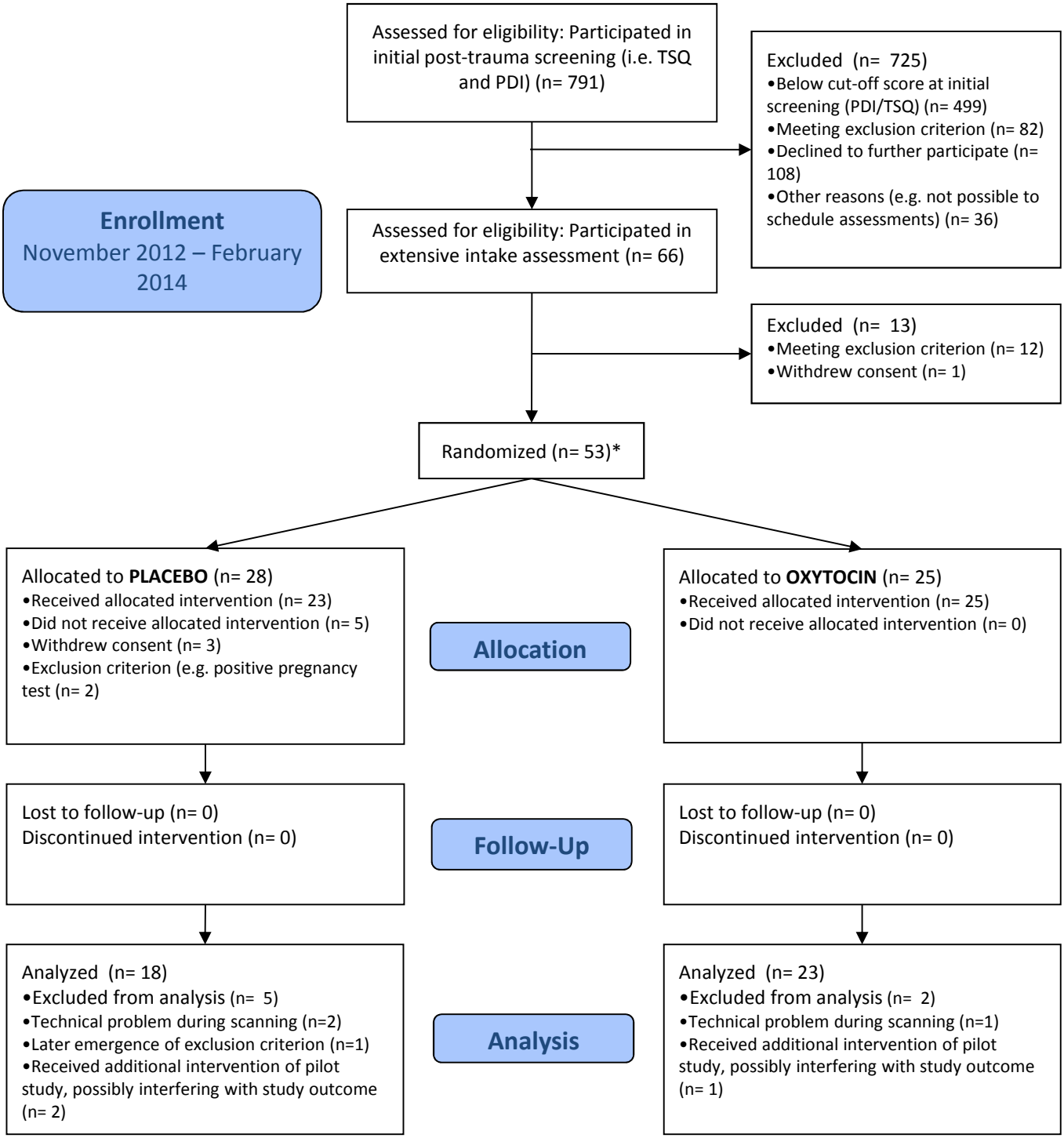
CONSORT
TRANSPARENT REPORTING of TRIALS

CONSORT 2010 Flow Diagram



* Prior to the start of the official enrollment period in November 2012, a pilot study was conducted in 5 individuals on an other MRI scanner than the one used for the current study. Participants of the pilot study were randomized using the same randomization method as used after the start of the official enrollment period. In the pilot study, 4 individuals were randomized to the oxytocin condition, and 1 individual was randomized to the placebo condition.

Additional text CONSORT Flow Diagram

The aimed sample size (i.e. total of 40 datasets for each fMRI analysis, approximately 20 per treatment condition) was based on the study of Desmond & Glover (2002), 'Estimating sample size in functional MRI (fMRI) Neuroimaging studies: statistical power analyses'. The randomization sequence was generated by the Clinical Research Unit of the AMC, which was incorporated Oracle® Clinical Software (Oracle Corporation, Redwood Shored, CA, USA) used for the blinded allocation of participants to placebo or oxytocin, using a block size of 4. Medication allocation was concealed using a randomization code, which was accessed by the pharmacy personnel preparing the investigational product only. The study was conducted in a double-blinded way, in which both the participants and researchers involved in data collection were blind to treatment allocation. The treatment coding key remained concealed until data collection was completed, except in case of adverse reactions or other safety concerns (not applicable for this study). The enrollment period of this study started in November 2012 and was completed in February 2014, after the data collection was completed for all participants.