Disclosure of Suicidal Thoughts Protocol

PREVENT Policy Statement

GPs are responsible for the on-going clinical care of participants. Therefore, all trial staff directly involved with research participants, including MBCT therapists, have a duty of care to ensure that the GP is aware of any suicidal thoughts expressed by participants.

Researchers must initiate the suicidal thoughts protocol each time a participant expresses potentially significant suicidal thoughts or thoughts of self harm above a certain level. This may be as a result of responses to questionnaire items or the participant may disclose information during an interview that leads the researcher to believe that there are thoughts of suicide or harm to self or others. In both instances, the researcher should inform the participant's GP and notify the site Clinical Lead (or nominated deputy).

Therapists are expected to use their clinical judgement to assess the seriousness of risk and follow normal clinical procedures with respect to communicating disclosure to the participant's GP. Therapists may contact the study team to seek advice from the Clinical Lead and/or to determine history of previous disclosure. Therapists **must** communicate any disclosure made to GPs to the trial manager.

Symptoms of depression include low self-esteem, feelings of hopelessness, thoughts of self harm, and suicide ideation, particularly with severe episodes. Consequently, the questionnaires administered to trial participants include items to detect these thoughts. Participants may also disclose information during an interview or therapy session leading the researcher/therapist to believe that there is potentially a significant suicidal risk. It is important that participants discuss these thoughts with an appropriate health professional to ensure access to necessary support.

In the case of PREVENT, GPs are responsible for the on-going clinical care of participants. Therefore, researchers and therapists have a duty of care to ensure that the GP is aware of any potentially significant suicide ideation expressed by participants.

It is expected that therapists will use their clinical judgement to assess the seriousness of risk and follow normal clinical procedures with respect to communicating disclosure to the participant's GP. In addition, therapists may contact the study team to seek advice from the clinical lead and/or to determine history of previous disclosure. Therapists must communicate any disclosure made to GPs to the trial manager.

Researchers are not clinically trained and should receive adequate training/supervision and work within their competence. If a participant discloses any potentially significant thoughts of suicide or self-harm, researchers should complete a Suicidal Thoughts Report (below) and inform the participant's GP of the nature of information disclosed.

Definition of 'Potentially Significant Suicidal Thoughts'

In the PREVENT study, significant suicidal thoughts are identified by:

1. A response of 2 or above to question 9 (suicidal thoughts or wishes) on the **BDI** questionnaire.

Q9.
0. I don't have any thoughts of killing myself
1. I have thoughts of killing myself, but I would not carry them out
2. **I would like to kill myself**
3. **I would kill myself if I had the chance**

OR

2. A rating of 3 or above on the **GRID-HAMD** question number 3.

Q3. Suicide
This past week, have you had any thoughts that life is not worth living, or that you'd be better off dead? What about having thoughts of hurting or even killing yourself?
0. Absent
1. Feels life is not worth living
2. Wishes he/she were dead or any possible thoughts of death to self
3. **Suicidal ideas of gesture**
4. **Attempts at suicide**

OR

3. Patients who disclose information during the **SCID** interview (face-to-face or telephone) that they have had recurrent thoughts of death or suicide at a similar level to those described in items 1 and 2 above.

OR

4. Information disclosed at any other time that would indicate significant suicidal thoughts

Researcher Action required

Before conducting an assessment with a participant (either telephone or face-to-face), the researchers should review all previous data on suicidal thought and ensure that contact details for the site Clinical Lead (or nominated deputy) are current. When assessments are being conducted over the telephone it is important that the researcher has accurate information about where the participant is calling from so that if needed this can be forwarded to the participant's GP and/or emergency services.

Whenever a researcher becomes aware that a participant has thoughts of suicide, the researcher should reinforce the importance of maintaining a dialogue with his/her GP and ask for permission to pass the information to his/her GP. Suggested scripts can be found in Figure 1.

If the participant agrees to this communication, the researcher should telephone the participant's GP within 48 hours* to pass on the information obtained. If the participant's GP is not available then the researcher should ask to speak to the duty doctor. The researcher should make it clear to the GP that no clinical risk assessment has been performed and that clinical responsibility for the study participants remains with the GP. A letter counter-signed by the site Clinical Lead should be sent to the GP confirming this notification. A copy of this letter should be filed in the Participant Contact File. If the participant does not agree to their GP being informed, the researcher should contact the site Clinical Lead to discuss.

The researcher will also complete a Suicidal Thoughts Report (below) and files this in the Participant's Research File. This report should not contain any information that could identify the patient.

*If the participant discloses something to the researcher that leads them to believe the participant to be in immediate danger of acting on suicidal thoughts, the researcher must immediately contact the participant's GP. If it not possible to speak to the participant's GP the researcher should request to talk to the duty GP. If the assessment is being conducted outside of office hours the researcher should contact the Crisis Team. Once this contact has been completed, the researcher should contact the site Clinical Lead to inform them of the situation. If possible, this contact should be made whilst the participant is still with the researcher, if this is not possible the researcher must make every effort to obtain a contact telephone number and address for the participant.

If the assessment is being carried out over the telephone there are instructions at the end of this protocol detailing how to call another person using a VOIP phone without cutting off the participant.

A letter should be sent to the participant's GP, copying in the participant, detailing the disclosure made and the resulting action taken.