Checklist: World Health Organization Trial Registration Data Set

Data category	**Information**
Primary registry and trial identifying number	ISRCTN 16876240
Date of registration in primary registry	06/07/20
Secondary identifying numbers	N/A
Source(s) of monetary or material support	Medical Research Council UK
Primary sponsor	Joint Institute of Psychiatry, Psychology & Neuroscience and the South London and Maudsley NHS Foundation Trust.
Secondary sponsor(s)	N/A
Contact for public queries	Dr Patrick Smith, 020 7848 0506, patrick.smith@kcl.ac.uk
Contact for scientific queries	Dr Patrick Smith, as above
Public title	Online post-traumatic stress disorder treatment for young people and their carers
Scientific title	As above
Countries of recruitment	UK
Health condition(s) or problem(s) studied	Post-Traumatic Stress Disorder (PTSD)
Intervention(s)	Internet delivered Cognitive Therapy for PTSD in Young People (iCT-PTSD-YP)
Key inclusion and exclusion criteria	Young people: 1. Aged 12-17 years old 2. Main presenting problem is PTSD (diagnosed using CAPS-5-CA) and there is a not a co-morbid problem that would preclude treatment of PTSD 3. PTSD symptoms relate to a single trauma 4. Participant has access to compatible smartphone or larger computing device (e.g. laptop, desktop computer, iPad) with internet access and to a safe and confidential space in which to engage in iCT 5. Participant speaks English to a level that allows therapy without the need for an interpreter, and reads English to a level that allows independent use of iCT Parents or carers: 1. Parent or carer of a young person who meets all of the inclusion criteria above and none of the exclusion criteria below 2. Parent or carer speaks English to a level that allows participation in therapy without the need for an interpreter, and reads English to a level that allows independent use of iCT 3. Parent or carer has access to compatible smartphone or larger computing device (e.g. laptop, desktop computer, iPad) with internet access

Study type	Two-arm parallel-group single-blind (outcome assessor) early-stage randomized controlled trial
Date of first enrolment	25/08/20
Target sample size	34
Recruitment status	recruiting
Primary outcome(s)	Feasibility As this is an early-stage trial, the primary outcomes are feasibility outcomes and adherence metrics. Feasibility data on acceptability, compliance, retention, and delivery will be collected. Clinical The primary clinical outcome is presence or absence of PTSD 16 weeks after randomisation, determined by administration of a gold standard semi-structured interview by a trained reliable assessor who is blind to treatment allocation.
Key secondary outcomes	Secondary clinical outcomes are continuous scores on a battery of reliable and valid questionnaires measuring severity of PTSD, anxiety, and depression, completed by young people and carers.