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An open randomised feasibility trial of the equipping youth to help one another treatment programme

Submission date
25/03/2015

Recruitment status
No longer recruiting

Registration date
25/03/2015

Overall study status
Completed

Last Edited
18/02/2020

Condition category
Mental and Behavioural Disorders

[X] 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 is about whether a psychological treatment group is helpful for people with learning disabilities who have a history of committing crimes. The programme aims to teach people how to deal better with anger and social problems.

Who can participate?
Adults (aged at least 18) with learning disabilities, a history of criminal behaviour and detained in hospital under the Mental Health Act

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention) take part in the Equipping Youth to Help One Another treatment programme (EQUIP) over a 10-12 week period. The programme consists of 40 sessions, with four one hour sessions taking place every week. These sessions cover anger management, social skill training, social decision making and mutual help training. Those in group 2 (control) are given normal care. All participants and their carers are asked about behaviour and emotional problems experienced by the participants before they begin the treatment and after it ends, comparing the results to see if there has been any changes. We also ask people what they thought about treatment and attempt to figure out how easy it was to sign people up for the study. We also try to work out how much treatment costs, and what happened to those people in the control group (group 2).

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
A number of NHS Trusts within the UK, including the Hertfordshire University Partnership NHS Foundation Trust

When is the study starting and how long is it expected to run for?
April 2015 to February 2019

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

Who is the main contact?
Dr Peter Langdon

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number
177890

ClinicalTrials.gov number

Secondary identifying numbers
18629, IRAS 177890

Study information

Scientific Title
An open randomised feasibility trial of the Equipping Youth to Help One Another Treatment Programme (EQUIP)

Study objectives
To test the EQUIP treatment programme with patients who have intellectual and developmental disabilities and a history of criminal offending behaviour in order to estimate appropriate parameters to inform the design of a definitive randomised control trial.
Objectives:
1. To examine the acceptability of the intervention.

2. To determine the recruitment rate.
3. To test methods of collecting data on resource-use and quality of life.
4,To describe and characterise TAU.
5. To examine whether there is evidence to suggest that treatment has the potential to bring about changes in moral reasoning, distorted cognitions, and problem-solving ability functioning in comparison to TAU.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London – Hampstead, ref: 15/LO/0464

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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
Topic: Mental Health; Subtopic: Learning difficulties development disorders; Disease: Learning difficulties

Interventions
EQUIP Treatment Group: EQUIP is a manualised treatment programme comprising a total of 40 sessions comprising:
1. Mutual Help Meetings
2. Equipment Meetings
The treatment programme is delivered over 10 to 12 weeks, with four one-hour sessions taking place each week involving one session of anger management, one session of social skills training, and one session of social decision making, followed by one Mutual Help Session. For all sessions, there should be at least two facilitators present. Various modification
Follow Up Length: 12 month(s); Study Entry : Single Randomisation only

Intervention Type
Behavioural

Primary outcome measure

The primary outcome measure will be a proxy measure of behavioural problems called the Emotion Problems Scale -Behaviour Rating Scales [EPS-BRS; 23]. The EPS-BPS is a 135-item questionnaire which asks respondents questions about the behaviour of the participant over the last month. The person completing the EPS-BPS must know the participant well, and for this trial, this will be a member of the nursing team. They will be asked to rate how frequently the participants engages in various behaviours. The EPS-BRS is comprised of 12 subscales:
1. Thought/behaviour disorder
2. Verbal aggression
3. Sexual maladjustment
4. Non-compliance
5. Hyperactivity
6. Distractibility
7. Anxiety
8. Somatic concerns
9. Withdrawal
10. Depression
11. Low self-esteem
Four subscales are summed to form the Externalising Behaviour Problems Scale, while three subscales are summed to form the Internalising Behaviour Problems Scale.

Participants who provide consent will be asked to complete assessment measures within a four week period following randomisation, and then again at 16 weeks after randomisation.

Secondary outcome measures

Secondary outcome measures:
1. Moral development: the Sociomoral Reflection Measure (SRM-SF) is a production measure of moral reasoning and has been shown to possess high levels of test-retest reliability, and excellent internal consistency. The measure comprises eleven questions, and generally takes about twenty minutes to present. The questions relate to the following seven constructs:
1.1.Contract (questions one to three)
1.2. Truth (question four)
1.3. Affiliation (questions five and six)
1.4. Life (questions seven and eight)
1.5. Property (question nine)
1.6. Law (question ten)
1.7. Legal Justice (question eleven)
Verbatim answers to the questions are scored according to a set of rules and heuristics, and the development of proficient and reliable scoring occurs through the use of practice scoring material. Responses to each question are assigned a developmental rating which corresponds to a moral stage associated with Gibb's Socio-Moral Reasoning Theory,
2. Emotional Problems: the Emotion Problems Scale – Self Report Inventory (EPS-SRI) is a 147-item self-report questionnaire designed for use with people with IDDs. The questionnaire has six subscales:
2.1. Positive impression
2.2. Thought/behaviour disorder
2.3. Impulse control
2.4. Anxiety
2.5. Low self-esteem
2.6. Depression
3. Distorted Cognitions: The How I Think (HIT) Questionnaire is a measure of cognitive distortions based upon the four-categories. These are:

3.1. Self-Centred
3.2. Blaming Others
3.3. Minimizing/Mislabelling
3.4. Assuming the Worst
Total and mean scores are derived for the four-categories of distorted thinking as well as four behavioural referent subscales:
3.5.. Opposition-Defiance
3.6. Physical Aggression
3.7. Lying
3.8. Stealing
An Anomalous Responding scale is also calculated, along with three Summary Scales:
3.9. Overt Scale
3.10. Covert Scale
3.11.Total Score
The Overt Scale is calculated from the Opposition-Defiance and Physical Aggression subscales, while the Covert Scale is calculated from the Lying and Stealing subscales. The total score is calculated from all subscales
4. Social Problem Solving: the Social Problem Solving Inventory Revised is a 25-item self-report inventory that assesses general problem solving style, and it has been adapted for use with people with IDDs
5. Health Economics: Estimation of cost-effectiveness, within a health-technology assessment, is an iterative process. Here we aim to monitor levels of resource-use and quality of life (QoL), to inform the decision as to how costs and benefits would be measured in any future more definitive study. The NICE methods guide recommends that costs are calculated from the perspective of the NHS and personal social services (PSS). Within this feasibility we will thereby seek to monitor levels of resource-use associated with the intervention, including face-to-face contact with a trained therapist and any training/manual provided to supporters/carers, and the use of other NHS and PSS resource-items, including therapy received by the control arms as part of TAU, medication use, in-patient services and health professional visits (e.g. GP /physiotherapist). Appropriate unit costs (e.g. Curtis) will subsequently be attached to all items of resource-use. The NICE methods guide recommends the use of QALYs (Quality Adjusted Life Year) as part of a health technology assessment. We plan to use the EQ-5D-5L to estimate the quality of life component of the QALY in this population group, where both self-complete and proxy versions are available. We will also collect data on Health Service Resource Use and more general details about the hospital or secure unit in which people are living. Analysis: the main purpose of the analysis is to inform how the decision as to how the above data on costs and effects would be collected within a more definitive study. Thus, we will estimate completion rates and seek to identify big cost drivers, in order to inform this decision. The cost of the intervention will also be estimated. Additionally, though the results of this will need to be treated with caution, a preliminary cost-effectiveness analysis will also be performed.

Additional Measures:
6. At four weeks following randomisation, participants will be asked to complete the Wechsler Abbreviated Scale of Intelligence – Second Edition. This is a short measure of general intellectual functioning. We will assess acceptability by randomly selecting 25% of our participants and inviting them to take part in semi structured interviews following the completion of the outcome assessments. We will examine views on several key areas, which include:
6.1. Accessibility of the intervention
6.2. Helpful and unhelpful aspects, including barriers to change
6.3. Understanding and usefulness of content

6.4. Relationships with professionals within treatment, and e) perceived effectiveness. We will also carry out these interviews with participants who were randomised to the control arm in order to try to capture contamination.

Participants who provide consent will be asked to complete assessment measures within a four week period following randomisation, and then again at 16 weeks after randomisation.

Overall study start date
01/04/2015

Completion date
28/02/2019

Eligibility

Key inclusion criteria
Target Population: Sixty adults aged 18 or older who have a confirmed diagnosis of an intellectual or other developmental disability (e.g. autistic spectrum conditions) detained within hospital using the Mental Health Act (2007) who have a history of criminal offending behaviours split equally between the two arms.

Inclusion Criteria:
1. Diagnosis of intellectual or other developmental disability made by a Clinical Psychologist, Psychiatrist or other appropriately qualified professional
2. Detained within hospital using the Mental Health Act (2007)
3. A history of criminal offending behaviours, defined as clear evidence of a conviction for an indictable offence, or evidence to suggest that an individual has committed and indictable offence, but without an associated conviction. It is important to consider that for some people with IDDs who are detained in hospital there may be sufficient evidence to indicate that they have committed an indictable offence, but for various reasons they were not convicted (e.g. Crown Prosecution Service may have decided not to proceed)
Target Gender: Male & Female; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60; Description: Participants will be recruited inpatient hospitals in England.

Total final enrolment

85

Key exclusion criteria
Inability to give or withhold consent to take part as defined within the Mental Capacity Act, 2007

Date of first enrolment
01/04/2015

Date of final enrolment
31/08/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hertfordshire University Partnership NHS Foundation Trust
United Kingdom
AL3 5TL

Sponsor information

Organisation
University of Kent

Sponsor details
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University Of Kent At Canterbury
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00xkeyj56

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
Publication and dissemination will take place through peer review publication, conference presentations, and meetings with stakeholders, including participants.

Additional documents (such as study protocol, statistical analysis plan, other) are currently available from the CI Dr Peter Langdon and will be placed within an academic repository and made freely available at https://kar.kent.ac.uk/ at the end of the trial.

Intention to publish date
01/03/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to lack of consent from participants to make the data available.

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