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**ADEPT Standard Operating Procedure: Adverse Events**

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**Approved by:** ADEPT Trial Management Group

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## 1. Purpose

1.1. To describe the procedure for responding to and reporting adverse events, should any occur during the ADEPT trial.

1.2. "Adverse events" refer to:

1.2.1. A significant episode during or shortly after treatment (e.g. suicide, suicide attempts, mental health related hospital admissions) which if related to or directly caused by treatment amount to harm or severe harm

1.2.2. A sustained and clinically significant deterioration i.e. a worsened mental state after therapy is complete, which can include the emergence of new symptoms. For the purposes of the present study this would be reflected in a categorical negative change in scores on 1 or more of the depression measures used in the study across 2 follow-up points

1.2.3. Report of a negative experience of the psychological intervention and perceived harm on the part of the participant when interviewed for the nested qualitative study.

1.2.4. "Serious adverse events" refer to untoward occurrences that:

1.2.5. (a) result in death;

1.2.6. (b) are life-threatening;

1.2.7. (c) require hospitalisation or prolongation of existing hospitalisation;

1.2.8. (d) result in persistent or significant disability or incapacity;

1.2.9. (f) are otherwise considered medically significant by the investigator.

1.3. It should ensure that participants in ADEPT do not come to harm as a result of the study.

## 2. Scope

2.1. This SOP outlines the correct procedure for responding to adverse events and in ADEPT.

2.2. This SOP applies to all University of Bath, University of Bristol and University of Newcastle research staff, as well as NHS staff in Avon and Wiltshire Partnership Foundation Trust and Northumberland, Tyne and Wear Foundation Trust staff involved with the trial.

## 3. Related documentation

3.1. 'ADEPT procedure guide'
3.2. 'Adverse Events Record Form'

## 4. References

4.1. Parry, G.D., Crawford, M.J. and Duggan, C. (2016) Iatrogenic harm from psychological therapies-time to move on *British Journal of Psychiatry* **208:** 210-212.

## 5. Responsibilities

5.1. It is the responsibility of researchers and clinical staff to identify any adverse event or serious adverse event which they believe may have occurred as a result of the trial intervention or the research process.

5.2. On notification of an adverse event which may be related to the research process or intervention, a researcher or member of site staff should complete an adverse event report form within five days of the event. A note should also be added on RIO (see ADEPT RIO guide for local area).

5.3. On notification of a serious adverse event which may be related to the research process or intervention, a researcher or clinician should report the Chief Investigator Ailsa Russell on a.j.russell@bath.ac.uk.

## 6. Procedure for Adverse Events

6.1. Adverse event record form to be completed within 5 working days, paying specific attention to information regarding the nature and timescale of events i.e. when the event started, were there any specific changes to medication or behaviour preceding the event. Further information should be requested from the participant, clinical team or GP as necessary. A completed form should be securely sent to the Chief Investigator for review and assessment of relatedness and expectedness as follows:

6.1.1. Confirmation of seriousness (whether the adverse event is an adverse event or serious adverse event)

6.1.2. Causality – i.e. relatedness of the event to the study intervention, according the following definitions:

6.1.2.1. *Unrelated* – where an event is not considered to be related to the study intervention

6.1.2.2. *Possibly* – although a relationship to the study intervention cannot be completely ruled out, the nature of the event, the underlying disease, concomitant medication or temporal relationship make other explanations possible

6.1.2.3. *Probably* – the temporal relationship and absence of a more likely explanation suggest the event could be related to the study intervention

6.1.2.4. *Definitely* – Known effects of the study intervention, or based on challenge testing, suggest that study intervention is the most likely cause.

6.1.3. Expectedness of the event. Is the event an anticipated event even if the research had not been taking place?

## 7. Procedure for Serious Adverse Events

7.1. All Serious Adverse Events will be reported to the Chief Investigator within 24 hours of awareness of the Serious Adverse Event. All Serious Adverse Events that occur in relation to the intervention must be recorded, together with data including date of onset and resolution, outcome, severity and causality for the intervention.

7.2. All Serious Adverse Events of a related and unexpected nature will require onward reporting to the main REC, and this will be facilitated by the Chief Investigator, in accordance with any procedures of the Sponsor.

7.3. Related and unexpected Serious Adverse Events will be immediately reported to the Sponsor. In addition all investigators will be notified, and the Trial Steering Committee will be notified in accordance with Sponsor procedures and timeframe. Serious Adverse Events which after review are not thought to be treatment related will be brought to the Trial Steering Committee's attention at their next scheduled meeting. The numbers and details of Adverse Events and Serious Adverse Events will be reported to the Trial Management Group and Trial Steering Committee regularly.

**ADEPT Adverse Events Record Form**

*The research team are required to report quickly to the Main Research Ethics Committee (REC) any Serious Adverse Events (SAE) that may be related to the study intervention. Any SAEs not related to the study intervention or non-serious adverse events must also be monitored. To enable us to do so, please let us know immediately of any adverse events occurring to study participants and indicate if you think it is related to participation in the study.*

*Serious adverse events are defined as fatal, life-threatening, resulting in persistent or significant disability or incapacity, resulting in or prolonging hospitalisation, or those which are deemed by the reporter as medically significant.*

This form should be used at every follow-up session.

**Ask the participant: Have you had to seek help or medical help from any services since we last met?**

IF YES and this constitutes an adverse event, complete the form.

ADEPT participant number

Date Event Started

Date Event Stopped

Please describe the event, any treatment given and the outcome

Relationship to intervention: i.e. relating to activity scheduling in guided self-help

Please indicate why you consider this event to be serious (tick all that apply)

- Patient Died ❑
- Life Threatening ❑
- Involved inpatient hospitalisation ❑
- Involved persistent/significant disability/incapacity ❑
- Other significant medical issue ❑

Significant distress experienced ❑

Not a Serious Adverse Event (SAE) ❑

Date researchers notified

How notified (i.e. participant/carer/follow-up/withdrawal)

Name of person recording SAE

Reviewer name (AR/SB)

Seriousness of event

Serious Adverse Event ❑

Non-serious Adverse Event ❑

Relationship to event

Unrelated ❑

Unlikely to be related ❑

Possibly related ❑

Probably related ❑

Definitely related ❑

Unable to assess ❑

Expectedness of event to study intervention

Expected ❑

Unexpected ❑

N/a ❑

Action Recommended

Only SAEs that are probably/definitely related to the intervention and are unexpected should be reported to the REC and Sponsor within 7 days of the research team being notified.

Date reported to DMC

Date reported to TSC

Date reported to Sponsor

Date reported to REC