ISRCTN16864442 https://doi.org/10.1186/ISRCTN16864442

Tackling chronic depression (TACK) Phase 1

Submission date
26/03/2018

Recruitment status
No longer recruiting

Registration date
10/04/2018

Overall study status
Completed

Last Edited
27/03/2019

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

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+ involved mental health staff using a tablet computer to ask patients about their 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 see if DIALOG+ is acceptable by asking people with depression their opinions on the approach so they can adapt it to their needs. They will also be asking clinicians about their experience and views for adapting the intervention. Following this, they will conduct a study with nine staff members and 45 patients with depression to gain further experience with DIALOG+ and check whether a larger study testing it would be possible.

Who can participate?
Patients aged 18-80 who have had depression for at least 2 years, and are 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 6 sessions

delivered over a period of 6 months. Quality of life is assessed at baseline and 6 months (follow up).

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, but is actively recruiting from three sites:
1. Enhanced Primary Care, East London NHS Foundation Trust
2. Haringey North East Locality Team, Barnet, Enfield and Haringey NHS Mental Health Trust
3. Chelmsford & Essex Centre (C&E) Centre, Essex Partnership University NHS Foundation Trust

When is the study starting and how long is it expected to run for?
April 2017 to June 2019

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

Contact information

Type(s)
Scientific

Contact name
Dr Victoria Bird

ORCID ID
http://orcid.org/0000-0002-2053-7679

Contact details
Unit for Social and Community Psychiatry
Newham Centre for Mental Health
Cherry Tree Way
London
United Kingdom
E13 8SP

-
v.j.bird@qmul.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
33823

Study information

Scientific Title
Adapting and testing a technology supported and solution-focused intervention (DIALOG+) for people with chronic depression

Acronym
TACK

Study objectives
This research 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.

In previous research we developed an intervention called DIALOG+ which helped patients with another serious mental illness called schizophrenia. DIALOG+ involved mental health staff using a tablet computer to ask patients about their 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 first phase of the TACK programme seeks to investigate whether DIALOG+ can also help people with chronic depression. We will see if DIALOG+ is acceptable by asking people with depression their opinions on the approach so we can adapt it to their needs. We will also be asking clinicians about their experience and views for adapting the intervention. Following this, we will conduct a study with nine staff members and 45 patients with depression to gain further experience with DIALOG+ and check whether a larger study testing it would be possible.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Wales NHS Research Ethics Committee 5, 19/03/2017, ref: 17/WA/0085

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural, Complex Intervention

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Treatment

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
Recurrent depressive disorder

Interventions
Randomisation will be performed by an independent statistician from the Pragmatic Clinical Trials Unit (PCTU) who is not part of the trial team. The feasibility trial will be cluster randomised, with the clinician as unit of randomisation. As soon as five eligible patients (or all eligible and willing patients on the clinician's caseload where this is less than five) have been recruited, informed consent obtained and the baseline assessment completed, the clinician will be randomised to either the intervention or control arm. Clinicians will be randomised on a 2:1 basis with 6 allocated to the intervention arm and three included in the control arm.

Participants allocated to the intervention are will use the 'DIALOG+' intervention on a tablet computer, together with their clinician. The will include 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 will apply a 4-step therapeutic approach to these selected areas based on the principles of solution-focused therapy.

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

Both interventions will include 6 sessions delivered over a period of 6 months. Outcome measures to be taken at baseline and 6 months (follow up).

Intervention Type
Other

Phase
Phase I

Primary outcome measure
Quality of life, measured using the Manchester Short Assessment of Quality of Life (MANSA) at baseline and 6 months

Secondary outcome measures
Measured at baseline and 6 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. General mental health symptoms, observer rated by the Health of the Nation Outcome Scale (Honos)
3. Physical health satisfaction, measured by the SF-36
4. Economic evaluation through completion of the ICECAP-A (a measure of capability for the general adult population)
5. Satisfaction with care, measured using the Client Satisfaction Questionnaire (CSQ-8)
6. Health-related quality of life, measured using the Europol 5 dimension (EQ-5D-35L)
7. Social functioning, observer rated on the Global Assessment of Functioning (GAF)
8. 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)
9. The experience of receiving the DIALOG+ intervention, assessed using a bespoke questionnaire developed in partnership with the TACK Lived Experience Advisory Panel (only participants allocated to the intervention arm will complete this) at 6 month follow up

Overall study start date
06/04/2017

Completion date
30/09/2019

Eligibility

Key inclusion criteria
1. 18-80 years old
2. Clinical diagnosis of depression with a duration of illness of at least 2 years
3. Using NHS mental health services for the treatment of depression with regular contact with clinicians
4. Capacity to provide informed consent
5. Ability to speak and understand English
6. Low quality of life (as indicated by a score of <5 on the MANSA)
7. Evidence of current depression symptoms (score of >=10 on the MADRS)

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
48 patient participants; 12 clinician participant; UK sample size = 60

Key exclusion criteria
Patients:
1. Does not meet inclusion criteria
2. A mean score of 5 or more on the MANSA
3. A total score of less than 10 on the MADRS
4. Primary problem of current substance misuse
5. No capacity to provide informed consent
6. An inpatient on a psychiatric ward at the time of recruitment

Clinicians:
1. Does not meet inclusion criteria
2. Does not have any clinical contact with patients with depression

Date of first enrolment
01/04/2018

Date of final enrolment
29/03/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Enhanced Primary Care
East London NHS Foundation Trust
86 Old Montague Street
London
United Kingdom
E1 5NN

Study participating centre

Haringey North East Locality Team
Barnet, Enfield and Haringey NHS Mental Health Trust
St. Ann's Hospital
St. Ann's Road
Tottenham
London
United Kingdom
N15 3TH

Study participating centre
Chelmsford & Essex Centre (C&E) Centre
Essex Partnership University NHS Foundation Trust
Chelmsford
United Kingdom
CM2 0QH

Sponsor information

Organisation
East London NHS Foundation Trust

Sponsor details
20-24 Commercial Street
London
England
United Kingdom
E1 6LP
-
sponsor.noclor@nhs.net

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01q0vs094

Funder(s)

Funder type
Government

Funder Name

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

Results and Publications

Publication and dissemination plan

Study documentation is available on request from Dr Victoria Bird (v.j.bird@qmul.ac.uk). Dissemination activities will run throughout the whole programme of research. The Lived Experience Advisory Panel (LEAP) will take an active role in dissemination to ensure findings are accessible and meaningful to service users, carers and the general public. Dissemination will target different stakeholders including mental health service commissioners, clinicians, patients, carers and academics.

Results of the feasibility trial are planned to be published in a high impact, open access journal within one year of the overall trial end date.

Intention to publish date

30/06/2020

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No