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Process evaluation of the LvL UP Pilot trial: Intervention fidelity, dose, and mechanisms of action

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Context: Process evaluations alongside clinical trials can clarify mechanisms of engagement and generate implementation insights needed to move digital interventions into real-world practice. This study reports the findings of the process evaluation of the LvL UP pilot trial, a blended adaptive mobile health (mHealth) lifestyle intervention aimed at promoting mental well-being.

Methods: Of the 123 participants enrolled in the 8-week trial, 82 intervention participants received the conversational agent (CA)-delivered app with buddy support (LvL UP). At week 4, non-responders (completing fewer than 6 coaching sessions or rating session usefulness below 4 out of 5) were re-randomised to receive 3 additional Motivational Interviewing-informed human coaching sessions via text or continue with the app and buddy. Responders continued with the initial intervention. The evaluation focused on intervention fidelity, dose, and mechanisms of action including working alliance with CA and perceived app quality. Buddies completed a feedback survey at 8-weeks and semi-structured interviews were conducted with 19 participants and/or buddies.

Results: Most participants (78/82) were paired with a buddy, and among buddies completing the survey (n=58), all reported completing at least 1 support task/week as recommended. Among non-responders receiving human coaching sessions, 47% (9/19) completed all 3 sessions (median 41 min/session). Overall, participants engaged with the app on a median of 19 days (range=1–55 days) and completed a median of 9 tasks over the 8-week period. Only 35% of the participants (29/82) received the full intervention dose (at least 12 digital coaching sessions) and none met the intended use (1 task on the app daily). Working alliance with the CA was high (Mean=4.5/5, SD=0.7) and the app quality was rated as average (Mean=3/5, SD=1.1). Two mechanisms of action for app engagement were identified. Regression analyses showed that higher working alliance with the CA (b=0.18, p = .02) and higher perceived app quality (b=0.39, p < .001) were associated with greater app engagement. Qualitative data suggested that the app promoted behaviour change through behavioural cueing, however technical issues and limited personalisation hindered engagement. Additionally, support through buddies and coaches was perceived as acceptable and helpful, primarily fostering accountability towards healthy behaviour.

Conclusion: Participants who had higher perceived app quality and working alliance were more engaged with the app. The added perceived accountability to the human support components may contribute to engagement with healthy behaviour but not necessarily the app.

Implication: These findings suggest that understanding mechanisms of engagement is a prerequisite for scaling blended mHealth interventions. Additionally, adaptive approaches may support behavioural change in a scalable manner, fostering translation into real-world practice.