

Safety and Distress Management Protocols.

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Safety, harms and adverse events (AE)

Along with the potential benefits of psychological decentering training, potential harms and adverse events (AEs) experienced during the program will also be assessed. We will actively monitor AEs following a specific protocol based on guidelines recently established by Papaioannou et al. (2024) [BMJ 2024;387: e077418]. This protocol includes two steps: (1) identifying potential harms and (2) documenting potential harms

Recognizing and monitoring potential harms and AEs

1. **Changes in depression severity.** Since participants are at a higher risk of depression, the main expected harm may be a worsening of low mood and negative affect symptoms, to the point that some aspects of the young people's daily life and functioning are affected (e.g., difficulty maintaining friendships or attending school or activities). This outcome may not be directly attributable to the intervention because the risk of clinical deterioration is already higher in this group; subthreshold symptoms are a predictor of later clinical diagnosis.

Monitoring depression severity. Trial outcomes will be monitored for signs of deterioration in depression. Specifically, we will track whether participants' PHQ scores move from the at-risk range at baseline (PHQ scores = 10–14) to exceeding the threshold for a severe clinical presentation (PHQ scores = 20–27) during post-intervention or 6-month follow-up assessments.

2. **Sustained levels of distress.** A second potential harm may be increased self-reported levels of general distress. This may result from participation in a psychological intervention, particularly if some young people have relied on coping strategies such as avoidance, minimization, or distraction. For chronic difficulties, these strategies can provide short-term relief but may contribute to longer-term distress. Psychological interventions that aim to increase awareness of one's difficulties (such as psychological decentering training) can disrupt these strategies and may initially raise distress levels. However, a concern would be the persistence of any such distress over the course of the trial.

Monitoring sustained psychological distress. Additional outcomes will be monitored for signs of general psychological distress. We will track whether participants' WEMWBS scores move into the range associated with very low mental wellbeing (scores <36), particularly among those whose baseline scores were initially in the range typically associated with mild mental health difficulties (approximately 42–47).

3. **Participant-reported negative experiences.** Qualitative interviewing will also help us determine whether an AE is due to the intervention, the trial procedures, or outside factors.

Monitoring participant-reported negative experiences. During mid-intervention check-ins and post-intervention debrief appointments, participants will be asked the following questions: "Since the last assessment, has taking part in the study or

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intervention caused any distress, upset, or negative effects for you?" "Please briefly describe what happened." (Use this at the 3-week phone call and check-in).

Safeguarding and supporting participants

Optional check-ins.

During the briefing, participants will be informed that they can contact the research team at any time to discuss their experiences related to the trial, including concerns about changes in symptom severity, adverse outcomes, and/or harmful experiences. Participants will be given a central email address for the trial, which members of the research team will continuously monitor.

Virtual check-in appointments will be offered with one of the three clinical psychologists (TD, AP, MB). These members of the team are appropriately qualified to provide an initial, brief assessment and offer support, which may guide onward referral to primary care level services if appropriate.

An equivalent appointment will be offered to a young person whose depression severity and/or psychological distress exceed the above-stated thresholds, or where negative experiences are disclosed during the debrief.

This information will be recorded by study staff. Qualitative information gathered will include the nature of harms reported, allowing us to update our approach to recognising and recording harms if new information emerges.

Training and safeguarding

All staff involved in data collection will be trained to recognise and document potential harms associated with the trial. If monitoring indicates a significant escalation in depressive symptoms or psychological distress, the study distress management protocol will be activated (below) . This process will be overseen by one of the two clinical psychologists managing the project (MB and TD). It may include welfare contact and signposting to relevant support services where necessary.

Professional oversight

The Trial Management Committee will meet every three months for the duration of the trial. A standing item on the agenda will be a review of any safeguarding incidents arising, with a precise overview of management and resolution. These meetings provide an opportunity for professional oversight of our safety management procedures as well as peer supervision.

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Distress Management Protocol

FOR ALL PARTICIPANTS:

- Information sheets (ensure that the nature of the study is understood and that the participant's contribution is explained).
- Informed consent / voluntary participation / right to withdraw at any time/confidentiality / Data Protection Act.
- Ascertain the participant's reaction to the study (e.g., what was their opinion, was there anything they disliked, and whether they experienced any adverse effects, including concerns about how they are feeling).
- Check current mood status (ask how they are feeling at this moment, and whether they feel their mood is at, or has returned to, baseline levels). If all is well, the session can end. Otherwise, continue with the steps below.

FOR ONLINE SESSIONS: At the beginning of each session (e.g., briefing, check-in, debrief), confirm the participant's current location and a contact method (e.g., phone/email) in case of disconnection or concern.

ADDITIONAL MEASURES IN CASE OF DISTRESS:

- Provide a reassurance and encourage participants to find a space that is comfortable and familiar
- Participants should be supported in a calm and private environment to allow any adverse effects to settle. For online sessions, participants will be encouraged to remain in a comfortable and safe space. A member of the research team will remain present (via Zoom or equivalent) for as long as needed.
- Provide time to recover and reassurance.
- If the participant remains upset or wishes to talk further, they will be offered the opportunity to speak with a nominated clinical psychologist at a mutually convenient time.

Session management and escalation

If distress escalates during a check in session, the researcher will pause or discontinue the planned agenda as appropriate and focus on supporting the participant's well-being. Where a participant continues to experience distress, they will be offered a timely consultation with one of the clinical psychologists on the research team. This consultation will allow for further assessment and, where appropriate, signposting to relevant supports (e.g., parents/guardians, school supports, or GP).

In cases where there is concern regarding risk of harm to self or others, the research team will follow their legal and professional safeguarding responsibilities, including escalation to appropriate services where necessary.

Loss of contact (online sessions)

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If a participant disconnects during a session and there are concerns about their wellbeing, the researcher will attempt to re-establish contact using the participant's provided contact details. If contact cannot be re-established and there are concerns regarding risk, the safeguarding protocol will be activated.

Follow-up and support

Participants may be offered follow-up contact (e.g., telephone or email) where appropriate to check on their wellbeing and to ensure that relevant supports have been accessed.