

**PAEDIATRIC AUTISM COMMUNICATION TRIAL – GENERALISED
(PACT-G)**

ISRCTN: 25378536
NIHR REFERENCE: 13/119/18

Statistical Analysis Plan
Amendment to Version 1.2
Amendment: 07/12/2019

This SAP has been written based on Protocol V6

Trial Statisticians: Prof Andrew Pickles, Professor Richard Emsley and Kirsty James.

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PACT-G Statistical Analysis Plan

Page 1 of 1 Page Amendment

To amend the sentence on Page 12 Section 4.2

“Stratified by module, a regression of the endpoint ADOS-2 SA+RRB raw total score will include the stratifiers (site, age-group and gender), baseline ADOS-2 score and any other baseline variables found to predict missingness.”

To read

“Stratified by module, and for module 1 by child’s level of language (to allow for the three items that differ for children with/without words), a regression of the endpoint ADOS-2 SA+RRB raw total score will include the randomisation stratifiers (site, age-group and gender), baseline ADOS-2 score and any other baseline variables found to predict missingness.”