



## Serious Adverse Events

Thank you to those sites who have been reporting SAEs.

Just a reminder that participants are in the trial for 12 months from the date they were consented. SAEs therefore need to be monitored during this entire period, regardless of whether sites are in the intervention or control arm of the trial.

If you are unsure as to whether an event constitutes an SAE, please do get in contact with us before completing the form. Please provide us with the patient ID and details of the event.

**Handy tip:** Your patients should be flagged as being part of the trial on your systems if at all possible to facilitate prompt SAE reporting. If this is not possible please ensure that routine reviews are conducted of your trial patients.

SAEs can be related or unrelated to the trial and include any hospital inpatient stay.

## Site staff FAQs

*Can I prescribe other treatment for my patients who are in the TRIUMPH study for their LUTS e.g. medication, secondary care referral?*

Yes, please do continue with usual care for these patients regardless of whether they are in the intervention or control arm. We will collect data from their medical records after they have completed their 12 month questionnaire to review what care they have received for their LUTS during the trial. This also includes referrals to secondary care for their LUTS.

*My control patients are asking about the trial and when they will receive the booklet, what shall I say?*

All participants in the control arm will receive the booklet when the results of the trial are published. We will provide them with a lay summary of the trial results with the booklet.



### *Who can I contact about the trial?*

Please get in touch with the trial management team at the University of Bristol on:

**[triumph-study@bristol.ac.uk](mailto:triumph-study@bristol.ac.uk) or 0117 331 4519**

Trial managers: Jo Worthington/Jess Frost

Trial administrator: Charlotte McDonald

*Treating Urinary symptoms in Men in Primary Healthcare using non-pharmacological and non-surgical interventions (TRIUMPH)*

*This project is funded by the National Institute for Health Research Health Technology Assessment Programme (HTA) (16/90/03). The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA, NIHR, NHS or the Department of Health.*