

NEON-C: Trial to test the feasibility of providing online recorded mental health recovery stories to people with experience of caring for people with mental health problems

Submission date 02/12/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/01/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/02/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Mental health recovery narratives are people's stories of recovery from mental health problems. Recovery narratives can be presented in a form that cannot change, such as text, audio or video, in which case we have called them "recorded" recovery narratives.

The Narrative Experiences Online (NEON) Programme has been investigating whether receiving recorded mental health recovery narratives can improve quality of life for people affected by mental health difficulties. NEON has identified a range of potential benefits, including feeling more hopeful or connected to others, and learning about other people's experiences. NEON is currently being trialled in individuals with experience of what can be called psychosis to investigate whether receiving access to mental health recovery narratives can provide benefits (<http://www.isrctn.com/ISRCTN1152837>).

The NEON-C trial will examine whether it is feasible to use the same intervention to provide benefits to people with experience of caring for people with mental health problems.

Who can participate?

People aged 18 years or over, who have experience informally caring for someone with mental health concerns in the past 5 years. Participants need to be competent in English and are able to use a computer or smartphone (with support if needed). Informal carers interested in taking part should not be accessing mental health services. The person cared for does not need to have received any medical support for their mental health concerns.

What does the study involve?

Taking part in NEON-C will involve being randomly allocated to either receive access to the NEON Intervention, an interactive website providing access to hundreds of recovery narratives, or to receive access to the NEON Intervention after one year. Participants can use the NEON Intervention as much or as little as they want. At four points during the year, participants will

need to provide some information about themselves and their experiences, using some online forms, participants might also be invited to take part in an interview about their experiences, and their usage of the NEON Intervention will be logged. The information collected will help us to assess the success of the NEON Intervention, and to plan for a larger-scale trial with the same study population. We will publish our results in publications which are available to all.

What are the possible benefits and risks of participating?

Benefits include obtaining access to a diverse set of recovery narratives assembled by the NEON study team, and making a contribution to research which will shape clinical practice. Some recovery narratives might help participants feel more hopeful about their own future, or more connected to others with similar experiences. People can sometimes experience distress as they read, watch or listen to a recovery narrative, but this is typically short-lived. There is some evidence that encountering descriptions of self-harm in recovery narratives might contribute to recipients emulating these behaviours if they are at risk of self-harm.

Where is the study run from?

The study will run from 7 sites.

1. Nottinghamshire Healthcare NHS Foundation Trust (UK)
2. Sussex Partnership NHS Foundation Trust (UK)
3. Lincolnshire Partnership NHS Foundation Trust (UK)
4. East London NHS Foundation Trust (UK)
5. South London and Maudsley NHS Foundation Trust (UK)
6. Derbyshire Healthcare NHS Foundation Trust (UK)
7. Devon Partnership NHS Foundation Trust (UK)
8. North East London NHS Foundation Trust (UK)
9. Oxford Health NHS Foundation Trust (UK)
10. Leicestershire Partnership NHS Trust (UK)
11. Cornwall Partnership NHS Foundation Trust (UK)
12. Somerset Partnership NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

The NEON-C Trial will open in January 2020, and participants can join the trial up until April 2021.

Who is funding the study?

The National Institute for Health Research (NIHR) in the United Kingdom.

Who is the main contact?

Dr Stefan Rennick-Egglestone
stefan.egglestone@nottingham.ac.uk.

Study website

<http://www.researchintorecovery.com/neontrial>

Contact information

Type(s)

Scientific

Contact name

Dr Stefan Rennick-Egglestone

ORCID ID

<http://orcid.org/0000-0003-4187-011X>

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

249015

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS Project ID: 249015

Study information

Scientific Title

Narrative Experiences Online (NEON): Randomised controlled trial to test the feasibility of providing online recorded mental health recovery narratives to people with experience of caring for people with mental health problems , with a control of delayed access to recovery narratives (NEON-C Trial)

Acronym

NEON-C Trial

Study objectives

This is a feasibility trial which will develop knowledge to support the design of a future definitive trial.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 13/12/2019, Leicester Central Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; Tel: +44 (0)207 104 8234; Email: NRESCCommittee@nhs.net. EastMidlands-LeicesterCentral@nhs.net), REC ref: 19/EM/0326

Study design

Interventional randomized controlled trial with no masking delivered online with recruitment across England control of treatment as usual for 1 year followed by access to the intervention and 1:1 randomised allocation

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Mental health

Interventions

Participants will access the stories through an online interface called the NEON Intervention. The NEON Intervention draws on stories in the NEON Collection. This has been assembled from published to stories for which we have collected consent for use, and from donations of stories directly to the study.

Equal allocation across arms.

Arm 1: treatment as usual plus access to a collection of recorded recovery stories presented online for one year

Arm 2: treatment as usual for one year, followed by access to recorded recovery narratives

Randomisation:

In advance of trial start, an independent statistician will generate a file of random numbers, with properties as described in our protocol. This will be uploaded to the online interface, and used to randomly allocate participants.

Intervention Type

Other

Primary outcome measure

Manchester Short Assessment (MANSA) of health-related quality of life, captured at 1 week, 12 weeks and 52 weeks (primary endpoint) after baseline.

Secondary outcome measures

Secondary outcome measures will be assessed at baseline, one week, 12 weeks and 52 weeks after baseline:

1. Hope will be assessed through the Herth Hope Index (Herth, 1992)
2. Meaning in Life will be assessed through the Meaning in Life Questionnaire (Steger et al, 2006)

3. Empowerment will be assessed through the Mental Health Confidence Scale (Carpinello et al, 2000)
4. Symptomatology will be assessed through the CORE-10 (Barkham et al., 2013)

Overall study start date

06/08/2018

Completion date

22/09/2022

Eligibility

Key inclusion criteria

1. Aged 18 years or above
2. Any gender
3. Experience of being an informal carer for someone with experience of mental health problems within the last five years
4. Able to understand written and spoken English
5. Able to access or be supported to access the internet
6. Able to give online informed consent.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

Total final enrolment

54

Key exclusion criteria

1. If eligible for the NEON Trial (ISRCTN11152837).
2. If eligible for the NEON-O Trial (ISRCTN63197153).

Date of first enrolment

09/03/2020

Date of final enrolment

26/03/2021

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Nottinghamshire Healthcare NHS Foundation Trust

Duncan Macmillan House Porchester Road Mapperley

Nottingham

United Kingdom

NG3 6AA

Study participating centre

Sussex Partnership NHS Foundation Trust

Swandean Arundel Road

Worthing

United Kingdom

BN13 3EP

Study participating centre

Lincolnshire Partnership NHS Foundation Trust

St George's Long Leys Road

Lincoln

United Kingdom

LN1 1FS

Study participating centre

East London NHS Foundation Trust

Robert Dolan House Trust Headquarters 9 Alie Street

London

United Kingdom

E1 8DE

Study participating centre

South London and Maudsley NHS Foundation Trust

Bethlem Royal Hospital Monks Orchard Road

Beckenham

United Kingdom

BR3 3BX

Study participating centre

Derbyshire Healthcare NHS Foundation Trust

Ashbourne Centre Kingsway Hospital Kingsway
Derby
United Kingdom
DE22 3LZ

Study participating centre

Devon Partnership NHS Foundation Trust

Wonford House Dryden Road
Exeter
United Kingdom
EX2 5AF

Study participating centre

North East London NHS Foundation Trust

The West Wing
CEME Centre
Marsh Way
Rainham
United Kingdom
RM13 8GQ

Study participating centre

Oxford Health NHS Foundation Trust

Warneford Hospital
Warneford Lane
Headington
Oxford
United Kingdom
OX3 7JX

Study participating centre

Leicestershire Partnership NHS Trust

HQ Bridge Park Plaza
Bridge Park Road
Thurmaston
Leicester
United Kingdom
LE4 8PQ

Study participating centre**Cornwall Partnership NHS Foundation Trust**

Carew House
Beacon Technology Park
Dunmere Road
Bodmin
United Kingdom
PL31 2QN

Study participating centre**Somerset Partnership NHS Foundation Trust**

2nd Floor, Mallard Court
Express Park
Bristol Road
Bridgwater
United Kingdom
TA6 4RN

Sponsor information

Organisation

Nottinghamshire Healthcare NHS Foundation Trust

Sponsor details

Duncan Macmillan House
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Mapperley
Nottingham
England
United Kingdom
NG3 6AA
+44 (0)1157484321
Research@nottshc.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<https://www.nottinghamshirehealthcare.nhs.uk/>

Funder(s)

Funder type

Not defined

Funder Name

National Institute for Healthcare Research

Results and Publications

Publication and dissemination plan

The trialists will publish the trial protocol, which will incorporate a statistical analysis plan.

Dissemination through:

- 1. Publication of a trial report in a journal with an international audience
- 2. Publication of a lay summary through the study website

Intention to publish date

01/02/2024

Individual participant data (IPD) sharing plan

Current participant level data sharing statement as of 20/10/2023:
Data access is controlled to protect the confidentiality of trial participants, and in particular to avoid re-identification through combination of multiple data files. Data will be available on reasonable request until the end of the retention period, supervised by the study sponsor. After the retention period, availability through the study sponsor or Chief Investigator may be provided at their discretion. Contact the study sponsor through Research@nottshc.nhs.uk citing IRAS ID 249015. To obtain access, an end-user license must be signed by an authorised representative. Requests can be denied if the sponsor has reason to believe that the requestor has malicious intent, and whilst research publications are being generated by the study team or investigators. Only anonymous and pseudonymous elements of the datasets used or analysed during the study will be available. Informed consent information has been retained for audit but will not be shared. Some categories of demographic data will be redacted to avoid re-identification. A data dictionary will be provided.

Previous participant level data sharing statement:
Enquiries should be addressed to m.slade@nottingham.ac.uk or to the Research and Innovation department of the study sponsor, Nottinghamshire Healthcare NHS Foundation Trust. The trialists will provide a statement clarifying data availability in their published trial protocol.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/07/2020	22/07/2020	Yes	No
HRA research summary			26/07/2023	No	No
Results article		23/01/2024	13/02/2024	Yes	No

