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Next Level: Method of Levels for Psychosis

Submission date
12/09/2016

Recruitment status
No longer recruiting

Registration date
12/09/2016

Overall study status
Completed

Last Edited
09/08/2022

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
Psychosis is a broad term that refers to experiences such as hearing and seeing things that others cannot, or holding beliefs that others find strange or difficult to understand. Psychosis typically emerges in adolescence and early adulthood. If left untreated, psychosis is extremely distressing for individuals, leading to profound negative effects on an individual's psychological health, social networks, quality of life and social functioning. In addition, the economic costs to society of untreated psychosis are substantial. Method of Levels (MOL) is a type of talking therapy which is based on the theory that people experience mental distress when they lose control. People can experience a loss of control for several reasons, but one common reason is having conflicting goals. MOL helps people become aware of this conflict by talking through problems, helping people to resolve goal conflict and regain control. The aim of this study is to find out whether MOL is an effective therapy for people experiencing a first episode of psychosis and to find out whether a larger study looking at this is possible by looking at the number of participants who take part.

Who can participate?
Patients aged 16-65 under the care of Greater Manchester West Mental Health NHS Foundation Trust Early Intervention Services for their first episode of psychosis.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group continue to receive their usual care from their Early Intervention team. Those in the second group receive MOL in addition to their usual care. This involves being able to take part in as many MOL sessions as they like over a 10 month period, in which they talk about their problems with a psychologist trained in MOL therapy. At the start of the study and then again after 10 and 14 months, participants complete a number of questionnaires about the problems participants are experiencing and how they are feeling about themselves. In addition, the number of participants recruited to take part and the number who remained in the trial until the end are recorded to find out whether conducting a larger trial would be possible.

What are the possible benefits and risks of participating?
There are no definite benefits of taking part in this study. However, participants might benefit

from access to the Method of Levels therapy sessions. Participants might also benefit from having their mental health and level of risk assessed over a period of time. There are no notable risks involved with participating in this study

Where is the study run from?
Three Early Intervention Teams in the Greater Manchester West Mental Health NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
May 2016 to May 2019

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

Who is the main contact?
Mr Robert Griffiths
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Contact information

Type(s)
Public

Contact name
Mr Robert Griffiths

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
31862

Study information

Scientific Title
Next Level: Evaluating the feasibility and acceptability of Method of Levels therapy for people experiencing a first episode of psychosis

Study objectives
Current research questions as of 08/02/2018:
1. Is it feasible to recruit and retain people experiencing a first episode of psychosis in a randomised controlled trial of Method of Levels (MOL)?
2. Is MOL an acceptable psychological intervention for people experiencing a first episode of psychosis?
3. Is it feasible to deliver MOL to people experiencing a first episode of psychosis?
4. Are adaptations necessary to overcome problems or barriers to the implementation of MOL in early intervention services?

Previous research questions:
1. Is Method of Levels (MOL) an acceptable psychological intervention for people experiencing a first episode of psychosis?
2. Is it feasible to deliver MOL to people experiencing a first episode of psychosis who are using early intervention services?
3. Are adaptations necessary to overcome problems or barriers to the implementation of MOL in early intervention services?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Greater Manchester Central Research Ethics Committee, 17/08/2016, ref: 16/NW/0592

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Specialty: Mental Health, Primary sub-specialty: Psychosis; UKCRC code/ Disease: Mental Health/ Organic, including symptomatic, mental disorders

Interventions
Participants will be randomly allocated to either treatment as usual (TAU) or TAU plus Method of Levels (MOL) therapy. The online Sealed Envelope programme will be used to randomise participants to one of the two groups.

TAU group: Participants will continue to receive their usual care from their Early Intervention team.

TAU plus MOL group: Participants will be able to access as many sessions of Method of Levels therapy as they require during a 10 month treatment window, in addition to their usual care from the Early Intervention team. MOL sessions generally last between 15-60 minutes, but the exact length of sessions is decided by the client. Method of Levels (MOL) is a psychological therapy based on Perceptual Control Theory (PCT). PCT proposes that people experience psychological distress when they lose control. People can experience a loss of control for several reasons, but one common reason is having conflicting goals. MOL helps people become aware of this conflict, enabling people to resolve goal conflict and regain control. To do this, MOL therapists ask people to talk about their problems. The therapist then uses questions to help the client become aware of background thoughts that might be relevant to the problem. Through this process of talking about problems and noticing background thoughts, the client becomes aware of their conflicted goals and is able to resolve them. Therapy will be delivered face-to-face by a psychological therapist who has been trained in the delivery of Method of Levels therapy. The therapist will receive ongoing clinical supervision on the use of this approach.

Participants will be asked to complete questionnaires to assess their mental state at a baseline meeting and then 10 and 14 months later.

Intervention Type
Other

Primary outcome measure
1. Recruitment rate is measured using the number of participants consenting to participate in the trial at baseline
2. Retention rate is measured using the number of participants retained in the triil at 14 month follow up

Secondary outcome measures
1. Subjective well-being, symptoms, functioning and risk are measured using the CORE-OM at baseline, 10 months and 14 months
2. The problems troubling participants most are measured using the Psychological Outcome Profiles (PSYCHLOPS) at baseline, 10 months and 14 months
3. Reorganisation of goal conflict is measured using the Reorganisation of Conflict Scale (ROC) at baseline, each therapy session, 10 months and 14 months
4. Personal recovery from psychosis is measured using the Questionnaire about the Process of Recovery (QPR) at baseline, 10 months and 14 months
5. Individual, social, relational, and overall functioning are measured using the Outcome Rating

Scale (ORS) at baseline, each therapy session, 10 months and 14 months
6. Participant's perceptions of the therapeutic alliance are measured using the Session Rating Scale (SRS) at each therapy session

Overall study start date
01/05/2016

Completion date
31/05/2019

Eligibility

Key inclusion criteria
1. People aged 16-65 years
2. Current user of Greater Manchester West Mental Health NHS Foundation Trust Early Intervention Services (assessed as experiencing a first episode of psychosis)
3. Sufficient English language abilities (verbal and written) to complete written material (for example, outcome measures) and participate in psychological therapy

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 36; UK Sample Size: 36

Total final enrolment
36

Key exclusion criteria
1. People aged under 16
2. Not currently using of Greater Manchester West Mental Health NHS Foundation Trust Early Intervention Services.
3. Literacy or English language difficulties that make it difficult for the person to complete written material (for example, outcome measures) or to participate in psychological therapy
4. GMW Early Intervention service users who are currently serving a custodial prison

Date of first enrolment
15/09/2016

Date of final enrolment
07/04/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bolton Early Intervention Team
Bentley House
Viking Works
Weston Street
Bolton
United Kingdom
BL3 2RX

Study participating centre
Salford Early Intervention Team
Broadwalk Centre
51 Belvedere Road
Salford
United Kingdom
M6 5EJ

Study participating centre
Trafford Early Intervention Team
Crossgate House
Cross Street
Sale
United Kingdom
M33 7FT

Sponsor information

Organisation
The University of Manchester

Sponsor details
Christie Building
Oxford Road
Manchester
England
United Kingdom
M13 9PL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/027m9bs27

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

Publication and dissemination plan
The intention is to publish the study findings in peer reviewed journals in 2018/19. Findings will also be presented at relevant conferences. A plain English summary of the study will be produced to provide feedback to participants.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
Participant level data will be held by The University of Manchester, and the contact person will be Dr Sara Tai (Primary Investigator). Her email address is sara.tai@manchester.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/06/2019	11/05/2020	Yes	No
Protocol article	Rationale, design and baseline data	18/08/2018	09/08/2022	Yes	No
HRA research summary			28/06/2023	No	No