1. RESPOND SELF-HARM RISK PROTOCOL

1.1 OVERVIEW

Risk of self-harm is defined as:

a) a score of 2 or 3 in the relation to question 10 on the EPDS ***'The thought of harming myself has occurred to me:'***. An answer of ***'Sometimes'*** scores 2 and an answer of ***'Yes, quite often'*** scores 3.

b) The outcome of the suicide intent questions on the CIS-R is:
   i) **CIS-R SUICIDE INTENT:** Patient feels life isn't worth living
   ii) **CIS-R SUICIDE INTENT:** Patient has had suicidal thoughts
   iii) **CIS-R SUICIDE INTENT:** Patient has had suicidal plans

Whenever these instances occur, or if at any time, the researcher believes that there is a significant risk of a patient who is participating in the study self-harming that has not been communicated to their GP, the researcher will consult the Centre's PI or nominated deputy if unavailable.

The PI or deputy will examine the patient's data and if it is considered necessary, will assess the patient. If it is concluded that there is a significant risk, the patient's GP will be notified **with or without** the patient's consent. However, the PI or his deputy would contact the GP without first assessing the patient him/herself if the situation was urgent, again with or without the patient's consent.

1.2 ACTION

At EPDS-2

On receipt of the EPDS-2 questionnaire, the research associate will screen woman's response to item 10 relating to self-harm to assess risk. Regardless of consent status or total EPDS score, women who score 2 or 3 should be contacted by the researcher and the Self-harm Pro forma outlined below should be actioned. If for any reason the woman cannot be contacted, the researcher should inform the centre's PI or nominated deputy to discuss.

At the Home Visit interview

After the woman has completed the baseline questionnaires, the research associate will screen woman's response to item 10 on the EPDS0 questionnaire and the outcome of suicide intent questions on the CIS-R questionnaire. If risk of self-harm as defined in 1.1 is evident, the Self-harm Pro forma below should be actioned regardless of whether the woman is eligible to continue to randomisation.

Women eligible to continue in study:

If the woman agrees for the information to be passed to GP, randomisation should be delayed until woman's response has been discussed with GP and the GP is happy for the woman to participate in the study.

If the woman does not agree for information to be passed to GP, randomisation may proceed but the researcher should delay randomisation until they discussed with PI if they have any concerns about the woman's intent.

4-, 18-, and 44-week follow-up points after randomisation

On receipt of an EPDS questionnaire, the research associate will screen woman's response to item 10 relating to self-harm to assess risk. Women who score 2 or 3 should be contacted by the researcher and the Self-harm Pro forma outlined below should be actioned. If for any reason the woman cannot be contacted, the researcher should inform the centre's PI or nominated deputy to discuss.

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RESPOND SELF-HARM ACTION PRO FORMA

If at any time-point during the study period, a woman expresses risk of self-harm is as defined above the following procedure MUST be implement:

a) The RA should contact the woman as soon as possible and advise her to discuss these thoughts with her HV/GP. If this is the first-time that woman has expressed these thoughts or if the GP has not previously been informed, offer to pass this information to the HV/GP concerned. (see suggested script).
b) If the woman agrees, the HV/GP should be contacted by telephone to discuss and giving the option of withdrawing the woman from the study.
c) If the woman refuses to give her permission, the researcher should notify the PI who will then decide the next course of action.
d) The attached ACTION PRO FORMA form should be completed by the researcher, signed by the PI, and stored with the woman's confidential data.
e) If the woman cannot be contacted, the RA should inform the centre's PI or nominated deputy to discuss.

Suggested script

Thank you for completing the questionnaire we sent recently. It is a big help and it allows us to see how women feel in the weeks/months following the birth of their baby.

EPDS-2 script e.g.
The answers you gave suggested that you were feeling a bit down when you filled it in. I was wondering whether I could come and see you at home, to find out how you are feeling now. This will involve you completing a couple more questionnaires to see how you are feeling now. If you are still feeling low, the next part of our study might be suitable for you.

You may remember that the next part of the study is comparing two treatments that are helpful for women who are feeling low after having a baby. I can go through the study in more detail when I see you at home, but did you have any questions about it now?

When would be a convenient time to come and visit you? The appointment shouldn't take more than an hour.

I notice that during the last few weeks you have had thoughts of harming yourself and I wondered how you are feeling now?

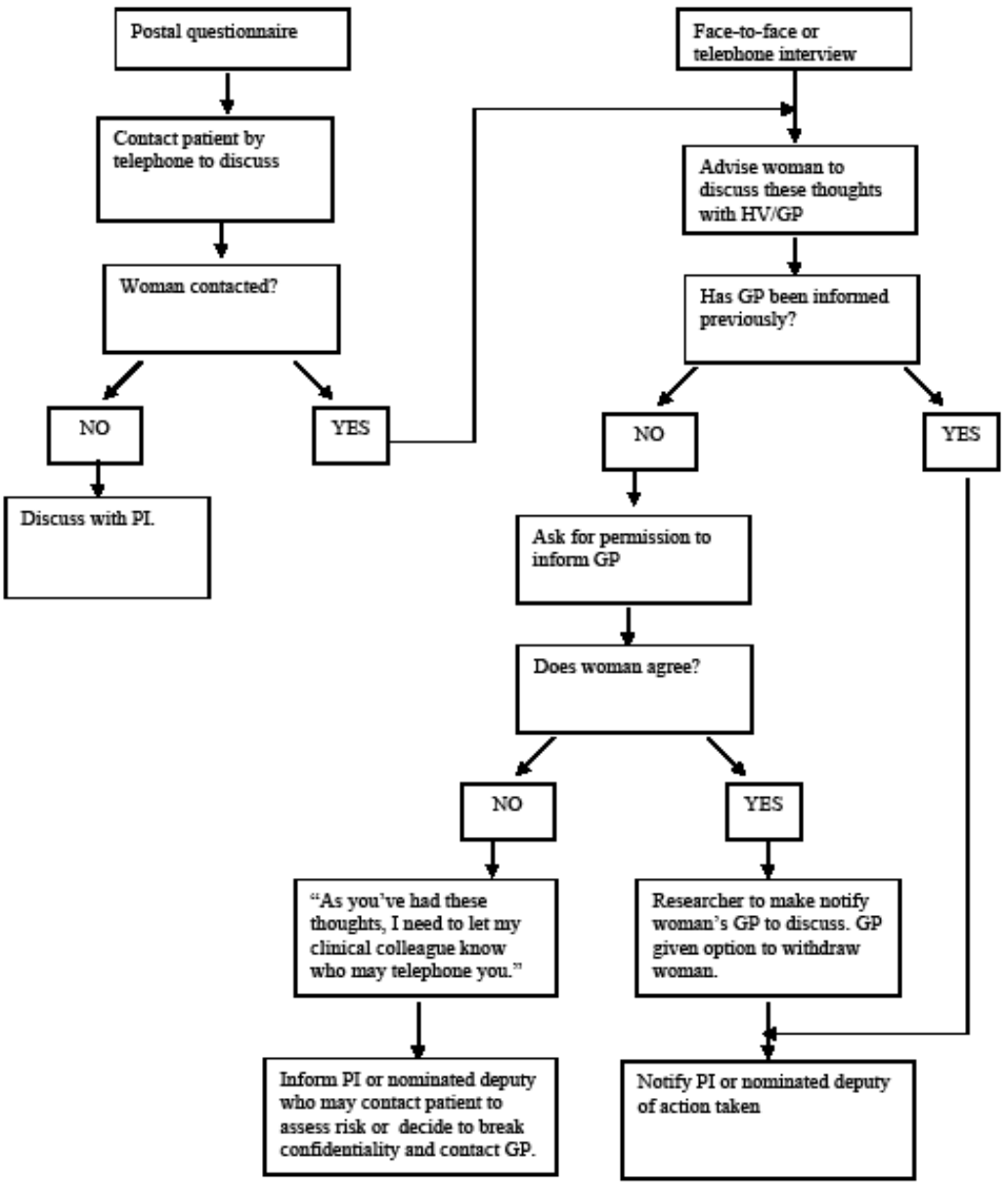
I will pass this information on to my clinical colleague in charge of the study and she/he may want to call you just to check that you are ok. It is also a good idea to talk to your own doctor or health visitor about these feelings, but sometimes it is a bit difficult to bring the subject up. If you like I can contact your health visitor or GP and let them know how you are feeling.

RESPOND SELF-HARM ACTION PRO FORMA

Risk of self-harm is defined as a score of 2 or 3 in the relation to question 10 on the EPDS or the outcome of the suicide intent questions on the CIS-R is one of the following:

a) CIS-R SUICIDE INTENT: Patient feels life isn't worth living
b) CIS-R SUICIDE INTENT: Patient has had suicidal thoughts
c) CIS-R SUICIDE INTENT: Patient has had suicidal plans

If at any time point during the study period risk of self-harm has been expressed by a woman either in postal, telephone or face-to-face interview then the following action must be taken and recorded by the researcher:



*** Nominated Bristol PI Debbie Sharp 0117** xxx-xxxx **& Deputy Glyn Lewis 0117** xxx-xxxx