Emotional competence self-help app versus cognitive behavioural self-help app versus self-monitoring app to prevent depression in young adults with elevated risk (ECoWeB PREVENT): an international, multicentre, parallel, open-label, randomised controlled trial

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Summary

Background Effective, scalable interventions are needed to prevent poor mental health in young people. Although mental health apps can provide scalable prevention, few have been rigorously tested in high-powered trials built on models of healthy emotional functioning or tailored to individual profiles. We aimed to test a personalised emotional competence app versus a cognitive behavioural therapy (CBT) self-help app versus a self-monitoring app to prevent an increase in depression symptoms in young people.

Methods This multicentre, parallel, open-label, randomised controlled trial, within a cohort multiple randomised trial (including a parallel trial of wellbeing promotion) was done at four university trial sites in the UK, Germany, Spain, and Belgium. Participants were recruited from schools, universities, and social media from the four respective countries. Eligible participants were aged 16–22 years with increased vulnerability indexed by baseline emotional competence profile, without current or past diagnosis of major depression. Participants were randomly assigned (1:1:1) to usual practice plus either the personalised emotional competence self-help app, the generic CBT self-help app, or the self-monitoring app by an independent computerised system, minimised by country, age, and self-reported gender, and followed up for 12 months post-randomisation. Outcome assessors were masked to group allocation. The primary outcome was depression symptoms (according to Patient Health Questionnaire-9 [PHQ-9]) at 3-month follow-up, analysed in participants who completed the 3-month follow-up assessment. The study is registered with ClinicalTrials.gov, NCT04148508, and is closed.

Findings Between Oct 15, 2020, and Aug 3, 2021, 1262 participants were enrolled, including 417 to the emotional competence app, 423 to the CBT app, and 422 to the self-monitoring app. Mean age was 18·8 years (SD 2·0). Of 1262 participants self-reporting gender, 984 (78·0%) were female, 253 (20·0%) were male, 15 (1·2%) were neither, and ten (0·8%) were both. 178 participants in the emotional competence app group, 191 in the CBT app group, and 199 in the self-monitoring app group completed the follow-up assessment at 3 months. At 3 months, depression symptoms were lower with the CBT app than the self-monitoring app (mean difference in PHQ-9 –1·18 [95% CI –2·01 to –0·34]; p=0·006), but depression symptoms did not differ between the emotional competence app and the CBT app (0·63 [–0·22 to 1·49]; p=0·15) or the self-monitoring app and emotional competence app (–0·54 [–1·39 to 0·31]; p=0·21). 31 of the 541 participants who completed any of the follow-up assessments received treatment in hospital or were admitted to hospital for mental health-related reasons considered unrelated to interventions (eight in the emotional competence app group, 15 in the CBT app group, and eight in the self-monitoring app group). No deaths occurred.

Interpretation The CBT app delayed increases in depression symptoms in at-risk young people relative to the self-monitoring app, although this benefit faded by 12 months. Against hypotheses, the emotional competence app was not more effective at reducing depression symptoms than the self-monitoring app. CBT self-help apps might be valuable public mental health interventions for young people given their scalability, non-consumable nature, and affordability.

Funding European Commission.

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Research in context

Evidence before this study

There is growing global concern about the high and steadily increasing rates of anxiety and depression in young people (ie, aged 14–24 years). Although effective mental health interventions are available, their effectiveness and coverage require improvement. Digital interventions such as mobile phone apps have been proposed as part of the solution. We searched MEDLINE, Google Scholar, and PsycINFO with the search terms "well-being", "mental health", "depression", "anxiety", AND "trials", "RCTs'' AND "mobile", "m-health", "apps", "digital" for trials using apps to promote wellbeing and prevent depression in young people, published from database inception to Aug 1, 2020. The average sample size for trials of apps for anxiety and depression is fewer than 100 participants per trial group, and few trials have examined indicated prevention of depression in young people. No trials have assessed the role of tailoring intervention content to the individual within the app, nor evaluated the potential of using a well established model of healthy emotional functioning—ie, an emotional competence model as a theoretical background to intervention content, moving away from a disease model of psychopathology. Such a shift has potential to reduce stigma, be more acceptable and engaging, and holistically tackle a wider set of integrated emotion-related abilities.

Added value of this study

To our knowledge, this Emotional Competence for Wellbeing in the Young (ECoWeB) PREVENT trial is the first large-scale,

randomised controlled trial to rigorously investigate the effect of mobile phone apps for the prevention of depression in young people across multiple countries, and with its parallel ECoWeB PROMOTE trial, to also investigate combined prevention or promotion approaches in young people with the same interventions. This trial is the first study to include personalised tailoring of content and an intervention based on emotional competence principles. There was no significant difference on any outcome between the emotional competence app versus either the CBT app or the self-monitoring app. The CBT app significantly lowered depression and improved functioning and health-related quality of life compared with the self-monitoring app at 3 months, although these effects were not sustained at 12-month follow-up.

Implications of all the available evidence

Self-help mobile phone apps with established effective content such as cognitive behavioural therapy might protect against depression and improve functioning in a high-risk sample of young people. However, certainty in the effect is reduced due to high levels of attrition, risk of bias, absence of clinical significance, and effects only lasting 3 months. The effect size is potentially meaningful for highly scalable, affordable, public health interventions for which small effects over large numbers can be of real-world benefit. There was no evidence to support the inclusion of an emotional competence focus within self-help apps. Personalisation approaches need further development.

Introduction

There is global concern about the high and increasing rates of poor mental health in young people (ie, aged 14–24 years) including the early onset of depression and anxiety.[1] Poor mental health during this formative period severely affects future life chances, with negative long-term impact on health, education, employment, and social outcomes.[1–4] The incidence of depression and anxiety markedly increases at ages 14–24 years, peaking during this period.[2] Consequentially, improvement in primary prevention of poor mental health is a priority.

Although there are evidence-based, primary prevention interventions for common mental health disorders, systematic reviews suggest that effect sizes are relatively small with scope to increase intervention efficacy.[4,5] Most interventions require considerable person-hours from professionals. Ideally, effective preventive interventions could be used repeatedly by any number of people simultaneously, unconstrained by the availability of professional support (ie, non-consumable), and scalable at the population level as public health interventions.

One potential solution involves digital platforms such as mobile phone apps because they enable good coverage and reach, are widely accessible, non-consumable, convenient, are usable any time and anywhere, and are

widely used by young people.[6] However, despite the development of more than 10 000 mental health apps, only a small proportion are based on robust science and established treatment principles or have been rigorously tested in well-powered, randomised controlled trials.[6–8] Although there is emerging evidence for apps as treatments for anxiety and depression,[6–8] the average sample size is fewer than 100 participants per trial group, and few trials evaluate outcomes after 6–12 weeks[8] or whether apps can prevent poor mental health in young people.[8] To our knowledge, Emotional Competence for Wellbeing in the Young (ECoWeB) is the first, fully powered, definitive trial of apps for preventing depression in young people across multiple countries and languages.

We explored two avenues to enhance the efficacy of preventive digital interventions. First, most prevention strategies have focused on traditional models of psychopathology aiming to reduce deficits and target vulnerabilities. Interventions based on dimensional models of healthy emotional functioning and the development of emotional competencies might be an effective alternative as they can be more acceptable and engaging to non-clinical populations, create a positive focus on building skills, and address a wider set of integrated emotion-related abilities. We developed interventions

based on the component process model of emotion,[9,10] which is a well established, evidence-based model hypothesising an integrated set of emotional competence skills necessary for adaptive functioning. The model proposes that individuals have varying abilities across different areas of emotional competence: (1) accurate, appropriate, and functional appraisals of situations (ie, emotion production); (2) perception and understanding of emotions in themselves and others (ie, emotion knowledge and perception); and (3) use of more adaptive versus less adaptive strategies to manage emotions (ie, emotion regulation). The model hypothesises that good emotional competence functioning contributes to reduced depression and anxiety, which is supported by extensive correlational and prospective data.[10–12] Targeting skills of emotional competence is a holistic approach that emphasises the improvement of healthy functioning, potentially reducing stigma, and avoids mentioning clinical disorders, which has been known to limit engagement in young people. Therefore, we tested the efficacy of a self-help app that focused on building emotional competence skills in young people.

Second, despite the arguments for personalised, preventive, and participatory medicine focused on individual mental health,[13] personalisation has scarcely been evaluated in the prevention of mental health disorders. Reviews of digital interventions report no trials on the personalisation of intervention content based on standardised baseline assessment or comparing personalised intervention content with non-personalised content.[14] We combined the emotional competence and personalisation approach such that individuals were offered specific psychoeducation, strategies, and training matched to their baseline emotional competence profile to increase their emotional competence skills, based on the hypothesis that a tailored intervention will be more acceptable and efficacious than a generic intervention. To provide a suitable active control for personalisation and test the benefits of other forms of digital self-help, we included a generic cognitive behavioural therapy (CBT) self-help app. As an attentional control, we included a self-monitoring app, reflecting the evidence that self-monitoring might be beneficial to mental health and is a common feature in wellbeing apps.[7,15]

As prevention has been shown to be more effective when targeted at specific high-risk groups (eg, people with subsyndromal symptoms or indicative risk factors), ECoWeB PREVENT recruited individuals with indicative elevated risk for poor mental health based on a baseline emotional competence profile (eg, elevated worry or rumination),[4,5] based on a cohort multiple randomised controlled trial design.[16] In parallel, the ECoWeB PROMOTE[17] trial recruited healthy young people without elevated risk to directly test universal wellbeing promotion within the same cohort.[18]

The aim of ECoWeB PREVENT was to test whether a personalised emotional competence self-help app can prevent the onset of and increase in depression symptoms compared with a CBT self-help app and a self-monitoring app control. We hypothesised that personalised digital emotional competence self-help would reduce symptoms of depression and anxiety and improve wellbeing, functioning, and quality of life at 3-month follow-up versus digital CBT self-help and versus digital self-monitoring, with all groups including usual practice. By contrast, the CBT self-help app would reduce symptoms of depression and anxiety and improve wellbeing, functioning, and quality of life at 3-month follow-up versus a self-monitoring app, including usual practice.

Methods

Study design

ECoWeB PREVENT is an international, multicentre, parallel, open-label, randomised controlled trial done at four university trial sites in the UK, Germany, Spain, and Belgium as part of a cohort multiple randomised controlled trial. Within the cohort multiple randomised controlled trial, only participants with elevated risk on baseline emotional competence profile were allocated to the ECoWeB PREVENT trial and randomly assigned to one of three groups (common to ECoWeB PREVENT and ECoWeB PROMOTE). Ethics approval was provided by each site's respective institutional research ethics boards. This study is registered with ClinicalTrials.gov (NCT04148508) and has been completed. Full details of the trial design and protocol have been published previously[18] and are available in the appendix (pp 4–120).

See **Online** for appendix

Participants

Eligible participants were aged 16–22 years; lived in the UK, Germany, Spain, or Belgium; had basic literacy in at least one of the respective languages; could provide informed consent or obtain parental consent if they were younger than 18 years (in Germany and Belgium); had regular access to a smartphone (Android or iOS); and had elevated vulnerability on the emotional competence profile, based on baseline assessment of emotional competence skills, with respect to three distinct components: rumination and worry, achievement appraisals (ie, perceived control and achievement value), and rejection sensitivity. Elevated vulnerability was defined as scoring in the worst performing quartile on at least one measure assessing each component and scoring in the worst performing tercile on the second measure for the same component (if two measures used). Individuals scoring in the worst quartile on measures of these components had elevated risk for subsequent depression and anxiety.[19,20] Thresholds were calculated by previous validation studies in young people across the four recruiting countries (see appendix pp 121–22 for recruitment details and eligibility).

As this was a primary prevention trial, participants were excluded from the cohort at baseline if presenting

with a current or past episode of major depressive disorder (according to psychiatric DSM-V criteria), determined in structured self-report electronic screening.[21] The Lifetime Depression Assessment Self-report questionnaire[21] assessed lifetime major depressive disorder diagnosis according to DSM-V criteria. Based on the Composite International Diagnostic Interview, it is effective for determining major depression through self-report in an online digital format, using a conditional sequence of pre-programmed questions assessing all the diagnostic criteria for depression, with logical cutouts so that subsequent questions are determined by previous answers, to minimise burden.[21] Other exclusion criteria were active suicidality; any self-reported history of severe mental health problems, such as bipolar disorder and psychosis; and currently receiving psychological therapy, counselling, or psychiatric medication including antidepressants. Those ineligible for the trial were automatically directed to relevant webpages explaining their exclusion and guided to sources of help where relevant.

Participants were recruited across the UK, Germany, Spain, and Belgium via online and website advertising, a social media and press campaign, newsletters and other circulars, and noticeboards within schools, colleges, and universities. Participants provided written electronic informed consent. Gender data were collected via self-report. Options were male, female, both, or neither.

Randomisation and masking

Participants were randomly assigned (1:1:1) to the emotional competence app plus usual care, the CBT app plus usual care, or the self-monitoring app plus usual care using a validated, bespoke, secure, encrypted web service (created and managed by the UK Clinical Research Collaboration-registered Exeter Clinical Trials Unit) and minimised according to recruitment country (UK, Germany, Spain, Belgium), age (<18 years vs ≥18 years), and self-reported gender (male, female, both, neither). The minimisation algorithm retained a stochastic element; the first 50 participants were allocated to their intervention arm by simple random allocation. All outcome assessors and statisticians were masked to treatment allocation.

Procedures

All interventions were different versions of the same app, designed for iOS and Android. All versions included a self-monitoring feature with a regular daily mood rating and diary option and ecological momentary assessments for a more detailed analysis of mood, activity, and situational context, all of which have been shown to increase engagement.[22] The menu included a dashboard to monitor notifications and progress and the ability for participants to graph and visualise graphically their self-monitoring entries.

The emotional competence app and CBT app contained challenges (ie, psychoeducation and learning exercises) and tools (ie, brief strategies to use in the moment when needed). Challenges and tools included text, pictures, animated videos, audio exercises to practise techniques (eg, self-compassion and relaxation), questionnaires with tailored feedback, and quizzes. To increase compliance and adherence to the app, completion of self-monitoring challenges and tools were gamified, badges were earnt for compliance and progress, and electronic vouchers were earnt (£10 or €10) when sets of badges were completed. Further details are provided in the appendix (pp 123–42) on the interventions, including elements to increase engagement. All interventions included usual practice, which included no provision of intervention, support from the local doctor or family doctor, local health services or youth services, or provision of intervention within their educational institution.

The emotional competence app featured content intended to train improvements in emotional competence. Each participant received content from two of four possible emotional competence modules (eg, achievement appraisal or social appraisal to improve functional emotional production, emotional knowledge, and targeting rumination to improve emotion regulation). Personalisation was based on providing two domains of emotional competence ranked worst in an individual's baseline emotional competence profile.

The CBT app was based on generic, well established CBT principles and strategies including behavioural activation, problem solving, and spotting and challenging negative thoughts, which have been shown to reduce symptoms of depression and anxiety in young adults via online delivery.[4,5,8] The CBT app was designed to include important elements of CBT, unlike most mental health apps that lack core CBT elements, such as cognitive restructuring and problem-solving.[23] The CBT app had identical architecture and features and an identical menu to the emotional competence app to match the interventions for delivery, structure, and format, but with different specific CBT content in animated videos, challenges, and tools. The self-monitoring app required access to an app that only supported self-monitoring of emotions.[21]

Assessments of current depression, current wellbeing, symptoms of depression and anxiety, social and education or work functioning, health-related quality of life, and emotional competence skills were done at baseline and 1-month, 3-month, and 12-month follow-up, with each follow-up incentivised with a £10 or €10 voucher for completion.

Between July and December, 2021, in-depth, qualitative, semi-structured interviews explored intervention feasibility and participants' motivation for participating in the study and their views of the emotional competence app. Questions were on engagement, usability, acceptability, appropriateness, self-reported outcomes, barriers

to engagement, and feedback about the content and features to inform possible future implementation based on the Proctor taxonomy of implementation constructs.[24]

Outcomes

The primary outcome was depression symptoms as assessed by Patient Health Questionnaire-9 (PHQ-9)[25] measured at 3 months (primary endpoint), via the electronic data capture website. Secondary outcomes were depression symptoms (per PHQ-9) at 12-month follow-up, anxiety severity (per Generalized Anxiety Disorder scale-7 [GAD-7]),[26] self-reported wellbeing (per Warwick–Edinburgh Mental Well Being Scale [WEMWBS]),[27] and social, home, and work or academic functioning (per Work and Social Adjustment Scale [WSAS]).[28] Health-related quality of life was assessed by EQ-5D-3 Levels (EQ-5D-3L). The Adult Service Use Schedule was adapted for young people to index the nature of usual practice, the relevant health and social care costs, and treatment and services received since the previous assessment at each follow-up, including admission to hospital and visits to the accident and emergency services.

Adherence was defined a priori based on the intervention logic model and the associated gamification rules. For the active intervention conditions, adherence required earning specific combinations of badges for app use. For the self-monitoring condition, it required creation of an app account. Emotional competence skills were assessed through a battery of well validated questionnaires and tasks adapted and shortened for web-use following a validation study across all four countries to maintain good psychometric properties. Additional details on the adherence criteria, levels of app engagement, and emotional competence measures are in the appendix (pp 143–47). Country of residence and birth, age, self-reported gender, educational level, and family's occupational status, were assessed at baseline only. Two single-item questions assessed the perceived effect of COVID-19 (ie, the pandemic and lockdown) on mental health.

Statistical analysis

The sample size calculation was based on a minimum clinically important difference for the primary outcome (2·59 [SD 5·4]).[29] At 90% power with a two-sided α of 0·05, 93 participants were required per group. Assuming 40% attrition at 3-month follow-up (primary endpoint),[22] 155 participants were needed per group (465 in total). From parallel calculations, 1500 participants were required for the EcoWeB PROMOTE trial. Assuming a 70:30 distribution of participants into the PROMOTE trial versus PREVENT trial (based on cutoffs for vulnerability on the emotional competence profile), we required 2142 participants for the overall cohort. However, after the trial started, a fire at a server centre in France in March 2021, caused the outage of the platform hosting the apps for 1 month. Based on the advice and approval of our independent trial steering committee, we adjusted our statistical analysis plan to replenish an additional 1500 participants (ie, participants potentially affected), giving a revised overall cohort target of 3800 participants (1107 in EcoWeB PREVENT).

Primary analyses compared the three treatment groups (emotional competence app *vs* self-monitoring app, CBT app *vs* self-monitoring app, emotional competence app *vs* CBT app) and used collected data only for primary and secondary outcomes at 3-month follow-up, using linear regression models with adjustment for baseline (pre-randomisation) score, age (as the dichotomised minimisation variable), gender, and country. Sensitivity analyses were conducted that adjusted the primary analysis for the effect of the COVID-19 pandemic and the effect of the app outage. Secondary analyses included Complier Average Causal Effect (CACE), repeated measures, and imputed follow-up data analyses, compliant with the intention-to-treat principle. CACE model analyses were done using an instrumental variable method implemented via two-stage least squares regression to estimate intervention effects accounting for adherence within the interventions, while retaining the benefits of randomisation for primary and secondary outcomes. Repeated measures analyses (using a mixed effects linear regression model with a random effect on participants) were used to compare primary and secondary outcomes across all follow-ups, including data from participants with observed data for at least one of the three follow-up timepoints. Imputed data models considered missing outcome data at follow-up as missing at least at random. All analyses were conducted with Stata, version 17.0. No interim analyses were conducted during the trial. Analyses followed a prespecified statistical analysis plan (approved by our trial steering committee) prepared in advance of any data analysis (appendix pp 148–91).

Role of the funding source

The funder of the study had no role in the study design, data collection, data analysis, data interpretation, and writing of the report.

Results

Between Oct 15, 2020, and Aug 3, 2021, 21277 individuals were screened for the ECoWeB cohort, 10030 accessed the baseline assessment, and 3794 were eligible for the ECoWeB cohort, of whom 1262 were eligible and consented for the ECoWeB PREVENT trial. 417 participants were randomly assigned to the emotional competence app, 423 to the CBT app, and 422 to the self-monitoring app (figure; table 1). The number of participants not completing follow-up assessments was 633 (50·2%) of 1262 participants at 1 month, 699 (55·4%) of 1262 at 3 months, and 726 (57·5%) of 1262

at 12 months. Missing rates for primary and secondary outcomes were similar and did not differ between the intervention conditions. Baseline characteristics were similar between treatment groups (table 1). Mean age was 18·8 years (SD 2·0). Of 1262 participants self-reporting gender, 984 (78·0%) were female, 253 (20·0%) were male, 15 (1·2%) were neither, and ten (0·8%) were both. Across all three groups, 21–25% of participants never set up an account to access the app. Compliance (ie, sign-up) with the self-monitoring app was 79% (334 of 422 participants). Compliance based on a priori usage threshold was 41% (172 of 417 participants) with the emotional competence app and 46% (195 of 423 participants) with the CBT app.

Figure: Trial profile
EC=emotional competence. CBT=cognitive behavioural therapy.

Some data on app usage were missing because of the app outage (28 participants in the emotional competence app group and 29 participants in the CBT app group).

At 3-month follow-up, primary analyses examining group mean differences on the primary outcome across all conditions adjusting for baseline score, age, country, and self-reported gender found evidence for a mean difference (p=0·023; table 2). Depression symptoms were lower with the CBT app than the self-monitoring app (mean difference in PHQ-9 –1·18 [95% CI –2·01 to –0·34]; p=0·006), but depression symptoms did not differ 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). There was a global effect of condition (p=0·015) at 3 months when examining caseness for major depression using standardised cutoffs on PHQ-9. Cases were lower with the CBT app (59 [31%] of 191) than with the self-monitoring app (85 [43%] of 199; odds ratio [OR] 0·50 [95% CI 0·31 to 0·81]) and were higher with the emotional competence app (69 [39%] of 178) than the CBT app (OR 1·63 [95% CI 1·01 to 2·64]; number needed to treat 8·33). Caseness did not differ with the emotional competence app versus the self-monitoring app (0·82 [0·52 to 1·30]). The three groups did not significantly differ at 12-month follow-up (p=0·41; table 2).

Work or academic and social functioning and health-related quality-of-life was higher with CBT app than the self-monitoring app group at 3 months. However, there was no benefit of the emotional competence app compared with the self-monitoring app on these outcomes at 3 months (tables 2, 3). At 12 months, there were no differences between the groups. There were no differences between groups on anxiety (GAD-7) or wellbeing (WEMWBS) at 3-month or 12-month follow-up. Use of services did not differ between the groups (appendix pp 205–206).

31 of the 541 participants who completed any of the follow-up assessments were admitted to or treated in the hospital (or both) for mental health reasons, self-harm or injury, or misuse of alcohol or substances (eight in the emotional competence app group, 15 in the CBT app group, eight in the self-monitoring app group). The independent trial steering committee judged these events as unrelated to interventions. No participants died during the 12-month follow-up.

Sensitivity analyses adjusting for the effect of COVID-19 and app outage gave similar effect estimates for the primary analysis (appendix pp 209–11). The results of the CACE analyses, repeated measures analyses, and imputed data analyses were broadly consistent with the primary analyses (appendix pp 211–13).

At 3 months, we interviewed eight participants (three from the UK and five from Spain). For the interview topic guide, see the appendix (pp 192–203). Analysis of the interviews suggested that young people
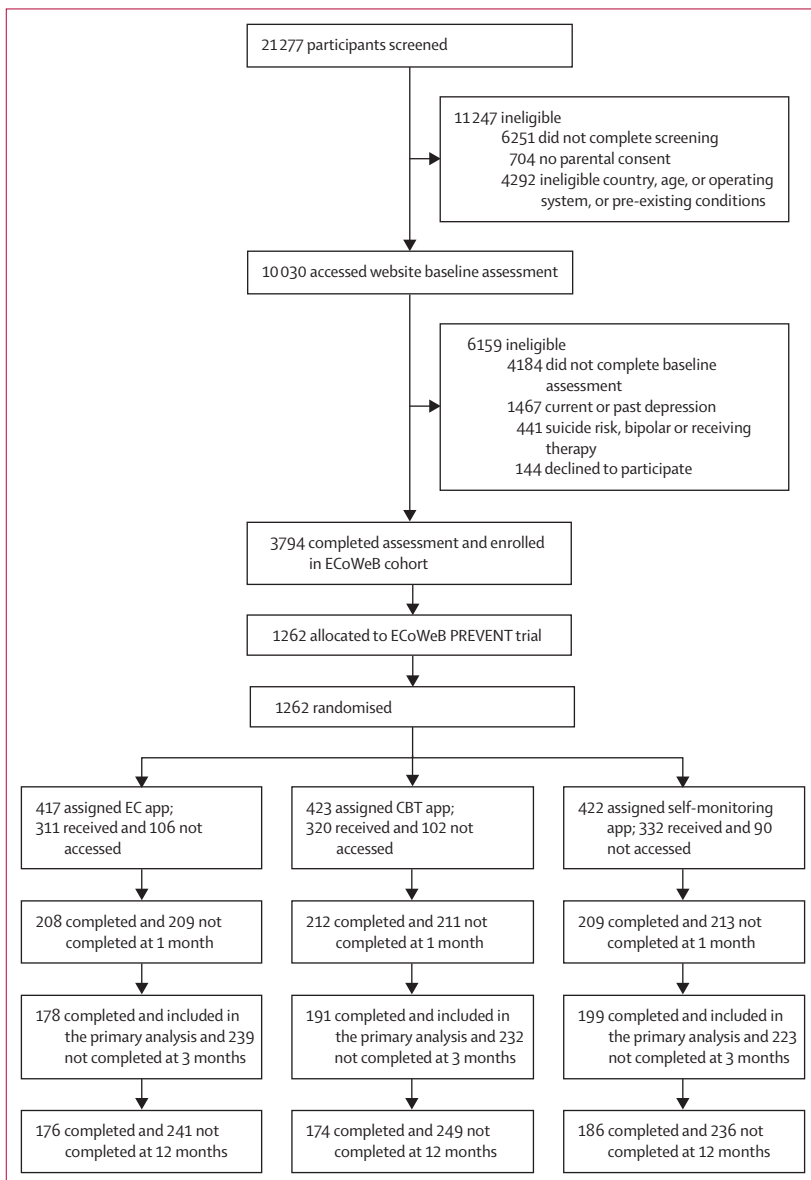
were motivated to participate for intrinsic (ie, altruism, curiosity, and self-help) and extrinsic (ie, financial reward) reasons. App engagement was highest when it was first downloaded and reduced over time. The app was experienced as simple, easy, and intuitive to use, with an attractive design. Some features were perceived as too long and repetitive (eg, the challenges). The self-monitoring and tools features were found most useful and practical with good overall acceptability. Participants recommended and deemed the app appropriate for people with emotional difficulties or dealing with academic stress. Potential improvements include better explanations and onboarding for some features, unlocking new features over time, and more interactive conditional responses (appendix pp 192–203).

Discussion

This ECoWeB PREVENT trial found that a generic CBT self-help app had beneficial protective effects compared with a self-monitoring control app on symptoms of depression, functioning, and quality of life in young people with increased vulnerability for depression. Contrary to our hypotheses, the emotional competence app was not more beneficial than the CBT app nor than the self-monitoring app.

To our knowledge, this is the first randomised controlled trial to test the efficacy of mental health self-help mobile phone apps in a robust, large-scale sample of at-risk young people from four European countries and followed up to 12 months. Previous trials have either typically used apps that have not developed on established CBT treatment principles, had small sample sizes (<100 participants per group), or had short-term follow-ups,[8] and have not examined the effects across multiple countries nor in young people specifically.[6–8,23]

CBT self-help apps could benefit the mental health of young people. Compared with the ECoWeB PROMOTE trial, which found no effect on the same outcomes with the same interventions in low-risk young people, ECoWeB PREVENT suggests that any benefit of the CBT self-help app is limited to a selective, at-risk population. Over 3 months, the CBT app prevented a statistically significant increase in depression symptoms and reduced the likelihood of meeting caseness for depression at a clinically significant level, with these effects fading by 12 months. These findings leave the benefit of the intervention uncertain, especially given the low rates of engagement. Consistent with other app trials,[6–8] app use was low and concentrated in the first month after access, suggesting that any benefit likely only lasted a few months beyond the period that young people used the app. Increasing routine, prolonged, and habitual app use through repeated nudging, contingent feedback, and increased interactivity might confer longer-term benefits, and further validation is required.

Although the benefits of the CBT app would not be clinically meaningful for psychotherapy in patients

	Emotional competence app (n=417)	CBT app (n=423)	Self-monitoring app (n=422)
Mean (SD) age, years*	18·8 (2·0); 412	18·8 (2·0); 422	18·8 (1·9); 419
Age, years†			
16–17	136 (33%)	140 (33%)	141 (33%)
18–22	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			
UK	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%)
Ethnicity			
White	349 (83%)	355 (84%)	356 (84%)
Mixed	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	5 (1%)	4 (1%)	4 (1%)
Prefer not to answer	6 (1%)	4 (1%)	4 (1%)
Movements restricted by COVID-19 lockdown‡	4·2 (1·5)	4·1 (1·6)	4·2 (1·6)
Mean (SD) and median (IQR) mental health affected by COVID-19§	3·8 (1·6); 4 (3–5)	3·8 (1·6); 4 (2–5)	4·0 (1·7); 4 (3–5)
Disruption due to app outage			
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 before outage	10 (2%)	16 (4%)	12 (3%)
Registered after outage	228 (55%)	233 (55%)	229 (54%)

Data are mean (SD); n, mean (SD), or n (%), unless otherwise specified. *Date of birth missing for nine participants. These participants were randomly assigned as they were older than 18 years but were later found to be younger than 18 years. †Nine participants had missing date of birth but were known to be younger than 18 years. ‡Question was "Are your current movements restricted by any lockdown due to coronavirus?", which was scored from 1 (not at all) to 7 (extremely restricted). §The question was, "To what extent is the coronavirus pandemic affecting your mental health now?", which was scored from 1 (not at all) to 7 (very much).

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

(mean difference in PHQ-9 –1·18), the effect on caseness for depression (number needed to treat 8·33) is similar to that of recommended low-intensity public health interventions (eg, standardised mean differences for smoking cessation hotlines and mass media messaging range from 0·20 to 0·25; number needed to treat 12–16)[30] and relevant to approximately 30% of young people. Since the app is automated, scalable, and non-consumable, and it can be rolled out economically (ie, ~£25/user per year for estimated set-up and maintenance, matching recommended intervention costs from National Institute for Health and Care Excellence), it could be a public mental health intervention. A small difference in mental

	3-month follow-up				12-month follow-up			
	EC app *vs* self-monitoring app	CBT app *vs* self-monitoring app	EC app *vs* CBT app	Global p value	EC app *vs* self-monitoring app	CBT app *vs* self-monitoring app	EC app *vs* CBT app	Global p value
Primary outcome								
PHQ-9	−0·54 (−1·39 to 0·31)	−1·18 (−2·01 to −0·34)	0·63 (−0·22 to 1·49)	0·023	−0·47 (−1·45 to 0·50)	0·17 (−0·81 to 1·15)	−0·64 (−1·63 to 0·34)	0·41
Secondary outcomes								
WEMWBS	0·17 (−1·29 to 1·63)	0·73 (−0·71 to 2·17)	−0·56 (−2·03 to −0·91)	0·58	−0·02 (−1·58 to 1·54)	−1·51 (−3·08 to 0·05)	1·50 (−0·08 to 3·07)	0·097
GAD-7	−0·23 (−1·05 to 0·59)	−0·13 (−0·93 to 0·67)	−0·10 (−0·93 to 0·73)	0·86	−0·53 (−1·42 to 0·37)	−0·08 (−0·98 to 0·82)	−0·45 (−1·36 to 0·47)	0·47
WSAS	−0·72 (−2·11 to 0·67)	−1·86 (−3·21 to −0·51)	1·14 (−0·27 to 2·54)	0·025	−1·69 (−3·06 to −0·33)	−0·82 (−2·19 to 0·56)	−0·88 (−2·28 to 0·52)	0·052
EQ-5D-3L	0·025 (−0·009 to 0·059)	0·041 (0·008 to 0·075)	−0·017 (−0·051 to 0·018)	0·047	0·021 (−0·014 to 0·056)	0·031 (−0·004 to 0·066)	−0·010 (−0·046 to 0·025)	0·21

Data are mean difference (95% CI), unless otherwise specified. Global p-values were reported for the three-group comparison within each regression model; 95% CIs are reported for each pairwise comparison. EC=emotional competence. CBT=cognitive behavioural therapy. PHQ-9=Patient Health Questionnaire-9. WEMWBS=Warwick–Edinburgh Mental Wellbeing Scale. GAD-7=Generalised Anxiety Disorder scale-7. WSAS=Work and Social Adjustment Scale. EQ-5D-3L=EQ-5D-3 Levels.

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

	Baseline			1-month follow-up			3-month follow-up			12-month follow-up		
	Emotional competence app	CBT app	Self-monitoring app	Emotional competence app	CBT app	Self-monitoring app	Emotional competence app	CBT app	Self-monitoring app	Emotional competence app	CBT app	Self-monitoring app
Primary outcome												
PHQ-9	7·4 (4·3); 417	7·7 (4·3); 423	7·6 (4·5); 422	8·0 (4·3); 208	8·1 (4·8); 212	8·3 (4·8); 209	8·4 (4·8); 178	7·7 (4·6); 191	8·8 (4·9); 199	8·3 (4·6); 176	9·1 (5·2); 174	8·7 (5·3); 186
Secondary outcomes												
WEMWBS	48·8 (7·2); 417	48·5 (7·2); 423	48·2 (7·7); 422	47·3 (8·1); 209	47·5 (8·2); 214	46·2 (8·4); 212	46·7 (7·7); 182	47·4 (8·8); 192	46·1 (9·0); 201	48·0 (7·3); 176	45·9 (8·6); 175	47·6 (8·6); 186
GAD-7	7·4 (4·4); 417	7·1 (4·4); 423	7·6 (4·4); 422	7·3 (4·0); 209	7·6 (4·4); 210	7·8 (4·6); 209	7·3 (4·5); 165	7·1 (4·5); 184	7·5 (4·4); 194	7·0 (4·3); 170	7·5 (4·7); 169	7·6 (4·6); 189
WSAS	14·0 (6·8); 417	13·5 (6·9); 423	13·8 (6·6); 422	12·7 (6·7); 209	12·8 (7·0); 210	13·3 (6·9); 209	13·6 (7·1); 165	12·2 (7·4); 184	14·3 (7·4); 194	12·5 (6·7); 170	13·4 (7·6); 169	14·2 (7·3); 189
EQ-5D-3L	0·90 (0·15); 417	0·89 (0·16); 423	0·88 (0·18); 422	NA*	NA*	NA*	0·86 (0·19); 165	0·89 (0·16); 184	0·83 (0·23); 194	0·86 (0·18); 170	0·87 (0·15); 169	0·84 (0·22); 189

Data are mean (SD); n. CBT=cognitive behavioural therapy. PHQ-9=Patient Health Questionnaire-9. WEMWBS=Warwick–Edinburgh Mental Wellbeing Scale. GAD-7=Generalised Anxiety Disorder scale-7. WSAS=Work and Social Adjustment Scale. EQ-5D-3L=EQ-5D-3 Levels. NA=not applicable. *EQ5D-3L was not collected at 1-month follow-up.

Table 3: **Summary of descriptive statistics for primary and secondary outcomes at baseline and 1-month, 3-month, and 12-month follow-up**

health outcomes per individual could yield a major impact at a population level.[3]

Contrary to our hypotheses, the combination of training emotional competence skills and personalisation within the app was not beneficial relative to generic CBT or self-monitoring. This could be due to multiple reasons. First, the personalisation algorithm might have been ineffective by using a simple rule to compensate for deficits rather than more complex or empirically derived (eg, machine-learning) algorithms. Second, not all elements in the emotional competence app might have been effective. Third, the emotional competence app had multiple modules with disparate content, which could have confused users, compared with the CBT app that had coherent content on one theme. Fourth, several emotional competence modules sought to train skills through extensive repeated practice, which participants might not have found engaging compared with brief single-session psychoeducation in the CBT app (appendix pp 123–42). Alternative personalisation approaches might still be effective.

Study strengths include the randomised design, inclusion of young people recruited from schools and universities and via social media across four European countries, the large sample size, the use of active and attentional control conditions including a CBT app containing well established components, 12-month follow-up, and measurement of multiple outcomes. Potential advantages of the cohort multiple randomised controlled trial design include: (1) effectively combining the benefits of a prospective, long-term, longitudinal cohort design with a randomised controlled trial;

(2) improving the efficiency of sample recruitment as the overall study can be open to eligible young people and advertised as participating in a cohort study to learn about young people's emotions; (3) enhancing recruitment and retention as individuals consent in advance to having an intervention offered if eligible and thus do not experience being allocated to a usual care self-monitoring condition.[16]

There were some important limitations. First, follow-up attrition rates were high. However, these rates are consistent with trials of similar apps, especially when there is no direct human support or contact (follow-up attrition 47·8% [95% CI 35·8–60]).[22] Furthermore, the trial remained sufficiently powered for conservative estimates. Second, as per our research question focusing on primary prevention, participants with a history of major depressive disorder were excluded. Such exclusion reduced the base rate of depression incidence during follow-up; thus, the benefits of these apps could not be reliably estimated for secondary and tertiary (relapse) prevention, for which the effect sizes might be larger. Third, because the emotional competence app group integrated the use of emotional competence content or techniques and personalisation of such content, their effects could not be separated; however, this was moot given our findings. Fourth, the study did not have a usual care control. Instead, we used the more conservative self-monitoring control. Fifth, we only examined apps in a self-guided format. Support from a human professional might improve engagement and outcome, although at the cost of constraining capacity. Sixth, the cohort predominantly comprised female and White participants and most young people were in education, which limits generalisability.

In sum, our findings indicate that contrary to the hypotheses, the emotional competence app did not show benefit compared with the CBT app or the self-monitoring app. However, among young people with increased worry or rumination, negative appraisals, or increased rejection sensitivity, the CBT app delayed the onset and increase in depression symptoms and improved functioning and health-related quality of life over 3 months relative to attentional control, despite low app engagement, with some uncertainty about lasting clinical benefit. Self-help mobile phone apps using well established, evidence-based CBT principles might be affordable and scalable public mental health interventions for young people.

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