ISRCTN63197153 https://doi.org/10.1186/ISRCTN63197153

Impact of receiving recorded mental health recovery narratives on quality of life in people experiencing non-psychosis mental health problems (NEON-O Trial)

Submission date
02/12/2019

Recruitment status
No longer recruiting

Registration date
09/01/2020

Overall study status
Completed

Last Edited
13/02/2024

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) study 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 psychosis to investigate whether receiving access to mental health recovery narratives can provide benefits (http://www.isrctn.com/ISRCTN11152837).
Our research suggests that any benefits of receiving recovery narratives might not be specific to a mental health experience or diagnosis. We are interested in understanding whether the NEON Intervention needs to be specialised to a group of people with similar experiences (as in the NEON Trial) or whether it can be used across a broad population. In parallel with the NEON Trial, we are also conducting the NEON-O Trial, where O refers to Other. NEON-O invites participation from people with experience of any mental health problem other than psychosis.

Who can participate?
People aged 18 years or over, who have experienced distress associated with mental health concerns in the past 6 months and have experience of mental health problem other than psychosis in the past 5 years. Participants need to be competent in English, and 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; no diagnosis is required, and we welcome participation from people who reject the concept of diagnosis.

What does the study involve?
Taking part in NEON-O 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, they may also be invited to take part in an interview about their experiences, and their usage of the NEON Intervention will be logged. Results will be published 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 is run from 12 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-O Trial opened on 9th March 2020, and participants can currently join the trial up until 30th 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
Institute of Mental Health
Triumph Road
Nottingham
United Kingdom
NG7 2TU
+44 (0)115 82 30926
stefan.egglestone@nottingham.ac.uk

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
The NEON-O Trial: a two-arm randomised controlled trial in which people with experience of non-psychosis mental health problems receive access to (arm 1) versus receive 1 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-O Trial

Study objectives
Current study hypothesis as of 25/11/2020:
Participants receiving access to mental health recovery narratives will have a clinically-important increase in quality of life at 1-year follow-up compared with those not receiving access to mental health recovery narratives in this period.

Previous study hypothesis:
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: NRESCommittee.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 one 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
2. Meaning in Life will be assessed through the Meaning in Life Questionnaire
3. Empowerment will be assessed through the Mental Health Confidence Scale
4. Symptomatology will be assessed through the CORE-10

Overall study start date
06/08/2018

Completion date
22/09/2022

Eligibility

Key inclusion criteria
1. Aged 18 years and above
2. Any gender
3. Experinece of mental health problem other than psychosis in the last five years
4. Experience of mental health-related distress in previous 6 months
5. Resident in England
6. Able to understand written and spoken English
7. Able to access or be supported to access the internet
8. Able to give online informed consent.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
994

Total final enrolment
1023

Key exclusion criteria
1. If included in the NEON Trial (ISRCTN number: ISRCTN11152837)

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
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
Porchester Road
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 Health 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 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
Protocol article	updated protocol	29/01/2022	31/01/2022	Yes	No
Statistical Analysis Plan		20/05/2023	22/05/2023	Yes	No
Other publications	Development and delivery cost	07/11/2022	27/06/2023	Yes	No
Interim results article	Baseline data analysis	27/06/2023	13/07/2023	Yes	No
HRA research summary			26/07/2023	No	No
Results article		01/02/2024	13/02/2024	Yes	No