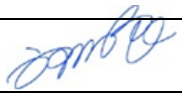
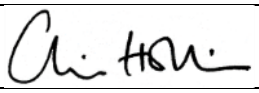
Online Remote Behavioural Intervention for Tics (ORBIT-UK): a single cohort usability study

Statistical Analysis Plan

Final version[2] 1.0
-Dec-2025

Based on protocol version[3]: Final Version 1.2 12-Sept-2025
Trial registration[1]: ISRCTN82718960

The following people have reviewed the Statistical Analysis Plan and are in agreement with the contents[6]				
Name*	**Job title**	**Trial Role**	**Signature**	**Date**
Olivia Hastings	Research Assistant	Coach		2/12/25
Beverley J Brown	Trial Manager	Trial Manager/Researcher		02/12/2025
Boliang Guo	Cstat	Study Statistician		02/12/2025
Charlotte L Hall	Principal research fellow	Co-Chief Investigator		02/12/2025
Chris Hollis	Professor	Chief Investigator		02/12/2025

Abbreviations

Abbreviation	Description
ADHD	Attention Deficit Hyperactivity Disorder
AE	Adverse Event
BT	Behavioural Therapy
C&A-GTS-QoL	Children & Adolescent Gilles de la Tourette Syndrome Quality of Life Scale
CAMHS	Child and Adolescent Mental Health Services
CBIT	Comprehensive Behavioural Intervention for Tics
CGI-I	Clinical Global Impressions – Improvement Scale
CI	Chief Investigator
CRF	Case Report Form
CYP	Child and Young People
DHI	Digital Health Interventions
ERP	Exposure and Response Prevention
GBO	Goal Based Outcomes
GCP	Good Clinical Practice
HRT	Habit Reversal Therapy
HTA	Health Technology Assessment
ICBT	Internet-based Cognitive Behavioural Therapy
ICF	Informed Consent Form
ISRCTN	International Standard Randomised Controlled Trials Number
Main REC	Main Research Ethics Committee
NHS	National Health Service
NHFCT	Nottinghamshire Healthcare NHS Foundation Trust
NICE	National Institute for Health and Care Excellence
OCD	Obsessive Compulsive Disorder
ORBIT	Online Remote Behavioural Intervention for Tics
PI	Principal Investigator
PIC	Patient Identification Centre

PIS	Participant Information Sheet
PMG	Project Management Group
PPI	Patient and Public Involvement
PTQ	Parent Tic Questionnaire
QALY	Quality-Adjusted Life-Year
RCT	Randomised Control Trial
REC	Research Ethics Committee
RSG	Research Steering Group
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SPM	Senior Project Manager
SUS	System Usability Scale
SUSAR	Suspected Unexpected Serious Adverse Reaction
TM	Trial Manager
TS	Tourette Syndrome
YGTSS	Yale Global Tic Severity Scale
YGTSS-TTSS	Yale Global Tic Severity Scale – Total Tic Severity Score

Changes from Protocol

The table below details changes to the planned analyses in the SAP compared to the protocol which after discussion with the TMG are not considered to require a protocol amendment.

Protocol version and section	**Protocol text**	**SAP version and section**	**SAP text**	**Justification**
n/a – no changes to SAP as per protocol updates	Protocol V1.2 26-Sept-2025			

Amendments to versions (4)

Version	**Date**	**Change on/comment**	**Statistician**

Additional contributors to the SAP (non-signatory) (5)

Name	Trial role	Job Title	Affiliation

Contents

1. Introduction

This document details the rules proposed and the presentation that will be followed [1], as closely as possible, when analysing and reporting the main results from the study titled *"Online Remote Behavioural Intervention for Tics: A Single Cohort Usability Study*". These analyses will aim to aid assessing the usability, acceptability and preliminary outcomes of ORBIT on the new platform within a tic disorder service and will be included in the clinical study report.

The purpose of the plan is to:

- Ensure that the analysis is appropriate for the aims of the trial, reflects good statistical practice, and that interpretation of a priori and post hoc analyses respectively is appropriate.
- Explain in detail how the data will be handled and analysed to enable others to perform or replicate these analyses.

Additional exploratory or auxiliary analyses of data not specified in the protocol may be included in this analysis plan. This analysis plan will be made available if required by journal editors or referees when the main papers are submitted for publication. Additional analyses suggested by reviewers or editors will be performed if considered appropriate. This should be documented in a file note.

Amendments to the statistical analysis plan will be described and justified in the final report of the trial and where appropriate in publications arising from the analysis. Health economic and qualitative analysis plans are beyond the scope of this document.

1.1 Background and rationale (7)

Tourette's syndrome is a common, disabling childhood-onset condition. Exposure and response prevention (ERP) is an effective treatment for tics, yet access remains limited due to a shortage of trained therapists and uneven geographical distribution of services. The ORBIT trial (Hollis et al., 2021) demonstrated that internet-delivered ERP is both clinically and cost-effective, but was developed on university systems, not suitable for widescale roll-out. To enable adoption by the NHS, the original ORBIT intervention (Hollis et al., 2021) has been redeveloped on an NHS-compliant platform. Prior to launching ORBIT-UK as a patient-ready product, we need to test the platform's usability. Findings will inform the development of a service pathway and adoption plan.

This study aims to evaluate the usability of the ORBIT-UK platform and service pathway. The intervention, adapted from the previous ORBIT trial, will be developed into an NHS-ready clinical product suitable for real-world rollout and adoption. Using a single-cohort design, the study will assess uptake, acceptability, and performance of ORBIT-UK within an NHS tic disorder service. It will identify platform strengths and weaknesses through real-world evaluation, gather stakeholder feedback on feasibility and acceptability, and summarise baseline and post-intervention clinical outcomes.

1.2 Objectives (8)

As this is not a clinical trial, we do not differentiate between primary and secondary objectives. The objectives for this study are as follows:

1) to test the acceptability of the ORBIT-UK platform and the feasibility of the ORBIT-UK service pathway in the NHS

2) to gather feedback from Young People, Supporters, Coaches, and clinicians on the acceptability of the platform and service pathway

3) to identify strengths and weaknesses of the platform through usability testing

4) to present the change from baseline to post-intervention in clinical outcome measures to explore symptom changes

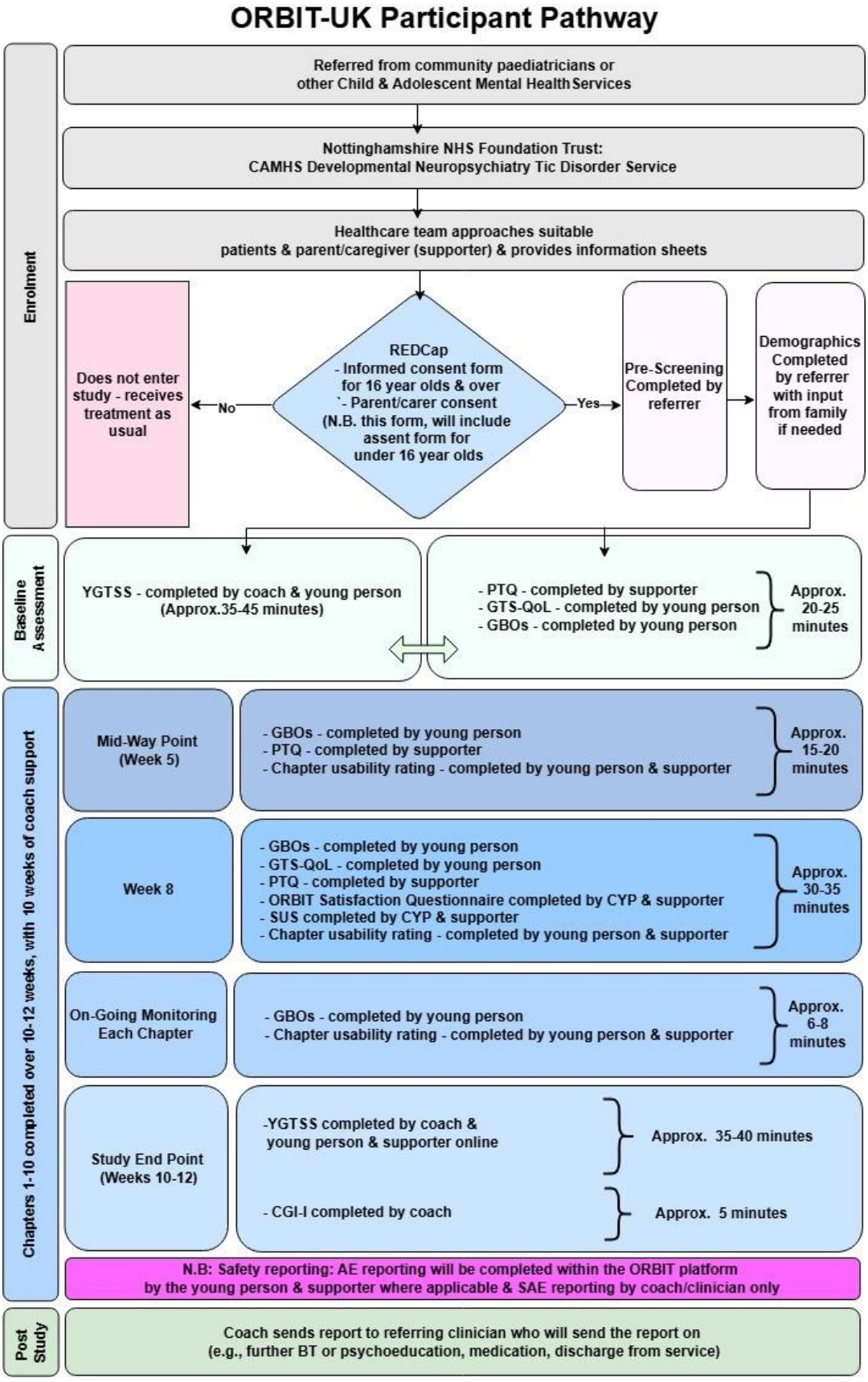
5. To investigate the safety of the ORBIT-UK platform. This will be assessed through SAE reporting throughout the study.

2. Study methods

2.1 Trial design *(9)*

This study is a 10-12-week, single cohort usability study for children and young people with tics. Participants will receive 10 weeks of online, remotely delivered, coach-supported behavioural therapy for tics. The primary endpoint will be 3-months post completion of baseline measures. The overall study duration will be 13 months (from the first participant enrolled to last post-intervention assessment), and the individual participant duration will be a maximum of 12 weeks. See Figure 1. for an overview of the study.

Figure 1. Study overview



2.2 Randomisation & Blinding (10)

All participants will receive the web-based ORBIT intervention; therefore no randomisation or blinding procedures are needed.

2.3 Sample size (11)

As an exploratory study, the sample size (N=20) will be used to evaluate the usability of the ORBIT-UK platform. This is in line with observed sample sizes in in other feasibility and pilot studies in the UKCRN Database (Billingham, Julious & Whitehead, 2013)

2.4 Framework (12)

A single cohort study to assess acceptability and usability of the ORBIT-UK platform and the feasibility of the ORBIT-UK service pathway in the NHS. Participants will be recruited from the Nottinghamshire Healthcare NHS Foundation Trust (NHCFT) Tic Disorder Service. The intervention will be delivered within the Nottinghamshire Healthcare NHS Foundation Trust (NHCFT) Tic Disorder Service as well. The NHCFT receives referrals from PICs (CAMHS and paediatric services).

2.5 Statistical interim analyses and stopping guidance (13)

There is no interim analysis planned.

2.6 Timing of final analysis (14)

The dataset will be locked for final analysis once the last recruited participant's last follow-up outcome data is available.

2.7 Timing of outcome assessments (15)

The name of each outcome measure, the timepoints that they are assessed at and who they will be completed by are shown in Table 1 below.

Table 1. Timing of outcome measures

Months post-enrolment	**0**	**0**	**0-3**	**1**	**2**	**3**	**Completed by**
Time Point	Screening	Baseline (Pre-treatment)	Per-Chapter/on-going	Mid-treatment (5wk)	8-weeks	10-12 weeks (treatment end)	
Consent	X						P/YP
Automated pre-screening filter (Part A)	X						CL
Referral form and demographics (Part B)	X						CL
PTQ		X		X	X		P
YGTSS		X				X	CO/YP
CGI-I						X	CO
GBO		X	X	X	X	X	YP
Chapter rating			X	X	X	X	S/YP
C&A GTS-QOL		X			X		YP
SUS					X		S/YP
Adverse effects/side effects		X	X	X	X	X	S/YP
ORBIT Satisfaction					X		S/YP
Exit interview						X	S/YP/CL/CO

Key: P = parent; S = supporter; YP = young person; CL = clinician; CO = coach; PTQ = Parent Tic Questionnaire; YGTSS = Yale Global Tic Severity Scale; CGI-I = The Clinical Global Impressions Improvement Scale; C&A-GTS-QOL = The child and adolescent version of the Gilles de la Tourette Syndrome Quality of Life Scale; GBO = Goals Based Outcome.

3. Statistical Principals

3.1 Confidence intervals and P values (16-18)

As there is no significance testing planned, there will be no need to prespecify significance level, and no multiplicity adjustment needed. nevertheless [3], all confidence intervals presented will be 95% and two-sided.

3.2 Adherence and protocol deviations (19)

Protocol deviations will be defined as any departure from the approved study procedures outlined in the protocol, including data collection, consent, or intervention delivery steps. Adherence and compliance refer to the extent to which participants complete the intervention as intended, measured by engagement with the ORBIT-UK platform (e.g., completion of required modules, minimum of 4 completed chapters, and interaction with the coach), and will be treated as an outcome measure in the usability assessment. Non-adherence to the intervention will not be considered a protocol deviation for the purposes of this study.

Compliance will be assessed by the number of chapters completed within the ORBIT-UK platform. Adherence to the minimum therapeutic dose is defined as completion of the first four core chapters, which contain the essential intervention content. Full completion is defined as completing all ten chapters of the intervention.

Protocol deviations will be classified prior to any data analysis. The number and percentage of participants with major and minor deviations will be summarised by the end of the follow-up time period, with details of the type of deviation provided.

3.3 Analysis populations (20)

All participant data collected during the study will be included in the analyses, regardless of level of intervention completion. The primary analysis population will therefore comprise all participants who provide informed consent and engage with the ORBIT-UK platform at any point during the study. This approach ensures that usability and adherence outcomes reflect real-world engagement patterns.

Descriptive statistics will summarise demographic and baseline characteristics for the full sample, including age, gender, and tic severity scores. Continuous variables will be reported using means, standard deviations, medians, and ranges, while categorical variables will be summarised using frequencies and percentages. Percentages of participants meeting adherence and compliance thresholds will be summarised post-intervention.

Missing data will not be imputed for usability and adherence outcomes; analyses will be based on observed data only. For exploratory clinical outcomes, sensitivity analyses may be considered using appropriate imputation methods.

Subgroup analyses are not planned for this usability study but may be explored descriptively for key demographic variables to inform future studies.

4. Trial population

4.1 Screening data (21)

The number of patients screened will be presented in a CONSORT style flowchart diagram.

4.2 Eligibility (22)

Inclusion criteria

1. Aged 9 to 17 years: patient confirmed at screening

2. Suspected or confirmed Tourette syndrome/ chronic tic disorder: Including Moderate/severe tics: Score >15 on the Yale Global Tic Severity Scale (YGTSS) Total Tic Severity Score (TTSS); TTSS score>10 if motor or vocal tics only: Coach will assess this at initial assessment via video conference
3. Competent to provide written, informed consent (parental consent for child aged <16): referring clinician confirms at screening appointment
4. Broadband internet access and regular PC/laptop/Mac/mobile device user, with mobile phone SMS: patient confirmed at screening
5. Clinical suitability for ORBIT-UK confirmed by referrer from the patients' usual care team
6. A parent/carer/legal guardian aged 18+ who is willing and able to act as a Supporter

Exclusion criteria

1. Presentation of functional tics (Functional Neurological Disorder)
2. Moderate/severe intellectual disability: Confirmed through qualitative judgement of the referrer from the patients' usual care team.
3. Immediate risk to self or others: Confirmed through referrer from the patients' usual care team.
4. Parent or child not able to speak or read/write English: Patient confirmed through screening by the referring clinician

Additional Eligibility Criteria (Supporters, Clinicians and Coaches)

1. Supporters: A supporter can be a parent, caregiver or legal guardian who are 18 years or older and have the capacity to support CYP through the intervention.
2. Clinicians: Only clinicians who appear on the ORBIT site delegation log will be eligible to be approached to be interviewed
3. Coaches: Only Coaches who appear on the ORBIT site delegation log will be eligible to be approached to be interviewed.

The number of ineligible and eligible patients will be reported, with reasons for ineligibility and presented in CONSORT style flowchart diagrams.

4.3 Recruitment (23)

A CONSORT style flow diagram will be used to summarise the number of patients who were:

- approached by sites
- assessed for eligibility at screening
    - eligible at screening
    - ineligible at screening*
- eligible and participate the study
- eligible but not participate the study *
- lost to follow-up*
- discontinued the intervention*

*Reason will be provided

4.4 Withdrawn/follow-up (24)

The level of consent withdrawal will be tabulated (classified as "consent to continue follow-up and data collection" "consent to continue data collection only", "complete – no further follow-up or data collection")." The numbers (with reasons) of losses to follow-up (drop-outs and withdrawals) over the course of the trial will be presented in a CONSORT style flowchart diagram.

4.5 Baseline patient characteristics (25)

Patients will be described with respect to the following;

1. **Child Information:** age, gender, and ethnicity.
2. **Supporter Information:** Relationship of main caregiver to the child, Highest level of education completed by mother and father; Parent/Carers' occupation
3. **Clinical Information:** Known diagnoses

Patient demographic and background information will be taken at baseline. The details of descriptive statistics are reported in 5.2.1. Tests of statistical significance will not be undertaken for baseline characteristics; rather the clinical importance of any imbalance will be noted [4]

5. Analysis

5.1 Outcome definitions (26)

Table 1: Summary of the outcome measures

Outcome measures	Completed by	Scale, description and source	Derivation of scores	Time point (Week 0/Week 5/Week 8/Week 10)			
Yale Global Tic Severity Scale (YGTSS) (Leckman et al 1989)	CO/YP	Semi-structured clinician-administered interview that assesses the frequency, intensity, complexity, interference, and distribution of motor and vocal tics over the past week, as well as tic-related impairment.	Yields a Total Tic Severity Score (0–50), derived from separate motor and vocal tic scores, and an Impairment Score (0–50), with higher scores reflecting greater symptom severity and functional impact.	X			X
Parent Tic Questionnaire (PTQ) (Chang et al., 2009)	S	Assesses the number, frequency, and intensity of motor and vocal tics in children and adolescents with tics from their parent/carer's perspective. The questionnaire contains two separate lists, one of 14 common motor tics, one of 14 common vocal tics. For each tic recorded as present, parents/carers indicate the frequency and intensity of that tic.	Each tic receives a severity score by adding the frequency and intensity ratings (range 0–8). Individual tic scores are then summed to yield a Total Motor Tic Score and a Total Vocal Tic Score, which are combined to produce an Overall Tic Severity Score.	X	X	X	
The Child and Adolescent Gilles de la Tourette	YP	27-item self-report measure assessing health-related quality of life in young people with TS across psychological, physical,	Subscale scores are calculated by summing item scores within each domain, and a Total QoL	X		X	

Outcome measures	Completed by	Scale, description and source	Derivation of scores	Time point (Week 0/Week 5/Week 8/Week 10)			
Syndrome - Quality of Life Scale (C&A GTS-QoL) (Cavanna et al., 2013)		obsessive–compulsive, and cognitive domains over the previous 4 weeks. There are two versions—one for children aged 6–12 years and one for adolescents aged 13–18 years—and each item is rated on a 5-point scale (0–4).	Score is obtained by summing all items, with higher scores indicating greater quality-of-life impairment				
The System Usability Scale (SUS) (Brooke, 1996)	YP/S	Ten-item Likert questionnaire designed to assess the usability of a website or platform. Participants will rank each statement from 1 to 5, based on how strongly they agree with the statement about the usability of the platform, with 1 being strongly agree and 5 being strongly disagree	To calculate a total score, for each of the odd numbered questions The SUS has established reliability, validity and sensitivity (Lewis, 2018). To calculate the total SUS score, for items 1,3,5,7,9 subtract 1 from the score. For items 2,4,6,8,10, minus the score from 5. Multiply the sum of these scores by 2.5 to obtain the total score. SUS scores have a rage of 0 to 100.			X	
Clinical Global Impressions – Improvement Scale (CGI-I) (Guy, 1976)	CO	This is a single item, 7-point Likert scale that allows the Coach to assess improvement from baseline.	Lower scores indicate greater improvement; higher scores indicate worsening.				X
ORBIT Satisfaction Questionnaire (Hollis et al 2021)	YP/S	8-item questionnaire using a 5 point Likert scale (0-4) to indicate satisfaction.	Higher scores indicating greater treatment satisfaction			X	
Goal Based Outcomes (GBOs) (Law & Jacob, 2013)	YP	GBOs are realistic and appropriate goals for the intervention, such as 'to have better control over my tics' or 'to feel less worried about my tics'.	Progression towards these goals will be rated by the YP at the end of each chapter on a 0-10 scale, with 0 being no progress towards the goal and 10 meaning the goal has been fully reached. YP will set between 1-3 goals.	X	X	X	X

Key: YP = young person, S = supporter, CO = coach

5.2 Analysis methods (27)

The analyses will be primarily descriptive [3, 5].

5.2.1 Summary of primary and secondary outcomes analysis

All patient demographic and outcome measures will be summarised by follow-up times, with n (non-missing sample size), mean, standard deviation, median, maximum and minimum for continuous variables, the frequency and percentages (based on the non-missing sample size) of observed levels for all categorical measures.

5.2.2 Analysis of primary and secondary outcome

The recruitment and adherence rates and their precision will be calculated. All questionnaire outcome measures will be summarised through descriptive statistics across time points; the change of each outcome score from baseline to each follow up time and its precision will be quantified by relevant regression modelling.

5.3 Missing data (28)

In line with the study aim, which is not testing treatment effectiveness, missingness for all outcome measures will be summarised across follow-up time if repeatedly measured.

5.4 Additional analyses/exploratory analysis (29)

There is no additional analysis planned so far.

5.5 Harms & Adverse events (30)

The number (and percentage) of patients experiencing each AE/SAE will be presented by severity (across follow-up time) [6]. For each patient, only the maximum severity experienced of each type of AE will be displayed. The number (and percentage) of occurrences of each AE/SAE will also be presented if any. No formal statistical testing will be undertaken.

5.6 Statistical software (31)

The analysis will be carried out using Stata 19.5, All the data will be stored in UoN secure server and analysed in UoN computers. All the data and analytic code will be archived as per instruction from study PI Prof Chris Hollis who will be the data custodian for this study.

6. References (32)

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