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Pilot befriending trial in people with intellectual disability

Submission date
28/01/2019

Recruitment status
No longer recruiting

Registration date
07/02/2019

Overall study status
Completed

Last Edited
22/03/2023

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
Intellectual disability (ID) is a life-long condition characterised by an Intelligence Quotient (IQ) below 70 and impaired adaptive functioning, arising before the age of 18. People with intellectual disability have complex health needs but experience substantial inequalities in health, including poorer access to health services, higher rates of physical heath disorders and higher mortality rates. People with intellectual disability have higher rates of mental illness and the same or higher prevalence of depression compared to the general population; in addition they are more likely to experience chronic depression. Despite experiencing higher rates of chronic depression, people with intellectual disability often experience behavioural side effects from antidepressant treatment (e.g. aggression and agitation), encounter inequalities in accessing psychological therapies and the evidence base for the effectiveness of psychological treatments in depression for people with intellectual disability is limited. Therefore there is a need to consider alternative accessible interventions and befriending interventions have shown promise. Befriending is a relationship between two or more individuals, initiated, supported and monitored by an agency. Befriending aims to help individuals who are lonely, isolated and have limited opportunities for social and community participation. This is by increasing social and emotional support and by enhancing social networks and community participation. Befriending has been found to have some beneficial effects on depression but at present there are no published trials on the impact of befriending on depressive symptoms in people with intellectual disability. The main aim of this study is to assess the recruitment rate of participants, the number of successfully matched pairs and the drop-out rate of individuals with intellectual disability and volunteers. The study will also examine the effects of befriending on symptoms of depression in people with intellectual disability, as well as other outcomes such as self-esteem, loneliness and quality of life, and will examine the impact of befriending on volunteers such as their wellbeing and attitudes towards people with intellectual disability.

Who can participate?
Individuals aged 18 and over with mild or moderate learning disability, who have a score of five or more on the Glasgow Depression Scale for people with Learning Disability (GDS-LD), can provide informed consent and are not attending education/day service more than two days a

week.
Individuals aged 18 and over, who can agree to be available once a week for at least an hour over a six month period and do not have a criminal record.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive a booklet of local community resources and amenities. Those in the second group receive a booklet of local community resources and amenities and are also matched with a volunteer for one to one befriending. All participants have access to the care that they normally receive. In the intervention group, volunteers meet with the individual with intellectual disability for at least one hour per week over a six month period. Using the booklet of local community resources, the volunteer supports the individual with intellectual disability to access activities in the community depending on the individual's needs and requests. Participants with intellectual disability are assessed on depressive symptoms, self-esteem, quality of life, loneliness and social satisfaction, social support, social participation, health related quality of life and service use and costs. Volunteers are assessed on self-esteem, psychological wellbeing and quality of life, loneliness and attitudes towards intellectual disability.

What are the possible benefits and risks of participating?
By participating, individuals with intellectual disabilities may be linked into social activities which may be sustainable outside of the befriending relationship. Volunteers may gain skills and knowledge in working with people with intellectual disability. There are no direct risks of taking part in the study but people with intellectual disability may become upset when their befriending relationship ends.

Where is the study run from?
The study is being run by University College London (UK) and takes place in one NHS Trust and two charities in the UK

When is the study starting and how long is it expected to run for?
July 2018 to June 2020

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

Who is the main contact?
Dr Afia Ali
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
240552

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 40759, IRAS 240552

Study information

Scientific Title
A pilot randomised controlled trial of one to one befriending by volunteers, compared to usual care, in reducing symptoms of depression in people with intellectual disability (ID)

Study objectives
The primary aim of this pilot randomised controlled trial is to assess the recruitment rate of individuals with intellectual disability and volunteers, the number of successfully matched pairs and the drop-out rate of individuals with intellectual disabilities and volunteers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London- City and East Research Ethics Committee, Bristol Research Ethics Committee Centre, Whitefriars, Level 3, Block B, Lewins Mead, Bristol, BS1 2NT, Tel: +44 (0)2071048033/53, Email: nrescommittee.london-cityandeast@nhs.net, 02/01/2019, ref: 18/LO/2188

Study design
Randomised; Both; Design type: Treatment, Psychological & Behavioural, Other, Qualitative

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Community

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
Depression in people with intellectual disability

Interventions
Current interventions as of 24/02/2020:
Participants are randomly assigned to the control or intervention arm of the study using a web based system called Sealed Envelope, which is based on blocked randomisation using randomly varying block sizes, stratified by centre. Those in the control arm receive usual care and a booklet of local community resources and amenities. Those in the intervention arm receive a booklet of local community resources and amenities and are also matched with a volunteer for one to one befriending at least one hour per week for six months. Volunteers are trained in befriending and receive monthly supervision during the six month intervention period. If participants with intellectual disability and their volunteers wish to continue their befriending relationship after the six month intervention period, they may do so. Their relationship will continue to be monitored by the local befriending service.

A total of 50 participants who are eligible will be approached with a view to randomising 40 participants to either one to one befriending by a volunteer or a control group (usual care). In the intervention arm, participants will be matched to a volunteer who will meet with the individual at least once a week for one hour, over a six month period. The control group will have access to usual care.

The trialists will examine information about the recruitment rate of participants with ID and volunteers, the number of participants with ID who are successfully matched to a volunteer and the number of volunteers or participants with ID who drop out of the study. The trialists will explore if befriending reduce symptoms of depression, psychological distress and loneliness, and improves social participation, self-esteem and quality of life in people with ID and if it reduces health and social care costs. They will explore potential benefits to the volunteers (wellbeing and attitudes towards people with ID. These measures will be recorded at baseline, at the end of the intervention (6 months) and at 12 months.

Previous interventions:
Participants are randomly assigned to the control or intervention arm of the study using a web based system called Sealed Envelope, which is based on blocked randomisation using randomly varying block sizes, stratified by centre. Those in the control arm receive usual care and a booklet of local community resources and amenities. Those in the intervention arm receive a booklet of local community resources and amenities and are also matched with a volunteer for one to one befriending at least one hour per week for six months. Volunteers are trained in befriending and receive monthly supervision during the six month intervention period. If

participants with intellectual disability and their volunteers wish to continue their befriending relationship after the six month intervention period, they may do so. Their relationship will continue to be monitored by the local befriending service.

A total of 50 participants with ID from two community befriending organisations will be randomised to either one to one befriending by a volunteer or a control group (Usual Care). In the intervention arm, participants will be matched to a volunteer who will meet with the individual at least once a week for one hour, over a six month period. The control group will have access to usual care.

The trialists will examine information about the recruitment rate of participants with ID and volunteers, the number of participants with ID who are successfully matched to a volunteer and the number of volunteers or participants with ID who drop out of the study. The trialists will explore if befriending reduce symptoms of depression, psychological distress and loneliness, and improves social participation, self-esteem and quality of life in people with ID and if it reduces health and social care costs. They will explore potential benefits to the volunteers (wellbeing and attitudes towards people with ID. These measures will be recorded at baseline, at the end of the intervention (6 months) and at 12 months.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 26/02/2020:
1. Recruitment rate of participants with intellectual disability and volunteers over a six month period
2. The number of matched pairs of volunteers and participants with intellectual disability over a six month period
3. The number of people with intellectual disability and volunteers who drop out of the study by the end of follow up at 12 months and reasons why
4. Adverse events/negative consequences of befriending measured at 6 months
5. Acceptability of the intervention measured by exploring the views of participants, volunteers, carers and befriending services post intervention at 6 months
6. Adherence and fidelity of the intervention assessed by analysing volunteer diaries of meetings (e.g. number of sessions, type of activity) post intervention at 6 months

Previous primary outcome measure as of 24/02/2020:
1. Recruitment rate of participants with intellectual disability and volunteers over a six month period
2. The number of matched pairs of volunteers and participants with intellectual disability over a six month period
3. The number of people with intellectual disability and volunteers who drop out of the study by the end of follow up at 12 months and reasons why
4. Adverse events/negative consequences of befriending
5. Acceptability of the intervention
6. Adherence and fidelity of the intervention

Previous primary outcome measure:
Feasibility outcomes; Timepoint(s): 6 months and 12 months post randomisation
1. Recruitment rate of participants with intellectual disability and volunteers over a six month period

2. The number of matched pairs of volunteers and participants with intellectual disability over a six month period
3. The number of people with intellectual disability and volunteers who drop out of the study by the end of follow up at 12 months and reasons why

Secondary outcome measures
Outcomes in participants with intellectual disability:
1. Depressive symptoms are measured using the Glasgow Depression Scale for people with Learning Disability (GDS-LD) at baseline, 6 months and 12 months.
2. Self-esteem is measured using the adapted Rosenberg self-esteem scale for people with intellectual disabilities at baseline, 6 months and 12 months.
3. Quality of life is measured using the Maslow Assessment of Needs Scale-Learning Disability (MANS-LD) and five items from the adapted World Health Organisation Quality of Life questionnaire (WHO-QOL-8) at baseline, 6 months and 12 months
4. Loneliness and social satisfaction are measured using the Modified Worker Loneliness Questionnaire (MWLQ) at baseline, 6 months and 12 months
5. Social support is measured using the Social Support Self Report for intellectually disabled adults (SSSR) at baseline, 6 months and 12 months
6. Social participation is measured using the Guernsey Community Participation and Leisure Assessment (GCPLA) at baseline, 6 months and 12 months
7. Health related quality of life is measured using the EuroQol-Youth (EQ-5D-Y), which is used to calculate Quality adjusted life years (QALYs), assessed at baseline, 6 months and 12 months
8. Service use and costs assessed using the modified Client Services receipt Inventory (CSRI) at baseline, 6 months and 12 months

Outcomes in volunteers:
1. Self-esteem is measured using the Rosenberg self-esteem scale at baseline, 6 months and 12 months
2. Psychological wellbeing and quality of life are measured using the Warwick- Edinburgh mental wellbeing scale (WEMWBS) at baseline, 6 months and 12 months
3. Loneliness is measured using the UCLA loneliness scale at baselines, 6 months and 12 months
4. Attitudes of volunteers is assessed using the Attitudes Towards Intellectual Disability Questionnaire (ATTID) at baseline, 6 months and 12 months

Overall study start date
01/07/2018

Completion date
30/06/2020

Eligibility

Key inclusion criteria
Individuals with ID will need to be:
1. Aged 18 or over
2. Have mild or moderate intellectual disability (ID) (IQ 35 to 69), which will be assessed using the Wechsler Abbreviated Scale of Intelligence
3. A score of 5 or more on the Glasgow Depression Scale for People with learning Disabilities (GDS-LD (42). This score is below the threshold for a diagnosis of depression but will indicate the

presence of depressive symptoms
4. Should not be attending education/day service for more than two days a week
5. Be able to provide informed consent

Volunteers will need to be:
1. Aged 18 or over
2. Agree to being available once a week for at least one hour over a period of six months

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40 participants with ID and 20 volunteers (60 in total)

Total final enrolment
26

Key exclusion criteria
Individuals with ID will be excluded if they have:
1. Severe ID (IQ less than 35 and/or are non-verbal or have very limited communication and comprehension and therefore would not be able to complete the questionnaires) or no ID (IQ above 70)
2. A score below 5 on the GDS-LD
3. Unable to communicate in English
4. Unable to provide consent

Volunteers will be excluded if they:
1. Have a criminal record (any documented offence) recorded on their DBS
2. Are unable to provide two references or have unsuitable references

Date of first enrolment
15/04/2019

Date of final enrolment
01/10/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Waltham Forest Learning Disability Service (lead centre)
30 Coleridge Road
Walthamstow
London
United Kingdom
E17 6QU

Study participating centre
Redbridge Integrated Learning Disability team
852 Cranbrook Road
Barkingside
Ilford
United Kingdom
IG6 1HZ

Study participating centre
Havering Community learning disability team
The Hermitage
Billet Lane
Hornchurch
United Kingdom
RM11 1XL

Study participating centre
Barking and Dagenham Community Learning Disability Team
Community learning disability team
2nd floor, Civic Centre
Wood Lane
Dagenham
United Kingdom
RM10 7BN

Study participating centre
Outward
Newland House
4 Daneland Walk
Hale Village
London

United Kingdom
N17 9FE

Study participating centre
The Befriending Scheme
1 The Croft
Sudbury
United Kingdom
CO10 1HN

Sponsor information

Organisation
University College London

Sponsor details
Joint Research Office
1st Floor Maple House
149 Tottenham Court Road
London
England
United Kingdom
W1T 7NF
+44 (0)203 447 5557
uclh.randd@nhs.net

Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 16/122/57

Results and Publications

Publication and dissemination plan

The protocol can be accessed on the NIHR website: https://www.journalslibrary.nihr.ac.uk/programmes/phr/1612257/#/

The results of the study will be made available to the participants and the organisations taking part.
The results will be published in a peer reviewed scientific journal within one year of the study end date and will be presented at conferences and shared with stakeholders through a public engagement seminar.

Intention to publish date

30/06/2021

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	21/06/2020	15/01/2021	Yes	No
Funder report results		01/10/2021	20/12/2021	No	No
Results article		27/09/2021	22/03/2023	Yes	No
HRA research summary			28/06/2023	No	No