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

Submission date
24/05/2018

Recruitment status
No longer recruiting

Registration date
13/08/2018

Overall study status
Completed

Last Edited
07/11/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] 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
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Contact information

Type(s)
Scientific

Contact name
Dr Stefan Rennick-Egglestone

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Quality of life

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

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

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

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.

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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?
Results article		23/10/2024	07/11/2024	Yes	No

Protocol article	protocol	20/07/2020	22/07/2020	Yes	No
HRA research summary			26/07/2023	No	No
Interim results article	Baseline data analysis	27/06/2023	13/07/2023	Yes	No
Other publications	Development and delivery cost	07/11/2022	27/06/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan		20/05/2023	22/05/2023	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes