# Emotional competence self-help mobile phone app versus cognitive behavioural self-help app versus self-monitoring app to promote mental wellbeing in healthy young adults (ECoWeB PROMOTE): an international, multicentre, parallel, open-label, randomised controlled trial

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## Summary

**Background** Based on evidence that mental health is more than an absence of mental disorders, there have been calls to find ways to promote flourishing at a population level, especially in young people, which requires effective and scalable interventions. Despite their potential for scalability, few mental wellbeing apps have been rigorously tested in high-powered trials, derived from models of healthy emotional functioning, or tailored to individual profiles. We aimed to test a personalised emotional competence self-help app versus a cognitive behavioural therapy (CBT) self-help app versus a self-monitoring app to promote mental wellbeing in healthy young people.

**Methods** This international, multicentre, parallel, open-label, randomised controlled trial within a cohort multiple randomised trial (including a parallel trial of depression prevention) was done at four university trial sites in four countries (the UK, Germany, Spain, and Belgium). Participants were recruited from schools and universities and via social media from the four respective countries. Eligible participants were aged 16–22 years with well adjusted emotional competence profiles and no current or past diagnosis of major depression. Participants were randomised (1:1:1) to usual practice plus either the emotional competence app, the CBT 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. The primary outcome was mental wellbeing (indexed by the Warwick–Edinburgh Mental Well Being Scale [WEMWBS]) at 3-month follow-up, analysed in participants who completed the 3-month follow-up assessment. Outcome assessors were masked to group allocation. The study is registered with ClinicalTrials.gov, NCT04148508, and is closed.

**Findings** Between Oct 15, 2020, and Aug 3, 2021, 2532 participants were enrolled, and 847 were randomly assigned to the emotional competence app, 841 to the CBT app, and 844 to the self-monitoring app. Mean age was 19·2 years (SD 1·8). Of 2532 participants self-reporting gender, 1896 (74·9%) were female, 613 (24·2%) were male, 16 (0·6%) were neither, and seven (0·3%) were both. 425 participants in the emotional competence app group, 443 in the CT app group, and 447 in the self-monitoring app group completed the follow-up assessment at 3 months. There was no difference in mental wellbeing between the groups at 3 months (global p=0·47). The emotional competence app did not differ from the CBT app (mean difference in WEMWBS –0·21 [95% CI –1·08 to 0·66]) or the self-monitoring app (0·32 [–0·54 to 1·19]) and the CBT app did not differ from the self-monitoring app (0·53 [–0·33 to 1·39]). 14 of 1315 participants were admitted to or treated in hospital (or both) for mental health-related reasons, which were considered unrelated to the interventions (five participants in the emotional competence app group, eight in the CBT app group, and one in the self-monitoring app group). No deaths occurred.

**Interpretation** The emotional competence app and the CBT app provided limited benefit in promoting mental wellbeing in healthy young people. This finding might reflect the low intensity of these interventions and the difficulty improving mental wellbeing via universal digital interventions implemented in low-risk populations.

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## Research in context

### Evidence before this study

There is a growing global focus on promoting mental wellbeing and increasing flourishing in young people. Although there are effective interventions for mental health promotion and socio-emotional learning, their effectiveness, efficiency, and coverage require improvement. Digital interventions, such as those delivered via mobile phone apps, have been proposed to be part of the solution. The average sample size for trials using mobile phone apps for anxiety and depression is fewer than 100 participants per group and few trials have examined apps to promote mental wellbeing in a general population of young people. No trials have examined the role of tailoring intervention content to the individual within the app. Furthermore, no trials have evaluated the potential of using a well established model of healthy emotional functioning, such as an emotional competence model as a theoretical background to intervention content, moving away from a disease model of psychopathology. We searched MEDLINE, Google Scholar, and PsycINFO from database conception to Aug 1, 2020, with the search terms "well-being", "mental health", "depression", "anxiety", AND "trials", "RCTs" AND "mobile", "m-health", "apps", "digital" to identify trials using apps to promote mental health in young people.

### Added value of this study

To our knowledge, this is the first, large-scale, randomised controlled trial to rigorously investigate the effect of mobile phone apps for mental wellbeing promotion in young people across multiple countries, and with its parallel ECoWeB PREVENT trial, to also investigate prevention approaches in this population with the same interventions. This ECoWeB PROMOTE trial is the first study to include personalised tailoring of content and an intervention based on emotional competence principles. We found no difference between a personalised emotional competence app, a digital CBT self-help app, and a self-monitoring app at 3 months and 12 months in mental wellbeing in young people without elevated risk for anxiety and depression (based on emotional competence profiles) and without a history of depression.

### Implications of all the available evidence

This study indicates that low-intensity automated digital self-help interventions are unlikely to play a meaningful role as scalable interventions to promote mental wellbeing in high-functioning young people. These findings are consistent with the wider literature that indicates that universal interventions to promote mental health are often not effective. Efforts to improve wellbeing in a general population of young people might be better directed away from low-intensity digital self-help.

## Introduction

There is growing recognition of the importance of mental health and mental wellbeing in young people. Mental health during the formative developmental period (ie, aged 12–24 years) substantively influences future life chances, impacting long-term health, education, employment, and social outcomes.[1–4] In addition to preventing anxiety and depression,[2] there is a call to promote mental wellbeing and positive mental health based on evidence that mental health is more than an absence of mental disorders, which varies on a continuum from poor mental wellbeing (ie, languishing) to good mental wellbeing (ie, flourishing).[5] Increased flourishing benefits the individual, the economy, and the wider society, with this effect being particularly magnified in young people.[5]

Interventions that promote mental wellbeing need to be highly scalable and widely available to be effective at a population level. One approach is building interventions into existing contexts that reach large numbers of young people, such as educational settings. School-based social and emotional learning interventions have supported the development of new skills, although mental wellbeing has not always been assessed as an outcome.[6]

An alternative method of reaching many young people is through digital means, such as the internet or mobile phone apps. Internet programmes to promote mental wellbeing using cognitive behavioural therapy (CBT) approaches have been found to be effective in adults[7] and have been adapted for mobile app delivery. Mobile phone apps have particular advantages because they are highly scalable, their usage is not limited by geography or time of day, they can be used repeatedly by nearly unlimited people simultaneously, and they are widely used by young people.[8] However, despite thousands of apps on the market being directed at mental wellbeing, few are based on robust science, and fewer have been evaluated in robust randomised controlled trials.[8,9] Two recent meta-analyses of randomised controlled trials of app interventions found small positive effect sizes on mental wellbeing for apps incorporating CBT, mindfulness, and positive psychology elements, although many trials were underpowered, had short follow-ups, did not exclusively focus on young people, or included participants with a history of mental health disorders or elevated symptoms of anxiety and depression, such that they evaluated indicated prevention rather than promotion of universal mental wellbeing.[10,11] To our knowledge, this Emotional Competence for Wellbeing in the young (ECoWeB) trial is the first fully powered definitive trial of mobile phone apps for promoting wellbeing in a general sample of young people across multiple countries.

One logical approach to promote emotional wellbeing is to build young peoples' skills in understanding and managing their emotions. Interventions developed on dimensional models of healthy emotional functioning

and with a positive focus on building skills and strengths might be more acceptable and engaging to a wider, non-clinical population. To ensure that our intervention was based on well validated, theoretical models of emotional competence, we developed an intervention based on an established and evidence-based model of adaptive emotional functioning, the Component Process Model of Emotion (CPM).[12] This model hypothesises that there are multiple domains of emotional competence, there are individual differences in abilities across these domains, and increased emotional competence skills support enhanced emotional wellbeing. These hypotheses are supported by extensive correlational and prospective evidence.[12–14] The key domains are emotion production, reflecting the ability to make accurate, realistic, and helpful emotion-generating appraisals of situations; emotion knowledge and perception, reflecting the ability to accurately recognise and understand emotions in oneself and others; and emotion regulation, reflecting the ability to use functional rather than dysfunctional strategies to manage emotions. Targeting such emotional competence skills could provide a more holistic approach that tackles a wider set of integrated emotion-related abilities and potentially reduce stigma, known to limit engagement in young people, by focusing on improved emotional functioning for all, rather than focusing on disorders. As such, this approach is well suited to mental wellbeing promotion at the population level. We adapted validated interventions consistent with the CPM model into a mobile phone app format and tested the efficacy of this self-help digital intervention focused on building emotional competence skills in young people.

A second approach to potentially improve wellbeing promotion is to personalise emotional competence training to each participant. To our knowledge, personalisation has not yet been evaluated in the promotion of mental wellbeing, even though personalisation has been proposed to make interventions more engaging and efficiacious.[15] A review of digital interventions reported no trials examining personalisation of intervention content based on standardised baseline assessment nor trials examining personalisation of intervention content versus non-personalised content.[16] We adopted a personalisation approach in which individuals were offered psychoeducation, strategies, and training to build their emotional competence skills in emotional competence domains based on their baseline emotional competence profile. We hypothesised that a tailored intervention would be more acceptable and efficacious than a generic intervention. To provide a suitable, active, generic intervention as a control and to test the potential benefits of digital self-help, we included a CBT self-help app. We also included a self-monitoring app as an attentional control because self-monitoring has been proposed to be beneficial and is a frequent feature in wellbeing mobile phone apps.[9,17]

Wellbeing promotion approaches are typically aimed at the general population, although uncertainty remains on what degree wellbeing can be enhanced in healthy, functioning individuals. ECoWeB PROMOTE recruited healthy young people without elevated risk or history of depression to directly test universal promotion of mental wellbeing, based on a cohort multiple randomised controlled trial design.[18] In parallel, within the same cohort, the ECoWeB PREVENT trial recruited individuals with indicative elevated risk for poor mental health based on a baseline emotional competence profile (eg, elevated worry or rumination) to directly test selective prevention of depression.[19] Both randomised trials used the same intervention groups.

The aim of ECoWeB PROMOTE was to test whether provision of the personalised emotional competence self-help app can promote wellbeing relative to the CBT self-help app and the self-monitoring app, all in addition to usual practice. We hypothesised that the emotional competence app would improve mental wellbeing, work or academic and social functioning, and quality of life and reduce symptoms of depression and anxiety at 3 months compared with the CBT app and the self-monitoring app. Additionally, we hypothesised the CBT app would improve mental wellbeing, work or academic and social functioning, and quality of life and reduce depression and anxiety symptoms at 3 months compared with the self-monitoring-app.

## Methods

### Study design

ECoWeB PROMOTE 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, participants without elevated risk on baseline emotional competence profile were allocated to ECoWeB PROMOTE and randomly assigned to one of three groups (common to ECoWeB PROMOTE and ECoWeB PREVENT).

Ethics approval was provided by the respective institutional research ethics boards at each site. Full details of the trial design and protocol have been published previously[20] and are available in the appendix (pp 3–120).

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); and had regular access to a smartphone (Android or iOS). Exclusion criteria were presenting with or had a past episode of major depressive disorder (according to psychiatric DSM-V criteria), as determined in structured self-report electronic screening.[21] The Lifetime Depression Assessment Self-report questionnaire[20] assessed lifetime major depression diagnosis according

to DSM-V criteria. Based on the Composite International Diagnostic Interview, it is effective for determining a major depression diagnosis through self-report in an online digital format, using a conditional sequence of pre-programmed questions assessing all the diagnostic criteria for depression, with logic cutouts so subsequent questions are determined by previous answers, to minimise burden.[20] Other exclusion criteria were active suicidality; any self-reported history of severe mental health problems, such as bipolar disorder and psychosis; currently receiving psychological therapy, counselling, or psychiatric medication including antidepressants; and elevated hypothesised vulnerability on the emotional competence profile based on the baseline assessment of emotional competence skills. This final criterion was to ensure that mental wellbeing promotion focused on a healthy cohort (and was used as an inclusion criterion for the parallel ECoWeB PREVENT trial).[19] The relevant emotional competence components assessed were rumination, worry, achievement appraisals, 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 were used for that component). Individuals scoring in the worst quartile on measures of these components had elevated risk for subsequent anxiety and depression.[22] Thresholds were defined using previous validation studies in young people across the four recruiting countries. 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. Parental consent was sought for relevant participants via a link to pass onto parents or guardians. 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 group by simple random allocation. All outcome assessors and statisticians were masked to treatment allocation.

### Procedures

All interventions were different versions of the same mobile phone app, designed for iOS and Android use. 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.[23] 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 included challenges (ie, psychoeducation and learning exercises) and tools (ie, brief strategies for young people 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 retention and adherence to the app, completion of self-monitoring challenges and tools were gamified, badges were earnt for progress and compliance, and electronic vouchers were earnt (£10 or €10) when sets of badges were completed. Further details on the interventions, including elements to increase engagement, are provided in the appendix (pp 123–42). 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 and social appraisal to improve functional emotional production, emotional knowledge and perception, and targeting rumination to improve emotion regulation). Personalisation was based on providing the two emotional competence modules targeting the two domains 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.[4,9–11] 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.[24] 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 a mobile phone app that only supported self-monitoring of emotions.

Assessments of current mental 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, 1 month, 3 months, and 12 months post-randomisation, 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 on the emotional competence app only. 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 (appendix pp 192–202).[25] We interviewed at 3-month follow-up.

### Outcomes

The primary outcome was wellbeing as assessed by the 14-item Warwick–Edinburgh Mental Well Being Scale (WEMWBS)[26] measured 3 months post-randomisation (primary endpoint), via the central electronic data capture website. Secondary outcomes were wellbeing (as assessed by WEMWBS) at 12-month follow-up, depression as assessed by the Primary Health Questionnaire-9 (PHQ-9),[27] anxiety severity (per the Generalized Anxiety Disorder scale-7 [GAD-7]),[28] social, home, and work or academic functioning (per the Work and Social Adjustment Scale [WSAS]),[29] and health-related quality of life (per EQ-5D-3 levels [EQ-5D-3L]). The Adult Service Use Schedule was adapted for young people to index the nature of usual practice, relevant health and social care costs, and the treatment and services received since the previous assessment at each follow-up, including hospital admission and hospital treatment and visits to 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. The self-monitoring condition 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, level of app engagement, and emotional competence measures are provided in the appendix (pp 143–47). Country of residence, age, self-reported gender, educational level, family's occupational status, and country of birth were assessed only at baseline. Two single-item questions assessed the perceived effect of COVID-19 (ie, the pandemic and lockdowns) on mental health.

### Statistical analysis

The sample size calculation was based on a minimum clinically important difference for the primary outcome (3·00 [SD 11·3]).[30] At 90% power and two-sided α of 0·05, 300 participants were required per group. Assuming 40% attrition[23] at 3-month follow-up (primary endpoint), 500 participants were required per group (1500 in total). From parallel calculations, 465 participants were required for the ECoWeB PREVENT trial. Assuming a 70:30 distribution of participants into the ECoWeB PROMOTE trial versus ECoWeB PREVENT trial (based on cutoffs for vulnerability on the emotional competence profile) provided an estimate of 2142 participants for the overall cohort. However, after the trial started, a fire at a server centre in France in March, 2021, caused an 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, number of participants potentially affected), giving a revised overall cohort target of 3800 participants (2500 in ECoWeB PROMOTE).

Primary analyses compared the three interventions (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), self-reported gender, and country. Sensitivity analyses were conducted that adjusted the primary analysis for effect of the pandemic and for the effect of app outage. Secondary analyses included Complier Average Causal Effect (CACE) analyses, repeated measures analyses, and imputed follow-up data analyses, compliant with the intention-to-treat principle. CACE model analyses were carried out 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-ups. Imputed 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.

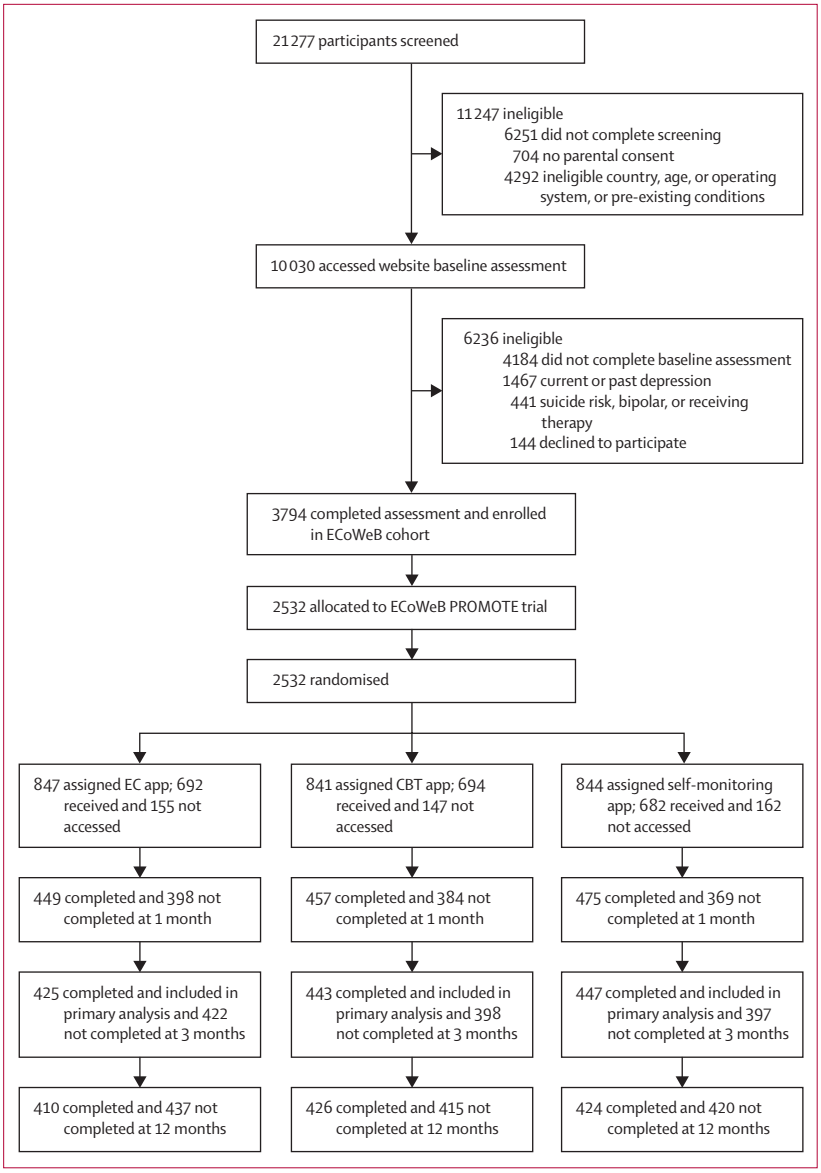


***Figure:*** **Trial profile**
EC=emotional competence, CBT=cognitive behavioural therapy.

| | Emotional competence app (n=847) | CBT app (n=841) | Self-monitoring app (n=844) |
|---|---|---|---|
| Mean age, years* | 19·2 (1·8); 843 | 19·2 (1·9); 837 | 19·0 (1·8); 837 |
| Age, years† | | | |
| 16–17 | 192 (23%) | 203 (24%) | 228 (27%) |
| 18–22 | 655 (77%) | 638 (76%) | 616 (73%) |
| Gender | | | |
| Female | 621 (73%) | 642 (76%) | 633 (75%) |
| Male | 220 (26%) | 191 (23%) | 202 (24%) |
| Neither | 3 (<1%) | 7 (1%) | 6 (1%) |
| Both | 3 (<1%) | 1 (<1%) | 3 (<1%) |
| Country | | | |
| UK | 254 (30%) | 256 (30%) | 256 (30%) |
| Germany | 288 (34%) | 287 (34%) | 293 (35%) |
| Spain | 139 (16%) | 137 (16%) | 140 (17%) |
| Belgium | 166 (20%) | 161 (19%) | 155 (18%) |
| Ethnicity | | | |
| White | 752 (89%) | 726 (86%) | 725 (86%) |
| Mixed | 39 (5%) | 44 (5%) | 52 (6%) |
| Asian | 23 (3%) | 37 (4%) | 39 (5%) |
| Black | 6 (1%) | 12 (1%) | 7 (1%) |
| Arab | 9 (1%) | 8 (1%) | 5 (1%) |
| Other | 13 (2%) | 8 (1%) | 11 (1%) |
| Prefer not to answer | 5 (1%) | 6 (1%) | 5 (1%) |
| Mean and median participants' movements restricted by COVID-19 lockdown‡ | 4·2 (1·5); 4 (3–5) | 4·2 (1·5); 4 (3–5) | 4·2 (1·5); 4 [3–5] |
| Mean and median participants' mental health affected by COVID-19 pandemic§ | 3·5 (1·5); 3 (2–5) | 3·6 (1·6); 4 (2–5) | 3·5 (1·5); 3 [2–5] |
| App outage disruption | | | |
| 1-month and 3-month follow-up after outage | 257 (30%) | 254 (30%) | 253 (30%) |
| 1-month follow-up before outage, 3-month follow-up after outage | 157 (19%) | 167 (20%) | 169 (20%) |
| 3-month follow-up before outage | 54 (6%) | 45 (5%) | 44 (5%) |
| Registered after outage | 379 (45%) | 375 (45%) | 378 (45%) |

Data are mean (SD); n, mean (SD), or n (%), unless otherwise stated. *Date of birth missing for 15 participants. These participants were randomly assigned as older than 18 years, but later were found to be younger than 18 years.
†15 participants had missing date of birth but 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).
§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**

## Results

Between Oct 15, 2020, and Aug 3, 2021, 21 277 individuals were screened for the ECoWeB cohort, 10 030 accessed the baseline assessment, and 3794 were eligible for the ECoWeB cohort, of whom 2532 were eligible and consented for the ECoWeB PROMOTE trial. 847 participants were randomly assigned to the emotional competence app, 841 participants to the CBT app, and 844 participants to the self-monitoring app, with each group receiving usual care (figure; table 1). The number of participants not completing follow-up assessments were 1151 (46·5%) of 2532 participants at 1 month, 1217 (48·1%) at 3 months, and 1272 (50·2%) at 12 months. Missing rates for primary and secondary outcomes were similar and did not differ between the groups (table 2).

Baseline characteristics were similar between groups (table 1). Mean age was 19·2 years (SD 1·8). Of 2532 participants self-reporting gender, 1896 (74·9%)

were female, 613 (24·2%) were male, 16 (0·6%) were neither, and seven (0·3%) were both. Across the three groups, 17·5–19·2% of participants never set up an account to access the app. Compliance (ie, sign-up) with the self-monitoring app was 80·8% (682 of 844 participants). Compliance based on a priori usage threshold was 47% (399 of 847) in the emotional competence app and 49% (408 of 841) in the CBT app. Some data on app usage were missing because of the app outage (81 participants in the emotional competence app group and 80 participants in the CBT app group).

At 3-month follow-up, primary analyses examining group mean differences on the primary outcome of mental wellbeing across all conditions adjusting for baseline score, age, country, and self-reported gender found no global difference (global p=0·47; table 2). Mental wellbeing did not differ between the emotional competence app and the CBT app (mean difference WEMWBS –0·21 [95% CI –1·08 to 0·66]) or between the emotional competence app and self-monitoring app (0·32 [–0·54 to 1·19]). Mental wellbeing also did not differ between the CBT app and the self-monitoring app (0·53 [–0·33 to 1·39]). A global difference occurred between the three groups at 12-month follow-up (global p=0·045; table 2). Mental wellbeing was lower in the emotional competence app than the CBT app (mean difference WEMWBS –1·17 [95% CI –2·11 to –0·24]), although this difference did not meet the threshold for a minimally clinically important difference. No difference occurred in mental wellbeing between the emotional competence app relative to the self-monitoring app (–0·76 [–1·69 to 0·18]) or between the CBT app relative to the self-monitoring app (0·42 [–0·51 to 1·34]).

The results for all the secondary outcomes were similar to those for the primary outcome, with no global differences between the three groups at 3 months or 12 months (tables 2, 3). There was no difference in use of services between the groups (appendix pp 204–08). 14 participants were admitted to hospital or treated in hospital (or both) for mental health reasons, self-harm or

| | 3-month follow-up | | | | 12-month follow-up | | | |
|---|---|---|---|---|---|---|---|---|
| | EC app *vs* self-monitoring app (mean difference [95% CI]) | CBT app *vs* self-monitoring app (mean difference [95% CI]) | EC app *vs* CBT app (mean difference [95% CI]) | Global p value | EC app *vs* self-monitoring app (mean difference [95% CI]) | CBT app *vs* self-monitoring app (mean difference [95% CI]) | EC app *vs* CBT app (mean difference [95% CI]) | Global p value |
| **Primary outcome** | | | | | | | | |
| WEMWBS | 0·32 (–0·54 to 1·19) | 0·53 (–0·33 to 1·39) | –0·21 (–1·08 to 0·66) | 0·47 | –0·76 (–1·69 to 0·18) | 0·42 (–0·51 to 1·34) | –1·17 (–2·11 to –0·24) | 0·045 |
| **Secondary outcomes** | | | | | | | | |
| PHQ-9 | 0·19 (–0·28 to 0·66) | –0·12 (–0·58 to 0·35) | 0·31 (–0·16 to 0·78) | 0·43 | 0·20 (–0·36 to 0·75) | 0·04 (–0·51 to 0·60) | 0·15 (–0·40 to 0·71) | 0·77 |
| GAD-7 | 0·20 (–0·27 to 0·67) | 0·15 (–0·32 to 0·62) | 0·05 (–0·42 to 0·52) | 0·68 | 0·26 (–0·25 to 0·77) | 0·03 (–0·47 to 0·53) | 0·24 (–0·27 to 0·74) | 0·54 |
| WSAS | 0·34 (–0·39 to 1·07) | -0·33 (–1·05 to 0·40 | 0·66 (–0·07 to 1·40) | 0·21 | 0·40 (–0·41 to 1·21) | 0·00 (–0·79 to 0·80) | 0·39 (–0·42 to 1·20) | 0·55 |
| EQ-5D-3L | –0·009 (–0·028 to 0·010) | –0·014 (–0·033 to 0·005) | 0·005 (–0·015 to 0·024) | 0·36 | –0·010 (–0·030 to 0·010) | 0·006 (–0·014 to 0·026) | –0·015 (–0·035 to 0·005) | 0·31 |

EC=emotional competence. CBT=cognitive behavioural therapy. WEMWBS=Warwick-Edinburgh Mental Well Being Scale. PHQ-9=Patient Health Questionnaire-9. 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** | | | | | | | | | | | | |
| WEMWBS | 52·8 (6·5); 847 | 53·1 (6·6); 841 | 52·6 (6·6); 844 | 50·0 (7·0); 449 | 51·5 (6·7); 457 | 50·3 (7·3); 475 | 50·8 (7·9); 425 | 51·3 (7·4); 443 | 50·3 (7·6); 447 | 50·0 (7·5); 410 | 51·4 (7·3); 426 | 50·8 (8·0); 424 |
| **Secondary outcomes** | | | | | | | | | | | | |
| PHQ-9 | 4·7 (3·2); 847 | 4·6 (3·2); 841 | 5·0 (3·4); 844 | 6·3 (3·7); 445 | 5·4 (3·4); 453 | 6·3 (3·9); 470 | 6·1 (4·1); 423 | 5·7 (3·8); 442 | 6·1 (3·9); 447 | 6·5 (4·6); 410 | 6·3 (4·5); 425 | 6·4 (4·5); 422 |
| GAD7 | 4·6 (3·3); 847 | 4·4 (3·2); 841 | 4·5 (3·1); 844 | 5·5 (3·6); 441 | 5·1 (3·5); 453 | 5·3 (3·5); 463 | 5·4 (4·0); 417 | 5·3 (3·9); 432 | 5·2 (3·8); 438 | 5·7 (4·0); 399 | 5·4 (3·9); 425 | 5·4 (4·2); 420 |
| WSAS | 9·6 (5·8); 847 | 9·5 (5·6); 841 | 9·6 (5·6); 844 | 10·3 (6·3); 441 | 9·5 (6·0); 451 | 9·8 (5·9); 463 | 10·0 (6·6); 415 | 9·3 (6·1); 432 | 9·7 (6·4); 438 | 10·3 (6·5); 399 | 10·0 (6·4); 424 | 9·9 (6·6); 420 |
| EQ-5D-3L* | 0·94 (0·11); 847 | 0·94 (0·11); 841 | 0·94 (0·11); 844 | NA | NA | NA | 0·91 (0·17); 414 | 0·91 (0·17); 432 | 0·91 (0·15); 438 | 0·90 (0·17); 399 | 0·92 (0·16); 424 | 0·91 (0·15); 420 |

Data are mean (SD); n. CBT=cognitive behavioural therapy. WEMWBS=Warwick–Edinburgh Mental Well Being Scale. PHQ-9=Patient Health Questionnaire-9. GAD-7=Generalised Anxiety Disorder scale-7. WSAS=Work and Social Adjustment Scale. EQ-5D-3L=EQ-5D-3 Levels. *EQ-5D-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**

injury, or misuse of alcohol or substances (five in the emotional competence app group, eight in the CBT app group, and one 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 to the primary analysis (appendix pp 208–09). The results of the CACE, repeated measures analyses, and imputed data analyses were consistent with the primary analyses (appendix pp 210–12).

Analysis of the interviews provided insights about the feasibility of the intervention. 21 participants were interviewed at 3-month follow-up. They perceived the emotional competence app as appropriate and relevant for young people of different ages, genders, and backgrounds. However, several participants commented that the app's content was better suited to university and school students, and they had discontinued using the app after their examinations had finished. Many participants perceived the app was aimed at improving mental health problems as opposed to being a universal intervention intended to improve wellbeing, which represented a barrier to engagement. Participants who reported the app being irrelevant to them could see it being useful for friends and family who were stressed, anxious, or going through a difficult time (appendix pp 192–202).

## Discussion

This ECoWeB PROMOTE trial found that, contrary to our hypothesis, there was no added benefit of the emotional competence app or the CBT app relative to the self-monitoring app to promote mental wellbeing. To our knowledge, this is the first randomised controlled trial to test the efficacy of mental health self-help mobile phone apps to promote mental wellbeing in a robust, large-scale sample of healthy young people recruited across different countries followed up for 12 months and including a personalisation approach. Previous trials typically used apps that have not developed on established models of healthy emotional functioning, had small sample sizes (<100 participants per group), or had short-term follow-ups, and have not examined the effects across multiple countries nor in a general population of young people.[8–11]

The findings suggest that unguided self-help apps have minimal benefit on mental wellbeing and mental health promotion in the general population of healthy, functioning, young people without history of major depression. Neither the emotional competence app nor the CBT app outperformed self-monitoring. The absence of statistical and clinically meaningful differences between the groups might be partly due to the apps' low intensity and infrequent use (appendix pp 123–142) thus providing weak exposure to the intervention. These results might also reflect how difficult it is to promote mental wellbeing in untargeted interventions aimed at a general population of young people, consistent with evidence from large-scale trials that untargeted psychological interventions did not promote wellbeing and improve mental health in young people.

These results are consistent with broader findings that selective and indicative psychological approaches to prevent poor mental health are typically more effective than universal prevention.[4] In our parallel ECoWeB PREVENT trial, the CBT app was beneficial for mental health in young people with elevated risk for poor mental health, consistent with previous trials.[11] Our results and the wider literature suggest that digital apps do not enhance mental wellbeing and mental health in young people with well adjusted emotional competence profiles and that such resources might be better directed towards selective or indicated prevention.

One barrier to the efficacy of untargeted interventions might be their limited perceived relevance and utility to potential users. Individuals with well adjusted emotional competence profiles might perceive little benefit from using the app because they are not currently experiencing anxiety or low mood, and, as such, might not engage with the content or practise the skills sufficiently. This analysis is consistent with the pattern of app use observed, which decreased rapidly during the first month, and with the qualitative feedback provided. Self-help apps, which are more interactive, provide more tailored feedback, and make more use of artificial intelligence, chatbots, and avatars, might be more engaging and have better outcomes.

Study strengths include the randomised design, inclusive cohort approach—ie, recruiting young people from schools and universities, and via social media across four European countries—large sample size, use of rigorous 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 include effectively combining the benefits of a prospective, long-term, longitudinal cohort design with a randomised controlled trial; improving the efficiency of sample recruitment as the overall study can enrol eligible young people and can be advertised as a cohort study on learning about and improving young people's emotions; 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 condition.[18]

An important limitation was the rate of follow-up attrition. However, the observed 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 35·8–60·0]).[23] Furthermore, the trial remained sufficiently powered for conservative estimates. Second, we did not use a usual care control, but instead used a more conservative self-monitoring control. Third,

participants were predominantly female, White, young, and in education thus potentially limiting generalisability. Fourth, because the emotional competence app group integrated the use of emotional competence content or techniques and personalisation to such content, their effects could not be separated; however, this is moot given our findings. 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 reducing capacity.

In sum, our findings show that self-help apps were of limited benefit in young adults who did not have increased vulnerability for anxiety and depression as indexed on measures of emotional competence. These results add to an evidence base suggesting that efforts at reducing the global burden of poor mental health in young people might be more effectively concentrated in prevention for selective and indicated at-risk populations rather than in universal efforts to promote mental wellbeing.

#### Contributors

ERW was the principal investigator, prepared the first draft of the manuscript, obtained funding, and designed the trial. AN, TE, RST, and FCW contributed to the design of the ECoWeB trial. ERW, AN, and RST drafted the study protocol. FCW, RST, and CHu drafted the statistical analysis plan. ERW and AN coordinated the overall multicentre trial and the trial in the UK. CHu prepared the health economics plan. ERW, TE, TR, JL, GS-K, BA, BP, JRJF, VEIH, AH, MFr, KK, VV, EG, KRS, KS, FB, BWS, RP, and CHö designed and prepared the content of the emotional competence self-help intervention, contributed to the development of adapted measures, and coordinated development of the app intervention. JRJF, VEIH, AH, and RP validated the adapted assessment measures. TE, MV, and JL coordinated the trial in Germany. JRJF, AH, and VEIH coordinated the trial in Belgium. CB, AG-P, CS-R, and GM coordinated the trial in Spain. AG-P, CS-R, and GM prepared the content and logistics of the social media campaign for recruitment. TC set up the logistics for the trial's data collection. MFa and HB designed and delivered the qualitative implementation framework research. FCW completed the data analysis. AN and FCW directly accessed and verified the underlying data reported in the manuscript. All authors had full access to all the data and had final responsibility for the decision to submit for publication.

#### Declaration of interests

ERW receives royalties from Guilford Press for a CBT treatment manual he authored and was an expert member of the NICE Guidelines for treatment of adult depression. MFr is a founder and shareholder of Monsenso. BWS is a founder and shareholder of audEERING. All other authors declare no competing interests.

#### Data sharing

De-identified individual participant data and a data dictionary defining each field used for analysis will be made available on publication after approval of an analysis proposal by the ECoWeB steering committee by contacting the corresponding author (e.r.watkins@exeter.ac.uk).

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