Adverse Events and Serious Adverse Events

Adverse Event (AE): *Any untoward medical occurrence in a study participant.*

Serious Adverse Event (SAE): *Any untoward and unexpected medical occurrence or effect that:*

- *Results in death*
- *Is life-threatening [refers to an event during which the participant was at risk of death at the time of the event; it does not refer to an event which might have caused death had it been more severe in nature]*
- *Requires hospitalisation, or prolongation of existing hospitalisation*
- *Results in persistent/significant disability or incapacity*
- *Is a congenital abnormality or birth defect*

Expected AE/SAE

There are no expected AE's/SAE's. Any planned treatments at the start of the study will not be considered as AE's/SAE's.

Related AE/SAE:

The AE/SAE resulted from administration of any of the research procedures (causal to the research process or intervention).

There are no AE's/SAE's expected to be related specifically to the study intervention, although there may be events related to increased physical activity e.g. cardiovascular/musculoskeletal. However, study recommendations for physical activity are in line with the current, widely publicised UK government guidelines. However, the physical activity leaflet and main trial information sheet given to participants state that any increase in physical activity should be gradual and advises participants to contact their GP if they have any concerns or feel unwell as a result of increased physical activity (including experiencing severe breathlessness, chest pain, fainting or dizziness).

Reporting responsibilities:

Where the adverse event meets one of the above categories for an SAE, an SAE form should be completed by the MI counsellor, GP or research team member and faxed to the WILMA Trial Manager within 24 hours of becoming aware of the event. SAEs will also be recorded on the 6-

month follow-up questionnaire and follow-up CRFs (i.e. hospitalisations in the preceding 3 months at each time point). In addition, we will ask patients to contact the research team directly by telephone if they are hospitalised at any point during the trial: a member of the research team will then complete an SAE form on the participant's behalf.

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Evaluating and reporting:

The WILMA Trial Manager and the Chief Investigator and the clinical member of the team will assess the nature of the SAE for causality and expectedness. Following the initial report, follow up data may be requested by the WILMA Trial Manager. Where the SAE and is both related and unexpected, the WILMA Trial Manager will notify the Chair of the TSC and the main REC within 15 days of receiving notification of the SAE. All SAEs will be recorded and reported annually to the main REC. A standard template will be used to record SAEs.

Risk of harm

MI counsellors will also be asked to notify the study team directly should they be concerned at any time that a participant has, or is likely to cause significant harm to themselves: the study team will then inform the participant's GP. MI counsellors will be asked to inform the appropriate authorities directly should they become concerned at any time that a participant has, or is likely to cause significant harm to others.