**Appendix 1: Advice for all participants in the TARS study**

**(including Support as Usual and Intervention participants).**

 

As you know, the TARS study is for smokers who wish to reduce their smoking but not quit.

As part of our duty of care we offer the following guidance to all participants in the TARS study.

1. Health experts agree that the best thing to improve health and prevention of many diseases in the future is to quit smoking.
2. To quit smoking the best approach is to set a quit date, and use the local Stop Smoking Services (ADD LOCAL WEBSITE URL HERE – see links below) who can provide behavioural support and nicotine replacement therapy i.e., gum, patches, lozenges), or can refer to a GP to prescribe Champix or Zyban. Alternatively, you may wish to ask your GP or nurse, or pharmacist about the options.
3. You may also be interested in the use of e-cigarettes and vaping which can help smoking reduction and cessation. Local e-cigarettes and vaping shops, as well as the internet can provide more information. The charity ASH provides some guidance on their use at: <http://ash.org.uk/stopping-smoking/ash-briefing-on-electronic-cigarettes-2/> Please contact your local TARS researcher if you would like to receive a paper copy of this guidance.
4. Physical activity can help prevent weight gain when quitting smoking and reduce cravings, as well as helping to deal with stress and low mood.

Appendix 2. Additional details regarding the reporting of TARS adverse events.

Of the seven SAEs in the intervention arm, three were hospitalisations (i.e. cardiac arrest; childbirth; elective hernia repair), one was a significant medical event (suicide attempt) and one was a report of persistent incapacity (mental health crisis whereby the participant was unable to leave the house).

Of the two SAEs reported in the control group, there was one death (‘bleed to the brain’) and one hospitalisation (cardiac arrest).

Note that SAE reporting requirements were revised after the trial had started, to withdraw the original requirement to report hospitalisations for planned/elective procedures (e.g. surgical and medical procedures, and investigations). We include here the two hospitalisations for planned/elective procedures reported prior to the change in SAE reporting requirements. There were an additional 67 participant-reported hospitalisations (62 participants) deemed non-reportable according to the revised reporting protocol, 26 in the intervention arm and 41 in the control arm.

Table of Serious Adverse Events classified by MEDdra System Organ Class (n=7 SAEs, n=7 participants)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Allocation** | **Classification** | **Summary of event** | **MEDdra System Organ Class** | **Principle Investigator’s assessed relatedness** | **Outcome of SAE at time of****report** |
| SAU | Hospitalisation | Hospitalised with cardiac arrest | Cardiac disorders | Unrelated | Recovered |
| Intervention | Hospitalisation | Hospital admission after cardiac arrest | Cardiac disorders | Unrelated | Recovered |
| Intervention | Significant Medical Event | Attempted suicide | Psychiatric disorders | Unlikely  | Ongoing |
| Intervention | Persistent/significant disability/incapacity | Participant cited a 'mental breakdown' and unable to leavethe house. | Psychiatric disorders | Unlikely | Ongoing |
| SAU | Death | Sudden and unexpected death. Cause of death given as 'bleed to the brain'. | Nervous system disorders | Unrelated | Death |
| Intervention | Hospitalisation | In hospital for caesarean delivery of twins | Pregnancy, puerperium & perinatal conditions | Unrelated | Recovered |
| Intevention | Hospitalisation | Planned elective surgery for a hernia, which subsequentlybecame infected. | Surgical and medical procedures | Unrelated | Recovered |