetsi E, Machando D, Rusakaniko S, et al. Validation of screening tools for depression and anxiety disorders in a primary care population with high HIV prevalence in Zimbabwe. J Affect Disord 2016 Jul 01;198:50-55. [doi: 10.1016/j.jad.2016.03.006] [Medline: 27011359]
27. Williams N. The GAD-7 questionnaire. Occupational Medicine 2014 Apr 03;64(3):224. [doi: 10.1093/occmed/kqt161]
28. Manea L, Boehnke JR, Gilbody S, Moriarty AS, McMillan D. Are there researcher allegiance effects in diagnostic validation studies of the PHQ-9? A systematic review and meta-analysis. BMJ Open 2017 Sep 29;7(9):e015247 [FREE Full text] [doi: 10.1136/bmjopen-2016-015247] [Medline: 28965089]

29. Jelsma J, Mhundwa K, De Weerdt W, De Cock P, Chimera J, Chivaura V. The reliability of the Shona version of the EQ-5D. Cent Afr J Med 2001 Jan;47(1):8-13. [doi: 10.4314/cajm.v47i1.8584] [Medline: 11961858]
30. Madhombiro M, Dube B, Dube M, Zunza M, Chibanda D, Rusakaniko S, et al. Intervention for alcohol use disorders at an HIV care clinic in Harare: a pilot and feasibility study. Addict Sci Clin Pract 2019 Apr 05;14(1):16 [FREE Full text] [doi: 10.1186/s13722-019-0143-7] [Medline: 30953549]
31. Dambi JM, Corten L, Chiwaridzo M, Jack H, Mlambo T, Jelsma J. A systematic review of the psychometric properties of the cross-cultural translations and adaptations of the Multidimensional Perceived Social Support Scale (MSPSS). Health Qual Life Outcomes 2018 May 02;16(1):80 [FREE Full text] [doi: 10.1186/s12955-018-0912-0] [Medline: 29716589]
32. Dambi JM, Tapera L, Chiwaridzo M, Tadyanemhandu C, Nhunzvi C. Psychometric evaluation of the Shona version of the Multidimensional Scale of Perceived Social Support Scale (MSPSS-Shona) in adult informal caregivers of patients with cancer in Harare, Zimbabwe. Malawi Med J 2017 Jun;29(2):89-96 [FREE Full text] [doi: 10.4314/mmj.v29i2.3] [Medline: 28955413]
33. Hertzog MA. Considerations in determining sample size for pilot studies. Res Nurs Health 2008 Apr;31(2):180-191. [doi: 10.1002/nur.20247] [Medline: 18183564]
34. Abas M, Nyamayaro P, Bere T, Saruchera E, Mothobi N, Simms V, et al. Feasibility and acceptability of a task-shifted intervention to enhance adherence to HIV medication and improve depression in people living with HIV in Zimbabwe, a low income country in sub-Saharan Africa. AIDS Behav 2018 Jan;22(1):86-101 [FREE Full text] [doi: 10.1007/s10461-016-1659-4] [Medline: 28063075]
35. Kamvura TT, Turner J, Chiriseri E, Dambi J, Verhey R, Chibanda D. Using a theory of change to develop an integrated intervention for depression, diabetes and hypertension in Zimbabwe: lessons from the Friendship Bench project. BMC Health Serv Res 2021 Sep 07;21(1):928 [FREE Full text] [doi: 10.1186/s12913-021-06957-5] [Medline: 34488732]
36. Feldacker C, Holeman I, Murenje V, Xaba S, Korir M, Wambua B, et al. Usability and acceptability of a two-way texting intervention for post-operative follow-up for voluntary medical male circumcision in Zimbabwe. PLoS One 2020;15(6):e0233234 [FREE Full text] [doi: 10.1371/journal.pone.0233234] [Medline: 32544161]
37. Doyle AM, Bandason T, Dauya E, McHugh G, Grundy C, Dringus S, et al. Mobile phone access and implications for digital health interventions among adolescents and young adults in Zimbabwe: Cross-sectional survey. JMIR Mhealth Uhealth 2021 Jan 13;9(1):e21244 [FREE Full text] [doi: 10.2196/21244] [Medline: 33439136]
38. Molebatsi K, Musindo O, Ntlantsana V, Wambua GN. Mental health and psychosocial support during COVID-19: A review of health guidelines in sub-Saharan Africa. Front Psychiatry 2021;12:571342 [FREE Full text] [doi: 10.3389/fpsyt.2021.571342] [Medline: 34093251]
39. Adepoju P. Africa turns to telemedicine to close mental health gap. Lancet Digit Health 2020 Nov;2(11):e571-e572 [FREE Full text] [doi: 10.1016/S2589-7500(20)30252-1] [Medline: 33103096]
40. Gwaka L, May J, Tucker W. Towards low‐cost community networks in rural communities: The impact of context using the case study of Beitbridge, Zimbabwe. E J Info Sys Dev Countries 2018 Apr 19;84(3):e12029 [FREE Full text] [doi: 10.1002/isd2.12029]
41. Donker T, Petrie K, Proudfoot J, Clarke J, Birch M, Christensen H. Smartphones for smarter delivery of mental health programs: a systematic review. J Med Internet Res 2013 Nov 15;15(11):e247 [FREE Full text] [doi: 10.2196/jmir.2791] [Medline: 24240579]
42. Naslund JA, Aschbrenner KA, Araya R, Marsch LA, Unützer J, Patel V, et al. Digital technology for treating and preventing mental disorders in low-income and middle-income countries: a narrative review of the literature. Lancet Psychiatry 2017 Jun;4(6):486-500 [FREE Full text] [doi: 10.1016/S2215-0366(17)30096-2] [Medline: 28433615]
43. Walsh S, Golden E, Priebe S. Systematic review of patients' participation in and experiences of technology-based monitoring of mental health symptoms in the community. BMJ Open 2016 Jun 21;6(6):e008362 [FREE Full text] [doi: 10.1136/bmjopen-2015-008362] [Medline: 27329437]
44. Tremain H, McEnery C, Fletcher K, Murray G. The therapeutic alliance in digital mental health interventions for serious mental illnesses: Narrative review. JMIR Ment Health 2020 Aug 07;7(8):e17204 [FREE Full text] [doi: 10.2196/17204] [Medline: 32763881]


## Abbreviations

**CFIR:** Consolidated Framework for Implementation Research
**CMD:** common mental health disorder
**EQ-5D:** EuroQol-5 dimensions
**GAD-7:** Generalized Anxiety Disorder-7
**HRQoL:** health-related quality of life
**MAUQ:** mHealth App Usability Questionnaire
**mHealth:** mobile health
**MSPSS:** multidimensional scale of perceived social support
**PHQ-9:** Patient Health Questionnaire-9

**PI:** principal investigator
**PST:** problem-solving therapy
**RA:** research assistant
**RCT:** randomized clinical trial
**SSQ:** Shona Symptoms Questionnaire
**WHO:** World Health Organization
**WHODAS:** World Health Organization Disability Assessment Schedule

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Short Paper

# Motor Resonance During Action Observation and Its Relevance to Virtual Clinical Consultations: Observational Study Using Transcranial Magnetic Stimulation

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## Abstract

**Background:** Virtual clinical interactions have increased tremendously since the onset of the COVID-19 pandemic. While they certainly have their advantages, there also exist potential limitations, for example, in establishing a therapeutic alliance, discussing complex clinical scenarios, etc. This may be due to possible disruptions in the accurate activation of the human mirror neuron system (MNS), a posited physiological template for effective social communication.

**Objective:** This study aimed to compare motor resonance, a putative marker of MNS activity, estimated using transcranial magnetic stimulation (TMS) elicited while viewing virtual (video-based) and actual or real (enacted by a person) actions in healthy individuals. We hypothesized that motor resonance will be greater during real compared to virtual action observation.

**Methods:** We compared motor resonance or motor-evoked potential (MEP) facilitation during the observation of virtual (presented via videos) and real (enacted in person) actions, relative to static image observation in healthy individuals using TMS. The MEP recordings were obtained by 2 single-pulse (neuronal membrane excitability–driven) TMS paradigms of different intensities and 2 paired-pulse (cortical gamma-aminobutyric acid-interneuron–driven) TMS paradigms.

**Results:** This study comprised 64 participants. Using the repeated measures ANOVA, we observed a significant time effect for MEP facilitation from static to virtual and real observation states when recorded using 3 of the 4 TMS paradigms. Post hoc pairwise comparisons with Benjamini-Hochberg false discovery rate correction revealed significant MEP facilitation in both virtual and real observation states relative to static image observation; however, we also observed a significant time effect between the 2 action observation states (real > virtual) with 2 of the 4 TMS paradigms.

**Conclusions:** Our results indicate that visual cues expressed via both virtual (video) or real (in person) modes elicit physiological responses within the putative MNS, but this effect is more pronounced for actions presented in person. This has relevance to the appropriate implementation of digital health solutions, especially those pertaining to mental health.

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**KEYWORDS**

mirror neuron activity; virtual interactions; digital psychiatry; telepsychiatry; virtual mental health interventions; motor resonance

## Introduction

With the emergence of the COVID-19 pandemic, and the communication challenges in clinical scenarios thereof [1], we have witnessed an increasing worldwide reliance on digital media that support virtual clinical interactions [2]. This increase in virtual modes of communication has become ubiquitous, traversing many other spheres of daily living like work and education [3]. While there are definite advantages to using

virtual communication tools in clinical settings [4], potential limitations do exist. Emerging research has identified challenges in establishing a therapeutic alliance in psychotherapy delivered via face-to-face videoconferencing modes [5]. Such challenges can potentially stem from an inaccurate perception and expression of thoughts and emotions while using virtual communication tools, which have been attributed to disruptions in the human mirror neuron system (MNS) during virtual or digital communications [6-8]. However, few studies have empirically examined the differences in putative MNS activity between virtual and real action observation scenarios. Activity within the human MNS can directly be measured only via intracranial depth electrodes [9], which comes with pragmatic challenges. Examining changes in cortical physiology to observe actions using alternative methods like transcranial magnetic stimulation (TMS), electroencephalography, functional neuroimaging, and others have therefore been more commonly used as indirect measures of putative MNS activity in humans [10].

## Methods

### Experiment

We present results from a TMS experiment in healthy volunteers that probed motor resonance or motor-evoked potential (MEP) facilitation during action observation relative to rest states, which is an indirect measurement of MNS activity in humans [11-14]. While there are no studies that definitively examine if motor resonance does indeed capture MNS activity, this method is one of the investigational approaches recommended for the study of possible MNS activity under the social processes of the US National Institute of Mental Health's Research Domain Criteria [15]. Specifically, we compared MEP facilitation during the observation of virtual (presented via videos) and real (enacted in person) actions, relative to static image observation. The MEP recordings were obtained by 2 single-pulse (neuronal membrane excitability–driven) TMS paradigms of different intensities and 2 paired-pulse (cortical gamma-aminobutyric acid [GABA]-interneuron–driven) TMS paradigms [13,16]. We hypothesized that MEP facilitation will be greater during real compared to virtual action observation when elicited using all 4 TMS paradigms.

The data were obtained from 2 studies comparing motor resonance between patients with schizophrenia [17] or bipolar disorder [18] and healthy individuals. Data from only healthy individuals were used in this study. All participants provided written informed consent. Participants recruited as healthy individuals were screened for any current or past psychiatric morbidity using the Mini International Neuropsychiatric Interview screening checklist [19].

The TMS experiment was performed using a MagPro R30 system with MagOption (MagVenture); electromyography was obtained using a single-channel MEP monitor device mounted on the TMS device, and this data was analyzed using Signal-4 Software (Cambridge Electronic Devices). After localizing the motor hand area in the left hemisphere, we determined stimulus intensities to elicit 50-µV (resting motor threshold [RMT]) and 1-mV ($SI_{1mV}$) amplitudes of MEP in at least 6 out of 10 trials. The mean (SD) for RMT and $SI_{1mV}$ were 36.6 (SD 6.7) mV and 48.1 (SD 10.2) mV, respectively. Thereafter, we administered 10 pulses each of the 120% RMT, $SI_{1mV}$, and short- and long-interval cortical inhibition (SICI and LICI, respectively) paradigms over the left motor cortex in a pseudorandom sequence at 5-second intervals while obtaining MEP recordings from the right first dorsal interosseus muscle. These recordings were obtained as the participants observed 3 states, presented in a random order across participants: (1) a static image of a hand and a lock and key, (2) a video of locking and unlocking actions with a key held in the right hand (virtual observation), and (3) the same action enacted by a volunteer (real observation). While SICI was measured at interstimulus intervals of 3 milliseconds between the subthreshold (80% RMT) and suprathreshold stimuli ($SI_{1mV}$), LICI was measured at 100 milliseconds between 2 suprathreshold stimuli ($SI_{1mV}$). SICI and LICI were expressed as a percentage of the ratio between the conditioned MEPs and the nonconditioned MEPs with $SI_{1mV}$. MEP recordings with 120% RMT and $SI_{1mV}$ were expressed in millivolts. In order to evaluate changes in MEP across the 3 experimental observation states (static, virtual, and real action observation), we performed a 1-way (within-subjects) repeated measures ANOVA. The omnibus tests for each TMS paradigm were 2-tailed, and results were regarded as significant at an $\alpha$ probability level (*P* value) of <.05. In addition, we performed post hoc pairwise comparisons with Benjamini-Hochberg false discovery rate correction to understand the statistical significance of MEP facilitation between pairs of experimental observation states.

### Ethics Approval

The National Institute of Mental Health and Neurosciences ethics committee approved the study protocols of the 2 studies [17,18] from which we derived the data (NIMHANS/71$^{ST}$IEC/2010 and NIMH/DO/IEC (BEH.Sc.DIV)/2018).

## Results

This study comprised 64 participants (mean age 29.5, SD 8.5 years; females: n=31, 48%, males: n=33, 52%; mean years of education 13, SD 4.1 years).

The 1-way repeated measures ANOVA (Table 1) revealed a significant time effect for MEP facilitation from static to virtual and real observation states when recorded using the 120% RMT, $SI_{1mV}$, and SICI paradigms, but not with LICI.

Post hoc pairwise comparisons with Benjamini-Hochberg false discovery rate correction revealed significant MEP facilitation in both virtual (120% RMT and $SI_{1mV}$) and real (120% RMT, $SI_{1mV}$, and SICI) observation states relative to static image observation (Figure 1); moreover, there was also a significant time effect between the 2 observation states (real > virtual) for the $SI_{1mV}$ and SICI paradigms (Figure 1).

**Table 1.** Motor-evoked potentials (in millivolts) with single- and paired-pulse stimulation paradigms during static and action observation experimental states.

| TMS[a] paradigm and observation states | Mean (SD) | *F* (*df*)[b] |
|---|---|---|
| **$SI_{1mV}$[c] (mV)** | | 8.4 (2, 126)[d] |
| Static | 0.82 (0.26) | |
| Virtual action observation | 0.87 (0.24) | |
| Real action observation | 0.92 (0.24) | |
| **120% RMT[e] (mV)** | | 6.6 (2, 110)[d] |
| Static | 0.68 (0.31) | |
| Virtual action observation | 0.76 (0.29) | |
| Real action observation | 0.77 (0.32) | |
| **SICI[f,g] (%)** | | 4.3 (2, 102)[d] |
| Static | 69.9 (28.4) | |
| Virtual action observation | 73.2 (32.7) | |
| Real action observation | 79.7 (35.8) | |
| **LICI[f,h] (%)** | | 0.35 (2, 126) |
| Static | 42.6 (39.4) | |
| Virtual action observation | 44.2 (43.7) | |
| Real action observation | 42 (43.7) | |

[a]TMS: transcranial magnetic stimulation.

[b]F statistic represents the time effect from a 1-way (within-subjects) repeated measures ANOVA.

[c]$SI_{1mV}$: stimulus intensity to elicit 1 mV motor-evoked potential (MEP).

[d]*P*<.05.

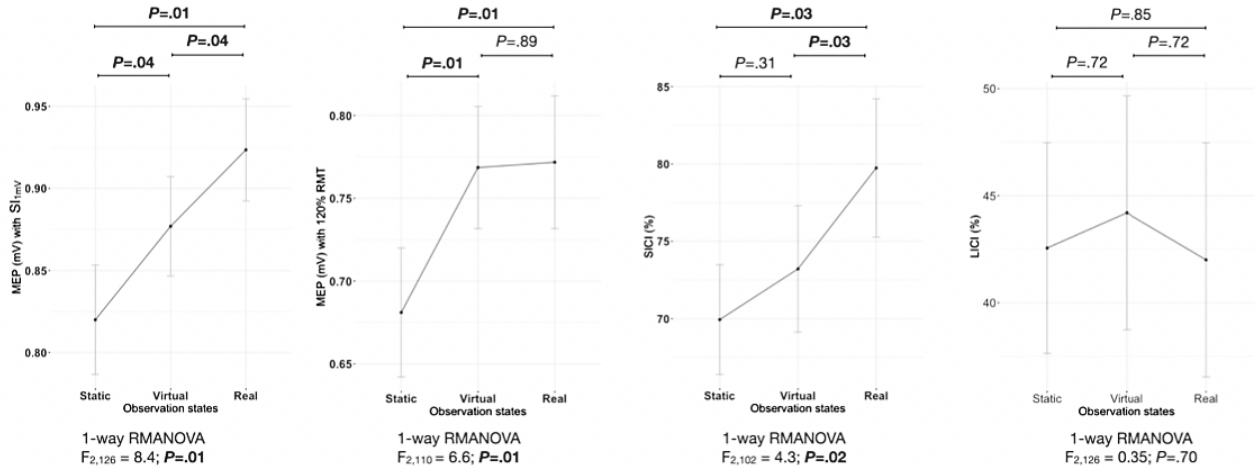
[e]RMT: resting motor threshold.

[f]SICI and LICI were expressed as a percentage of the ratio between the conditioned and nonconditioned MEP with a stimulus intensity of $SI_{1mV}$, that is, (conditioned MEP/nonconditioned MEP) × 100.

[g]SICI: short-interval cortical inhibition.

[h]LICI: long-interval cortical inhibition.

**Figure 1.** Motor evoked potentials during static, virtual, and real action observation conditions. Note: the data represent means and standard errors of the mean (error bars); *P* values for pair-wise comparisons (at the top of the plots) were obtained following post hoc Benjamini-Hochberg false discovery rate correction. LICI: long-interval cortical inhibition; MEP: motor-evoked potential; RMANOVA: repeated measures ANOVA; RMT: resting motor threshold; $SI_{1mV}$: stimulus intensity to elicit 1 mV MEP; SICI: short-interval cortical inhibition.



## Discussion

We observed motor resonance as evidenced by a significant time effect for MEP facilitation in both action observation states relative to static image observation using 3 out of 4 TMS paradigms. Even though MEP facilitation was observed in both real and virtual actions, the magnitude of this facilitation was significantly greater for real actions in 2 ($SI_{1mV}$ and SICI) of the 3 paradigms. Together, these findings indicate that putative MNS activity was observed in response to both virtual and real action observation stimuli, but more so with the real action stimuli. It is perhaps reassuring, especially from a clinical scenario, that actions observed through virtual modes of communication elicit similar physiological responses as real enacted actions. This might partly explain how the quality of doctor-patient communication is broadly similar between video-based and face-to-face consultations [4,20]. However, virtual clinical encounters do demand more explicit forms of verbal communication [21] along with sufficient use of nonverbal gestures [22] than face-to-face consultations to ensure sufficient social information sharing. Our findings that motor resonance was greater in real (than virtual) actions may partly explain such limitations of video-based consultations and encourage the use of these technologies in less complex or less sensitive clinical situations and where there is already a trustful doctor-patient relationship in place [23].

Important caveats do exist in the interpretation of these results. We did not measure social information processing in real time as subjects observed actions. Further, the time effect was not significant for LICI; a similar lack of MEP facilitation and therefore motor resonance was noted with the LICI paradigm in our earlier study [17]. This might partly be due to the more robust inhibition of MEP observed in the $GABA_B$ (metabotropic)-mediated LICI as opposed to the less pronounced inhibition of MEP in the $GABA_A$ (ionotropic)-mediated SICI [24].

In summary, we provide preliminary evidence that visual cues expressed via both virtual (video) or real (in person) modes elicit physiological responses within the putative MNS, but this effect is more pronounced for actions presented in person. Future studies need to (1) replicate these observations in clinical contexts, using different approaches of eliciting putative MNS responses; (2) examine social cue perception and mental state attributions during virtual and in-person social interactions; and (3) examine the associations between cortical physiology (eg, putative MNS activity) and social cognition abilities across virtual and in-person social and clinical interactions. These findings will have relevance to the appropriate implementation of digital health solutions, especially those pertaining to mental health.

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### Authors' Contributions

UMM conceptualized this work, supervised and collected data, performed the analysis, and prepared the first draft of the manuscript. RB collected data and edited the manuscript. AR collected data. MK conceptualized the second experiment and supervised data collection. JT conceptualized the first experiment, supervised data collection, and edited the manuscript.

### Conflicts of Interest

None declared.

### References

1. Mehta UM, Venkatasubramanian G, Chandra PS. The "mind" behind the "mask": Assessing mental states and creating therapeutic alliance amidst COVID-19. Schizophr Res 2020 Aug;222:503-504 [FREE Full text] [doi: 10.1016/j.schres.2020.05.033] [Medline: 32425355]
2. Thirthalli J, Manjunatha N, Math SB. Unmask the mind! Importance of video consultations in psychiatry during COVID-19 pandemic. Schizophr Res 2020 Aug;222:482-483 [FREE Full text] [doi: 10.1016/j.schres.2020.06.005] [Medline: 32553433]
3. Iivari N, Sharma S, Ventä-Olkkonen L. Digital transformation of everyday life - How COVID-19 pandemic transformed the basic education of the young generation and why information management research should care? Int J Inf Manage 2020 Dec;55:102183 [FREE Full text] [doi: 10.1016/j.ijinfomgt.2020.102183] [Medline: 32836640]
4. Thiyagarajan A, Grant C, Griffiths F, Atherton H. Exploring patients' and clinicians' experiences of video consultations in primary care: a systematic scoping review. BJGP Open 2020 Mar 17;4(1):bjgpopen20X101020. [doi: 10.3399/bjgpopen20x101020]
5. Mercadal Rotger J, Cabré V. Therapeutic alliance in online and face-to-face psychological treatment: comparative study. JMIR Ment Health 2022 May 02;9(5):e36775 [FREE Full text] [doi: 10.2196/36775] [Medline: 35499910]
6. Dickerson K, Gerhardstein P, Moser A. The role of the human mirror neuron system in supporting communication in a digital world. Front Psychol 2017 May 12;8:698 [FREE Full text] [doi: 10.3389/fpsyg.2017.00698] [Medline: 28553240]

7. Morgan N. How well do we humans connect in the virtual world? Part 2. Public Words. 2018. URL: https://publicwords.com/2018/09/20/how-well-do-we-humans-connect-in-the-virtual-world-part-2/ [accessed 2022-05-25]
8. Preston C. The neuroscience of remote work. Psychology Today. 2021 Dec 20. URL: https://www.psychologytoday.com/us/blog/mental-health-in-the-workplace/202112/the-neuroscience-remote-work [accessed 2022-05-25]
9. Mukamel R, Ekstrom AD, Kaplan J, Iacoboni M, Fried I. Single-neuron responses in humans during execution and observation of actions. Curr Biol 2010 Apr 27;20(8):750-756 [FREE Full text] [doi: 10.1016/j.cub.2010.02.045] [Medline: 20381353]
10. Bonini L, Rotunno C, Arcuri E, Gallese V. Mirror neurons 30 years later: implications and applications. Trends Cogn Sci 2022 Sep;26(9):767-781 [FREE Full text] [doi: 10.1016/j.tics.2022.06.003] [Medline: 35803832]
11. Fadiga L, Fogassi L, Pavesi G, Rizzolatti G. Motor facilitation during action observation: a magnetic stimulation study. J Neurophysiol 1995 Jun 01;73(6):2608-2611. [doi: 10.1152/jn.1995.73.6.2608] [Medline: 7666169]
12. Maeda F, Chang VY, Mazziotta J, Iacoboni M. Experience-dependent modulation of motor corticospinal excitability during action observation. Exp Brain Res 2001 Sep 24;140(2):241-244. [doi: 10.1007/s002210100827] [Medline: 11521156]
13. Strafella AP, Paus T. Modulation of cortical excitability during action observation: a transcranial magnetic stimulation study. Neuroreport 2000 Jul 14;11(10):2289-2292. [doi: 10.1097/00001756-200007140-00044] [Medline: 10923687]
14. Enticott PG, Hoy KE, Herring SE, Johnston PJ, Daskalakis ZJ, Fitzgerald PB. Reduced motor facilitation during action observation in schizophrenia: a mirror neuron deficit? Schizophr Res 2008 Jul;102(1-3):116-121. [doi: 10.1016/j.schres.2008.04.001] [Medline: 18485674]
15. Social processes: workshop proceedings. National Institute of Mental Health. URL: https://www.nimh.nih.gov/research-priorities/rdoc/social-processes-workshop-proceedings.shtml [accessed 2018-03-13]
16. Kujirai T, Caramia MD, Rothwell JC, Day BL, Thompson PD, Ferbert A, et al. Corticocortical inhibition in human motor cortex. J Physiol 1993 Nov;471:501-519 [FREE Full text] [doi: 10.1113/jphysiol.1993.sp019912] [Medline: 8120818]
17. Mehta U, Thirthalli J, Basavaraju R, Gangadhar B, Pascual-Leone A. Reduced mirror neuron activity in schizophrenia and its association with theory of mind deficits: evidence from a transcranial magnetic stimulation study. Schizophr Bull 2014 Sep;40(5):1083-1094 [FREE Full text] [doi: 10.1093/schbul/sbt155] [Medline: 24214933]
18. Abhishek R. Endophenotype potential of social cognition and mirror neuron activity in bipolar-I disorder: a transcranial magnetic stimulation study (thesis). Bengaluru, India: National Institute of Mental Health and Neurosciences; 2019.
19. Sheehan DV, Lecrubier Y, Sheehan KH, Amorim P, Janavs J, Weiller E, et al. The Mini-International Neuropsychiatric Interview (M.I.N.I.): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. J Clin Psychiatry 1998;59 Suppl 20:22-33;quiz 34. [Medline: 9881538]
20. Tates K, Antheunis ML, Kanters S, Nieboer TE, Gerritse MB. The effect of screen-to-screen versus face-to-face consultation on doctor-patient communication: an experimental study with simulated patients. J Med Internet Res 2017 Dec 20;19(12):e421 [FREE Full text] [doi: 10.2196/jmir.8033] [Medline: 29263017]
21. Shaw S, Wherton J, Vijayaraghavan S, Morris J, Bhattacharya S, Hanson P, et al. Advantages and limitations of virtual online consultations in a NHS acute trust: the VOCAL mixed-methods study. Southampton, United Kingdom: NIHR Journals Library; 2018.
22. Bleyel C, Hoffmann M, Wensing M, Hartmann M, Friederich H, Haun MW. Patients' perspective on mental health specialist video consultations in primary care: qualitative preimplementation study of anticipated benefits and barriers. J Med Internet Res 2020 Apr 20;22(4):e17330 [FREE Full text] [doi: 10.2196/17330] [Medline: 32310139]
23. Moeller A, Christensen L, Hansen J, Andersen P. Patients' acceptance of video consultations in the mental health services: a systematic review and synthesis of qualitative research. Digit Health 2022;8:20552076221075148 [FREE Full text] [doi: 10.1177/20552076221075148] [Medline: 35154803]
24. Basavaraju R, Sanjay TN, Mehta UM, Muralidharan K, Thirthalli J. Cortical inhibition in symptomatic and remitted mania compared to healthy subjects: a cross-sectional study. Bipolar Disord 2017 Dec;19(8):698-703 [FREE Full text] [doi: 10.1111/bdi.12546] [Medline: 28833861]


## Abbreviations

**GABA:** gamma-aminobutyric acid
**LICI:** long-interval cortical inhibition
**MEP:** motor-evoked potential
**MNS:** mirror neuron system
**RMT:** resting motor threshold
**SICI:** short-interval cortical inhibition
**TMS:** transcranial magnetic stimulation

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Original Paper

# Long-term Effectiveness and Predictors of Transdiagnostic Internet-Delivered Cognitive Behavioral Therapy for Emotional Disorders in Specialized Care: Secondary Analysis of a Randomized Controlled Trial

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## Abstract

**Background:** Transdiagnostic internet-delivered cognitive behavioral therapy (iCBT) for emotional disorders has been shown to be effective in specialized care in the short term. However, less is known about its long-term effects in this specific setting. In addition, predictors of long-term effectiveness may help to identify what treatments are more suitable for certain individuals.

**Objective:** This study aimed to analyze the long-term effectiveness of transdiagnostic iCBT compared with that of treatment as usual (TAU) in specialized care and explore predictors of long-term effectiveness.

**Methods:** Mixed models were performed to analyze the long-term effectiveness and predictors of transdiagnostic iCBT (n=99) versus TAU (n=101) in public specialized mental health care. Outcomes included symptoms of depression and anxiety, health-related quality of life (QoL), behavioral inhibition and behavioral activation, comorbidity, and diagnostic status (ie, loss of principal diagnosis) from baseline to 1-year follow-up. Sociodemographic characteristics (sex, age, and education) and clinical variables (principal diagnosis, comorbidity, and symptom severity at baseline) were selected as predictors of long-term changes.

**Results:** Compared with baseline, transdiagnostic iCBT was more effective than TAU in improving symptoms of depression (*b*=–4.16, SE 1.80, 95% CI –7.68 to –0.67), health-related QoL (*b*=7.63, SE 3.41, 95% CI 1.00-14.28), diagnostic status (*b*=–0.24, SE 0.09, 95% CI –1.00 to –0.15), and comorbidity at 1-year follow-up (*b*=–0.58, SE 0.22, 95% CI –1.00 to –0.15). From pretreatment assessment to follow-up, anxiety symptoms improved in both transdiagnostic iCBT and TAU groups, but no significant differences were found between the groups. Regarding the predictors of the long-term effectiveness of transdiagnostic iCBT compared with that of TAU, higher health-related QoL at follow-up was predicted by a baseline diagnosis of anxiety, male sex, and the use of psychiatric medication; fewer comorbid disorders at follow-up were predicted by older age and higher baseline scores on health-related QoL; and fewer depressive symptoms at follow-up were predicted by baseline diagnosis of depression. However, this pattern was not observed for baseline anxiety diagnoses and anxiety symptoms.

**Conclusions:** The results suggest that transdiagnostic iCBT is more effective than TAU to target depressive symptoms among patients with emotional disorders. Anxiety symptoms remained stable at 1-year follow-up, with no differences between the groups. Results on predictors suggest that some groups of patients may obtain specific gains after transdiagnostic iCBT. Specifically, and consistent with the literature, patients with baseline depression improved their depression scores at follow-up. However, this pattern was not found for baseline anxiety disorders. More studies on the predictor role of sociodemographic and clinical variables

in long-term outcomes of transdiagnostic iCBT are warranted. Future studies should focus on studying the implementation of transdiagnostic iCBT in Spanish public specialized mental health care.

**Trial Registration:** ClinicalTrials.gov NCT02345668; https://clinicaltrials.gov/ct2/show/NCT02345668

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**KEYWORDS**

transdiagnostic; anxiety; depression; long term; predictors

## Introduction

### Background

In the past 20 years, epidemiological studies have systematically shown the high prevalence of emotional disorders (ie, anxiety and depression) and the disability and costs associated with these disorders [1-3]. The current COVID-19 pandemic has affected the social, work, and personal functioning of billions of people across the globe [4]. One of the most noteworthy effects of the pandemic has been its impact on mental health, with increases in the prevalence and severity of psychological disorders, including anxiety and depression [5,6]. Because of some social changes wrought by this situation (eg, social distancing), the need for interventions that do not involve face-to-face contact (eg, digital interventions) is growing. Therefore, it is important for people to have access to effective digital interventions such as internet-delivered interventions.

In the field of internet-delivered interventions, most of the research has focused on internet-delivered cognitive behavioral therapy (iCBT). The literature has shown that iCBT for emotional disorders is accessible [7], easy to disseminate [8], safe [9], and effective in both short- and long-term periods. Regarding long-term outcomes, several studies have been carried out that support the long-term effectiveness and efficacy of iCBT at 1-year follow-up [10] or longer periods [11]; for example, Eriksson et al [10] reported 1-year follow-up outcomes of a randomized controlled trial (RCT) that evaluated an iCBT program compared with treatment as usual (TAU) for depression in primary care, with results that supported its effectiveness. In another study, Wootton et al [12] showed that a self-guided iCBT program for obsessive-compulsive disorder (OCD) was effective in reducing OCD symptoms and that these gains were maintained at 1-year follow-up. In sum, research suggests that iCBT also has lasting effects on patients with anxiety and depressive disorders.

Among the range of iCBT programs, transdiagnostic iCBT for emotional disorders has shown its efficacy and effectiveness in a growing number of RCTs. Several meta-analyses have shown that transdiagnostic iCBT is effective in the short term, with pooled effect sizes (Hedges *g*) in the medium-to-large range for overall measures of anxiety (0.78-0.82), depression (0.79-0.84), and quality of life (QoL; 0.48-0.56) after treatment [13,14]. However, most of these available meta-analytic studies mainly report posttreatment outcomes, which suggests that more research is needed on the long-term effects of transdiagnostic iCBT. It is crucial to study not only the short-term effectiveness but also the long-term outcomes of these interventions for several reasons; for instance, high chronicity and relapse rates among anxiety and depressive disorders have commonly been reported in the literature [15,16]. This aspect is directly related to the direct (eg, psychiatric and psychological treatment resources) and indirect (eg, work and social costs) costs associated with the management of these disorders worldwide, which have been reported to be huge [17]. Therefore, it is important to develop interventions that show both short- and long-term effectiveness.

In addition to studying the long-term effectiveness of iCBT, it is essential to study possible predictors because a given treatment is not likely to work in the same way for everyone. Research on predictors of change can help to make recommendations about which treatments are more appropriate for certain individuals and which ones are less likely to be beneficial for them. Specifically, predictors of long-term effectiveness can help to determine for which patients transdiagnostic iCBT is more suitable in the long term. The most frequent predictors in the iCBT arena usually include baseline clinical characteristics (eg, clinical severity at baseline, comorbidity, and diagnosis) [18,19] and sociodemographic variables (eg, age, sex, and education) [20,21]. However, most of the studies conducted in this area have mainly focused on predictors of posttreatment outcomes or short-term follow-up results (eg, 3-month follow-up) [22,23].

### Objectives

To the best of our knowledge, studies on the long-term effectiveness of iCBT in public specialized mental health care are scarce in the literature. However, the high demand for mental health resources as well as the lack of resources in this specific setting [24,25] highlight the need for evidence-based interventions that are also effective in the long term. In a previously published RCT, we examined the effectiveness of a transdiagnostic iCBT compared with that of TAU in public specialized mental health care [26]. Transdiagnostic iCBT was found to be more effective than TAU on measures of anxiety (Cohen $d$=0.35), depression (Cohen $d$=0.41), and health-related QoL (Cohen $d$=–0.45) after treatment. However, the effects of this intervention in the long term (1-year follow-up) have not yet been analyzed. Therefore, the aim of this investigation was 2-fold: to analyze the long-term outcomes of transdiagnostic iCBT for emotional disorders compared with those of TAU and to analyze potential predictors of the long-term effectiveness of transdiagnostic iCBT versus TAU.

## Methods

### Study Design

This study analyzes long-term data (1-year follow-up) from a previously published RCT that compared transdiagnostic iCBT with TAU in public specialized mental health care services [26]. The protocol of the original study was registered at ClinicalTrials.gov (NCT02345668). The study design of the RCT has been fully described elsewhere [27].

### Ethics Approval

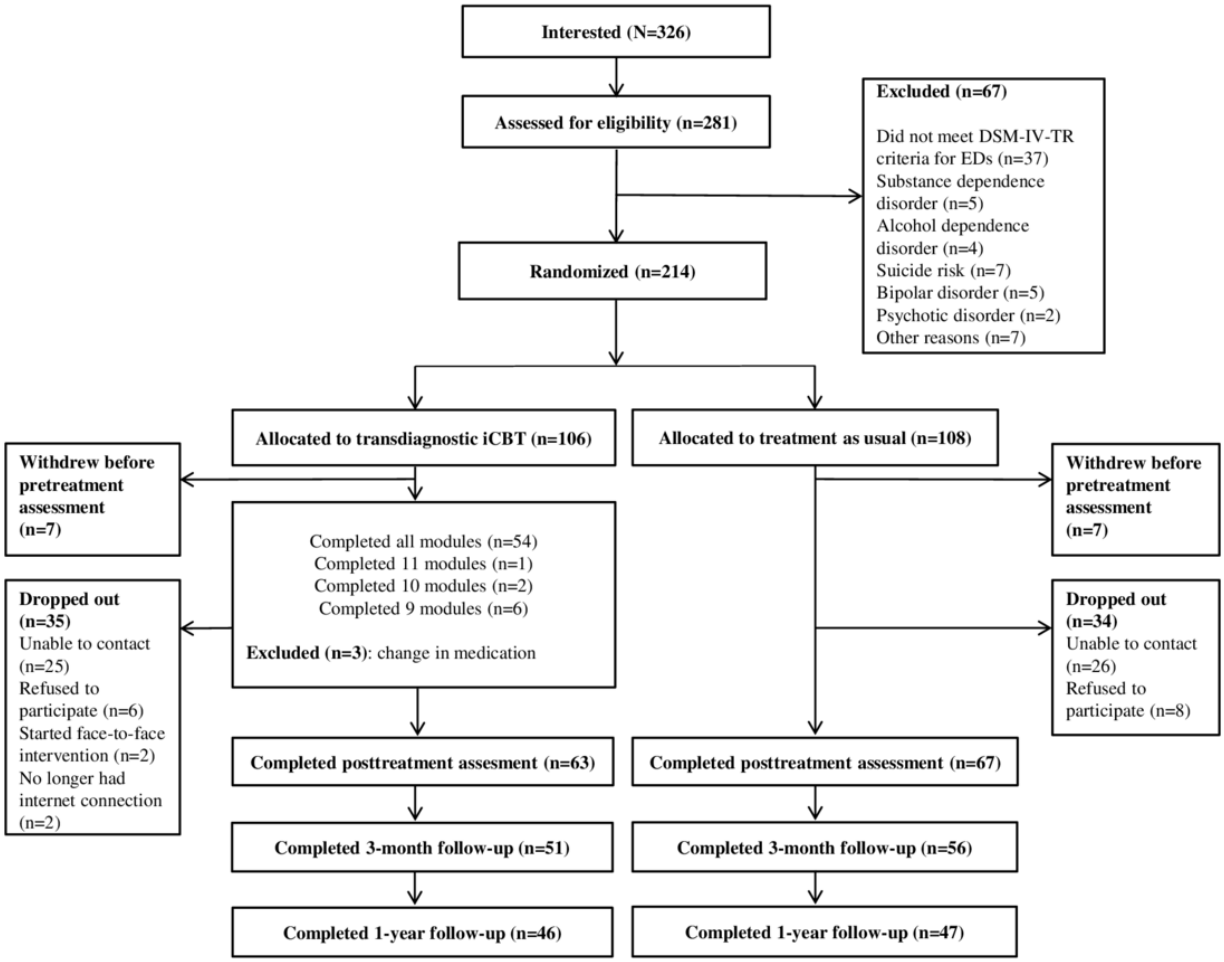
This study was granted ethics approval by the ethics committee of Universitat Jaume I (Castellón de la Plana, Spain) and the clinical research ethics committees of the 3 hospitals that participated in the trial (Consorcio Hospitalario Provincial de Castellón, Hospital Universitario de la Ribera, and Hospital Universitario Vall d'Hebron).

### Participants and Procedure

Participants were adults who attended public mental health units in Spain to seek psychological or psychiatric help between July 2015 and June 2019. Potential participants were identified by the psychiatrists and psychologists at these centers and referred to the study researchers for eligibility assessment (refer to the study by González-Robles et al [26] for a full description of the recruitment process). To participate in the study, patients had to meet the following eligibility criteria: (1) aged ≥18 years; (2) ability to understand and read Spanish; (3) access to the internet at home and an email address; (4) fulfill Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision, diagnostic criteria [28] for emotional disorders, including major depressive disorder, dysthymic disorder, depression not otherwise specified, panic disorder, agoraphobia, social anxiety disorder, generalized anxiety disorder, anxiety not otherwise specified, and OCD; (5) provide written informed consent; (6) absence of schizophrenia, bipolar disorder, and alcohol or substance dependence disorder; (7) absence of high risk of suicide; (8) absence of a disabling medical disease that prevented the participant from undergoing psychological treatment; and (9) not receiving another psychological treatment during the study (in the experimental group). Pharmacological treatment was allowed, but participants had to be taking the same dose during the 2 months before enrolling in the study. In addition, participants in the experimental group whose medication was increased or changed during the study period were excluded from the trial (decreases in pharmacological treatment were accepted).

The flowchart of participants from baseline to 1-year follow-up is presented in Figure 1. A total of 326 patients expressed interest in the study, of whom 281 (86.2%) were assessed for eligibility. Of these 281 participants, 67 (23.8%) were excluded from the study, and the remaining 214 (76.2%) participants were randomized to either transdiagnostic iCBT (n=106, 49.5%) or TAU (n=108, 50.5%). In addition, a few (transdiagnostic iCBT: 7/106, 6.6%; TAU: 7/108, 6.5%) patients withdrew from the study before the pretreatment assessment; therefore, they were excluded from the analyses. Thus, of the 200 participants in the final sample at baseline, 99 (49.5%) were randomized to transdiagnostic iCBT and 101 (50.5%) to TAU. One-year follow-up data were obtained from 47% (46/99) of the participants in the transdiagnostic iCBT condition and 47% (47/101) of the participants in the TAU condition.

**Figure 1.** Flowchart of participants. DSM-IV-TR: Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision; ED: emotional disorder; iCBT: internet-delivered cognitive behavioral therapy.




## Instruments

### *Principal Outcomes*

The Beck Depression Inventory, Second Edition (BDI-II) [29] is a self-report scale consisting of 21 items about the symptoms that characterize major depressive disorder. Scores on each item range from 0 to 3, and the maximum score is 63 points. The instrument has demonstrated internal consistency in both the original version (Cronbach α=.76-.95) and the Spanish version (Cronbach α=.87-.89) [30]. The Cronbach α value for the BDI-II in this study at baseline was .90.

The Beck Anxiety Inventory (BAI) [31] is a 21-item self-report questionnaire that assesses anxiety, with a maximum score of 63 points. Each item has a 4-point severity scale (from 0=not at all to 3=severely) that addresses anxiety symptoms experienced during the previous week. Several validation studies have shown adequate psychometric properties, with good-to-excellent internal consistency (Cronbach α between .85 and .94) and convergent and divergent validity. The Spanish version of the BAI has demonstrated high internal consistency (Cronbach α=.93) [32]. The Cronbach α value for the BAI in this study at baseline was .92.

### *Secondary Outcomes*

The EQ-5D-3L [33] is a generic instrument that measures health-related QoL and consists of 2 parts. Part 1 assesses self-reported problems in each of the following 5 domains: mobility, self-care, daily activities, pain or discomfort, and anxiety or depression. Part 2 records the participant's self-assessed health on a visual analog scale, a 10-cm vertical line on which the best and worst imaginable health states score 100 and 0, respectively. In this study, health-related QoL was assessed using the visual analog scale.

The behavioral inhibition system (BIS) and behavioral activation system (BAS) scales [34,35] contain 20 items rated from 1 to 4, with 7 BIS subscale items that evaluate individuals' emotional responses to impending negative events and 13 BAS subscale items that evaluate individuals' behavioral and emotional responses to potentially positive events. The BIS and BAS scales have shown good reliability in individuals with emotional disorders (Cronbach α=.73-.92) and good convergent and divergent validity as indicators of temperament. The internal consistency of the Spanish version ranges between Cronbach α=.65 and Cronbach α=.82. The Cronbach α values for the BIS and BAS subscales in this study at baseline were .61 and .80, respectively.

## Interventions

### *Transdiagnostic iCBT*

All participants received a 12-module transdiagnostic iCBT protocol through the web platform designed by our research

group [36]. The core components of the treatment are based on the unified protocol [37,38] and some treatment strategies from dialectical behavioral therapy (eg, what and how techniques) [39]. Participants are trained to learn and practice adaptive transdiagnostic iCBT skills through the following components: (1) present-focused emotional awareness (modules 4 and 5), (2) cognitive flexibility (modules 6 and 7), (3) identification and modification of emotional avoidance patterns and emotion-driven behaviors (modules 8 and 9), and (4) exposure (interoceptive and situational; modules 10 and 11). The treatment contains 4 additional modules: an introduction module (module 1), a module to facilitate the patient's engagement with the therapy (module 2), a module with psychoeducation on emotions (module 3), and a relapse prevention module at the end of the treatment (module 12). In addition, transdiagnostic iCBT includes a module 0 (welcome module) with information and recommendations about how to use the protocol. The modules are presented sequentially to enable step-by-step movement through the program. All participants had access to the protocol for a maximum period of 18 weeks, and they were allowed to use the program any time they wanted to during the trial period (ie, including the follow-up periods). Additional details about this treatment have been reported elsewhere [26,27]. The treatment modules and their goals are depicted in Textbox 1.

**Textbox 1.** Treatment modules and their goals.

- 0. Welcome module: gives information about the protocol (eg, general aim and number of modules) and recommendations about how to use the treatment protocol
- 1. Introduction to treatment: provides a framework on the role of emotion regulation in emotional disorders
- 2. Motivation for change: promotes patients' motivation for change by analyzing the pros and cons of changing and trains them in goal setting
- 3. Understanding the role of emotions: provides psychoeducation on the nature, role, and functions of emotions and trains the patient in identifying emotion components
- 4. Nonjudgmental emotional awareness and acceptance of emotional experiences: trains the patient in nonjudgmental emotional awareness and the acceptance of emotional experiences
- 5. Practicing present-focused awareness: provides additional training in nonjudgmental present-focused awareness in different domains, namely physical sensations, thoughts, emotions, and daily activities
- 6. Learning to be flexible: teaches the patient how to identify maladaptive cognitive patterns (ie, thinking traps)
- 7. Practicing cognitive flexibility: trains the patient in modifying maladaptive cognitive patterns (ie, cognitive reappraisal) and also provides psychoeducation to the patient about intrusive thoughts and how to manage them
- 8. Emotional avoidance: trains the patient to understand and identify maladaptive emotion avoidance patterns
- 9. Emotion-driven behaviors (EDBs): patients learn the concept of EDB and to replace maladaptive EDB with other more adaptive behaviors (ie, opposite action)
- 10. Accepting and facing physical sensations: teaches patients about the role of physical sensations in emotional response and trains them in interoceptive exposure
- 11. Facing emotions in the contexts where they occur: trains the patient to face situation-elicited avoided emotions through exposure procedures
- 12. Relapse prevention: patients review what they have learned throughout the program, schedule future practice of skills, and learn how to cope with high-risk situations

### *TAU Provision*

TAU was delivered by psychiatrists and clinical psychologists at mental health units in Spain. TAU in this study was provided by 3 hospitals: Consorcio Hospitalario Provincial de Castellón (Castellón de la Plana), Hospital Universitario de la Ribera (Valencia), and Hospital Universitario Vall d'Hebron (Barcelona). To maximize the external validity of this RCT, participants in this condition were allowed to receive psychiatric treatment (ie, prescription and monitoring of antidepressant and anxiolytic medication), psychological treatment (including case management, group psychotherapy, empathic listening, and supportive counseling), or a combination of the two. The frequency of visits during the 18-week treatment period varied depending on the type of treatment (ie, psychiatric or psychological) provided to the participant. Patients in the TAU condition who were already receiving any of the aforementioned treatments at the time of enrollment were informed that they would continue to receive these services during the treatment period. Furthermore, participants who were receiving any treatment other than those provided at the mental health unit were excluded from the trial.

### Statistical Analyses

First, independent samples 2-tailed *t* tests for continuous data and chi-square tests for categorical data were performed to confirm that there were no demographic or clinical differences between transdiagnostic iCBT and TAU at baseline. Missing data were explored, and we concluded that 33.63% of the values were missing overall at the construct level. The Little missing completely at random test showed that data were missing completely at random ($\chi^2_{80}$=76.1; *P*=.60). Furthermore, completers did not differ significantly from dropout cases on the baseline variables: age ($t_{198}$=1.23; *P*=.22), sex ($c^2_1$=0.02; *P*=.90), marital status ($c^2_3$=0.28; *P*=.96), and education ($c^2_2$=2.21; *P*=.33). Multiple imputation of missing values is not

necessary before performing longitudinal mixed model analysis [40].

Mixed effects models were conducted to analyze the long-term effects and predictors of transdiagnostic iCBT using the *lmer* function from the *lme4* R package [41] with R software (version 4.0.2; The R Foundation for Statistical Computing) [42]. Analyses were conducted via restricted maximum likelihood estimation [43,44]. In contrast to multiple imputation methods (ie, to fill in missing data) or complete case data through detection methods (which result in biased estimations), the restricted maximum likelihood estimation method allows incomplete and unbalanced data to be modeled by finding parameters that maximize the likelihood using all the available data, providing a less biased estimate of variance components with smaller sample sizes [43,45,46]. To compute the magnitude of between-group changes at 1-year follow-up, effect sizes (Cohen *d*) were calculated by dividing the differences in means by the pooled SD. Effect sizes were interpreted according to the Cohen convention: effect sizes of 0.20 are considered low, effect sizes of 0.50 are considered medium, and effect sizes of ≥0.80 are considered large [47].

Mixed effects models were performed on 5 dependent variables (DVs): depression (ie, BDI-II score), anxiety (ie, BAI score), BIS (ie, BIS scale score), BAS (ie, BAS scale score), health-related QoL (ie, EQ-5D-3L score), comorbidity (ie, number of diagnoses), and diagnostic status (ie, dummy variable: 0=does not meet diagnostic criteria and 1=meets diagnostic criteria). The models had 2 main components: fixed effects and random effects. First, variance across participants and hospitals was modeled as random effects in the model (ie, participant and hospital as random effects that account for individual differences in DVs). Second, group (ie, transdiagnostic iCBT vs TAU) and time (ie, pretreatment assessment, posttreatment assessment, 3-month follow-up, and 1-year follow-up) were modeled as fixed effects. Furthermore, we selected different baseline variables as potential predictors of long-term outcomes, including demographic variables (ie, sex, 0=male and 1=female; age, and education, 0=nonuniversity [basic and medium studies] and 1=university), clinical status (ie, medication. 0=no and 1=yes; principal diagnosis, 0=depression, 1=anxiety, and 2=OCD; comorbidity, number of clinical diagnoses, and diagnostic status, 0=does not meet diagnostic criteria and 1=meets diagnostic criteria), dispositional traits (ie, behavioral inhibition and behavioral activation), and symptomatology (anxiety [BAI], depression [BDI-II], and health-related QoL [EQ-5D-3L]). Given that we were interested in long-term changes (ie, 1-year follow-up compared with baseline), we focused on group1×time4 interactions (ie, transdiagnostic iCBT×1-year follow-up) to analyze the long-term effects and predictors [48].

Specification of the random effect structure was modeled following the recommendations by Barr et al [49,50]. First, a null model was estimated as a baseline point of comparison (ie, model 0). The null models only included the random intercepts (ie, participant and hospital) without the fixed effects. Second, models were computed by testing the long-term effects on the different DVs (ie, model 1). Third, a 2-step approach was used to analyze the long-term predictors [51,52]: first, univariate mixed models were computed to investigate the independent contribution of each potential predictor separately (ie, model 2); next, significant predictors in univariate models (ie, group1×time4×predictor; $P<.05$) were entered simultaneously into the multivariate mixed models using backward deletion (ie, model 3). This procedure helped us to obtain a final adjusted model for each DV.

Effect sizes for each model are presented as the model-derived fixed-effect parameter regression weights [53,54]. Model fit was evaluated using the likelihood ratio test, Akaike information criteria, and Bayesian information criteria.

## Results

### Baseline Data

The participants (N=200) had a mean age of 38.64 (SD 10.61; range 18-68) years, and the majority were female (138/200, 69%). Table 1 shows the sociodemographic and clinical characteristics for both conditions at baseline. There were no significant differences between transdiagnostic iCBT and TAU at baseline on any of the sociodemographic and clinical characteristics. Moreover, no significant differences were found for medication, principal diagnosis, number of comorbid diagnoses, or clinical severity on any of the measures.

**Table 1.** Sociodemographic and clinical characteristics of the sample at baseline (N=200).

| Characteristic | Transdiagnostic iCBT[a] (n=99) | TAU[b] (n=101) | Chi-square (*df*) | *t* test (*df*) | *P* value |
|---|---|---|---|---|---|
| Age (years), mean (SD) | 38.64 (10.61) | 38.25 (11.03) | N/A[c] | 0.25 (1) | .80 |
| **Sex, n (%)** | | | 1.3 (1) | N/A | .26 |
| Female | 72 (72.7) | 66 (65.3) | | | |
| Male | 27 (27.3) | 35 (34.7) | | | |
| **Marital status, n (%)** | | | 1.1 (3) | N/A | .78 |
| Single | 22 (22.2) | 26 (25.7) | | | |
| Married or partnered | 63 (63.6) | 65 (64.4) | | | |
| Divorced or widowed | 14 (14.1) | 10 (9.9) | | | |
| **Education, n (%)** | | | 2.1 (2) | N/A | .35 |
| Basic studies | 26 (26.3) | 36 (35.6) | | | |
| Secondary studies | 41 (41.4) | 35 (34.6) | | | |
| University studies | 32 (32.3) | 30 (29.7) | | | |
| **Principal diagnosis, n (%)** | | | 2.7 (8) | N/A | .95 |
| GAD[d] | 23 (23.2) | 26 (25.7) | | | |
| AG[e] | 16 (16.2) | 13 (12.9) | | | |
| PD[f] | 9 (9.1) | 5 (5) | | | |
| SAD[g] | 4 (4) | 4 (4) | | | |
| OCD[h] | 8 (8.1) | 12 (11.9) | | | |
| MDD[i] | 20 (20.2) | 22 (21.8) | | | |
| DD[j] | 7 (7.1) | 6 (5.9) | | | |
| Anxiety NOS[k] | 10 (10.1) | 9 (8.9) | | | |
| Depression NOS | 2 (2) | 3 (3) | | | |
| **Comorbidity, n (%)** | | | 2.3 (3) | N/A | .50 |
| 1 | 49 (49.5) | 41 (40.6) | | | |
| 2 | 29 (29.3) | 38 (37.6) | | | |
| 3 | 15 (15.2) | 13 (12.9) | | | |
| ≥4 | 6 (6.1) | 8 (7.9) | | | |
| **Medication, n (%)** | | | 5.2 (3) | N/A | .16 |
| None | 29 (29.3) | 18 (17.8) | | | |
| Antidepressant | 22 (22.2) | 20 (19.8) | | | |
| Anxiolytic | 10 (10.1) | 17 (16.8) | | | |
| Both | 38 (38.4) | 46 (45.5) | | | |

[a]iCBT: internet-delivered cognitive behavioral therapy.
[b]TAU: treatment as usual.
[c]N/A: not applicable.
[d]GAD: generalized anxiety disorder.
[e]AG: agoraphobia.
[f]PD: panic disorder.
[g]SAD: social anxiety disorder.
[h]OCD: obsessive-compulsive disorder.
[i]MDD: major depressive disorder.
[j]DD: dysthymic disorder.

[k]NOS: not otherwise specified.

## Long-term Effectiveness

### *Principal and Secondary Outcomes*

Table 2 displays the means, SEs, and effect sizes for transdiagnostic iCBT versus TAU for depression and anxiety symptoms, health-related QoL, and behavioral inhibition and behavioral activation from baseline to 1-year follow-up.

Regarding depressive symptoms, there was a significant main effect of time (*b*=–5.85, SE 1.26, 95% CI –8.30 to –3.40), indicating that BDI-II scores were, on average, 5.85 points greater at baseline than at 1-year follow-up when the other variables in the model were kept constant. The main effect of group was not significant (*b*=–0.71, SE 1.76, 95% CI –4.04 to 2.85); thus, both groups showed similar BDI-II scores on average. The results also revealed a significant group×time interaction (*b*=–4.16, SE 1.80, 95% CI –7.68 to –0.67). Tukey-corrected post hoc comparisons indicated that both groups significantly reduced their depressive symptoms at 1-year follow-up; however, these reductions were larger in the transdiagnostic iCBT group.

Regarding anxiety symptoms, there was a significant main effect of time (*b*=–5.37, SE 1.42, 95% CI –8.13 to –2.61), indicating that BAI scores were, on average, 5.37 points greater at baseline than at 1-year follow-up when the other variables in the model were kept constant. The main effect of group was not significant (*b*=2.67, SE 1.73, 95% CI –5.64 to 1.11); thus, both groups showed similar BAI scores on average. The group×time interaction was not significant (*b*=–1.54, SE 2.03, 95% CI –5.49 to 2.41). Tukey-corrected post hoc comparisons indicated that both groups similarly reduced their anxiety symptoms at 1-year follow-up.

Regarding health-related QoL, there was a significant main effect of time (*b*=6.19, SE 2.38, 95% CI 1.54-10.83), indicating that EQ-5D-3L scores were, on average, 6.19 points greater at 1-year follow-up than at baseline when the other variables in the model were kept constant. The main effect of group was not significant (*b*=2.29, SE 2.59, 95% CI –2.75 to 7.34); thus, both groups showed similar EQ-5D-3L scores on average. The results also revealed a significant group×time interaction (*b*=7.63, SE 3.41, 95% CI 1.00-14.28). Tukey-corrected post hoc comparisons indicated that only transdiagnostic iCBT participants significantly improved health-related QoL at 1-year follow-up, whereas no changes were found in the TAU group.

Regarding the BIS scale, the time main effect (*b*=0.24, SE 0.45, 95% CI –.64 to 1.13) and group main effect (*b*=–0.07, SE 0.43, 95% CI –0.92 to 0.77) were not significant. The results revealed a significant group×time interaction (*b*=–2.37, SE 0.65, 95% CI –3.63 to –1.10). Tukey-corrected post hoc comparisons indicated that only participants in the transdiagnostic iCBT group significantly reduced BIS scale scores at 1-year follow-up, whereas no changes were found in the TAU group. Regarding the BAS scale, the time main effect (*b*=–1.08, SE 0.67, 95% CI –2.38 to 0.23), group main effect (*b*=–0.58, SE 0.87, 95% CI –2.28 to 1.12), and group×time interaction (*b*=1.84, SE 0.96, 95% CI –0.03 to 3.71) were not significant.

**Table 2.** Means, SEs, and between-group effect sizes (Cohen *d*) from baseline to 1-year follow-up.

| | Baseline | | One-year follow-up | | |
|---|---|---|---|---|---|
| | Transdiagnostic iCBT[a], mean (SE) | TAU[b], mean (SE) | Transdiagnostic iCBT, mean (SE) | TAU, mean (SE) | Cohen *d* (95% CI) |
| BDI-II[c] | 23.4 (1.4) | 24.1 (1.4) | 13.4 (1.7) | 18.3 (1.6) | 0.43 (0.02 to 0.85) |
| BAI[d] | 20.0 (1.3) | 22.3 (1.2) | 13.1 (1.6) | 16.9 (1.6) | 0.34 (–0.07 to 0.75) |
| EQ-5D-3L | 55.8 (2.0) | 53.5 (1.9) | 69.6 (2.6) | 59.7 (2.5) | –0.57 (–0.98 to –0.15) |
| BIS[e] scale | 23.3 (0.3) | 23.4 (0.3) | 21.2 (0.4) | 23.6 (0.4) | 0.87 (–1.30 to –0.45) |
| BAS[f] scale | 35.3 (0.6) | 35.8 (0.6) | 36.0 (0.8) | 34.8 (0.8) | 0.22 (–0.19 to 0.63) |

[a]iCBT: internet-delivered cognitive behavioral therapy.

[b]TAU: treatment as usual.

[c]BDI-II: Beck Depression Inventory, Second Edition.

[d]BAI: Beck Anxiety Inventory.

[e]BIS: behavioral inhibition system.

[f]BAS: behavioral activation system.

### *Diagnostic Status and Comorbidity*

Regarding diagnostic status (ie, loss of baseline principal diagnosis), there was a significant main effect of time (*b*=–0.54, SE 0.07, 95% CI –0.86 to –0.20), indicating that changes in diagnostic status were significant at 1-year follow-up compared with baseline when the other variables in the model were kept constant. However, the main effect of group was not significant (*b*=0.00, SE 0.05, 95% CI –0.37 to 0.18); thus, both groups showed similar changes in diagnostic status. The results also revealed a significant group×time interaction (*b*=–0.24, SE 0.09, 95% CI –1.00 to –0.15). Tukey-corrected post hoc comparisons

indicated that patients in both groups significantly improved their diagnostic status at 1-year follow-up; however, these changes were significantly higher in the transdiagnostic iCBT group. Specifically, 22% (22/99) of the patients in the transdiagnostic iCBT group met the diagnostic criteria at 1-year follow-up versus 45.5% (46/101) of the patients in the TAU group.

Finally, regarding comorbidity (ie, number of Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision, diagnoses), there was a significant main effect of time (*b*=–0.53, SE 0.17, 95% CI –0.86 to –0.20), indicating that comorbidity was, on average, 0.53 points greater at baseline than at 1-year follow-up when the remaining variables in the model were kept constant. However, the main effect of group was not significant (*b*=–0.10, SE 0.14, 95% CI –0.37 to 0.18); thus, both groups showed similar comorbidity on average. The results also revealed a significant group×time interaction (*b*=–0.58, SE 0.22, 95% CI –1.00 to –0.15). Tukey-corrected post hoc comparisons indicated that both groups significantly reduced comorbidity at 1-year follow-up; however, these reductions were larger in the transdiagnostic iCBT group. Specifically, comorbidity decreased from 1.78 (SE 0.1) diagnoses at baseline in the transdiagnostic iCBT group to 0.70 (SE 0.1) at 1-year follow-up. By contrast, comorbidity in the TAU group changed from 1.88 (SE 0.1) diagnoses at baseline to 1.38 (SE 0.2) at 1-year follow-up.

## Predictors of Long-term Effectiveness

### *Overview*

Fixed-effect parameter estimates and their corresponding 95% CIs for each predictor of long-term changes separately are shown in Multimedia Appendix 1. As indicated previously, we first conducted univariate mixed models to investigate the independent contribution of each potential predictor of long-term changes separately. Significant predictors in univariate models were then entered simultaneously into a multivariate mixed model. In the following paragraphs, we report the results on predictors for the following variables: (1) depressive and anxiety symptoms as well as behavioral inhibition and behavioral activation, (2) health-related QoL, (3) diagnostic status, and (4) comorbidity.

### *Changes in Depression, Anxiety, and Behavioral Inhibition and Behavioral Activation*

The principal diagnosis (anxiety: *b*=9.07, SE 3.99, 95% CI 1.15-16.72; OCD: *b*=15.97, SE 7.25, 95% CI 2.10-29.88) and comorbidity (*b*=5.14, SE 2.13, 95% CI 1.05-9.22) at baseline predicted changes in depressive symptoms at 1-year follow-up. However, none of the predictors were significantly related to changes in anxiety symptoms, behavioral inhibition, or behavioral activation. Post hoc comparisons of the principal diagnosis at baseline showed the following results: (1) there were significant differences in depressive symptoms at follow-up between transdiagnostic iCBT and TAU only in participants with depressive disorders at baseline and not in participants with anxiety and OCD diagnoses. Specifically, participants with depressive disorders showed significant decreases in depressive symptoms at follow-up in the transdiagnostic iCBT group, whereas no changes were found in the TAU group; (2) participants with anxiety disorders showed significant reductions in depressive symptoms at 1-year follow-up in both transdiagnostic iCBT and TAU groups; (3) however, no changes in depressive symptoms were found in participants with OCD; and (4) participants with depressive disorders in the transdiagnostic iCBT group showed greater depressive symptoms at baseline than participants with anxiety and OCD diagnoses, but these differences disappeared at follow-up. However, these differences were not found in the TAU group. By contrast, transdiagnostic iCBT participants showed a significant positive association between comorbidity and depressive symptoms both at baseline and at 1-year follow-up (ie, participants with severe depressive symptoms showed greater comorbidity), but this association was significantly stronger in the transdiagnostic iCBT group at follow-up, and it was not significant in the TAU group. Finally, when these predictors were entered simultaneously into the mixed model, a principal diagnosis of anxiety at baseline (*b*=11.17, SE 5.66, 95% CI 0.61-21.88) and comorbidity (*b*=5.40, SE 2.13, 95% CI 1.37-9.38) remained significant, whereas a principal diagnosis of OCD at baseline was no longer significant (*b*=14.35, SE 10.01, 95% CI –4.39 to 33.26). The final model significantly improved the model fit ($\chi^2_7$=111.6; *P*<.001).

### *Changes in Health-Related QoL*

Sex (*b*=16.40, SE 7.19, 95% CI 2.48-30.28), medication (*b*=17.99, SE 8.82, 95% CI 0.95-35.04), and a principal diagnosis of anxiety at baseline (*b*=–15.76, SE 7.61, 95% CI –30.33 to –1.10) predicted changes in health-related QoL at 1-year follow-up. Post hoc comparisons showed that there were significant differences in health-related QoL at follow-up between the transdiagnostic iCBT group and the TAU group in male participants but not in female participants. Specifically, significant health-related QoL improvements at follow-up were found in the male participants in the transdiagnostic iCBT group but not in the male participants in the TAU group. Similarly, significant differences in health-related QoL between transdiagnostic iCBT and TAU were found only in participants who were taking medications at baseline. Specifically, significant health-related QoL improvements at follow-up were found in participants taking medications in the transdiagnostic iCBT group but not in the TAU group. Finally, post hoc comparisons showed that only participants with an anxiety diagnosis in the transdiagnostic iCBT group experienced significant increases in health-related QoL at follow-up, whereas no changes were found in the TAU group. Moreover, when these predictors were entered simultaneously into the mixed model, sex (*b*=14.45, SE 7.20, 95% CI 0.88-27.98) and a principal diagnosis of anxiety at baseline (*b*=–14.86, SE 7.67, 95% CI –29.37 to –0.46) remained significant, whereas medication was no longer significant (*b*=15.09, SE 8.93, 95% CI –1.69 to 31.96). The final model significantly improved the model fit ($\chi^2_{32}$=64.3; *P*<.001).

### *Changes in Diagnostic Status*

Age (*b*=–0.02, SE 0.01, 95% CI 0.03-0.001) and health-related QoL (*b*=–0.01, SE 0.01, 95% CI –0.02 to –0.001) predicted changes in diagnostic status at follow-up. First, there was a

negative association between age and diagnostic status in the transdiagnostic iCBT group at follow-up (ie, older people had fewer diagnoses at follow-up), whereas this relationship was positive in the TAU group (ie, older people had more diagnoses at follow-up). Second, there was a significant negative association between health-related QoL and diagnostic status at follow-up in the transdiagnostic iCBT group (ie, participants with better health-related QoL had fewer diagnoses at follow-up). However, this association was not significant in the TAU group. Finally, when these predictors were entered simultaneously into the mixed model, health-related QoL remained significant (*b*=–0.01, SE –0.01, 95% CI –0.02 to –0.001), whereas age was no longer significant (*b*=–0.01, SE –0.01, 95% CI –0.02 to –0.01). The final model significantly improved the model fit ($\chi^2_7$=296.4; *P*<.001).

### *Changes in Comorbidity*

Age (*b*=–0.04, SE 0.02, 95% CI –0.08 to 0.000), education (*b*=0.89, SE 0.49, 95% CI –0.004 to 1.83), and health-related QoL (*b*=–0.02, SE 0.01, 95% CI –0.04 to 0.000) were marginally significant predictors of comorbidity changes at 1-year follow-up. First, age and comorbidity at follow-up were negatively associated in the transdiagnostic iCBT group but not in the TAU group (ie, older people had less comorbidity). Second, no significant differences in comorbidity were found between participants with nonuniversity and university education in the transdiagnostic iCBT group; that is, both participants with nonuniversity and university education significantly reduced their comorbidity in this group. Moreover, participants with nonuniversity education in the transdiagnostic iCBT group had less comorbidity than participants with nonuniversity education in the TAU group at follow-up. Third, a significant negative association between comorbidity and health-related QoL was found in the transdiagnostic iCBT group at follow-up (ie, higher scores in health-related QoL were associated with less comorbidity), but this association was not significant in the TAU group. Finally, when these predictors were entered simultaneously into the mixed model, only health-related QoL remained significant (*b*=–0.03, SE 0.02, 95% CI –0.05 to –0.04), whereas age (*b*=–0.03, SE 0.02, 95% CI –0.08 to 0.01) and education (*b*=0.91, SE 0.51, 95% CI –0.05 to 1.89) were no longer significant. The final model significantly improved the model fit ($\chi^2_7$=127.5; *P*<.001).

## Discussion

### Overview

The objective of this study was 2-fold. The first objective was to analyze the long-term effectiveness of a transdiagnostic iCBT protocol for emotional disorders in public specialized mental health care services. In addition, we were interested in examining potential predictors of long-term outcomes. We discuss the findings in the next 2 sections.

### Long-term Effectiveness

Taken together, transdiagnostic iCBT was shown to be more effective than TAU at 1-year follow-up for the treatment of emotional disorders in specialized care. Specifically, in comparison with TAU, transdiagnostic iCBT was more effective in reducing symptoms of depression and improving health-related QoL at 1-year follow-up, with effect sizes in the small-to-moderate range. Furthermore, participants in the transdiagnostic iCBT group had a better diagnostic status (ie, of the 99 patients in the transdiagnostic iCBT group, 22, 22%, met the diagnosis criteria at 1-year follow-up, whereas of the 101 patients in the TAU group, 46, 45.5%, met the diagnosis criteria at 1-year follow-up) and showed less comorbidity (0.7 diagnoses in the transdiagnostic iCBT group vs 1.38 diagnoses in the TAU group). Regarding anxiety, both groups improved their scores from pretreatment assessment to 1-year follow-up, without significant differences between the groups. These results suggest that transdiagnostic iCBT was at least as effective as TAU for anxiety symptoms in the long term. In this regard, it should be noted that participants in the TAU group were also undergoing some treatment (pharmacological or psychological treatment) provided by clinicians of the national health system, that is, patients in the TAU group received an active treatment. As a recent meta-analysis on the efficacy of the unified protocol shows, studies that used active control conditions (including TAU) as comparison groups exhibited lower effect sizes than those that used passive control groups (eg, waitlist control group) [55]. Moreover, we do not know how many of the patients in the TAU group continued to receive treatment between follow-up periods (and the types of treatments they received), which might have also influenced the follow-up results. In any case, although the results go in this direction, this hypothesis should be tested using an appropriate study design (eg, noninferiority trial design). Another noteworthy finding is that the scores on behavioral inhibition were significantly lower in patients from the transdiagnostic iCBT condition, with an effect size in the large range (Cohen *d*=0.87), whereas no differences were found for behavioral activation. The study of how these and other related dimensions (eg, neuroticism and extraversion as well as positive and negative affect) change after treatment is of paramount importance in the context of transdiagnostic treatments that target shared psychopathological processes [55,56]. Nevertheless, these results are comparable to those obtained in trials that measure close constructs such as positive and negative affect [57]. The pattern of results that we obtained in behavioral inhibition and behavioral activation resembles the pattern of results in negative and positive effects after transdiagnostic iCBT found in the literature, that is, large gains in negative affect and low-to-moderate gains in positive affect [55]. With the exception of the study by Carl et al [58], to our knowledge, no other studies on transdiagnostic iCBT have included this measure in their trials. Future research may benefit from including measures of behavioral inhibition and behavioral activation to study the potential of transdiagnostic iCBT in successfully addressing these specific temperament dimensions.

Overall, the results support the long-term effectiveness of transdiagnostic iCBT in comparison with that of TAU for a number of measures, including depression, health-related QoL, behavioral inhibition, diagnostic status, and comorbidity. These results add to those of our previously published RCT, which showed that transdiagnostic iCBT in public specialized care was both effective and safe in the short term for individuals

with emotional disorders [26]. Improvements in anxiety symptoms remained stable at 1-year follow-up, with no difference between the conditions. However, it should be noted that transdiagnostic iCBT was compared with an active treatment condition, where most patients were receiving either pharmacological or psychological treatment.

To our knowledge, this is the first study to report on the long-term effectiveness of transdiagnostic iCBT for emotional disorders in public specialized mental health care and support its application in this setting. On the basis of our results, we believe that the implementation of iCBT in public specialized mental health care might help to deal with long-lasting barriers (eg, lack of resources) and the difficulties arising from the current COVID-19 pandemic by increasing dissemination of, and access to, evidence-based interventions.

## Predictors of Long-term Effectiveness

### *Overview*

The second goal of the study was to analyze potential predictors of long-term effectiveness. To do so, we explored the predictor role of different baseline variables, including sociodemographic characteristics (ie, age, sex, and education) and clinical variables (ie, symptom severity, principal diagnosis, and comorbidity) in the following outcomes at 1-year follow-up: depressive symptoms, anxiety symptoms, health-related QoL, behavioral inhibition and behavioral activation, comorbidity (ie, number of diagnoses), and diagnostic status (ie, loss of principal diagnosis). Overall, a heterogeneous pattern of predictors of long-term outcomes was observed, but we found several relationships that are worth discussing.

### *Changes in Depression, Anxiety, and Behavioral Inhibition and Behavioral Activation*

We found that participants in the transdiagnostic iCBT group with a baseline diagnosis of depression had fewer depressive symptoms at follow-up. In addition, participants with depressive disorders at baseline in the transdiagnostic iCBT group showed more severe depressive symptoms than patients with baseline anxiety and OCD. These results are in line with research showing that individuals with more severe depression improve more than patients with mild depression after receiving psychotherapy [18,19,59]. By contrast, no differences in depressive symptoms at follow-up were found in patients with anxiety disorders and OCD between the 2 conditions, suggesting that transdiagnostic iCBT might be specially indicated for reducing depressive symptoms in patients who enter transdiagnostic iCBT with a principal diagnosis of depression. No significant predictors were found for behavioral inhibition and behavioral activation.

### *Changes in Health-Related QoL*

A baseline principal diagnosis of anxiety predicted better health-related QoL at follow-up after transdiagnostic iCBT but not after TAU, which suggests that transdiagnostic iCBT might be particularly beneficial for health-related QoL in patients with primary anxiety disorders. In addition, being male and being on medication at baseline predicted improvements in health-related QoL at follow-up after transdiagnostic iCBT but not after TAU. With regard to being male, sex has not usually been reported as a predictor of outcomes in the cognitive behavioral therapy literature [60,61].

### *Changes in Diagnostic Status and Comorbidity*

Age at baseline predicted changes in diagnostic status at follow-up. Specifically, older participants were more likely to not meet the diagnostic criteria for their principal baseline diagnosis at follow-up after transdiagnostic iCBT, whereas an opposite pattern was observed for older participants in the TAU group. Moreover, older individuals who received transdiagnostic iCBT also showed less comorbidity at follow-up than older individuals who received TAU. Taken together, these findings suggest that older individuals with emotional disorders are adequate targets for transdiagnostic iCBT in specialized care, at least in terms of improving their diagnostic status and comorbidity. Likewise, participants with nonuniversity and university education had significantly less comorbidity at follow-up. Moreover, participants with nonuniversity education in the transdiagnostic iCBT group had significantly less comorbidity at follow-up than participants with nonuniversity education in the TAU group. These results support the notion that, regardless of sociodemographic variables such as age and educational level, iCBT probably works equally well [21].

## Limitations

The results should be interpreted in the context of some limitations. First, attrition was high in both conditions at 1-year follow-up. However, it should be noted that data were missing completely at random. Moreover, dropout rates in internet interventions are high even at short-term follow-ups [62]. Second, the sample size was small, which may affect the representativeness of the findings achieved in this study. Third, baseline to 1-year follow-up disorder-specific symptoms (eg, panic disorder symptoms and social anxiety disorder symptoms) could not be analyzed because of the small sample size. Finally, although no differences were observed between the groups in anxiety symptoms, a noninferiority trial design would be needed to confirm that transdiagnostic iCBT was not inferior to TAU in improving anxiety symptoms in the long term.

## Conclusions

The findings show that transdiagnostic iCBT in public specialized care is in general effective for the treatment of emotional disorders in the long term. Together with our previously published RCT, we have provided research that shows both the short- and long-term effectiveness of transdiagnostic iCBT in public specialized mental health care. In addition, it should be highlighted that specialized mental health care in Spain is provided by psychiatrists and clinical psychologists with the highest degree of specialization in the treatment of psychological disorders in the national public health care system, which the authors believe adds value to the findings of this study. On the basis of these results, we encourage other researchers to conduct studies with a specific focus on implementation in this setting to achieve widespread integration of iCBT in the Spanish national public health care system, which has also been deeply affected by the consequences of the COVID-19 pandemic. In our analysis of predictors, the results

showed trends suggesting that transdiagnostic iCBT predicts improvements in depression for patients with baseline depression. However, we did not find such patterns for baseline anxiety disorders and anxiety symptoms. As this is, to our knowledge, the first study to explore predictors of long-term outcomes in transdiagnostic iCBT, further studies should be conducted to shed light on the predictor role of sociodemographic and clinical variables for these interventions. Finally, in addition to sociodemographic and clinical variables, other variables specific to iCBT, such as the association between program use (eg, number of log-ins, time spent in each treatment module, and number of activities completed) and outcome in iCBT, should be further studied. Although research exists on the association among these variables, the findings mostly refer to posttreatment results [63-65]. Hence, we recommend that future research should analyze the association between program use and outcomes not only in the treatment period but also in the follow-up periods.

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## Conflicts of Interest

None declared.

Multimedia Appendix 1
Fixed-effect parameter estimates and their corresponding 95% CIs for each predictor of long-term changes separately.
[DOCX File , 105 KB - mental_v9i10e40268_app1.docx ]

Multimedia Appendix 2
CONSORT-eHEALTH checklist (V 1.6.2).
[PDF File (Adobe PDF File), 98 KB - mental_v9i10e40268_app2.pdf ]

## References

1. Baxter A, Vos T, Scott KM, Ferrari AJ, Whiteford HA. The global burden of anxiety disorders in 2010. Psychol Med 2014 Aug;44(11):2363-2374. [doi: 10.1017/S0033291713003243] [Medline: 24451993]
2. Cuijpers P, Beekman AT, Reynolds CF. Preventing depression: a global priority. JAMA 2012 Mar 14;307(10):1033-1034 [FREE Full text] [doi: 10.1001/jama.2012.271] [Medline: 22416097]
3. Kessler RC, Berglund P, Demler O, Jin R, Merikangas KR, Walters EE. Lifetime prevalence and age-of-onset distributions of DSM-IV disorders in the National Comorbidity Survey Replication. Arch Gen Psychiatry 2005 Jun 01;62(6):593-602. [doi: 10.1001/archpsyc.62.6.593] [Medline: 15939837]
4. Dubey S, Biswas P, Ghosh R, Chatterjee S, Dubey MJ, Chatterjee S, et al. Psychosocial impact of COVID-19. Diabetes Metab Syndr 2020;14(5):779-788 [FREE Full text] [doi: 10.1016/j.dsx.2020.05.035] [Medline: 32526627]
5. Hawes M, Szenczy AK, Klein DN, Hajcak G, Nelson BD. Increases in depression and anxiety symptoms in adolescents and young adults during the COVID-19 pandemic. Psychol Med 2021 Jan 13:1-9 [FREE Full text] [doi: 10.1017/S0033291720005358] [Medline: 33436120]
6. Lima C, Carvalho P, Lima I, Nunes J, Saraiva J, de Souza R, et al. The emotional impact of Coronavirus 2019-nCoV (new Coronavirus disease). Psychiatry Res 2020 May;287:112915 [FREE Full text] [doi: 10.1016/j.psychres.2020.112915] [Medline: 32199182]
7. Andrews G, Basu A, Cuijpers P, Craske MG, McEvoy P, English CL, et al. Computer therapy for the anxiety and depression disorders is effective, acceptable and practical health care: an updated meta-analysis. J Anxiety Disord 2018 Apr;55:70-78 [FREE Full text] [doi: 10.1016/j.janxdis.2018.01.001] [Medline: 29422409]
8. Andersson G, Titov N. Advantages and limitations of internet-based interventions for common mental disorders. World Psychiatry 2014 Feb;13(1):4-11 [FREE Full text] [doi: 10.1002/wps.20083] [Medline: 24497236]
9. Karyotaki E, Kemmeren L, Riper H, Twisk J, Hoogendoorn A, Kleiboer A, et al. Is self-guided internet-based cognitive behavioural therapy (iCBT) harmful? An individual participant data meta-analysis. Psychol Med 2018 Nov;48(15):2456-2466 [FREE Full text] [doi: 10.1017/S0033291718000648] [Medline: 29540243]
10. Eriksson MC, Kivi M, Hange D, Petersson E, Ariai N, Häggblad P, et al. Long-term effects of Internet-delivered cognitive behavioral therapy for depression in primary care - the PRIM-NET controlled trial. Scand J Prim Health Care 2017 Jun 06;35(2):126-136 [FREE Full text] [doi: 10.1080/02813432.2017.1333299] [Medline: 28585868]

11. Andersson G, Rozental A, Shafran R, Carlbring P. Long-term effects of internet-supported cognitive behaviour therapy. Expert Rev Neurother 2018 Jan 08;18(1):21-28. [doi: 10.1080/14737175.2018.1400381] [Medline: 29094622]
12. Wootton B, Karin E, Titov N, Dear BF. Self-guided internet-delivered cognitive behavior therapy (ICBT) for obsessive-compulsive symptoms: a randomized controlled trial. J Anxiety Disord 2019 Aug;66:102111. [doi: 10.1016/j.janxdis.2019.102111] [Medline: 31301476]
13. Newby J, Twomey C, Yuan Li SS, Andrews G. Transdiagnostic computerised cognitive behavioural therapy for depression and anxiety: a systematic review and meta-analysis. J Affect Disord 2016 Jul 15;199:30-41. [doi: 10.1016/j.jad.2016.03.018] [Medline: 27060430]
14. Păsărelu CR, Andersson G, Bergman Nordgren L, Dobrean A. Internet-delivered transdiagnostic and tailored cognitive behavioral therapy for anxiety and depression: a systematic review and meta-analysis of randomized controlled trials. Cogn Behav Ther 2017 Jan;46(1):1-28. [doi: 10.1080/16506073.2016.1231219] [Medline: 27712544]
15. Richards D. Prevalence and clinical course of depression: a review. Clin Psychol Rev 2011 Nov;31(7):1117-1125. [doi: 10.1016/j.cpr.2011.07.004] [Medline: 21820991]
16. Yonkers KA, Bruce SE, Dyck IR, Keller MB. Chronicity, relapse, and illness--course of panic disorder, social phobia, and generalized anxiety disorder: findings in men and women from 8 years of follow-up. Depress Anxiety 2003 May 07;17(3):173-179. [doi: 10.1002/da.10106] [Medline: 12768651]
17. Wittchen H, Jacobi F, Rehm J, Gustavsson A, Svensson M, Jönsson B, et al. The size and burden of mental disorders and other disorders of the brain in Europe 2010. Eur Neuropsychopharmacol 2011 Sep;21(9):655-679. [doi: 10.1016/j.euroneuro.2011.07.018] [Medline: 21896369]
18. Driessen E, Cuijpers P, Hollon SD, Dekker JJ. Does pretreatment severity moderate the efficacy of psychological treatment of adult outpatient depression? A meta-analysis. J Consult Clin Psychol 2010 Oct;78(5):668-680. [doi: 10.1037/a0020570] [Medline: 20873902]
19. Bower P, Kontopantelis E, Sutton A, Kendrick T, Richards DA, Gilbody S, et al. Influence of initial severity of depression on effectiveness of low intensity interventions: meta-analysis of individual patient data. BMJ 2013 Feb 26;346(feb26 2):f540 [FREE Full text] [doi: 10.1136/bmj.f540] [Medline: 23444423]
20. Eskildsen A, Hougaard E, Rosenberg NK. Pre-treatment patient variables as predictors of drop-out and treatment outcome in cognitive behavioural therapy for social phobia: a systematic review. Nord J Psychiatry 2010 Apr 08;64(2):94-105. [doi: 10.3109/08039480903426929] [Medline: 20055730]
21. Cuijpers P, Karyotaki E, Reijnders M, Huibers MJ. Who benefits from psychotherapies for adult depression? A meta-analytic update of the evidence. Cogn Behav Ther 2018 Mar 18;47(2):91-106. [doi: 10.1080/16506073.2017.1420098] [Medline: 29345530]
22. Andersson E, Ljótsson B, Hedman E, Enander J, Kaldo V, Andersson G, et al. Predictors and moderators of internet-based cognitive behavior therapy for obsessive–compulsive disorder: results from a randomized trial. J Obsessive Compulsive Related Disord 2015 Jan;4:1-7. [doi: 10.1016/j.jocrd.2014.10.003]
23. El Alaoui S, Hedman E, Ljótsson B, Bergström J, Andersson E, Rück C, et al. Predictors and moderators of internet- and group-based cognitive behaviour therapy for panic disorder. PLoS One 2013 Nov 7;8(11):e79024 [FREE Full text] [doi: 10.1371/journal.pone.0079024] [Medline: 24244406]
24. Martín-Jurado A, de la Gándara Martín JJ, Castro Carbajo S, Moreira Hernández A, Sánchez-Hernández J. [Concordance analysis of referrals from Primary Care to Mental Health]. Semergen 2012 Sep;38(6):354-359. [doi: 10.1016/j.semerg.2011.12.005] [Medline: 22935831]
25. Kohn R, Saxena S, Levav I, Saraceno B. The treatment gap in mental health care. Bull World Health Organ 2004 Nov;82(11):858-866 [FREE Full text] [Medline: 15640922]
26. González-Robles A, Díaz-García A, García-Palacios A, Roca P, Ramos-Quiroga JA, Botella C. Effectiveness of a transdiagnostic guided internet-delivered protocol for emotional disorders versus treatment as usual in specialized care: randomized controlled trial. J Med Internet Res 2020 Jul 07;22(7):e18220 [FREE Full text] [doi: 10.2196/18220] [Medline: 32673226]
27. González-Robles A, García-Palacios A, Baños R, Riera A, Llorca G, Traver F, et al. Effectiveness of a transdiagnostic internet-based protocol for the treatment of emotional disorders versus treatment as usual in specialized care: study protocol for a randomized controlled trial. Trials 2015 Oct 31;16(1):488 [FREE Full text] [doi: 10.1186/s13063-015-1024-3] [Medline: 26519046]
28. Diagnostic and Statistical Manual of Mental Disorders, 4th edition. Washington, DC: American Psychiatric Association; 1994.
29. Beck A, Steer RA, Brown GK. BDI-II, Beck Depression Inventory Manual. San Antonio, TX: Psychological Corporation; 1996.
30. Sanz J, Navarro ME, Vázquez C. Adaptación española del inventario para la depresión de beck--II(BDI-II): 1. Propiedades psicométricas en estudiantes universitarios [Spanish adaptation of the Beck Depression Inventory-II (BDI-II): 1. Psychometric properties with university students]. Análisis y Modificación de Conducta 2003;29(124):239-288.
31. Beck A, Steer A. Beck Anxiety Inventory Manual. San Antonio, TX: Psychological Corporation; 1993.

32. Magán I, Sanz J, García-Vera MP. Psychometric properties of a Spanish version of the beck anxiety inventory (BAI) in general population. Span J Psychol 2014 Apr 10;11(2):626-640. [doi: 10.1017/s1138741600004637]
33. Badia X, Roset M, Montserrat S, Herdman M, Segura A. [The Spanish version of EuroQol: a description and its applications. European Quality of Life scale]. Med Clin (Barc) 1999;112 Suppl 1:79-85. [Medline: 10618804]
34. Carver CS, White TL. Behavioral inhibition, behavioral activation, and affective responses to impending reward and punishment: the BIS/BAS scales. J Personality Soc Psychol 1994 Aug;67(2):319-333. [doi: 10.1037/0022-3514.67.2.319]
35. Caseras X, Àvila C, Torrubia R. The measurement of individual differences in behavioural inhibition and behavioural activation systems: a comparison of personality scales. Personality Indiv Diff 2003 Apr;34(6):999-1013. [doi: 10.1016/s0191-8869(02)00084-3]
36. Psicologia y Tecnologia homepage. Psicologia y Tecnologia. URL: https://psicologiaytecnologia.labpsitec.es/ [accessed 2022-01-12]
37. Barlow D, Ellard KK, Fairholme CP, Farchione TJ, Boisseau CL, Allen LB, et al. Unified Protocol for Transdiagnostic Treatment of Emotional Disorders: Workbook (1 edn). Oxford, United Kingdom: Oxford University Press; 2010.
38. Barlow D, Farchione TJ, Fairholme CP, Ellard KK, Boisseau CL, Allen LB, et al. Unified Protocol for Transdiagnostic Treatment of Emotional Disorders: Therapist Guide (1 edn). Oxford, United Kingdom: Oxford University Press; 2010.
39. Linehan MM. Cognitive-Behavioral Treatment of Borderline Personality Disorder. New York, United States: Guilford Publications; 1993.
40. Twisk J, de Boer M, de Vente W, Heymans M. Multiple imputation of missing values was not necessary before performing a longitudinal mixed-model analysis. J Clin Epidemiol 2013 Sep;66(9):1022-1028. [doi: 10.1016/j.jclinepi.2013.03.017] [Medline: 23790725]
41. Bates D, Kliegl R, Vasishth S, Baayen H. Parsimonious mixed models. arXiv 2015.
42. R: A language and environment for statistical computing. Vienna, Austria: R Foundation for Statistical Computing; 2020.
43. Graham JW. Missing data analysis: making it work in the real world. Annu Rev Psychol 2009 Jan 01;60(1):549-576. [doi: 10.1146/annurev.psych.58.110405.085530] [Medline: 18652544]
44. Little R, Rubin DB. Bayes and multiple imputation. In: Statistical Analysis with Missing Data, Second Edition. Hoboken, New Jersey, United States: Wiley; 2002.
45. Molenberghs G, Kenward MG. Missing Data in Clinical Studies. Hoboken, New Jersey: Wiley; 2007.
46. Schafer JL, Yucel RM. Computational strategies for multivariate linear mixed-effects models with missing values. J Computation Graphical Stat 2002 Jun;11(2):437-457. [doi: 10.1198/106186002760180608]
47. Lachenbruch PA, Cohen J. Statistical power analysis for the behavioral sciences (2nd edition). J Am Stat Assoc 1989 Dec;84(408):1096. [doi: 10.2307/2290095]
48. Kodal A, Fjermestad KW, Bjelland I, Gjestad R, Öst LG, Bjaastad JF, et al. Predictors of long-term outcome of CBT for youth with anxiety disorders treated in community clinics. J Anxiety Disord 2018 Oct;59:53-63 [FREE Full text] [doi: 10.1016/j.janxdis.2018.08.008] [Medline: 30273789]
49. Barr DJ. Random effects structure for testing interactions in linear mixed-effects models. Front Psychol 2013;4:328 [FREE Full text] [doi: 10.3389/fpsyg.2013.00328] [Medline: 23761778]
50. Barr DJ, Levy R, Scheepers C, Tily HJ. Random effects structure for confirmatory hypothesis testing: keep it maximal. J Mem Lang 2013 Apr;68(3):255-278 [FREE Full text] [doi: 10.1016/j.jml.2012.11.001] [Medline: 24403724]
51. Hedman E, Lindefors N, Andersson G, Andersson E, Lekander M, Rück C, et al. Predictors of outcome in internet-based cognitive behavior therapy for severe health anxiety. Behav Res Ther 2013 Oct;51(10):711-717. [doi: 10.1016/j.brat.2013.07.009] [Medline: 23994252]
52. Vigerland S, Serlachius E, Thulin U, Andersson G, Larsson J, Ljótsson B. Long-term outcomes and predictors of internet-delivered cognitive behavioral therapy for childhood anxiety disorders. Behav Res Ther 2017 Mar;90:67-75. [doi: 10.1016/j.brat.2016.12.008] [Medline: 28012300]
53. Cumming G. The new statistics: why and how. Psychol Sci 2014 Jan 12;25(1):7-29. [doi: 10.1177/0956797613504966] [Medline: 24220629]
54. Rodríguez-Gómez P, Romero-Ferreiro V, Pozo MA, Hinojosa JA, Moreno EM. Facing stereotypes: ERP responses to male and female faces after gender-stereotyped statements. Soc Cogn Affect Neurosci 2020 Nov 06;15(9):928-940 [FREE Full text] [doi: 10.1093/scan/nsaa117] [Medline: 32901810]
55. Carlucci L, Saggino A, Balsamo M. On the efficacy of the unified protocol for transdiagnostic treatment of emotional disorders: a systematic review and meta-analysis. Clin Psychol Rev 2021 Jul;87:101999. [doi: 10.1016/j.cpr.2021.101999] [Medline: 34098412]
56. Barlow DH, Harris BA, Eustis EH, Farchione TJ. The unified protocol for transdiagnostic treatment of emotional disorders. World Psychiatry 2020 Jun 11;19(2):245-246 [FREE Full text] [doi: 10.1002/wps.20748] [Medline: 32394551]
57. Barlow DH, Sauer-Zavala S, Carl JR, Bullis JR, Ellard KK. The nature, diagnosis, and treatment of neuroticism. Clin Psychol Sci 2013 Oct 14;2(3):344-365. [doi: 10.1177/2167702613505532]
58. Carl JR, Gallagher MW, Sauer-Zavala SE, Bentley KH, Barlow DH. A preliminary investigation of the effects of the unified protocol on temperament. Compr Psychiatry 2014 Aug;55(6):1426-1434 [FREE Full text] [doi: 10.1016/j.comppsych.2014.04.015] [Medline: 24933653]

59. Whiston A, Bockting CL, Semkovska M. Towards personalising treatment: a systematic review and meta-analysis of face-to-face efficacy moderators of cognitive-behavioral therapy and interpersonal psychotherapy for major depressive disorder. Psychol Med 2019 Oct 16;49(16):2657-2668. [doi: 10.1017/s0033291719002812]
60. Hamilton KE, Dobson KS. Cognitive therapy of depression. Clin Psychol Rev 2002 Jul;22(6):875-893. [doi: 10.1016/s0272-7358(02)00106-x]
61. Schindler A, Hiller W, Witthöft M. What predicts outcome, response, and drop-out in CBT of depressive adults? A naturalistic study. Behav Cogn Psychother 2012 Dec 05;41(3):365-370. [doi: 10.1017/s1352465812001063]
62. van Ballegooijen W, Cuijpers P, van Straten A, Karyotaki E, Andersson G, Smit JH, et al. Adherence to Internet-based and face-to-face cognitive behavioural therapy for depression: a meta-analysis. PLoS One 2014 Jul 16;9(7):e100674 [FREE Full text] [doi: 10.1371/journal.pone.0100674] [Medline: 25029507]
63. Manwaring JL, Bryson SW, Goldschmidt AB, Winzelberg AJ, Luce KH, Cunning D, et al. Do adherence variables predict outcome in an online program for the prevention of eating disorders? J Consulting Clin Psychol 2008;76(2):341-346. [doi: 10.1037/0022-006x.76.2.341]
64. Enrique A, Palacios JE, Ryan H, Richards D. Exploring the relationship between usage and outcomes of an internet-based intervention for individuals with depressive symptoms: secondary analysis of data from a randomized controlled trial. J Med Internet Res 2019 Aug 01;21(8):e12775 [FREE Full text] [doi: 10.2196/12775] [Medline: 31373272]
65. González-Robles A, Suso-Ribera C, Díaz-García A, García-Palacios A, Castilla D, Botella C. Predicting response to transdiagnostic iCBT for emotional disorders from patient and therapist involvement. Internet Interv 2021 Sep;25:100420 [FREE Full text] [doi: 10.1016/j.invent.2021.100420] [Medline: 34401379]


## Abbreviations

**BAI:** Beck Anxiety Inventory
**BAS:** behavioral activation system
**BDI-II:** Beck Depression Inventory, Second Edition
**BIS:** behavioral inhibition system
**DV:** dependent variable
**iCBT:** internet-delivered cognitive behavioral therapy
**OCD:** obsessive-compulsive disorder
**QoL:** quality of life
**RCT:** randomized controlled trial
**TAU:** treatment as usual


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Original Paper

# Use of an Online Forum for Relatives of People With Psychosis and Bipolar Disorder: Mixed Methods Study

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## Abstract

**Background:** Relatives of people with psychosis or bipolar disorder experience high levels of distress but are typically not offered the support they need. Online peer forums may offer a solution, but knowledge about who uses them, how, and why is limited. This study reported on online forum use during the Relatives Education and Coping Toolkit (REACT) trial.

**Objective:** We aimed to report who used the forum and why; how sociodemographic factors are associated with participation; the relationship among frequency, type of use, and outcomes; and how the forum was used.

**Methods:** The relationships between key sociodemographic characteristics, levels of forum use, and distress were statistically analyzed. We used thematic and semantic analyses to understand the reasons for relatives joining the forum and the key topics initiated by them. We also used the University Centre for Computer Corpus Research on Language Semantic Analysis System to compare how relatives and REACT supporters (moderators) used the forum.

**Results:** A total of 348 participants with full forum use data from REACT were included in this study. The forum was accessed by 59.4% (207/348) of the relatives across the entire age range, with no significant associations between sociodemographic factors and forum participation, or between level or type of use and relatives' distress levels. Relatives joined the forum primarily to find people in similar circumstances, express concerns, and talk about stressful events. Relatives were most concerned about recent events, negative emotions linked to caring, experiences of conflict or threat, and concerns about suicide. These posts underscored both the challenges the relatives were facing and the fact that they felt safe sharing them in this context.

**Conclusions:** Although only a proportion of REACT participants engaged actively with its forum, they were widely distributed across age and other sociodemographic groupings. Relatives used the forum for information, support, and guidance and to offer detailed information about their experiences. The topics raised highlighted the burden carried by relatives and the potential value of easy-access, moderated, peer-supported forums in helping relatives to manage the challenges they faced.

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**KEYWORDS**

psychosis; bipolar disorder; relative; carer; mental health; forum; online; digital health; Relatives Education and Coping Toolkit; REACT; trial

## Introduction

### Background

Psychosis and bipolar disorder (BD) are severe mental health problems affecting 2% to 4% of the global population, respectively [1,2], with a cost of £9.2 billion (US $10.1 billion) per year to the English economy [3]. Relatives of individuals with these conditions deliver vital but unpaid care [4]. However, this caring role often comes at a huge cost to the relatives themselves in terms of burden and distress [5,6].

There is increasing awareness of the need to support relatives of people with mental health problems [7]. The National Institute for Health and Care Excellence [8] recommends that relatives receive education, information, and support [9]. With support, relatives have better health outcomes [10].

Despite this, most relatives receive little support [11-13]. Furthermore, most evidence is for face-to-face interventions, which have not been widely adopted. This reflects a lack of provision of family interventions across the United Kingdom as well as some relatives not taking up such approaches when offered. The Royal College of Psychiatrists Report of the Early Intervention in Psychosis Audit, for instance, indicated that of more than 1901 families in early intervention services, only 31% were offered family intervention, of whom 38% took up this offer [14]. A crucial question is how support for relatives can be delivered accessibly and cost-effectively at scale. Web-based interventions have been established for several mental health conditions, including depression and anxiety [15,16], with increasing evidence for the benefits for people with severe mental health problems [17] and their relatives [12,18]. Online forums offer an accessible space where users can connect anonymously [19], with growing evidence of the benefits of forum engagement [20]. However, the use of forums by relatives has been largely ignored, with some exceptions [21-24], especially for relatives of people with mental health difficulties.

### Objectives

This paper aimed to report on forum use from a large national UK digital mental health trial (Relatives Education and Coping Toolkit [REACT]) [24-26]. The REACT trial found that the intervention was inexpensive and acceptable, and was a safe method of delivering support for relatives of people with psychosis and BD. Both the REACT intervention and access to a digital resource directory were associated with significant increases in carer well-being and reduction in distress; however, there was no difference between the 2 trial arms in these outcomes at either 12 or 24 weeks of follow-up. Of the 800 participants in the REACT trial, 399 (49.8%) were in the active intervention arm, with access to a peer-supported moderated forum. Here, we report on their patterns of REACT forum use during the trial. Specifically, we aimed to explore (1) who used the forum and why; (2) how sociodemographic characteristics are associated with participation, taking into consideration previous research on patterns of use of digital resources linked to age, sex, education, and employment or income [27]; (3) the relationship among frequency, type of use, and outcomes; and (4) how the forum was used.

## Methods

### The REACT Forum and Trial

REACT was originally developed as a printed toolkit or web page and reduces relatives' distress [26]. To increase access and flexibility, REACT was adapted into an internet-based digital intervention [25] built in WordPress (Automattic Inc.) with a number of plug-ins. These included bbPress (Automattic Inc.) to run the REACT group forum. The content of the toolkit was informed by family intervention models for people with psychosis [11]. The key components of the toolkit were as follows: 12 information modules, a comprehensive resource directory, a group forum, and a confidential direct messaging service. A *meet the team* page ensured that relatives were fully informed about who was delivering the content of the site. *Mytoolbox* offered users a confidential space to save links to any information they might keep. A blog page offered a flexible space for additional communication with site users, edited by the REACT supporters. The screenshots in Figure 1 show the look and feel of the REACT website.

REACT users were offered support through confidential direct messaging with REACT supporters and peer support through a moderated online forum. The REACT supporters were available on the site from Monday to Friday, from 9 AM to 4:30 PM, excluding bank holidays and university holiday closures. Their key role was to provide emotional support and to guide relatives to relevant parts of the toolkit or other resources, as appropriate.

**Figure 1.** Screenshots of Relatives Education and Coping Toolkit (REACT).


## Training REACT Supporters From the REACT Trial

The REACT supporters had experience of caring for someone with BD or psychosis, but were otherwise not required to have any other educational or clinical experience. REACT supporters were trained to moderate the online REACT forum and to respond to direct confidential messages. The training was provided by the clinical supervisor (SJ) and the chief investigator (FL) before the launch of REACT and focused on providing empathetic support and guiding relatives to use the toolkit in the best way to help them with their concerns. The supporters were not formally clinically trained, as their focus was on providing support and specifically not on providing advice. This preparatory work included group discussions on the nature of the work and the distinctions between support and advice. REACT supporters also reviewed vignettes of possible forum posts to gain practice in response options in advance of the REACT site going live. Potential responses were reviewed with SJ. REACT supporters then received regular supervision from SJ, covering issues raised on the forum and any risk concerns, as well as supporter well-being and ensuring forum coverage during periods of leave. These sessions occurred 1.8 times per month on 1-2 times per month across the duration of the trial. SJ was also available for ad hoc meetings, when required. The IT support lead (Andrew Walker) provided technical training to ensure that the supporters were very familiar with the whole of the REACT site and with how to access the automated emails informing them about posts. The REACT supporters were also provided with, and helped develop, several written documents: a training document regarding supporter roles and the site; a REACT Supporter Manual that included examples of posts and risk emails; a thorough Risk Protocol and Matrix that outlined what to do in the event of risk being identified on the site; and several documents regarding the use of the site, for example, how to search for a forum post and how to hide inappropriate content.

REACT supporters were required to check the forum at least three times a day, from Monday to Friday. They identified dangerous behaviors or concerns, categorizing them as low or high risk. Low risk was defined as no indication of immediate or serious threat of severe harm or risk to life but the presence of either clear evidence of high levels of distress or concerns for risk of harm or abuse toward participants or others (safeguarding risks). Where high distress was identified, REACT supporters responded with a standardized email. Where a safeguarding issue was identified, REACT supporters consulted their clinical supervisor and National Health Service trust safeguarding team. High risk was defined as the presence of clear evidence of immediate and serious risk to life or child welfare. If an immediate risk was identified, the REACT supporters called the police or social services, depending on the risk. Risk was identified based on participants' post content rather than on their post frequency. REACT supporters also monitored the forum for inappropriate posts and could hide them if necessary. All risks and inappropriate posts were discussed during clinical supervision or at an earlier meeting if needed.

REACT also contained an extensive resource directory. The REACT trial was a web-based, 2-arm, pragmatic randomized controlled trial comparing the REACT intervention to only providing access to the resource directory. Outcomes were assessed at baseline, the 12-week follow-up, and the 24-week

follow-up. The primary outcome was relatives' distress, assessed using the General Health Questionnaire (GHQ)-28 [28]. Participants were recruited to the REACT trial from April 22, 2016, to September 30, 2017. A range of web-based (Facebook, Twitter, and charity websites) and offline recruitment strategies (clinical services and third sector providers) were used, all directing potential participants to the study home page.

## Participants

Participants in this study comprised 348 individuals randomized into the REACT intervention arm. From the original 399 participants allocated to REACT, 51 (12.8%) were excluded because their complete web use data were not recorded.

The inclusion criteria were (more details are presented in the trial paper by Lobban et al [24]) the following:

- Aged ≥16 years
- Living in the United Kingdom
- Relative or close friend of someone with psychosis or BD
- Currently experiencing distress
- Currently seeking help (self-identified)
- Having access to the internet
- Sufficient English fluency to comprehend the intervention and forum content

Participants were identified as "currently experiencing distress" because of their relative or close friend, by their selecting "rather more than usual" or "much more than usual" on the GHQ-28 item "Have you been feeling nervous and strung up all the time?" This was included to avoid a floor effect on levels of distress at baseline, and this item was used because it correlated most highly with the GHQ-28 score in the REACT feasibility trial [26]. An age cutoff of ≥16 years was used as this is the legal age of consent, and the REACT intervention aimed to be inclusive of all carers of people with psychosis or bipolar; many carers were aged 16 to 18 years.

## Analysis

### Overview

Participants' forum activity was recorded from randomization until the date of their primary outcome assessment (GHQ-28 score at 24 weeks) or, if the assessment was not completed, the date on which it would have taken place. Participants were classified based on their use levels as nonusers (did not access forum at all), observers (accessed the forum but did not post), or users (accessed and posted on the forum at least once). Analyses were conducted using Stata (StataCorp; version 14). A Cronbach α level of $P<.05$ was used as a general indicator of statistical significance. A complete case analysis approach was adopted. Use levels of the forum were identified based on participant IDs. As there were a number of exploratory analyses, all results have been interpreted cautiously.

### Who Used the Forum and for What Reasons

To outline who used the forum, descriptive statistics were calculated based on the level of use and different demographic factors (age, gender, highest education level, and employment status).

To explore why relatives started using the forum, 2 coauthors (DA and ES) classified the functions of relatives' first posts by adapting the Rohr [29] coding scheme. The Rohr coding scheme is based on the concept of "discursive moves" defined as the kinds of contributions that entries make to the ongoing interchange, in turn based on the Locher [30] and Morrow [31] catalog of discursive moves. All functions were retained from the Rohr coding scheme except functions associated with the moderators' posts (eg, "official welcome," described as users being welcomed to the forum by a moderator). We inductively added the category "other" for posts discussing technical aspects of the forum's use. Initially, a small random subsample of first posts was examined to ensure that they would be categorized into the same theme by the 2 coauthors. A standardized procedure for coding agreement such as interrater reliability was not adopted because a reflexive approach to thematic analysis was used. As Braun and Clarke [32] write, "this approach fully embraces qualitative research values and the subjective skills the researcher brings to the process—a research team is not required for quality."

The analysis focused on the messages written by 19.2% (67/348) of the relatives, which is a sample of participants who had complete web use data available. One first post could be coded for more than one function.

### Sociodemographic Factors Associated With Participation

Associations between sociodemographic factors (age, gender, education level, and employment status) and forum use levels were compared using Fisher exact tests, split according to no active participation (no posts), low active participation (up to five forum posts), and high active participation (>5 forum posts). A total of 5 forum posts were chosen as a cutoff based on a consensus team decision that 5 posts is the minimum number to be actively engaged with the forum; the 5-post cutoff identified the top one-third of the posters.

### Relationship Among Frequency, Type of Use, and Outcomes

We calculated the mean GHQ-28 scores (the primary outcome of the REACT trial) at each time point (baseline, 12 weeks, and 24 weeks) and for each forum use level (nonuser, observer, and user). Spearman correlation coefficients were used to assess the relationship between the number of forum posts and GHQ-28 scores.

### How Was the Forum Used?

To explore how relatives and REACT supporters used the forum differently, 2 data sets were created, consisting of the following categories:

- Topics initiated by relatives ("User Topics"): 33,201 words
- Topics initiated by supporters ("Supporter Topics"): 335,819 words

To explore potential differences between the 2 data sets, the University Centre for Computer Corpus Research on Language Semantic Analysis System (USAS) was used in the web-based software Wmatrix [33].

USAS is a tagging program that automatically assigns a semantic category label (or semantic tag) to every word or phrase in a linguistic data set, or "corpus." The category scheme consists of 21 general semantic domains (eg, "Emotion") and 232 more specific subdomains (eg, "Sad" as a subdomain of "Emotion"). Unlike other types of content analysis systems such as Linguistic Inquiry and Word Count [34], the USAS tagger takes into account the meaning of a word or phrase in context to assign an appropriate tag. A central aspect of this contextual disambiguation is the tagger's ability to assign single tags to phrases or multiword expressions, including phrasal verbs (eg, "look after") and proper names (eg, "Milton Keynes"). The tool has been shown to have a level of accuracy of approximately 91% [35].

We used the web-based concordancer, Wmatrix, which applies the USAS semantic tagger to any text loaded into the system, to compare topics initiated by relatives with topics initiated by REACT supporters in terms of the relative frequencies of the 232 specific semantic domains to establish which semantic domains are "key" or "overused" in the former compared with the latter, according to the following 2 statistical measures:

- LogRatio: a measure of effect size, that is, the binary log of the ratio of relative frequencies in the 2 data sets [36].
- Log Likelihood: a measure of statistical significance that is sensitive to the size of the evidence that a difference exists [29].

We set a minimum LogRatio score of 0.5, meaning that the relevant semantic domain is 50% more frequent in the target corpus (relatives) than in the reference corpus (supporters) and a minimum Log Likelihood threshold of 6.63, providing a confidence measure equivalent to $P$=.01 [37].

### Ethics Approval

All procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. All participants provided written informed consent, and all procedures were approved by the Lancaster National Research Ethics Service Committee (15/NW/0732).

## Results

### Who Used the Forum and for What Reasons

Active forum use was distributed across all age bands of the trial, except for those aged ≥70 years. For this age group, participants were either nonusers or only observers (Table 1). Most forum participants were considered observers. The users were aged 40 to 69 years. Overall, more women than men participated in the REACT forum, with a higher percentage of women in the observer and user groups. There were few differences in education, except for a suggestion that users were more likely to have engaged with higher education. No meaningful differences were observed in terms of employment, which was similarly distributed across no paid employment, part-time employment, and full-time employment for all 3 groups.

**Table 1.** Demographic characteristics of forum users (N=348).

| Characteristic | Nonuser (never logged in; N=141), n (%) | Observer (no posts; N=140), n (%) | User (at least one post; N=67), n (%) | Total |
|---|---|---|---|---|
| **Age (years)** | | | | |
| <30 | 19 (13) | 13 (9) | 3 (4) | 35 |
| 30-39 | 18 (13) | 15 (11) | 12 (18) | 45 |
| 40-49 | 39 (28) | 30 (21) | 13 (19) | 82 |
| 50-59 | 31 (22) | 45 (32) | 21 (31) | 97 |
| 60-69 | 25 (18) | 31 (22) | 18 (27) | 74 |
| ≥70 | 9 (6) | 6 (4) | 0 (0) | 15 |
| **Sex** | | | | |
| Female | 99 (70) | 114 (81) | 58 (87) | 271 |
| Male | 42 (30) | 26 (19) | 9 (13) | 77 |
| **Highest education level** | | | | |
| School level | 25 (18) | 25 (18) | 7 (10) | 57 |
| Further (UK college level) | 41 (29) | 39 (28) | 18 (27) | 98 |
| Higher (UK university level) | 75 (53) | 76 (54) | 42 (63) | 193 |
| **Employment status** | | | | |
| None or unpaid | 54 (38) | 59 (42) | 25 (37) | 138 |
| Part-time | 32 (23) | 32 (23) | 16 (24) | 80 |
| Full-time | 55 (39) | 49 (35) | 26 (39) | 130 |

The total word count of the first 67 posts was 14,070. Posts varied between 25 and 866 words, with a mean of 210 words. Posts were manually coded for the following functions to capture patterns in content and interactional characteristics.

- *greeting*: a formal opening move (eg, "Hello")
- *meta-comment*: a comment on the experience of using the forum (eg, "New here so just finding my way about")
- *background information*: provide information about oneself or the issue at hand (eg, "My wife suffers some severe symptoms, has many triggers")
- *request for advice or information or support*: asking for guidance (eg, "So is there any advice or techniques anyone can suggest")
- *provision of advice or information or support*: providing guidance (eg, "So if you have a crisis team, I would recommend contacting them")
- *thank*: thank in anticipation of the advice or information or support, or for writing or reading (eg, "Thank you," "Thanks for sharing this")
- *well-wishing*: wish someone well (eg, "All the very best for the future")
- *farewell*: a formal closing move (eg, "Regards")

A total of 22 (32.8%) posts began with a greeting; 21 (31.3%) made a meta-comment about using the forum; 64 (95.5%) provided background information about the relative or the issue that prompted them to post on the forum; 14 (20.9%) included a request for advice, information, and support; 13 (19.4%) provided advice about possible courses of action; 11 (16.4%) expressed gratitude to others for advice or simply for writing and reading posts; 3 (4.5%) included well-wishes; and 1 (1.5%) ended with a formal farewell.

Most posts (53/67, 79.1%) provided information about the posters' circumstances, without requests for advice or information. This suggests that the forum was primarily used to find people in similar circumstances, express concerns, and talk about stressful events. Some contributors made this explicit, with comments such as "Hello, I am so happy I have found this link! All your messages are deeply resonating in me."

## Are Sociodemographic Factors Associated With Participation?

We looked at the distribution of the total number of forum posts across all participants except for a single outlier (who posted in the forum 205 times) to show the distribution of lower values more clearly. This revealed a significant negative skew, with 81% (281/348) of the sample not posting at all and 93% (325/348) of the sample posting ≤5 times. The average number of posts, with outliers excluded, was 6.8 (SD 9.3).

Participants were classified as having "highly participated" if they were in the top one-third of active forum users, that is, those who posted >5 times in the forum (Table 2). There were no statistically significant relationships indicated among age, gender, education or employment, and level of forum use. Numerically there was an indication that the high-use group had a preponderance of participants aged 50 to 59 years, but the association between high or low use was not significant.

**Table 2.** Demographic characteristics of relatives according to amount of forum use (N=348).

| Characteristic | No active participation (no posts; N=281), n (%) | Low active participation (1-5 posts; N=44), n (%) | High active participation (>5 posts; N=23), n (%) | Total | Fisher exact test, *P* value |
|---|---|---|---|---|---|
| **Age (years)** | | | | | .27 |
| <30 | 32 (11) | 3 (7) | 0 (0) | 35 | |
| 30-39 | 33 (12) | 8 (18) | 4 (17) | 45 | |
| 40-49 | 69 (25) | 9 (20) | 4 (17) | 82 | |
| 50-59 | 76 (27) | 11 (25) | 10 (43) | 97 | |
| 60-69 | 56 (20) | 13 (30) | 5 (22) | 74 | |
| ≥70 | 15 (5) | 0 (0) | 0 (0) | 15 | |
| **Sex** | | | | | .18 |
| Female | 213 (76) | 38 (86) | 20 (87) | 271 | |
| Male | 68 (24) | 6 (14) | 3 (13) | 77 | |
| **Highest education level** | | | | | .64 |
| School level | 50 (18) | 4 (9) | 3 (13) | 57 | |
| Further (UK college level) | 80 (28) | 12 (27) | 6 (26) | 98 | |
| Higher (UK university level) | 151 (54) | 28 (64) | 14 (61) | 193 | |
| **Employment status** | | | | | .94 |
| None or unpaid | 113 (40) | 15 (34) | 10 (43) | 138 | |
| Part-time | 64 (23) | 11 (25) | 5 (22) | 80 | |
| Full-time | 104 (37) | 18 (41) | 8 (35) | 130 | |

## Relationships Among Frequency, Type of Use, and Outcomes

The primary outcome for the REACT trial was the GHQ-28 scores. Therefore, we explored the relationship between this and forum use based on the nonuser, observer, and user categories. The mean levels of GHQ scores at each time point are very similar for each use group (Table 3).

Spearman correlations were calculated for those who used the forum to explore any relationships between forum use and GHQ-28 scores. As Table 4 indicates, all these correlations were small and nonsignificant.

**Table 3.** General Health Questionnaire-28 (GHQ-28) scores of relatives by time and level of forum use.

| Values | GHQ-28 at baseline | | | GHQ-28 at 12 weeks | | | GHQ-28 at 24 weeks | | |
|---|---|---|---|---|---|---|---|---|---|
| | Nonuser (n=141) | Observer (n=140) | User (n=67) | Nonuser (n=77) | Observer (n=108) | User (n=60) | Nonuser (n=83) | Observer (n=110) | User (n=59) |
| Value, mean (SD) | 40.9 (15.6) | 39.8 (13.4) | 41.2 (16.0) | 29.9 (16.3) | 31.8 (17.0) | 29.9 (12.3) | 30.2 (17.8) | 30.7 (16.0) | 28.7 (16.2) |
| Value, median (IQR) | 39 (29-51) | 39 (29-49) | 38 (29-53) | 26 (17-42) | 29 (19.5-39) | 28 (22-35.5) | 26 (16-43) | 28 (18-41) | 26 (17-37) |
| Value, range | 5-83 | 18-83 | 17-76 | 4-73 | 5-80 | 3-63 | 2-76 | 6-78 | 5-79 |
| Missing, n (%) | 0 (0) | 0 (0) | 0 (0) | 64 (45) | 32 (23) | 7 (10) | 58 (41) | 30 (21) | 8 (12) |

**Table 4.** Correlations between forum use and General Health Questionnaire-28 (GHQ-28) scores at each assessment point.

| Assessment point for GHQ-28 score | Spearman correlation coefficient (*P* value) for forum users only | Spearman correlation coefficient (*P* value) for forum users only (outlier removed) | Spearman correlation coefficient (*P* value) for all REACT[a] participants (outlier removed) |
|---|---|---|---|
| Baseline | −0.003 (.98) | 0.005 (.96) | 0.006 (.91) |
| 12 weeks | −0.113 (.38) | −0.071 (.59) | 0.005 (.94) |
| 24 weeks | −0.091 (.49) | −0.054 (.68) | −0.034 (.58) |

[a]REACT: Relatives Education and Coping Toolkit.

## How Was the Forum Used?

Only REACT supporters could start a new thread (eg, include “happiness and wellbeing,” “treatment services,” “all things legal,” and “dealing with difficult behaviour”), but relatives could start a new topic within an existing forum, which is something they did 131 times. These relative-initiated topics (and their descriptions) totaled 33,201 words (User Topics), in contrast with supporter-initiated topics, which totaled 335,819 words (Supporter Topics).

Table 5 lists the 21 semantic domains statistically overused in User Topics than in Supporter Topics. The rightmost column gives examples of the words included under each semantic domain.

The 21 overused domains include the following major themes:

- Time, including beginnings, endings, age, and recency
- Negative emotions, including fear, depression, and anxiety
- Conflict and abuse, including anger, threats, and abuse
- Illness and hospitalization, including psychosis and discharge
- Death and suicide

Overall, this suggests that users typically initiated topics to talk about particularly acute problems relating to their relative’s condition and, therefore, their own situation. These problems sometimes involve actual, feared, or threatened violence or suicide, and have often worsened before the decision to write on the forum. Some examples are given in Table 6, which indicate both the extent of the challenges experienced by these relatives and their frankness about them on the forum.

**Table 5.** Semantic domains used more by relatives than supporters.

| Code | Raw frequency Corpus 1 | Relative frequency Corpus 1 | Raw frequency Corpus 2 | Relative frequency Corpus 2 | LL[a] | LogRatio | Label | Example words |
|---|---|---|---|---|---|---|---|---|
| X7- | 17 | 0.05 | 20 | 0.02 | 10.79 | 1.63 | Unwanted | *Rubbish* [b] *, rejected* |
| A13.4 | 63 | 0.20 | 90 | 0.08 | 29.58 | 1.35 | Degree: Approximators | *About, almost* |
| T3 | 48 | 0.15 | 70 | 0.06 | 21.73 | 1.32 | Time: Old, new and young; age | *Age, one, aged* |
| T1.1 | 66 | 0.21 | 102 | 0.09 | 26.80 | 1.23 | Time: General | *Appointment or appointments* |
| M3 | 54 | 0.17 | 86 | 0.08 | 20.66 | 1.19 | Vehicles and transport on land | *Car, drive* |
| A1.7- | 35 | 0.11 | 57 | 0.05 | 12.79 | 1.16 | No constraint | *Discharge or discharged, escape* |
| T3- | 27 | 0.09 | 47 | 0.04 | 8.51 | 1.06 | Time: New and young | *Recently* |
| E5- | 59 | 0.19 | 103 | 0.09 | 18.48 | 1.06 | Fear or shock | *Scared, fear, terrified* |
| H4 | 65 | 0.21 | 118 | 0.10 | 18.53 | 1.00 | Residence | *Home, live* |
| E4.1- | 101 | 0.32 | 192 | 0.17 | 25.55 | 0.93 | Sad | *Depression, depressed* |
| L2 | 28 | 0.09 | 54 | 0.05 | 6.81 | 0.91 | Living creatures: animals, birds, etc | *Dog, cat or cats* |
| L1- | 31 | 0.10 | 60 | 0.05 | 7.47 | 0.91 | Dead | *Suicide, death, died, suicidal* |
| T1.1.1 | 150 | 0.47 | 311 | 0.27 | 29.45 | 0.81 | Time: Past | *Last year, yesterday* |
| T3- | 54 | 0.17 | 121 | 0.11 | 8.11 | 0.70 | Time: New and young | *New* |
| E3- | 91 | 0.29 | 204 | 0.18 | 13.65 | 0.70 | Violent or Angry | *Angry, abuse, anger, threatening* |
| T1.1.2 | 208 | 0.66 | 486 | 0.42 | 26.50 | 0.64 | Time: Present; simultaneous | *Now, today, at the moment, currently* |
| T2- | 89 | 0.28 | 213 | 0.19 | 10.23 | 0.60 | Time: Ending | *Stop, ended up* |
| B2- | 310 | 0.98 | 747 | 0.65 | 34.58 | 0.59 | Disease | *Psychosis, symptoms, unwell, disorder, ill* |
| N4 | 209 | 0.66 | 520 | 0.45 | 20.07 | 0.54 | Linear order | *Then, first, last, finally* |
| T2+ | 88 | 0.28 | 222 | 0.19 | 7.88 | 0.52 | Time: Beginning | *Started, start, finally* |
| E6- | 160 | 0.51 | 407 | 0.35 | 13.73 | 0.51 | Worry | *Anxiety, worry, stress, worried* |

[a]LL: Log Likelihood.

[b]Italicized text represents example words.

**Table 6.** Themes illustrating how relatives used the forum.

| Theme | Title | Text |
|---|---|---|
| Time, including beginnings, endings, age and recency | How to get supported housing | "Just over a month ago my husband was diagnosed as having BD. Last Thursday after a very violent outburst with police involved and trip to hospital my eldest son who is 35 has been diagnosed with borderline personality disorder. He was off work last week with a physical problem, but today is hiding under the bedcovers having not slept with worrying." |
| Negative emotions, including fear, depression, and anxiety | Starting a family | "I'm really struggling at the moment, and no one really to talk to, and even when I do they don't really seem to understand... It's so exhausting keeping up with the switches and changes, the rejection and lack of empathy..." |
| Conflict and abuse, including anger, threats, and abuse | How to deal with verbal abuse and aggression | "I was wondering if anyone had any suggestions on how to handle abusive behaviour? My husband is hypomanic at the moment and this unfortunately involves aggressive and abusive behaviour—shouting, bullying, demeaning, berating, controlling..." |
| Illness and hospitalization, including psychosis and discharge | How to get supported housing | "Good morning all. I need some advice on how to get some help for my son. He is currently living in a general purpose housing association flat. He...has schizophrenia, with alcohol and gambling addictions. [...] His life is absolutely chaotic... [...] I have talked to his care coordinator but she seems to have no time to help us...Has anyone any advice?" |
| Death and suicide | How can we support him? | "He has a history of attempting suicide and we are so scared that we will lose him and that is his ultimate threat. His Dad and I are at the point that we can't support him at this level any more." |

# Discussion

## Principal Findings

This paper drew on data from a national trial examining the effectiveness of interactive digital support for relatives of people with psychosis or BD. Using detailed forum data, this paper explored who used the forum and why; how sociodemographic characteristics were associated with participation; the relationship among frequency, type of use, and outcomes; and how the forum was used.

In terms of who used the forum and why, it was found that there were no differences in sociodemographic variables among users, observers, and nonusers. Relatives who accessed the forum covered the whole age range; those aged ≥70 years did not include active forum participants but did include observers. There was a range of reasons behind participants' first use of the forum. Typically, relatives' first posts indicated a desire to connect with others in similar circumstances and share experiences rather than specific requests for advice or information.

It was found there were no associations between patterns of use and sociodemographic variables. Women and participants who had engaged with higher education were more likely to be users, but the differences were small. This contrasts with prior research on the use of digital resources in general and may be linked to the level of need for support in this group of carers [27].

Previous research has indicated that the 1% rule (90% of social media users observe but do not participate, 9% contribute in a limited way, and 1% contribute substantially [38,39]) applies to a number of digital social networks for mental health. In contrast to this, in this study, 59% (207/348) of the people accessed the forum and of those who did, 33% (67/207) posted. This level of engagement may reflect the lack of other support available to the relatives in this study. Levels of use were not significantly associated with relatives' well-being at any of the assessment points in the study. This may reflect previous research indicating that observers can benefit from reading posts without posting themselves [40].

To determine how the forum was used, patterns of relative-initiated and REACT supporter–initiated posts were compared. Relatives engaged more strongly with domains linked to acute issues with their relatives and their own personal situation. These spanned across themes of time, negative emotions, conflict and abuse, and death and suicide. The details provided in posts of these types highlight the scale of the challenges experienced by relatives and the fact that they felt safe to share extensive and often painful personal details in this context. This is consistent with qualitative interviews with REACT participants, which highlighted the crucial importance of peer support through both REACT supporters and through sharing with other relatives [25].

## Comparisons With Prior Work

The reasons relatives joined the forum mainly consisted of a desire to connect with others and share their experiences, with relatives identifying the value of peer support and information sharing in their posts. This is consistent with the wider literature on mental health that indicates that people with lived experiences are often successful in promoting hope, empowerment, and social inclusion in peers by sharing personal experiences [41]. Relatives felt that they were able to offer detailed information about their experiences, possibly aided by the anonymity of the platform. Anonymity was confirmed to be important in qualitative interviews with the participants, published in the study by Lobban et al [25].

Previous research has suggested that older people do not use forums [42]; however, our findings suggest that older people do use forums, but they may be less active. Previous research has also suggested that digital resources might better serve people with higher levels of education [43], which is a finding that, this study supports, as people with higher levels of education tended to use the forums more.

Previous research on forum use by relatives has been extremely limited. Smith-Merry et al [22] conducted qualitative interviews with relatives and people living with psychosis from the Schizophrenia a National Emergency Australia forums. Consistent with this study, participants highlighted the importance of social connections, information, and practical advice, although it was not possible to identify the priorities of relatives. Terbeck and Chesterman [22] explored posts in 5 different forums by parents of children with suspected attention-deficit or hyperactivity disorder. Their content analysis indicated that parents typically received empathic and supportive responses to their initial posts, predominantly regarding dissatisfaction with professionals. This led the authors to suggest that such forums may decrease faith in health services and lead to "doctor shopping." This was not the dominant pattern in the REACT forum data. Some participants did post about service limitations, but this was part of a range of topics that went beyond clinical care. Mazur and Mickle [23] explored web-based forum posts of parents of children with attention-deficit or hyperactivity disorder, BD, and depressive and anxiety disorders across 4 different forums. Content analysis indicated the importance of advice seeking and addressing feelings of helplessness across parents as well as concerns regarding verbal or physical conflict in relation to their child. Similar themes arose in this study, particularly around concerns regarding conflicts and abuse in relation to one's relatives.

### Limitations

Although this paper provides important insights into forum use among relatives of people with serious mental illness, caution is needed when generalizing the results to the general population of relatives. This study was based on users of the REACT forum, all of whom were highly distressed and were taking part in the REACT trial. They may differ from those not experiencing high levels of distress or not actively involved in research and in seeking support because of their caring role. Furthermore, people from ethnic minority backgrounds were underrepresented in this study, as the overwhelming majority (331/348, 95%) of participants were from a White ethnic background. Future studies would benefit from a more diverse sample.

### Conclusions

Overall, this study indicates that, although only a proportion of users of digital support interventions for relatives engage actively with the forums, they are widely distributed across age and other sociodemographic groupings. Sociodemographic variables were not linked to levels of use. Relatives used the forums for information, support, and guidance and felt that they were able to offer detailed information about their experiences, possibly aided by the anonymity of the platform. Anonymity was confirmed as important in qualitative interviews with the participants, published in the study by Lobban et al [25]. Given that some common themes emerged, which may be useful for other forum user groups, development of good practice guidance across user groups is important for future studies to provide an understanding of forum use and the associated benefits and challenges at a larger scale. The topics raised highlight the extent of the burden carried by relatives and the potential value of easy-access, moderated, peer-supported forums in helping relatives to manage the challenges in their lives.

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## Authors' Contributions

SJ was a grant holder on the Relatives Education and Coping Toolkit (REACT) trial and led the writing of this paper; FL was the chief investigator for the REACT trial. All other authors are listed alphabetically. DA and ES led the linguistic analysis of the forum data, and SD and ARH led the statistical analysis of the forum data. HR was the trial manager for the REACT trial. SF was a REACT supporter and moderator of the forum. All authors contributed to the writing of the manuscript and approved the final version.

## Conflicts of Interest

FL and SJ were part of the team that developed the Relatives Education and Coping Toolkit intervention, so this is not an independent evaluation.

## References

1. McGrath JJ, Saha S, Al-Hamzawi AO, Alonso J, Andrade L, Borges G, et al. Age of onset and lifetime projected risk of psychotic experiences: cross-national data from the world mental health survey. Schizophr Bull 2016 Jul 02;42(4):933-941 [FREE Full text] [doi: 10.1093/schbul/sbw011] [Medline: 27038468]

2. Merikangas KR, Akiskal HS, Angst J, Greenberg PE, Hirschfeld RM, Petukhova M, et al. Lifetime and 12-month prevalence of bipolar spectrum disorder in the National Comorbidity Survey replication. Arch Gen Psychiatry 2007 May 01;64(5):543-552 [FREE Full text] [doi: 10.1001/archpsyc.64.5.543] [Medline: 17485606]
3. McCrone P. Paying the Price The Cost of Mental Health Care in England to 2026. London, United Kingdom: King's Fund; 2008.
4. Valuing Carers 2011: calculating the value of carers' support. Carers UK. 2011 Jun 1. URL: https://www.carersuk.org/for-professionals/policy/policy-library/valuing-carers-2011-calculating-the-value-of-carers-support [accessed 2022-08-15]
5. Lowyck B, De Hert M, Peeters E, Wampers M, Gilis P, Peuskens J. A study of the family burden of 150 family members of schizophrenic patients. Eur Psychiatry 2004 Nov 16;19(7):395-401. [doi: 10.1016/j.eurpsy.2004.04.006] [Medline: 15504645]
6. Perlick D, Clarkin JF, Sirey J, Raue P, Greenfield S, Struening E, et al. Burden experienced by care-givers of persons with bipolar affective disorder. Br J Psychiatry 1999 Jul 03;175(1):56-62. [doi: 10.1192/bjp.175.1.56] [Medline: 10621769]
7. Care Act 2014. legislation.gov.uk. 2014. URL: https://www.legislation.gov.uk/ukpga/2014/23/contents/enacted [accessed 2021-03-23]
8. Bipolar Disorder: the Assessment and Management of Bipolar Disorder in Adults, Children and Young People in Primary and Secondary Care. London, United Kingdom: The Royal College of Psychiatrists; 2014.
9. Psychosis and Schizophrenia in Adults: Prevention and Management. London: National Institute for Health and Clinical Excellence; 2014.
10. Sin J, Gillard S, Spain D, Cornelius V, Chen T, Henderson C. Effectiveness of psychoeducational interventions for family carers of people with psychosis: a systematic review and meta-analysis. Clin Psychol Rev 2017 Aug;56:13-24 [FREE Full text] [doi: 10.1016/j.cpr.2017.05.002] [Medline: 28578249]
11. Lobban F, Postlethwaite A, Glentworth D, Pinfold V, Wainwright L, Dunn G, et al. A systematic review of randomised controlled trials of interventions reporting outcomes for relatives of people with psychosis. Clin Psychol Rev 2013 Apr;33(3):372-382 [FREE Full text] [doi: 10.1016/j.cpr.2012.12.004] [Medline: 23410719]
12. Sin J, Henderson C, Spain D, Cornelius V, Chen T, Gillard S. eHealth interventions for family carers of people with long term illness: a promising approach? Clin Psychol Rev 2018 Mar;60:109-125 [FREE Full text] [doi: 10.1016/j.cpr.2018.01.008] [Medline: 29429856]
13. Lorca-Cabrera J, Grau C, Martí-Arques R, Raigal-Aran L, Falcó-Pegueroles A, Albacar-Riobóo N. Effectiveness of health web-based and mobile app-based interventions designed to improve informal caregiver's well-being and quality of life: a systematic review. Int J Med Inform 2020 Feb;134:104003. [doi: 10.1016/j.ijmedinf.2019.104003] [Medline: 31790857]
14. Early Intervention in Psychosis Audit report. Healthcare Quality Improvement Partnership. 2016 Jul 4. URL: https://www.hqip.org.uk/resource/early-intervention-in-psychosis-audit-report/#.YzsGMXZBzIV [accessed 2022-10-03]
15. Arnberg FK, Linton SJ, Hultcrantz M, Heintz E, Jonsson U. Internet-delivered psychological treatments for mood and anxiety disorders: a systematic review of their efficacy, safety, and cost-effectiveness. PLoS One 2014 May 20;9(5):e98118 [FREE Full text] [doi: 10.1371/journal.pone.0098118] [Medline: 24844847]
16. Teesson M, Newton NC, Slade T, Chapman C, Birrell L, Mewton L, et al. Combined prevention for substance use, depression, and anxiety in adolescence: a cluster-randomised controlled trial of a digital online intervention. Lancet Digital Health 2020 Feb;2(2):e74-e84. [doi: 10.1016/s2589-7500(19)30213-4]
17. Alvarez-Jimenez M, Alcazar-Corcoles M, González-Blanch C, Bendall S, McGorry P, Gleeson J. Online, social media and mobile technologies for psychosis treatment: a systematic review on novel user-led interventions. Schizophr Res 2014 Jun;156(1):96-106. [doi: 10.1016/j.schres.2014.03.021] [Medline: 24746468]
18. Barbeito S, Sánchez-Gutiérrez T, Becerra-García JA, González Pinto A, Caletti E, Calvo A. A systematic review of online interventions for families of patients with severe mental disorders. J Affect Disord 2020 Feb 15;263:147-154. [doi: 10.1016/j.jad.2019.11.106] [Medline: 31818771]
19. Kummervold PE, Gammon D, Bergvik S, Johnsen JK, Hasvold T, Rosenvinge JH. Social support in a wired world: use of online mental health forums in Norway. Nord J Psychiatry 2002 Jul 12;56(1):59-65. [doi: 10.1080/08039480252803945] [Medline: 11869468]
20. Kendal S, Kirk S, Elvey R, Catchpole R, Pryjmachuk S. How a moderated online discussion forum facilitates support for young people with eating disorders. Health Expect 2017 Feb 03;20(1):98-111 [FREE Full text] [doi: 10.1111/hex.12439] [Medline: 26725547]
21. Smith-Merry J, Goggin G, Campbell A, McKenzie K, Ridout B, Baylosis C. Social connection and online engagement: insights from interviews with users of a mental health online forum. JMIR Ment Health 2019 Mar 26;6(3):e11084 [FREE Full text] [doi: 10.2196/11084] [Medline: 30912760]
22. Terbeck S, Chesterman LP. Parents, ADHD and the internet. Atten Defic Hyperact Disord 2012 Sep 27;4(3):159-166. [doi: 10.1007/s12402-012-0081-7] [Medline: 22736404]
23. Mazur E, Mickle CL. Online discourse of the stressors of parenting children with mental health disorders. J Child Fam Stud 2017 Oct 16;27(2):569-579. [doi: 10.1007/s10826-017-0912-4]
24. Lobban F, Akers N, Appelbe D, Chapman L, Collinge L, Dodd S, et al. Clinical effectiveness of a web-based peer-supported self-management intervention for relatives of people with psychosis or bipolar (REACT): online, observer-blind, randomised

controlled superiority trial. BMC Psychiatry 2020 Apr 14;20(1):160 [FREE Full text] [doi: 10.1186/s12888-020-02545-9] [Medline: 32290827]
25. Lobban F, Akers N, Appelbe D, Iraci Capuccinello R, Chapman L, Collinge L, et al. A web-based, peer-supported self-management intervention to reduce distress in relatives of people with psychosis or bipolar disorder: the REACT RCT. Health Technol Assess 2020 Jun;24(32):1-142 [FREE Full text] [doi: 10.3310/hta24320] [Medline: 32608353]
26. Lobban F, Glentworth D, Chapman L, Wainwright L, Postlethwaite A, Dunn G, et al. Feasibility of a supported self-management intervention for relatives of people with recent-onset psychosis: REACT study. Br J Psychiatry 2013 Nov;203(5):366-372. [doi: 10.1192/bjp.bp.112.113613] [Medline: 24072754]
27. Elena-Bucea A, Cruz-Jesus F, Oliveira T, Coelho P. Assessing the role of age, education, gender and income on the digital divide: evidence for the European Union. Inf Syst Front 2020 May 19;23(4):1007-1021 [FREE Full text] [doi: 10.1007/s10796-020-10012-9]
28. Goldberg D, Hillier V. A scaled version of the General Health Questionnaire. Psychol Med 1979 Feb;9(1):139-145. [doi: 10.1017/s0033291700021644] [Medline: 424481]
29. Rudolf von Rohr MT. "You will be glad you hung onto this quit": Sharing information and giving support when stopping smoking online. In: Meeting Health Information Needs Outside Of Healthcare: Opportunities and Challenges. Waltham, MA: Chandos Publishing; 2015.
30. Locher MA. Advice Online Advice-giving in an American Internet Health Column. Amsterdam, Netherlands: John Benjamins Publishing Company; 2006.
31. Morrow P. Telling about problems and giving advice in an Internet discussion forum: some discourse features. Discourse Stud 2006;8(4):531-548.
32. Braun V, Clarke V. One size fits all? What counts as quality practice in (reflexive) thematic analysis? Qual Res Psychol 2020 Aug 12;18(3):328-352. [doi: 10.1080/14780887.2020.1769238]
33. Semantic Tagger Framework. UCREL Semantic Analysis System (USAS). URL: http://ucrel.lancs.ac.uk/usas/ [accessed 2022-10-06]
34. Tausczik Y, Pennebaker JW. The psychological meaning of words: LIWC and computerized text analysis methods. J Language Social Psychol 2009 Dec 08;29(1):24-54. [doi: 10.1177/0261927X09351676]
35. Rayson P, Archer DE, Piao S, Mcenery T. The UCREL semantic analysis system. In: Proceedings of the Workshop: Beyond Named Entity Recognition Semantic Labeling for NLP Tasks in LREC'04. 2004 Presented at: Workshop: Beyond Named Entity Recognition Semantic Labeling for NLP Tasks in LREC'04; Jan, 2004; Lisbon, Portugal.
36. Hardie A. Log Ratio – an informal introduction. ESRC Centre for Corpus Approaches to Social Science. 2014 Apr 28. URL: http://cass.lancs.ac.uk/log-ratio-an-informal-introduction/ [accessed 2022-10-11]
37. Dunning T. Accurate methods for the statistics of surprise and coincidence. Computational Linguistics 1993 Mar;19(1):61-74.
38. Nielsen J. The 90-9-1 Rule for Participation Inequality in Social Media and Online Communities. Nielsen Norman Group. 2006 Oct 8. URL: http://www.nngroup.com/articles/ [accessed 2013-09-18]
39. van Mierlo T. The 1% rule in four digital health social networks: an observational study. J Med Internet Res 2014 Feb 04;16(2):e33 [FREE Full text] [doi: 10.2196/jmir.2966] [Medline: 24496109]
40. Nonnecke B, Preece J. Why lurkers lurk. In: Proceedings of the Americas Conference on Information Systems 2001. 2001 Presented at: Americas Conference on Information Systems 2001; Aug 3-5, 2001; Boston, Massachusetts, USA.
41. Repper J, Carter T. A review of the literature on peer support in mental health services. J Ment Health 2011 Aug;20(4):392-411. [doi: 10.3109/09638237.2011.583947] [Medline: 21770786]
42. Dosani S, Harding C, Wilson S. Online groups and patient forums. Curr Psychiatry Rep 2014 Nov 2;16(11):507 [FREE Full text] [doi: 10.1007/s11920-014-0507-3] [Medline: 25273668]
43. Nguyen A, Mosadeghi S, Almario CV. Persistent digital divide in access to and use of the internet as a resource for health information: results from a California population-based study. Int J Med Inform 2017 Jul;103:49-54. [doi: 10.1016/j.ijmedinf.2017.04.008] [Medline: 28551001]

## Abbreviations

**BD:** bipolar disorder
**GHQ:** General Health Questionnaire
**REACT:** Relatives Education and Coping Toolkit
**USAS:** University Centre for Computer Corpus Research on Language Semantic Analysis System

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Original Paper

# Social Media Use and Health-Related Quality of Life Among Adolescents: Cross-sectional Study

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## Abstract

**Background:** Using social media is a time-consuming activity of children and adolescents. Health authorities have warned that excessive use of social media can negatively affect adolescent social, physical, and psychological health. However, scientific findings regarding associations between time spent on social media and adolescent health-related quality of life (HRQoL) are not consistent. Adolescents typically use multiple social media platforms. Whether the use of multiple social media platforms impacts adolescent health is unclear.

**Objective:** The aim of this study was to examine the relationship between social media use, including the number of social media platforms used and time spent on social media, and adolescent HRQoL.

**Methods:** We analyzed the data of 3397 children (mean age 13.5, SD 0.4 years) from the Generation R Study, a population-based cohort study in the Netherlands. Children reported the number of social media platforms used and time spent on social media during weekdays and weekends separately. Children's HRQoL was self-reported with the EuroQol 5-dimension questionnaire–youth version. Data on social media use and HRQoL were collected from 2015 to 2019. Multiple logistic and linear regressions were applied.

**Results:** In this study, 72.6% (2466/3397) of the children used 3 or more social media platforms, and 37.7% (1234/3276) and 58.3% (1911/3277) of the children used social media at least 2 hours per day during weekdays and weekends, respectively. Children using more social media platforms (7 or more platforms) had a higher odds of reporting having some or a lot of problems on "having pain or discomfort" (OR 1.55, 95% CI 1.20 to 1.99) and "feeling worried, sad or unhappy" (OR 1.99, 95% CI 1.52 to 2.60) dimensions and reported lower self-rated health (β –3.81, 95% CI –5.54 to –2.09) compared with children who used 0 to 2 social media platforms. Both on weekdays and weekends, children spent more time on social media were more likely to report having some or a lot of problems on "doing usual activities," "having pain or discomfort," "feeling worried, sad or unhappy," and report lower self-rated health (all $P<.001$).

**Conclusions:** Our findings indicate that using more social media platforms and spending more time on social media were significantly related to lower HRQoL. We recommend future research to study the pathway between social media use and HRQoL among adolescents.

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**KEYWORDS**

adolescents; social media platforms; social media; health-related quality of life; EuroQol 5-dimension questionnaire, youth version

## Introduction

The number of adolescents who use social media daily has doubled in western countries, from 34% in 2010 to 70% in 2020 [1]. Social media use can be defined as using various media platforms, such as Facebook, Twitter, YouTube, and so on, to quickly create and share content with the public [2]. Data suggest that in the European countries, 92% of children aged 14 to 16 years use social media and 39% visit social media platforms at least once a day [3]. Using social media is among the most common activities of today's children [4-6]. Meanwhile, extensive social media use may impact children's physical and psychosocial well-being [7,8].

Findings on whether social media use improves or reduces children's well-being are inconsistent [6,9]. Engagement via social media platforms provides opportunities for keeping in touch with families and friends and other social interactions that may increase children's emotional well-being [10]. Social media can also be a valuable resource for peer support, allowing children to get advice from others or share their own experiences [11,12]. By expanding the quantity and quality of communications, social media use enhances children's social well-being [13].

However, studies have also shown that excessive social media use might decrease children's well-being [14,15]. For example, one study among children suggested that excessive social media use may expose them to idealized depictions of others [16]. This may trigger negative social comparisons that cause users to believe others are happier and have better lives, increasing anxiety and decreasing their mental well-being [17,18]. Moreover, Nie et al [19] suggested that more time spent on social media may lead to less time spent on health-promoting behaviors such as physical activity, reducing the children's physical well-being. Studies have started to evaluate the number of social media platforms (ie, Facebook, Instagram) that a person uses [20,21], since adolescents do not typically use just one social media platform; more than 70% use multiple social media platforms [22]. Previous studies have shown that people who use multiple platforms are more likely to be exposed to news or posts about others' successes, which may increase users' dissatisfaction with their own lives and thus decrease well-being [23-25]. Overall, the inconsistent findings on a broad range of child health outcomes suggest more research is needed. Specifically, health-related quality of life (HRQoL) might be a relevant outcome to study in order to evaluate the impact of the use of social media platforms on children's health and well-being [26]. HRQoL is a multidimensional concept, including disease state and physical, psychological, and social well-being [27].

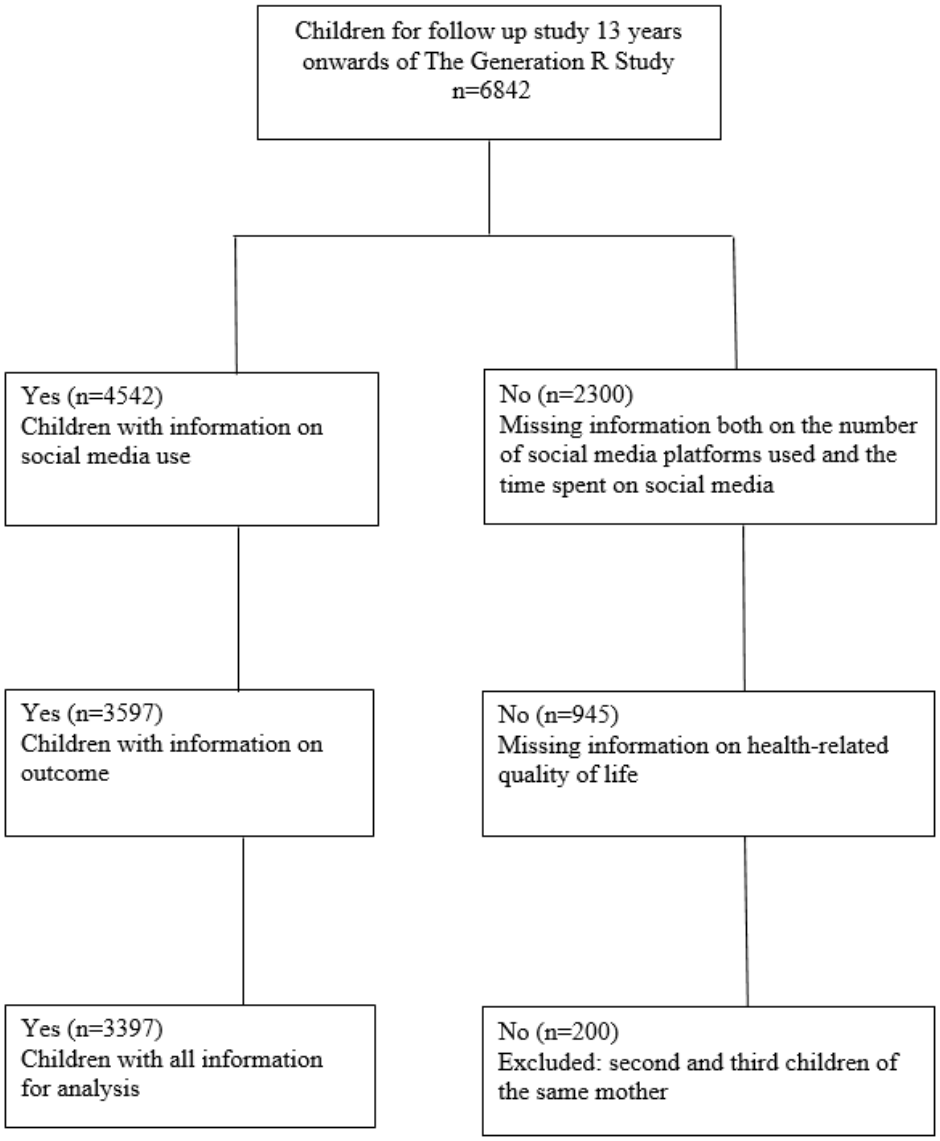
The aim of this study was to examine the relationship between the number of social media platforms used, time spent on social media, and HRQoL among children aged 13 years. We hypothesized that children who use multiple social media platforms and spend more time on social media would be likely to have lower HRQoL.

## Methods

### Design and Study Population

A cross-sectional study was designed using date from a cohort study—the Generation R Study. The Generation R Study is an ongoing prospective cohort study from fetal life onward in Rotterdam, The Netherlands. Detailed information on the Generation R Study has been published elsewhere [28]. Briefly, all pregnant women with an expected delivery date from April 2002 through January 2006 living in Rotterdam were invited to participate. A total of 6842 children participated in the assessment at age 13 years (2015-2019). Children with missing data on the number of social media platforms used or the time spent on social media were excluded (n=2300), as were children with missing data on HRQoL (n=945). To avoid data clustering, second (n=192) and third children (n=8) of the same mother were excluded, leaving a study population of 3397 children (Figure 1). Written informed consent was obtained from all participants.

**Figure 1.** Flowchart of participants.




## Ethics Approval

The Medical Ethics Committee of the Erasmus University Medical Center approved the study (MEC 217.595/2002/202).

## Measures

### *Exposure Variables*

Children were asked to report which social media platforms they used. Nine widely used social media platforms (ie, Facebook, Instagram, Musical.ly, Pinterest, Skype, Snapchat, Twitter, WhatsApp, YouTube), "Other, namely:_," and never used (ie, I do not use these platforms) were listed as the response options. To operationalize this variable, the number of different platforms used was counted. The variable was then divided into 0 to 2 platforms, 3 to 4 platforms, 5 to 6 platforms, and 7 or more platforms.

The time spent on social media was examined separately on weekdays and weekends since children spend more time on their phones or other devices at the weekends than on weekdays, as they are at school during the weekdays [29]. The time spent on social media was measured by self-reported questionnaire. Children gave answers to the following questions: "On average, how many hours per day do you usually spend on social media during weekdays?" and "On average, how many hours per day do you usually spend on social media during weekend days?" Response options for these questions were <30 minutes, 30 minutes to 2 hours, 2 to 4 hours, 4 to 6 hours, and >6 hours.

### *Outcome Variable*

Children's HRQoL was measured using EuroQol 5-dimension questionnaire–youth version (EQ-5D-Y) developed by the European Quality of Life Group [30]. The EQ-5D-Y questionnaire consists of 2 parts to measure the generic health of children: the EQ-5D descriptive system and the visual analog scale (VAS). Children were asked to rate their health in the present day on 5 dimensions: "mobility" (refers to physical ability to walk or move about, both inside and outside), "looking after myself" (refers to an age-appropriate degree of independence in daily personal care, specifically covering washing and dressing), "doing usual activities" (refers to the ability to participate in child-specific activities, such as going to school, hobbies, sports, playing, and doing things with family or friends), "having pain or discomfort" (refers to

physical/bodily soreness or uncomfortable physical sensation of a lower grade of intensity than pain such as aches, nausea, dizziness), and "feeling worried, sad or unhappy." Children could choose from 3 levels (no problems, some problems, or a lot of problems) to answer each dimension. Because few children chose "a lot of problems" in each dimension, the 3 levels under each dimension were collapsed into 2 levels in this study (no problems and some or a lot of problems) [31]. The VAS records children's self-rated health ("How good is your health TODAY?") on a vertically numbered VAS score from 0 to 100. Zero was labeled as "the worst imaginable health state" while 100 was labeled as "the best imaginable health state." The feasibility, validity, and reliability of the EQ-5D-Y have been documented [32].

### *Covariates*

Based on the literature, several variables were considered as the potential confounders in this study: child's age, sex, ethnic background, family composition, net household income, and maternal educational level. Child ethnic background (Western, non-Western) was based on parental countries of birth obtained from questionnaire when the child was aged 6 years [33]. Family composition (1-parent family, 2-parent family) and net household income per month (<€2000 [US $1933] per month, €2000-€3600 [US $1933-$3479] per month, >€3600 [US $3479] per month) were obtained by parent-report questionnaire when the child was aged 13 years. Maternal educational level was obtained when the child was aged 6 years by parent-report and was defined by the highest education attained. It was divided into 3 categories: low, middle, and high.

### Statistical Analyses

Descriptive analyses were applied to characterize the study population. Distribution of the reported problems in the 5 dimensions of HRQoL by the number of social media platforms used and the time spent on social media were assessed by chi-square tests and shown in Multimedia Appendix 1. The VAS score by the number of social media platforms used and the time spent on social media were evaluated by 1-way analysis of variance and shown in Multimedia Appendix 1. The relationship between the number of social media platforms used and HRQoL was investigated using logistics regression for the 5 dimensions and linear regression for VAS score. All models were adjusted for the child's age, sex, ethnic background, family composition, maternal educational level, and net household income and additionally adjusted for time spent on social media. The relationship between the time spent on social media and HRQoL was investigated using logistics regression for 5 dimensions and linear regression for VAS score and shown in Multimedia Appendix 2. All models were adjusted for the covariates. All models were run separately with weekday and weekend social media use.

Missing data on covariates were imputed using multiple imputation methods, and 10 imputed data sets were generated. Pooled effect estimates (odds ratios [ORs] and β coefficients) and confidence intervals from these 10 imputed data sets were reported, and $P<.05$ was used to indicate statistical significance. Statistical analyses were performed using SPSS for Windows (version 24.0, IBM Corp).

### Nonresponse Analyses

Children with missing data on HRQoL (n=945) were compared with children without missing data (n=3397) using chi-square tests. Data were more often missing for children from mothers with a low educational level, a low household income, or a 1-parent family (all $P<.05$). No statistical difference was found in the number of social media platforms used and time spent on social media between children with or without data on HRQoL.

### Sensitivity Analyses

To examine the robustness of our results, the relationship between the number of social media platforms used and HRQoL was examined using the continuous variable of the number of social media platforms used and shown in Multimedia Appendix 3.

Additionally, one variable-parental supervision was added as a confounder into the regression models and shown in Multimedia Appendices 4 and 5. This variable was obtained by a parent-reported questionnaire when the child was aged 13 years. Parents answered the question "I sit at the computer together with my child if they are on social media." Response options were never, rarely, sometimes, often, and always.

## Results

### Sample Characteristics

In total, 3397 children were included in this study. The mean age of the children was 13.5 (SD 0.4) years; 46.9% (1594/3397) were boys. More than two-thirds (2466/3397, 72.6%) of the children used 3 or more social media platforms. Of these, 37.7% (1234/3276) of the children used social media more than 2 hours on a weekday and 58.3% (1911/3277) did on a weekend day. From all 5 dimensions in HRQoL, children reported the most problems in "having pain or discomfort" (876/3385, 25.9%), followed by "feeling worried, sad, or unhappy" (557/3388, 16.4%). The average VAS score was 83.5 (SD 14.8; Table 1).

**Table 1.** General characteristics of the study population (n=3397).

| Characteristic | Total | Missing |
|---|---|---|
| Child's age (years), mean (SD) | 13.5 (0.4) | 112 (3.3) |
| Child's sex, boy, n (%) | 1594 (46.9) | 0 |
| **Child's ethnic background, n (%)** | | |
| Western | 2557 (76.0) | 33 (1.0) |
| Non-western | 807 (24.0) | —[a] |
| **Maternal education level, n (%)** | | |
| Low | 257 (8.2) | 268 (7.9) |
| Middle | 860 (27.5) | — |
| High | 2012 (64.3) | — |
| **Household income (€) per month, n (%)** | | |
| <2000 | 411 (13.7) | 398 (11.7) |
| 2000-3600 | 791 (26.4) | — |
| >3600 | 1797 (59.9) | — |
| **Family composition, n (%)** | | |
| 1-parent family | 542 (16.7) | 149 (4.4) |
| 2-parent family | 2706 (83.3) | — |
| **Number of social media platforms used, n (%)** | | |
| 0-2 | 931 (27.4) | 0 |
| 3-4 | 1154 (34.0) | — |
| 5-6 | 763 (22.5) | — |
| ≥7 | 549 (16.2) | — |
| **Time spent on social media** | | |
| **Weekdays (hours), n (%)** | | |
| <0.5 | 409 (12.5) | 121 (3.6) |
| 0.5-2 | 1633 (49.8) | — |
| 2-4 | 989 (30.2) | — |
| 4-6 | 164 (5.0) | — |
| >6 | 81 (2.5) | — |
| **Weekend days (hours), n (%)** | | |
| <0.5 | 251 (7.7) | 120 (3.5) |
| 0.5-2 | 1115 (34.0) | — |
| 2-4 | 1408 (43.0) | — |
| 4-6 | 321 (9.8) | — |
| >6 | 182 (5.6) | — |
| **Health-related quality of life** | | |
| **Mobility, n (%)** | | |
| No problems | 3199 (94.4) | 7 (0.2) |
| Some or a lot of problems | 191 (5.6) | — |
| **Looking after myself, n (%)** | | |
| No problems | 3340 (98.5) | 6 (0.2) |
| Some or a lot of problems | 51 (1.5) | — |
| **Doing usual activities, n (%)** | | |

| Characteristic | Total | Missing |
|---|---|---|
| No problems | 3155 (93.1) | 8 (0.2) |
| Some or a lot of problems | 234 (6.9) | — |
| **Having pain or discomfort, n (%)** | | |
| No problems | 2509 (74.1) | 12 (0.4) |
| Some or a lot of problems | 876 (25.9) | — |
| **Feeling worried, sad, or unhappy, n (%)** | | |
| No problems | 2831 (83.6) | 9 (0.3) |
| Some or a lot of problems | 557 (16.4) | — |
| EQ[b] VAS[c], mean (SD) | 83.5 (14.8) | 538 (15.8) |

[a]Not applicable.

[b]EQ: EuroQoL.

[c]VAS: visual analog scale.

Multimedia Appendix 1 shows the distribution of reported problems in the 5 dimensions and VAS score by the number of social media platforms used and the time spent on social media. Significant differences were found in "mobility," "doing usual activities," "having pain or discomfort," and "feeling worried, sad or unhappy" dimensions between children who spent different time on social media (all $P<.05$). The VAS score decreased with more social media platforms used and with more time spent on social media.

## Number of Social Media Platforms Used and HRQoL

Compared with children who used 0 to 2 platforms, those who used 5 to 6 platforms or 7 or more platforms were more likely to report having some or a lot of problems on "having pain or discomfort" dimension (5-6 platforms: OR 1.41, 95% CI 1.12 to 1.78; 7 or more platforms: OR 1.55, 95% CI 1.20 to 1.99). Compared with children who used 0 to 2 platforms, those who used more platforms were more likely to report having some or a lot of problems on "feeling worried, sad or unhappy" dimension (3-4 platforms: OR 1.42, 95% CI 1.09 to 1.85; 5-6 platforms: OR 1.61, 95% CI 1.25 to 2.08; 7 or more platforms: OR 1.99, 95% CI 1.52 to 2.60). Furthermore to using 7 or more social media platforms was related to lower VAS score (β –3.81, 95% CI –5.54 to –2.09; Table 2).

**Table 2.** The relationship between the number of social media platforms used and health-related quality of life among children aged 13 years.

| HRQoL[a] | 0-2 platforms | 3-4 platforms | 5-6 platforms | 7≥ platforms |
|---|---|---|---|---|
| Mobility, OR[b] (95% CI) | 1 (ref) | 1.04 (0.70 to 1.54) | 1.24 (0.81 to 1.89) | 0.94 (0.58 to 1.53) |
| Looking after myself, OR (95% CI) | 1 (ref) | 0.55 (0.27 to 1.13) | 0.61 (0.27 to 1.38) | 0.75 (0.32 to 1.76) |
| Ding usual activities, OR (95% CI) | 1 (ref) | 0.72 (0.51 to 1.02) | 0.70 (0.47 to 1.04) | 1.03 (0.69 to 1.53) |
| Having pain or discomfort, OR (95% CI) | 1 (ref) | 1.23 (0.99 to 1.52) | 1.41 (1.12 to 1.78) | 1.55 (1.20 to 1.99) |
| Feeling worried, sad or unhappy, OR (95% CI) | 1 (ref) | 1.42 (1.09 to 1.85) | 1.61 (1.25 to 2.08) | 1.99 (1.52 to 2.60) |
| EQ[c] VAS[d], (95% CI) | 1 (ref) | –0.35 (–1.74 to 1.03) | –0.91 (–2.45 to 0.63) | –3.81 (–5.54 to –2.09) |

[a]HRQoL: health-related quality of life.

[b]OR: odds ratio.

[c]EQ: EuroQoL.

[d]VAS: visual analog scale.

## Time Spent on Social Media and HRQoL

After adjusting for all variates, higher social media use both on weekdays and weekends were related to more problems reported in each dimension and lower VAS score (Multimedia Appendix 2). On a weekday, compared to children who used social media less than 30 minutes per day, children who used social media between 2 to 4 hours, 4 to 6 hours, or more than 6 hours were more likely to report having some or a lot of problems on 3 dimensions ("doing usual activities," "having pain or discomfort" and "feeling worried, sad, or unhappy" dimensions; all $P<.05$). Of those 3 dimensions, children who used social media more than 6 hours reported the highest odds ratio of reporting problems on "doing usual activities" dimension compared to children who used social media less than 30 minutes per day (OR 4.00, 95% CI 1.84 to 8.71). On the "mobility" dimension, only children who used social media more than 6 hours reported significantly more problems compared to those who used social media less than 30 minutes (OR 2.21, 95% CI 1.05 to 4.65).

With regard to the VAS score, higher social media use was related to lower VAS score. Children who used social media more than 6 hours per day had the lowest VAS scores compared with children who used less than 30 minutes per day (β –7.70, 95% CI –11.82 to –3.59). The results of the relationship between the time spent on social media and HRQoL during weekends were comparable to the results of weekdays, although effect estimates (ORs and β) were smaller.

### Findings From Sensitivity Analyses

The results showed that using more social media platforms was related to reported problems on the "having pain or discomfort" (OR 1.10, 95% CI 1.04 to 1.17) and "feeling worried, sad or unhappy" (OR 1.11, 95% CI 1.03 to 1.18) dimensions and lower VAS score (β –0.42, 95% CI –0.81 to –0.03) when regarding the number of social media platforms used as the continuous variable (Multimedia Appendix 3). Additionally adjusting for the confounder parental supervision, all the results were comparable to previous analyses, although effect estimates (ORs and β) were smaller (Multimedia Appendices 4 and 5).

## Discussion

### Principal Findings

This study investigated the relationship between the number of social media platforms used, time spent on social media, and HRQoL in children aged 13 years. The findings show that 72.6% of the children aged 13 years used 3 or more social media platforms. Around 40% of the children used social media at least 2 hours per day during weekdays (37.7%) and over half of the children on weekends (58.3%). Our findings also show that using more social media platforms and spending more time on social media were related to lower HRQoL.

### Number of Social Media Platforms Used and HRQoL

A higher number of social media platforms used was related to lower HRQoL, which is in line with our hypothesis. Children who used more social media platforms had a higher odds of reporting having some or a lot of problems on the 5 HRQoL dimensions and reported lower self-rated health than their counterparts. An increased number of social media platforms used may elevate the stress of meeting the expectations to check for updates and respond on time on several social media platforms [34]. Moreover, being bombarded with information and communication from numerous social media platforms may result in media multitasking problems [35]. Media multitasking is a specific type of media use behavior in which users simultaneously perform at least 2 media activities or frequently change from one media activity to another. The act may decrease children's psychological well-being, self-esteem, and overall HRQoL [36].

However, it is important to note that decreasing the number of social media platforms used for children may be challenging in today's world. Children may be reluctant to give up any platform because they use different platforms for different reasons [37]. For example, a child can have a Facebook account to keep in touch with friends, Pinterest for cooking, Twitter for news, and Instagram for blogging. Therefore, educational intervention may help adolescents, especially those beginning to use social media, to better understand which platforms are truly necessary to their lives and valuable for their goals and which ones may not be [38].

### Time Spent on Social Media and HRQoL

Our findings suggest that more social media use (on both weekdays and weekends) was related to a lower HRQoL, which is in line with the hypothesis. Children who spent more time on social media were more likely to report having some or a lot of problems on the 5 HRQoL dimensions, and report lower self-rated health than those who spent less time on social media. These findings are in line with previous studies demonstrating that social media use among children aged 13 years and older was inversely associated with HRQoL outcomes such as physical health status and psychological well-being [39,40].

Previous studies have shown that children who spend more time on social media might have a greater chance of being the victim of cyberbullying or direct attacks from others on their sense of well-being [41]. Sampasa et al [42] reported that social media use was associated with cyberbullying victimization and that the risk of being cyberbullied increased in a dose-response manner in children. Children who suffer from cyberbullying are more likely to have lower HRQoL [43]. On the other hand, studies also reported that children who had limited activities and/or high levels of feeling worried, sad or unhappy may perceive online social communication via social media as a possibility to gain social support and relieve themselves of negative feelings through the ease of online self-disclosure [44]. Future studies are recommended to study intermediate variables to better understand the pathway between adolescents' social media use and HRQoL.

### Strengths and Limitations

In this study, social media use was assessed with the number of social media platforms used and time spent on social media. Further, this study was conducted among children aged 13 years, a sensitive developmental period during which little is known about social media use and its impact on HRQoL. However, the following methodological considerations need to be taken into account. First, for our cross-sectional analyses data from children aged 13 years were used. During this measurement, data on time spent on social media and the type of social media used were collected. The next measurement was performed on child aged 18 years. We recommended follow-up studies to explore the longitudinal associations between social media use and HRQoL. Second, social media use was captured via self-reported questionnaire, which may lead to overestimating or underestimating the time spent on social media. More accurate measuring method such as passive sensing (eg, apps installed on the devices that track real-time use [45]), could be adopted in future studies.

### Conclusions

This study captured the number of social media platforms used and time spent on social media among children aged 13 years. Children using more social media platforms and spending more time on social media were more likely to report a lower HRQoL, including reporting having some or a lot of problems on the 5 HRQoL dimensions and lower self-rated health. Better

understanding of how social media platforms contribute to children's health and well-being may contribute to more support in adolescent social media use.

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## Authors' Contributions

YY, JYH, AvG, and HR conceptualized and designed the study. YY performed the statistical analyses and drafted the manuscript. AvG and HR supervised the data analyses. JYH and AvG contributed to methodology considerations. JYH, AvG, and HR reviewed the manuscript for intellectual content.

## Conflicts of Interest

None declared.

Multimedia Appendix 1
Distribution of the reported problems in the 5 dimensions of HRQoL and the VAS score by the number of social media platforms used and the time spent on social media among children aged 13 years.
[DOCX File , 15 KB - mental_v9i10e39710_app1.docx ]

Multimedia Appendix 2
The relationship between the time spent on social media and health-related quality of life among children aged 13 years.
[DOCX File , 14 KB - mental_v9i10e39710_app2.docx ]

Multimedia Appendix 3
Sensitivity analyses: the relationship between the number of social media platforms used and health-related quality of life.
[DOCX File , 13 KB - mental_v9i10e39710_app3.docx ]

Multimedia Appendix 4
Sensitivity analyses: the relationship between the number of social media platforms used and health-related quality of life.
[DOCX File , 13 KB - mental_v9i10e39710_app4.docx ]

Multimedia Appendix 5
Sensitivity analyses: the relationship between the time spent on social media and health-related quality of life.
[DOCX File , 14 KB - mental_v9i10e39710_app5.docx ]

## References

1. Abi-Jaoude E, Naylor KT, Pignatiello A. Smartphones, social media use and youth mental health. Can Med Assoc J 2020 Feb 10;192(6):E136-E141 [FREE Full text] [doi: 10.1503/cmaj.190434] [Medline: 32041697]
2. Carr CT, Hayes RA. Social media: defining, developing, and divining. Atlantic J Commun 2015 Feb 06;23(1):46-65. [doi: 10.1080/15456870.2015.972282]
3. Tsitsika AK, Tzavela EC, Janikian M, Ólafsson K, Iordache A, Schoenmakers TM, et al. Online social networking in adolescence: patterns of use in six European countries and links with psychosocial functioning. J Adolesc Health 2014 Jul;55(1):141-147. [doi: 10.1016/j.jadohealth.2013.11.010] [Medline: 24618179]
4. Keles B, McCrae N, Grealish A. A systematic review: the influence of social media on depression, anxiety and psychological distress in adolescents. Int J Adolesc Youth 2019 Mar 21;25(1):79-93. [doi: 10.1080/02673843.2019.1590851]
5. You Y, Yang-Huang J, Raat H, van Grieken A. Sociodemographic factors and social media use in 9-year-old children: the Generation R Study. BMC Public Health 2021 Oct 30;21(1):1966 [FREE Full text] [doi: 10.1186/s12889-021-12061-4] [Medline: 34717589]
6. Donelle L, Facca D, Burke S, Hiebert B, Bender E, Ling S. Exploring Canadian Children's Social Media Use, Digital Literacy, and Quality of Life: Pilot Cross-sectional Survey Study. JMIR Form Res 2021 May 26;5(5):e18771 [FREE Full text] [doi: 10.2196/18771] [Medline: 34037525]

7. D'Arienzo MC, Boursier V, Griffiths MD. Addiction to social media and attachment styles: a systematic literature review. Int J Ment Health Addiction 2019 Apr 18;17(4):1094-1118. [doi: 10.1007/s11469-019-00082-5]
8. Shannon H, Bush K, Villeneuve PJ, Hellemans KG, Guimond S. Problematic social media use in adolescents and young adults: systematic review and meta-analysis. JMIR Ment Health 2022 Apr 14;9(4):e33450 [FREE Full text] [doi: 10.2196/33450] [Medline: 35436240]
9. Arias-de la Torre J, Puigdomenech E, García X, Valderas JM, Eiroa-Orosa FJ, Fernández-Villa T, et al. Relationship between depression and the use of mobile technologies and social media among adolescents: umbrella review. J Med Internet Res 2020 Aug 26;22(8):e16388 [FREE Full text] [doi: 10.2196/16388] [Medline: 32663157]
10. Wang J, Jackson LA, Gaskin J, Wang H. The effects of Social Networking Site (SNS) use on college students' friendship and well-being. Comput Human Behav 2014 Aug;37:229-236. [doi: 10.1016/j.chb.2014.04.051]
11. Uhls YT, Ellison NB, Subrahmanyam K. Benefits and costs of social media in adolescence. Pediatrics 2017 Nov;140(Suppl 2):S67-S70 [FREE Full text] [doi: 10.1542/peds.2016-1758E] [Medline: 29093035]
12. Smith-Merry J, Goggin G, Campbell A, McKenzie K, Ridout B, Baylosis C. Social connection and online engagement: insights from interviews with users of a mental health online forum. JMIR Ment Health 2019 Mar 26;6(3):e11084 [FREE Full text] [doi: 10.2196/11084] [Medline: 30912760]
13. Dienlin T, Masur PK, Trepte S. Reinforcement or displacement? The reciprocity of FtF, IM, and SNS communication and their effects on loneliness and life satisfaction. J Comput Mediat Comm 2017 Feb 16;22(2):71-87. [doi: 10.1111/jcc4.12183]
14. Rutter LA, Thompson HM, Howard J, Riley TN, De Jesús-Romero R, Lorenzo-Luaces L. Social media use, physical activity, and internalizing symptoms in adolescence: cross-sectional analysis. JMIR Ment Health 2021 Sep 15;8(9):e26134 [FREE Full text] [doi: 10.2196/26134] [Medline: 34524096]
15. Ivie EJ, Pettitt A, Moses LJ, Allen NB. A meta-analysis of the association between adolescent social media use and depressive symptoms. J Affect Disord 2020 Oct 01;275:165-174. [doi: 10.1016/j.jad.2020.06.014] [Medline: 32734903]
16. Hoge E, Bickham D, Cantor J. Digital media, anxiety, and depression in children. Pediatrics 2017 Nov;140(Suppl 2):S76-S80 [FREE Full text] [doi: 10.1542/peds.2016-1758G] [Medline: 29093037]
17. Pera A. Psychopathological processes involved in social comparison, depression, and envy on Facebook. Front Psychol 2018;9:22 [FREE Full text] [doi: 10.3389/fpsyg.2018.00022] [Medline: 29410643]
18. Shensa A, Sidani JE, Lin LY, Bowman ND, Primack BA. Social media use and perceived emotional support among US young adults. J Community Health 2016 Jun;41(3):541-549. [doi: 10.1007/s10900-015-0128-8] [Medline: 26613936]
19. Nie NH. Sociability, interpersonal relations, and the internet. Am Behav Scientist 2016 Jul 27;45(3):420-435. [doi: 10.1177/00027640121957277]
20. Primack BA, Shensa A, Escobar-Viera CG, Barrett EL, Sidani JE, Colditz JB, et al. Use of multiple social media platforms and symptoms of depression and anxiety: a nationally-representative study among U.S. young adults. Comput Human Behav 2017 Apr;69:1-9. [doi: 10.1016/j.chb.2016.11.013]
21. Lin LY, Sidani JE, Shensa A, Radovic A, Miller E, Colditz JB, et al. Association between social media use and depression among US young adults. Depress Anx 2016 Apr;33(4):323-331. [doi: 10.1002/da.22466] [Medline: 26783723]
22. Beyens I, Pouwels J, van Driel I, Keijsers L, Valkenburg P. The effect of social media on well-being differs from adolescent to adolescent. Sci Rep 2020 Jul 01;10(1):10763 [FREE Full text] [doi: 10.1038/s41598-020-67727-7] [Medline: 32612108]
23. Wang J, Wang H, Gaskin J, Hawk S. The mediating roles of upward social comparison and self-esteem and the moderating role of social comparison orientation in the association between social networking site usage and subjective well-being. Front Psychol 2017;8:771 [FREE Full text] [doi: 10.3389/fpsyg.2017.00771] [Medline: 28553256]
24. Thorisdottir IE, Sigurvinsdottir R, Asgeirsdottir BB, Allegrante JP, Sigfusdottir ID. Active and passive social media use and symptoms of anxiety and depressed mood among Icelandic adolescents. Cyberpsychol Behav Soc Netw 2019 Aug;22(8):535-542 [FREE Full text] [doi: 10.1089/cyber.2019.0079] [Medline: 31361508]
25. Gerber JP, Wheeler L, Suls J. A social comparison theory meta-analysis 60+ years on. Psychol Bull 2018 Feb;144(2):177-197. [doi: 10.1037/bul0000127] [Medline: 29144145]
26. Jenkins RH, Shen C, Dumontheil I, Thomas MS, Elliott P, Röösli M, et al. Social networking site use in young adolescents: association with health-related quality of life and behavioural difficulties. Comput Human Behav 2020 Aug;109:106320. [doi: 10.1016/j.chb.2020.106320]
27. Aaronson N. Quality of life assessment in clinical trials: methodologic issues. Control Clin Trials 1989 Dec;10(4):195-208. [doi: 10.1016/0197-2456(89)90058-5] [Medline: 2605968]
28. Jaddoe VWV, van Duijn CM, Franco OH, van der Heijden AJ, van Iizendoorn MH, de Jongste JC, et al. The Generation R Study: design and cohort update 2012. Eur J Epidemiol 2012 Sep;27(9):739-756. [doi: 10.1007/s10654-012-9735-1] [Medline: 23086283]
29. Zhu R, Fang H, Chen M, Hu X, Cao Y, Yang F, et al. Screen time and sleep disorder in preschool children: identifying the safe threshold in a digital world. Public Health 2020 Sep;186:204-210. [doi: 10.1016/j.puhe.2020.07.028] [Medline: 32861085]
30. Wille N, Badia X, Bonsel G, Burström K, Cavrini G, Devlin N, et al. Development of the EQ-5D-Y: a child-friendly version of the EQ-5D. Qual Life Res 2010 Aug;19(6):875-886 [FREE Full text] [doi: 10.1007/s11136-010-9648-y] [Medline: 20405245]

31. Kim S, Jo M, Kim S. A cross sectional survey on health-related quality of life of elementary school students using the Korean version of the EQ-5D-Y. PeerJ 2017;5:e3115 [FREE Full text] [doi: 10.7717/peerj.3115] [Medline: 28344908]
32. Ravens-Sieberer U, Wille N, Badia X, Bonsel G, Burström K, Cavrini G, et al. Feasibility, reliability, and validity of the EQ-5D-Y: results from a multinational study. Qual Life Res 2010 Aug;19(6):887-897 [FREE Full text] [doi: 10.1007/s11136-010-9649-x] [Medline: 20401552]
33. Jaddoe V, Mackenbach J, Moll H, Steegers E, Tiemeier H, Verhulst F, et al. The Generation R Study: design and cohort profile. Eur J Epidemiol 2006;21(6):475-484. [doi: 10.1007/s10654-006-9022-0] [Medline: 16826450]
34. Lee AR, Son S, Kim KK. Information and communication technology overload and social networking service fatigue: a stress perspective. Comput Human Behav 2016 Feb;55:51-61. [doi: 10.1016/j.chb.2015.08.011]
35. Vannucci A, Ohannessian CM, Gagnon S. Use of multiple social media platforms in relation to psychological functioning in emerging adults. Emerg Adulthood 2018 Jun 20;7(6):501-506. [doi: 10.1177/2167696818782309]
36. Luo J, Yeung P, Li H. Relationship between media multitasking and self-esteem among Chinese adolescents: mediating roles of peer influence and family functioning. J Child Fam Stud 2019 Oct 11;29(5):1391-1401. [doi: 10.1007/s10826-019-01613-3]
37. Pantic I. Online social networking and mental health. Cyberpsychol Behav Soc Netw 2014 Oct;17(10):652-657 [FREE Full text] [doi: 10.1089/cyber.2014.0070] [Medline: 25192305]
38. Shimoga SV, Erlyana E, Rebello V. Associations of social media use with physical activity and sleep adequacy among adolescents: cross-sectional survey. J Med Internet Res 2019 Jun 18;21(6):e14290 [FREE Full text] [doi: 10.2196/14290] [Medline: 31215512]
39. Hamilton JL, Lee W. Associations between social media, bedtime technology use rules, and daytime sleepiness among adolescents: cross-sectional findings from a nationally representative sample. JMIR Ment Health 2021 Sep 15;8(9):e26273 [FREE Full text] [doi: 10.2196/26273] [Medline: 34524967]
40. Foody M, McGuire L, Kuldas S, O'Higgins Norman J. Friendship quality and gender differences in association with cyberbullying involvement and psychological well-being. Front Psychol 2019;10:1723 [FREE Full text] [doi: 10.3389/fpsyg.2019.01723] [Medline: 31396139]
41. Sampasa-Kanyinga H, Hamilton HA. Use of social networking sites and risk of cyberbullying victimization: a population-level study of adolescents. Cyberpsychol Behav Soc Netw 2015 Dec;18(12):704-710. [doi: 10.1089/cyber.2015.0145] [Medline: 26539738]
42. González-Cabrera J, León-Mejía A, Beranuy M, Gutiérrez-Ortega M, Alvarez-Bardón A, Machimbarrena JM. Relationship between cyberbullying and health-related quality of life in a sample of children and adolescents. Qual Life Res 2018 Oct;27(10):2609-2618. [doi: 10.1007/s11136-018-1901-9] [Medline: 29881894]
43. Dolev-Cohen M, Barak A. Adolescents' use of Instant Messaging as a means of emotional relief. Comput Human Behav 2013 Jan;29(1):58-63. [doi: 10.1016/j.chb.2012.07.016]
44. Oh HJ, Ozkaya E, LaRose R. How does online social networking enhance life satisfaction? The relationships among online supportive interaction, affect, perceived social support, sense of community, and life satisfaction. Comput Human Behav 2014 Jan;30:69-78. [doi: 10.1016/j.chb.2013.07.053]
45. Meyer M, Adkins V, Yuan N, Weeks HM, Chang Y, Radesky J. Advertising in Young Children's Apps: A Content Analysis. J Dev Behav Pediatr 2019 Jan;40(1):32-39. [doi: 10.1097/DBP.0000000000000622] [Medline: 30371646]


## Abbreviations

**EQ-5D-Y:** EuroQol 5-dimension questionnaire–youth version
**HRQoL:** health-related quality of life
**OR:** odds ratios
**VAS:** visual analog scale


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Original Paper

# Factors Influencing Increased Use of Technology to Communicate With Others During the COVID-19 Pandemic: Cross-sectional Web-Based Survey Study

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## Abstract

**Background:** Communication via technology is regarded as an effective way of maintaining social connection and helping individuals to cope with the psychological impact of social distancing measures during a pandemic. However, there is little information about which factors have influenced increased use of technology to communicate with others during lockdowns and whether this has changed over time.

**Objective:** The aim of this study is to explore which psychosocial factors (eg, mental health and employment) and pandemic-related factors (eg, shielding and time) influenced an increase in communication via technology during the first lockdown in the United Kingdom.

**Methods:** A cross-sectional, web-based survey was conducted between April and July 2020, examining thoughts, feelings, and behaviors associated with the pandemic, including communicating more using technology (eg, via messaging, phone, or video). We collected sociodemographic information, employment status, mental health service user status, and depression symptoms. We used hierarchical logistic regression to test which factors were associated with communicating more using technology during the lockdown.

**Results:** Participants (N=1464) were on average 41.07 (SD 14.61) years old, and mostly women (n=1141; 77.9%), White (n=1265; 86.4%), and employed (n=1030; 70.4%). Participants reported a mild level of depression (mean 9.43, SD 7.02), and were communicating more using technology (n=1164; 79.5%). The hierarchical regression indicated that people who were employed and experiencing lower levels of depression were more likely to report increased communication using technology during a lockdown period of the COVID-19 pandemic, and over time, men communicated more using technology. Increased use of technology to communicate was related to greater communication and the inability to see others due to the social distancing measures enacted during the lockdown. It was not related to a general increase in technology use during the lockdown.

**Conclusions:** Although most participants reported increased use of technology to communicate during a lockdown period of the COVID-19 pandemic, this was more apparent in the employed and those experiencing low levels of depression. Moving forward, we should continue to monitor groups who may have been excluded from the benefits of support and communication using technology.

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**KEYWORDS**

COVID-19; technology use; communication; demographics; digital health; mental health; pandemic; depression; health technology; psychosocial; lockdown; United Kingdom; cross-sectional; survey; social interaction; mental health; social connection; social connectivity

## Introduction

The COVID-19 pandemic and concomitant restrictions have had an enormous effect on our day-to-day lives [1,2], and technology has been fundamental in enabling us to contact others, access support, and maintain employment throughout periods of lockdown [3]. We wanted to explore whether there was an increase in technological communication during the first COVID-19–related lockdown in the United Kingdom (a period of time when stringent social distancing measures were implemented and people were told to severely limit time spent outside of their own home) and to investigate whether some psychosocial factors (eg, mental health, employment status, and other demographics) and pandemic-related factors (eg, shielding and time) may have contributed to this change.

## Methods

### Design

This cross-sectional study used the results of a web-based survey administered during the United Kingdom's first national lockdown period of the COVID-19 pandemic with a snowball sampling technique.

### Procedure

The survey was published online between April 24 and June 27, 2020. Participants were presented with an information sheet and asked to provided consent before completing the survey questions.

### Ethics Approval

Ethical approval was received from the King's College London Research Ethics Committee (HR-19/20-18180).

### Participants

Participants were UK residents aged ≥16 years and were recruited using social media and other web-based platforms (eg, community mental health forums and newsletters) as well as through mental health service user advisory groups.

### Measures

A clinical measure was selected to establish symptoms of depression, but pandemic-specific questions were developed through themes extracted from a series of qualitative interviews with mental health service users and caregivers about coping during the COVID-19 pandemic [4]. Measures of time and demographics were also collected.

#### *Clinical Measure*

Depression was measured using the patient health questionnaire (PHQ-9) [5], a self-report measure with 9 items corresponding to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition diagnostic criteria for major depressive disorder. Scores of 5, 10, 15, and 20 represent the cutoff point for mild, moderate, moderately severe, and severe depression, respectively. We divided participants into severe (>19) and mild to moderate (5-19) groups.

#### *Pandemic-Specific Questions*

1. Communicating using technology (whether they had been communicating more using technology [eg, messaging, phone, or video] during a lockdown period of the COVID-19 pandemic)
2. Social distancing (whether they were "shielding" and/or "cannot see people I want to see")
3. Communication (whether they were "talking to people more" and/or "speaking about my problems with someone")
4. Technology use (had they been "watching TV and films excessively to fill the time" and/or "checking social media and news" and/or "using health and wellness apps").

#### *Time*

The survey completion date was subtracted from the date the UK lockdown period of the COVID-19 pandemic started (March 23, 2020).

#### *Demographic Characteristics*

Participants were queried about their age, gender, ethnicity, employment status, and current mental health service use.

### Data Analysis

A hierarchical logistic regression was performed, using a forced entry method, and included time since the start of the lockdown, age, gender, ethnicity, mental health service user status, level of depression, and employment status (step 1), social distancing impacts (step 2), communication impacts (step 3), and technology use impacts (step 4) of the COVID-19 pandemic lockdown on the dependent variable—increased communication using technology. Interaction terms with "time" were included for all variables to investigate the change at different stages of the COVID-19 pandemic lockdown.

## Results

Participants (N=1464) were on average 41.07 (SD 14.61) years old, and mostly women (n=1141; 77.9%), White (n=1265; 86.4%), and employed (n=1030; 70.4%). Participants reported a mild level of depression (mean 9.43, SD 7.02). Moreover, most participants were communicating more using technology (n=1164; 79.5%) and some (15.1%; n=221) were shielding (Table 1).

Demographic and clinical variables contributed significantly to increased communication using technology and explained 13% of the variance (step 1: $X^2_{13}$=86.25, $P$<.001; Nagelkerke $R^2$=.13;

see Multimedia Appendix 1). People who were employed and had lower levels of depression were more likely to report increased communication via technology. As time in the lockdown period of the COVID-19 pandemic increased, men were more likely to be communicating more using technology. Social distancing (step 2: $X^2_4$=25.66, $P$<.001; Nagelkerke $R^2$=.17) and communication (step 3, $X^2_4$=44.78, $P$<.001; Nagelkerke $R^2$=.23) significantly contributed to the model, explaining an additional 3.7% and 6.3% of the variance, respectively. Those who reported social distancing ("I cannot see the people I want to see") and/or communication ("I am talking to people more" and "I am speaking openly about my problems with someone") impacts of lockdown were more likely to be communicating more using technology. Finally, technology impacts of lockdown did not significantly contribute to the model (step 4, $X^2_6$=8.53, $P$=.20; Nagelkerke $R^2$=.24). These results were not affected by removing nonsignificant interaction terms.

**Table 1.** Participant characteristics split by mental health service user status.[a]

| Characteristics | Service users (n=285) | Nonservice users (n=1179) | Total (N=1464) | *P* value |
|---|---|---|---|---|
| Age (years), mean (SD) | 36.9 (13.0) | 42.1 (14.8) | 41.1 (14.6) | <.001 |
| **Gender, n (%)** | | | | .02 |
| Women | 234 (82.1) | 907 (76.9) | 1141 (77.9) | |
| Men | 44 (15.4) | 259 (22.0) | 303 (20.7) | |
| **Ethnicity, n (%)** | | | | .30 |
| White | 251 (88.1) | 1014 (86) | 1265 (86.4) | |
| Ethnic minorities (excluding White minorities) | 30 (10.5) | 151 (12.8) | 181 (12.4) | |
| Employed, "yes," n (%) | 156 (54.7) | 874 (74.1) | 1030 (70.4) | <.001 |
| **Depression severity, n (%)** | | | | <.001 |
| Minimal | 30 (10.5) | 349 (29.6) | 379 (25.9) | |
| Mild | 41 (14.4) | 318 (27) | 359 (24.5) | |
| Moderate | 59 (20.7) | 177 (15) | 236 (16.1) | |
| Moderately severe | 44 (15.4) | 103 (8.7) | 147 (10) | |
| Severe | 70 (24.6) | 86 (7.3) | 156 (10.7) | |
| Shielding, "yes," n (%) | 66 (23.2) | 155 (13.1) | 221 (15.1) | <.001 |
| Communicating more using technology, "yes," n (%) | 206 (72.3) | 958 (81.3) | 1164 (79.5) | <.001 |

[a]Percentages do not add up to 100% where data were missing.

## Discussion

### Principal Findings

We found that the employed and those experiencing lower levels of depression were more likely to report that they were using technology to communicate more during the first lockdown period of the COVID-19 pandemic and that changes in technology use were motivated by social distancing and communication rather than changes in general technology usage during the first lockdown. Overall, these results indicate that use of technology to communicate with others (eg, to maintain social connection and access support networks) rose independently of any general change in technology use during this period (eg, watching television or checking social media).

During the COVID-19 pandemic, social distancing and self-isolation guidelines meant that people had to shift toward using technology to continue to communicate with others and seek social support. Our results suggest that people experiencing depression were less likely to have adapted to the changes in communication and this was largely anticipated, when one considers that depression can reduce motivation to engage in social interaction [6] and limit social problem-solving abilities [7]. Research has shown that people that have felt more connected to members of their community during the pandemic have experienced lower levels of depression, anxiety, and loneliness [8]. Communication via technology could be an effective coping strategy that individuals employ to maintain social connection, access support, and manage the psychological effects of lockdown [4,9-11]. It is concerning that people experiencing high levels of depression were less likely to report an increased use of technology to communicate with others because this may have left them more vulnerable to the deleterious mental health effects of the lockdown.

Those who were employed during the first COVID-19 lockdown period were more likely to report increased communication using technology. Technology has been an efficacious and convenient tool for communicating with colleagues, working, and accessing vital support networks during the lockdown [12,13]. Social distancing regulations and government advice stipulated that people should work from home wherever possible, and an increase in the prevalence of working from

home offers a reasonable explanation as to why those in employment were using technology for communication during the lockdown [13]. Conversely, individuals who were unemployed are likely to have been using technology to communicate with others prior to the COVID-19 lockdown period and to have continued to do so at a similar rate, because they did not face the same pressure to increase their use of technology. Additionally, individuals who are unemployed or from low-income households are more vulnerable to digital exclusion [14] and may have lacked access to the technological resources (eg, data packages, internet access) necessary to increase communication via technology.

The interaction between gender and time is harder to interpret but demonstrates that men were more likely to report a change in their use of technology as the lockdown progressed. This supports evidence that suggests that women found social isolation and distancing more difficult and were more likely to report using internet-based technologies to cope with the stress of the pandemic [10,15]. However, our results suggest that men may experience a delayed response to the impacts of social distancing, turning to technological communication much later in periods of lockdown.

### Strengths and Limitations

Cross-sectional designs cannot determine causality and data from longitudinal studies are needed to disentangle the precise relationship between the different factors examined. The variables we explored may be interrelated; for example, people who reported higher levels of depression may have been less likely to be employed and therefore less likely to report using technology earlier on during the COVID-19 pandemic. Furthermore, withdrawal associated with depression may not be specific to the effects of the COVID-19 pandemic. Although our sample had enough variation to identify specific factors that affect communication via technology, participants needed access to technology and the internet to take part in the web-based survey, which will have introduced sampling bias and likely concealed the most digitally excluded members of society.

### Conclusion

In a climate of unprecedented uncertainty, people have shown incredible resilience and resourcefulness, but have become ever more reliant on technology. Although many people reported that they were communicating more using technology, this change has been most apparent in people who were employed and less prominent in those experiencing higher levels of depression. It is also evident that increased technology use was partly driven by the social distancing and communication consequences of the lockdown rather than a general increase in technology use. As the COVID-19 pandemic continues, we expect that there will be a greater integration of technology into our lives, and therefore we must continue to examine changing technology use and monitor groups who may be excluded from the benefits of support and communication using technology.

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## Conflicts of Interest

None declared.

Multimedia Appendix 1
Hierarchical logistic regression analysis demonstrating the predictors of communicating more using technology during lockdown.
[DOC File , 147 KB - mental_v9i10e31251_app1.doc ]

## References

1. Dawson DL, Golijani-Moghaddam N. COVID-19: Psychological flexibility, coping, mental health, and wellbeing in the UK during the pandemic. J Contextual Behav Sci 2020 Jul;17:126-134 [FREE Full text] [doi: 10.1016/j.jcbs.2020.07.010] [Medline: 32834970]
2. Holmes EA, O'Connor RC, Perry VH, Tracey I, Wessely S, Arseneault L, et al. Multidisciplinary research priorities for the COVID-19 pandemic: a call for action for mental health science. Lancet Psychiatry 2020 Jun;7(6):547-560 [FREE Full text] [doi: 10.1016/S2215-0366(20)30168-1] [Medline: 32304649]
3. Shah SGS, Nogueras D, van Woerden HC, Kiparoglou V. The COVID-19 pandemic: a pandemic of lockdown loneliness and the role of digital technology. J Med Internet Res 2020 Nov 05;22(11):e22287 [FREE Full text] [doi: 10.2196/22287] [Medline: 33108313]
4. Bruno E, Simblett S, Lang A, Biondi A, Odoi C, Schulze-Bonhage A, RADAR-CNS Consortium. Wearable technology in epilepsy: the views of patients, caregivers, and healthcare professionals. Epilepsy Behav 2018 Aug;85:141-149. [doi: 10.1016/j.yebeh.2018.05.044] [Medline: 29940377]

5. Spitzer RL, Kroenke K, Williams JB. Validation and utility of a self-report version of PRIME-MD: the PHQ primary care study. Primary Care Evaluation of Mental Disorders. Patient Health Questionnaire. JAMA 1999 Nov 10;282(18):1737-1744. [doi: 10.1001/jama.282.18.1737] [Medline: 10568646]
6. Pelizza L, Ferrari A. Anhedonia in schizophrenia and major depression: state or trait? Ann Gen Psychiatry 2009 Oct 08;8:22 [FREE Full text] [doi: 10.1186/1744-859X-8-22] [Medline: 19811665]
7. Donaldson C, Lam D. Rumination, mood and social problem-solving in major depression. Psychol Med 2004 Oct;34(7):1309-1318. [doi: 10.1017/s0033291704001904] [Medline: 15697057]
8. White RG, Van Der Boor C. Impact of the COVID-19 pandemic and initial period of lockdown on the mental health and well-being of adults in the UK. BJPsych Open 2020 Aug 17;6(5):e90 [FREE Full text] [doi: 10.1192/bjo.2020.79] [Medline: 32799958]
9. Bavel JJV, Baicker K, Boggio PS, Capraro V, Cichocka A, Cikara M, et al. Using social and behavioural science to support COVID-19 pandemic response. Nat Hum Behav 2020 May;4(5):460-471. [doi: 10.1038/s41562-020-0884-z] [Medline: 32355299]
10. Prowse R, Sherratt F, Abizaid A, Gabrys RL, Hellemans KGC, Patterson ZR, et al. Coping with the COVID-19 pandemic: examining gender differences in stress and mental health among university students. Front Psychiatry 2021;12:650759 [FREE Full text] [doi: 10.3389/fpsyt.2021.650759] [Medline: 33897499]
11. Brooks SK, Webster RK, Smith LE, Woodland L, Wessely S, Greenberg N, et al. The psychological impact of quarantine and how to reduce it: rapid review of the evidence. Lancet 2020 Mar 14;395(10227):912-920 [FREE Full text] [doi: 10.1016/S0140-6736(20)30460-8] [Medline: 32112714]
12. Kamal MM. The triple-edged sword of COVID-19: understanding the use of digital technologies and the impact of productive, disruptive, and destructive nature of the pandemic. Information Systems Management 2020 Sep 12;37(4):310-317. [doi: 10.1080/10580530.2020.1820634]
13. Robbins T, Hudson S, Ray P, Sankar S, Patel K, Randeva H, et al. COVID-19: A new digital dawn? Digit Health 2020;6:2055207620920083 [FREE Full text] [doi: 10.1177/2055207620920083] [Medline: 32313668]
14. Beaunoyer E, Dupéré S, Guitton MJ. COVID-19 and digital inequalities: reciprocal impacts and mitigation strategies. Comput Human Behav 2020 Oct;111:106424 [FREE Full text] [doi: 10.1016/j.chb.2020.106424] [Medline: 32398890]
15. Pahayahay A, Khalili-Mahani N. What media helps, what media hurts: a mixed methods survey study of coping with COVID-19 using the media repertoire framework and the appraisal theory of stress. J Med Internet Res 2020 Aug 06;22(8):e20186 [FREE Full text] [doi: 10.2196/20186] [Medline: 32701459]



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