

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

| | | |
|--|---|---|
| Submission date 30/01/2020 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 11/02/2020 | Overall study status Ongoing | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 21/01/2026 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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?

Dr Trishna Patel

t.patel@uel.ac.uk

Dr Kavus Davis

Kavus.Davis@nelft.nhs.uk

Contact information

Type(s)

Scientific

Contact name

Dr Trishna Patel

ORCID ID

<https://orcid.org/0000-0002-7995-7328>

Contact details

University of East London

School of Psychology

Stratford Campus

London
United Kingdom
E15 4LZ
+44 (0)20 8223 6392
t.patel@uel.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

266408

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

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

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

65 years

Sex

All

Total final enrolment

0

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

United Kingdom

England

Study participating centre

Psychological Therapies Service (Waltham Forest)

26 Low Hall Lane

Walthamstow

London

England

E17 8BE

Sponsor information

Organisation

University of East London

ROR

<https://ror.org/057jrqr44>

Funder(s)

Funder type

Not defined

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

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 |