NHS
Health Research Authority

National Research Ethics Service

London - Queen Square Research Ethics Committee

[redacted]

29 April 2016

Professor Gill
Livingston UCL

Division of psychiatry

[redacted]

Dear Professor Livingston

Study title:	**DREAMS START (Dementia Related Manual for Sleep; Strategies for Relatives)**
REC reference:	**16/LO/0670**
Protocol number:	**1**
IRAS project ID:	**199820**

The Research Ethics Committee reviewed the above application at the meeting held on 21 April 2016.

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 favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Rachel Heron, nrescommittee.londonqueensquare@nhs.net Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Mental Capacity Act 2005

I confirm that the Committee has approved this research project for the purposes of the Mental Capacity Act 2005. The Committee is satisfied that the requirements of section 31 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Conditions of the favourable opinion

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

1. Participant Information Sheets

    a) The block of text under 'what is the purpose of the study' should be broken up with space between paragraphs and possibly a sub-heading (ie 'Outline of Procedures') to make it easier to read.

    b) Please check the grammar in the following sentences: 'If you agree, you or your relative will be asked to sign a consent' (form?) and 'you can ask o move' (under the heading 'What are the possible disadvantages to taking part?')

    c) Please provide complete contact telephone number for Professor Livingstone.

    d) Please ensure that all information sheets contain information about the destruction of audio recordings.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

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 HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, at 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

Clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

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 request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

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 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(s) (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. I 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.

Summary of discussion at the meeting

Dr Claudia Cooper was welcomed to the meeting. She was advised that an observer was present, and raised no objection.

Social or scientific value; scientific design and conduct of the study

Relevance of the research to the impairing condition

The Committee agreed the research is connected with an impairing condition affecting persons lacking capacity or with the treatment of the condition.

Justification for including adults lacking capacity to meet the research objectives

The Committee agreed the research could not be carried out as effectively if it was confined to participants able to give consent.

was agreed that a representative sample could not be achieved without including those patients with dementia who had lost capacity

The Committee noted that the intervention manual was not yet developed and asked about the progress of this. *Dr Cooper advised that it was 80% complete but would be 'tweaked' as the study progressed. On request, she had provided a draft version of the manual for review.*

The Committee asked about randomisation of participants, or whether they would be matched for any characteristics.

Dr Cooper stated that allocation to study groups would be random, as befitted a pilot study.

She had a query for the Committee, which was whether it would be acceptable to provide the actigraph data to the Control group (as they had worn it for the trial and it would seem unfair not to provide the data). She advised that they would provide simple feedback with a contact number in case the participant wished to discuss them.

In discussion after Dr Cooper had left the meeting the Committee agreed that this would be acceptable.

The Committee discussed whether there was enough information in the Draft manual and in the information sheets to approve the study, and agreed that there was.

Recruitment arrangements and access to health information, and fair participant selection

The Committee raised the possibility that carers would potentially benefit from this research, and therefore may allow their own interests to over-ride those of their relatives. The Committee asked Dr Cooper her view on whether the carer was the most appropriate consultee in this situation.

Dr Cooper stated that the carer would have a vested interest in the health of their relative, and was emphatic that she did not consider this to be a problem.

Arrangements for appointing consultees

The Committee considered the arrangements set out in the application for appointing consultees under Section 32 of the Mental Capacity Act to advise on whether participants lacking capacity should take part and on what their wishes and feelings would be likely to be if they had capacity.

After discussion the Committee agreed that reasonable arrangements were in place for identifying personal consultees and for nominated consultees independent of the project where no person can be identified to act as a personal consultee.

The Committee agreed that procedures in place were adequate and that the procedures were not burdensome for the person lacking capacity

Favourable risk benefit ratio; anticipated benefit/risks for research participants (present and future)

The Committee asked for a description of the intervention, as this had not been clear in the application*. Dr Cooper explained that the intervention involved a psychology graduate meeting with the family carer, to take them through the manual. This would involve completing exercises, talking about the background to the sleep problems, and the additional reasons ie melatonin production in dementia. The difficulties caused for the carer by the sleep disturbance would be discussed. Homework would be given in between this and the second session, which would use CBT principles in taking to the carer. The data from the Actigraph would be used in this session. This process was still under development.*

Dr Cooper explained that although the CBT intervention was not delivered by experts, the graduates would be supervised by experts. Other tactics would be used such as daylight and engaging the person in activities they enjoyed. This was part of the manual which was still under development.

Balance between benefit and risk, burden and intrusion

The Committee noted that while the research would not benefit participants lacking capacity it is intended to provide knowledge of the causes or the treatment or care of sleep disturbance in dementia. After discussion, the Committee agreed that the risk to participants is likely to be negligible and the research will not significantly interfere with their freedom of action or privacy or be unduly invasive or restrictive.

The Committee did note that the intervention would be likely to benefit carers of those with sleep disturbance in dementia, and that the benefit for the individual with dementia was less clear, however it was agreed that the research was not unduly invasive or restrictive and had the potential to benefit participants.

The Committee decided that the research did not require Site-Specific Assessment at non-NHS sites as it involves no clinical interventions and all study procedures at sites would be undertaken by the Chief Investigator's team and the Committee was satisfied that the risk to participants is likely to be negligible.

Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity

The Committee asked who was responsible for assessing capacity.

Dr Cooper responded that this would be the person taking consent. In response to another question from the Committee, she advised that it would be unusual for anyone to lose capacity during the 3 month trial, but if they did the MCA procedures would be followed and they would seek a consultee.

Additional safeguards

The Committee was satisfied that reasonable arrangements would be in place to comply with the additional safeguards set out in Section 33 of the Mental Capacity Act.

Informed consent process and the adequacy and completeness of participant information

Information for consultees

The Committee reviewed the information to be provided to consultees about the proposed research and their role and responsibilities as a consultee.

The Committee considered that the information was not adequate for the following reasons: and requested the following changes:

The Committee noted that the text was continual and this made it hard to read. The Committee agreed that the blocks of text needed to be broken up. The Committee also noted that only one of the information sheets explained the process for destroying audio recordings – this needed to be on all of the information sheets. Both of these points applied

to all information sheets, and not only the consultee information. The Committee agreed that the consultee information was otherwise satisfactory.

Other ethical issues were raised and resolved in preliminary discussion before her attendance at the meeting.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UCL Insurance certificate 2015-2016]	NA	13 July 2015
GP/consultant information sheets or letters [Letter to GP and trust health professional DREAMS]	1	01 February 2016
Interview schedules or topic guides for participants [Interview guide focus groups 1 DREAMS]	1	01 February 2016
Interview schedules or topic guides for participants [Individual interview guide DREAMS]	1	01 February 2016
IRAS Checklist XML [Checklist_04042016]		04 April 2016
Letter from funder [Agree to fund letter]		14 December 2015
Non-validated questionnaire [Patient demographics]	1	01 February 2016
Non-validated questionnaire [Family carer demographics]	1	01 February 2016
Non-validated questionnaire [DREAMS side effects]		
Other [Dreams session 1 draft manual]	1	30 March 2016
Other [Dreams draft manual session 2]	1	30 March 2016
Other [Dreams draft manual session 3]	1	30 March 2016
Participant consent form [Consent form DREAMS RCT focus groups]	1	01 February 2016
Participant consent form [Consent form DREAMSpatients]	1	01 February 2016
Participant consent form [Consultee declaration form DREAMS]	1	01 February 2016
Participant consent form [Consent form DREAMS RCT relatives]	1	01 February 2016
Participant information sheet (PIS) [PIS DREAMS patient v1 01.02.2016]	1	01 February 2016
Participant information sheet (PIS) [PIS DREAMS relatives v1]	1	01 February 2016
Participant information sheet (PIS) [PIS DREAMS consultee version1 01.02.2016]	1	01 February 2016
Participant information sheet (PIS) [PIS DREAMS AS focus groups v1 01.02.2016]	1	01 February 2016
REC Application Form [REC_Form_24032016]		24 March 2016
REC Application Form [REC_Form_04042016]		04 April 2016
Referee's report or other scientific critique report [referees comments shortlisting]		19 March 2015
Referee's report or other scientific critique report [referees from HTA full application]		
Research protocol or project proposal [DREAMS START (Dementia Related Manual for Sleep; Strategies for Relatives) feasibility and pilot study]	1	20 January 2016
Summary CV for Chief Investigator (CI) [Short CV GL 2016]	NA	23 March 2016
Validated questionnaire [caregiver HSQ]	NA	
Validated questionnaire [CSRI DREAMS]	1	23 March 2016
Validated questionnaire [DEMQOLproxy family carer]	NA	
Validated questionnaire [Zarit interview]	NA	
Validated questionnaire [Neuroepworth sleep scale]		

Validated questionnaire [Neuropsychiatric Inventory]		
Validated questionnaire [HADS]		
Validated questionnaire [Pittsburgh Sleep quality Index]		
Validated questionnaire [Sleep disorders Inventory]		
Validated questionnaire [The sleep condition indicator]		

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

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/0670	**Please quote this number on all correspondence**

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

[redacted]

Signed on behalf of

Dr Eamonn Walsh Chair

E-mail: nrescommittee.london-queensquare@nhs.net

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers" [*SL-AR2 for other studies]*

Copy to: *Smaragda Agathou*

Ms Lynis Lewis, NoCLoR

London - Queen Square Research Ethics Committee

Attendance at Committee meeting on 21 April 2016

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Yogi Amin	Consultant in Neuroanaesthesia & Neurocritical Care	No	
Miriamtha Dahdal	Teaching Assistant	No	
Dr Simon Eaton	Senior Lecturer in Paediatric Surgery and Metabolic Biochemistry	Yes	
Miss Sarah Gregory	Clinical Research Officer	No	
Dr Katie Harron	Statistician	No	
Dr Khalil Hassanally	GP	No	
Mrs Jenny Johnson	Charity Trustee	Yes	
Eleanor Rose Lee-Millais	Nurse	Yes	
Dr Lorraine Ludman	Chartered Psychologist	Yes	
Mrs Claire Reynolds	Radiotherapy Radiographer	No	
Miss Sheetal Sumaria	Pharmacist	Yes	
Dr Eamonn Walsh	Lecturer	Yes	
Mr Jonathan Watkins	Social Worker	No	
Ms Danielle Wilson	Clinical Trials Facility Manager	Yes	
Miss Zalika Xavier	Vaccine Sales Representative	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Rachel Heron	REC Manager

NHS
Health Research Authority

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[redacted]

09 May 2016

Prof Gill Livingston

UCL

Division of psychiatry

[redacted]

Dear Prof Livingston

Study title:	**DREAMS START (Dementia Related Manual for Sleep; Strategies for Relatives)**
REC reference:	**16/LO/0670**
Protocol number:	**1**
IRAS project ID:	**199820**

Thank you for your letter of 9 May 2016. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 29 April 2016

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Participant information sheet (PIS) [PIS DREAMS patient v1.1 06.05.2016]	1.1	06 May 2016
Participant information sheet (PIS) [PIS DREAMS relatives v1.1 06.05.2016]	1.1	06 May 2016
Participant information sheet (PIS) [PIS DREAMS consultee v1.1 06.05.2016]	1.1	06 May 2016
Participant information sheet (PIS) [PIS DREAMS AS focus groups v1.1 06.05.2016]	1.1	06 May 2016

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors	NA	13 July 2015
only) [UCL Insurance certificate 2015-2016]		
GP/consultant information sheets or letters [Letter to GP and trust health professional DREAMS]	1	01 February 2016
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Validated questionnaire [Neuropsychiatric Inventory]		
Validated questionnaire [HADS]		
Validated questionnaire [Pittsburgh Sleep quality Index]		
Validated questionnaire [Sleep disorders Inventory]		
Validated questionnaire [The sleep condition indicator]		

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

16/LO/0670 **Please quote this number on all correspondence**

Yours sincerely

[redacted]

Rachel Heron
REC Manager

E-mail: nrescommittee.london-queensquare@nhs.net

Copy to: *Smaragda Agathou*

Ms Lynis Lewis, NoCLoR