



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 (Appendix A) 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 (Appendix A) 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.

Figure 1: Researcher Action Required – including suggested scripts

Participant Discloses Potentially Significant Suicidal Thoughts:
 1) Qu9 on BDI ≥ 2 OR 2) Qu3 on GRID-HAMD ≥ 3 OR 3) Criteria 9 on SCID indicating significant suicidal thoughts OR 4) Anything else disclosed that would indicate significant suicidal thoughts

Is the participant in immediate danger of acting on suicidal thoughts?

YES

I am very concerned for your safety and feel it's very important that we contact your GP/someone who can help (if Crisis Team) to ensure that you receive some immediate support to help you with these very troubling thoughts you are having.

If on telephone: Are you OK to stay on this line whilst I do this? If not, what number can I reach you on in the next 10 minutes?

Immediately contact participant's GP, or Crisis Team if outside of hours detailing content of disclosure. Ensure you have a method to contact the participant if they are not with you.

- 1) Contact Site Clinical Lead to inform them of action taken
- 2) Complete a Suicidal Thoughts Report
- 3) Send GP a letter, counter signed by Clinical Lead detailing information disclosed and action taken

No

I am concerned about some of the things you have told me. Have you spoken to your doctor about them? It is important that your doctor knows about the way you feel, as s/he will be able to make sure that you have the necessary support in place. Are you happy for me to mention to him/her the things you have told me?

Patient Agrees to you contacting GP:

- 1) Complete a Suicidal Thoughts Report
- 2) Telephone GP within 48 hours detailing information disclosed
- 3) Send GP a letter, counter signed by Clinical Lead detailing information disclosed

Patient now Agrees to you

Patient DOES NOT Agree to you contacting GP:

Many people find it hard to bring these things up during a consultation, but your doctor can offer you help with these feelings. If he/she knows how you are feeling, he/she will be able to talk to you about it and together you can decide on the best way to treat you.

If patient continues to refuse:

That's fine, but as I am not a medical doctor, I do have to let my clinically qualified colleague who is a member of the trial team know about the way you are feeling. If it is alright, he/she might want to talk to you for a few minutes about the way you are feeling.

Contact Clinical Lead who make contact with the participant and their GP



Appendix A Suicidal Thoughts Report – File in Research File

Participant ID (Do not include any identifiable information): _____ Date: _____

Time period: Telephone Screen / Baseline / Rand Assessment / MBCT+1month / 9m / 12m / 18m / 24m

BDI suicide item score:

Hamilton suicide item score:

Suicide risk information:

Include whether the participant has reported any of the following:

- *History of previous suicide attempts*
- *Current suicidal ideation*
- *Suicide plans / preparations*
- *Escalation in suicidal ideation*
- *Protective factors*
- *Regular contact with GP?*

Date reported: ____/____/____

Additional notes / actions taken:

*As part of the PREVENT protocol, suicide risk is **managed** by the patient's GP.*

Date action taken: ____/____/____

Researcher: _____ Signed: _____ Date: ____/____/____

Clinical Lead: _____ Signed: _____ Date: ____/____/____



Appendix B - GP Risk Letter – Copy filed in Patient Contact File

Surgery Address

Date

Dear Dr _____

POTENTIAL SUICIDE RISK

Re: Participant Name _____ DOB

As you know, PATIENT NAME, is taking part in the PREVENT trial comparing mindfulness-based cognitive therapy with antidepressant medication for the treatment of recurrent depression. As part of this research I speak with him/her on a number of occasions to assess his/her wellbeing and depressive symptoms. I am writing to update you about our discussions/meeting today.

As part of the assessment we ask about depression using a standardised interview and questionnaire. PATIENT NAME reported that he / she(verbal report / score on relevant item). I have not undertaken a formal assessment with PATIENT NAME but I have recommended that he / she arrange to make an appointment to come and see you to discuss this further.

As ever, the clinical management of this patient remains your responsibility, but it is part of our study protocol to inform you of any suicidal thoughts disclosed to ourselves so that you can take account of them in your clinical management of this patient.

Yours sincerely,

Site Researcher

Supervised by Site Clinical Lead

Cc: Participant



Contact Details – Exeter Based Researchers

Willem Kuyken – Clinical Lead
Office: 01938 724659
Mobile: 07985050583

Alison Evans – Lead Therapist
Office: 01392 725755
Mobile: 07974813469
Home: 01271 378368

Claire Brejcha
Mobile: 07792157735

Jenny Wilks
Mobile: 07976 418 532
Home: 01803 865047

Richard Byng
Mobile: 07765 400752
Home: 01803 762249

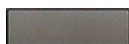
Crisis Team: Exeter
Crisis Resolution Home Treatment Team (East and Mid Devon)
07968 845048

Please note, this number is to make an urgent referral to the Crisis Team and should not be given out to participants / clients / members of the public under any circumstances. The participant's / client's GP can also make an urgent referral to the Crisis Team and should be the first port of call.

Setting up a Conference Call

Use the Conference feature to initiate a conference call for a group of three to six people including yourself. The maximum number of people supported in a conference call depends on the IP Phone configuration.

Conf



1. During a call, press the **Conference** key to place the party on hold.

You hear a dial tone.

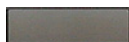


2. Dial the number of the person to add to the conference call.

Alternatively, instead of dialing a number, you can press the **Directory** key, and use the **Corporate Directory** or **Personal Directory**, **Redial List**, and **Callers List** to find and dial the number of the person you want to add to the conference call.

You can talk to the called person privately without being heard by the party on hold.

Conf



3. Press the **Conference** key again to connect all parties.



(Goodbye)

4. If the party you attempt to add to the conference is unavailable, press the **Goodbye** key.

The attempted call ends.



5. Press the line (DN) key beside the flashing icon to return to your original call.