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Brief psychological treatment of functional cognitive symptoms

Submission date
25/02/2022

Recruitment status
No longer recruiting

Registration date
24/10/2022

Overall study status
Completed

Last Edited
31/10/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Functional cognitive disorder (FCD) is a relatively new term in neurology and psychiatry. It is used to describe patients who experience real difficulties with their memory yet show no signs of a neurological condition such as dementia. Brain scans and other investigations do not reveal an abnormality that could account for the symptoms.
Diagnostic memory clinics (DMCs) were developed to improve the access of people with dementia to diagnosis and support. Over the past decade, increased numbers of people have been seen in these clinics. A significant proportion of those seen, however, are found to have a functional cognitive disorder. Despite the symptoms being disabling and persistent, memory clinic teams are unsure how to help these patients. Instead, they are discharged back to their GP without any support or treatment.
The cause of these memory symptoms is not well understood. Most researchers believe that low mood and anxiety contribute to the symptoms but are not the full explanation. It has been proposed that patients with FCD are unusually alert to memory lapses. These lapses in turn increase fear of memory failure and doubts about the accuracy of recalled memories. This sets up a vicious cycle of increased monitoring for memory lapses and a corresponding decrease in the amount of attention available to be directed towards the world.
There is some evidence that brief psychological treatments can be beneficial. These involve education about the condition and stress management advice. A recent study that combined outcomes from multiple independent studies showed that this treatment delivered in small groups improved psychological well-being. However, the majority of studies were of low quality. Also, the proposed interventions were lengthy, involving up to 13 hour-long sessions. The authors concluded that a large-scale research trial is now "urgently needed".
At St George's Hospital, a centre of excellence for functional neurological disorders, researchers have developed a five-session group treatment. Initial pilot data suggests it improves quality of life and decreases distress. The aim is to study the feasibility of delivering this group intervention to patients with FCD within local memory clinics.
This study design has benefitted from the involvement of patients with FCD, including from the charity FND Hope, from the start. Their involvement has helped refine the study design and particularly the outcome measures to ensure these are appropriate and acceptable.

Who can participate?
1. An established diagnosis of FCD made in DMC/CNC and confirmed by the research team
2. Aged 18 years or over

What does the study involve?
Participants will be randomly allocated to either the ACT group intervention or a treatment as usual (TAU) control group. Self-report clinical outcome measures will be collected after consenting to participate and again 8, 16, and 26 weeks later.

What are the possible benefits and risks of participating?
The possible benefits of participating include improvement in symptoms and functioning, increased understanding of the condition and its causes, and helping to develop an effective intervention. Risks are that there may be no improvements despite giving up time and effort to participate, distress through increased focus on symptoms, and hopelessness if no improvement occurs. As this is a group treatment there can be the risk of sharing information with others, although discussion of sensitive personal issues is kept to a minimum and principles of confidentiality will be agreed among participants at the start of treatment. The intervention does not delve into distressing or traumatic memories but if these do become a concern or suicidal ideation emerges the trial has a protocol to manage these situations.

Where is the study run from?
St George's Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2020 to July 2024

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

Who is the main contact?
Dr Norman Poole
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
313730

Protocol serial number
NIHR202743, CPMS 53251, IRAS 313730

Study information

Scientific Title
Acceptance and commitment therapy for functional cognitive disorders - feasibility study

Acronym
ACT4FND

Study objectives
Feasibility study:
The researchers plan to investigate whether the brief group Acceptance and Commitment Therapy (ACT) intervention is feasible to deliver to patients with functional cognitive disorders (FCD) identified within local memory clinics. They also aim to further refine the ACT intervention so it can be manualised and adapted for online delivery.

The feasibility study aims to assess:
1. The willingness of clinicians in diagnostic memory clinics (DMCs) to randomise to a brief group intervention vs treatment as usual (TAU)
2. The willingness of FCD patients be randomised to a brief group intervention vs TAU
3. Acceptability of the face-to-face and/or online group intervention and refine in response to feedback
4. Appropriateness and acceptability of clinical outcome measures
5. Follow-up rates, response rates to questionnaires, adherence with the intervention
6. Fidelity of intervention
7. Time needed to collect and analyse data
8. Healthcare utilisation
9. Signal of efficacy in clinical outcomes

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/09/2022, South East Scotland Research Ethics Committee 2 (2ndFloor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, UK; +44 131 536 9000; ruth.fraser4@nhslothian.scot.nhs.uk), ref: 22/SS/0059

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Functional cognitive disorder

Interventions
Simple randomisation is provided by King's Clinical Trials Unit. Participants will be randomised to either the ACT group intervention (Condition A) or a control group (Condition B). The intervention is weekly for 4 weeks then a final session 4 weeks later, so five sessions in total. Each session is 2 hours. The latter Condition B arm is a treatment as usual (TAU) control.

Self-report clinical outcome measures will be collected after consenting to participate and again at 8-, 16-, and 26-weeks post-randomisation. These timepoints can detect immediate and sustained change following the interventions. The measures can be completed face-to-face with the Research Assistant (RA) or online (COVID-19 and/or patient preference dependent).
T0: Baseline measures, before intervention (Condition A or Condition B) begins (week 0)
T1: At week 8 post-randomisation (4th session will have been completed for Condition A group; TAU will have been provided for subjects in Condition B)
T2: At week 16 post-randomisation (group and booster sessions will have been completed in Condition A; at 3-4 months post TAU in Condition B)
T3: At week 26 post-randomisation

Proposed clinical outcome measures:
Acceptance and Action Questionnaire II
Self-evaluation of Memory Systems Questionnaire
Patient Health Questionnaire-9
WHO Disability Assessment Schedule 2.0
EuroQol-5D (EQ-5D)
ICEpop CAPability measure for Adults
Client Service Receipt Inventory

Intervention Type
Other

Primary outcome(s)
The acceptability of the intervention and the feasibility of conducting a definitive RCT to test efficacy, assessed using the following outcomes:
1. Rates of referral (% of total seen in DMC during study recruitment period; data source: electronic patient records), eligibility (% of those referred meeting inclusion criteria; data source: study database) and enrolment (% of those eligible who agree to participate; data source: study database). Measured over the course of the study and reported at the end using descriptive statistics
2. Clinical and sociodemographic characteristics of ineligible and non-consenting subjects measured using the study database over the course of the study and reported at the end using

descriptive statistics
3. Intervention adherence (% of starters who complete ≥4/5 group sessions) measured using the study database over the course of the intervention period and reported at the end using descriptive statistics
4. Intervention acceptability (% satisfied/very satisfied measured with a five-point Likert satisfaction scale and thematic analysis of qualitative responses from one-to-one interviews), measured over the course of the intervention period and reported at the end using descriptive statistics. Acceptability also explored using qualitative methodology during the intervention period
5. Intervention fidelity measured using the Acceptance and Commitment Therapy Fidelity Measure during ACT sessions selected at random over the course of the intervention period and reported at the end using descriptive statistics
6. Intervention safety (% and description of adverse events and serious adverse events in Conditions A and B) measured using the study database over the course of the study and reported at the end using descriptive statistics
7. Appropriateness and acceptability of clinical outcome measures (by thematic analysis of qualitative responses from one-to-one interviews) explored using qualitative methodology during and after the intervention period
8. Response rates to questionnaires (% completed at T0, T1, T2, & T3) collected from the study database at baseline, 8, 16 and 26 weeks
9. Time needed to collect and analyse data time in days, collected during the intervention period and at the 6-month follow up timepoint

Key secondary outcome(s))

Current secondary outcome measures as of 07/11/2022:
1. Psychological flexibility is measured using the Acceptance and Action Questionnaire II (AAQ-II) at baseline, 8 weeks, 16 weeks, and 26 weeks
2. Self-appraisal of memory functioning is measured using the Acceptance Multifactorial Memory Questionnaire (MMQ) at baseline, 8 weeks, 16 weeks, and 26 weeks
3. General level of distress and day-to-day functioning is measured using the World Health Organisation Disability Assessment Schedule (WHODAS 2.0) at baseline, 8 weeks, 16 weeks, and 26 weeks
4. Health-related quality of life is measured using the EQ-5F-5L at baseline, 8 weeks, 16 weeks, and 26 weeks
5. Level of depression is measured using the PHQ-9 at baseline, 8 weeks, 16 weeks, and 26 weeks
6. Level of anxiety is measured using the GAD-7 at baseline, 8 weeks, 16 weeks, and 26 weeks
7. Service utilisation is assessed using the Adult Service Use Schedule (AD-SUS) at baseline and again at 26 weeks
8. Assessment of non-health benefits is measured using the ICEpop CAPability measure for Adults (ICECAP-A) at baseline, 8 weeks, 16 weeks, and 26 weeks
9. Self-reported improvement at the end of the study period is assessed using the Clinical Global Impression – Global Improvement (CGI –I) Scale (self-report), at 26 weeks
10. Satisfaction with the interventions offered (Treatment as Usual and ACT) assessed using a Likert 5-point satisfaction with treatment scale at 16 weeks

Previous secondary outcome measures:
1. Psychological flexibility measured using the Acceptance and Action Questionnaire II (AAQ-II) at baseline, 8, 16 and 26 weeks
2. Metacognition (perception of own memory functioning) measured using the Self-evaluation of Memory Systems Questionnaire (SMSQ) at baseline, 8, 16 and 26 weeks
3. Mood and anxiety measured using the Patient Health Questionnaire-9 (PHQ9) and Generalised

Anxiety Disorder 7-item (GAD7) scales at baseline, 8, 16 and 26 weeks
4. Level of disability measured by the WHO Disability Assessment Schedule 2.0 (WHODAS 2.0) at baseline, 8, 16 and 26 weeks
5. Quality of life measured using EuroQol-5D (EQ-5D) at baseline, 8, 16 and 26 weeks
6. Wellbeing measured using the ICEpop CAPability measure for Adults (ICECAP-A) at baseline, 8, 16 and 26 weeks
7. Service utilisation and cost estimate measured using the Client Service Receipt Inventory (CSRI) at baseline, 8, 16 and 26 weeks
8. Medication advice and/or referral to local primary care psychology collected from participants' notes at 26 weeks

Completion date
31/07/2024

Eligibility

Key inclusion criteria
1. An established diagnosis of FCD made in DMC/CNC and confirmed by the research team
2. Aged 18 years or over
3. Capacity to provide written informed consent
4. MMSE score ≥25

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
44

Key exclusion criteria
1. Disabling cognitive symptoms in the context of a primary psychiatric disorder (e.g., depression, severe generalised anxiety disorder, schizophrenia)
2. Greater than mild-moderate depressive or anxiety disorders (PHQ9 score ≥15 and/or GAD7 score ≥15)
3. At "medium" or "high" risk of deliberate self-harm and/or suicide (based on RiO electronic medical records structured risk assessment form)
4. Another predominant functional disorder (e.g., functional seizures)

5. Diagnosis of dementia
6. Diagnosis of learning disability
7. Insufficient command of English to engage without an interpreter

Date of first enrolment
04/11/2022

Date of final enrolment
30/10/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
South West London and St George's Mental Health NHS Trust
Springfield University Hospital
61 Glenburnie Road
London
United Kingdom
SW17 7DJ

Study participating centre
St George's Hospital
Blackshaw Rd
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SW17 0QT

Sponsor information

Organisation
South West London and St George's Mental Health NHS Trust

ROR
https://ror.org/003pb1s55

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
Anonymised participant-level data will be made available at the study end upon reasonable request, which would typically include a protocol and statistical analysis plan, consistent with the data sharing policy (available on request from the Chief Investigator). Where relevant, trial data can be used to contribute to prospective meta-analyses and individual patient data meta-analyses. Requests for data sharing will be considered by the Chief Investigator (Dr Norman Poole, Norman.Poole@swlstg.nhs.uk) and the trial data monitoring committee.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/05/2023	15/05/2023	Yes	No
Basic results		31/10/2024	31/10/2024	No	No
Participant information sheet	version 1.0	11/07/2022	24/10/2022	No	Yes