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Patient care, the patient's way: an evaluation of method of levels therapy

Submission date
30/01/2020

Recruitment status
No longer recruiting

Registration date
11/02/2020

Overall study status
Ongoing

Last Edited
16/12/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Psychological health services in the UK are predominantly expert-led and diagnosis driven. Based on clinical recommendations, a widely used psychological therapy that is heavily disorder-focused (i.e., diagnosis-led) is Cognitive Behaviour Therapy (CBT). There are different models of CBT based on different disorders (e.g., CBT for depression, CBT for panic etc.). In reality, patients often have multiple diagnoses and thus utilising a transdiagnostic-orientated approach (i.e., one that is not focused on specific disorders/diagnoses) might be a more helpful alternative.
Method of Levels (MOL) is an innovative transdiagnostic cognitive therapy based entirely on levels of psychological distress as judged by the patient rather than on diagnoses, symptoms or observable behaviour. MOL is based on Perceptual Control Theory (PCT: Powers, 2005), a theory not attached to notions of normality or abnormality – the main tenet is 'behaviour is the control of perception', hence symptom classification is meaningless as each individual will be controlling for different goal states.
MOL aims to be patient-led (patient-perspective care) by allowing the patient to take more control over how therapy is accessed and used. MOL involves the patient being assessed for psychological distress (i.e., how bothered the patient is by their distress). This acknowledges distress as a changing process and hence is less stigmatising. As therapy is not diagnosis-led, multiple diagnoses are not an issue. Session length is dictated by the patient who does not need to name the problem. Patients self-identify change as they decide when to stop attending. Within this model, it is acknowledged that change is idiosyncratic and therefore therapy should be offered accordingly – patient-led rather than service-led.
The overarching goal of the study is to demonstrate potential improvements to psychological services (more efficient use of resources/lower rates of non-attendance/better outcomes) and to maximise patient participation in terms of nature and frequency of care, ultimately to move towards providing a service that is more patient-orientated and-led.

Who can participate?
Patients aged 18 – 65 years who meet eligibility to receive psychological input from the Psychological Therapies Service in Waltham Forest, London (North East London NHS Foundation Trust) can take part (updated 10/03/2020). The majority of difficulties within the service fall under anxiety, depression or interpersonal issues.

What does the study involve?
The current study will implement and evaluate a MOL intervention within an NHS secondary care psychological service, with patients who have longstanding and multiple psychological difficulties. Questionnaire data will be collected from participants for three weeks prior to starting therapy, during therapy (maximum 9 months) and at 1 and 3 month follow-up. The questionnaires will focus on the psychological difficulties the participant is bothered by and how these are experienced and managed. The questionnaire data will be used to monitor changes throughout the study. In addition to these questionnaires, participants will also be invited to take part in an individual interview to explore their experiences of MOL and the patient-led booking system. Both questionnaire and interview data will be analysed separately to determine how well MOL works in this type of setting.

What are the possible benefits and risks of participating?
Participants who take part in the study will receive psychological input much sooner than if they remain on the psychological waiting list.
Receiving psychological therapy can make participants more aware of difficult emotions and/or experiences; MOL is not expected to cause greater distress than other psychological therapies routinely offered by the service. Participants are free to withdraw at any point and/or opt for routine psychological therapy. Contact numbers of supporting agencies will be provided to seek immediate support outside of the study.

Where is the study run from?
Psychological Therapies Service (Waltham Forest) (UK)

When is the study starting and how long is it expected to run for?
February 2020 to April 2026

Who is funding the study?
Investigator-initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
266408

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2 6 6408, IRAS 266408

Study information

Scientific Title
Patient care, the patient's way: an evaluation of method of levels therapy in secondary care

Study objectives
Objective 1 -
1: Are scores on symptom measures, psychological distress and goal conflict reorganisation statistically different pre and post therapy?
2: If yes, what are the treatment effect sizes?

Objective 2 -
1: What are patients' experiences of a) MOL and b) the patient-led booking system?
2: What changes need to be implemented?

Objective 3 -
1: What is the average number of sessions a) attended, b) not-attended and c) cancelled?
2: What is the average a) time interval between appointments and b) length of therapy sessions?
3: What is the difference between patients' expectation of the number of sessions required and the number attended?
4: What is the treatment efficiency?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/11/2019, London - Queen Square Research Ethics Committee (REC) (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH; +44 (0)207 104 8061; NRESCommittee.London-QueenSquare@nhs.net) ref: 19/LO/1681

Study design
Single centre interventional open clinical trial

Primary study design
Interventional

Secondary study design
Open clinical trial (studying a novel intervention)

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Mental health

Interventions
Intervention - Method of Levels (MOL) therapy
Delivery - Face-to-face by a clinical psychologist
Who will be offered the intervention - All participants referred for Psychology eligible to take part will be offered the intervention.

MOL is an innovative transdiagnostic cognitive therapy based entirely on levels of psychological distress as judged by the patient rather than on diagnoses, symptoms or observable behaviour. MOL aims to be patient-led (patient-perspective care) by allowing the patient to take more control over how therapy is accessed and used.

Duration -
Baseline: 3 weeks
Intervention: maximum 9 months
Interviews and follow-up: maximum 3 months
Total possible time in study: 13 months

Intervention Type
Behavioural

Primary outcome measure
During the 3 week baseline, intervention phase (at the end of each therapy session) and at 1 and 3 month follow-up.
1. Clinical Outcomes in Routine Evaluation-outcome measure (CORE-OM)
2. Patient Health Questionnaire (PHQ-9)
3. Generalised Anxiety Disorder assessment (GAD-7)
4. Psychological distress measured by the Outcome Rating Scale (ORS)
5. Reorganisation of Conflict (RoC) subscale

Secondary outcome measures
Patient experience of the service measured using individual semi-structured interviews. These will take place following the intervention phase. Only one meeting will be offered (40-60 minutes). Either face-to-face at the service or via telephone/Skype.

Overall study start date
01/07/2019

Completion date
01/04/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 10/03/2020:
1. Patients who meet eligibility to receive psychological input from the Psychological Therapies Service in Waltham Forest, London (North East London NHS Foundation Trust) will meet inclusion criteria for the study. Referrals for psychosis, memory problems or addiction/substance misuse are directed to other services, the majority of difficulties within the service fall under anxiety, depression or interpersonal issues
2. Aged between 18 and 65
3. Able to consent to take part
4. Able to understand written information provided
5. Able to engage in therapy without an interpreter

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Previous inclusion criteria:
1. Patients who meet eligibility to receive psychological input from the service will meet inclusion criteria for the study. Referrals for psychosis, memory problems or addiction/substance misuse are directed to other services, the majority of difficulties within the service fall under anxiety, depression or interpersonal issues
2. Aged between 18 and 65
3. Able to consent to take part
4. Able to understand written information provided
5. Able to engage in therapy without an interpreter

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
Patients will not be eligible to take part if they require an interpreter or written material to be translated from English

Date of first enrolment
01/12/2022

Date of final enrolment
01/06/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Psychological Therapies Service (Waltham Forest)
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E17 8BE

Sponsor information

Organisation
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Sponsor type
University/education

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ROR
https://ror.org/057jrqr44

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Two academic papers will be submitted to peer-reviewed journals. The first paper will focus on the treatment effectiveness and efficiency (objectives 1 and 3) and will be submitted to the British Journal of Clinical Psychology (impact factor: 2.593) or Cognitive Therapy and Research (impact factor: 2.432). Estimated date, 30/12/2021. The second paper will involve a thematic analysis of patient experiences and acceptability of MOL and the patient-led booking system (objective 2), which will be submitted to Psychotherapy Research (impact factor: 2.953). Estimated date, 01/08/2022. The research team will also aim to present study findings at high-profile national and international conferences held for a range of mental health practitioners and academics (e.g. British Association for Behavioural and Cognitive Psychotherapies Annual Conference, July and World Congress of Behavioural and Cognitive Therapies Conference, July). A strategy will be developed to disseminate more locally at Trust events and via social media communications, such as the NELFT annual R&D conference (free to attend), talks and a written summary for staff in the service, NELFT intranet pages, bulletin boards and/or newsletters. UEL has agreed to hold a dissemination event inviting practitioners, academics, policymakers and other stakeholders. Once accepted and published the study will also be placed onto UEL's ResearchFish database.

Intention to publish date
30/12/2026

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are not expected to be made available due to anonymity and confidentiality reasons.

IPD sharing plan summary
Not expected to be made available

Study outputs

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