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A mindfulness-based, cognitive, social, digital relapse-prevention intervention for youth with depression in Australia: study protocol for a randomised controlled trial of Rebound

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ABSTRACT

Introduction Major depressive disorder (MDD) causes significant disease burden and functional impairment during adolescence and young adulthood. While most young people recover from their first episode, around two-thirds will experience one or more relapses, which can become more severe and treatment-resistant with each episode. To address relapse in MDD, we developed a moderated online social therapy platform (titled *Rebound*) that integrates: (i) peer-to-peer social networking; (ii) tailored third-wave therapeutic content targeting mindfulness, self-compassion and rumination; and (iii) three types of human support (clinicians, peer workers, career consultants), informed by self-determination theory. The aim of this trial is to determine whether, in addition to treatment as usual (TAU), *Rebound*, an 18-month complex digital intervention, is superior to 18 months of enhanced TAU in preventing relapse and managing depressive symptoms.

Methods and analysis This study is a rater-masked randomised controlled trial. The treatment conditions include *Rebound* plus TAU or enhanced TAU alone. We aim to recruit 255 young people with at least one episode of MDD, aged 14–27 years. The study includes monthly assessment points over 18 months. The study includes a 48-month recruitment period and an 18-month treatment phase. The primary outcome is depressive relapse at 18 months, as measured by the Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), Research Version (SCID-5-RV). Secondary outcomes include the severity of depressive symptoms, time to relapse, time to remission, remission status, severity of anxiety symptoms, study and employment outcomes and cost-effectiveness. We will also examine four therapeutic mechanisms (mindfulness, self-compassion skills, social support and reduced rumination) to understand the 'how and why' of the intervention effects.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ *Rebound* is the first intervention to harness scalable digital technology to deliver a mindfulness-based intervention to prevent depressive relapse and manage depressive symptoms in youth diagnosed with major depressive disorder (MDD).
⇒ *Rebound* was developed by a multidisciplinary team in partnership with young people and clinicians, which may enhance the acceptability of the intervention.
⇒ The purpose of *Rebound* is to scale across and embed within youth mental health services.
⇒ The *Rebound* study is the longest known study (18 months) of a digital intervention addressing relapse in youth diagnosed with MDD.
⇒ Due to the nature of psychosocial interventions, participants and clinicians were not masked to treatment allocation.

Ethics and dissemination Melbourne Health Human Research Ethics Committee (HREC/42967/MH-2018) provided ethics approval for this study. Findings will be made available through scientific journals and forums and to the public via social media and the Orygen website.
Trial registration number ANZCTR, ACTRN12619001412123.

INTRODUCTION

Adolescence and young adulthood are a time of forming social connections, exploring identity and engaging in work and study.[1] Alongside already significant physical and emotional development, the onset and recurrence of major depressive disorder (MDD) can significantly affect a young person's

social functioning, physical health and quality of life.[2] MDD is a common and often recurrent mental health condition, affecting approximately 12% of young people aged between 15 and 24 years.[3 4] Globally, depression is the leading cause of disability[5] and has increased in prevalence since the COVID-19 pandemic.[6] Around 80% of children and young people accessing mental health services have a diagnosis of MDD.[7] Depressive symptoms, alongside anxiety, represent the most common presenting problem of those accessing Australian, entry-level youth mental health services like headspace.[8] While most young people recover from their first episode of MDD, around two-thirds will experience a relapse.[9] The course of MDD shows a worsening pattern, with each episode occurring sooner, increasing in severity and becoming more resistant to effective treatments.[10] Therefore, treatments must be timely, efficient and effective for those experiencing their first episode or who are at risk of subsequent episodes of depression. Unfortunately, even in high-income countries like Australia, the mental health system offers the opposite: delayed access to care due to limited availability of services and long waitlists and while in care, insufficient or mismatched treatments as indicated by many young people not reaching clinically significant improvement by the end of care.[8 11]

Digital mental health interventions may help to address systemic challenges by providing timely, accessible, evidence-based treatments.[12] Digital interventions can be offered to young people while waiting for face-to-face care, during care, and on discharge and can extend the in-person 'therapy hour' by building on skills and concepts introduced in therapy.[13] This means that digital interventions can treat current and emerging mental health disorders and support relapse prevention after remission. Moreover, digital mental health interventions are feasible and acceptable for use with young people experiencing depression.[14] Digital health interventions have been shown to reduce the rate of hospital admissions and emergency service use and be both cost-saving and cost-effective for young people with serious mental ill-health over 18 months compared with treatment as usual (TAU).[15 16]

Despite the benefits of digital mental health interventions, engagement with and completion of online therapy content tend to be low.[17] Real-time or 'synchronous' human support from a trained mental health professional improves engagement rates as mental health professionals can provide supportive accountability and motivational support.[18 19] Furthermore, to provide an effective intervention, human support needs to lead to 'effective' engagement, which includes behaviour change.[20] Behaviour change may also be supported by trained mental health professionals through the application of behaviour change techniques. Self-determination theory (SDT) is a theory of motivation that posits individuals are motivated in the most sustainable and healthy ways when they experience optimal levels of autonomy, competence and relatedness.[21] SDT has been operationalised into evidence-based behaviour change techniques that can be applied to the provision of human support online.[22]

Rebound is a complex digital mental health intervention[23] as it targets youth depression and prevents depressive relapse through the integration of several interacting components: (1) youth-friendly, evidence-based therapeutic content targeting mechanisms of mindfulness, self-compassion and rumination; (2) three types of human support (clinicians, peer workers and career consultants) applying evidence-based SDT-informed behaviour change techniques; and (3) a supportive online community of peers and peer workers sharing lived and living experience of mental ill-health, who aim to increase social support and decrease loneliness. *Rebound* has been iteratively developed with young people and a multidisciplinary team of clinicians, creative writers and developers over the past decade, using the Moderated Online Social Therapy (MOST) model.[24–26] In a single-arm pilot trial (n=42), *Rebound* has been found to be safe, acceptable, and feasible and significantly improved depressive symptoms at a 12-week follow-up.[14]

The primary aims of the current study are:

1. To evaluate, via a randomised controlled trial (RCT), the effectiveness of the *Rebound* platform in preventing relapse of MDD in young people with MDD (aged 14–27 years).
2. To evaluate the cost-effectiveness of the *Rebound* platform via a concurrent within-trial economic evaluation.
3. To examine four therapeutic mechanisms (mindfulness skills, self-compassion, social support and reduced rumination).

The primary hypothesis is that relative to enhanced TAU, TAU plus *Rebound* will reduce the accumulated relapse rate over 18 months among young people with MDD. The secondary hypotheses are that relative to enhanced TAU, TAU plus *Rebound* will generate improvements in depressive symptoms, reduce time to relapse and time to remission, reduce remission rates, improve anxiety symptoms, and improve study and employment outcomes over 18 months; be more cost-effective; and help to prevent relapse in MDD by increasing mindfulness skills, self-compassion, social support and reducing rumination.

METHOD

Study design

The study design is a prospective, parallel group, rater-masked RCT. Approximately 255 participants with MDD will be allocated to either enhanced TAU or TAU in tandem with a complex moderated online social media intervention (TAU+*Rebound*).

The trial includes a 48-month recruitment period and an 18-month treatment phase, with the study being completed within 5.5 years. The design comprises monthly assessment points across 18 months. The protocol development addressed all aspects of Good Clinical Practice,[27] CONSORT EHEALTH criteria[28] and SPIRIT guidelines.[29]

Setting

Participant recruitment commenced in October 2019 at services in the North-Western Melbourne (Victoria, Australia) catchment, specifically the Youth Mood Clinic (YMC), a programme of Orygen Specialist Program (OSP) and headspace centres led by Orygen (in the Melbourne suburbs of Sunshine and Glenroy).[30 31] Orygen is the world's leading research and knowledge translation organisation focusing on mental ill-health in young people.

Orygen Digital, the digital mental health division of Orygen and Centre for Youth Mental Health at University of Melbourne, designs, delivers and evaluates evidenced-based digital services for youth mental health. In April 2020, Orygen Digital commenced implementation of the MOST platform across all Victorian youth mental health services as part of the Victorian State Government's response to the COVID-19 pandemic and the recommendations of the Royal Commission into Victorian Mental Health system.[11] Due to the overlap between study and implementation sites, participant recruitment from Victorian sites ceased in October 2020. Instead, satellite recruitment sites were established at headspace services in the Illawarra region, New South Wales (NSW), operated by Grand Pacific Health (Wollongong, Bega, Nowra, Goulburn) and two services within the South Eastern Sydney Local Health District (Bondi Junction Community Mental Health Centre and headspace Bondi Junction).

Patient and public involvement

The *Rebound* intervention has been co-designed with young people, following strict participatory design principles[32] with continual feedback from young people across the development, pilot and intervention period. Consistent with best practice in developing novel interventions,[33] we have obtained feedback from participants in the *Rebound* pilot[14] about the need for more visually engaging therapy content. As a result, we have incorporated graphic narratives and comics to enhance engagement with therapy content in *Rebound*. Participants in the intervention group will be invited to regular focus groups with the emphasis being on feedback and questions about the intervention. More broadly, the protocol and participant information and consent forms have been reviewed by the Orygen Youth Research Council, and the investigator group carefully considered the burden of the trial schedule of assessments on participants.

Participants

Inclusion criteria for participants are: (a) age 14 to 27 years inclusive; (b) able to read and converse in English; (c) able to provide informed consent; (d) able and willing to nominate an emergency contact person, such as a close family member; (e) diagnosis of MDD (current, partial or full remission) corresponding to the current episode of care as measured by the SCID-5-RV;[34] and (f) ≥ 1 episode of MDD if in partial remission at time of screening assessment or ≥2 episodes of MDD (including the current episode) if current MDD or MDD in full remission at time of screening assessment.

Exclusion criteria are: (a) inability to converse in or read English; (b) acute risk of self-harm requiring urgent intervention (ie, suicidal ideation with a current plan and intent to enact this plan) at time of screening assessment; (c) a diagnosed permanent developmental delay or intellectual disability; (d) current or past episode of mania or hypomania; and (e) previous exposure to a MOST platform.

Enrolment and randomisation

Participants are recruited from primary and specialist youth mental health services. In Victoria, study research assistants (RAs) attend weekly clinical review meetings at YMC and headspace services to identify eligible clients. In NSW, a study clinical liaison has been appointed at satellite sites to actively facilitate recruitment at the site. The study liaison attends clinical review meetings, engages with treating clinicians and screens clinical files to identify potentially eligible clients. The study liaison introduces the trial to the client and obtains consent to share contact details with Orygen. Young people can also self-refer via the study recruitment page on the Orygen website.

The RA contacts potential participants, provides a detailed explanation about the trial and offers to answer questions. All participants are required to provide informed, signed consent. Parental or legal guardian consent is required for participants under 18 years of age. Once consent is obtained, the participant is enrolled in the trial and a screening assessment to assess eligibility is conducted by the RA. Once eligibility is established, the baseline assessment is completed. After completing the baseline assessment, the participant is randomised by the RA via a secure online Research Project Management System (RPMS). The RPMS sends an automated email to the study coordinator and principal investigator, notifying them of the outcome of randomisation. The study coordinator informs the participant of the allocation. Participants are reimbursed for their time for each assessment completed.

The randomisation schedule is generated by a statistician independent of the study, programmed in the RPMS and not accessible by the study team. Participants are randomly assigned to the treatment condition via the RPMS using randomly permutated blocks with a 1:1 allocation ratio. Participants are stratified by current MDD status (current, partial or full remission), number of previous MDD episodes (≤ 2 or ≥ 3), age (<18 years and ≥18 years), sex at birth and by treatment centre.

Enhanced treatment as usual (TAU)

TAU consists of a range of treatment options delivered by the treating service prior to discharge[30 31] and/or generic medical or mental health services typically available to young people in the absence of enrolment in the study. These can include follow-up by a general practitioner, private psychiatrist, primary care youth mental health

Table 1 Self-determination theory (SDT)-informed platform features

SDT principle	Brief definition	Moderated Online Social Therapy platform feature
Autonomy	Freely chosen actions, including genuine interest, value and appreciation for the activity	Personalised approach and flexibility in support and content options
Competence	A sense of growth through progressive mastery over a task	Bite-sized therapeutic content, demonstrating progress in content completion, toolkit of saved items
Relatedness	Meaningful and supportive bi-directional social connections	Online community and talking points

services or adult mental health services, which deliver multidisciplinary psychiatric care (including medical follow-up, case management and acute psychiatric care as appropriate). Online psychoeducation is also offered to those allocated to enhanced TAU to match the additional support offered to the intervention group. Psychoeducation is beneficial as an adjunctive treatment for depression and is readily translated into web-format.[35] The study team developed a web application called 'Empower Your Mood' (EYM) that includes psychoeducation modules on depression symptoms, causes and course, behaviour and mood, information on diet, exercise, sleep, social support and getting support. In contrast to the *Rebound* platform, EYM is a static website and does not include clinician support or an online community. All modules are available for 18 months to match the *Rebound* intervention's timeframe.

Intervention

Rebound is a complex, multicomponent intervention[23] based on the MOST model.[14 15 24–26] The design of *Rebound* considers SDT principles to best support intrinsic motivation[36] (see table 1). Each component of *Rebound* will be introduced in turn.

Therapeutic content

To scaffold the building of competence, the therapeutic content on *Rebound* is presented in 'bite-size' chunks—thematically related 'activities' that are organised into 'tracks'—that are clustered within 'journeys'. There are five activity types: *comics*, *reflective actions*, *actions*, *talking points* and *pages*. *Comics* are illustrated multipaneled narratives that bring therapeutic concepts to life via recurring characters and story (see figure 1 for an excerpt), *reflective actions* provide a clear prompt for reflection, *actions* suggest a practical step (eg, behavioural experiment), *talking points* prompt young people and peer workers to post their thoughts and reactions to the content, and *pages* summarise each track and provide psychoeducation. Users have the option to save activities to a 'toolkit', so they have an accessible, personalised and labelled bank of strategies when needed.

Rebound includes five 'journeys', each with a different focus: managing depression ('Improve Your Mood'), managing anxiety ('Find Your Calm'), overcoming social anxiety ('Find Your Confidence'), managing insomnia ('Feeling Tired') and enhancing social functioning ('Social Hacks'). There is also one journey based on work and study-related issues. Users can access one journey at a time and on-demand 'Explore' activities alongside their journey.

Participants randomised to the TAU+*Rebound* condition are initially offered the Improve Your Mood journey, which adopts a trans-therapeutical approach to depressive relapse prevention using Mindfulness-Based Cognitive Therapy, Acceptance and Commitment Therapy and Cognitive Behavioural Therapy principles. The Improve Your Mood journey contains over 50 activities, which are available over the 18 months of the trial. The Improve Your Mood journey targets rumination and worry, behavioural inactivation and avoidance by introducing the following strategies: mindfulness, behavioural activation, values, defusion, cognitive restructuring, acceptance, self-compassion and gratitude.

Peer-to-peer online social networking ('the community')

The online 'community' allows young people and peer workers to develop a profile listing their interests ('members' page) and to post text, images and links ('feed' page). On the community feed, peer workers post regularly about their lived and living experience of mental health (see figure 2) and contribute ice breaker–type posts about their interests. When contributing a post to the feed, users also have the option to apply the 'vent' function to the post, which allows users to include certain offensive words (most commonly swear words) that would otherwise be blocked by the MOST system. Vent posts are by default collapsed in the feed so that their viewing is optional, and other users who wish to see such posts are required to click expand to view them. Users may 'react' (eg, 'I get you', 'thinking of you') or comment in response to a post. The community is designed to facilitate social support and enhance relatedness.

The community also includes Talk it Out (TiO), a structured problem-solving function that steps a young person through developing a question (eg, How can I manage stress?), provides an opportunity for the young person to crowdsource solutions and checks in with their progress. TiO was informed by the Social Problem-Solving Framework.[37]

Human support

There are three types of human support (or 'moderation') offered via *Rebound*: clinicians, peer workers and career consultants. These moderators work together to provide care for each user of *Rebound* using SDT-informed

Figure 1 Excerpt of the 'Three Minute Breathing Space' comic.

engagement strategies (see table 2). *Rebound* moderators meet fortnightly as a whole team and weekly in discipline-specific groups to review engagement on the platform

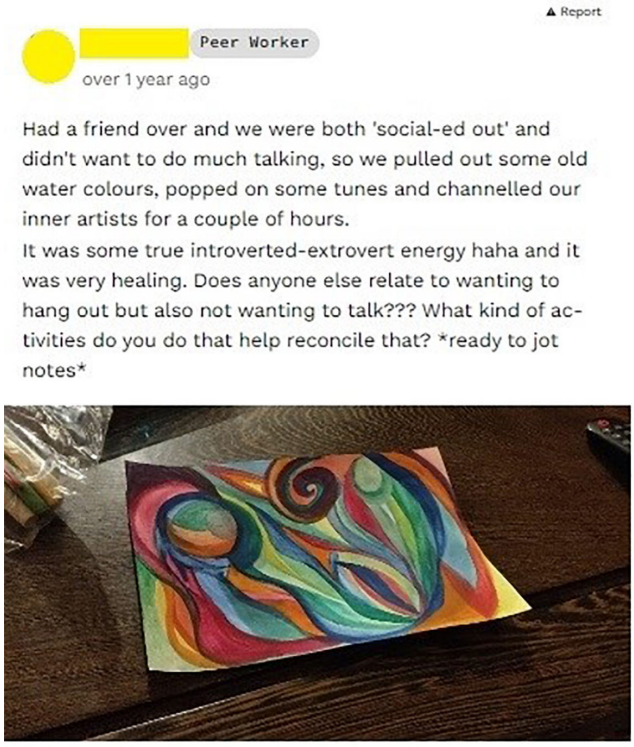

Figure 2 An example community post (de-identified and used with permission).

and revise SDT-related strategies to support motivation. Moderators can also communicate with one another via chat messaging and activity logs on *Rebound*.

Clinicians. Each young person on *Rebound* is allocated a qualified mental health clinician (eg, clinical psychologist, social worker) with experience working with young people. During the initial 'welcome call', clinicians welcome young people to the platform, provide a platform orientation, support goal setting and develop a formulation. After this, clinicians contact the young person weekly for 12 months (via phone/SMS/chat) to support engagement with therapy content, suggest and tailor therapy content, and act as a liaison between the young person and other forms of human support. In their final 6 months, clinicians reduce contact to monthly.

To maintain usability, relevance and uptake of content, clinical moderators tailor journey content to each user's immediate needs. Tailoring is also based on the user's remission status. For example, for participants who are actively depressed, activities related to behavioural activation/motivation, sleep hygiene and avoidance may be prioritised, while those in full remission may focus on mindfulness, values/strengths, wellness planning and developing their toolkit. Cognitive strategies (ie, restructuring, defusion) and self-compassion are addressed regardless of remission status. Users may also choose to switch to a different journey in consultation with their allocated clinician.

Importantly, the clinician monitors the clinical status of young people in their caseload and conducts twice-daily safety checks of the platform. The clinical team

Table 2 Self-determination theory (SDT)-informed engagement strategies[22]

SDT concept	Strategies[22]	Relevance to moderation on *Rebound*
Autonomy	Use non-judgemental language that suggests, rather than demands. Note sources of internal and external pressure. Encourage the user to develop their own understanding of their mental health. Provide a clear rationale for suggestions. Explore the user's values and aspirations. Provide choices (including the choice not to change). Encourage experimentation with new skills, with debriefing.	Clinical formulation development. Encouraging reflection in 1:1 interactions. Moderation team being mindful to not place pressure on user in interactions. Explore sources of internal/external pressure in 1:1 interactions, particularly with peer work/clinicians. Create culture within moderation team of speaking to one another non-judgementally and then spread culture to platform. Apply strategies to goal setting on platform. Link journey/platform engagement to values. Develop shared rationale for journey/platform engagement. Provide choices about goal setting, journey tailoring, mode and frequency of contact. Support engagement in reflective actions. Encourage light, fun and experimental actions.
Competence	Discuss barriers and how to overcome them. Clarify goals. Support the user to set realistic goals. Validate progress being made. Support the user to develop a plan to meet their goals. Encourage the user to self-monitor progress. Explore dealing with unhelpful internal and external pressure.	Ensure user knows that you are figuring out the barriers together—reduces power imbalance. Complete part of journey with user to identify and troubleshoot barriers in real time. Clinicians help user to identify what they expect of themselves and encourage consideration of what they have capacity for. Peer workers share experiences of process of change. Clinicians and career consultants help user to set personalised and realistic goals on a realistic timeline. Clarify differences between long-term and short-term goals. Clarify differences between goal-setting on MOST vs other types of support (eg, face-to-face). Career consultants provide feedback on resumes and cover letters. Clinicians provide encouragement and validation when progress made (eg, completion of activities). Clinicians provide feedback on reflective actions and skill development (eg, mindfulness); user identifies strengths through questionnaire, and moderators can identify and point out strengths in action. Setting realistic amounts of activity on platform per day (eg, 2 min, one activity) in order to meet longer term goals (eg, complete journey). Using non-controlling language, acknowledging the present 'capacity' of the user. Reminding them of when they have overcome pressure in the past. Encouraging them to explore what is internal/external pressure. Ask questions to prompt reflection on why they are doing what they're doing—align with core values. Provide a rationale for why we are asking user to engage. Acknowledge pressure that can be experienced. Provide information about work rights. Encourage boundaries.
Relatedness	Respect the user's perspective. Encourage the user to ask questions. Demonstrate unconditional positive regard. Demonstrate genuine interest in the user. Listen empathetically. Check the user's available supports and link them in to support where needed.	Provide validation and empathy in all interactions. Validate before jumping to problem-solving. Encourage user to ask questions of moderators and in the community, particularly using TalkitOut. Encourage self-reflection on progress. Build trust so that user feel comfortable asking questions. Regularly ask if user have any questions. Unconditional positive regard in all interactions. Genuine interest in all interactions. Offer choices for types of support. Check in on supports later in user's time on platform. Assess supports during welcome call/initial interactions with user. Career consultants refer user to external supports and resources as needed.

meet weekly for peer supervision. Clinicians complete fidelity checklists bi-monthly and discuss their self-identified strengths and weaknesses during supervision to strengthen fidelity to the moderation model and processes.

Peer workers. Peer workers are trained young people with lived and living experience of mental ill-health. Peer workers are integral to the provision of social support via *Rebound*—a proposed mechanism of action in the study (eg,[38] Peer workers moderate the online 'community' and chat with young people on the platform. Peer workers also lead monthly online 'hangouts' to reinforce connections. The peer work model is also designed to normalise experiences, counteract stigma, and promote platform engagement.

Career consultants. Career consultants provide specialised support for work and study issues via phone and chat including support with job applications, interviews and career assessments.

Safety protocol

The safety protocol is comprised of three levels of security including: (1) system and privacy protection; (2) online safety and (3) clinical safety.

The *Rebound* platform is hosted on an Amazon Web Services web server. Amazon Web Services and Orygen Digital meet standards of responsible business practice. Identity management and networking are handled by Orygen Digital's Engineering Department according to Orygen (National) Standards, which meet Australian research requirements. In addition, MOST has a wide range of measures to secure the application and database against unauthorised access. These measures conform to industry best practice as defined by the Open Web Application Security Project (www.OWASP.org). Privacy and online safety are managed in accordance with the Australian Communications and Media Authority.

At onboarding, the *Rebound* clinician carries out an initial orientation with *Rebound* participants, including details of the terms of use. Participants are required to accept and comply with the guidelines for safe use of *Rebound*. When needed, participants are offered guidance on appropriate usage of the system. All users are asked to nominate an emergency contact person, such as a close family member. *Rebound* includes a 'report function' that enables young people to report a concern about any material posted by a user. The moderator assesses the report and responds accordingly, which may include removing material and, in some cases, deactivating or restricting the poster person's account. Participants are also able to hide their profile and activity should they become concerned about their privacy.

Clinical risk is managed through both manual and automated procedures. First, clinical moderators monitor the system two times per day on weekdays and one time per day on weekends for evidence of clinical risk or deterioration. Any detected increased risk activates the *Rebound* risk and safety protocol, which includes one or more of the following: a risk assessment with the young person, informing the research team, alerting the emergency contact nominated by the participant and liaising with suitable emergency services where necessary. In addition, the system incorporates visible emergency guidelines and contact information. Finally, *Rebound* includes an automated keyword detection function, which activates each time a participant posts a contribution indicative of clinical risk or that contains potentially offensive words. The function blocks posts with notifications sent to the young person and the moderator, who can 'unblock' the post should they determine it unproblematic.

In the event of a clinically significant deterioration of symptoms, increased risk of suicide or a hospital admission, a clinical moderator performs an assessment to determine the risks and benefits of a temporary withdrawal from *Rebound*. Based on this assessment, and in consultation with the young person, the clinical moderation team determines whether their account is temporarily suspended, or their level of access is restricted. Following suspensions or restrictions to a user's account, the clinician will contact the young person at monthly intervals to ascertain whether the account is to be reactivated.

Outcome measures

Multiple methods will be employed to assess study outcomes (see table 3). These include independent observer ratings, self-report and usage data from the *Rebound* system.

Primary outcome and measure

The primary outcome is *relapse rate* (accumulated over 18 months) of MDD. Relapse will be defined as a return, for at least 2 weeks, of symptoms sufficient to meet DSM-5 criteria for MDD (as determined by the SCID-5-RV)[34] at any time in the 18 months post randomisation. This definition of relapse is the one most commonly used in clinical studies.[39] Measurement of relapse will be carried out every 3 months (ie, at 3, 6, 9, 12, 15 and 18 months). Telephone administration of the SCID is a valid method for measuring MDD.[40] Data from the Quick Inventory of Depressive Symptomatology Self-Report[41] may also be used to supplement the SCID assessment. A number of strategies will be embedded to promote participant retention, including a generous assessment window, flexible availability of RAs, minimal data collection at most timepoints and honing RA interview skills to minimise time commitment at larger assessment points.

Secondary outcomes and measures

Secondary outcomes and measures include:

1. *Depressive* symptoms will be measured by the QIDS self-report instrument[41] monthly for 18 months.
2. *Time to relapse* will be derived from the SCID-5-RV (Module A: Mood Episodes) at 3, 6, 9 12, 15 and 18 months.
3. *Time to remission* will be derived from the SCID-5-RV (Module A – Mood Episodes) at 3, 6, 9, 12, 15 and 18 months.

Table 3 Schedule of outcomes and measures

	Screening/ baseline	3 months	6 months	9 months	12 months	15 months	18 months
Primary outcome and measure							
Relapse of MDD (SCID-5-RV: depression module)	x	x	x	x	x	x	x
Secondary outcomes and measures							
Depressive symptoms (QIDS-SR)	Monthly						
Time to relapse (SCID-5-RV: depression module)	x	x	x	x	x	x	x
Time to remission (SCID-5-RV: depression module)	x	x	x	x	x	x	x
Rate of remission (SCID-5-RV: depression module)	x	x	x	x	x	x	x
Time in remission (SCID-5-RV: depression module)	x	x	x	x	x	x	x
Anxiety (GAD-7)	x		x		x		x
Vocational status (RUQ)	x		x		x		x
Cost-effectiveness (RUQ)	x		x		x		x
Therapeutic mechanisms and measures							
Mindfulness skills (FMI)	x		x		x		x
Self-compassion (SCS-SF)	x		x		x		x
Social support (SPS)	x		x		x		x
Rumination (RRS-SF)	x		x		x		x
Exploratory outcomes and measures							
Stress (PSS)	x		x		x		x
Social anxiety (LSAS)	x		x		x		x
Loneliness (UCLA Loneliness Scale)	x		x		x		x
Self-efficacy (Self-Efficacy Scale)	x		x		x		x
Self-esteem (Rosenberg SES)	x		x		x		x
Social and general functioning (SOFAS)	x		x		x		x
Suicidal ideation and attempts in past 6 months (CSSRS)	x		x		x		x
Deliberate self-harm (Risk Taking and Self-Harm Inventory†)	x		x		x		x
Psychological well-being (BPNSS)	x		x		x		x
Quality of life (AQoL-8D)	x		x		x		x
Behavioural activation (BADS-SF)	x		x		x		x
Sleep quality (PSQI)	x		x		x		x
Strengths use (SUS)	x		x		x		x
Medication adherence (RUQ)*	x		x		x		x

Continued

Table 3 Continued

	Screening/ baseline	3 months	6 months	9 months	12 months	15 months	18 months
Substance use (ASSIST)*	x		x		x		x
Digital phenotype (AWARE-Light)	Continuous						
Affective and cognitive reactivity and social support (SEMA3 application)	Daily						
Intervention group-only outcomes and measures							
Intervention acceptability (qualitative evaluation via semistructured interview)							x
Therapeutic alliance (WAI-C, WAI-T)	x		x		x		x
Intervention use (ie, frequency, duration, pattern)	Continuous						

*Potential covariates.
†Risk Taking and Self-Harm Inventory for Adolescents.
AQoL-8D, Assessment of Quality of Life - 8 Dimensions; ASSIST, Alcohol, Smoking and Substance Involvement Screening Test ; BADS-SF, Behavioural Activation for Depression Scale-short form; BPNSS, Basic Psychological Needs Satisfaction Scale; CSSRS, Columbia-Suicide Severity Rating Scale; FMI, Freiburg Mindfulness Inventory; GAD-7, Generalized Anxiety Disorder 7-item scale; LSAS, Liebowitz Social Anxiety Scale; MDD, major depressive disorder; PSQI, Pittsburgh Sleep Quality Index; PSS, Perceived Stress Scale; QIDS-SR, Quick Inventory of Depressive Symptomatology-Self-Report; RRS-SF, Ruminative Responses Scale - short form; RUQ, Resource Use Questionnaire; SCID-5-RV, Structured Clinical Interview for DSM-5 Disorders, Research Version; SCS-SF, Self-Compassion Scale Short Form; SEMA3, Smartphone Ecological Momentary Assessment; SES, Self-Esteem Scale; SOFAS, Social and Occupational Functioning Assessment Scale; SPS, Social Provisions Scale; SUS, Strengths Use Scale; UCLA, UCLA Loneliness Scale (Version 3); WAI-C, Working Alliance Inventory client version; WAI-T, Working Alliance Inventory therapist version.

4. *Rate of remission* will be derived from the SCID-5-RV (Module A – Mood Episodes) at 3, 6, 9, 12, 15 and 18 months.
5. *Time in remission* will be derived from the SCID-5-RV (Module A: Mood Episodes) at 3, 6, 9, 12, 15 and 18 months.
6. *Anxiety* will be measured by the Generalized Anxiety Disorder 7-item scale[42] at baseline, 6, 12 and 18 months.
7. *Vocational status* will be self-reported by participants at baseline, 6, 12 and 18 months (including the participant's report of employment and educational activities in between assessments).
8. *Cost-effectiveness* will be assessed using a self-reported Resource Use Questionnaire (RUQ) to determine the broader resource use of participants (eg, community mental health services, hospitalisations, work and educational impacts) and the Assessment of Quality of Life - 8 Dimensions (AQoL-8D) questionnaire, which measures health-related quality of life and can be used to calculate quality-adjusted life years (QALYs).[43]

Measures of therapeutic mechanisms

Therapeutic mechanisms include: *mindfulness skills*, measured by the Freiburg Mindfulness Inventory;[44] *self-compassion*, measured by the Self-Compassion Scale Short Form;[45] *rumination*, measured by the Ruminative Responses Scale-Short Form;[46] and *social support*, measured using the Social Provisions Scale.[47] Measures are administered at baseline, 6, 12 and 18 months.

Other measured outcomes

Additional exploratory outcomes, potential covariates and intervention-only outcomes are outlined in table 3.

Data analysis and management

Sample size

Sample size was determined by power analysis using G*Power 3. The primary outcome is difference in accumulated relapse rate over 18 months. A previous relapse prevention study in youth MDD reported a relapse rate at an 18-month follow-up of 62% for TAU and 36% in the relapse prevention group (OR=2.9).[48] Since *Rebound* will be compared against an enhanced TAU, we assume a smaller effect (OR=2.5), for which a total sample of 192 people is required to achieve 85% power (alpha=0.05). A total of 255 participants will be recruited, allowing for a 25% attrition rate. This compares favourably with the attrition rates in the *Rebound* pilot (7%) and is comparable at an 18-month follow-up to the Horyzons RCT (25%).[14 15]

Data management

The RPMS is used to manage all outcome data. The RPMS includes an electronic Case Report Form (eCRF). The RAs record participant-level data on an eCRF. These data are subsequently entered into the eCRF section of the RPMS. Self-report data are entered directly by the participant. The RPMS is accessed using a secure website

and is stored on a secure server. It is designed to maintain the privacy and confidentiality of participant information and to ensure the integrity of the data. Access to RPMS is restricted to study personnel, and the level of access is dependent on the person's role.

Analysis of outcomes

Primary analyses will be undertaken on an intention-to-treat basis. Group differences in accumulated relapse rate at 18 months (primary outcome) will be tested using Fisher's exact test. The Cox proportional hazards regression model (survival analysis) will be used to model time to relapse and rate of remission in each group, which will also be used to derive the hazard function reflecting the instantaneous probability of relapse/remission at any time over the 18-month follow-up.[49] Finally, group differences (*Rebound* plus TAU vs enhanced TAU) in change over time in the continuous secondary outcomes across the 18-month follow-up will be examined using random-effects models. Random-effects models allow for estimation of between-person differences (ie, group effects) in within-person slopes (ie, change trajectories in secondary outcomes) and are the preferred methods for analysing clinical trial data.[50]

Mechanism of action analyses will be conducted using a multilevel structural equation modelling framework to assess mediation.[51] Specifically, person-specific slopes representing change over time in the proposed mechanism-of-action variables will be examined as mediators of the effect of treatment group (*Rebound* vs control) on risk of relapse.

Additional analyses will use multiple imputation to assess the robustness of the findings to the choice of method for handling missing data. Additional comparisons between treatment groups based on completers-only analyses will be conducted. Analyses will be undertaken in accordance with The International Council for Harmonisation (ICH) 9 guidelines including a full analysis as well as per protocol set. The per protocol sample will be defined based on receiving a prespecified minimal exposure to the online intervention (ie, more than 16 logins over the 18-month intervention period).

The economic evaluation will comprise a cost-consequences analysis comparing the incremental costs of the *Rebound* platform (vs treatment as usual) to a wide range of incremental study outcomes (eg, QALYs, relapse rate). Inclusion of the AQoL-8D questionnaire facilitates the derivation of QALYs and enables a cost-utility analysis to be undertaken. A study-specific RUQ was adapted for this study from another RUQ frequently used in Australian mental health-related economic evaluations.[52] The RUQ encompasses: community-based health service use; hospitalisations; accommodation services; medication and diagnostic tests; impacts on education and employment; and other relevant services. Best practice within-trial economic evaluation methods will be adopted[53]; and the comparative cost-effectiveness of the *Rebound* platform (vs treatment as usual) will be summarised using the incremental cost-effectiveness ratio metric (eg, cost per QALY). If the *Rebound* platform is found to be effective, then the lifetime and population cost-effectiveness of the intervention will be evaluated using modelling techniques.

Monitoring

Adverse events will be recorded throughout the trial and serious adverse events will be reported to the sponsor (Orygen). The study was assessed as low risk by the sponsor, and a trial management group will be established in place of a data monitoring committee. The sponsor monitoring plan includes an initial monitoring visit early in the recruitment phase which will determine the ongoing monitoring schedule. Discontinuation of the study will be considered where:

- A participant attempts suicide, and it is highly likely that the attempt was caused by the Rebound intervention.
- There are repeated instances of participants notifying moderators about triggering or distressing content posted by other users.

Decisions about study discontinuation will be determined by the trial management group in consultation with the sponsor.

DISCUSSION

Accessible, timely and evidence-based treatments are imperative to meet the demands of the present youth mental health crisis.[4 54] Rebound is a complex digital intervention;[23] unique in its length (18 months); engagement principles (using SDT-informed strategies and a multidisciplinary approach); and presentation of youth-friendly, third-wave mindfulness-based content. It is the first accessible, scalable treatment to prevent relapse in youth MDD, addressing a major gap in public youth mental health services. The study includes: an active control group, an extended follow-up, cost-effectiveness analysis and evaluation of theory-driven mechanisms of action. This is likely to advance models of relapse in youth depression and inform future intervention development.

Furthermore, the findings of this study serve to advance our knowledge of digital adaptations of mindfulness-based approaches and how to best engage young people online and prevent depressive relapse. If the trial is successful, there is a clear translation pathway for findings to the rollout of MOST.[13] Recruitment of trial participants was finalised in September 2023. Follow-up assessments will conclude in March 2025.

Dissemination

Findings will be made available through scientific journals and forums and to the public via social media and the Orygen website. De-identified individual participant data will be available after publication for 3 years via the Health Data Australia catalogue (https://www.researchdata.edu.au/health). Requests must include a methodologically

sound proposal. Specific conditions of use may apply and will be specified in a data sharing agreement (or similar) that the requester must agree to before access is granted (online supplemental file 1). Study protocol, informed consent material and statistical analysis plan will also be available.

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Contributors MA-J is the guarantor. MA-J is the principal investigator, initiated and designed the trial, and has oversight and responsibility for the whole trial. JG jointly oversees the conduct of the trial, and brings expertise in evaluating novel digital youth mental health interventions. SNM and DC contributed equally—both drafted the manuscript and led the teams responsible for intervention delivery and recruitment and data collection, respectively. All authors contributed to the design of the trial and critically revised the protocol manuscript. Authors brought specific expertise in MDD and other serious mental health conditions in youth (CD, SR, HH, CG-B, SH, SB), self-determination theory (RMR), behavioural activation (AP), information systems research and development (RL), and digital psychological interventions for mood disorders and strengths-based approaches to mental disorders (GM). In addition, SDA led the passive sensing component of the trial, CM and YYL led the economic evaluation of Rebound, PR and JP contributed to content development, BP is the site investigator for Orygen headspaces, SR is the site investigator for the Youth Mood Clinic, LV led the qualitative analysis, VL led the primary statistical analysis and PK led the EMA component of the trial.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, conduct, reporting or dissemination plans of this research. Refer to the Methods section for further details.

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Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Title	Preventing relapse of major depressive disorder in youth: RCT of a novel mindfulness-based cognitive online social therapy
Short Title	Rebound
Project Number	2018.217
Project Sponsor	Orygen National
Coordinating Principal Investigator	Professor Mario Alvarez
Principal Investigator	(Insert Site PI)
Study Coordinator	Mrs Daniela Cagliarini
Location	• (Insert locations)

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you are receiving treatment at (site) and have been identified as having experienced depression.

The aim of this research project is to test a new website designed to assist young people in their recovery from depression. The new website is called Rebound.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the assessments and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend, your case manager or your doctor.

Your participation is voluntary

Your participation in this study is completely voluntary and there will be no cost to you. If you do not want to take part in this study you do not have to. You should feel under no obligation to participate in this study. Choosing not to take part in this study will not affect your current and future medical care in any way.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to have the tests and treatments that are described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

The researchers have developed a new online program, called Rebound, for young people recovering from depression. The program was co-designed with young people who have experience of mental illness and has been successfully pilot tested. This means a small number of people tested Rebound so that we could find out if it was practical and safe to do a larger study. This program includes some of the features of websites that you may already be familiar with along with some important new features. For example, it allows the user to display their own profile and communicate online with other young people who have experienced depression, in the Rebound online 'community'. This is a private online space which is only open to young people who have been treated at a participating centre.

There are online moderators in Rebound, based at Orygen National (Melbourne), whose job is to help users make the most of the system and to encourage a positive and supportive experience. In addition, there are peer support workers who are young people who have personal experience of mental illness and who are available in Rebound to provide encouragement and share their own experiences. Also it will be up to each user whether or not they use their real name but everyone on the system will be a real person, including the moderators.

As well as being a social networking website the program also includes lots of online therapy material. This therapy content has been specially designed to help young people recover from depression, and the aim is that users can complete these in their own time. The therapy journeys include information and interactive activities about depression, how to identify and use personal strengths, how to build your social confidence, how to stay well, and many other topics.

We have designed Rebound because we believe it is important to have a resource that young people recovering from depression can use when and where it is convenient for them. Also, we thought it would be helpful for young people if they could share their experiences and receive positive encouragement from others going through similar experiences.

Because we do not yet know if Rebound is effective in helping young people recover from depression, we are comparing Rebound with the effects of receiving online information about depression and recovery that doesn't include therapist or peer support. In order to make this comparison we will be allocating 50% of participants in the study to Rebound plus usual care and 50% of participants in the study to receive the online information plus usual care. Each participant who consents to participate will have an equal chance of being in each of these two

groups.

This research has been initiated by researchers from Orygen National, The Australian Catholic University, and The Department of Computing and Information Systems at The University of Melbourne. This research has been funded by a grant from The National Health and Medical Research Council (NHMRC).

3 What does participation in this research involve?

This trial is being conducted under the "Teletrials" model. This means that while you will receive your usual treatment at (site), your participation in the study will involve visits via teleconference or phone with study team members at Orygen National, the lead trial site.

Study Design

If you agree to participate you will be taking part in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random). This is also a blind study, which means that the study research assistant will not know which group each participant has been allocated to. Your treating team will know which treatment you are receiving. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

Consent

You will first have a meeting with the study research assistant, who will explain the study to you and answer any questions you may have. You will be provided with this document to take home and read. You will be given time to decide whether or not you would like to participate. You can talk to your treating team, your family or friends. If you do decide that you would like to take part, you will be asked to sign the consent form at the end of this document.

Screening and Baseline Assessment

To determine whether or not you are eligible for the study, you will be asked to take part in an interview with the study research assistant who will ask some questions about the symptoms you have been experiencing, as well as asking specific questions that will help them find out relevant information about you. These assessments and interviews are referred to as the screening assessment.

Once you have completed the screening assessment and this initial assessment indicates that you are eligible for this study, you will then complete what is referred to as a baseline assessment. The baseline assessment is a more thorough interview to help research study staff better understand the symptoms you have been experiencing and includes questions that measure symptoms of depression, social wellbeing and functioning, psychological wellbeing, perceived stress levels, worry, quality of life, self-efficacy, social support, loneliness, satisfaction with life, sleep, use of personal strengths, and mindfulness skills. The research assistant will also ask about your use of medications, other substances, and health services. Together, the screening and baseline assessment is expected to take around 2 hours. You can take breaks as needed, or the interview can be scheduled over two appointments.

Group Allocation

Once the questionnaires and interviews have been completed you will be informed whether you have been allocated to Group 1 or Group 2. You will have an equal chance of being allocated to either group.

If you are one of the first participants to join the project you may not have access to Rebound immediately. Rebound will launch after enough people have been recruited in order to make sure that there is sufficient online activity.

Group 1

If you are allocated to Group 1 you will have access to all of your usual treatments in addition to having access to Rebound. Rebound will be available until the end of the study. Participants in this group will be provided with log-in details to access Rebound, and complete an online orientation to the system to help you get the most out of using Rebound. The moderator will then contact you via phone to answer any questions and discuss how you can make the most of Momentum.

You will be able to use Rebound from any computer, tablet or mobile phone that has internet access. It is up to you when and how often you log on and what you do when you log on. However, based on prior experience and research, we believe it is most helpful to spend a little bit of time on Rebound at least 4-5 times a week and to practice strategies at other times when you're not online. If you stop using Rebound for a while we will call you to see how you are going. So that we can keep Rebound a safe and private program there will be some rules that all users will be expected to follow, such as being respectful to other users and keeping messages in Rebound confidential.

Please note that inappropriate use of the Rebound system (e.g. derogatory or disrespectful statements) may lead to your Rebound account being temporarily or permanently suspended. It is also important to note that online moderators will monitor Rebound twice a day during weekdays and once a day during weekends and on public holidays. Therefore, Rebound has not been designed and is not equipped to respond to emergency situations. Details of who to contact in an emergency are provided within the Rebound system.

Group 2

If you are allocated to Group 2 you will have access to all of your usual treatments in addition to having access to a website with information about depression and recovery, called Empower your Mood. This website will not include expert or peer moderation, or social networking features.

Follow up assessments

All participants, no matter which group they are in, will be asked to meet with the study research assistant to repeat some of the questionnaires at 6, 12 and 18 months after your initial study interview. These follow-up meetings will take approximately 1.5 hours. In addition, each participant will be asked to complete a short online assessment every month and a phone assessment every 3 months, in between face-to-face interviews, to assess symptoms of depression. These assessments will take up to 15 minutes.

Group 1 only assessments

If you are allocated to Group 1, you will be asked to complete a questionnaire about your online moderator one month after you get access to Rebound and again at 6, 12 and 18 months. You may also be asked to complete an interview about your experience of using Rebound at the end of the study. This interview will be audio recorded and transcribed into written text via a video conferencing platform.

SEMA

Participants owning a smartphone will also be asked to use a mobile application, called SEMA, which will administer a short questionnaire, including questions about current mood and social interactions, once per day for the first 12 months of your involvement in the study. The survey will be sent at the same time every evening at a time suitable to you. You will receive an initial notification to complete a questionnaire and up to 2 reminders approximately 45 and 88 minutes later. You will have up to 90 minutes to complete the survey. Each SEMA questionnaire will take approximately 2 minutes to complete. We understand that completing a survey each day may be not possible or desirable for all participants so you can let us know if you need to take a break from this.

Reimbursement

There are no additional costs associated with participating in this research project, nor will you be paid. All treatment and tests required as part of the research project will be provided to you free of charge.

At each of the four face-to-face interviews, you will be reimbursed $30 per hour for your time, up to a maximum of $60 per interview. Additionally, you will be reimbursed for time taken to complete the SEMA questionnaires (30c per survey), the online and phone questionnaires about depression symptoms ($5online survey and $10/phone survey).

Optional Research Activities

Passive Sensing

All participants will have a choice to opt into an additional part of this project, which involves the collection of data through a “passive sensing” application. Passive sensing describes the way someone uses their personal devices (i.e. smartphone). If you decide to take part in this part of the study, sensors that may be tracked on your phone are detailed below:

- Applications: Captures the applications being used on the smartphone.
- Communication: Captures the number of incoming/outgoing calls and SMS messages, without recording the content of these calls or messages.
- Locations: Captures your location.
- Screen usage: Captures when you lock/unlock your phone and use the screen, including time and duration of phone use. This sensor does not capture what is on the screen at any time.
- Screen interaction: Captures when you use the keyboard, without recording what is typed. This sensor also captures when you click and scroll on your smartphone.
- Battery level: Captures your device’s battery level.

We would like to collect passive sensing data for the first 9 months of the study. You will have the option to select precisely which smartphone sensors you want to activate and share with the research team and which ones you do not want to activate and share. You will also be able to select duration and timing of sensing (by turning the application on and off). Someone from the research team will show you how to do this. You will have the option to withdraw from this aspect of the study at any point, in which case the application would be uninstalled from your smartphone and no further data would be collected. The data collected through this passive sensing app will be compared to the other information collected, such as mood and wellbeing, will help researchers understand the relationship between these activity patterns and symptoms of ill-health.

Health Data Linkage

To analyse the cost-effectiveness of Rebound, we would like your permission to retrieve health data through the relevant data linkage agency in your State of residency. This will include, but is not limited to, the total number of times you have been admitted to hospital over the 18 month participation period.

Medicare and PBS

We will also ask you to fill out a separate consent for the use of your Medicare and Pharmaceutical Benefits Scheme (PBS) data. Medicare collects information on your doctor visits and lab tests while the PBS collects information on the prescription medications you have filled at pharmacies. This information helps us understand costs that may be different due to the study group to which you are assigned. This separate consent is sent securely to the Department of Human Services who holds this information confidentially. At the end of the study, your Medicare and PBS data will be linked to your other study information for analysis.

Future Research

Finally, we would like your permission to use the data we collect for this study (excluding MBS and PBS data) for future research projects that are closely related to this project but are not described here. This might include a student Honours, Masters or PhD project where the student wishes to look more closely at a specific part of the Rebound study. By giving us permission to do so, you will help us to maximize the outcome of our research effort. If you agree, we will not recontact you about the future project your data is used for. Any project using the data will have been approved by a Human Research Ethics Committee (HREC). The data will only be used in a coded way and researchers will not have access to your personalised data.

Optional Feedback Sessions

Meet ups

All participants allocated to group 1 maybe invited by online moderators or peer workers to meet other Rebound users at meet-ups. The purpose of these meet-ups is for Rebound participants to meet the Rebound designers and other participants as well as to share your views, experiences and suggestions using the website. Your attendance at the Rebound meet-ups will be entirely optional and will not affect in any way your ability to access the Rebound program. The Rebound meet-ups will take place at a suitable time for participants via video conferencing service. At some of these meet-ups you will be asked to participate in a focus group lasting approximately 30 minutes where the group will be asked about their experience of using Rebound. These sessions will be audio-recorded if you give your permission. During the Rebound meet-ups participants will also be asked to complete a brief questionnaire about their experience using Rebound.

4 Other relevant information about the research project

We plan to involve approximately 255 young people in this study. There are two groups involved in the study: Group 1 and Group 2. Both groups will have full access to all of their usual treatments and all of the appropriate treatments that are available in the community after your treatment ends.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not impact your routine treatment, your relationship with those treating you or your relationship with your treating service.

6 What are the alternatives to participation?

You do not have to take part in this research project to continue to receive treatment. Apart from Rebound there are other online programs currently available for mental health concerns (such as *Moodgym*) though they do not involve online social networking. You can discuss these options with your treating team. You can also discuss the options with your doctor.

7 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits from participating in Rebound may include increased social functioning (such as increased confidence with friends) and reduced risk of experiencing a relapse of depression. In addition, by participating in this study, regardless of which group you are in, you will be assisting the researchers to find out if Rebound can assist young people in their recovery from depression.

8 What are the possible risks and disadvantages of taking part?

Counselling can sometimes have unintended side effects and online therapy has some specific risks. Rebound has been designed to be a private social networking site, however, it is important to understand that no website is completely “hacker proof” so there is an extremely small chance that the privacy of Rebound users could be put at risk. Other risks to privacy could include Rebound users passing on details of other Rebound users, for example via the Internet. For these reasons we are encouraging all participants who are allocated to Rebound to think about whether they use their real name or an alternative name and to keep their name confidential so that only the Rebound moderators are aware of their personal details.

It is also possible that Rebound users might communicate things in the social network that may upset others. For this reason we have set up a “report button” in Rebound so that any user can let the moderators know about anything offensive or upsetting that has been posted. If you become concerned about how Rebound is being used by other users you can also contact us by phone to report your concerns or provide feedback via Rebound.

Whilst all care will be taken to maintain privacy and confidentiality of information shared at the Rebound workshops, you may experience embarrassment if one of the group members were to repeat things said in a confidential group meeting.

You should also be aware of your personal safety when interacting with other people in an online community. For your safety we recommend that all users of the Rebound program follow cybersmart safety precautions. The Rebound website will contain a link to cybersmart information.

If you become upset or distressed as a result of your participation in the research, the researcher is able to arrange for counselling or other appropriate support. The Rebound website will provide telephone numbers that you can call for personal assistance if you become distressed. Any counselling or support will be provided by staff who are not members of the research team, for example your treating clinician or, after you have been discharged from the service, another mental health practitioner in the community. In addition, you can suspend or end your participation in the research at any time.

If you are allocated to Rebound and you become unwell during the research project, the research team may speak with you about taking a break from your involvement with Rebound

until your health has improved. The team may also discuss this with your treating doctor or other health professional.

This research project involves the collection of information about your use of drugs. The questionnaire may reveal that you have previously used illegal drugs. That information will be stored in a re-identifiable (or coded) format. In the event that the research team is required to disclose that information, it may be used against you in legal proceedings or otherwise.

Because Rebound is unlike any other therapy programs, there may be additional risks that the researchers do not expect or do not know about. Tell a member of the research team immediately about any problems you experience as a result of participating in this research project.

9 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the research team will tell you about it and discuss with you whether you want to continue in the research project. If you decide to continue in the research project, you will be asked to sign an updated consent form.

Also, on receiving new information, the research team might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons.

10 Can I have other treatments during this research project?

Whilst you are participating in this research project, you may continue to use any treatments or supports you have been accessing for any condition or for other reasons.

11 Withdrawal from the study

If you do consent to participate, you may withdraw at any time. You can withdraw either from the whole study, or only from the part of the study relating to your MBS and/or PBS claims information. If you decide to withdraw from either the whole research study or only the MBS and/or PBS part of the study, please notify a member of the research team. You will need to complete and sign the 'Participant Withdrawal of Consent Form' which is provided at the end of this document. This form should be completed and supplied to the research team. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study coordinator and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the research team up to the time you withdraw will form part of the research project results. If you do not want this to happen, you should not join the research project.

12 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable effects of Rebound
- Rebound being shown not to be effective
- Decisions made by the investigators or local regulatory/health authorities.

13 What happens when the research project ends?

If you are allocated to Rebound it will be available to you until the study ends (estimated to be July 2022). You will have ongoing access to all of the currently available treatments in the community. We expect that the research project will take a total of 4 years to complete, ending in the second half of 2022. If you wish to receive information about the findings of the project, please indicate this to the research team and a summary of the study results can be provided to you at the conclusion of the project. Please note that we are not able to provide you with individual research results.

Part 2 How is the research project being conducted?

14 Storage, retention and destruction of your information

By signing the consent form you consent to the study research assistant and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Information collected by the research assistant will be stored in a secure computer file and in a locked filing cabinet at Orygen National in a non-identifiable format for a period of at least 25 years after the final publication arising from the study but may be kept indefinitely.

If you are allocated to the Rebound group your deidentified data will be linked to your Rebound account and will be accessible to the online therapist. This may help the online therapist better understand how you are doing and help to guide the treatment you are offered.

Confidentiality

We aim to keep all the information that we collect in the assessments strictly confidential. However, there are some exceptions to this: 1) information from the assessments may be communicated with your treating doctor/case manager/clinician to ensure that you receive the best care possible; 2) if we are concerned about risk to you or to someone else, we may need to discuss this with your treating doctor/case manager/clinician at the service where you receive treatment; 3) if as a result of the information you disclose in the interview relating to past trauma or abuse, we believe that someone else may be at risk. In some cases, we may contact the Department of Health and Human Services about risk to children under the age of 17 years. Mandatory reporting laws require us to report to Department of Health and Human Services any suspected cases of child abuse and neglect (Victorian Crimes Act 1958 Sect. 327). In cases where abuse is reported, information gathered by researchers is passed on to your clinical team and the appropriate clinical procedures normally used within your clinical service are implemented. This may involve reporting abuse to Department of Health and Human Services or other support services. We will try to the best of our ability to discuss this with you first.

Rebound Website

The Rebound website will be stored on an Amazon Web Services web server. The Rebound website collects usage statistics where the researchers will be able to track, if you are allocated to Rebound, which aspects of the program you have used and how often you have logged on.

Cloud Storage

Your study data (excluding MBS/PBS data) will be stored in the Cloud. “In the Cloud” refers to servers in a data centre that are managed by a third party and accessible through the Internet. When storing your study data, we will replace your name with a unique code on all your study data. The coded data will be encrypted and stored on a secure Cloud server to prevent

improper access.

SEMA

Responses to questions asked via the SEMA application will be stored in a completely de-identified format on the server of the Melbourne eResearch Group (MeG) at The University of Melbourne.

If you are allocated to the Rebound group, your deidentified data will be linked to your Rebound account and will be accessible to the online therapist. This may help the online therapist better understand how you are doing and help to guide the treatment you are offered.

Passive Sensing

If you opt into the passive sensing part of this research project, data collected via the passive sensing application on your smartphone will periodically synchronise its sensing data with a central database stored on the Melbourne School of Engineering IT servers. All passive sensing data will be encrypted to ensure participants safety and confidentiality.

Medicare and PBS

Your MBS/PBS data will be retrieved from DHS at the end of the study and will be provided in a non-identifiable format. Data held on removable storage media (such as a USB stick or CD/DVD) will be stored in a locked filing cabinet initially at Deakin University then at Orygen National. Data stored electronically will be stored on the Deakin University server. All data will be password protected and the only people who will have access to this non-identifiable data and password will be the individual/s responsible for the conduct of the analysis of this data.

Your MBS/PBS data will be safely destroyed in accordance with the 'DHS ICT Asset and Media Sanitisation Cyber Security Branch Policy and Standard' after 7 years from the publication of the projects' final report or after 10 years from the date of supply, whichever is sooner. A record of this will be kept in the study trial master file (TMF) which is held at Orygen National.

Audio Recording

Any audio recordings and transcriptions of the Rebound meet-ups, focus groups or user experience interview will be stored in a secure computer file at Orygen National.

Data Sharing

Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. At times, a participant may choose to participate in more than one research project at Orygen National, OYH or headspace. In such cases, we ask that the data collected (excluding MBS/PBS data) as part of one research project may be shared with other research projects conducted at Orygen National, OYH or headspace, provided that you have consented to participate in each one individually. As many of the same measures are used across different projects, the purpose of sharing data is to prevent unnecessary repetition of assessments and ensure that participation in both projects is as simple as possible for the participant. Data collected will not be shared between current research projects unless you have signed a formal written consent form for each respective project.

Health Records

Information about you may be obtained from your treating team and from your health records held at your treating service and other health services after your treatment ends for the purpose of this research. Information about your participation in this research project will be recorded in

your health records at (site). The research team may also share information gained during this research project with your treatment team. By signing the consent form you agree to the study team accessing your health records if they are relevant to your participation in this research project.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of Orygen National, The Melbourne Health Human Research Ethics Committee, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

Publication

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Information that is published from this study will only include summary information that describes the whole group of participants in this study and not to any individual participant.

Freedom of Information

In accordance with relevant Australian and Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Disclosure of Drug Use

Any information obtained for the purpose of this research project and for future research described in Section 3 that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law. This research project involves the collection of information about your use of drugs. That information will be stored in a re-identifiable (or coded) format. In the event that the research team is required to disclose that information, it may be used against you in legal proceedings or otherwise.

Data Repository
Your data (excluding MBS and PBS data) may be included in a data repository that allows researchers to collect and share coded information with each other. Coded information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things more quickly than before.

This means researchers may send coded information about your study data to a data repository. Researchers who would like to access your data for research purposes would need to request this of the database administrators to obtain access to your study data for research purposes only. These database administrators would know how to protect health and science information and will look at every request carefully to minimize risks to your privacy. It is not known at this stage whether or not the data repository will include national or international members, so by consenting to your data being used for future research, you may be consenting to transfer of your data overseas.

15 Complaints and compensation
The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the following people:

Clinical contact person

Name	Professor Mario Alvarez-Jimenez
Position	Director Orygen Digital
Telephone	0401772668
Email	mario.alvarez@orygen.org.au

If you or have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact the reviewing HREC approving this research:

Reviewing HREC approving this research and HREC Office contact details:

Name	Ms Jessica Turner
Position	Manager, Melbourne Health Human Research Ethics Committee
Telephone	(03) 9342 8530
Email	research@mh.org.au

Complaints contact person

If you have any complaints about any aspect of the project then you may contact:

Name	Insert local contact details
Position	
Telephone	
Email	

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. You can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

If you suffer an injury as a result of your participation in this research project you may be able to seek compensation through the courts. If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

16 Who is organising and funding the research?

This research project is funded by The National Health and Medical Research Council. Orygen National, , The Australian Catholic University and the Department of Computing and Information Systems at The University of Melbourne may benefit financially from this research project if, for example, the Rebound website is commercialised.

You will not benefit financially from your involvement in this research project.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Orygen National, The Australian Catholic University and the Department of Computing and Information Systems at The University of Melbourne, there will be no financial benefit to you or your family from these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

17 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Melbourne Health.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

PICF - Adult MH HREC 2018.217

Consent Form - *Adult providing own consent*

Title	Preventing relapse of major depressive disorder in youth: RCT of a novel mindfulness-based cognitive online social therapy
Short Title	Rebound
Protocol Number	2018.217
Project Sponsor	Orygen National
Coordinating Principal Investigator	Professor Mario Alvarez
Principal Investigator	(Insert site PI)
Study Coordinator	Mrs Daniela Cagliarini
Location	• (Insert location)

Consent Agreement

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I consent to the study team accessing my health record and sharing information with my treating team as relevant to the research project.

I give permission for my doctors, other health professionals, hospitals or laboratories to be contacted by the researchers and to release information to Orygen National, concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I consent to my data being shared between research projects conducted at Orygen National, OYH and headspace provided that I have signed a formal written consent form to participate in each project. I understand that I can withdraw my consent for this to occur at any time without affecting my participation in either study or my future health care.

I understand that I will be given a signed copy of this document to keep.

In addition, please indicate whether you give consent for the following **optional** activities:

I agree to participate in the passive sensing part of this study.

Yes □ No □ Participant Initials:_____ Date:_____

I agree to the collection of my health data through the data linkage agency in my state of residency.

Yes □ No □ Participant Initials:_____ Date:_____

I agree to the collection of my Medicare/PBS data.

Yes □ No □ Participant Initials:_____ Date:_____

I agree to my data being used for future research.

Yes □ No □ Participant Initials:_____ Date:_____

I agree to audio-recording and transcription of any feedback session I attend as part of my involvement in this study.

Yes □ No □ Participant Initials:_____ Date:_____

I agree to my data being included in a data repository.

Yes □ No □ Participant Initials:_____ Date:_____

Declaration by Participant

Name of Participant (please print) _____

Signature _____ Date _____

Witness to the informed consent process

Name (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

PICF - Adult MH HREC 2018.217

Form for Withdrawal of Participation - *Adult providing own consent*

Title	Preventing relapse of major depressive disorder in youth: RCT of a novel mindfulness-based cognitive online social therapy
Short Title	Rebound
Protocol Number	2018.217
Project Sponsor	Orygen National
Coordinating Principal Investigator	Professor Mario Alvarez
Principal Investigator	(Insert Site PI)
Study Coordinator	Mrs Daniela Cagliarini
Location	• (Insert trial site)

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship withmy treating service.

Please tick one of the following boxes:

☐ I wish to withdraw my participation and allow researchers to use all my information provided up until the point of withdrawal.

☐ I wish to withdraw my participation and have all my information destroyed from the whole study, where possible, and have no further participation.

☐ I wish to withdraw my participation and have all my Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS) claims destroyed from the study where possible.

☐ I wish to withdraw my participation but allow my MBS and/or PBS claims collected up to the withdrawal date to continue to be used in the study.

I understand that:

1. no further information about me will be collected for the study from the withdrawal date;
2. my information that has already been collected, and analysed and/or included in a publication, may not be able to be withdrawn or destroyed; and
3. my withdrawal from the study will not affect my access to Health Services or government benefits, and where relevant, will have no bearing on the medical care I receive.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.

This form should be forwarded by email to: daniela.cagliarini@orygen.org.au.
Alternatively, forms can be posted to:

Daniela Cagliarini
Orygen National
35 Poplar Rd, Parkville 3052.