Narrative Experiences Online (NEON): impact of recorded mental health recovery stories on quality of life in people experiencing psychosis

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered			
24/05/2018		[X] Protocol			
Registration date	Overall study status	[X] Statistical analysis plan			
13/08/2018	Completed	[X] Results			
Last Edited 07/11/2024	Condition category Mental and Behavioural Disorders	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 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 how others have recovered from mental health difficulties. The aim of the NEON Trial is to understand whether receiving online recorded recovery narratives benefits people with experience of what can be called psychosis.

Who can participate?

People aged 18 or over, who have experienced what can be called psychosis in the last five years, who are competent in English, and who can use a computer or smartphone (with support if needed). Participants do not need to have received any medical support for their mental health difficulties.

What does the study involve?

Participants are 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 provide some information about themselves and their experiences using online forms. This information will help the researchers to assess the success of the NEON Intervention, and they will publish their 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 your 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?

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

Who is funding the study? National Institute for Health Research (NIHR) (UK)

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

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

249015

Study information

Scientific Title

The Narrative Experiences Online (NEON) trial: a two-arm randomised controlled trial in which people with experience of psychosis receive access to (arm 1) versus receive one year delayed access to (arm 2) recorded mental health recovery narratives delivered online, with quality of life as a primary outcome, and hope, empowerment, meaning in life and symptomatology as secondary outcomes

Acronym

NEON

Study objectives

Current hypothesis as of 12/11/2019:

Participants receiving access to mental health recovery narratives will have improved quality of life at one-year follow-up compared with those not receiving access to mental health recovery narratives in this period.

Previous hypothesis:

Participants receiving mental health recovery stories will have improved quality of life at one-year follow-up compared with those not receiving mental health recovery stories.

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: NRESCommittee. EastMidlands-LeicesterCentral@nhs.net), REC ref: 19/EM/0326

Study design

An interventional trial, with no masking, delivered online with recruitment across England, a control of treatment as usual for one year followed by access to the intervention, and 1:1 randomized allocation

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Quality of life

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

Current interventions as of 12/11/2019:

Equal allocation across arms:

Arm 1: treatment as usual plus access to online recovery narratives for one year

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

Previous interventions:

An interventional trial, with no masking, delivered online with recruitment across England, and 1: 1 randomised allocation stratified for severity of condition. Randomisation will be through an algorithm that uses a generic random number generation library.

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

Arm 2: treatment as usual for 1 year

Duration of treatment: 1 year. No follow up beyond the end of the treatment period.

Intervention Type

Other

Primary outcome measure

Current primary outcome measure as of 12/11/2019:

Health-related quality of life assessed using the Manchester Short Assessment (MANSA) at 1 week, 12 weeks and 52 weeks (primary endpoint) after baseline

Previous primary outcome measure:

Health-related quality of life assessed using the Manchester Short Assessment (MANSA) at 1 week, 3 months and 1 year after baseline

Secondary outcome measures

Current secondary outcome measures as of 12/11/2019:

Assessed at 1 week, 12 weeks and 52 weeks after baseline:

1. Hope assessed through the Herth Hope Index (Herth, 1992)

- 2. Meaning in Life assessed through the Meaning in Life Questionnaire (Steger et al, 2006)
- 3. Empowerment assessed through the Mental Health Confidence Scale (Carpinello et al, 2000)
- 4. Symptomatology assessed through CORE-10 (Barkham et al, 2013)

Previous secondary outcome measures:

Assessed at 1 week, 3 months and 1 year after baseline:

- 1. Hope assessed through the Herth Hope Index (Herth, 1992)
- 2. Meaning in life assessed through the Meaning in Life Questionnaire (Steger et al, 2006)
- 3. Empowerment assessed through the Mental Health Confidence Scale (Carpinello et al, 2000)
- 4. Symptomatology assessed through a standardised measure (to be determined)
- 5. Quality of social relationships assessed through a non-standardised scale to be developed within the NEON study

Overall study start date

06/08/2018

Completion date

22/09/2022

Eligibility

Key inclusion criteria

Current inclusion criteria as of 12/11/2019:

- 1. Experience of psychosis in the last five years
- 2. Experience of mental health-related distress in the previous 6 months
- 3. Resident in England
- 4. Aged 18 years or above
- 5. Capable of accessing or being supported to access the internet, either on a personal computer, mobile device or at a community venue
- 6. Able to understand written and spoken English
- 7. Capable of providing online informed consent
- 8. Any gender

Previous inclusion criteria:

- 1. Aged 18-65
- 2. Any gender
- 3. Primary or secondary clinical diagnosis of psychosis (including e.g. schizophrenia, schizoaffective disorder, bipolar disorder)
- 4. Currently using mental health services in England
- 5. Able to understand English
- 6. Able to access or be supported to access the internet
- 7. Able to give online informed consent

Participant type(s)

Other

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

683

Total final enrolment

739

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

09/03/2020

Date of final enrolment

01/03/2021

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

Sponsor information

Organisation

Nottinghamshire Healthcare NHS Foundation Trust

Sponsor details

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

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/04ehjk122

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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

Intention to publish date

30/11/2024

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 reidentification. 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?
<u>Protocol article</u>	protocol	20/07/2020	22/07/2020	Yes	No
Statistical Analysis Plan	Development and delivery cost	20/05/2023	22/05/2023	Yes	No
Other publications		07/11/2022	27/06/2023	Yes	No

Baseline data analysis

Interim results article	27/06/2023	13/07/2023 Yes	No
HRA research summary		26/07/2023 No	No
Results article	23/10/2024	07/11/2024 Yes	No