

Effectiveness of Mobile Self-Help Applications for Depression Prevention in At-Risk Young Adults: An International Randomized Controlled Trial

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Abstract

Robust, scalable strategies are essential for averting the development of mental health difficulties in adolescents and young adults. While digital mental health applications offer a promising route to widespread prevention, only a limited number have undergone high-quality, sufficiently powered randomized trials that draw on established frameworks of adaptive emotional development and incorporate individualized tailoring. This trial was designed to compare the effectiveness of a personalized emotional competence mobile application with a standard cognitive behavioral therapy (CBT) self-help application and a self-monitoring application in preventing the escalation of depressive symptoms among young people. The study used a multicentre, parallel-group, open-label randomized controlled design, nested within a broader cohort multiple randomized trial framework that also included a parallel evaluation of wellbeing promotion. It was implemented across four university-based trial centers located in the United Kingdom, Germany, Spain, and Belgium. Recruitment occurred through educational institutions and social media channels in each participating country. Eligible participants were individuals aged 16–22 years who displayed heightened vulnerability according to their baseline emotional competence assessment and who reported no history of major depressive disorder. Using an independent computerized randomization system with minimization for country, age, and self-reported gender, participants were assigned in a 1:1:1 ratio to usual care supplemented with either the personalized emotional competence self-help app, the generic CBT self-help app, or the self-monitoring app. Follow-up extended for 12 months after randomization. Assessors of outcomes remained blinded to treatment allocation. The primary endpoint consisted of depressive symptom severity, as assessed by the Patient Health Questionnaire-9 (PHQ-9), at the 3-month follow-up visit, with analysis restricted to those who provided data at that time point. The trial was prospectively registered on ClinicalTrials.gov (NCT04148508) and has now concluded. From Oct 15 2020, to Aug 3 2021, 1262 young people were recruited into the study: 417 were allocated to the emotional competence app, 423 to the CBT app, and 422 to the self-monitoring app. Participants had a mean age of 18.8 years (standard deviation 2.0). Of the 1262 individuals who reported their gender, 984 (78.0%) were female, 253 (20.0%) were male, 15 (1.2%) identified as neither, and 10 (0.8%) as both. Completion rates for the 3-month assessment were 178 participants in the emotional competence group, 191 in the CBT group, and 199 in the self-monitoring group. At this primary endpoint, the CBT app produced a statistically significant reduction in depressive symptoms relative to the self-monitoring app (mean difference on the PHQ-9: -1.18 [95% confidence interval -2.01 to -0.34]; $P = 0.006$). In contrast, symptom levels did not differ meaningfully between the emotional competence app and the CBT app (0.63 [-0.22 to 1.49]; $P = 0.15$), nor between the self-monitoring app and the emotional competence app (-0.54 [-1.39 to 0.31]; $P = 0.21$). Across all follow-up completers ($n = 541$), 31 individuals required hospital-based mental health care for reasons judged unrelated to the trial interventions (eight in the emotional competence app arm, 15 in the CBT arm, and eight in the self-monitoring arm). No fatalities occurred during the study period. Overall, the emotional competence app did not produce the anticipated improvements relative to the CBT app or self-monitoring condition. Nevertheless, for young people displaying heightened worry or rumination, negative thinking patterns, or elevated sensitivity to rejection, the CBT app helped slow progression of depressive symptoms. It supported better functioning and quality of life across the initial 3 months compared with the control condition. Benefits occurred amid modest engagement, leaving questions about long-term clinical significance. Mobile self-help applications built on proven CBT foundations may offer an accessible, economical, and expandable approach to promoting mental health among young people.

Keywords: Depression prevention, Young adults, Mobile applications, Digital mental health, Cognitive behavioral therapy, Randomized controlled trial

Introduction

Worldwide attention has highlighted the substantial and escalating burden of mental health challenges among adolescents and young adults (aged 14–24 years), notably the premature development of depressive and anxiety disorders [1]. Difficulties experienced during this pivotal life stage can significantly impair subsequent opportunities, producing enduring detrimental consequences for physical wellbeing, academic achievement, workforce participation, and interpersonal relationships [1-4]. Rates of depression and anxiety exhibit a pronounced rise from age 14 to 24, attaining their maximum during these years [2]. As a result, strengthening primary prevention efforts to safeguard mental health has emerged as an urgent priority.

Although scientifically supported primary prevention programs exist for prevalent mental disorders, meta-analyses indicate that their benefits are generally modest, underscoring opportunities to augment intervention effectiveness [4, 5]. Many current programs also necessitate extensive professional time and resources. The most desirable preventive measures would allow simultaneous, repeated access by large numbers of users without depending on limited specialist availability (that is, non-consumable resources). They would be suitable for widespread implementation at the population level as public health initiatives.

Digital technologies, such as smartphone applications, offer a compelling option. They enable broad reach and availability, are convenient and user-friendly, support flexible use across contexts, and enjoy high adoption rates among younger demographics [6]. Despite the proliferation of more than 10 000 mental health applications, however, few are anchored in rigorous evidence or core therapeutic tenets, and even fewer have been subjected to thorough testing in large-scale, well-designed randomized controlled trials [6-8]. Although initial findings support the role of applications in managing anxiety and depression [6-8], typical studies

remain small, averaging under 100 participants per condition, and rarely track outcomes beyond 6–12 weeks [8] or assess preventive potential for mental health problems in youth [8]. The Emotional Competence for Wellbeing in the Young (ECoWeB) initiative, to our knowledge, is the first adequately powered, conclusive multicountry trial conducted across languages to examine mobile applications for depression prevention in this population.

Two complementary strategies were pursued to improve the performance of digital preventive tools. First, traditional prevention has predominantly used pathology-centered frameworks that focus on correcting deficits and mitigating risk factors. An alternative is frameworks that emphasize positive emotional development and competency building. Such models may appeal more to non-clinical audiences, promote an empowering orientation toward skill acquisition, and encompass a fuller spectrum of interrelated emotional capacities. Interventions were therefore constructed according to the component process model of emotion [9, 10], an established theoretical account that identifies a cohesive suite of emotional competence abilities required for successful adaptation. According to this model, people vary in proficiency across key domains: (1) generating accurate, suitable, and adaptive interpretations of events (emotion production); (2) recognizing and comprehending emotions in the self and others (emotion knowledge and perception); and (3) employing more constructive rather than counterproductive methods for emotion management (emotion regulation). Substantial correlational and longitudinal research links superior emotional competence to decreased depression and anxiety [10-12]. This competency-focused approach offers a comprehensive route to fostering healthy adaptation, may reduce stigma, and sidesteps diagnostic labels that can discourage participation among young people. The trial accordingly assessed a self-help application centered on cultivating emotional competence.

Second, despite widespread advocacy for individualized, preventive, and collaborative models of mental healthcare [13], personalization has received little empirical scrutiny in prevention research. Analyses of digital mental health tools have found no investigations that adjusted content using baseline standardized evaluations or compared personalized and standardized versions [14]. The present work merged emotional

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competence principles with personalization by providing users with targeted educational material, techniques, and exercises aligned with their specific baseline emotional competence profile. This matching was guided by the expectation that customized support would be more acceptable and impactful than uniform content. A generic cognitive behavioral therapy (CBT) self-help application was included as an active comparison to evaluate personalization effects and other digital approaches. A self-monitoring application functioned as the attentional control, reflecting evidence that monitoring alone can benefit mental health and constitutes a standard element in many wellbeing tools [7, 15].

Given that targeted prevention tends to produce stronger outcomes among those with pre-existing risk indicators (such as subsyndromal features) [4, 5], the ECoWeB PREVENT trial selected participants displaying suggestive signs of vulnerability based on their initial emotional competence assessment (for instance, pronounced worry or rumination). The study adopted a cohort multiple randomized controlled trial structure [16]. Concurrently, the ECoWeB PROMOTE trial [17] involved young people without heightened risk to evaluate universal promotion of wellbeing using the same applications within the common cohort framework [18].

The central goal of ECoWeB PREVENT was to determine whether a personalized emotional competence self-help application could prevent the development or intensification of depressive symptoms compared with a CBT self-help application and a self-monitoring control application, with usual care accessible across all conditions. The study predicted that the personalized emotional competence tool would yield greater decreases in depressive and anxiety symptoms, along with improvements in wellbeing, daily functioning, and quality of life at the 3-month assessment, relative to both the digital CBT self-help application and the digital self-monitoring application. Additionally, the CBT self-help application was expected to produce similar reductions in symptoms and improvements in other outcomes at 3 months when compared with the self-monitoring application, alongside usual practice in all groups.

Materials and Methods

Study design

ECoWeB PREVENT constituted a multinational, multicentre, parallel-group, open-label randomized

controlled trial implemented at four university research centers located in the United Kingdom, Germany, Spain, and Belgium. The trial was embedded within a broader cohort multiple randomized controlled trial structure. Only cohort participants who demonstrated increased risk on their initial emotional competence evaluation were randomized in ECoWeB PREVENT and assigned to one of three shared intervention conditions (also used in the parallel ECoWeB PROMOTE trial). The appropriate local institutional ethics committees approved the study at each site. The study was prospectively registered with ClinicalTrials.gov [NCT04148508] and is now complete. Detailed descriptions of the trial protocol and overall design appear in a prior publication [18].

Participants

To be eligible, individuals had to be 16–22 years old, reside in one of the four study countries (the UK, Germany, Spain, or Belgium), possess sufficient literacy skills in at least one of the relevant languages, and be able to provide informed consent (with parental consent required for those under 18 in Germany and Belgium). Additional requirements included regular access to a smartphone running either Android or iOS and elevated vulnerability as indicated by the baseline emotional competence assessment. This vulnerability was evaluated across three primary domains: rumination and worry, achievement appraisals (namely, perceived control and achievement value), and rejection sensitivity. Participants qualified as high-risk if they scored in the bottom quartile on at least one indicator within a domain and in the bottom tercile on the second indicator for the same domain (where two indicators were employed). Previous validation research confirmed that poor performance in the lowest quartile on these measures predicted higher subsequent risk for depression and anxiety [19, 20]. Thresholds were established using data from earlier studies involving young people from the participating countries.

Given the preventive nature of the trial, individuals were not enrolled if they reported a current or previous major depressive episode at baseline, as assessed through a structured DSM-V-based electronic screening tool [21]. Lifetime history of major depression was evaluated with the Lifetime Depression Assessment Self-report questionnaire [21], which applies DSM-V diagnostic standards. Derived from the Composite International Diagnostic Interview, this instrument effectively detects

major depression via self-report in digital formats through adaptive questioning that follows diagnostic criteria while using logical branching to limit unnecessary items [21]. Further exclusion criteria encompassed active suicidal thoughts, any reported history of major psychiatric illnesses (including bipolar disorder and psychosis), and current engagement in psychological therapy, counseling, or psychiatric pharmacotherapy (such as antidepressants). Those deemed ineligible received automatic redirection to explanatory information and links to appropriate support services.

Recruitment efforts spanned the four countries and involved online advertisements, website promotions, social media and media campaigns, institutional newsletters, and postings at educational institutions. All participants provided electronic written informed consent before enrolment. Gender was recorded through self-report, with categories including male, female, both, or neither.

Randomization and masking

Random assignment occurred in a 1:1:1 ratio to one of three conditions: the emotional competence app plus usual care, the CBT app plus usual care, or the self-monitoring app plus usual care. Allocation was managed through a reliable, purpose-built, encrypted online platform developed and overseen by the Exeter Clinical Trials Unit (registered with the UK Clinical Research Collaboration). Minimization was applied according to country of recruitment (UK, Germany, Spain, Belgium), age group (< 18 years versus ≥ 18 years), and self-reported gender (male, female, both, neither). A random element was retained within the minimization algorithm; the first 50 participants were assigned via unrestricted randomization. Both outcome evaluators and statisticians were kept unaware of participants' group allocations.

Procedures

All study arms utilized varied iterations of a single mobile application compatible with iOS and Android operating systems. Each iteration included a core self-monitoring module with daily mood evaluations, a personal diary, and ecological momentary assessments. These tools enabled detailed tracking of mood states, daily activities, and surrounding contexts, elements previously associated with heightened user involvement [22]. The interface featured a central dashboard displaying notifications and advancement metrics, as

well as functions allowing users to create graphical representations of their recorded self-monitoring information.

Both the emotional competence application and the CBT application offered structured challenges—encompassing psychoeducational content and skill-building exercises—and practical tools consisting of short, situation-specific strategies. Materials were presented through diverse formats, including written text, illustrative images, animated videos, guided audio practices (such as exercises in self-compassion and relaxation), customized feedback based on questionnaire responses, and knowledge-testing quizzes. To encourage consistent use, the completion of self-monitoring activities, challenges, and tools was embedded within a gamified framework. Participants accumulated badges for meeting usage targets and making progress, and received electronic vouchers valued at £10 or €10 upon completing badge collections. All conditions were supplemented by standard care, defined as the absence of any trial-specific intervention together with access to routine support from general practitioners, family doctors, community health or youth services, or institutional resources.

The emotional competence application focused on building emotional skills through targeted training. Participants were allocated material drawn from two out of four available modules (for instance, modules addressing achievement-related appraisal or social appraisal to enhance effective emotional expression, knowledge of emotions, and techniques for reducing rumination to support better emotion regulation). The assignment was tailored to the two emotional competence domains in which each individual demonstrated the lowest performance on their initial assessment profile.

The CBT application drew on established cognitive behavioral therapy principles and methods, notably behavioral activation, problem-solving skills, and techniques for recognizing and reframing negative cognitions. Such strategies have proven effective in diminishing depression and anxiety symptoms among young adults when provided through digital platforms [4, 5, 8]. Unlike many existing mental health applications that omit fundamental CBT practices, this version deliberately incorporated essential components including cognitive restructuring and structured problem-solving [23]. The CBT application maintained an identical technical framework, feature set, and navigational menu

to those of the emotional competence application, thereby ensuring consistency in overall delivery, organization, and user experience, while substituting CBT-specific content in videos, challenges, and tools. In contrast, the self-monitoring application granted access exclusively to emotion-tracking functionalities [21].

Evaluations of present depressive symptoms, overall wellbeing, combined depression and anxiety symptomatology, functioning in social, educational, and occupational domains, health-related quality of life, and emotional competence abilities took place at baseline and subsequently at 1 month, 3 months, and 12 months post-baseline. Completion of each follow-up assessment was rewarded with a £10 or €10 voucher.

From July to December 2021, qualitative data were gathered via detailed, semi-structured interviews. These explored the practical viability of the interventions, reasons for participant enrolment, and opinions on applying emotional competence. Discussion areas included engagement levels, ease of use, acceptability, suitability, perceived personal benefits, obstacles to regular use, and suggestions for content and design improvements. The interview guide was structured according to the Proctor taxonomy of implementation constructs to support potential future deployment [24].

Outcomes

The primary endpoint was depressive symptom levels, quantified via the Patient Health Questionnaire-9 (PHQ-9) [25] at the 3-month assessment (designated primary endpoint), using a secure electronic data collection system. Secondary endpoints encompassed depressive symptoms measured by the PHQ-9 at 12 months, anxiety severity assessed with the Generalized Anxiety Disorder scale-7 (GAD-7) [26], subjective wellbeing evaluated using the Warwick–Edinburgh Mental Well Being Scale (WEMWBS) [27], and functioning in social, domestic, and work or academic settings as captured by the Work and Social Adjustment Scale (WSAS) [28]. Health-related quality of life was measured with the EQ-5D-3 Levels instrument (EQ-5D-3L). An age-adapted version of the Adult Service Use Schedule recorded details of routine care received, associated health and social care expenditures, and services utilized since the last assessment. This included inpatient hospitalizations and emergency department visits.

Adherence was specified in advance according to the underlying intervention model and gamification parameters. In the active intervention groups, it was

defined by acquiring specific badge combinations reflecting application engagement. For the self-monitoring group, it required initial account registration. Emotional competence was measured using a collection of established and validated instruments and tasks, modified and condensed for online delivery following cross-national validation to preserve robust psychometric characteristics. Baseline data collection also included country of residence and birth, age, self-identified gender, highest educational qualification, and family socioeconomic position based on occupational status. Two brief single-item queries examined participants' perceptions of how the COVID-19 pandemic and related restrictions had affected their mental health.

Statistical analysis

The required sample size was determined based on the minimum clinically important difference established for the primary outcome (2.59 [SD: 5.4]) [29]. Achieving 90% power at a two-sided significance level of 0.05 necessitated 93 participants in each arm. To allow for an expected attrition rate of 40% by the 3-month primary endpoint [22], recruitment targets were increased to 155 individuals per group, yielding a total of 465 participants. Separate projections indicated that the EcoWeB PROMOTE trial would require 1500 participants. Given an anticipated 70:30 split of participants between the PROMOTE and PREVENT trials according to emotional competence vulnerability thresholds, the combined cohort required 2142 individuals overall. Following trial initiation, a fire at a French server facility in March 2021 interrupted platform access for one month. On the recommendation and endorsement of the independent trial steering committee, the statistical analysis plan was revised to enroll an additional 1500 participants to offset those potentially disrupted, establishing a new overall recruitment goal of 3800 individuals (with 1107 designated for the EcoWeB PREVENT trial).

The main analyses evaluated differences among the three study conditions—emotional competence application versus self-monitoring application, CBT application versus self-monitoring application, and emotional competence application versus CBT application. These evaluations relied on observed data for the primary and secondary endpoints at the 3-month assessment. They used linear regression models adjusted for baseline scores, age (dichotomized as the minimization variable), gender, and country of participation. Additional sensitivity analyses examined the influence of the

COVID-19 pandemic and the platform disruption on the primary results. Further evaluations included Complier Average Causal Effect (CACE) estimation, longitudinal repeated-measures models, and analyses employing multiple imputation, all aligned with intention-to-treat principles. CACE analyses utilized an instrumental variable technique via two-stage least squares regression to quantify treatment effects while adjusting for adherence and maintaining the advantages of random allocation. Mixed-effects linear regression models with participant-level random intercepts were applied for repeated-measures comparisons of outcomes across all time points, incorporating available data from any participant providing at least one follow-up observation. Models using imputed datasets assumed that missing outcome data were missing at random. All computations were executed in Stata version 17.0. No interim analyses took place. The complete set of analyses adhered to a detailed statistical analysis plan that received prior approval from the trial steering committee and was established before any outcome data were inspected.

Results and Discussion

From Oct 15 2020 to Aug 3 2021, screening was performed on 21,277 people for inclusion in the ECoWeB cohort. Of these, 10 030 proceeded to the

baseline evaluation, and 3794 met the cohort eligibility requirements. Ultimately, 1262 eligible individuals provided consent to participate in the ECoWeB PREVENT trial. Random allocation assigned 417 participants to receive the emotional competence application, 423 to the CBT application, and 422 to the self-monitoring application (**Figure 1; Table 1**). Follow-up data were unavailable for 633 (50.2%) of the 1262 participants at 1 month, 699 (55.4%) at 3 months, and 726 (57.5%) at 12 months. Patterns of missing data on primary and secondary measures were comparable across the three conditions. Demographic and clinical characteristics at baseline were well balanced between groups (**Table 1**). Participants had a mean age of 18.8 years (SD: 2.0). Among the 1262 individuals reporting gender, 984 (78.0%) were female, 253 (20.0%) were male, 15 (1.2%) identified as neither, and 10 (0.8%) as both. Between 21% and 25% of participants in each group failed to create an account to access the application. Account registration for the self-monitoring condition reached 79% (334 out of 422). Adherence according to the predefined threshold was achieved by 41% (172 out of 417) in the emotional competence group and 46% (195 out of 423) in the CBT group. Usage data were partially unavailable for 28 participants in the emotional competence arm and 29 in the CBT arm owing to the temporary platform outage.

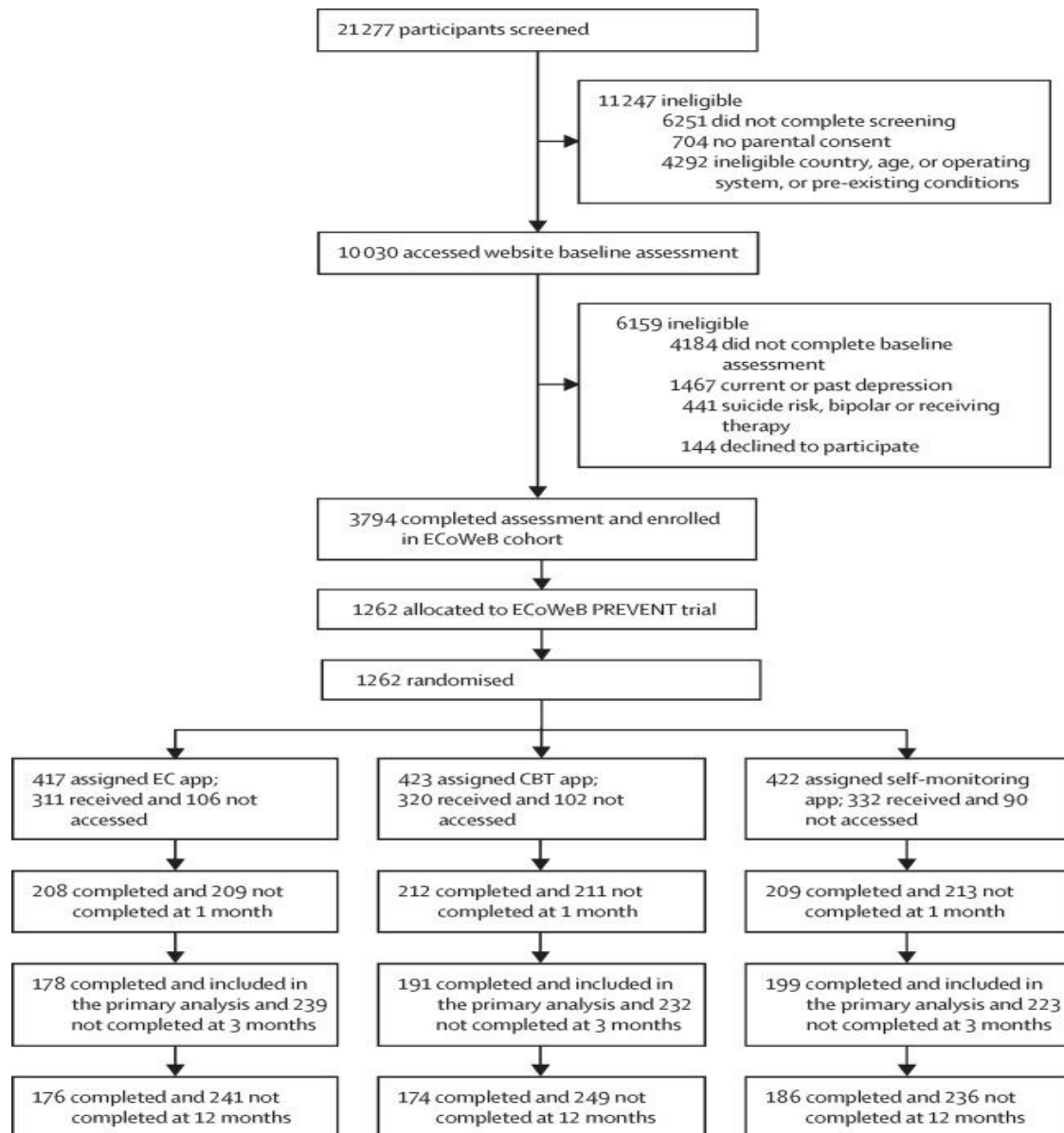


Figure 1. Trial profile. Abbreviations: EC = emotional competence, CBT = cognitive behavioral therapy.

Table 1. Baseline characteristics in the intention-to-treat population

Characteristic	Category	Emotional competence app (n = 417)	CBT app (n = 423)	Self-monitoring app (n = 422)
<i>Average age, years (Mean ± SD)*</i>	—	18.8 ± 2.0; 412	18.8 ± 2.0; 422	18.8 ± 1.9; 419
Age group†	16–17 years	136 (33%)	140 (33%)	141 (33%)
	18–22 years	281 (67%)	283 (67%)	281 (67%)
Gender	Male	86 (21%)	74 (17%)	93 (22%)
	Female	323 (77%)	339 (80%)	322 (76%)
	Neither	4 (1%)	8 (2%)	3 (1%)
	Both	4 (1%)	2 (<1%)	4 (1%)
Country of recruitment	United Kingdom	138 (33%)	139 (33%)	141 (33%)
	Germany	77 (18%)	77 (18%)	75 (18%)

	Spain	142 (34%)	148 (35%)	147 (35%)
	Belgium	60 (14%)	59 (14%)	59 (14%)
Ethnic background	White	349 (83%)	355 (84%)	356 (84%)
	Mixed ethnicity	22 (5%)	31 (7%)	26 (6%)
	Asian	23 (6%)	19 (4%)	21 (5%)
	Black	7 (2%)	8 (2%)	7 (2%)
	Arab	5 (1%)	2 (<1%)	4 (1%)
	Other ethnicity	5 (1%)	4 (1%)	4 (1%)
	Preferred not to answer	6 (1%)	4 (1%)	4 (1%)
Restriction of movement due to COVID-19 lockdown‡	Mean (SD)	4.2 (1.5)	4.1 (1.6)	4.2 (1.6)
Impact of COVID-19 on mental health§	Mean (SD); Median (IQR)	3.8 (1.6); 4 (3–5)	3.8 (1.6); 4 (2–5)	4.0 (1.7); 4 (3–5)
App outage timing	1-month and 3-month follow-up after outage	113 (27%)	113 (27%)	111 (26%)
	1-month follow-up before outage, 3-month follow-up after outage	66 (16%)	61 (14%)	70 (17%)
	3-month follow-up completed before outage	10 (2%)	16 (4%)	12 (3%)
	Registered after outage	228 (55%)	233 (55%)	229 (54%)

Data are expressed as mean (SD), n, mean (SD), or n (%), unless indicated otherwise.

* Date of birth records were absent for nine participants. These individuals met randomization criteria based on being over 18 years old but were subsequently found to be younger than 18.

† Nine participants had no date of birth information, yet were confirmed to be under 18 years of age.

‡ One question asked participants whether their current movements were restricted by any coronavirus-related lockdown, rated on a scale from 1 (not at all) to 7 (extremely restricted).

§ Another item inquired about the current impact of the coronavirus pandemic on mental health, scored from 1 (not at all) to 7 (very much).

Primary analyses at the 3-month follow-up, which investigated differences in group means for the main outcome across conditions while adjusting for baseline values, age, country, and self-reported gender, indicated a significant overall difference ($P = 0.023$); (**Table 2**). The CBT app produced lower levels of depressive symptoms relative to the self-monitoring app (PHQ-9

mean difference: -1.18 [95% CI: -2.01 to -0.34]; $P = 0.006$). No significant differences in depression symptoms appeared between the emotional competence app and the CBT app (0.63 [-0.22 to 1.49]; $P = 0.15$) or between the emotional competence app and the self-monitoring app (-0.54 [-1.39 to 0.31]; $P = 0.21$). Examination of major depression caseness based on standardized PHQ-9 cutoffs revealed a significant condition effect at 3 months ($P = 0.015$). Caseness was reduced in the CBT app group (59 [31%] of 191) compared with the self-monitoring app group (85 [43%] of 199; odds ratio 0.50 [95% CI: 0.31 to 0.81]). Conversely, caseness was higher in the emotional competence app group (69 [39%] of 178) than in the CBT app group (odds ratio 1.63 [95% CI: 1.01 to 2.64]; number needed to treat 8.33). No difference in caseness existed between the emotional competence app and self-monitoring app groups (0.82 [0.52 to 1.30]). At the 12-month follow-up, the three groups showed no significant variation in caseness ($P = 0.41$); (**Table 2**).

Table 2. Summary of primary analysis of primary and secondary outcomes at 3-month and 12-month follow-up.

Outcome	3-month follow-up		Global P-value	12-month follow-up		Global P-value
	EC App vs Self-Monitoring App	CBT App vs Self-Monitoring App	EC App vs CBT App	EC App vs Self-Monitoring App	CBT App vs Self-Monitoring App	EC App vs CBT App

Data consist of mean difference (95% CI), unless otherwise noted. Global P-values reflect the three-group comparison in each regression model, while 95% CIs accompany each pairwise comparison. Abbreviations: EC = emotional competence, CBT = cognitive behavioral therapy, PHQ-9 = Patient Health Questionnaire-9, WEMWBS = Warwick-Edinburgh Mental Wellbeing Scale, GAD-7 = Generalized Anxiety Disorder scale-7, WSAS = Work and Social Adjustment Scale. EQ-5D-3L = EQ-5D-3 Levels.

Group differences on these measures were no longer present at 12 months. Anxiety symptoms measured by the GAD-7 and wellbeing scores on the WEMWBS showed no group differences at either 3-month or 12-month follow-up. Patterns of service use were equivalent across the three arms.

[illegible]

EQ-5D-3L	WSAS	GAD-7	WEMWBS
0.90 (0.15); 417	14.0 (6.8); 417	7.4 (4.4); 417	48.8 (7.2); 417
0.89 (0.16); 423	13.5 (6.9); 423	7.1 (4.4); 423	48.5 (7.2); 423
0.88 (0.18); 422	13.8 (6.6); 422	7.6 (4.4); 422	48.2 (7.7); 422
NA*	12.7 (6.7); 209	7.3 (4.0); 209	47.3 (8.1); 209
NA*	12.8 (7.0); 210	7.6 (4.4); 210	47.5 (8.2); 214
NA*	13.3 (6.9); 209	7.8 (4.6); 209	46.2 (8.4); 212
0.86 (0.19); 165	13.6 (7.1); 165	7.3 (4.5); 165	46.7 (7.7); 182
0.89 (0.16); 184	12.2 (7.4); 184	7.1 (4.5); 184	47.4 (8.8); 192
0.83 (0.23); 194	14.3 (7.4); 194	7.5 (4.4); 194	46.1 (9.0); 201
0.86 (0.18); 170	12.5 (6.7); 170	7.0 (4.3); 170	48.0 (7.3); 176
0.87 (0.15); 169	13.4 (7.6); 169	7.5 (4.7); 169	45.9 (8.6); 175
0.84 (0.22); 189	14.2 (7.3); 189	7.6 (4.6); 189	47.6 (8.6); 186

Data are mean (SD); n. CBT = cognitive behavioral therapy, PHQ-9 = Patient Health Questionnaire-9, WEMWBS = Warwick-Edinburgh Mental Wellbeing Scale, GAD-7 = Generalized Anxiety Disorder scale-7, WSAS = Work and Social Adjustment Scale, EQ-5D-3L = EQ-5D-3 Levels, NA = not applicable.

* EQ-5D-3L was not assessed at the 1-month follow-up. Of the 541 participants who returned any follow-up data, 31 experienced hospital admission or treatment (or both) due to mental health issues, self-harm or injury, or problems with alcohol or substances (eight in the emotional competence app group, 15 in the CBT app group, and eight in the self-monitoring app group). The independent trial steering committee deemed all such events unrelated to the study interventions. No deaths were recorded over the 12-month observation period. Sensitivity analyses controlling for COVID-19 effects and app outages produced effect sizes comparable to the primary results. Compliers-average causal effect analyses, repeated-measures approaches, and analyses using imputed datasets produced findings that were largely consistent with the primary analyses. Semi-structured interviews took place at 3 months with eight young people (three from the UK and five from Spain). Qualitative analysis showed that motivations for participation included intrinsic factors such as altruism, curiosity, and personal development, as well as extrinsic factors such as financial incentives. Engagement with the app peaked soon after installation and gradually declined. Users generally found the application straightforward, intuitive, and visually appealing. However, some components, particularly the challenges, were viewed as excessively lengthy or repetitive. Features related to self-monitoring and available tools received the strongest endorsement for their practicality and usefulness,

supporting high acceptability. Participants viewed the app as suitable for those experiencing emotional difficulties or academic pressures. They suggested refinements such as improved initial guidance, phased introduction of new content, and enhanced interactivity via conditional elements.

Findings from the ECoWeB PREVENT trial indicate that a standard CBT-based self-help smartphone application offered protective advantages over a self-monitoring control condition. These advantages included reductions in depressive symptoms along with gains in daily functioning and overall quality of life among young individuals showing heightened risk for depression. Unexpectedly, and contrary to initial predictions, the emotional competence application did not outperform either the CBT app or the self-monitoring app.

This investigation constitutes, to current knowledge, the initial large-scale randomized controlled trial of mental health self-help mobile applications conducted in a broad sample of vulnerable young people drawn from four European nations, with assessments continuing through 12 months [8]. Earlier research in this domain has commonly relied on applications lacking firm foundations in established CBT methods, involved modest participant numbers (under 100 per condition), featured brief observation periods [8], or omitted evaluation across diverse countries and within youth-specific groups [6-8, 23].

Self-help tools grounded in CBT principles hold potential to bolster mental health in adolescents and young adults. Compared with results from the ECoWeB PROMOTE trial—which found no improvements with identical interventions in a low-risk cohort—these outcomes suggest that benefits from the CBT self-help app are primarily limited to those at elevated risk. During the first 3 months, use of the CBT app successfully countered a notable rise in depression symptoms and decreased the proportion of participants reaching clinical thresholds for depression. These positive changes, however, were no longer evident by 12 months. Low overall engagement further complicates interpretation of the intervention's value. Mirroring patterns reported in prior digital intervention studies [6-8], app usage remained modest and was largely confined to the period immediately after download. Consequently, benefits appear short-lived and tied closely to the window of active interaction. Approaches designed to foster sustained engagement—through persistent prompts, adaptive feedback, and enriched interactive elements—may help prolong effects and merit continued exploration.

While the observed symptom reduction linked to the CBT app falls short of thresholds typically regarded as clinically meaningful in formal psychotherapy settings (mean difference in PHQ-9 -1.18), its influence on depression caseness (number needed to treat 8.33) is comparable in scale to that of various established low-intensity population-level strategies (for instance, standardised mean differences for smoking cessation support lines and broad media campaigns generally fall between 0.20 and 0.25; number needed to treat 12–16) [30]. This level of impact is relevant to around 30% of young people. Given its automated nature, scalability, reusability, and low deployment cost (roughly £25 per user annually for development and upkeep, in line with National Institute for Health and Care Excellence guidance), the app could serve effectively as a broad public mental health resource. Small per-person improvements, when applied population-wide, can generate considerable overall benefit [3].

Results ran counter to expectations regarding the emotional competence app. Combining skill development in emotional competence with tailored personalization did not surpass the performance of standard CBT content or basic self-monitoring. Possible explanations include an overly simplistic personalization mechanism that employed basic compensatory rules rather than sophisticated, data-driven algorithms.

Additionally, certain modules within the emotional competence app may have lacked sufficient impact. The inclusion of numerous varied components could also have confused users, in contrast to the unified thematic focus of the CBT app. Furthermore, the emphasis on extended repetitive practice in several emotional competence sections may have reduced user interest compared with the more concise psychoeducational format of the CBT app. Different personalization methods could still be useful in future work.

Notable strengths of the study include its randomized allocation, recruitment from both educational institutions and social media channels spanning four European countries, a substantial participant pool, the use of active and attention-matched controls (including a CBT app built on validated techniques), extended 12-month monitoring, and a broad evaluation of relevant outcomes. The cohort multiple randomized controlled trial structure provided further benefits by: (1) integrating longitudinal cohort advantages with experimental rigor; (2) facilitating efficient enrolment through a general cohort invitation focused on understanding emotional experiences in youth; and (3) supporting higher participation and retention rates via prior consent for potential intervention assignment, minimizing dissatisfaction with control conditions [16].

Important constraints nevertheless exist. First, participant retention at follow-up assessments was limited. However, these attrition levels align with those documented in comparable unsupported app trials (47.8% [95% CI: 35.8–60]) [22], and statistical power remained adequate for cautious interpretation. Second, the study's emphasis on primary prevention led to the exclusion of individuals with previous major depressive episodes. This decision lowered expected depression incidence and prevented clear assessment of the apps' value for secondary or relapse prevention, contexts in which stronger effects might emerge. Third, the emotional competence condition merged skill training and personalization, precluding isolation of their individual contributions; the null findings rendered this distinction irrelevant. Fourth, the study included no standard usual-care control; the self-monitoring condition offered a stricter comparison. Fifth, the study tested only unguided self-help formats. Professional guidance could enhance engagement and results, though this would reduce scalability. Sixth, the sample was largely composed of female, White, and currently enrolled students, constraining broader applicability.

Conclusion

Overall, the emotional competence app did not produce the anticipated improvements relative to the CBT app or self-monitoring condition. Nevertheless, for young people displaying heightened worry or rumination, negative thinking patterns, or elevated sensitivity to rejection, the CBT app helped slow progression of depressive symptoms. It supported better functioning and quality of life across the initial 3 months compared with the control condition. Benefits occurred amid modest engagement, leaving questions about long-term clinical significance. Mobile self-help applications built on proven CBT foundations may offer an accessible, economical, and expandable approach to promoting mental health among young people.

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