Health Research Authority

North West - Liverpool Central Research Ethics Committee

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Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

26 November 2021

Professor Edmund Sonuga-Barke
Professor of Development Psychology, Psychiatry and Neuroscience
King's College London
Department of Child & Adolescent Psychiatry
16 De Crespigny Park
SE5 8AF

Dear Professor Sonuga-Barke

Study title:	**Online Parent Training for The Initial Management of ADHD Referrals: A two-arm parallel randomised controlled trial of a digital parenting intervention implemented on a treatment waitlist.**
REC reference:	**21/NW/0319**
Protocol number:	**n/a**
IRAS project ID:	**303121**

Thank you for your letter of 16 November 2021, responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above

research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral:

https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

If you have not already included registration details in your IRAS application form, you should notify the REC of the registration details as soon as possible.

Further guidance on registration is available at:
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit:
https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at:
https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports

- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Cover letter]		04 October 2021
Covering letter on headed paper [Cover letter]		15 November 2021
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [KCL clinical trials insurance]		30 June 2021
GP/consultant information sheets or letters [OPTIMA RCT GP enrolment letter]	V.1.0	04 August 2021
Interview schedules or topic guides for participants [OPTIMA RCT Interview schedules]	V.1.0	04 August 2021
IRAS Application Form [IRAS_Form_06102021]		06 October 2021
Letter from funder [Funding letter]		19 March 2019
Letter from sponsor [Confirmation of sponsorship for the study]		01 October 2021
Letters of invitation to participant [OPTIMA RCT Invitation email wording]	V.2.0	12 November 2021
Non-validated questionnaire [Childhood Oppositional and Defiance Speech Sample]	V.1.0	24 August 2021
Non-validated questionnaire [OPTIMA demographic questions about the parent]	V.1.0	20 September 2021
Non-validated questionnaire [OPTIMA medical and psychological difficulties questionnaire]	V.1.0	21 May 2021

Non-validated questionnaire [OPTIMA trial expectations questionnaire]	V.1.0	23 July 2021
Non-validated questionnaire [OPTIMA experience of parenting question]	V.1.0	26 July 2021
Non-validated questionnaire [OPTIMA demographic questions child]	V.2.0	15 November 2021
Non-validated questionnaire [CASUS01]	V.1.0	29 July 2021
Non-validated questionnaire [CASUS03]	V.1.0	29 July 2021
Non-validated questionnaire [CASUS06]	V.1.0	29 July 2021
Non-validated questionnaire [CASUS09]	V.1.0	29 July 2021
Non-validated questionnaire [CASUS12]	V.1.0	29 July 2021
Other [OPTIMA RCT safety card]	V.1.0	04 August 2021
Other [OPTIMA PPI panel meeting minutes]		06 July 2021
Other [OPTIMA PPI panel meeting minutes]		26 July 2021
Other [STEPS download guide]	V.1.0	12 November 2021
Other [OPTIMA RCT participant communication protocol]	V.2.0	15 November 2021
Participant consent form [OPTIMA RCT parent consent]	V.2.0	12 November 2021
Participant consent form [OPTIMA RCT Assent script]	V.2.0	15 November 2021
Participant consent form [OPTIMA RCT Child assent form]	V.1.0	15 November 2021
Participant consent form [OPTIMA RCT Clinician consent]	V.2.0	12 November 2021
Participant information sheet (PIS) [OPTIMA RCT Child Information Sheet]	V.2.0	12 November 2021
Participant information sheet (PIS) [OPTIMA RCT PIS parent FULL]	V.2.0	12 November 2021
Participant information sheet (PIS) [OPTIMA RCT PIS parent BRIEF]	V.2.0	12 November 2021
Participant information sheet (PIS) [OPTIMA RCT PIS child text]	V.2.0	12 November 2021
Participant information sheet (PIS) [OPTIMA RCT PIS clinician]	V.2.0	12 November 2021
Research protocol or project proposal [RCT Protocol]	V.2.0	15 November 2021
Summary CV for Chief Investigator (CI) [Chief Investigator CV]	n/a	12 August 2020
Summary of any applicable exclusions to sponsor insurance (non-NHS sponsors only) [Combined liability letter]		24 June 2021
Summary of any applicable exclusions to sponsor insurance (non-NHS sponsors only) [Medical malpractice insurance]		30 June 2021
Validated questionnaire [Child's Challenging Behaviour Scale]	Version 2	
Validated questionnaire [Child Health Utility 9D]		
Validated questionnaire [Child-parent relationship scale (closeness sub scale)]		
Validated questionnaire [EQ-5D-5L]		
Validated questionnaire [Social Communication Questionnaire]		
Validated questionnaire [SNAP-IV (ADHD and ODD)]		
Validated questionnaire [Caregiver Strain Questionnaire]		
Validated questionnaire [O'Leary Parenting Scale - Clinical		

Research Form]		
Validated questionnaire [Parenting Sense of Competence Scale - Clinical Research Form]		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:
https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 303121 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

PP

Mr Paul Mooney
Chair

Email:liverpoolcentral.rec@hra.nhs.uk

Enclosures: "After ethical review – guidance for researchers" *[SL-AR2]*

Copy to: Professor Reza Razavi

Lead Nation England: approvals@hra.nhs.uk