Evaluating the effects of a self-help mobile phone application on worry and rumination experienced by young adults: A randomised controlled trial.

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Abstract

Background: Delivery of preventative interventions via mobile phone applications offers an effective and accessible way to address the global priority of improving the mental health of adolescents and young adults. A proven risk factor for anxiety and depression is elevated worry and rumination, also known as repetitive negative thinking (RNT).

Objective: This was a prevention mechanism trial testing whether an RNT-targeting self-help mobile phone application (MyMoodCoach) reduces worry and rumination in young adults residing in the United Kingdom. A secondary objective was to test whether the app reduces symptoms of anxiety and depression and improves well-being.

Methods: A web-based, single-blind, two-arm parallel-group Randomised Controlled Trial (RCT) was conducted with N=236 people aged between 16 and 24 who self-reported high levels of worry or rumination. Eligible participants were randomised to an active intervention group (usual practice, plus up to 6 weeks of using the RNT-targeting mobile app, n=119) or a waitlist control group (usual practice with no access to the app until after six weeks, n =117). The primary outcome was changes in worry and rumination six weeks after randomisation. Secondary outcomes included changes in well-being and symptoms of anxiety and depression after six weeks and changes on all measures after 12 weeks.

Results: Participants randomly allocated to use the RNT-targeting self-help app showed significantly lower levels of rumination (mean difference -2.92, 95% CI [-5.57, -.28], P =.031, ?p2 = .02) and worry (mean difference -3.97; 95% CI [-6.21, -1.73], P <.001, ?p2 = .06) at six-week follow-up, relative to the waitlist control. Similar differences were observed for wellbeing (P <.001), anxiety (P = .03) and depression (P = .04). The waitlist control group also showed improvement when given access to the app after six weeks. Improvements observed in the intervention group after 6 weeks of using the app were maintained at the 12-week follow-up point.

Conclusions: The MyMoodCoach app had a significant positive effect on worry and rumination, well-being, anxiety, and depression in young adults, relative to waitlist controls, providing proof-of-principle that an unguided self-help app can effectively reduce repetitive negative thinking. This app therefore has potential for prevention of anxiety and depression although longer-term effects on incidence need to be directly evaluated. Clinical Trial: ClinicalTrials.gov, NCT04950257. Registered 6 July 2021 – Retrospectively registered (shortly after start of recruitment), https://www.clinicaltrials.gov/ct2/show/NCT04950257

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Abstract

Background: Delivery of preventative interventions via mobile phone applications offers an effective and accessible way to address the global priority of improving the mental health of adolescents and young adults. A proven risk factor for anxiety and depression is elevated worry and rumination, also known as Repetitive Negative Thinking (RNT).

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longer-term effects on incidence need to be directly evaluated.
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Keywords*: Worry; rumination; repetitive negative thinking; prevention-mechanism; well-being; depression; anxiety; mobile-based interventions*

Introduction

There is growing concern about the early onset of mental health disorders in adolescents and young adults [1]. Poor mental health during adolescence can severely affect a young person's future life chances, and can have a significant negative impact on health, education, and employment in later life [2,3]. Depression and anxiety are two of the most common mental health problems in adolescents and young adults, which significantly contribute towards global disability and produce a high economic burden [4]. In 2020, the prevalence of depression and anxiety disorders in adolescents globally was estimated at between 25% and 31% [5].

Although effective treatments for depression and anxiety have been developed and delivered in many countries, the evidence suggests that the overall prevalence of both disorders remains largely unchanged [6] Because the prevalence of these common mental health disorders is so high, it is not possible for traditional delivery models of psychological intervention, such as a course of face-to-face sessions, to fully address the global treatment need as there are unlikely to ever be sufficient trained mental health professionals[7]. Further, even if acute treatments were made widely available, as a consequence of the high levels of recurrence and relapse for depression and anxiety, it has been estimated that only a partial reduction of the overall prevalence for anxiety and depression could be achieved [6,8]. Effective prevention approaches are therefore considered essential in lowering overall prevalence rates as they have the potential to reduce both initial and recurrent episodes, thereby decreasing the demand for acute treatment [9]. Given the substantial increase in the incidence of depression and anxiety during mid-adolescence, peaking in young adulthood [2], adolescents and young adults are considered an important group for which prevention of poor mental health is urgently needed [10–12].

While prevention interventions for anxiety and depression already exist for adolescents and young people, systematic reviews suggest that effect sizes are relatively small [13–15]. Further, most prevention interventions are delivered in person and require considerable input from trained professionals, such as teachers and therapists, which can increase cost and limit their availability [16].]. Whilst there is some evidence that supported interventions may have better adherence and efficacy than unguided interventions, their coverage and volume of delivery is constrained because each individual supporting the intervention has a finite capacity, such that these interventions cannot be made available to all who may benefit. As such, to ensure the large-scale coverage needed for effective mental health prevention approaches, there is potential value in supplementing supported interventions with ones that can be delivered to multiple users simultaneously and do not require additional input from practitioners (i.e., non-consumable self-help interventions [17]). The use of such non-consumable self-help interventions would substantively increase the scalability and availability of preventative interventions making them more suitable for use as a public-health approach at a population level.

The use of the internet and mobile phones has been increasingly explored as an avenue that may be able to increase accessibility of prevention interventions and reduce the cost of intervention [18]. While internet and mobile based interventions have many similarities, their method of delivery can vary. Mobile based interventions, for example, are typically delivered through dedicated mobile applications (apps) and accessed on mobile phones whereas internet-based interventions utilise web-based (or compatible) platforms designed to be accessed via laptops or personal computers. Internet based interventions tend to deliver therapeutic content made up of pages working through a specific topic and more closely resemble a structured therapeutic session e.g., taking a set amount of time to complete and working through set content. Mobile apps, however, are based on more flexible use of "bite-sized" information and exercises, with less information on the screen, and allowing the user to "swipe" through available material to access the content they desire. The use of mobile phones is near ubiquitous in young people in the UK with an estimated 99% of those aged between 16 – 24 using a smart phone on a regular basis in 2023 [19]. Further, mobile apps can help integrate behavioural changes into daily life: the app is always available to the user, making it well-suited for changing unhelpful habits. Mobile apps, therefore, provide a unique avenue in which to engage young adults in health-related activities as well as promoting good mental health and prevention strategies [20,21]. Despite a huge increase in the number of mobile-based mental health apps over the last ten years [22], only a small number have been developed with scientific rigour. Further, many do not utilise established treatment principles nor have they been rigorously tested in robust well-powered Randomised Controlled Trials (RCTs) [23]. While emerging evidence suggests that mobile-based applications can deliver efficacious treatment interventions for anxiety and depression [24,25], there have not been many trials examining their use for well-being promotion and prevention of poor mental health in young people specifically [26,27].

A psychological processes thought to be key when promoting good well-being and preventing mental health problems is Repetitive Negative Thinking (RNT) [28]. RNT is defined as a pattern of thinking that is repetitive, difficult to manage, and focused on negative content, which can significantly impact an individual's well-being and emotional functioning [28–30]. RNT encompasses various thought patterns, but the exemplars of RNT are worry and rumination which have been identified as robust risk factors for several mental health disorders [31]. Worry is described as a relatively uncontrollable chain of negative thinking about the future in the form of 'What if' type questions. Such thoughts can focus on typical everyday activities (such as work and relationships) as well as more catastrophic concerns (such as worrying that you may get hit by a falling tree)[32]. Rumination is a form of dysfunctional, negative thinking, which focuses on analysing the causes and consequences of negative events. This can involve dwelling on past events and continually going over and over why things went wrong [32]. The degree of rumination experienced by an individual has been shown to predict the onset and duration of major depressive episodes [33,34] as well as the severity of depressive symptoms [35,36]. Rumination has also been shown to mediate the effects of other identified risk factors, such as neuroticism and stressful life events, on the onset of depressive episodes [37]. Worry has been identified as having strong associations with symptoms of depression and anxiety [38]. There is also evidence that increased levels of worry are predictive of greater symptom severity for both anxiety and depression [39] and that daily worrying predicts subsequent increases in anxiety [40]. There is extensive evidence that worry and rumination share a common process including evidence that they are highly correlated with each other and that this common factor accounts for their relationship with anxiety and depression, which

underpins the conceptualisation of the wider process of RNT [28,29]. There is robust evidence for RNT as a transdiagnostic risk factor, which is common across many psychological mood disorders including depression and anxiety [32,41]. The induction of RNT has been found to exacerbate symptoms of anxiety and depression such as negative thinking, delayed decision-making speed, poor problem solving, and negative affect [42–45]. There is extensive evidence that RNT predicts future levels of depressive and anxiety related symptoms as well as the onset of depression[28,46]. As rumination and worry have been shown to be proximal risk factors, which effect onset, maintenance, and relapse, RNT is considered an underlying mechanism for both anxiety and depression and is identified as an important target for preventative interventions [41,47].

There are several interventions that have been designed specifically to reduce RNT and improve general mental well-being, including those which have been trialled as digital interventions delivered via the internet. A randomised control trial of a preventative intervention designed to target excessive levels of RNT found that both a group based and internet version of a rumination focussed Cognitive Behavioural Therapy programme (RfCBT) significantly reduced RNT (d = 0.53 to 0.89) and symptom levels of anxiety and depression (d = 0.36 to 0.72) compared to a waitlist group [48]. Another trial involving 235 high risk participants found that an internet-based version of the programme reduced the risk of depression by 34% relative to controls and that participants showed a significant improvement in RNT and depressive symptoms in the short to medium term [49]. While there is promising evidence, therefore, that preventative interventions focussed on reducing RNT are effective when delivered via the internet, there is limited research exploring the efficacy of RNT-targeting interventions delivered via a mobile phone app.

The Assessing and Enhancing Emotional Competence for Well-being in the Young project (ECoWeB) aimed to address the gap in large-scale trial evidence for preventative apps by developing, and evaluating, a self-guided mobile-phone app (MyMoodCoach). The app for this large-scale trial was designed to promote emotional wellbeing and prevent mental health problems in adolescents and young adults through engaging and personalized tools that trained psychological skills [50]. Specifically, this app was personalized by targeting the two most problematic components of Emotional Competence skills (from a set of four – Emotional Regulation; Emotional Appraisal-achievement context; Emotional Appraisal – social context; Emotional Perception and Knowledge) for the user, which were identified in their baseline assessments [50]. One of these components was addressed via a module focused on targeting RNT for individuals identified as having elevated levels of RNT at baseline (reflecting poor Emotional Regulation Emotional Competence skills). The current trial was an off-shoot study of this larger project that focused on testing the value of an app that targeted RNT alone. Hence, the variant of the app tested in the current trial was a standalone version of the same app used in the large-scale trial that only provided content from the module focussed on targeting RNT to try and shift users towards using more adaptive emotional regulation skills.

Developing trials to evaluate preventative interventions can take considerable time and resources. Whereas outcomes for prevention interventions typically focus on reduction of incidence (i.e., new cases) for a specific mental health problem, prevention mechanism trials focus on the underlying aetiological processes allowing for greater examination of proximal mechanisms. Prevention mechanism trials, therefore, offer an efficient way of establishing whether interventions can reduce risk factors associated with pathology thereby evaluating their potential for prevention [51]. Since worry and rumination are established risk factors for anxiety and depression, this study was a prevention mechanism trial to test whether use of an app targeting RNT can reduce worry and rumination in young people, thus evaluating its potential as a preventative intervention. Our primary hypothesis was that people allocated to

the RNT-targeting mobile app would show significantly lower levels of rumination and worry relative to those allocated to the waitlist control arm. A second hypothesis was that those allocated to the mobile app would also report significantly lower symptoms of anxiety and depression and higher well-being relative to waitlist control.

Method

Study Design

A superiority two-arm parallel-group RCT was conducted comparing an active intervention arm (usual practice plus up to six weeks of using the RNT-targeting mobile app) with a waitlist control arm (usual practice with access to the app only after a six week wait). As it was not possible to blind participants to their allocated groups, this was a single blind RCT with only the researcher blind to participant group allocation. Further details can be found in the trial protocol [52]. This study was conducted according to Consolidated Standards of Reporting Trials (CONSORT) [53,54] and extensions for non-pharmacologic treatment interventions as well as CONSORT-EHEALTH for improving and standardising evaluation reports of Web-based and mobile health interventions [55].

Recruitment

We recruited young adults aged between 16 and 24 residing in the United Kingdom (UK). The study was advertised on social media platforms, including Facebook and Instagram, as well as an internal research recruitment system (Sona) used by the University of Exeter. Only participants who reported elevated levels of RNT at baseline were eligible for this trial. This was defined as scoring above the 50th percentile (i.e., top half of scale) on either the Ruminative Response Scale (RRS; >34) or the Penn State Worry Questionnaire (PSWQ; >41). Participants also had to be aged between 16 and 24, currently residing in the UK, possess basic literacy in English and have access to a smartphone (either Android or iOS). Recruitment commenced on May 14th, 2021, and ceased on October 11th, 2021.

Participants were excluded at baseline if they reported elevated symptoms of depression indicating they required more specialist treatment, defined as having a score of 20 or higher on the Patient Health Questionnaire (PHQ-9) [56] because this suggests a severe level of symptoms where a more intensive treatment from a mental health professional would be indicated. Participants who reported elevated symptoms of anxiety were included and automatically provided with additional information for accessing support if required. Other exclusion criteria included: active suicidality or self-reported to be currently receiving treatment for a mental health problem (i.e., psychological therapy, counselling, or psychiatric medication) at baseline. Those who self-reported having a current diagnosis for clinical depression, bipolar disorder or psychosis were also excluded. A summary is given in the CONSORT flow diagram (Figure 1).

Screening and Consent Procedure

Potential participants were directed to a website providing further information about the study and were prompted to answer some pre-screening questions, regarding their age and current experiences of mental health. Individuals who were not suitable at this stage (e.g., outside of the specified age range) were automatically directed to a webpage explaining why they were

not suitable for the trial. Participants who passed this pre-screening stage were then provided with an information sheet and asked to consent to providing contact details and complete a baseline assessment where suitability for the trial (i.e., level of RNT; symptoms for anxiety and depression) was assessed more thoroughly. Following the baseline assessment, participants who met all eligibility criteria were then asked to consent to take part in the trial before being randomised into one of the two arms. Everyone accessing the trial website was provided with contact details for the research team.

Randomisation

Randomisation was conducted independently using a pre-generated computerised allocation algorithm. Randomisation was in a 1:1 ratio and stratified across each arm according to gender (male, female, non-binary) and level of RNT (50-75th percentile vs 75 percentile or higher). Participants scoring in the highest quartile (at or above 75th percentile) on either the RRS or PSWQ and in the top tercile on the other measure were identified as having high RNT, based on criteria used by Topper et al [48], which have previously been found to predict increased risk for subsequent depression [10].

Participant Flow

Overall, 297 people completed the pre-screening process of whom 272 went on to complete baseline questionnaires and have their suitability for the trial assessed more thoroughly. In total, 236 participants met the eligibility criteria and were randomised to either receive access to the digital RNT-targeting self-help app straight away (n=119) or after a period of six weeks (n=117). The rate of follow-up attrition was 19.07% (n=45, intervention arm = 24, waitlist control = 21) at six weeks and 38.14% (n=90, intervention arm = 46, waitlist control = 44) at 12 weeks. These calculations included eleven participants (4.6%) who contacted the research team requesting to withdraw from the study, one of which did so after completing their six-week follow-up. There was no missing data from any of the participants who completed their surveys. Further details are given in the CONSORT flow diagram (Figure 1).

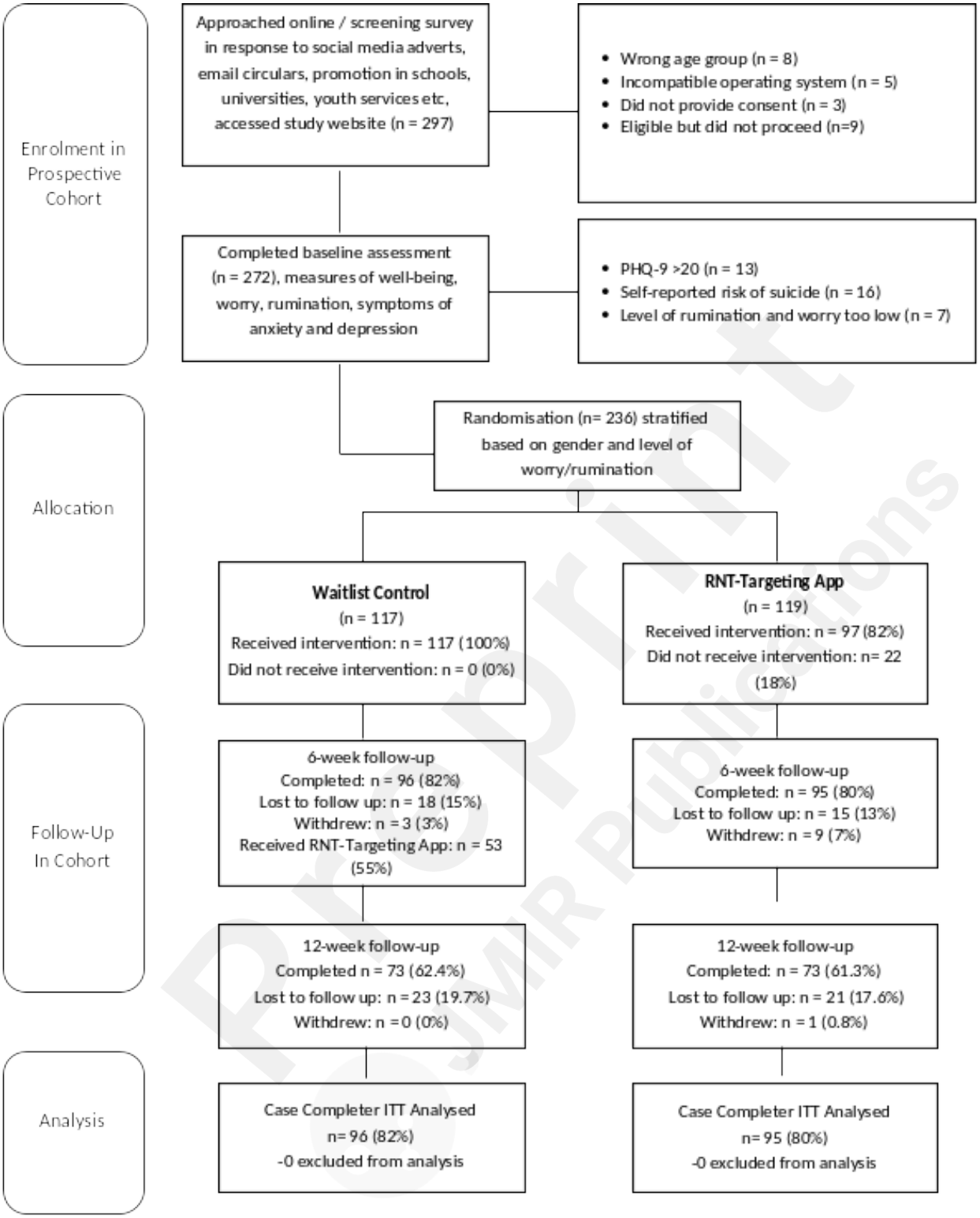

Figure 1
CONSORT Flow Diagram for the Trial

Interventions

Digital RNT- Targeting Self-Help App (Intervention Arm)

The self-help app used in this trial (called MyMoodCoach) was a focused version of the app evaluated in the main ECoWeB trial [50]. This standalone version was not personalised to each user and was specifically focused on reducing RNT to help improve emotion regulation, i.e., it only included the emotional regulation rumination-focused module. The app included self-monitoring, psychoeducation, and active self-help exercises based on RNT-specific strategies from an evidence-based RfCBT intervention [48,49,57–59], adapting these evidence-based interventions from an internet-delivery context to an app format. Core elements of the intervention were designed to break the ruminative habit and enable users to shift towards a more helpful processing style. This involved coaching participants to spot warning signs for rumination and worry, and then plan alternative strategies. These included being more active, slowing things down, breaking tasks down, opposite action, relaxation, concrete thinking, becoming absorbed, self-compassion, and assertiveness. Participants were prompted to practice alternative strategies in response to their warning signs. The user interface includes text, pictures, audio-recordings, animations, audio-exercises, and questionnaires with tailored automated feedback. There was also a self-monitoring component which prompted users five times a day to rate their mood and level of rumination.. The app featured a menu structure including a dashboard to monitor notifications and progress, a library function that had psychoeducation and explanatory animated videos, and an explore function to graph the self-monitoring responses made by the participant. The app also included Challenges that provide learning exercises (for example, behavioural exercises) and Tools that are brief strategies that young people can use in the moment when they need them (for example, compassion and relaxation exercises). The app was entirely automated (i.e., self-guided) and designed for use on both iOS and Android phones. The app was accessed for free via each participant's smart phone app store.

Changes from the proven internet versions of the intervention [9,11] included: information condensed so that "bite-sized" content reflecting one point of information was presented per swipe of the mobile phone screen and could be consumed in brief moments of time (rather than by scrolling down web-pages each with multiple points of information); greater flexibility of use such that users could select any element of the app in any order from the menu (e.g., use of Tools or Challenges) unlike the internet-delivered interventions which tended to be more modular and arranged in a fixed structure and order, as a "lesson" or "session" that might take an hour to work through in its entirety. Some screenshots for the app are given in Figure 2 and further details can be accessed via the supplementary materials provided.

Waiting List Control Group

The waiting list control group received access to the RNT-targeting digital self-help app after a six week wait.

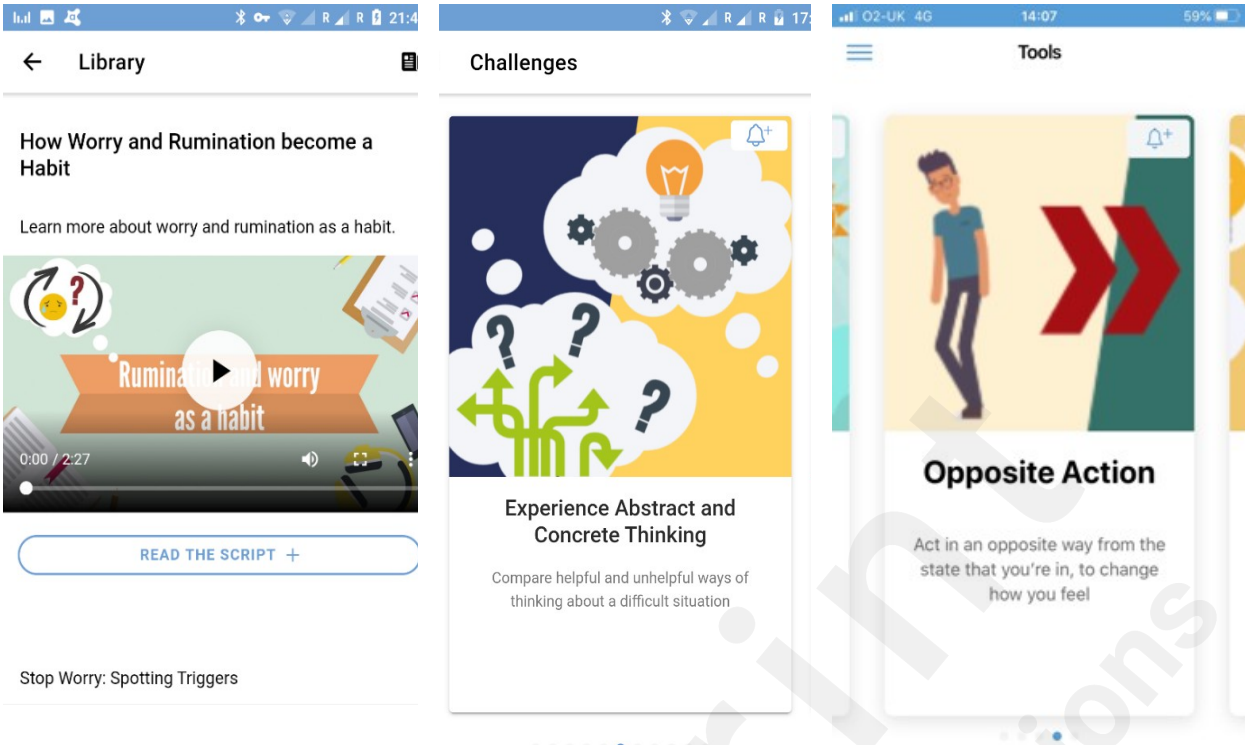

Figure 2
Screenshots from the MyMoodCoach App from left to right: Screen from the library of visual resources, Screen within the Challenges menu to enter the Abstract and Concrete Thinking Challenge, Screen within the Tools menu to enter the Opposite Action Tool.

Baseline and Follow-up Assessments

All outcome measures were completed online by participants at baseline, with follow up assessments at six-weeks, and 12-weeks post-randomisation. Demographic information, including age, gender, employment status and ethnicity, was collected only at baseline. Additional feedback about experiences of using the mobile app was only collected at the 12-week follow-up point. Automated emails were sent to participants at each follow-up point with a link to complete their survey. Further reminders were sent manually via email and text message if there was no response to the automated reminders.

As an incentive, all participants who completed their follow-up surveys were entered into a prize draw. Participants recruited via the University of Exeter Sona system could choose whether to be entered into the prize draw or receive course credits. Out of those eligible to participate in the trial, 82 chose to receive course credit (32.7%). The researcher who was blind to treatment allocation was the only team member involved in sending out reminders to complete follow up surveys. Other members of the team were available to follow-up on issues of risk and answer technical queries from participants. Throughout the trial process there were no deviations from the planned procedure with no incidents of unblinding being reported.

Outcomes

The primary outcome for this trial was changes in levels of rumination and worry at the primary endpoint (six weeks after randomisation). Rumination was measured using the Ruminative Response Scale (RRS) [36]. The measure consists of 22 items that assess the tendency for an individual to respond to depressed moods with focus on either the self,

depressive symptoms, or negative consequences. Items are scored from 1(almost never) to 4(almost always) and total scores can range from 22 to 88 with higher scores indicating a higher level of rumination. The RRS has good internal consistency in an adolescent population (α =.88) [60] and test–retest reliability ranges from moderate to high (r = .47 for over 1 year, r = .80 for over 5 months)[33,61].

Worry was measured using the Penn State Worry Questionnaire (PSWQ) [62], a 16 item self-assessment which assesses the intensity, tendency and uncontrollability of worrying thoughts using a 5-point Likert scale for each item. Items are scored from 1 (not at all typical of me) to 5 (very typical of me) and total scores can range from 16 to 80 with higher scores indicating greater levels of worry. The measure has a high internal consistency in both clinical and non-clinical samples (α = .88 - .95) as well as good test-retest reliability (r = .72 - .93 for 2 weeks and 1 month respectively) [62].

Secondary outcomes for this study included changes in mental well-being and symptoms of anxiety and depression at the primary endpoint, as well as changes on all measures between six-week and 12-week follow-up. Mental well-being was measured using the Warwick-Edinburgh Mental Well-being Scale (WEMWBS)[63]. The WEMWBS has demonstrated high internal consistency in both student and general populations (α = .89 – .91), with good test-retest reliability (ICC = .83, p < .01)[63]. The Generalized Anxiety Disorder questionnaire (GAD -7) [64] was used to assess symptoms of anxiety. Symptoms of depression were assessed using The Patient Health Questionnaire (PHQ-9) [65]. Both measures have demonstrated good internal consistency (α = .86 - .92) as well as good test-retest reliability (.83 - .84) [66].

To assess user's perspective on the app, participants were asked to rate the app on its ease of use, look and feel, features and content on a 5-point Likert scale of 1 (terrible) to 5 (brilliant) as well as provide qualitative feedback about the positives and negatives of using the app. These questions were devised by the lead researcher and adapted from components of the Technology Acceptance Model (TAM) and User Experience (UX) design approaches [67,68].

Statistical Analysis

Power

An estimated minimum clinically important difference (MCID) for the primary outcome of the RRS was used to calculate the sample size for this study. One recommended approach for identifying the MCID is half of the standard deviation (SD) for the respective index [69] . A conservative estimate of the normative SD for the RRS was identified based on previous research (SD = 7.58 – 8.51) [48]. A reduction of four points on the RRS, therefore, was identified as an appropriate MCID. Using an alpha of .05 with 90% power, for a MCID OF 4, required 85 participants per group (170 in total). Allowing for a 20% follow-up attrition rate, we aimed to recruit a minimum of 204 participants (102 per arm).

Analysis Plan

Data was analysed using SPSS (Version 28) and the statistical analytical plan was finalised prior to data being unblinded. The primary analysis was based on intention-to-treat (ITT) and all participants, regardless of their level of engagement, were included [70]. Missing data was handled via multiple imputations (MI) using a linear regression model with a monotone

imputation method. As MI had equivalent results to case completer analyses, only the case completer ITT analysis results have been reported. Analysis of Covariance (ANCOVA) at six weeks was used for both primary and secondary outcomes, with baseline score as the covariate. ANCOVA was also used for both primary and secondary outcomes at 12 weeks with six-week follow-up scores as the covariate.

Feedback about user experience was collated and analysed using NVivo software which identified common words and phrases occurring within the data to generate preliminary codes. The same software was then used to automatically group the identified codes into suggested themes. These preliminary themes were then checked and refined by the primary researcher before being finalised.

Ethics Approval

Ethical approval for this study was obtained from the Ethics Committee of the School of Psychology, University of Exeter (Ref: eCLESPsy001977v5.1). All participants provided written informed consent. Data was collected in a pseudonymised manner and stored securely.

Results

Baseline demographics across both arms for the study are shown in Table 1. All participants were aged between 16 and 24, and predominantly White female students.

Table 1
Baseline Demographics for each condition

Baseline Characteristics	RNT-Targeting app (n =119)	Waitlist control (n=117)
Age, *M* (SD)	18.44 (2.01)	18.56 (2.4)
Gender, n (%)		
Male	15 (12.6)	16 (13.7)
Female	109 (84)	98 (83.8)
Non-Binary/Third Gender	4 (3.4)	3 (2.6)
Ethnicity, n (%)		
White	95 (79.8)	96 (82.1)
Black / African / Caribbean / Black British	2 (1.7)	1 (0.9)
Asian/ Asian British	14 (11.8)	15 (12.8)
Mixed or other ethnic group	8 (6.7)	5 (4.3)
Employment, n (%)		
Employed (full-time)	5 (4.2)	9 (7.7)
Employed (part time)	11 (9.2)	14 (12.0)
Unemployed	8 (6.7)	4 (3.4)
Student	95 (79.8)	90 (76.9)
History of Mental Health Problems, n (%)		
Yes	18 (15.1)	19 (16.2)

Outcome at primary endpoint (six weeks)

Means and standard deviations for each measure and arm at each time point are shown in

Table 2. One-way Condition (Intervention vs. Control) ANCOVAs found a significant main effect of intervention condition on rumination, F (1, 188) = 4.72, P = .031, η_p^2 = .02, worry, F (1, 188) = 12.24, P < .001, η_p^2 = .06, depression F (1, 188) = 4.14, P = .043, η_p^2 = .02 and anxiety F (1, 188) = 5.43, P = .02, η_p^2 = .03. These significant effects reflect that after adjusting for the covariate of baseline scores, participants randomised to use the RNT-targeting app in the intervention arm reported significantly lower rumination, worry, depression and anxiety at six-week follow-up than those randomised to the waitlist control (Mean difference: rumination, -2.92, 95% CI [-5.57, -.28]; worry, -3.97; 95% CI [-6.21, -1.73]; depression, -1.34, 95% CI [-2.63, -.04]; anxiety, -1.46, 95% CI [-2.7, -.23]). Participants randomised to the intervention arm reported a significantly higher well-being at six weeks relative to the waitlist control group, F (1, 188) = 12.38, P < .001, η_p^2 = .06, with an adjusted mean difference of 3.78 between the two groups, 95% CI [1.66, 5.9].

Outcome at follow-up (twelve weeks)

At 12 weeks, participants who were initially allocated to use the RNT-targeting app maintained the changes which were made on all measures during the first six weeks, with no significant changes observed between the two follow up points (see Table 3). After being introduced to the app at six weeks, participants in the waitlist control showed significant reductions in rumination, worry, anxiety and depression and increases in well-being (see Table 3). One-way ANCOVAs found no statistically significant differences between the two groups for any of the measures at the 12-week follow-up point, F (1,143) ≤ 1.17, P ≥ .281.

Figure 3
Graph of mean RRS scores for RNT-Targeting app and waitlist control participants with 95% CI error bars

Table 2
Means and Standard Deviations for all measures at each follow up point

	Baseline		6-week follow-up		12-week follow-up	
	RNT-Targeting app (N = 119)	Waitlist Control (N = 117)	RNT-Targeting app (N= 95)	Waitlist Control (N = 96)	RNT-Targeting app (N = 73)	Waitlist Control (N = 73)
RRS, M (SD)	51.08 (11.62)	51.51 (10.76)	49.91 (11.52)	52.88 (11.68)	47.86 (10.78)	49.3 (11.1)
PSWQ, M (SD)	59.87 (10.82)	60.24 (10.4)	56.81 (9.38)	60.65 (11.08)	55.18 (10.49)	58.04 (11.08)
WEMWBS, M (SD)	43.56 (7.92)	44.09 (7.08)	46.24 (8.95)	42.96 (7.47)	47.62 (6.96)	45.86 (7.13)
GAD-7, M (SD)	9.40 (4.67)	9.04 (4.79)	7.97 (4.62)	9.14 (5.1)	7.45 (3.78)	7.90 (4.77)
PHQ-9, M SD	8.61 (4.25)	8.56 (4.48)	8.57 (5.16)	9.73 (5.19)	7.85 (4.33)	8.49 (4.3)

Note - RRS = Ruminative Response Scale; PSWQ = Penn State Worry Questionnaire; WEMWBS = Warwick-Edinburgh Mental Well-being Scale; GAD-7 = Generalised Anxiety Disorder – 7; PHQ-9 = Patient Health Questionnaire-9

Figure 1
Graph of mean PSWQ scores for RNT-targeting app and waitlist control participants with 95% CI error bars

Table 3
Within Subjects contrasts between the 6 and 12 week follow up point

	RNT – Targeting app		Waitlist control	

	F (1,144)	P	Effect size (η_p^2)	F (1,144)	P	Effect size (η_p^2)
RRS	2.63	.11	.02	22.09	<.001	.13
PSWQ	1.47	.23	.01	12.20	<.001	.09
WEMWBS	.93	.34	.01	20	<.001	.12
GAD-7	1.12	.30	.01	9.8	.002	.07
PHQ-9	2.82	.10	.02	9.8	.002	.07

Note - RRS = Ruminative Response Scale; PSWQ = Penn State Worry Questionnaire; WEMWBS = Warwick-Edinburgh Mental Well-being Scale; GAD-7 = Generalised Anxiety Disorder – 7; PHQ-9 = Patient Health Questionnaire-9

Adherence

Overall, 97 out of 119 participants in the intervention arm (81.5%) and 53 out of 96 (55.2%) in the waitlist control signed into the app. To estimate app usage, we calculated the mean number of days participants completed a daily mood rating (including those who never signed into the app). For those randomly allocated to use the RNT-targeting app, this was 8 days (SD = 10.92, range = 0 - 40) during the first six-week period, and for the waiting list control, this was 3 days (SD = 6.31, range = 0 – 31) once given access to the app.

User Experience

When identifying good things about the app, participants consistently highlighted the mood tracker and tool features as being beneficial. Participants also identified that the app provided them with useful skills to help improve their emotional management such as identifying unhelpful patterns, reflection, and analysing their emotions more critically. Several participants noted that the app helped them feel relaxed and that it was most useful when they were experiencing heightened levels of distress or going through “a dark time”. When identifying areas to improve, several features appeared to affect participants’ motivation to regularly engage with it. Nine comments highlighted that the app sent too many notifications which became very annoying, and eleven comments alluded to the app being difficult to navigate and quite tiring to engage with on a regular basis. Eight comments noted experiencing frequent bugs and crashes. Twenty-six comments noted some design issues such as the range of emotions in the app being too limited; the questions used to evaluate daily events being repetitive; and the user interface being “too clinical” and not aesthetically pleasing. Overall, the average satisfaction rating from all participants who provided ratings regarding their experience (N = 137) was 3.74 out of 5 with an SD of .73 (Ease of use: M = 3.99, SD = .9; Look and Feel: M = 3.45, SD = 1.08; Features and Functionality: M = 3.72, SD = .87; Content: M = 3.8, SD = .94).

Discussion

This was a prevention-mechanism trial that aimed to test whether an RNT-targeting self-help mobile phone application (MyMoodCoach) was effective at reducing worry and rumination in young adults. A further objective was to pilot the efficacy of the app in reducing symptoms of anxiety and depression and improving well-being.

As hypothesised, participants randomised to the MyMoodCoach app showed a significant decrease in both worry and rumination, relative to participants in the waitlist control condition. As hypothesised, participants randomized to the app also showed significant increases in wellbeing and reduction in anxiety and depression relative to the waitlist control group. All these changes were sustained at the 12-week follow-up point suggesting that any benefit of using the app is likely to persist over several months. Moreover, once they were given access to the app, participants in the waitlist control showed similar changes in RNT, anxiety, depression, and wellbeing, paralleling the benefits observed in the initial active intervention arm.

Patterns of change across the trial indicate that symptoms of depression during the first six weeks stayed constant in the intervention arm while worsening in the wait list control group. This suggests that engaging in an intervention designed to target RNT may have a preventive effect on depressive symptoms consistent with the wider literature on rumination and worry as vulnerability factors for depression [39,71,72]. Further, this is consistent with previous RCTs that found that targeting RNT can have a medium-term preventive effect reducing the onset of depression [48,49]. The reduction of both anxiety and depression from a self-help app that explicitly targeted worry and rumination is also consistent with theoretical models proposing that RNT is a transdiagnostic risk factor which can affect symptoms associated with both disorders [41]. This research thus provides proof-of-principle of the value of targeting RNT as a mechanism to prevent anxiety and depression, consistent with the prevention mechanism trial approach. However, because we did not explicitly assess new onsets of major depression or anxiety disorders, and the follow-up was only short-term, longer-term follow-ups with assessment of incidence are needed to rigorously test the potential of the self-help app targeting RNT as a prevention intervention. Despite app usage only being modest, it still had an effect. Further, the percentage of those not using the app (14%) was below the mean percentage of 'non-users' reported in a recent meta-analytic review of adherence in mobile interventions (41.2%) [73].

As well as showing potential as a prevention intervention, the observed benefits of the app indicate several clinical applications that could help reduce burden on services. As the intervention is focused on worry and rumination, the app could be offered to people who do not meet the severity threshold to access treatment for anxiety or depression, but still show high levels of RNT. It could also be offered as an interim approach for people on a waiting list for treatment as using the app may either reduce their associated symptoms or prevent their symptoms from getting worse. Moreover, as the app is targeting associated risk factors rather than a specific mental health problem, it may also help reduce the impact of stigma, which can prevent people from seeking support when distressed, and potentially increase engagement [74].

The study had several limitations. First, as all screening questionnaires were based on self-report, completed remotely, and no diagnostic interview was conducted, we cannot be sure that participants did not have a disorder at baseline. This also meant that we could not directly ascertain the effect of the app on the incidence of episodes of anxiety disorders and major depression. Second, participants were mainly white, female students, which may limit the generalizability of the findings, although we note a much greater proportion of females to males in the sample was expected given our inclusion criteria because elevated RNT tends to be much more common in females than males and has been found to partially account for the increased rates (nearly double) of depression and anxiety reported in females relative to males

[75,76]. As such, this gender imbalance is not necessarily problematic for the purposes of developing an RNT-targeting preventative intervention for anxiety and depression but rather it accurately reflects the distribution of RNT in the target population. Future studies, however, will need to encourage more participation from other gender identities to confirm whether the app is effective for those who do not identify as female. Third, whilst the follow-up period in this study was appropriate for a prevention-mechanism trial, a longer-term follow-up is needed to test the effect of the RNT-targeting app on preventing the incidence of episodes of major depression and generalized anxiety.

Conclusion

Despite some limitations, the MyMoodCoach app has the potential to offer a valuable contribution towards large-scale effective preventions for young people [77]. These results provide proof-of-principle that the intervention can effectively target worry and rumination as possible prevention mechanisms for anxiety and depression in young people. As RNT is a well-established vulnerability factor, it is likely that this intervention will have a positive impact on incidence of anxiety and depression in the medium-term.

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Conflicts of Interest

The authors declare no competing interests, except for MF, who is a co-founder and shareholder of Monsenso, whose solution delivered the app.

Abbreviations

ANCOVA: Analysis of Covariance

CI: Confidence Interval

CONSORT: Consolidated Standards of Reporting Trials

CONSORT-EHEALTH: Consolidated Standards of Reporting Trials for Electronic Health

ECoWEB: Assessing and Enhancing Emotional Competence for Well-being in the Young project

GAD-7: Generalized Anxiety Disorder Questionnaire

iOS: iPhone Operating System

ITT: Intention-to-treat

MCID: Minimum clinically important difference

MI: Multiple imputations

PHQ-9: Patient Health Questionnaire

PSWQ: Penn State Worry Questionnaire

RCT: Randomised Controlled Trial

RfCBT: rumination focused Cognitive Behavioural Therapy

RNT: Repetitive Negative Thinking

RRS: Ruminative Response Scale

SD: Standard deviation

UK: United Kingdom

WEMWBS: The Warwick-Edinburgh Mental Well-being Scale

Author contributions

EW and DE designed the trial. EW and AN coordinate the trial and randomisation process. DE and EW prepared the statistical analysis plan and statistical analysis was conducted by DE. EW, TE, MF and TR contributed towards the design and preparation of content for the RNT-Targeting app and helped coordinate development of the app intervention. DE and EW contributed to the writing of the draft manuscript, AN, MF, TE and TR reviewed and approved the final version.

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Supplementary Files

Figures

CONSORT Flow Diagram for the trial.

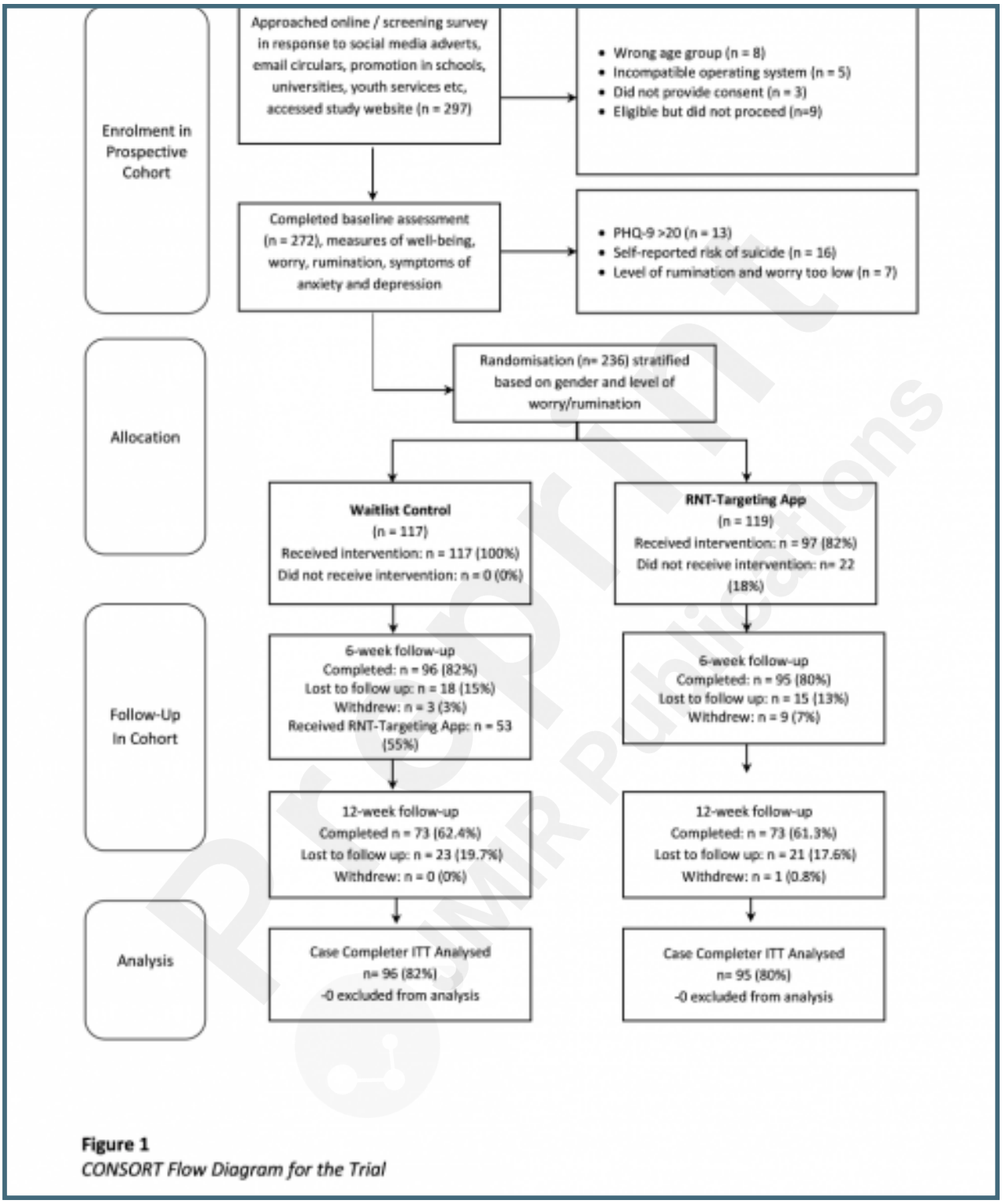

Figure 1
CONSORT Flow Diagram for the Trial

Screenshots from the app.

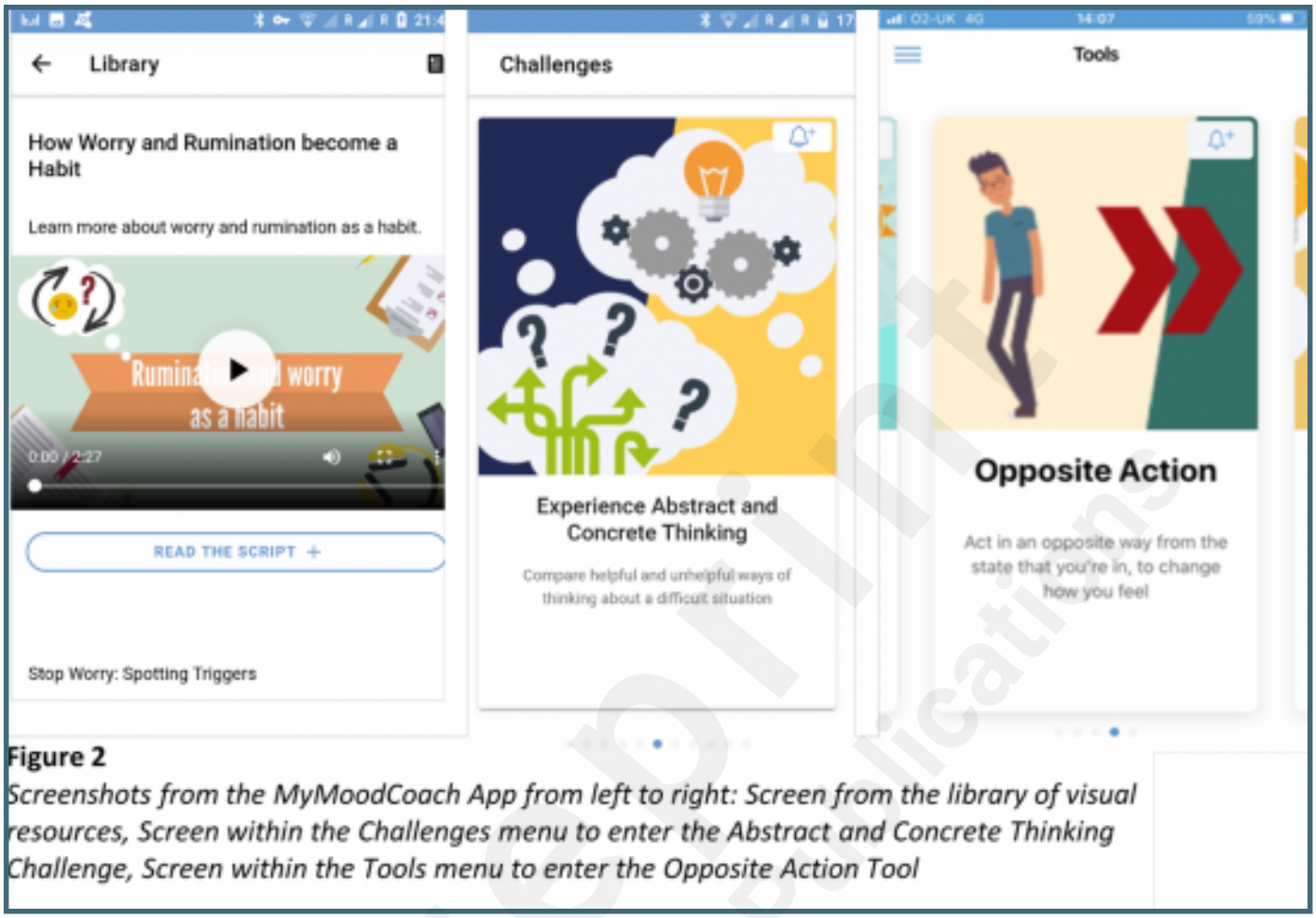

Figure 2

Screenshots from the MyMoodCoach App from left to right: Screen from the library of visual resources, Screen within the Challenges menu to enter the Abstract and Concrete Thinking Challenge, Screen within the Tools menu to enter the Opposite Action Tool

Graph of RRS scores.

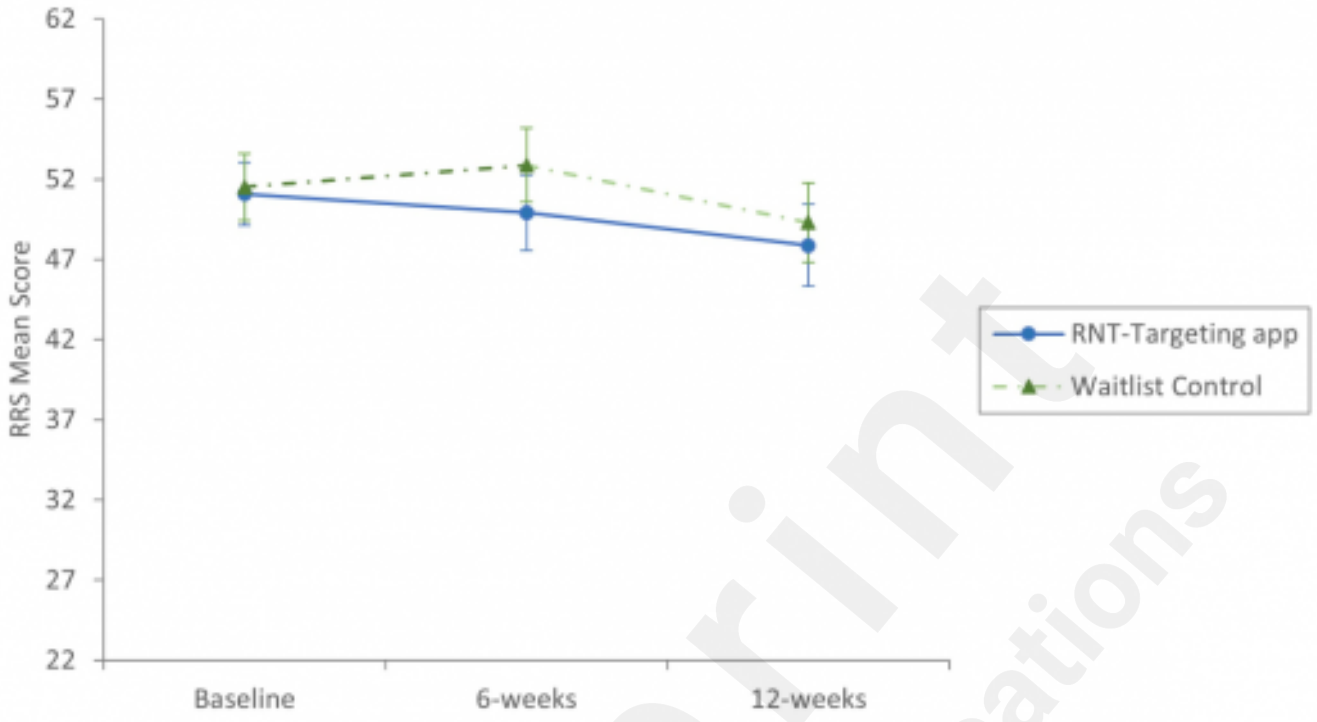

Figure 3
Graph of mean RRS scores for RNT-Targeting app and waitlist control participants with 95% CI error bars

Graph of PSWQ scores.

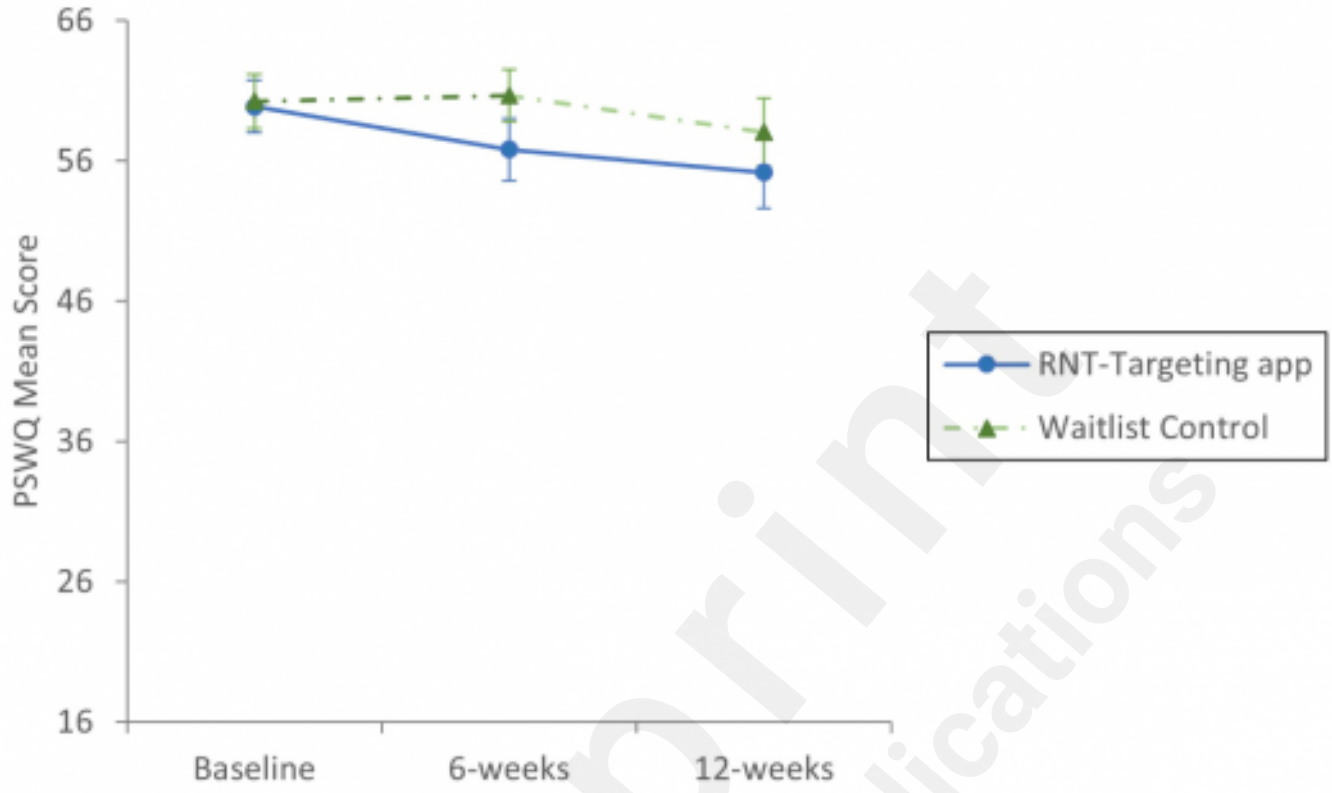

Figure 4

Graph of mean PSWQ scores for RNT-targeting app and waitlist control participants with 95% CI error bars

Multimedia Appendixes

Additional Information about the RNT-Targeting app.
URL: http://asset.jmir.pub/assets/c9f47257dc8fda096b0cf10681f5d52b.docx

CONSORT (or other) checklists

CONSORT-EHEALTH completed form.
URL: http://asset.jmir.pub/assets/e17af987aafac0f5265127e550ba6960.pdf

CONSORT Checklist.
URL: http://asset.jmir.pub/assets/66786d5c29d45a1ddd20b7671d399271.pdf

Related publication(s) - for reviewers eyes onlies

Revised article with tracked changes.
URL: http://asset.jmir.pub/assets/fda2bd37bacc2d13f1574a311037b381.pdf

Response to reviewers comments.
URL: http://asset.jmir.pub/assets/1fc0f1c7e785a9f8760e05ce5cf27bb0.pdf