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Tackling chronic depression (TACK II)

Submission date	Recruitment status	[X] Prospectively registered
03/06/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
13/06/2019	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/02/2023	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Current plain English summary as of 21/01/2022:
Background and study aims
This study aims to develop a new approach to help people with depression. Depression is a common mental health problem affecting one in four people at some point in their life. It can result in high levels of distress, increased suicide risk and a loss of interest in daily activities. Most people with depression find treatment helpful. However, for some people (about one in five), depression continues for more than two years, despite receiving mental health treatment. This is called chronic depression. Approaches for chronic depression are limited, and people often continue to have a poor quality of life. An intervention called DIALOG+ has been developed which helps patients with another serious mental illness called schizophrenia. DIALOG+ involves mental health staff using a tablet computer to structure conversations about patient's satisfaction with different areas of life and then working together to find solutions to concerns raised. After using DIALOG+, patients were more satisfied with life and had fewer symptoms. Patients and staff found the approach helpful and it saved the NHS money. The aim of this research is to find out whether DIALOG+ can also help people with chronic depression. The researchers will run a clincial trial in different sites across England to see if DIALOG+ can improve quality of life for people with depression and to see how cost effective the intervention is.

Who can participate?
Patients aged 18-100 who have had depression for at least 2 years can participate in the study. However patients have to be referred to the study by their treating clinician.

What does the study involve?
Clinicians are randomly allocated to the intervention group or the control group. Patients allocated to the intervention group use the 'DIALOG+' intervention on a tablet computer, together with their clinician, using the DIALOG+ scale to rate how satisfied they are with different areas of their life, and then choosing which areas need to be discussed in the meeting. The clinician applies a 4-step approach to these selected areas based on the principles of solution-focused therapy.

Participants allocated to the control group have their routine meetings with their care coordinator as usual. At the end of the session they complete the DIALOG scale on a tablet computer to rate how satisfied they are with different areas of their life. They do this without

any input from their clinician. Both interventions include multiple sessions delivered over a period of 12 months. Quality of life, and other secondary outcomes, will be assessed at baseline, 3 months, 6 months and 12 months.

What are the possible benefits and risks of participating?
It is not known whether participants will experience any direct benefits from taking part in this study, but it is hoped that they will enjoy and value their role in helping to test a new treatment and providing their thoughts on how it can be developed further to be a more effective treatment for long-term depression. Participants who complete the assessments will be reimbursed for their time and will be paid a fee of £20. It is believed that this study is safe and participants are not expected to suffer any harm or injury because of taking part. It is possible that some people may become distressed whilst taking part due to discussing sensitive issues. In the event of this happening the intervention session will be stopped and the individual will be asked if they want to continue. If they do wish to continue then they will be given time to recover. However, they may leave the session at any time and there will be a member of the participant's healthcare team available to talk to them should they need to.

Where is the study run from?
The study is run from the Newham Centre for Mental Health, in East London. The research will take place in multiple sites across England, including;
1. East London NHS Foundation Trust
2. Oxford Health NHS Foundation Trust
3. Gloucestershire Health & Care NHS Foundation Trust (formally 2gether NHS Foundation Trust)
4. Sheffield Health and Social Care NHS Foundation Trust
5. Essex Partnership NHS Foundation Trust
6. Devon Partnership NHS Foundation Trust
7. Somerset NHS Foundation Trust
8. North East London NHS Foundation Trust
9. South London and Maudsley NHS Foundation Trust

When is the study starting and how long is it expected to run for?
The study will begin in July 2019 and is expected to run until February 2023 (updated 21/04 /2022, previously: for 33 months ending April 2022).

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

Who is the main contact?
Dr Victoria Bird
v.j.bird@qmul.ac.uk
Dr Philip McNamee
philip.mcnamee@nhs.net

Previous plain English summary as of 10/03/2020:
Background and study aims
This study aims to develop a new approach to help people with depression. Depression is a common mental health problem affecting one in four people at some point in their life. It can result in high levels of distress, increased suicide risk and a loss of interest in daily activities. Most people with depression find treatment helpful. However, for some people (about one in five), depression continues for more than two years, despite receiving mental health treatment. This is called chronic depression. Approaches for chronic depression are limited, and people often continue to have a poor quality of life. An intervention called DIALOG+ has been

developed which helps patients with another serious mental illness called schizophrenia. DIALOG+ involves mental health staff using a tablet computer to structure conversations about patient's satisfaction with different areas of life and then working together to find solutions to concerns raised. After using DIALOG+, patients were more satisfied with life and had fewer symptoms. Patients and staff found the approach helpful and it saved the NHS money. The aim of this research is to find out whether DIALOG+ can also help people with chronic depression. The researchers will run a clincial trial in different sites across England to see if DIALOG+ can improve quality of life for people with depression and to see how cost effective the intervention is.

Who can participate?
Patients aged 18-80 who have had depression for at least 2 years can participate in the study. However patients have to be referred to the study by their treating clinician.

What does the study involve?
Clinicians are randomly allocated to the intervention group or the control group. Patients allocated to the intervention group use the 'DIALOG+' intervention on a tablet computer, together with their clinician, using the DIALOG+ scale to rate how satisfied they are with different areas of their life, and then choosing which areas need to be discussed in the meeting. The clinician applies a 4-step approach to these selected areas based on the principles of solution-focused therapy.

Participants allocated to the control group have their routine meetings with their care coordinator as usual. At the end of the session they complete the DIALOG scale on a tablet computer to rate how satisfied they are with different areas of their life. They do this without any input from their clinician. Both interventions include multiple sessions delivered over a period of 12 months. Quality of life, and other secondary outcomes, will be assessed at baseline, 3 months, 6 months and 12 months.

What are the possible benefits and risks of participating?
It is not known whether participants will experience any direct benefits from taking part in this study, but it is hoped that they will enjoy and value their role in helping to test a new treatment and providing their thoughts on how it can be developed further to be a more effective treatment for long-term depression. Participants who complete the assessments will be reimbursed for their time and will be paid a fee of £20. It is believed that this study is safe and participants are not expected to suffer any harm or injury because of taking part. It is possible that some people may become distressed whilst taking part due to discussing sensitive issues. In the event of this happening the intervention session will be stopped and the individual will be asked if they want to continue. If they do wish to continue then they will be given time to recover. However, they may leave the session at any time and there will be a member of the participant's healthcare team available to talk to them should they need to.

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2. Oxford Health NHS Foundation Trust
3. Gloucestershire Health & Care NHS Foundation Trust (formally 2gether NHS Foundation Trust)
4. Sheffield Health and Social Care NHS Foundation Trust
5. Essex Partnership NHS Foundation Trust
6. Devon Partnership NHS Foundation Trust

When is the study starting and how long is it expected to run for?
The study will begin in July 2019 and is expected to run for 33 months (ending April 2022).

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

Who is the main contact?
Dr Victoria Bird
v.j.bird@qmul.ac.uk
Dr Philip McNamee
philip.mcnamee@nhs.net

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Previous plain English summary as of 03/03/2020:
Background and study aims
This study aims to develop a new approach to help people with depression. Depression is a common mental health problem affecting one in four people at some point in their life. It can result in high levels of distress, increased suicide risk and a loss of interest in daily activities. Most people with depression find treatment helpful. However, for some people (about one in five), depression continues for more than two years, despite receiving mental health treatment. This is called chronic depression. Approaches for chronic depression are limited, and people often continue to have a poor quality of life. An intervention called DIALOG+ has been developed which helps patients with another serious mental illness called schizophrenia. DIALOG+ involves mental health staff using a tablet computer to structure conversations about patient's satisfaction with different areas of life and then working together to find solutions to concerns raised. After using DIALOG+, patients were more satisfied with life and had fewer symptoms. Patients and staff found the approach helpful and it saved the NHS money. The aim of this research is to find out whether DIALOG+ can also help people with chronic depression. The researchers will run a clincial trial in different sites across England to see if DIALOG+ can improve quality of life for people with depression and to see how cost effective the intervention is.

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Where is the study run from?
The study is run from the Unit for Social and Community Psychiatry (based at the Newham Centre for Mental Health in East London). The research will take place in multiple trial sites across England, including;
1. Oxford Health NHS Foundation Trust
2. Gloucestershire Health & Care NHS Foundation Trust (renamed from 2gether NHS Foundation Trust)
3. Sheffield Health and Social Care NHS Foundation Trust
4.Essex Partnership NHS Foundation Trust
5. Devon Partnership NHS Foundation Trust

When is the study starting and how long is it expected to run for?
The study will begin in July 2019 and is expected to run for 33 months (ending April 2022).

Who is funding the study?
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Who is the main contact?
Dr Victoria Bird
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Where is the study run from?
The study is run from the Newham Centre for Mental Health, in East London. The research will take place in multiple sites across England, including;
1. East London NHS Foundation Trust
2. Oxford Health NHS Foundation Trust
3. 2gether NHS Foundation Trust
4. Sheffield Health and Social Care NHS Foundation Trust

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Dr Philip McNamee
philip.mcnamee@nhs.net

Study website
https://tack.elft.nhs.uk/

Contact information

Type(s)
Scientific

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Type(s)
Public

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Dr Victoria Bird

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
263211

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 42123, IRAS 263211

Study information

Scientific Title
Testing a technology-supported and solution-focused intervention (DIALOG+) for people with chronic depression: a cluster randomised controlled trial

Acronym
TACK II

Study objectives
The aim is to assess the effectiveness of DIALOG+ for patients with chronic depression on improving quality of life and clinical outcomes such as depression symptoms at 12 months after the treatment has started.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/05/2019, NHS Wales REC 6 (no address; 01874 615949; Wales.REC6@wales.nhs.uk), ref: 19/WA/0160.

Study design
Randomised; Both; Design type: Treatment, Process of Care, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Management of Care, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Depression

Interventions

Current intervention as of 21/01/2022:
This is a multi-site cluster randomised controlled trial.
We will seek patients who are currently receiving care for chronic depression within mental health services.
The trial will take place across 9 sites in NHS England. In total we will be looking to recruit around 112 clinicians and 376 patients.
The aim of the study is to assess the clinical and cost effectiveness of DIALOG+ for patients with chronic depression.
This means understanding how good the intervention is both on symptoms and in terms of value for money.
Clinicians who have experience of delivering mental health interventions within NHS services will be recruited. The researcher will meet with the clinician and any queries or concerns will be clarified and addressed. Staff will be given time to consider whether or not they wish to participate in the study. On agreement to participate, they will be asked to sign a consent form.
Once a clinician has been recruited, they will check their caseload for patients who meet the eligibility criteria. Patients who are identified in this way will be given a Trial ID and the clinician will ask the patient for consent to be approached by a researcher. If the answer is yes, the researcher will contact the patient and arrange to meet, where they will be given an information sheet to read, and an opportunity to discuss the study in further depth. It will be made clear that if the patient agrees to participate that they have a 50/50 chance of receiving treatment that involves:
(i) use of the DIALOG+ software on a tablet computer during their routine meetings (experimental group), or
(ii) completion of the DIALOG scale on the tablet computer at the end of their meeting (control group). If the patient
consents, they will be asked to fill in two "screening" which will ascertain if they are suitable for the study. One of these questionnaire measures symptoms of depression (MADRS) and the other quality of life (MANSA). To be eligible for the study, patients will need to score 10 or more on the MADRS and lower than 5 on the MANSA. Patients who do not meet these thresholds will be thanked for their interest and reimbursed with £5 for having completed the short questionnaire. Eligible patients will go on to complete a full baseline assessment booklet which is made up of questionnaires assessing clinical, social and service related outcomes. This takes around 45-60 minutes and will ask people for some personal characteristics and clinical information. They will be paid £20 for their time.
Once between 1 and 6 patients have been identified then the clinician will be 'cluster randomised'. This means that all patients seen by the same clinician will receive the same intervention. Patients have an equal chance of either being randomly allocated to the DIALOG+ arm, or the active control arm.
We will recruit 376 patients in this manner.
Randomisation will be done by via a randomisation database that is designed by the Pragmatic Clinical Trials Unit (PCTU).
Clinicians in both trial arms will receive one-on-one training from a researcher in how to use a tablet computer, and also the DIALOG+ intervention (experimental) or the DIALOG scale (active control group). Participants in the intervention arm will then use the DIALOG+ intervention once per month for 6 months, and then 3 times within the next 6 months during their routine meetings with clinicians. The DIALOG+ intervention involves rating satisfaction with 11 items of life, and then using this information to set goals based on solution focused principles.
Participants in the control group will fill in the same 11 item rating of satisfaction (DIALOG scale) at the end of their meeting with the clinician – but without any discussion of these ratings or input from their clinician.

After 3 months, the patients will be contacted again over the phone, and asked to fill out two short questionnaires: the MANSA and the BDI-II. The patient will be offered £5 for completing this short assessment.
After 6 months, the patients will be contacted again and a face to face assessment with a researcher will be arranged.
The same questionnaires that were completed at recruitment will be completed again to measure any changes from baseline which. The patient will be offered £20 for completing this short assessment. For those participants in the intervention arm, they will also be asked to complete a 'DIALOG+ Experience Questionnaire' which explores their experience of using the intervention. This will be completed by an unblinded researcher. Finally at 12 months, the final face to face assessment with the researcher will be completed. The same questionnaires that were completed at recruitment and at 6 months will be completed again to measure any changes from baseline. The patient will be offered £20 for completing this short assessment.The DIALOG+ Experience Questionnaire will also be completed at this time-point.

PROCESS EVALUATION/ FIDELITY ASSESSMENT
Embedded within the trial will be a research study to explore the barriers in delivering this DIALOG+ intervention and seeking ways to improve the training of DIALOG+.
As part of this, 60 patients and clinicians will be invited to be interviewed by the research team to gain an insight into receiving or delivering the intervention. Participants will be purposefully sampled based on which site they came from, how many sessions they attended and other factors that will help with improving the intervention. The interviews will last around 45 minutes and patients will be reimbursed £15 for their time.
Additionally at point of consent, participants will be asked whether or not they would be happy for their meetings with clinicians to be audio- or video-recorded. Those that agree will have one of their sessions recorded. This will be analysed by a member of the research team to see if the training in the intervention was sufficient.
Finally, the DIALOG+ software (i.e. the app) will automatically record how many sessions were received, what domains were explicitly discussed in DIALOG+ and what actions were agreed. This data will be extracted in order to explore how and when the intervention was delivered and to see if this effects the responses to the questionnaires. Tablets and the intervention app are password protected.

Previous intervention:
This is a multi-site cluster randomised controlled trial.
We will seek patients who are currently receiving care for chronic depression within mental health services.
The trial will take place across multiple sites in NHS England. In total we will be looking to recruit 112 clinicians and 448 patients.
The aim of the study is to assess the clinical and cost effectiveness of DIALOG+ for patients with chronic depression.
This means understanding how good the intervention is both on symptoms and in terms of value for money.
Clinicians who have experience of delivering mental health interventions within NHS services will be recruited. The researcher will meet with the clinician and any queries or concerns will be clarified and addressed. Staff will be given time to consider whether or not they wish to participate in the study. On agreement to participate, they will be asked to sign a consent form.
Once a clinician has been recruited, they will check their caseload for patients who meet the eligibility criteria. Patients who are identified in this way will be given a Trial ID and the clinician will ask the patient for consent to be approached by a researcher. If the answer is yes, the researcher will contact the patient and arrange to meet, where they will be given an information sheet to read, and an opportunity to discuss the study in further depth. It will be made clear that

if the patient agrees to participate that they have a 50/50 chance of receiving treatment that involves:
(i) use of the DIALOG+ software on a tablet computer during their routine meetings (experimental group), or
(ii) completion of the DIALOG scale on the tablet computer at the end of their meeting (control group). If the patient
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Once between 3 and 6 patients have been identified then the clinician will be 'cluster randomised'. This means that all patients seen by the same clinician will receive the same intervention. Patients have an equal chance of either being randomly allocated to the DIALOG+ arm, or the active control arm.
We will recruit 448 patients in this manner.
Randomisation will be done by via a randomisation database that is designed by the Pragmatic Clinical Trials Unit (PCTU).
Clinicians in both trial arms will receive one-on-one training from a researcher in how to use a tablet computer, and also the DIALOG+ intervention (experimental) or the DIALOG scale (active control group). Participants in the intervention arm will then use the DIALOG+ intervention once per month for 6 months, and then 3 times within the next 6 months during their routine meetings with clinicians. The DIALOG+ intervention involves rating satisfaction with 11 items of life, and then using this information to set goals based on solution focused principles.
Participants in the control group will fill in the same 11 item rating of satisfaction (DIALOG scale) at the end of their meeting with the clinician – but without any discussion of these ratings or input from their clinician.
After 3 months, the patients will be contacted again over the phone, and asked to fill out two short questionnaires: the MANSA and the BDI-II. The patient will be offered £5 for completing this short assessment.
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factors that will help with improving the intervention. The interviews will last around 45 minutes and patients will be reimbursed £15 for their time.
Additionally at point of consent, participants will be asked whether or not they would be happy for their meetings with clinicians to be audio- or video-recorded. Those that agree will have one of their sessions recorded. This will be analysed by a member of the research team to see if the training in the intervention was sufficient.
Finally, the DIALOG+ software (i.e. the app) will automatically record how many sessions were received, what domains were explicitly discussed in DIALOG+ and what actions were agreed. This data will be extracted in order to explore how and when the intervention was delivered and to see if this effects the responses to the questionnaires. Tablets and the intervention app are password protected.

Intervention Type
Other

Primary outcome measure
Quality of life, as measured on the Manchester Short Assessment of Quality of Life (MANSA), 12 months after randomisation

Secondary outcome measures
The following measures are all collected at baseline, 6 months, and 12 months:
1. Depression symptoms, measured by two scales, the Montgomery–Samberg Depression Rating Scale (MADRS; observer rated) and Beck Depression Inventory (BDI-II; self-report*)
2. Severity of illness, will be measured by the Clinical Global Impression scale (CGI-I, clinician rated)
3 Economic evaluation through completion of the ICECAP-A (a measure of capability for the general adult population)
4. Satisfaction with care, measured using the Client Satisfaction Questionnaire (CSQ-8)
5. Health-related quality of life, measured using the Europol 5 dimension (EQ-5D-35L)
6. Data on health service usage in the past 6 months by the participant, collected via an amended version of the Client Service Receipt Inventory (CSRI).

*The MANSA and the BDI-II will also be collected at 3 months.

Additionally, those participants allocated to receive DIALOG+ will be given an additional questionnaire to measure their experience of receiving the DIALOG+ intervention. This is a specially designed questionnaire developed in partnership with the TACK Lived Experience Advisory Panel. This questionnaire will be completed at 6 months add 12 months.

Overall study start date
01/04/2019

Completion date
17/02/2023

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 21/01/2022:
Clinician Participants
1. Qualification as a mental health or healthcare professional (including Band 4 Support Workers,

Social Workers and Occupational Therapists)
2. Experience of working in a healthcare setting for at least 6 months
3. Currently (or within the last 6 months) treated individuals with chronic depression
4. Have at least 4 patients with chronic depression on their caseload, or have the ability to 'case swap' with other team members, and seeing these patients regularly (e.g. once a month)
5. No plans to leave their post within the next 6 months

Patient Participants
1. 18-100 years old
2. Exhibiting symptoms of depression or non-psychotic low mood with a duration of illness of at least 2 years (can be co-morbid with other conditions such as anxiety, personality disorder etc.)
3. Receiving treatment from an NHS mental health service with regular contact with clinicians
4. Capacity to provide informed consent
5. Ability to speak and understand English

Previous participant inclusion criteria:
Clinician Participants
1. Qualification as a mental health or healthcare professional (including Band 4 Support Workers, Social Workers and Occupational Therapists)
2. Experience of working in a healthcare setting for at least 6 months
3. Currently (or within the last 6 months) treated individuals with chronic depression
4. Have at least 4 patients with chronic depression on their caseload, or have the ability to 'case swap' with other team members, and seeing these patients regularly (e.g. once a month)
5. No plans to leave their post within the next 6 months

Patient Participants
1. 18-80 years old
2. Exhibiting symptoms of depression or non-psychotic low mood with a duration of illness of at least 2 years (can be co-morbid with other conditions such as anxiety, personality disorder etc.)
3. Receiving treatment from an NHS mental health service with regular contact with clinicians
4. Capacity to provide informed consent
5. Ability to speak and understand English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
Planned Sample Size: 548 (Trial Clinicians: 112; Trial Patient Participants: 376; Process Evaluation Participants: 60); UK Sample Size: 548

Total final enrolment
487

Key exclusion criteria
Clinician Participants
1. Do not have at least 4 eligible patients on their caseload.
2. Do not have any frequent clinical contact with eligible patients.

Patient Participants
1. Primary diagnosis of a substance misuse problem (F10 - F19).
2. Diagnosis of an organic, including symptomatic, mental disorder (F00-F09) e.g. Alzheimer's.
3. Inpatient on a psychiatric ward at the time of recruitment.
4. Does not have current clinical contact with a mental health professional.

Date of first enrolment
01/07/2019

Date of final enrolment
31/01/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Warneford Hospital
Oxford Health NHS Foundation Trust
Warneford Lane
Oxford
United Kingdom
OX3 7JX

Study participating centre
Sheffield Health & Social Care NHS Foundation Trust
Fulwood House
Old Fulwood Road
Sheffield
United Kingdom
S10 3TH

Study participating centre

Gloucestershire Health & Care NHS Foundation Trust
Fritchie Centre
Charlton Lane
Cheltenham
United Kingdom
GL53 9DZ

Study participating centre
Essex Partnership NHS Foundation Trust
The Lodge
Runwell Chase
Runwell
Wickford
United Kingdom
SS11 7XX

Study participating centre
Devon Partnership NHS Foundation Trust
Wonford House
Dryden Rd
Exeter
United Kingdom
EX2 5AF

Study participating centre
Somerset NHS Foundation Trust
Trust Management
Lydeard House
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
North East London NHS Foundation Trust
West Wing
C E M E Centre
Marsh Way
Rainham
United Kingdom
RM13 8GQ

Study participating centre
South London and Maudsley NHS Foundation Trust
Bethlem Royal Hospital
Monks Orchard Road
Beckenham
United Kingdom
BR3 3BX

Sponsor information

Organisation
East London NHS Foundation Trust

Sponsor details
20-24 Commercial Street
London
England
United Kingdom
E1 8DE
-
sponsor.noclor@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://www.noclor.nhs.uk/

ROR
https://ror.org/01q0vs094

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0615-20010

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
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/07/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof Victoria Bird (v.j.bird@qmul.ac.uk). Outcome data will be available for secondary or meta-analysis at least 12 months after the publication of the programme final report. Requests should be submitted in writing with a brief explanation of the how the data will be used and for what purpose. Raw data will be completely anonymised and will follow GDPR guidelines.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		28/03/2022	15/02/2023	Yes	No
HRA research summary			28/06/2023	No	No