Correction: mHealth app using machine learning to increase physical activity in diabetes and depression: clinical trial protocol for the DIAMANTE Study


This article has been corrected since it was published online. The recruitment of participants into randomized trials was significantly impacted by the COVID-19 pandemic. The authors have updated the original DIAMANTE clinical trial protocol to document three large changes in the recruitment and data analysis plans for this study:

1. Given that patients at the San Francisco Health Network were not routinely going to clinics for in-person visits at the height of the pandemic in 2020 and early 2021, we had to alter recruitment strategies (Ramos et al, 2021). In order to meet our recruitment targets within the funding timeline, we added a new online recruitment sample to the trial. Specifically, we placed targeted ads on Craigslist, Facebook, and Google to market the study to English- and Spanish-speaking individuals with diabetes living throughout the U.S. These social media ads targeted major metropolitan areas of the US with high proportions of patients with diabetes and/or larger proportions of Spanish-speaking residents, to have some similarities with the San Francisco Health Network recruitment sample. 2. Importantly, the inclusion criteria for the study were unchanged with this additional sampling. All participants recruited online screened positive for depressive symptoms (PHQ-8>5), as well as self-reported a diabetes diagnosis from a medical professional (Bang et al, 2009). In addition, all online participants completed full informed consent and verified smartphone ownership by downloading the DIAMANTE app prior to study enrollment. 3. With the addition of a new online recruitment pool geographically dispersed across the U.S., we were no longer able to capture clinical outcomes among all participants, specifically haemoglobin A1c (HbA1c) measurement. Therefore, HbA1c was removed as a secondary outcome for the trial. Importantly, the primary outcome of step count collected via the smartphone app, as well as secondary mental health and usage/usability outcomes, were not affected. 4. Finally, given the potential differences in study samples from the San Francisco Health Network and the online social media recruitment pool, we added a new secondary analysis to examine the impact of the intervention stratified by these two recruitment sources. The primary analysis examining the impact of adaptive and random text messaging within the RCT arms was unaffected by the additional recruitment source.

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