



Health Research Authority
London - Bromley 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

23 August 2016

Dr Martina Di Simplicio
Career Development Fellow
MRC
15 Chaucer Road
Cambridge
Cb2 7EF

Dear Dr Di Simplicio

Study title:	Imaginator: a pilot study of a brief functional imagery training intervention for self-harm in young people, supported by a smart-phone 'app'
REC reference:	16/LO/1311
IRAS project ID:	208173

Thank you for your letter of 09 August 2016, responding to the Committee's 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 Alternate Vice-Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, [Section 40 \(2\)](#) nrescommittee.london-bromley@nhs.net.

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.

Conditions of the favourable opinion

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

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission 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 NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

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 clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact **Section 40 (2)**, the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

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).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission 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 sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Approved documents

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

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [Leaflet]	1.0	05 July 2016
Covering letter on headed paper [Response to REC PO letter 208173]		09 August 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor's Indemnity letter]	October 2008 version 1	
GP/consultant information sheets or letters [Letter to GP study start]	1.0	05 July 2016
GP/consultant information sheets or letters [Letter to GP study completion]	1.0	05 July 2016
IRAS Application Form [IRAS_Form_05072016]		05 July 2016
IRAS Checklist XML [Checklist_09082016]		09 August 2016
Letter from funder [CLAHRC Funding letter]		20 January 2016
Non-validated questionnaire [Young people Service Use Interview]	1.0	21 March 2016
Non-validated questionnaire [Self-Harm questionnaire]	1.0	05 July 2016
Non-validated questionnaire [Self-Harm Imagery Interview]	1.0	05 July 2016
Non-validated questionnaire [Craving for self-harm questionnaire]	1.0	05 July 2016
Non-validated questionnaire [Motivation to reduce self-harm questionnaire]	1.0	05 July 2016
Non-validated questionnaire [Feedback Interview]	1.0	05 July 2016
Other [App text and screenshots]	1.0	05 July 2016
Participant consent form [Consent to Contact form]	1.0	05 July 2016
Participant consent form [Consent Form with reference to Amended PIS 1.1]	1.1	09 August 2016
Participant information sheet (PIS) [Amended Full PIS]	1.1	09 August 2016
Participant information sheet (PIS) [Amended Full PIS with track changes]	1.1	09 August 2016

Participant information sheet (PIS) [Amended Short PIS]	1.1	09 August 2016
Participant information sheet (PIS) [Amended Short PIS with track changes]	1.1	09 August 2016
Referee's report or other scientific critique report [Peer Review report]		08 December 2015
Referee's report or other scientific critique report [Funders review and response]		03 November 2015
Research protocol or project proposal [Protocol]	1.0	22 June 2016
Summary CV for Chief Investigator (CI) [Di Simplicio CV]		
Validated questionnaire [MINI psychiatric interview]		
Validated questionnaire [Affective Liability Scale]		
Validated questionnaire [Columbia Suicidality Scale]		
Validated questionnaire [Depression Anxiety and Stress Scale]		
Validated questionnaire [Dysfunctional Emotion Regulation Scale]		
Validated questionnaire [Impact of Future Events Scale]		
Validated questionnaire [Obsessive Compulsive Inventory]		
Validated questionnaire [Impulsivity Scale]		
Validated questionnaire [Wellbeing Scale]		
Validated questionnaire [Imagery Vividness Scale]		

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.

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

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

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 Training

We are pleased to welcome researchers and R&D staff at our training days – see details at
<http://www.hra.nhs.uk/hra-training/>

16/LO/1311

Please quote this number on all correspondence

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

Yours sincerely

Section 40 (2)



Chair

Email: nrescommittee.london-bromley@nhs.net

Enclosures: "After ethical review – guidance for
researchers"

Copy to: *Prof Susan Gathercole*
Section 40 (2) Research & Development | Cambridge &
Peterborough NHS Foundation Trust ,